NOTICE OF A
SPECIAL MEETING OF THE
CALOPTIMA BOARD OF DIRECTORS

THURSDAY, JANUARY 7, 2021
2:00 P.M.

505 CITY PARKWAY WEST, SUITES 108-109
ORANGE, CALIFORNIA 92868

BOARD OF DIRECTORS

Supervisor Andrew Do, Chair	Isabel Becerra, Vice Chair
Clayton Chau, M.D.	Clayton Corwin
Mary Giammona, M.D.	Victor Jordan
J. Scott Schoeffel	Supervisor Michelle Steel
Trieu Tran, M.D.	Vacant

Supervisor Doug Chaffee, Alternate

CHIEF EXECUTIVE OFFICER	CHIEF COUNSEL	CLERK OF THE BOARD
Richard Sanchez	Gary Crockett	Sharon Dwiers

This agenda contains a brief description of each item to be considered. Except as provided by law, no action shall be taken on any item not appearing on the agenda. To speak on an item, complete a Public Comment Request Form identifying the item and submit to the Clerk of the Board. To speak on a matter not appearing on the agenda, but within the subject matter jurisdiction of the Board of Directors, you may do so during Public Comments. Public Comment Request Forms must be submitted prior to the beginning of the Consent Calendar and/or the beginning of Public Comments. When addressing the Board, it is requested that you state your name for the record. Address the Board as a whole through the Chair. Comments to individual Board Members or staff are not permitted. Speakers are limited to three (3) minutes per item.

In compliance with the Americans with Disabilities Act, those requiring accommodations for this meeting should notify the Clerk of the Board's Office at (714) 246-8806, at least 72 hours prior to the meeting.

The Board Meeting Agenda and supporting materials are available for review at CalOptima, 505 City Parkway West, Orange, CA 92868, Monday-Friday, 8:00 a.m. – 5:00 p.m. These materials are also available online at www.caloptima.org. Board meeting audio is streamed live on the CalOptima website at www.caloptima.org.

To ensure public safety and compliance with emergency declarations and orders related to the COVID-19 pandemic, individuals are encouraged not to attend the meeting in person. As an alternative, members of the public may:

1) **Listen to the live audio at + 1 (562) 247-8422 Access Code: 914-608-492 or**
2) **Participate via Webinar at** https://attendee.gotowebinar.com/register/4902189496845755920 **rather than attending in person. Webinar instructions are provided below.**

CALL TO ORDER
Pledge of Allegiance
Establish Quorum

PRESENTATIONS/INTRODUCTIONS
None.

PUBLIC COMMENTS
At this time, members of the public may address the Board of Directors on matters not appearing on the agenda, but within the subject matter jurisdiction of the Board of Directors. Speakers will be limited to three (3) minutes.

MANAGEMENT REPORTS
1. CalOptima 2020-2022 Strategic Plan Review Session

2. COVID-19 Update

REPORTS
3. Consider Expansion and Extension of the Orange County COVID-19 Nursing Home Prevention Program, and its associated Grant, related to Support of Orange County Nursing Facilities During the Coronavirus Pandemic

4. Consider Authorizing Homeless Health Initiative Vaccination Intervention and Member Incentive Strategy in Response to the Coronavirus Pandemic

5. Consider Authorizing Coronavirus (COVID-19) Vaccination Member Incentive Program for Calendar Year 2021

6. Consider Ratifying a Letter of Agreement for Emergency Transition of Tustin Care Center Residents and Authorization of an Amendment to the Professional Services Contract with GN Medical Associates dba CareConnect Medical Group for Future Emergency Transition Care Coordination Services

7. Authorize Health Network Medi-Cal Capitation Rate Increases for the Period of January 1, 2021, through June 30, 2021, due to COVID-Related Expenses

BOARD MEMBER COMMENTS

ADJOURNMENT

How to Join

1. Please register for Special Meeting of the CalOptima Board of Directors on January 7, 2021 at 2 p.m. at: https://attendee.gotowebinar.com/register/4902189496845755920
2. After registering, you will **receive a confirmation email containing a link to join** the webinar at the specified time and date.

   Note: This link should not be shared with others; it is unique to you.

   Before joining, be sure to check system requirements to avoid any connection issues.

3. **Choose** one of the following **audio options:**

   TO USE YOUR COMPUTER'S AUDIO:

   When the webinar begins, you will be connected to audio using your computer's microphone and speakers (VoIP). A headset is recommended.

   --OR--

   TO USE YOUR TELEPHONE:

   If you prefer to use your phone, you must select "Use Telephone" after joining the webinar and call in using the numbers below.

   United States: + 1 (562) 247-8422

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   Audio PIN: Shown after joining the webinar

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CalOptima

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CalOptima 2020–2022 Strategic Plan Review Session

Special Meeting of the CalOptima Board of Directors

January 7, 2021

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Welcome and Introductions

Supervisor Andrew Do, Chair, CalOptima Board of Directors, and Vice Chair, Orange County Board of Supervisors

Richard Sanchez, CEO, CalOptima

Rachel Selleck, Executive Director, Public Affairs

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CalOptima
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Meeting Overview and Materials

- Meeting Overview
  - Strategic Plan Planning and Development Process Overview
  - CalOptima 2020–2022 Strategic Plan Implementation and Initiatives
  - Environmental Landscape of Health Care
  - Strategic Plan Discussion
  - Board Member Comments
- Materials
  1. 2020 – 2022 Strategic Plan
  2. 2020 – 2022 Strategic Plan Environmental Scan
  3. Strategic Priority Initiatives as of 12/21/2020
  4. Strategic Plan Consultant Professional Experience

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CalOptima
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Strategic Plan Planning, Development Process, and Implementation Overview

Athena Chapman, President, Chapman Consulting
Caroline Davis, President, Davis Health Strategies LLC
Debra Kegel, Director, Strategic Development
Rachel Selleck, Executive Director, Public Affairs

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Planning and Development Process Overview (April–December 2019)

- Interviewed CalOptima Board, Executive Staff, and Advisory Committee Chairs and Vice Chairs
- Conducted Strategic Planning Session with CalOptima Board of Directors
- Completed Environmental Scan
- Identified Themes and Priorities
- Developed First Draft of 2020–2022 Strategic Plan
- Facilitated Meetings with Advisory Committees and Health Networks
- Presented Draft Strategic Plan to CalOptima Board of Directors
- Integrated Final Input and Comments
- Presented Final 2020–2022 Strategic Plan to CalOptima Board of Directors

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Strategic Priorities and Objectives

Innovate & Be Proactive

- Anticipate Likely CMS And DHCS Priorities
- Identify and Collaborate on Local Priorities and Needs
- Leverage New Federal and State Programs and Services to Improve Access and Quality of Care for Members
- Seek Opportunities to Further Integrate Care for Members

Expand CalOptima's Member-Centric Focus

- Focus on Population Health
- Strengthen Provider Network and Access to Care
- Enhance Member Experience and Customer Service

Strengthen Community Partnerships

- Increase Collaboration with Providers and Community Stakeholders to Improve Care
- Utilize Strong Advisory Committee Participation to Inform Additional Community Engagement Strategies

Increase Value and Improve Care Delivery

- Evaluate and Implement Value-Based Purchasing Strategies that Drive Quality
- Deploy Innovative Delivery Models to Address Social Determinants of Health and Homelessness
- Maintain Focus on Providing High-Quality Care Provided to Members

Enhance Operational Excellence and Efficiency

- Maintain Strong Culture of Compliance
- Preserve CalOptima's Financial Stability
- Invest in Infrastructure and Efficient Processes
- Engage Workforce and Identify Development Opportunities

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CalOptima
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Strategic Initiatives

Innovate and Be Proactive

- Clinical Operations
- COVID-19 Response
- Homeless Health
- Organizational Operations
- Quality Improvement
- Social Determinants of Health

Expand CalOptima's Member-Centric Focus

- Clinical Operations
- Member Access

Strengthen Community Partnerships

- Community Engagement
- COVID-19 Response

Increase Value and Improve Care Delivery

- Behavioral Health
- COVID-19 Response
- Organizational Operations
- Quality Improvement

Enhance Operational Excellence and Efficiency

- Clinical Operations
- COVID-19 Response
- Employee Support
- Organizational Operations

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Environmental Landscape of Health Care

Athena Chapman, President, Chapman Consulting
Caroline Davis, President, Davis Health Strategies LLC

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Environmental Landscape Highlights

- Federal landscape
  - Centers for Medicare & Medicaid Services (CMS) strategic priorities
  - Affordable Care Act
  - Public Charge Rule impacts on access
- State landscape
  - Newsom Administration agenda
  - California Health and Human Services Agency principles, per Secretary Mark Ghaly, M.D., MPH
  - California Advancing and Innovating Medi-Cal (CalAIM)/ 1115 Waiver Renewal
  - Future of the Coordinated Care Initiative and Cal MediConnect

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Environmental Landscape Highlights (cont.)

- County landscape
  - Labor market
  - Health coverage rates in Orange County
  - Whole Person Care transition
  - Health Homes Program
  - CalOptima health networks and access
  - Community collaboration
    - Community engagement
    - System of care data integration
    - Behavioral Health/Be Well OC
    - Homelessness

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Environmental Considerations Under Current Health Care Landscape

- Changes to delivery model to address the COVID-19 pandemic
- Shifting federal and state regulatory guidance
- Health equity/disparities illuminated by COVID-19 and social justice movement
- Elections and political climate
- Federal, state and local budgets
- Medi-Cal rate cuts, retroactive adjustments and rate efficiencies
- Supreme Court decision on the Affordable Care Act

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Environmental Considerations Under Current Health Care Landscape (cont.)

- Delay of state initiatives
  - CalAIM
    - Waiver extension (1-year request)
    - Whole Person Care transition
  - Quality reporting and sanctions
- Cal MediConnect transition to aligned Dual Eligible Special Needs Plans (D-SNP)
- Medi-Cal procurement and new Medi-Cal contract boilerplate
- Medi-Cal Rx
- Release of Governor's Proposed Budget

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Strategic Plan Discussion

Rachel Selleck, Executive Director, Public Affairs
Athena Chapman, President, Chapman Consulting
Caroline Davis, President, Davis Health Strategies LLC

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Strategic Planning Discussion

- Strategic Priorities

- Strategic Initiatives Categories
  - Behavioral Health
  - Clinical Operations
  - Community Engagement
  - COVID-19 Response
  - Employee Support
  - Member Access
  - Organizational Operations
  - Quality Improvement
  - Social Determinants of Health
- Multi-year and annual goals

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CalOptima
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Our Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner

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STRATEGIC PLAN 2020–2022

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A Message From the CEO

Like many of you, I consider the beginning of the new 2020 decade as an opportunity to look ahead and to plan. So, it is the perfect time to launch CalOptima's next Strategic Plan, for 2020–2022. The guidance it offers and the priorities it sets have been carefully considered by a wide variety of leaders, including our Board of Directors, advisory committee members, executive staff, community stakeholders and industry consultants. Collaboration strengthens our plan and reflects our Better. Together. approach to quality health care for Orange County's vulnerable low-income residents.

If this decade is anything like the last, the one constant will be change. Recognition of this fact is central to the content of CalOptima's Strategic Plan. An overview of the health care landscape explains the federal, state and local drivers of change, followed by our strategic priorities and objectives in this environment.

Responding effectively in dynamic conditions does not mean CalOptima will alter our mission or vision, both of which are focused on members. Our commitment to members is as strong as ever, and you will see that dedication underlying all the priority areas, from innovation and community partnerships to value, quality and operational excellence. While we may adjust our efforts along the way in response to regulatory changes or community needs, we will not waver about putting members first.

And one final comment about 2020 — it's CalOptima's 25th anniversary year. We celebrate you and all the providers, community-based organizations, elected officials and stakeholders who partner with us. Together, we have accomplished so much, including statewide recognition year after year as a leading Medi-Cal health plan. Our shared goal of a healthier Orange County has brought us far and will carry us confidently into the future.

Michael Schrader
Chief Executive Officer

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About CalOptima

CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner

CalOptima's Vision

To be a model public agency and community health plan that provides an integrated and well-coordinated system of care to ensure optimal health outcomes for all our members

Programs

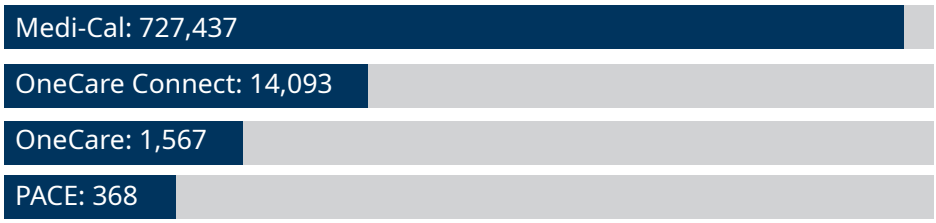
Medi-Cal (California's Medicaid Program): For low-income children, adults, seniors and persons with disabilities.

OneCare Connect Cal MediConnect Plan (Medicare-Medicaid Plan): For people who qualify for both Medicare and Medi-Cal, combining Medicare and Medi-Cal benefits. Also included are benefits for worldwide emergency care, dental care, vision care and fitness. Other benefits are transportation to medical services and a Personal Care Coordinator.

OneCare (HMO SNP): A Medicare Advantage Special Needs Plan for low-income seniors and people with disabilities who qualify for both Medicare and Medi-Cal. Benefits are covered in one single plan, making it easier to get health care.

Program of All-Inclusive Care for the Elderly (PACE): A long-term comprehensive health care program that helps older adults remain as independent as possible. PACE coordinates and provides all needed preventive, primary, acute and long-term care services so seniors can continue living in their community. PACE provides all the acute and long-term care services covered by Medicare and Medi-Cal.

As of October 31, 2019, CalOptima has approximately 743,000 members:



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Health Insurance Coverage in Orange County

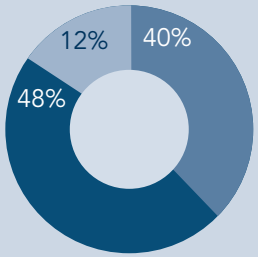
CalOptima covers more than 20% of Orange County residents.

Current Health Insurance Coverage Type	Orange County
Uninsured	6.7%
Medicare and Medicaid (Dual Eligibles)	3.0%
Medicare	11.2%
Medicaid	19.1%
Employment-Based	51.8%
Privately Purchased	7.5%
Other Public Coverage	0.7%

Source: California Health Interview Survey, 2017

CalOptima Profile

Members by Age



Age 0–18	40%
Age 19–64	48%
Age 65+	12%

As of October 31, 2019

Low Administrative Costs

CalOptima spends nearly 96 cents of every dollar on member care and only 4 cents on program administration, which reinforces our commitment and mission as a community health plan that provides quality health care services in a cost-effective, compassionate manner.

96¢ of every **$1**

Provider Network Composition

CalOptima has a strong provider network to serve our members. As of October 31, 2019, this includes:

- 1,567 primary care providers
- 6,944 specialists
- 40 acute and rehab hospitals
- 35 community health centers
- 570 pharmacies
- 100 long-term care facilities
- 5 PACE alternative care settings

High-Quality Care

CalOptima offers high-quality care to our members:

- For five years in a row, CalOptima was the top rated Medi-Cal plan in California, according to the National Committee for Quality Assurance (NCQA) Medicaid Health Insurance Plan Ratings (2014–2019).
- For 2019–2020, no other health plan received a higher rating.
- NCQA has awarded an accreditation status of Commendable to CalOptima Medi-Cal.

Health Care Landscape Review

CalOptima's 2020–2022 Strategic Plan reflects the need to be responsive to a wide variety of federal, state and local priorities, considerations and issues. The landscape review is a summary of highlights from a comprehensive Environmental Scan that was completed to inform the Strategic Plan.

Federal Landscape

At the federal level, the policy landscape has been characterized by uncertainty for the past three years, and this is expected to continue for the foreseeable future. The Centers for Medicare & Medicaid Services (CMS), which provides the federal funding for, and oversight of, California's Medi-Cal program, has established a set of strategic priorities focused on driving innovation, implementing patient-centric approaches, and demonstrating results that improve care and lower costs. CalOptima will look to CMS's goals to prioritize development of innovative approaches that are aligned with the federal government. In addition, federal immigration policy may negatively impact Medi-Cal enrollment.

State Landscape

Within California, the health policy landscape is in transition with the election of Governor Gavin Newsom. Governor Newsom has an ambitious health care agenda focused on expanding coverage for all Californians and reigning in costs. Within the California Department of Health Care Services (DHCS), key initiatives are underway that will shape the future of the Medi-Cal program and impact CalOptima's work over the next three years.

Medi-Cal Vision: 2021 and Beyond

The current federal Section 1115 Medicaid waiver, referred to as Medi-Cal 2020, expires at the end of 2020. As part of renewing the waiver, DHCS has launched a major restructuring of Medi-Cal, known as California Advancing and Innovating Medi-Cal (CalAIM), which is designed to reduce the complexity of the program, focus on population health and increase the use of value-based purchasing strategies. CalOptima will contribute to the CalAIM discussions and, ultimately, to the implementation of Medi-Cal's next chapter.

Prescription Drug Carve-Out

On his first day in office, Governor Newsom signaled his intent to address rising pharmacy costs by shifting to bulk purchasing of prescription drugs for all government programs, including Medi-Cal (the largest purchaser in the state). CalOptima will continue to work closely with DHCS on the design of the carve-out to minimize the impacts on our members and their health.

Future of the Coordinated Care Initiative and Cal MediConnect

The Coordinated Care Initiative (CCI) focuses on integrating delivery of medical, behavioral and long-term services and supports (MLTSS) benefit into California's Medi-Cal care delivery system. The CCI also includes the Cal MediConnect (CMC) duals demonstration, combing Medicare and Medi-Cal into a single program. CCI and CMC are currently operating in only seven counties and the federal authority for CMC is scheduled to sunset on December 31, 2022. As part of the CalAIM initiative, DHCS has proposed that all Medi-Cal managed care plans, including CalOptima, be required to operate a Dual Eligible Special Needs Plan (D-SNP) by January 1, 2023, and assume responsibility for all Medi-Cal long-term care services effective January 1, 2021. CalOptima will engage with DHCS and CMS on the CCI and CMC transitions.

Health Care Landscape Review (continued)

Orange County Landscape

CalOptima is an integral part of the business community and the health care sector in Orange County. As the sole Medi-Cal plan in the County, CalOptima is in a unique position to impact care delivery and partner with County agencies and other stakeholders to improve access to care and quality for all members.

Homelessness and Behavioral Health

In Orange County, as across the state, the population of individuals experiencing homelessness has increased significantly over the past few years. Orange County has focused on developing a system of care that recognizes a multifaceted approach is necessary to respond to the needs of County residents experiencing homelessness. CalOptima has committed enhanced funding for homeless health programs in the County. For example, CalOptima is funding programs in collaboration with its community health centers to provide members on-call medical services in the field and increased preventive and primary care at shelters, establishing an internal homeless response team, and supporting hospital discharge coordination, recuperative care and respite care.

In 2018, local public and private stakeholders came together to work on behavioral health issues. Under this initiative, known as Be Well OC, a regional wellness center will be constructed in Orange County to serve individuals with mental health needs regardless of payor source. CalOptima is participating in this collaborative by prepaying for services at the Be Well OC wellness center. Be Well OC is part of the larger Mind OC initiative to integrate behavioral health services across silos to address social determinants of health.

CalOptima Workforce Needs

CalOptima will continue to face an extremely competitive employment environment over the next three years. The high cost of living in Orange County coupled with the County's low unemployment rate, staff retirements and turn-over contribute to a tight labor market.

Physician Networks and Access to Care

Across California, there are concerns about access to care, the rising cost of living, and a lack of physicians and other health workers. These issues are particularly acute in the Medi-Cal program. To address access issues, CalOptima will continue to develop stronger networks with innovative value-based payment arrangements over the next three years.

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Strategic Plan Development Process

To develop our 2020–2022 Strategic Plan, we gathered input from a wide range of CalOptima stakeholders:

Step 1

CalOptima's Board members, executive team and advisory committee leaders were interviewed to gather feedback about the 2017–2019 Strategic Plan as well as the issues and challenges facing the health plan over the next three years.

Step 2

Then, we held a Strategic Planning Session with the Board to review the findings from the interviews and to identify and discuss the priorities for the next Strategic Plan given the health care landscape in which CalOptima operates.

Step 3

Following the Strategic Planning Session, we held a joint meeting of all the advisory committees to solicit their input on the strategic priorities. We also convened health network representatives to gather their input on the next Strategic Plan.

Step 4

The draft 2020–2022 Strategic Plan was presented to the Board on November 7, 2019, for review and discussion.

Step 5

The final 2020–2022 Strategic Plan was adopted by the Board on December 5, 2019.

Strategic Priorities and Objectives

Our members are the essential focus of the Strategic Priorities and Objectives for the 2020–2022 Strategic Plan and are supported by the programs and services provided by CalOptima.

Innovate and Be Proactive

- Anticipate Likely CMS and DHCS Priorities
- Identify and Collaborate on Local Priorities and Needs
- Leverage New Federal and State Programs and Services to Improve Access and Quality of Care for Members
- Seek Opportunities to Further Integrate Care for Members

Expand CalOptima's Member-Centric Focus

- Focus on Population Health
- Strengthen Provider Network and Access to Care
- Enhance Member Experience and Customer Service

Strengthen Community Partnerships

- Increase Collaboration with Providers and Community Stakeholders to Improve Care
- Utilize Strong Advisory Committee Participation to Inform Additional Community Engagement Strategies

Increase Value and Improve Care Delivery

- Evaluate and Implement Value-Based Purchasing Strategies that Drive Quality
- Deploy Innovative Delivery Models to Address Social Determinants of Health and Homelessness
- Maintain Focus on Providing High-Quality Care to Members

Enhance Operational Excellence and Efficiency

- Maintain Strong Culture of Compliance
- Preserve CalOptima's Financial Stability
- Invest in Infrastructure and Efficient Processes
- Engage Workforce and Identify Development Opportunities

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Board of Directors

Paul Yost, M.D. (Chair)
Anesthesiologist, CHOC Children's and St. Joseph Hospital
Designed seat: Licensed physician, representing a health network

Dr. Nikan Khatibi (Vice Chair)
Anesthesiologist, Pain Specialist and Addiction Medicine Physician
Designated seat: Licensed medical professional, not representing a health network

Ria Berger
CEO, Healthy Smiles for Kids of Orange County
Designated seat: Community clinic representative

Doug Chaffee
Orange County Board of Supervisors Supervisor, Fourth District
Designated seat: Orange County Board of Supervisors (alternate)

Ron DiLuigi
Retired Health Care Executive
Designated seat: Legal resident of Orange County

Andrew Do
Orange County Board of Supervisors Supervisor, First District
Designated seat: Orange County Board of Supervisors

Alexander Nguyen, M.D., MPH
Psychiatrist, Long Beach Veterans Affairs Medical Center
Designated seat: Family member of a CalOptima member

Lee Penrose
Health Care Executive
Designated seat: Current or former hospital administrator

Richard Sanchez, REHS, MPH
Director, Orange County Health Care Agency
Designated seat (non-voting): Orange County Health Care Agency

J. Scott Schoeffel
Attorney
Designated seat: Legal or finance professional

Michelle Steel
Orange County Board of Supervisors Supervisor, Second District
Designated seat: Orange County Board of Supervisors

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The 2020–2022 Strategic Plan was created with the assistance of Athena Chapman and Caroline Davis from Champan Consulting. This plan was adopted by the CalOptima Board of Directors on December 5, 2019, and provides a framework for future direction. This document does not authorize expenditure of funds or commitment of resources.

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ENVIRONMENTAL SCAN

STRATEGIC PLAN 2020–2022

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Introduction

CalOptima's mission is "to provide members with access to quality health care services delivered in a cost-effective and compassionate manner," and the health plan's vision is "to be a model public agency and community health plan that provides an integrated and well-coordinated system of care to ensure optimal health outcomes for all our members." The environment in which the health plan realizes its mission and vision is complex, reflecting the intersection of federal- and state-level priorities with local needs and goals. This document provides an overview of the federal, state and local landscape that sets the stage for the opportunities and challenges to CalOptima's work and interacts with its daily operations and longer-term strategic vision.

The information from the environmental scan has been integrated with the themes and insights obtained from the interviews with CalOptima's Board of Directors, executive team and advisory committees. This provides the framework for the 2020–2022 CalOptima Strategic Plan. The data in the environmental scan is as of July 2019.

CalOptima

In 1993, the Orange County Board of Supervisors created CalOptima as a County Organized Health System (COHS). Initially created to serve the Medi-Cal program, CalOptima currently offers the following four programs:

- Medi-Cal – a public-sector health insurance program that serves low-income individuals and families.
- OneCare Connect Cal MediConnect Plan – a program that serves members eligible for both Medi-Cal and Medicare coverage (i.e., the dual-eligible population). This program combines the Medicare and Medi-Cal benefits into a single plan and offers additional benefits as well.
- OneCare – A Dual Eligible Special Needs Plan (D-SNP) for individuals who qualify for both Medicare and Medi-Cal.
- Program of All-Inclusive Care for the Elderly (PACE) – a community-based program that supports frail seniors by providing coordinated and integrated services to help them continue living independently. PACE provides the acute and long-term care services covered by both Medicare and Medi-Cal.

As of July 2019, CalOptima has more than 750,000 enrollees across the following products:

- Medi-Cal: 739,771
- OneCare Connect: 14,257
- OneCare: 1,530
- PACE: 335[i]

As a COHS plan, CalOptima is the sole Medi-Cal managed care plan in Orange County, which makes it an integral part of the safety net. CalOptima has demonstrated it can take advantage of its unique role and have a direct impact on care delivery, cost and quality for this population. For five years in a row, from 2014–2019, CalOptima received recognition as the top-rated health plan in California for outstanding quality, according to the National Committee for Quality Assurance (NCQA). For 2019–2020, no other health plan received a higher rating. CalOptima's NCQA accreditation was recently renewed at the Commendable level again.

Additionally, CalOptima has continued to explore additional lines of business and pilot programs that are in line with the needs of its community and to test new ways to deliver high-quality care for its members. CalOptima is in a strong strategic position to build on its successes and continue to explore additional ways to support its membership and local community.

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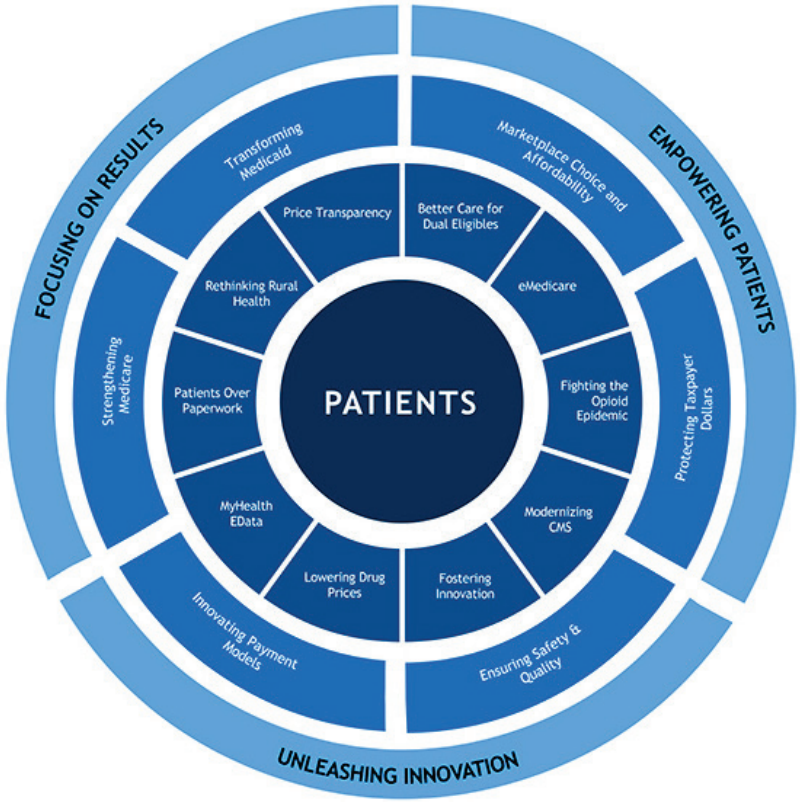
Federal Landscape

For the past several years, the federal health policy landscape has been defined by uncertainty, and this will continue into the foreseeable future. This debate could be restarted depending on the outcomes of the 2020 election. Further, lawsuits seeking to repeal the Affordable Care Act (ACA) continue to work their way through the federal court system. The growth in the federal deficit also increases the likelihood of Congressional action to reduce Medicaid and Medicare spending, which could include converting Medicaid financing into a block grant or per capita cap structure.

The Centers for Medicare & Medicaid Services (CMS), which provides the federal funding and oversight for the Medicaid program, has established 16 strategic initiatives, which are shown below.[ii]



The CMS strategic priorities are focused on driving innovation, implementing patient-centric approaches, and demonstrating results that improve care and lower costs. These priorities can be used to guide how CalOptima can strategically position itself and prepare to proactively work toward the CMS goals. They also provide insights about potential areas of focus at the federal level for both Medicaid and Medicare. The ability to anticipate changes at the federal level and minimize the disruption caused by the implementation of new federal requirements and initiatives will allow CalOptima to be proactive and innovative.

In separate but relevant activity, the federal Administration's recent actions related to public programs may have a negative impact on total Medicaid enrollment. A recent fact sheet from the Kaiser Family Foundation notes concerns about current immigration policy and the impacts on enrollment in public sector programs (including Medicaid) by lawfully present immigrants, citizen children immigrants and undocumented populations.[iii] The recently published "public charge" rule is also likely to lead to a decline in Medicaid enrollment as it expands the programs used to deem a legal immigrant a "public charge" (which can make it more difficult for an individual to gain legal permanent residency status or obtain a visa to enter the U.S.) to include Medicaid.[iv] It is expected the public charge rule will be challenged in court, but the Medicaid enrollment impacts in California may be felt more immediately than this issue can be resolved.

State Landscape

Within California, the health policy landscape is in transition with the election of Governor Newsom in November 2018. The appointment of a consumer-focused and innovative health policy team demonstrates that the Governor intends to continue to drive significant changes across the health care landscape in California. Newsom has an ambitious health care agenda that includes moving California to some form of universal coverage. Additionally, the Newsom Administration

has used its health care platform to take several significant actions in its first six months:

- Appointment of Nadine Burke Harris, M.D., as the first Surgeon General for California. Surgeon General Dr. Burke Harris has a strong focus on how Adverse Childhood Experiences (ACE) and social determinants of health impact health outcomes
- Appointment of Tom Insel as the first state Mental Health Czar with a directive to develop a blueprint to address behavioral health issues across the state
- Release of an Executive Order on bulk pharmacy purchasing to reduce rising prescription drug costs, including the carve-out of pharmacy from Medi-Cal managed care plans
- Release of an Executive Order that calls for the development of a "Master Plan for Aging" by October 2020 with input from a Cabinet-Level Workgroup that will work with a Stakeholder Advisory Committee comprised of a diverse set of stakeholders with both a research and long-term care subcommittee structure
- Establishment of the Healthy California for All Commission to develop a plan that includes options for advancing progress toward achieving a health care delivery system in California that provides coverage and access through a unified financing system for all Californians
- Enactment of a provision to expand full scope Medi-Cal coverage for undocumented adults up to age 26 using state General Funds to cover the costs of enrollment and coverage
- Enactment of a California-specific individual mandate penalty and increased subsidies for individuals and families above the ACA amounts to provide stability in the individual insurance market and increase coverage for individuals with incomes above the Medi-Cal eligibility requirements

Implementation of the Governor's health policy agenda is the responsibility of the Secretary of the California Health & Human Services (CHHS) Agency, Mark Ghaly, M.D. The Secretary oversees 15 departments, including the Department of Health Care Services (DHCS) and the Department of Managed Health Care (DMHC). While CalOptima works closely with DHCS, it is important to understand the larger health care context in California as the state continues to move toward additional integration across public programs to address social determinants of health and complex issues such as homelessness. This will require collaboration with multiple state-level departments, which will impact CalOptima's work.

CHHS' current guiding principles include the following:

1. Adopt a culture of collaboration and innovation.
2. Focus on outcomes and value generation.
3. Use data to drive action.
4. Put the person back in person-centered.
5. See the whole person.[v]

These principles will guide DHCS' work, and CalOptima can use them to think proactively and strategically about likely actions that will be taken over the next several years. Some initiatives are starting to take shape at DHCS and should be factored into CalOptima's next Strategic Plan to ensure necessary resources will be available and that the health plan can be as proactive in its preparations as possible. While DHCS does not have a current strategic plan,[vi] the department has shared priorities that are in line with the CHHS vision to provide a better patient experience with improved outcomes and lower costs.

The following graphic, which may be updated in the next strategic plan, defines the high-level goals of DHCS.[vii] This highlights many of the same themes outlined by CHHS and CMS, including the focus on the member, providing high-quality care, and using public dollars in an effective and efficient manner.

With the rapid growth of the program due to the addition of the Medi-Cal expansion population in 2014, Medi-Cal is the largest Medicaid program in the nation, providing coverage to one-third of all Californians. In more recent years, Medi-Cal enrollment growth has leveled off (and even declined slightly), but the 2019–2020 state budget provision extending Medi-Cal eligibility to undocumented immigrants between the ages of 19–25 is projected to provide full-scope Medi-Cal coverage to an additional 138,000 individuals when it takes effect in 2020.[viii] As discussed above, however, it is possible enrollment will be lower than anticipated due to federal immigration policy.

Currently, DHCS is engaged in several initiatives and pilots that point to its direction to increase person-centered care and to integrate across programs. These include the Coordinated Care Initiative, Whole-Person Care Pilots, Health Homes Program and the Whole-Child Model. CalOptima is currently involved with all these initiatives at some level and has demonstrated a commitment to being innovative and testing new programs that meet the strategic priorities of the state. As these pilots and programs are evaluated and DHCS determines how it will incorporate lessons learned into the broader Medi-Cal program, it is inevitable that there will be some expansion of the programs and some adjustments for the pieces that did not yield expected results. CalOptima is in a strong position to move forward with the state as these projects evolve and to provide input and feedback to DHCS to drive sustainable changes to the Medi-Cal program.

Key Medi-Cal initiatives underway at DHCS that will shape the future direction of the program, and impact CalOptima's work, are discussed below.

Expiration of Federal Section 1115 Medicaid Waiver (Medi-Cal 2020)

The current federal Section 1115 Medicaid waiver expires at the end of 2020. Currently, the entire managed care program (including the authority under which CalOptima operates) is included in the Section 1115 waiver. In addition, the waiver includes authorization for the Whole-Person Care (WPC) pilots, Public Hospital Redesign & Incentives in Medi-Cal (PRIME), the Global Payment Program, Dental Transformation Initiatives, the Drug Medi-Cal Organized Delivery System, California Children's Services (CCS) pilots, and the Coordinated Care Initiative (CCI). The federal government has changed its guidance to states regarding the calculation of "budget neutrality" (all Section 1115 waivers are required to demonstrate they do not cost the federal government more than would otherwise have been spent in the absence of the waiver), which will result in less federal funding for California under a new waiver. This shortfall will drastically reduce the amount of funding available for DHCS to invest

in pilot programs and initiatives and will require the transition of many of the activities under the current waiver into sustainable models, which may involve moving those components into the managed care program. The theme of consolidation, alignment and standardization across the Medi-Cal program is expected to be a significant part of the waiver renewal and is reflected in other activities by DHCS as outlined below. However, because many of these pilot programs, such as WPC, vary significantly in design and target populations by county, standardization will present unique challenges for each county, and DHCS will have to identify the components that will be included statewide.

DHCS California Advancing and Innovating Medi-Cal (CalAIM) Initiative

In 2018, DHCS convened a comprehensive set of stakeholders for its Care Coordination Assessment Project to discuss how to improve Medi-Cal care coordination and developed key themes and next steps from these meetings. [ix] Key findings included the desire to standardize benefits across counties, streamline assessments across programs, and reduce the number of carve-out benefits (such as specialty mental health, dental and long-term care). DHCS has used the recommendations from the Care Coordination Assessment Project to develop its next set of policy initiatives and program changes, including the newly announced CalAIM initiative. CalAIM is a multiyear initiative with the following objectives: "(1) reducing variation and complexity across the delivery system; (2) identifying and managing member risk and need through population health management strategies; and (3) improving quality outcomes and driving delivery system transformation through value-based initiatives and payment reform."[x]

Throughout 2019 and 2020, DHCS intends to engage stakeholders to discuss both CalAIM and the renewal of Medi-Cal's federal waivers. DHCS has indicated it will transition all existing managed care authorities into a single, consolidated federal Section 1915(b) waiver that will include the Medi-Cal Managed Care Plans, the County Mental Health Plans, the Drug Medi-Cal Organized Delivery System Plans and the Dental Managed Care Plans. While DHCS has yet to release a detailed CalAIM proposal, it has shared some limited information about the stakeholder workgroups that will be formed to provide input on the development of CalAIM.[xi] Workgroup topics include: (1) Population Health Management and Annual Health Plan Open Enrollment; (2) NCQA Accreditation; (3) Enhanced Care Management and In Lieu of Services; (4) Behavioral Health; and (5) Full Integration Pilots.

DHCS Stakeholder Advisory Committee

The DHCS Stakeholder Advisory Committee (SAC) was originally established to provide input on the development of the federal Section 1115 waiver. However, it has evolved over time to become the body DHCS uses to discuss issues well beyond the federal waiver, including health care reform and state developments more broadly. With the upcoming renewal of the Section 1115 waiver, DHCS has stated it will begin to discuss in October 2019 the specific proposals related to transitioning the Medi-Cal 2020 waiver into a sustainable model.

DHCS Behavioral Health Stakeholder Advisory Committee

The Behavioral Health Stakeholder Advisory Committee (BH-SAC) is a newly formed, stakeholder workgroup focused on the issues related to the delivery of behavioral health services in Medi-Cal. The current system, which is bifurcated between the health plans (which are responsible for delivering mild-to-moderate services) and the counties (which are responsible for specialty mental health services), is under scrutiny and criticism from many stakeholders. DHCS recently received federal approval to extend the current federal Section 1915(b) Specialty Mental Health Services waiver to the end of 2020 to align with renewal of the Section 1115 waiver. As noted above, DHCS intends to submit a single, consolidated federal Section 1915(b) waiver that will include all of the managed care programs across Medi-Cal, including specialty mental health services.

Prescription Drugs Executive Order

On his first day in office, Governor Newsom announced an Executive Order (EO) intended to control rising pharmacy costs.[xii] The EO includes a shift to bulk purchasing for all government programs, including Medi-Cal (the largest purchaser of prescription drugs in the state). This will involve carving out the Medi-Cal pharmacy benefit from the health plans, so the state can negotiate for all its programs collectively, which it anticipates will result in lower costs. Even with concerns from Medi-Cal stakeholders and opposition from health plans, DHCS has been instructed to move forward on a very aggressive timeline and complete the transition by January 2021. DHCS recently released an RFP to select a single vendor to manage the entire pharmacy benefit under a fee-for-service arrangement.[xiii] Despite running counter to other actions designed to integrate services and benefits across the Medi-Cal program, it appears pharmacy will be carved out. Once the shift occurs, the Medi-Cal health plans will need to be prepared to work with the state's pharmacy vendor to access pharmacy data for their members and coordinate care.

DHCS Managed Care Accountability Set

In early 2019, DHCS announced a major change in quality reporting requirements for the Medi-Cal health plans: health plans must report on the complete CMS Core Measures Set for both adults and children (known as the Managed Care Accountability Set in California).[xiv] This represents a significant increase in the number of measures reported and is being implemented for Measurement Year 2019. Additionally, DHCS currently requires that health plans meet a Minimum Performance Level (MPL) of the 25th percentile and will move to a 50th percentile MPL effective for Measurement Year 2019. While negotiations between the health plans and DHCS have helped reduce the administrative burden and potential for sanctions in the first year of the transition, this is a heavy lift for the health plans and DHCS, and another indicator of a new Administration that is determined to make changes and maintain aggressive implementation timelines. With themes of quality and value throughout both the federal and state priorities, it is likely the pressure to demonstrate high-value care will continue to be a growing focus of DHCS.

Future of the Coordinated Care Initiative (CCI)

CCI, which is currently operating in seven counties, includes the mandatory enrollment of dual eligibles into Medi-Cal managed care, implementation of a managed long-term services and supports (MLTSS) benefit, and assumption of risk by the health plans for long-term care placements.[xv] It also includes the Cal MediConnect (CMC) duals demonstration, which has been extended through 2022.[xvi] The CCI has been placed into state law with no sunset date and an expansion of certain elements would be in line with other efforts by DHCS to align and integrate benefits statewide. Notably, DHCS recently announced that, starting in January 2021 (which aligns with the waiver renewal timeline), it will carve in long-term care benefits to all its managed care models, signaling the move toward standardization of benefits across the state.

The CCI program requires federal waiver authority, and the CMC program requires continued federal approval and negotiation of a three-way contract between DHCS, CMS and the health plans. The future and status of this program is less certain and may be resolved as part of the Section 1115 waiver discussions and negotiations.

Medi-Cal Managed Care Rates

DHCS must submit actuarially sound managed care rates to CMS for review and approval. The capitation rates paid to health plans are tied directly to the Medi-Cal benefits included in the health plan contracts. Per federal regulations, 42 CFR Section 438.4 (a) defines actuarially sound capitation rates as *"projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO … for the time period and the population covered under the terms of the contract."* This means that Medi-Cal Managed Care Plan capitation rates only reflect the costs of providing services to populations included in the contract with DHCS.

The complicated rates structure, which has evolved over many years, has led to thousands of individual rate cells that have to be calculated

by DHCS every year. DHCS has been moving to speed up its rate development process, which is currently under almost a two-year delay, to provide more timely rates to health plans and to meet CMS requirements for prospective rate setting. In addition, DHCS has recently indicated it is examining how to move to a regional rate-setting model, which would streamline its work and require significantly fewer rate cells. However, many factors will continue to complicate the rate development process, some of which are outside of DHCS' control. These include directed payments to certain providers, retroactive implementation of benefits, delays in CMS review and approval, and other legislative and administrative activities that impact the Medi-Cal program. As DHCS moves to increase value-based payments and streamline the rate setting process, providing quality data that reflects the cost of providing high-value care will become even more important. Health plans will want to provide input on these transitions to identify downstream and unintended negative consequences and to promote the timely payment of rates.

Encounter Data Reporting

DHCS has continued to put significant pressure on the health plans to provide complete, accurate and timely encounter data. Under federal Medicaid regulations, CMS can withhold federal funds if the state does not submit this data as required. Additionally, the DMHC has initiated an encounter data task force that is charged with working to standardize and improve encounter data reporting across all health plans (Medi-Cal, Commercial, Medicare, etc.). CalOptima will need to be prepared to respond to any future actions that the state takes as it works to enhance encounter data reporting, which is used for both utilization oversight and rate setting purposes. CalOptima should proactively identify where it can improve encounter data collection and be prepared to work collaboratively with its networks and DHCS.

County Landscape

CalOptima is an integral part of the business community and the health care sector in Orange County. It is important to understand how the federal and state priorities intersect with the local landscape and the needs of the community.

Health Insurance Coverage in Orange County

As shown in the table below, Orange County has more than 30 percent of its population enrolled in public programs, which include Medicare and Medi-Cal, in 2017. [xvii] As the sole Medi-Cal plan in the County, CalOptima has a unique position to impact care delivery and examine ways to reach the additional uninsured. For example, CalOptima offers several plans for individuals with both Medicare and Medi-Cal. Its PACE program for frail seniors has experienced successful growth, in part due to its implementation of the alternative care setting model allowing members to receive services at local Community-Based Adult Services locations. Its OneCare Connect plan, on the other hand, has experienced enrollment and financial performance challenges; the future of this program is uncertain as CMS has approved extension of this program only through 2022.

Current Health Insurance Coverage Type	Statewide	Orange County
Uninsured	7.3%	6.7%
Medicare and Medicaid (Dual Eligibles)	4.3%	3.0%
Medicare	10.9%	11.2%
Medicaid	25.0%	19.1%
Employment-Based	44.4%	51.8%
Privately Purchased	6.5%	7.5%
Other Public	1.5%	0.7%

Competitive Orange County Labor Market

According to the 2019 Orange County Community Indicators Report, the cost of living in Orange County is 91 percent higher than the national average and among the highest in California. The high cost of living is driven largely by high housing costs. In addition, Orange County's unemployment rate (3.0 percent as of June 2019) continues its six-year trend of outperforming state and national unemployment

rates (4.2 percent and 3.8 percent respectively).[xviii] The high cost of living coupled with a low unemployment rate are both challenges for CalOptima. As a public plan, CalOptima has difficulty competing with the private sector for staff in terms of salary. In addition, the low unemployment rate in the County means the hiring environment is very competitive.

Community Collaboration

Community Engagement

CalOptima believes in strengthening its partnerships by enhancing communications with local community organizations and supporting these important partners serving members' health care needs. For fiscal year (FY) 2018–19, CalOptima participated in 126 community events to engage members and the public about CalOptima and its programs, health care and support services. Additionally, CalOptima hosts the quarterly Community Alliances Forum, which is designed to keep CalOptima connected to community stakeholders. CalOptima also participates in more than 30 collaborative meetings throughout Orange County. Finally, CalOptima understands the importance of keeping the local community informed about health plan activities. Through its monthly community announcements and quarterly e-newsletter (known as "Community Connections"), CalOptima provides updates on initiatives and shares information about events and training with more than 2,500 individuals and organizations.

System of Care Data Integration

The County of Orange has launched an integrated data initiative for the County's System of Care for individuals experiencing homelessness. When complete, this initiative will support information sharing across County agencies that offer residents services such as health care, law enforcement, court system, social services and other community resources. Shared data will enhance the coordination of services for "high utilizers" of the County's System of Care and may provide opportunities for early intervention before residents become high utilizers. CalOptima will explore opportunities for data exchange to benefit the mutual individuals we serve.

Behavioral Health/Be Well OC

In 2018, local public and private stakeholders came together to work on behavioral health issues. In addition to CalOptima, key participants include the Orange County Board of Supervisors, Providence St. Joseph Health and Kaiser Permanente. Under this initiative, a regional wellness center is envisioned in Orange County to serve individuals with mental health needs regardless of payor source. The Be Well OC initiative integrates across silos to address social determinants of health and recognizes that issues related to the justice system and housing have a significant impact on health and must be considered as part of a comprehensive solution. This mirrors concerns and priorities highlighted by the state and federal government. CalOptima is well positioned to leverage this local experience to demonstrate its commitment to population health management and effective delivery system transformation.

Homelessness

In Orange County, as across the state, the homeless population has increased significantly over the past few years because of increased housing costs and stagnant wages. To address this problem, Orange County has focused on creating a system of care that uses a multi-faceted approach to respond to the needs of County residents experiencing homelessness. The system of care includes five components: behavioral health, health care, housing, community corrections and public social services.[xix] The County's WPC pilot is an integral part of this work as it is structured to focus on Medi-Cal beneficiaries struggling with homelessness.

CalOptima has responded to this crisis by committing enhanced funding for homeless health programs in the County. Homeless health initiatives supported by CalOptima include:

- Recuperative Care – As part of WPC, services provide post-acute care for up to a 90-day stay for homeless CalOptima members.
- Medical Respite Care – As an extension to the recuperative care program, CalOptima provides additional respite care beyond 90 days of recuperative care under WPC.

- Clinical Field Teams – In collaboration with community health centers, Orange County Health Care Agency's Outreach and Engagement team and other agencies, the pilot program provides immediate treatment/urgent care to individuals experiencing homelessness.
- Homeless Clinic Access Program – The pilot program will focus on increasing access to care by providing incentives for community clinics to establish regular hours to provide primary and preventative care services at Orange County shelters.
- Hospital Discharge Process for Members Experiencing Homelessness – Support is designed to assist hospitals with the increased cost associated with discharge planning under the new state legislative requirements.

As noted above, addressing homelessness is one of the Governor's priorities, and CalOptima can expect the state will be looking for innovative partners to combat this public health crisis.

Health Homes Program (HHP)

HHP is one of the initiatives DHCS has implemented to increase person-centered care and to integrate across programs. CalOptima has elected to bring this program to Orange County to provide increased coordinated care for its highest-risk Medi-Cal members. Eligible members choosing to participate will receive high-touch services, such as in-person health needs assessment, accompaniment to key medical appointments, and housing navigation and sustainability services.

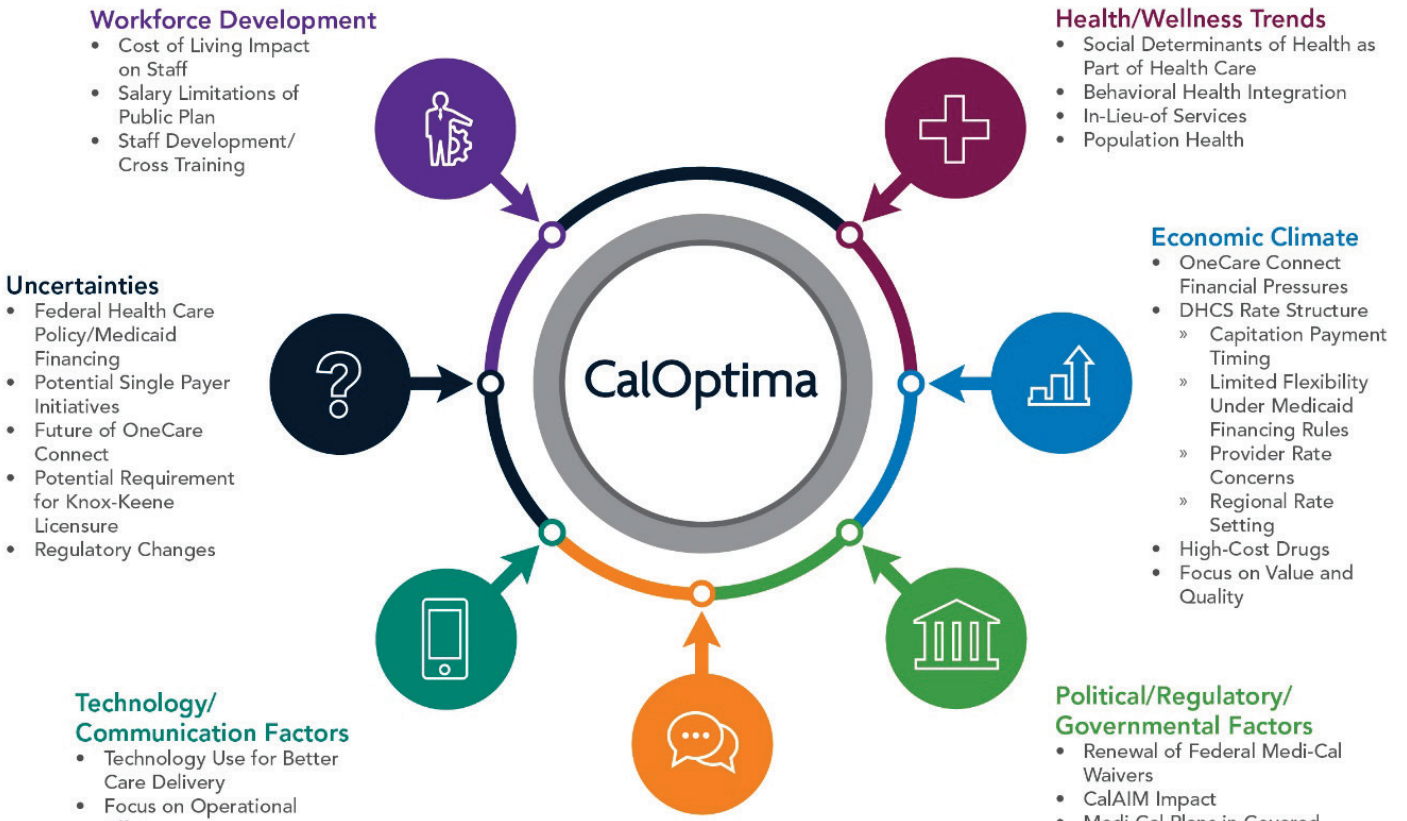
Whole-Person Care Pilot (WPC) Transition to CalOptima

The WPC pilot is expected to transition to the Medi-Cal managed care plans when the waiver expires at the end of 2020. The Orange County Health Care Agency is the lead entity for WP;, and CalOptima has a limited role by providing personal care coordinator services, and access to covered Medi-Cal benefits and funding towards WPC recuperative care. Because details are limited at this time, and it is unclear how DHCS may restructure the individual pilot programs as they transition into managed care, CalOptima will have to be prepared to work collaboratively with WPC stakeholders once DHCS releases more detailed guidance and timeframes. HHP implementation will provide a foundation for this transition.

CalOptima Health Networks and Access

Across California, there are concerns about access to care, the rising cost of living, and a lack of physicians and other health workers. These issues are particularly acute in the Medi-Cal program, which recently launched a physician loan forgiveness program to encourage new physicians to serve this population. CalOptima is engaged in an assessment of its health network structure and reimbursement arrangements to develop stronger networks with value-based payment arrangements. The delivery system study, being conducted by Pacific Health Consulting Group, is expected to be finalized in early 2020 and will present options for CalOptima and its contracted health networks to consider. It is increasingly challenging to recruit and maintain providers with the low reimbursement rates and significant administrative workload associated with the Medi-Cal program (e.g., all providers must now enroll with DHCS). Continued investment in its health networks and collaboration with providers will allow CalOptima to be innovative and meet the needs of members.

Environmental Considerations



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Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Behavioral Health	Behavioral Health Ad Hoc Workgroup Coordination	Expand collaborative opportunities and build a synergistic relationship among the Coalition of Orange County Community Health Centers, their member community health centers and CalOptima to promote health equity of the most vulnerable populations in Orange County, specific to mental health and substance use disorder treatment services.	Increase Value and Improve Care Delivery	6/19/2020	Ongoing
Behavioral Health	Behavioral Health Integration (BHI) Redesign	Develop, document and improve departmental processes for BHI due to transition of care services for OneCare and OneCare Connect from Magellan to CalOptima as of January 1, 2020, and assist with redesign of BHI department organization and internal team processes to improve member experience.	Increase Value and Improve Care Delivery	7/1/2019	Ongoing
Clinical Operations	Enhance Real-Time Monitoring	Implement formalized real-time and near real-time monitoring processes with standards development for tracking, trending, feedback and remediation of utilization management activities.	Enhance Operational Excellence and Efficiency	5/1/2020	Ongoing
Clinical Operations	Medi-Cal Pharmacy Benefit Carve-Out	Carve out Medi-Cal pharmacy benefits to Medi-Cal Fee for Service, effective April 1, 2021. Excluded from the carve-out are OneCare, OneCare Connect, Program of All-Inclusive Care for the Elderly (PACE) and physician-administered drugs.	Enhance Operational Excellence and Efficiency	12/1/2019	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

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Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Clinical Operations	Pediatric Integrated Care Survey	Pilot the implementation of a family-reported survey instrument, developed by Boston Children's Hospital, that measures family experience of care integration in a subset of the Whole Child Model (WCM) population. Both CalOptima and CHOC Health Alliance are participants in the initiative, which will inform quality improvement and interventions to improve integration of services for WCM members.	Expand CalOptima's Member-Centric Focus	2/1/2021	☐ Not Yet Started
Clinical Operations	Pharmacy Benefit Management (PBM)	Negotiate contract with current PBM for dates of service starting January 1, 2022, or pursue a Request for Proposal (RFP) depending on outcome of contract negotiations. Initiative would ensure quality and efficient administration of pharmacy benefit for members in our Medicare programs. Note: Contract with MedImpact was extended through 2024.	Enhance Operational Excellence and Efficiency	11/1/2020	☑ Complete 12/31/2020
Community Engagement	CalOptima Collaboration in the Community	Provide targeted outreach and education projects/activities to (1) increase engagement and collaboration with providers and community stakeholders; and (2) engage our advisory committees and other community stakeholders to identify members' needs, community health issues, priorities and opportunities.	Strengthen Community Partnerships	1/1/2020	▷ Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Community Engagement	Quarterly Safety Net Meetings	Provide a platform for CalOptima and the Coalition of Orange County Community Health Centers to convene on a quarterly basis with a shared strategic agenda to identify opportunities for both organizations to partner and provide value to ongoing health care initiatives.	Strengthen Community Partnerships	4/17/2020	Ongoing
Community Engagement	Vietnamese Leadership Collaborative	Identify key stakeholders serving the Vietnamese community and launch the Vietnamese Leadership Collaborative to lead and address health care issues impacting our Vietnamese membership.	Strengthen Community Partnerships	3/1/2021	Not Yet Started
COVID-19 Response	Community Stakeholder Outreach and Engagement During COVID-19 Pandemic	Provide targeted outreach activities/projects to (1) serve as a reliable source of resource information to community stakeholders; (2) share information about CalOptima and Medi-Cal through virtual platforms; and (3) support community stakeholder sponsored events with information materials and branded items.	Strengthen Community Partnerships	3/1/2020	Ongoing
COVID-19 Response	COVID-19 Pandemic Response	Respond efficiently and proactively to our staff, providers, community partners and others during the pandemic, and adjust as necessary to the resulting regulatory changes from our federal, state and local partners.	Enhance Operational Excellence and Efficiency	3/1/2020	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
COVID-19 Response	Orange County COVID-19 Nursing Home Prevention Program	Engage nursing homes to undergo intensive COVID-19 infection prevention training to provide greater depth and assurance of infection prevention, develop a toolkit and implement training to improve the infection prevention readiness for COVID-19 surge across OC nursing homes.	Innovate and Be Proactive	5/28/2020	Ongoing
COVID-19 Response	PACE Virtual Care	Provide a technology platform for PACE providers and clinicians to connect virtually with PACE participants to meet current COVID-19 physical distancing requirements.	Increase Value and Improve Care Delivery	5/7/2020	Complete 11/24/2020
Employee Support	Emergency Mass Notification System	Provide CalOptima a vehicle to help protect, alert and communicate with CalOptima employees at times of need and/or during emergencies.	Enhance Operational Excellence and Efficiency	4/19/2020	Ongoing
Employee Support	HR Learning Management System and eLearning Content RFP and Implementation	Implement a new learning management system for CalOptima University employee training, development and education programs. Contracted vendor on target for implementation mid-2021.	Enhance Operational Excellence and Efficiency	7/1/2019	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Member Access	Long-Term Care at Home (LTCH)	Provide members with greater access to skilled care at home and facilitate transition from the hospital and skilled nursing facility to home, subject to DHCS approval of its proposed LTCH initiative. Note: LTSS collaborated with DHCS and managed care plan stakeholders to assess the program design and provide structure feedback. On August 26, 2020, DHCS terminated the development of the LTCH program based on the inability to reach agreement with the Administration on a design process.	Expand CalOptima's Member-Centric Focus	5/22/2020	☑ Closed 8/26/2020
Member Access	Preventive Care Outreach (Outbound Call Campaign per All Plan Letter 19-010)	Contact all Medi-Cal beneficiaries under age 21 who have not used, or who have underutilized, preventive care services available under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services, and encourage these beneficiaries to use EPSDT services.	Expand CalOptima's Member-Centric Focus	5/1/2020	▷ Ongoing
Member Access	Private Duty Nursing (PDN) - Case Management Responsibilities for Medi-Cal Eligible Members	Ensure Medi-Cal eligible members under the age of 21 know their right to PDN benefits, which fall under the EPSDT services. Note: Notices were sent to families with members under 21.	Expand CalOptima's Member-Centric Focus	1/1/2020	☑ Complete 11/30/2020

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Organizational Operations	Communications Support	Provide supportive communication strategies, messaging and materials for various strategic initiatives identified by other departments.	Innovate and Be Proactive	1/1/2020	Ongoing
Organizational Operations	DHCS Health Network Certification	Monitor and certify CalOptima's subcontracted networks pursuant to regulatory standards and requirements set forth by DHCS, including time and distance standards, timely access, mandatory provider types and provider to member ratios. CalOptima is in the process of identifying network deficiencies, reviewing results with networks and updating policy accordingly. Note: In March 2022, CalOptima will submit documentation verifying that its networks have met the adequacy standards per DHCS guidance.	Increase Value and Improve Care Delivery	10/1/2019	Ongoing
Organizational Operations	Directed Payments	Operationalize DHCS' Directed Payments programs (Physician Services, Hyde, Developmental Screening Services, Adverse Childhood Experiences Screening, Value-Based Payment and Family Planning Services) to incentivize specific providers for specific services using Proposition 56 (Tobacco tax) funds.	Increase Value and Improve Care Delivery	7/1/2018	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Organizational Operations	E-Signature Change Healthcare/Adobe	Improve efficiencies for providers and CalOptima through Adobe e-signature functionality for provider contracts produced by CalOptima's Contracting Department.	Enhance Operational Excellence and Efficiency	12/2/2019	☑ Complete 7/31/2020
Organizational Operations	Intergovernmental Transfer (IGT) Drawdown Process	Work with DHCS and participating governmental entities to facilitate the transfer of public funds in order to access the highest federally allowable reimbursement rate for Orange County. IGT funds are part of CalOptima's operating income/expenses and must be used for Medi-Cal covered services for the Medi-Cal population.	Increase Value and Improve Care Delivery	7/1/2020	▷ Ongoing
Organizational Operations	Non-Contracted Ground Emergency Medical Transportation (GEMT)	Provide additional funding to non-contracted GEMT providers that service Medi-Cal beneficiaries to support quality improvement efforts through the Quality Assurance Fee.	Increase Value and Improve Care Delivery	7/1/2018	▷ Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Organizational Operations	OneCare Network Build for 2023	Build a OneCare provider network to support continuity and access to care for members participating in OneCare Connect who are expected to transition to OneCare in 2023. As a plan under the Cal MediConnect demonstration project, OneCare Connect is due to sunset at the end of 2022, at which time it is anticipated that existing OneCare Connect members will transition to OneCare. Board authority will be requested as needed.	Increase Value and Improve Care Delivery	9/1/2021	Not Yet Started
Organizational Operations	Organizational Support for Regulatory Guidance Implementation	Facilitate multidepartment activities related to new regulatory requirements to support compliance and organizational policy and process alignment, while ensuring uninterrupted member care. Examples include: Cost Avoidance and Post-Payment Recovery for Other Health Coverage (OHC) (All Plan Letter 20-010); CMS Part C and D Final Rule Requirements (OneCare, OneCare Connect and PACE); D-SNP (OneCare) Contract Year 2021 Provisions; and Medi-Cal Contract Amendment Implementation.	Enhance Operational Excellence and Efficiency	1/1/2020	Ongoing
Organizational Operations	PACE Encounters	Develop end-to-end process for PACE encounters. This process begins with capture of center-based services and ends with validation and monitoring. This will ensure that all encounters are submitted and reported accurately to support CMS risk adjustment for Medicare payments.	Enhance Operational Excellence and Efficiency	1/4/2021	Not Yet Started

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Organizational Operations	Provider Experience Value Stream Enhancement	Facilitate improvement of interdepartmental processes that impact the provider experience and satisfaction including onboarding, letters of agreement, contract uploads and agreement updates, quality monitoring, and provider dispute resolutions.	Enhance Operational Excellence and Efficiency	6/1/2019	Ongoing
Organizational Operations	Provider Trust Exclusion Monitoring	Streamline the required exclusion monitoring review process and implement a workflow that will reduce likelihood of Medicare and Medi-Cal fraud and meet regulatory compliance.	Enhance Operational Excellence and Efficiency	7/1/2019	Ongoing
Organizational Operations	RFP for Provider Data Management Solution System	Issue an RFP to select a vendor, upon Board approval, to produce an integrated provider/partner data system that will merge existing systems used by CalOptima. These systems include Facets, McKesson, Cactus and Guiding Care, among others. The new system will collect data, spot discrepancies, assist in reconciling and validating the data and share it with other systems to which CalOptima exports. The end goal is a single provider data management platform that will be the internal source of truth for all CalOptima provider data with full interoperability.	Innovate and Be Proactive	9/1/2020	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Quality Improvement	Office Ally Electronic Health Record (EHR) Implementation	Build repository of member EHR data from Office Ally providers to close member data gaps for population health management, reduce provider abrasion by requesting fewer medical records for quality related review (HEDIS, PQIs), and assist with turnaround time for Utilization Management denials.	Increase Value and Improve Care Delivery	11/4/2019	Ongoing
Quality Improvement	Post-Acute Infection Prevention Quality Initiative (PIPQI)	Reduce the spread of multi-drug resistant organisms in long-term care facilities and hospital admissions/readmissions through the administration of topical products to reduce bacteria on the body that can produce harmful infections.	Innovate and Be Proactive	10/1/2019	Ongoing
Quality Improvement	Virtual Care Strategy	Improve member access and convenience by (1) supporting use of virtual visits during COVID-19 and beyond; (2) contracting with specialty providers with a virtual care focus for CCN members; (3) contracting with a vendor offering virtual visits including after-hours access for acute non-emergency medical conditions and behavioral health conditions; (4) contracting with a vendor offering eConsults for CCN members and PCPs through CalOptima-contracted specialists; and (5) establishing member texting.	Innovate and Be Proactive	5/7/2020	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Social Determinants of Health	Homeless Health Initiative: Clinical Field Team (CFT) Pilot	Meet the immediate urgent care needs of individuals experiencing homelessness throughout the county wherever they may be located. These on-call urgent care services are provided by contracted community health centers that serve members and others regardless of insurance status. By the end of the pilot, establish a sustainable program to continue these services.	Innovate and Be Proactive	4/1/2019	Ongoing
Social Determinants of Health	Homeless Health Initiative: Homeless Response Team (HRT)	Provide a dedicated team of case managers and care coordinators to administer the CFT pilot. HRT responsibilities include staffing the call line; making dispatches to contracted providers; scheduling, reporting and coordinating with community organizations, providers and health networks; developing relationships with homeless service providers; and engaging members and homeless service providers in the community.	Innovate and Be Proactive	4/1/2019	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Social Determinants of Health	Homeless Health Stakeholder Engagement	Facilitate Homeless Health Stakeholder Engagement Strategy sessions to solicit input on outreach, engagement strategies and best practices from key homeless advocates and stakeholders who have an established presence in the community.	Innovate and Be Proactive	12/1/2020	Ongoing
Social Determinants of Health	In Lieu of Services – Recuperative Care Request	Develop a business case for implementation of recuperative care as an in lieu of service when no longer available under the Whole Person Care pilot. This will include collaboration with the county to leverage WPC experience and the prior DHCS CalAIM proposal. CalOptima will seek authorization from the Board of Directors prior to a formal application to DHCS to authorize recuperative care as an in lieu of service.	Innovate and Be Proactive	10/1/2020	Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Strategic Priority Initiatives

&	Projects*	Purpose	Primary Strategic Priority	Planned Start Date	Status
Social Determinants of Health	Intergovernmental Transfer (IGT) Community Grants	Provide oversight and report grant activity progress and achieved outcomes made toward the grants' goals and objectives. The CalOptima Board of Directors authorized the allocation of IGT funds toward community grants. Twelve community grants were awarded in the following categories: Adult Dental Services, Children's Dental Services, Children's Mental Health Services, Food Distribution Services for Children and Families, Primary Care Services and Social Determinants of Health, and Increase Access to Medication-Assisted Treatment.	Innovate and Be Proactive	10/1/2019	▷ Ongoing

* CalOptima will seek Board of Directors and/or regulatory approval, as needed

Board of Directors Meeting
January 7, 2021

CalOptima 2020–2022 Strategic Plan Consultants

Athena Chapman currently serves as the President of Chapman Consulting where she provides strategic planning, meeting facilitation, and organizational support to a variety of health care related organizations. Previously, Ms. Chapman served as the Vice President of State Programs for the California Association of Health Plans (CAHP) where she represented California's health plans regulated by the Department of Health Care Services (DHCS).

Prior to joining CAHP in 2012, Ms. Chapman worked at the Medi-Cal Managed Care Division at the Department of Health Care Services, focusing on managed care quality, policy, oversight, and contracting. Ms. Chapman began her career in health care policy as Presidential Management Fellow with the Centers for Medicare and Medicaid Services (CMS), where she monitored the effective delivery of managed care programs for Medicaid and Medicare beneficiaries in the western region.

Ms. Chapman earned her master's degree in public policy from George Mason University and bachelor's degree in Sociology from the University of San Diego (Cum Laude).

Caroline Davis currently serves as the President of Davis Health Strategies, working with health care-related organizations focused on improving care for vulnerable and safety-net populations. Ms. Davis is a recognized health policy expert with more than 20 years of experience in health care financing, policy development and implementation at the federal, state and local levels, with an emphasis on Medicaid, Medicare, and programs for the uninsured.

Ms. Davis has extensive experience with California's health programs for low-income populations, especially the state's Medicaid (Medi-Cal) program. Previously, Ms. Davis served as the Senior Policy Director for the Local Health Plans of California (LHPC) where she provided leadership and strategic direction to identify policy and advocacy positions for California's 16 locally based health plans as well as analysis of the operational impacts of Medi-Cal legislative and regulatory proposals.

Ms. Davis earned her master's degree in public policy from Duke University and her bachelor's degree (Cum Laude) from Carleton College.

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CalOptima

Better. Together.

COVID-19 Update
Response to Board Directive

Special Meeting of the CalOptima Board of Directors
January 7, 2021

Richard Sanchez, Chief Executive Officer
Dr. Emily Fonda, Interim Chief Medical Officer

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Overview

- Current COVID-19 Efforts
- CalOptima Member COVID-19 Population Analysis
- Proposed COVID-19 Efforts
- COVID-19 Vaccination Outreach

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Current COVID-19 Efforts

- Orange County (OC) Nursing Home Program
  - Intensive infection protection training conducted by UCI epidemiology team
- Post Acute Infection Prevention Quality Incentive
  - Supports the substitution of regular liquid soap with chlorhexidine soap in nursing homes
- Implemented State's LTC 10% rate increase
- 24/7 Virtual Urgent Care Pilot (CCN)
  - Virtual urgent care visits, including after-hour access for all CalOptima members regardless of network assignment for both medical and behavioral health conditions

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Current COVID-19 Efforts (cont'd.)

- Behavioral Health Support
  - Telehealth is offered for members seeking behavioral health services.
  - 24/7 CalOptima Behavioral Health Line

- Homeless Health Initiatives
  - Homeless Clinical Access Program/Clinical Field Team Pilot
    - Allows for urgent and scheduled visits to be conducted via telehealth
    - Added COVID testing as a resource to homeless members seen by community health centers participating in the Clinical Field Team Pilot
  - Project Homekey
    - Funding non-Medical covered Day Habilitation services for members residing at program properties

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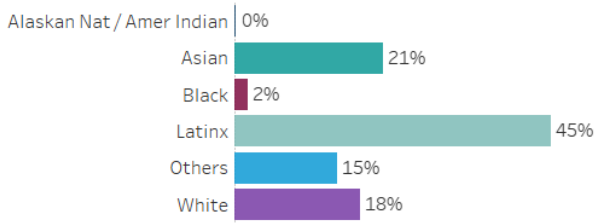
CalOptima Member COVID-19 Population Analysis

December 2020

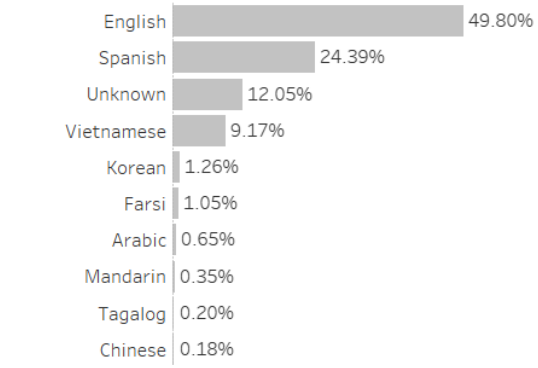
Member Age Group: All

All Total Members	All High Risk Conditions	All Experiencing Homelessness	All LTC Residents
806,334	200,978	12,130	4,148

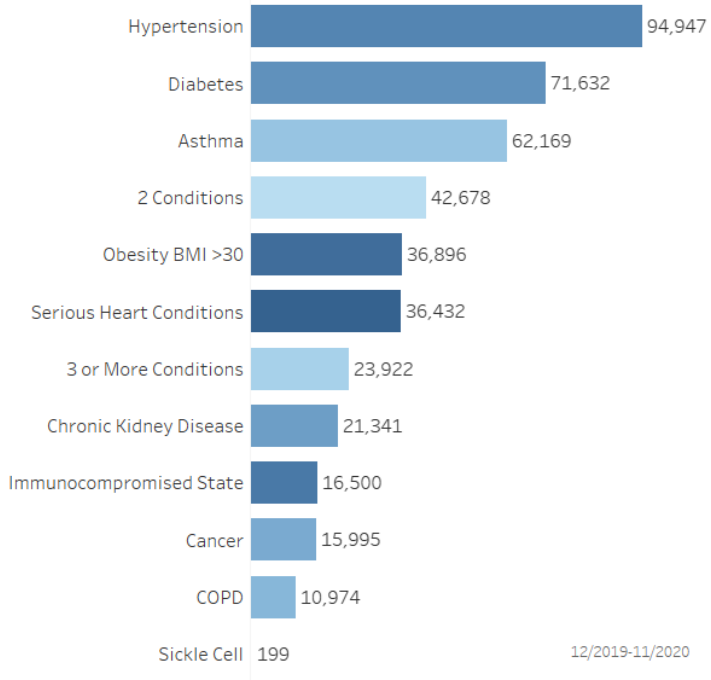
Member Counts by Ethnicity: All



Member Counts: Top Ten Languages: All



Member Counts by High Risk Condition (Per CDC): All



Data pulled on 12.28.20 Data Source: EA_ConditionPrevalence; Time Frame: 12/2019 – 11/2020; EA_EQ_Member Detail; Time Frame: December 2020; Line of Business: All

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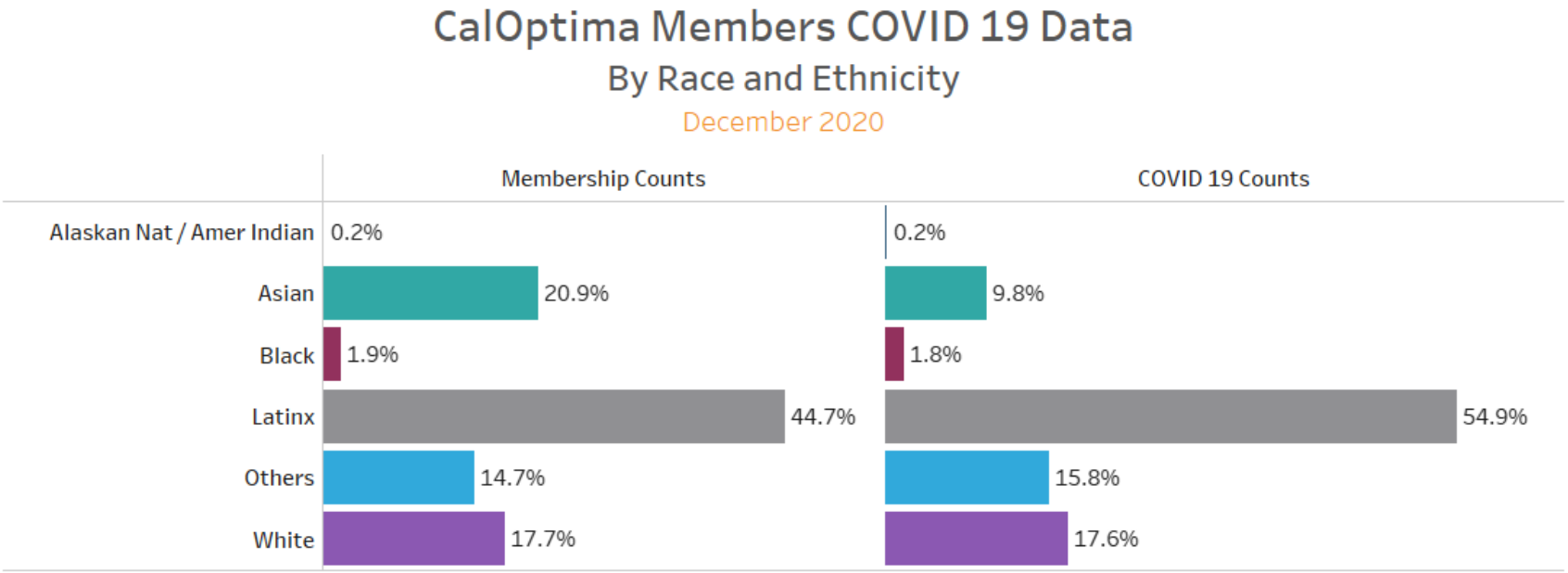
CalOptima Members COVID-19 Data: December 2020

- Latinx account for 54.9% of coronavirus cases and make up 44.7% of the CalOptima's membership
- Blacks account for 1.8% of cases and make up 1.9% of the membership



COVID 19 cases coded in Claims and Encounters received though 12/18/20

Proposed COVID-19 Efforts

- OC Nursing Home Program Expansion (Item 3)
- COVID Vaccination Incentive Programs (Items 4 - 5)
  - Homeless Population
  - General Membership
- Gerinet LOA Ratification and Contract Amendment for nursing facility placement assistance (Item 6)
- Enhanced Provider Rates (Item 7)
  - Rate increases for Medi-Cal capitation between January 1, 2021 – June 30, 2021 for COVID-related expense

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Proposed COVID-19 Efforts (cont'd.)

- Community Vaccination Events
  - In partnership with community organizations that provide housing/food resources
  - Hosted in targeted geographic areas as an extension of County efforts
  - Leverage transport available through CalOptima
- FFS Hospital COVID-related Supplemental Reimbursement
  - January 1, 2021-June 30, 2021
- FFS Professional Service Provider COVID-related PM Reimbursement (one-time)

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COVID-19 Vaccination Outreach

- **Communications Strategy:** build confidence around the vaccine and share information about accessibility.
  - Key Audiences:
    - Members
    - Providers
    - Community-Based Organizations
  - Tactics:
    - Text messaging
    - Phone calls
    - Direct mailings/collateral distribution throughout the community
    - Member materials (e.g. FAQs, banner ads, on hold messaging)
    - Provider materials
    - Advertising
    - Speakers Bureau

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Our Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner

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CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken January 7, 2021
Special Meeting of the CalOptima Board of Directors

Report Item

3. Consider Expansion and Extension of the Orange County COVID-19 Nursing Home Prevention Program, and its associated Grant, related to Support of Orange County Nursing Facilities During the Coronavirus Pandemic

Contacts

Emily Fonda, M.D., MMM, CHCQM, Interim Chief Medical Officer, (714) 246-8887
Tracy Hitzeman, RN, CCM, Executive Director, Clinical Operations, (714) 246-8549
Ladan Khamseh, Chief Operating Officer, (714) 246-8866

Recommended Actions

1. Approve allocation of Intergovernmental Transfer (IGT) 10 funds in the amount of $1.2 million to support the expansion and extension of the Orange County COVID-19 Nursing Home Prevention Program that will be delivered by the University of California at Irvine (UCI) epidemiological team in Calendar Year (CY) 2021;
2. Authorize the Chief Executive Officer (CEO), with the assistance of Legal Counsel, to amend the Grant Agreement with the Regents of the UCI to expand the scope of services and increase the grant amount, as necessary, to provide for UCI's participation in the extended and expanded Orange County COVID Nursing Home Prevention Program; and
3. Authorize the CEO to implement the Orange County Nursing Facilities Support Program for CY 2021 prior to CalOptima's receipt of IGT 10 funds from the State of California.

Background

Data has shown that individuals residing in nursing facilities are among the most vulnerable to infection, hospitalization and poor outcomes due to COVID-19 illness. In an effort to mitigate the spread of COVID-19 among the nursing home population, on May 7, 2020, the CalOptima Board of Directors approved IGT 9 funding of a $629,723 quality performance grant with the Regents of the University of California, on behalf of UCI, which was matched by the Orange County Health Care Agency (OCHCA). The purpose of this quality performance grant administered by the UCI Epidemiology team led by Susan Huang, M.D., MPH, Professor, Division of Infectious Diseases and Medical Director, Epidemiology & Infection Prevention, was to develop a COVID-19 toolkit and implement training to protect nursing facility staff and patients and for environmental infection prevention. Funds also covered intensive training using video assistance in a key subgroup and supported testing services. The term of the current IGT 9 funded grant is expected to end when 12-month grant project is completed, which may be as early as May 14, 2021 and no later than August 31, 2021.

Separately, more work is needed as the response to the pandemic shifts to vaccination efforts. Vaccination of long-term care residents and staff is the highest priority in the phased approach to vaccine distribution, which began in late December 2020. However, early estimates of COVID-19 vaccine uptake by nursing facility staff is approximately 15%-20%, reportedly due to some misinformation circulating in the community. Expansion of this program to include messaging that builds confidence around getting vaccinated is attempting to positively impact the vaccine uptake statistic among nursing facility staff.

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In order to continue the infection control efforts given the increase in COVID-19 outbreaks among nursing facilities and to address the staff resistance to acceptance of the vaccination, CalOptima staff proposes expanding the scope of work and extending the term of the existing grant agreement through the utilization of IGT 10 funds. CalOptima staff did reach out to OCHCA, and though they are supportive of the program, they are unable to provide any financial assistance to support this program continuation and expansion.

Intergovernmental Transfers are transfers of public funds between eligible government entities which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has participated in ten Voluntary Rate Range IGT transactions. Funds from IGTs 1 through 9 have been received and IGT 10 funds will be distributed in two separate installments and are expected from the state in 2021. It is anticipated that CalOptima's share of IGT 10 funds will be approximately $66 million ($43.3 million in Spring 2021 and $22.7 million in Fall 2021).

Discussion

The resurgence of COVID-19 severely impacts Orange County nursing facilities and leads to this proposal for both an expansion and extension of the Orange County COVID-19 Nursing Home Prevention Program, which includes the following elements to be developed and delivered by a UCI epidemiological team:

Urgent Expansion to Support Vaccine Uptake (2/1/21–5/31/21)

- Host informational webinars to increase knowledge and dispel myths about the Covid-19 vaccine for nursing home staff and residents in English and Spanish
- Offer in-person Q&A to nursing facility staff by UCI Infectious Disease Staff in English and Spanish
- Establish a telephonic and text-enabled helpline for vaccine questions for nursing facility staff in English and Spanish manned by UCI Infectious Disease Staff
- Provide posters and breakroom washable laminates to address vaccine hesitancy and lack of knowledge
- Support vaccine uptake tracking
- Co-brand CalOptima-UCI communication materials promoting COVID vaccine uptake

COVID-19 Nursing Home Prevention Team Extension (6/1/21–5/30/22)

- Ongoing infection prevention support for COVID-19 safety until pandemic ends
- COVID-19 infection prevention – maintenance and redress
    - Posters and helpline for COVID issues
    - Webinar on major environmental cleaning gaps
    - Webinar on what to retain post-pandemic
    - Weekly video montages and quantified tracking on infection prevention practices for 12 nursing homes to identify gaps and improvement
    - Use of UV marker to train on environmental cleaning gaps
    - Conversion of toolkit/website for longstanding efforts on seasonal flu/colds
- COVID-19 monitoring next winter/flu season
    - Sampling sweeps for COVID-19 in nursing homes in late fall/early winter

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- COVID-19 impact on Multi-Drug Resistant Organisms (MDROs)/emerging pathogens
    - Sampling sweeps for recidivism in MDROs and Candida Auris due to cohorting for COVID

Due to timing issues, Staff requests that the Board authorize the CEO to implement the Orange County Nursing Facilities Support Program for CY 2021 prior to CalOptima's receipt of IGT 10 funds from DHCS. Providing funding expeditiously for this program will directly support and improve care for CalOptima's long term care members.

It should be noted that since IGT 10 funds are accounted for in the same fashion as the Medi-Cal capitation revenue CalOptima receives from the DHCS, to the extent that these funds are not expended on covered, medically necessary Medi-Cal services or qualifying quality initiatives, the expenditures would be charged to CalOptima's administrative loss ratio (ALR), rather than the medical loss ratio (MLR).

Fiscal Impact

The recommended action to allocate $1.2 million in IGT 10 funds to support the Orange County COVID Nursing Home Prevention Program expansion and extension has no net fiscal impact to CalOptima's Fiscal Year 2020-21 Operating Budget approved by the Board on June 4, 2020. Staff anticipates any cash expended to implement the program will be replenished when IGT 10 funds are received from DHCS. Expenditure of IGT funds is for restricted, one-time purposes for covered Medi-Cal services to CalOptima members and does not commit CalOptima to future budget allocations.

Rationale for Recommendation

The proposed expansion and extension of the Orange County COVID Nursing Home Prevention Program will support CalOptima's efforts to continue providing access to quality health care to members residing at skilled nursing facilities during the COVID-19 public health crisis.

Concurrence

Gary Crockett, Chief Counsel

Attachments

1. Entities Covered by this Recommended Action
2. CalOptima Board Action dated February 6, 2020, Consider Pursuit of Proposals with Qualifying Funding Partners to Secure Medi-Cal Funds Through the Voluntary Rate Range Intergovernmental Transfer Program for Rating Period 2019-20 (IGT 10)
3. CalOptima Board Action dated May 7, 2020, Consider Actions Related to Support Orange County Nursing Facilities During the Coronavirus (COVID-19) Pandemic
4. UCI Proposal: OC Nursing Home COVID Prevention Team: Urgent Expansion Proposal for Vaccine Uptake

/s/ Richard Sanchez *12/31/2020*
Authorized Signature **Date**

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Attachment to the January 7, 2021 Special Board of Directors Meeting – Agenda Item 3

ENTITIES COVERED BY THIS RECOMMENDED BOARD ACTION

Legal Name	Address	City	State	Zip code
Regents of the University of California at Irvine	120 Theory, Suite 200	Irvine	CA	92697
Regents of the University of California, Irvine/University of California, Irvine (UCI Health)	333 City Blvd. West, Suite 200	Orange	CA	92868

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CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken February 6, 2020
Regular Meeting of the CalOptima Board of Directors

Report Item

15. Consider Pursuit of Proposals with Qualifying Funding Partners to Secure Medi-Cal Funds Through the Voluntary Rate Range Intergovernmental Transfer Program for Rating Period 2019-20 (IGT 10)

Contact

Candice Gomez, Executive Director, Program Implementation, (714) 246-8400

Recommended Actions

Authorize the following activities to secure Medi-Cal funds through the Voluntary Intergovernmental Transfer (IGT) Rate Range Program:

1. Submission of a proposal to the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range IGT Program for Rating Period 2019-20 (IGT 10);
2. Pursuit of IGT funding partnerships with the University of California-Irvine, the Children and Families Commission, the County of Orange, the City of Orange, and the City of Newport Beach to participate in the upcoming Voluntary Rate Range IGT Program for Rating Period 2019-20 (IGT 10); and,
3. Authorize the Chief Executive Officer to execute agreements with these entities and their designated providers as necessary to seek IGT 10 funds.

Background

Intergovernmental Transfers (IGT) are transfers of public funds between eligible government entities which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has participated in eight Rate Range IGT transactions. Funds from IGTs 1 through 8 have been received and IGT 9 funds are expected from the state in the first quarter of 2020. IGTs 1 through 9 covered the applicable twelve-month state fiscal year (FY) periods (i.e., FY 2010-11 through FY 2018-19). IGT 1 through 7 funds were retrospective payments for prior rate range years and were designated to be used to provide enhanced/additional benefits to existing Medi-Cal beneficiaries, as represented to CMS. These funds have been best suited for one-time investments or as seed capital for enhanced health care services for the benefit of Medi-Cal beneficiaries.

The IGT funds received under IGTs 1 through 7 have supported special projects that address unmet healthcare needs of CalOptima members, such as vision and dental services for children, obesity prevention and intervention services, provider incentives for adolescent depression screenings, recuperative care for homeless members, and support for members through the Personal Care Coordinator (PCC) program.

Beginning with IGT 8, the IGT program covers the current fiscal year and funds will be incorporated into the contract between DHCS and CalOptima for the current fiscal year. Unlike previous IGTs (1-7), beginning with IGT 8 funds must be used in the current rate year for CalOptima covered Medi-Cal services per DHCS direction. IGT 8 funds have been allocated to the Homeless Health Initiative. IGT 9 funds have not yet been received, nor allocated; CalOptima staff anticipates returning with recommendations on an allocation plan in a separate Board action; however, as indicated,

per DHCS, the use of these funds is limited to covered Medi-Cal benefits for existing CalOptima members.

For the approved and funded IGT transactions to date, the net proceeds have been evenly divided between CalOptima and the respective funding partners, and funds retained by CalOptima have been invested in addressing Member's unmet healthcare needs.

Discussion

On December 20, 2019, CalOptima received notification from DHCS regarding the Rating Period 2019 - 20 Voluntary Rate Range IGT Program (IGT 10). Unlike the prior IGTs, which covered the applicable twelve-month state fiscal year, IGT 10 covers eighteen months including the periods of July 1, 2019 through June 30, 2020 and July 1, 2020. through December 31, 2020. CalOptima's proposal, along with the funding entities' supporting documents are due to DHCS no later than February 19, 2020.

The five eligible funding entities from the previous IGT transactions have been contacted regarding their interest in participation in IGT 10. All five funding entities have informally indicated that they are interested in participation in the IGT program this year. The formal DHCS required Letter of Interest is due to CalOptima by February 14, 2020 for delivery to DHCS by February 19, 2020. These entities are:

1. University of California, Irvine,
2. Children and Families Commission of Orange County,
3. County of Orange,
4. City of Orange, and
5. City of Newport Beach.

Board approval is requested to authorize staff to submit the proposal letter to DHCS for participation in the 2019-20 Voluntary IGT Rate Range Program and to authorize the Chief Executive Officer to enter into agreements with each of the five proposed funding entities submitting a letter of interest (or their designated providers) for the purpose of securing available IGT funds. Consistent with the nine prior IGT transactions, it is anticipated that the net proceeds will be split evenly between the respective funding entities and CalOptima.

Staff will return to the Board with additional information regarding the IGT 10 transaction and a proposed expenditure plan for CalOptima's share of the net proceeds at a later date.

Fiscal Impact

The recommended actions to submit a proposal to DHCS and pursue IGT funding partnerships with five governmental funding entities for IGT 10 is expected to generate one-time IGT revenue that will be invested in covered Medi-Cal services for CalOptima members. As such, there is no net fiscal impact on CalOptima's current and future operating budgets.

Rationale for Recommendation

Consistent with the previous nine IGT transactions, submission of the proposal and authorization of funding agreements will allow the ability to maximize Orange County's available IGT funds for Rate Year 2019-20 (IGT 10). Also, consistent with the 2020-22 Strategic Plan, it would increase funding to support delivery of covered Medi-Cal services for CalOptima members.

Concurrence

Gary Crockett, Chief Counsel

Attachment

1. Entities Covered by this Recommended Board Action
2. Department of Health Care Services Voluntary IGT Rate Range Program Notification Letter

/s/ Michael Schrader — *01/28/2020*

Authorized Signature — **Date**

Attachment 1 to February 6, 2020 Board of Directors Meeting – Agenda Item 15

ENTITIES COVERED BY THIS RECOMMENDED BOARD ACTION

Legal Name	Address	City	State	Zip code
Children and Families Commission of Orange County	1505 E. 17th Street, 230	Santa Ana	CA	92705
City of Newport Beach	100 Civic Center Drive	Newport Beach	CA	92660
City of Orange	300 E. Chapman Avenue	Orange	CA	92866
Orange County Health Care Agency	405 W. 5th Street, 7th Floor	Santa Ana	CA	92701
University of California, Irvine UCI Health	333 City Blvd. West, Suite 200	Orange	CA	92868

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State of California—Health and Human Services Agency
Department of Health Care Services

RICHARD FIGUEROA
ACTING DIRECTOR

GAVIN NEWSOME
GOVERNOR

DEC 2 0 2019

Nancy Huang
Interim Chief Financial Officer
CalOptima
505 City Parkway West
Orange, CA 92868

SUBJECT: Rating Period 2019–20 (July 1, 2019 through December 31, 2020) Voluntary Rate Range Program – Request for Medi-Cal Managed Care Plan's (MCP) Proposal

Dear Ms. Nancy Huang:

The Rating Period 2019-20 Voluntary Rate Range Program, authorized by Welfare and Institutions (W&I) Code sections 14164, 14301.4, and 14301.5, provides a mechanism for funding the non-federal share of the difference between the lower and upper bounds of a MCP's actuarially sound rate range, as determined by the Department of Health Care Services (DHCS). Governmental funding entities eligible to transfer the non-federal share are defined as counties, cities, special purpose districts, state university teaching hospitals, and other political subdivisions of the state, pursuant to W&I Code section 14164(a). These governmental funding entities may voluntarily transfer funds to DHCS via intergovernmental transfer (IGT). These voluntary IGTs, together with the applicable Federal Financial Participation (FFP), will be used to fund payments by DHCS to MCPs as part of the capitation rates paid for the service periods of July 1, 2019 through June 30, 2020, and July 1, 2020 through December 31, 2020.

DHCS shall not direct the MCP's expenditure of payments received under the Rating Period 2019-20 Voluntary Rate Range Program. These payments are subject to all applicable requirements set forth in the MCP's contract with DHCS. These payments must also be tied to covered Medi-Cal services provided on behalf of Medi-Cal beneficiaries enrolled within the MCP's rating region.

The funds transferred by an eligible governmental funding entity must qualify for FFP pursuant to Title 42 Code of Federal Regulations (CFR) Part 433, Subpart B, including the requirements that the funding source(s) shall not be derived: from impermissible sources such as recycled Medicaid payments, Federal money excluded from use as state match, impermissible taxes, and non-bona fide provider-related donations. Impermissible sources do not include patient care or other revenue received from

programs such as Medicare or Medicaid to the extent that the program revenue is not obligated to the state as the source of funding.

DHCS shall continue to administer all aspects of the IGT related to the Rating Period 2019-20 Voluntary Rate Range Program, including determinations related to fees.

PROCESS FOR RATING PERIOD 2019-20:

MCPs should refer to the estimated Rating Period 2019-20 (service periods July 1, 2019 through June 30, 2020, and July 1, 2020 through December 31, 2020) county/region-specific non-federal share required to fund available rate range amounts for the MCP (see Attachment C). As a reminder, participation in the Rating Period 2019-20 Voluntary Rate Range Program is voluntary on the part of the transferring entity and the MCP. Note that for service periods July 1, 2019 through June 30, 2020 and July 1, 2020 through December 31, 2020, the Contribution (Non-Federal Share) amounts are based on Estimated Member Months, and the actual amounts may change based on actual enrollment. Note that for service period July 1, 2020 through December 31, 2020, the Contribution (Non-Federal Share) amounts are based on Projected Contribution PMPMs, and the actual amounts may change based on the risk adjustment process that DHCS uses as part of its rate development methodology.

If an MCP elect to participate in the Rating Period 2019-20 Voluntary Rate Range Program, the MCP must adhere to the process for participation outlined below:

Soliciting Interest

The MCP shall contact potential governmental funding entities to determine their interest, ability, and desired level of participation in the Rating Period 2019-20 Voluntary Rate Range Program. All providers and governmental funding entities who express their interest directly to DHCS will be redirected to the applicable MCP to facilitate negotiations related to participation. If, following the submission of the MCP's proposal, one or more governmental funding entities included in the MCP's proposal are unable or unwilling to participate in the Voluntary Rate Range Program, the MCP shall attempt to find other governmental funding entities able and willing to participate in their place.

The MCP must inform all participating governmental entities that, unless DHCS determines a statutory exemption applies, IGTs submitted in accordance with W&I Code section 14301.4 are subject to an additional 20 percent assessment fee (calculated on the value of their IGT contribution amount) to reimburse DHCS for the administrative costs of operating the Voluntary Rate Range Program and to support the Medi-Cal program. DHCS will determine if a fee waiver is appropriate.

Submission Requirements

Once the MCP has coordinated with the relevant governmental funding entities, the following documents must be submitted to DHCS in accordance with the requirements and procedures set forth below:

- The MCP must submit a **proposal** to DHCS. This proposal must include:

    1. A cover letter signed by the MCP's Chief Executive Officer or Chief Financial Officer on MCP letterhead.
    2. The MCP's primary contact information (name, e-mail address, mailing address, and phone number).
    3. County/region-specific summaries of the selected governmental funding entities, related providers, and participation levels specified for Rating Period 2019-20. The combined amounts or percentages must not exceed 100 percent of the estimated non-federal share of the available rate range amounts provided by DHCS. If the MCP is unable to use the entire available rate range, the MCP must indicate the unfunded amount and percentage.
    4. All letters of interest (described below) and supporting documents must be attached to the proposal. If the Rating Period 2019-20 Voluntary Rate Range Program Supplemental Attachment described below is not collected by the MCP and attached to the proposal at the time of submission, please indicate if the information will be submitted to DHCS directly by each governmental funding entity.

- The MCP must obtain a **letter of interest** from each governmental funding entity included in the MCP's proposal to DHCS. The highlighted sections in the letter of interest form provided in Attachment A must be filled out completely and printed on the participating governmental funding entity's letterhead. A separate letter of interest must be provided for each county or rating region. An individual who is authorized to sign the certification on behalf of the governmental funding entity must sign the letter of interest.

- The MCP must distribute to governmental funding entities and ensure submission to DHCS, either by the MCP or the governmental funding entity, of the **Rating Period 2019-20 Voluntary Rate Range Program Supplemental Attachment** (see Attachment B) by Wednesday, February 19, 2020.

- The proposals and letters of interest are due to DHCS ***by 5pm on* Wednesday, February 19, 2020**. Please send a PDF copy of the required documents by e-

mail to Sandra.Dixon@dhcs.ca.gov. ***Failure to submit all required documents by the due date may result in exclusion from the Rating Period 2019-20 Voluntary Rate Range Program.***

Each proposal is subject to review and approval by DHCS. The review will include an evaluation of the proposed provider participation levels in comparison to their uncompensated contracted Medi-Cal costs and/or charges. DHCS reserves the right to approve, amend, or deny the proposal at its discretion.

Upon DHCS' approval of the governmental funding entities and non-federal share amounts for the Rating Period 2019-20 Voluntary Rate Range Program, DHCS will provide the necessary funding agreement templates, forms, and related due dates to the specified governmental funding entities and MCP contacts. The governmental funding entities will be responsible for completing all necessary funding agreement documents, responding to any inquiries necessary for obtaining approval, and obtaining all required signatures.

If you have any questions regarding this letter, please contact Sandra Dixon at (916) 345-8269 or by email at Sandra.Dixon@dhcs.ca.gov.

Sincerely,

Jennifer Lopez
Division Chief
Capitated Rates Development Division

Attachments

cc: Michael Schrader
CalOptima
505 City Parkway West
Orange, CA 92868

Sandra Dixon
Capitated Rates Development Division
Department of Health Care Services
1501 Capitol Avenue, MS 4413
P.O. Box 997413
Sacramento, CA 95899-7413

ATTACHMENT A – LETTER OF INTEREST

Jennifer Lopez
Division Chief
Capitated Rates Development Division
Department of Health Care Services
1501 Capitol Avenue, MS 4413
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Ms. Lopez:

This letter confirms the interest of _Insert Participating Funding Entity Name, a governmental entity, federal I.D. Number _Insert Federal Tax I.D. Number, in working with Managed Care Plan's Name (hereafter, "the MCP") and the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range Program, including providing an Intergovernmental Transfer (IGT) to DHCS to be used as a portion of the non-federal share of actuarially sound Medi-Cal managed care capitation rate payments incorporated into the contract between the MCP and DHCS for the service periods of July 1, 2019 through June 30, 2020, and July 1, 2020 through December 31, 2020. This is a non-binding letter, stating our interest in helping to finance health improvements for Medi-Cal beneficiaries receiving services in our jurisdiction. The governmental entity's funds are being provided voluntarily, and the State of California is in no way requiring the governmental entity to provide any funding.

_Insert Participating Funding Entity Name is willing to contribute approximately $_____ for the Rating Period 2019-20 (July 1, 2019 through December 31, 2020) as negotiated with the MCP. We recognize that, unless a waiver is approved by DHCS, there will be an additional 20-percent assessment fee payable to DHCS on the funding amount, for the administrative costs of operating the voluntary rate range program.

The following individual from our organization will serve as the point of communication between our organization, the MCP and DHCS on this issue:

Entity Contact Information:

(Please provide complete information including name, street address, e-mail address and phone number.)

I certify that I am authorized to sign this certification on behalf of the governmental entity and that the statements in this letter are true and correct.

Sincerely,

Signature

Attachment B

Voluntary Rate Range Program Supplemental Attachment
Rating Period 2019-20 (July 1, 2019 through December 31, 2020)

Provider Name:	
County:	
Health Plan:	

Instructions

Complete all yellow-highlighted fields. **Submit this completed form via e-mail to Sandra Dixon (sandra.dixon@dhcs.ca.gov) at the Department of Health Care Services (DHCS) by no later than February 19, 2020.**

1. In the table below, report charges/costs and payments received or expected to be received from the Health Plan indicated above for Medi-Cal services (Inpatient, Outpatient, and All Other) provided to Medi-Cal beneficiaries enrolled in the Health Plan and residing in the County indicated above, for dates of service from July 1, 2018 - June 30, 2019.

	Charges	Costs	Payments from Health Plan*	Uncompensated Chares (charges less payments)	Uncompensated Costs (Costs less payments)
Inpatient				$	$
Outpatient				$	$
All Other				$	$
Total	$	$	$	$	$

* Include payments received and anticipated to be received for service dates of July 1, 2018 through June 30, 2019.

2. Are you able to fund 100% of the higher of the uncompensated charges or uncompensated costs (as stated above)? *(Yes / No)*

If No, please specify the amount of funding available:

3. Describe the scope of services provided to the specified Health Plan's Medi-Cal members, and if these services were provided under a contract arrangement.

4. Please provide the following information:

(i) The name of the entity transferring funds:

(ii) The operational nature of the entity (county, city, special purpose district, state university teaching hospitals or other political subdivisions of the state) transferring funding:

(iii) The source of the funds:
(Funds must not be derived from impermissible sources such as recycled Medicaid payments, federal funds excluded from use as State match, impermissible taxes, and non-bona fide provider-related donations. Impermissible sources do not include patient care or other revenue received from programs such as Medicare or Medicaid to the extent that the program revenue is not obligated to the State as the source of

(iv) Does the transferring entity have general taxing authority? *(Yes / No)*

If No, does the transferring entity receive State appropriations (identify level of appropriation)? This may include, but not limited to, annual State appropriations for various programs, or realignment funds to support programs transferred by State Law to local control. *(Yes / No)*

5. Comments / Notes

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ATTACHMENT C

TOTAL AVAILABLE RATE RANGE

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CalOptima - Orange (HCP 506)
IGT - 2019/20 (July 2019 - June 2020)

	Total	50% FFP (Non-MCHIP,SPD and LTC)	88% FFP (MCHIP - 7/2019 to 9/2019)	76.5% FFP (MCHIP - 10/2019 to 6/2020)	BCCTP[3]	WCM[4]	93% FFP Optional Expansion (7/2019 - 12/2019)	90% FFP Optional Expansion (1/2020 - 6/2020)
Total Funds Available	$ 143,831,947	$ 60,609,553	$ 2,248,273	$ 6,744,806	$ 567,560	$ 20,884,320	$ 26,388,727	$ 26,388,708
Federal Match	$ 98,389,329	$ 30,304,777	$ 1,978,480	$ 5,159,777	$ 189,344	$ 12,465,598	$ 24,541,516	$ 23,749,837
Governmental Funding Entity's Portion	$ 45,442,618	$ 30,304,776	$ 269,793	$ 1,585,029	$ 378,216	$ 8,418,722	$ 1,847,211	$ 2,638,871
	31.6%	50.0%	12.0%	23.5%	66.6%	40.3%	7.0%	10.0%

Rate Categories[1]	Member Months (per Mercer est.)	Lower Bound (per Mercer Rate Worksheets)	Upper Bound (per Mercer Rate Worksheets)	Difference between Upper and Lower Bound	Other Departmental Usage[2]	Available PMPM (less Other Dept. Usage)	Estimated Available Total Fund
Child - non MCHIP	2,271,664	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 15,356,449
Child - MCHIP 7/2019 - 9/2019	303,510	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 2,051,728
Child - MCHIP 10/2019 - 6/2020	910,531	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 6,155,190
Adult - non MCHIP	1,007,518	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 19,948,856
Adult - MCHIP 7/2019 - 9/2019	9,788	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 193,802
Adult - MCHIP 10/2019 - 6/2020	29,363	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 581,387
SPD	448,861	$ 814.48	$ 859.81	$ 45.33	$ -	$ 45.33	$ 20,346,869
SPD/Full-Dual	24,336	$ 205.34	$ 215.02	$ 9.68	$ -	$ 9.68	$ 235,572
BCCTP	7,026	$ 1,430.69	$ 1,511.47	$ 80.78	$ -	$ 80.78	$ 567,560
LTC	15,492	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 4,721,807
LTC - MCHIP 7/2019 - 9/2019	9	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,743
LTC - MCHIP 10/2019 - 6/2020	27	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 8,229
LTC/Full-Dual	0	$ 6,630.57	$ 6,780.31	$ 149.74	$ -	$ 149.74	$ -
WCM	146,382	$ 1,876.85	$ 2,019.52	$ 142.67	$ -	$ 142.67	$ 20,884,320
Optional Expansion 7/2019 - 12/2019	1,394,753	$ 424.87	$ 450.10	$ 25.23	$ 6.31	$ 18.92	$ 26,388,727
Optional Expansion 1/2020 - 6/2020	1,394,752	$ 424.87	$ 450.10	$ 25.23	$ 6.31	$ 18.92	$ 26,388,708
	7,964,012	$ 333.59	$ 353.87	$ 20.27	$ 2.21	$ 18.06	$ 143,831,947

[1] The supplemental payments (Maternity, BHT and HEP C) and CCI population are not included in the rate range calculation.

[2] Other Departmental Usages decreases available rate range funding.

[3] BCCTP Federal Match is based on the portion of the population enrolleed in a BCCTP aid code associated with a FFP percentage of 65%.

[4] WCM Federal Match is based on the FFP percentage associated with the aid codes within each rating categories.

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CalOptima - Orange (HCP 506)
IGT - 2019/20 (July 2020 - December 2020)

	Total	50% FFP (Non-MCHIP and SPD)	76.5% FFP (MCHIP - 7/2020 to 9/2020)	65% FFP (MCHIP - 10/2020 to 12/2020)	BCCTP [3]	WCM [4]	90% FFP Optional Expansion
Total Funds Available	$ 71,458,138	$ 30,053,529	$ 2,227,321	$ 2,227,321	$ 282,165	$ 10,402,926	$ 26,264,876
Federal Match	$ 47,878,762	$ 15,026,765	$ 1,703,901	$ 1,447,759	$ 94,133	$ 5,967,816	$ 23,638,388
Governmental Funding Entity's Portion	$ 23,579,376	$ 15,026,764	$ 523,420	$ 779,562	$ 188,032	$ 4,435,110	$ 2,626,488
	33.0%	50.0%	23.5%	35.0%	66.6%	42.6%	10.0%

Rate Categories [1]	Member Months (per Mercer est.)	Lower Bound (per Mercer Rate Worksheets)	Upper Bound (per Mercer Rate Worksheets)	Difference between Upper and Lower Bound	Other Departmental Usage [2]	Available PMPM (less Other Dept. Usage)	Estimated Available Total Fund
Child - non MCHIP	1,126,338	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 7,614,045
Child - MCHIP 7/2020 - 9/2020	300,973	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 2,034,577
Child - MCHIP 10/2020 - 12/2020	300,973	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 2,034,577
Adult - non MCHIP	493,892	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 9,779,062
Adult - MCHIP 7/2020 - 9/2020	9,596	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 190,001
Adult - MCHIP 10/2020 - 12/2020	9,596	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 190,001
SPD	224,524	$ 814.48	$ 859.81	$ 45.33	$ -	$ 45.33	$ 10,177,673
SPD/Full-Dual	12,241	$ 205.34	$ 215.02	$ 9.68	$ -	$ 9.68	$ 118,493
BCCTP	3,493	$ 1,430.69	$ 1,511.47	$ 80.78	$ -	$ 80.78	$ 282,165
LTC	7,757	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,364,256
LTC - MCHIP 7/2020 - 9/2020	9	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,743
LTC - MCHIP 10/2020 - 12/2020	9	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,743
LTC/Full-Dual	0	$ 6,630.57	$ 6,780.31	$ 149.74	$ -	$ 149.74	$ -
WCM	72,916	$ 1,876.85	$ 2,019.52	$ 142.67	$ -	$ 142.67	$ 10,402,926
Optional Expansion	1,388,207	$ 424.87	$ 450.10	$ 25.23	$ 6.31	$ 18.92	$ 26,264,876
	3,950,524	$ 334.30	$ 354.61	$ 20.31	$ 2.22	$ 18.09	$ 71,458,138

[1] The supplemental payments (Maternity, BHT and HEP C) and CCI population are not included in the rate range calculation.

[2] Other Departmental Usages decreases available rate range funding.

[3] BCCTP Federal Match is based on the portion of the population enrolleed in a BCCTP aid code associated with a FFP percentage of 65%.

[4] WCM Federal Match is based on the FFP percentage associated with the aid codes within each rating categories.

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken May 7, 2020
Regular Meeting of the CalOptima Board of Directors

Report Item

7. Consider Actions Related to Supporting Orange County Nursing Facilities During the Coronavirus (COVID-19) Pandemic

Contact

Emily Fonda, M.D., MMM CHCQM, Deputy Chief Medical Officer, (714) 246-8400
Tracy Hitzeman, RN, CCM, Executive Director Clinical Operations (714)246-8400

Recommended Actions

1. Authorize the CEO, with the assistance of Legal Counsel, to enter into a Grant Agreement with the Regents of the University of California at Irvine (UCI) to provide funding to support the Orange County COVID Nursing Home Prevention Program, contingent upon equal financial participation from the Orange County Health Care Agency (OCHCA); and
2. Approve the recommended allocation of intergovernmental transfer (IGT) 9 funds in the amount not to exceed $629,723 to support the Orange County COVID Nursing Home Prevention Program.

Background

On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency under section 319, of the Public Health Service Act (42U.S.C.247d) in response to a novel coronavirus known as SARS-CoV-2 (coronavirus). On February 27, 2020, Orange County declared a local health emergency. The Governor of California declared a State of Emergency on March 4, 2020. On March 11, 2020, the World Health Organization declared the coronavirus a pandemic.

On March 11, 2020, the Orange County Health Care Agency provided recommendations for COVID-19 community mitigation strategies. While social distancing has been encouraged to limit the spread of COVID-19, beginning on March 17, 2020, state and local agencies began implementing stay-at-home orders to prohibit professional, social, and community gatherings outside of a list of "essential activities." These requirements have and continue to affect CalOptima's provider networks as the coronavirus pandemic develops.

On March 13, 2020, the President of the United States declared a national emergency based on the spread of this coronavirus.

The California Department of Public Health, recognizing that individuals residing in nursing facilities are among the most vulnerable to infection and serious illness due to COVID-19 has issued guidance to the skilled nursing facilities (SNFs) to limit transmission of the virus, which includes mandated reporting of COVID 19 positive residents and preparation for grouping these residents into cohorts.

In order to help mitigate the spread in congregate living facilities, CalOptima modified its Post-Acute Infection Prevention (PIPQI) program, originally approved by the CalOptima Board of Directors (Board) on June 6, 2019, to increase the number of participating facilities and provide flexibility in the program due to social distancing. Specifically, on April 2, 2020 the Board approved allocation of IGT 9

funds in the area of Quality Performance specifically to support continuation and expansion of the PIPQI program. At that time, $4.5 million remained allocated towards member access and engagement initiatives. Additionally, on April 16, 2020, the Board approved modifications to the PIPQI program during the COVID-19 crisis, suspending skin testing to confirm the presence of CHG and allowing early disbursement of incentive payments.

As discussed at prior CalOptima Board meetings, IGT 9 dollars are accounted for in the same fashion as the Medi-Cal capitation revenue CalOptima receives from the DHCS in that, to the extent that these funds are not expended on covered, medically necessary Medi-Cal services or qualifying quality initiatives, the expenditures would be charged to CalOptima's administrative loss ratio (ALR).

Unfortunately, the COVID-19 pandemic continues to have a deleterious effect on congregate living facilities in other states as well as within Orange County. As of April 22, 2020, Orange County has four nursing facilities reporting residents and/or staff who are COVID-19 positive, some of whom are hospitalized, and three residents who have expired. As a result, CalOptima, in partnership with the OCHCA, are exploring new options to decrease the spread of COVID-19 in the community.

At the April 2, 2020, meeting, the Board approved the recommended allocation of IGT 9 funds in the amount of $45 million for initiatives within four focus areas: member access and engagement, quality performance, data exchange and support and other priority areas. At that time, the Board approved five initiatives totaling $40.5 million. Staff would return to the Board with recommendations for allocating the remaining $4.5 million towards member access and engagement.

Discussion

UCI has been actively pursuing methods to combat the spread of COVID-19. Susan Huang, MD, MPH, Professor, Division of Infectious Diseases and Medical Director, Epidemiology & Infection Prevention established a project to develop a toolkit and implementation training to improve prevention, readiness and restrict, to the extent possible, the impact of the anticipated COVID-19 surge to Orange County nursing homes and the local systems of care.

The primary goals of the Orange County COVID Nursing Home Prevention Program developed by UCI include:

1. Engaging nursing homes to undergo intensive COVID-19 infection prevention training to provide greater depth and assurance of infection prevention readiness in a key subgroup that can serve as a high-fidelity resource; and
2. Supporting serologic and point prevalence PCR testing of residents and staff in select nursing homes to inform trajectory toward spread and immunity.
3. Developing a toolkit and implementation training to improve the infection prevention readiness for COVID-19 surge across OC nursing homes;

The project includes collaboration with OCHCA and leveraging their efforts in developing the local public health response to clusters and cases in SNFs, as well as incorporating CDC and public health guidance. CalOptima's PIPQI program was developed as a means of infection prevention by replacing liquid soap with Chlorhexidine (CHG) soap for bathing and using Iodophor nasal swabs every other week. As a result of the program, long-term residents in program-participating facilities showed

markedly lower rates of Multi Drug Resistant Organism (MDRO) colonization and lower rates of hospital admissions due to infection and lower utilization costs for CalOptima members. The PIPQI program includes outreach and engagement, establishment of protocols, facility staff training, and quality testing. The UCI COVID Nursing Home Prevention Program will operate concurrently and build upon training and successes realized through CalOptima's PIPQI program.

Funding for the project requires a $629,723 contribution each from OCHCA and CalOptima. Staff recommends an allocation of $629,723 in IGT 9 funding under the Board-approved focus area of member access and engagement to support this project. OCHCA and CalOptima worked in partnership with UCI to align the project goals, deliverables, and funding schedules.

Fiscal Impact

The recommended action to ratify the grant agreement with UCI to provide funding to support the Orange County COVID Nursing Home Prevention Program has no net fiscal impact to CalOptima's operating budget. Staff estimates that IGT 9 revenue from the California Department of Health Care Services will be sufficient to cover the allocated expenditures for the recommended project.

Rationale for Recommendation

The recommended actions will support CalOptima's efforts to continue providing quality healthcare to members residing at SNFs during the COVID-19 public health crisis.

Concurrence

Gary Crockett, Chief Counsel

Attachments

1. Entities Covered by this Recommended Board Action
2. CalOptima Board Action dated June 6, 2019, Approve Post-Acute Infection Prevention Quality Initiative and Authorize Quality Initiative and authorize Quality Incentive Payments
3. CalOptima Board Action dated April 2, 2020, Consider Approval of Allocation of Intergovernmental Transfer (IGT) 9 Funds
4. CalOptima Board Action dated April 16, 2020, Consider Authorizing Modifications to the Post-Acute Infection Prevention Quality Initiative During the Coronavirus Disease (COVID-19) Crisis

/s/ Richard Sanchez — *04/29/2020*

Authorized Signature — **Date**

Attachment 1 to May 7, 2020 Board of Directors Meeting – Agenda Item 7

ENTITIES COVERED BY THIS RECOMMENDED BOARD ACTION

Legal Name	Address	City	State	Zip code
Regents of the University of California at Irvine	120 Theory, Suite 200	Irvine	CA	92697-1050

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken June 6, 2019
Regular Meeting of the CalOptima Board of Directors

Report Item

33. Consider Approval of Quality Initiative Related to Post-Acute Infection Prevention and Authorization of Related Funding for Quality Initiative Payments

Contact

David Ramirez, M.D., Chief Medical Officer, (714) 246-8400
Emily Fonda, M.D., MMM, CHCQM, Medical Director, (714) 246-8400
Ladan Khamseh, Chief Operating Officer, (714) 246-8400

Recommended Actions

1. Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
2. Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

Background

The Centers for Disease Control and Prevention (CDC) and the University of California-Irvine (UCI) recently collaborated on an extensive study in 2017 through 2019 to suppress the spread of Multi-Drug-Resistant Organisms (MDRO) in Skilled Nursing Facilities (SNFs) across Orange County. The ambitious study also garnered the support of the California Department of Public Health as well as the Orange County Health Care Agency. This regional collaborative established a structured "…decolonization strategy to reduce the transmission of MDROs both countywide and within healthcare facilities." The name of the collaborative is SHIELD OC.

SHIELD OC is comprised of intervention protocols for both hospitals and nursing homes. There were 16 Orange County SNFs contracted with CalOptima that participated through to the conclusion of the study.

The study was focused on MDRO decolonization through "…the use of topical products to reduce bacteria on the body that can produce harmful infections." In SNFs, the study protocol involved the implementation of two interventions: (1) the consistent use of Chlorhexidine (CHG) antiseptic soap for routine bathing and showering of residents, and (2) the scheduled use of povidone-iodine nasal swabs on residents.

The preliminary study outcomes were very promising and gained the close attention of CDC senior leadership, who have reached out to CalOptima regarding the project on more than one occasion. Long term care (LTC) residents in facilities following the study protocol showed markedly lower rates of MDRO colonization, which translated into lower rates of hospital admissions and lower utilization costs for CalOptima members. The implications of the study, as well as the innovative regional collaboration model, have also garnered the interest of the press. News regarding the collaborative recently aired on National Public Radio and appeared in *USA Today* articles. The lead author in the study, Dr. Susan Huang, was also recently interviewed in a local news radio segment on KNX 1070.

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The study concluded on May 2, 2019. At the SHIELD OC Wrap Up Event, concerns were expressed by facility participants as well as the CDC that the end of the project funding would prevent the SNFs in the study from continuing the study protocol efforts. Without continuation of the interventions, the momentum of the efforts by the participating SNFs would be interrupted, and the considerable gains made in regional decolonization could potentially be unraveled. While the responsibility of infection prevention in post-acute settings is not solely the responsibility of CalOptima, the extensive project has provided significant safety and health benefits to CalOptima members who reside in these facilities. After the conclusion of the study, the collaborative will face an absence of funding and direction. This presents an opportunity for CalOptima to take a leadership role in supporting the care delivery system by offering value-based quality incentives to facilities that follow evidence-based patient safety practices in the institutionalized population segment which are congruent with CalOptima's mission as well as the National Quality Assurance Committee (NCQA) Population Health Management Standards of Delivery System Support.

Discussion

As proposed, the Post-Acute Infection Prevention Quality Initiative will provide an avenue through which CalOptima can incentivize SNFs to provide the study protocol interventions. The study protocols have been recognized to meaningfully suppress the spread of MDROs and will support the safety and health of CalOptima members receiving skilled interventions at or residing in SNFs. Implementation of the quality initiative is in line with CalOptima's commitment to continuous quality improvement.

The initiative would be comprised of two separate phases. Summarily, in Phase I, CalOptima-contracted SNFs in Orange County could initiate a commitment to implementing the study protocol and CalOptima would respond by providing funding to the facility for setup and protocol training. For each participating SNF, Phase I would last for two quarters. In Phase II of the quality initiative, after the SNF has been trained and can demonstrate successful adoption of the protocol, each SNF would be required to demonstrate consistent adherence to the study protocol as well as meet defined quality measures in order to be eligible to continue receiving the quality initiative payments on a retrospective quarterly basis.

Phase I

CalOptima to provide quality initiative funding to SNFs demonstrating a commitment to implementing the SHIELD OC study protocol. The quality initiative is intended to support start up and training for implementation of the protocols not currently in standard use in SNFs but, as per the SHIELD OC study, have been demonstrated to effectively suppress the spread of MDROs.

Contracted SNFs in Orange County must complete an Intent to Implement MDRO Suppression form, signed by both its Administrator and Director of Nursing.

CalOptima will then initiate payment for the first quarter of setting up and training. Payment will be based on an average expected usage cost per resident, to be determined by CalOptima for application across all participating facilities, so the amount of payment for each facility will be dependent on its size. These payments are intended to incentivize the facilities to meet the protocol requirements. The facility must demonstrate use of the supplies and the appropriate

application of the study protocol to the assigned CalOptima staff to qualify for the second quarterly Phase I payment.

The following supplies are required of the facility:

- 4% Chlorohexidine Soap
- 10% Iodine Swab Sticks

The following activities will be required of the facility:

- Proof of appropriate product usage.
- Acceptance of training and monitoring of infection prevention protocol by CalOptima and/or CDC/UCI staff.
- Evidence the decolonization program handouts are in admission packets.
- Monitoring and documentation of compliance with CHG bathing.
- Monitoring and documentation of compliance with iodophor nasal swab.
- Documentation of three peer-to-peer bathing skills assessments per month.

Phase II

CalOptima will provide retrospective quality initiative payments on a quarterly basis for facilities that completed Phase I and meet Phase II criteria outlined below. The amount of each Phase II facility payment will reflect the methodology used in Phase I, accounting for facility size at the average expected usage cost. These payments are intended to support facilities in sustaining the quality practices they adopted during Phase I to suppress MDRO infections.

To qualify for Phase II quality initiative payments, the participating facility must continue demonstrating adherence to the study protocol through the requirements as outlined above for Phase I.

In addition, the facility must also meet minimum quality measures representative of effective decolonization and infection prevention efforts, to be further defined with the guidance of the UCI and CDC project leads. The facilities in Phase II of the initiative must meet these measures each quarter to be eligible for retrospective payment.

The 16 SNFs that participated in SHIELD OC would be eligible for Phase II of the quality initiative at implementation of this quality initiative since they have already been trained in the project and demonstrated adherence to the study protocol. Other contracted SNFs in Orange County not previously in SHILED OC and beginning participation in the quality initiative would be eligible for Phase I.

The proposed implementation of the quality initiative is Q3 2019.

Fiscal Impact

The recommended action to implement a Post-Acute Infection Prevention Quality Initiative program and make payments to qualifying SMFs, beginning in FY 2019-20 to CalOptima-contracted SNFs in Orange County is projected to cost up to and not to exceed $2.3 million annually. Management plans to include projected expenses associated with the quality initiative in the upcoming CalOptima FY 2019-20 Operating Budget.

Rationale for Recommendation

The quality initiative presents an avenue for CalOptima to actively support an innovative regional collaborative of high visibility that has been widely recognized to support the safety and health of individuals receiving care in SNFs.

Concurrence

Gary Crockett, Chief Counsel

Attachment

1. PowerPoint Presentation
2. SHIELD OC Flyer
3. Letter of Support

/s/ Michael Schrader *5/29/2019*
Authorized Signature **Date**

Post-Acute Infection Prevention Quality Initiative

Regular Meeting of the Board of Directors

June 6, 2019

Dr. Emily Fonda, MD, MMM, CHCQM

Medical Director

Care Management, Long-Term Services and Supports and Senior Programs

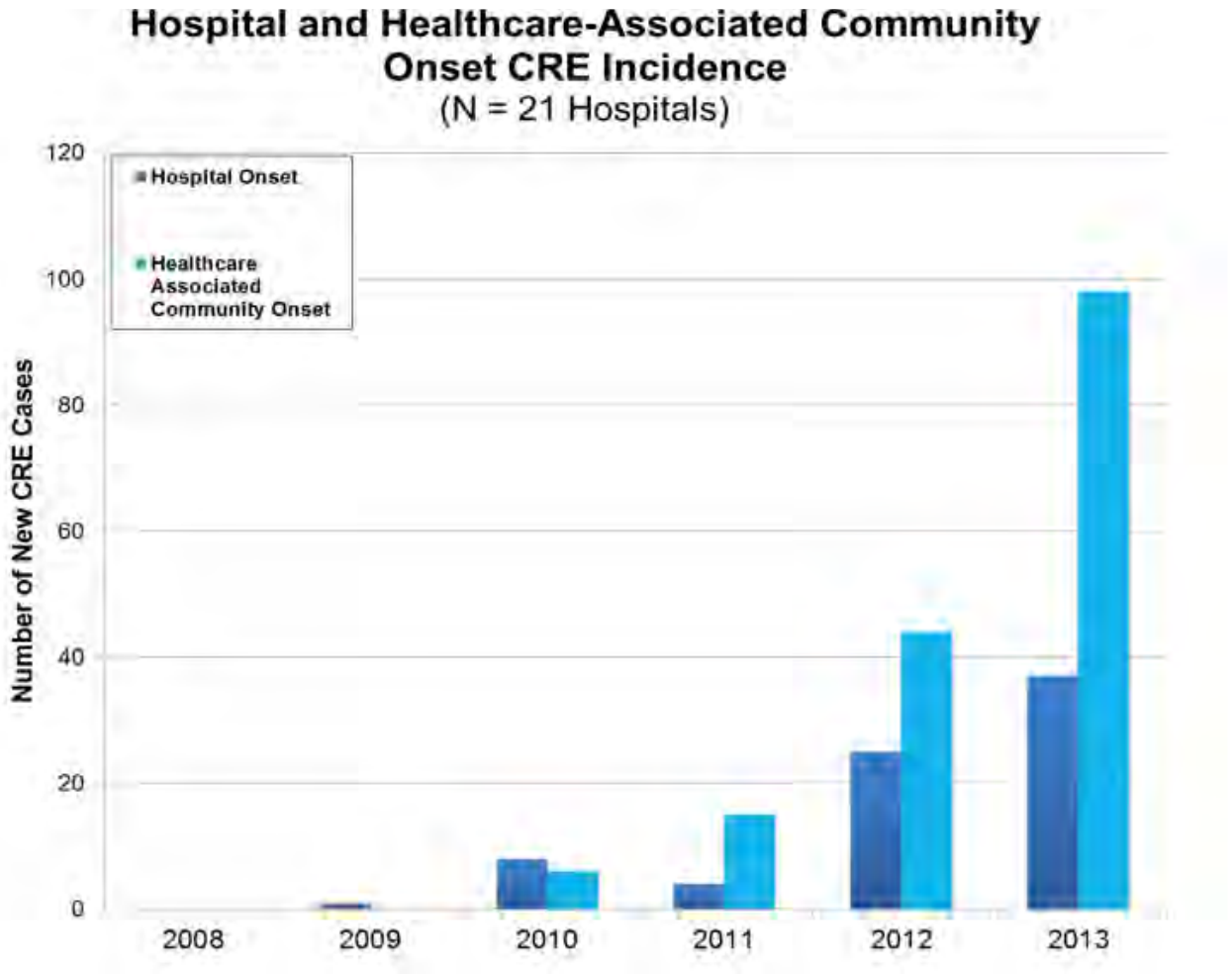
Background

- Efforts to lower hospitalization rates from long-term care (LTC) placed us in contact with Dr. Huang and her study
  - Through the Long-Term Services and Supports (LTSS) Quality Improvement Subcommittee
- Susan Huang, MD, MPH, Professor, Division of Infectious Diseases at U.C. Irvine — lead investigator for Project SHIELD Orange County (OC)
  - 36 facility decolonization intervention protocol supported by the Center for Disease Control and Prevention (CDC)
  - 16 of those facilities are CalOptima-contracted skilled nursing facilities
- Early results at wrap-up event on 1/30/19 ➔ overall 25 percent lower colonization rate of multidrug resistant organisms in OC skilled nursing facilities

Background

- Rise of Multi-Drug Resistant Organisms (MDROs)
  - Methicillin Resistant *Staphylococcus aureus* (MRSA)
  - Vancomycin Resistant Enterococcus (VRE)
  - Multi-Drug Resistant Pseudomonas
  - Multi-Drug Resistant Acinetobacter
  - Extended Spectrum Beta Lactamase Producers (ESBLs)
  - Carbapenem Resistant Enterobacteriaceae (CRE)
  - Hypervirulent KPC (NDM)
  - *Candida auris*
- **10–15%of hospital patients harbor at least one of the above**
- **65% of nursing home residents harbor at least one of the above**

CRE Trends in Orange County, CA



Gohil S. AJIC 2017; 45:1177-82

CDC Interest

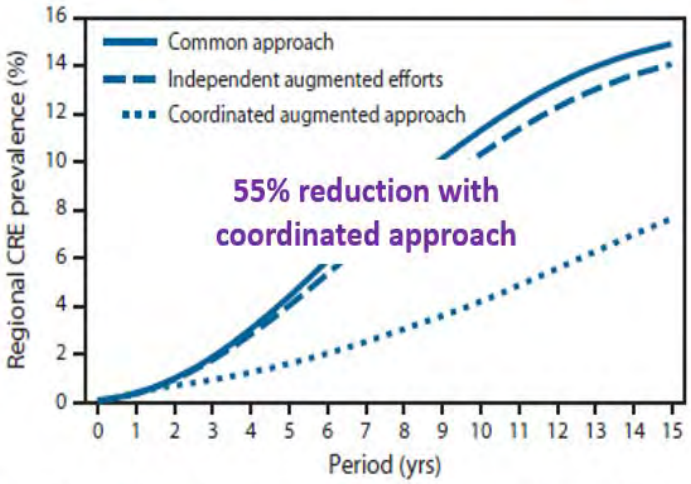
Orange County has historically had one of the highest carbapenem-resistant enterobacteriaceae (CRE) rates in California according to the OC Health Care Agency

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 64
August 4, 2015

Vital Signs: Estimated Effects of a Coordinated Approach for Action to Reduce Antibiotic-Resistant Infections in Health Care Facilities — United States

Rachel B. Slayton, PhD[1]; Damon Toth, PhD[2]; Bruce Y. Lee, MD[3]; Windy Tanner, PhD[2]; Sarah M. Bartsch, MPH[3]; Karim Khader, PhD[2]; Kim Wong, PhD[4]; Kevin Brown, PhD[2]; James A. McKinnell, MD[5]; William Ray[2]; Loren G. Miller, MD[6]; Michael Rubin, MD, PhD[2]; Diane S. Kim[7]; Fred Adler, PhD[8]; Chenghua Cao, MPH[7]; Lacey Avery, MA[1]; Nathan T.B. Stone, PhD[8]; Alexander Kallen, MD[1]; Matthew Samore, MD[2]; Susan S. Huang, MD[7]; Scott Fridkin, MD[1]; John A. Jernigan, MD[1]

FIGURE 3. Projected countywide prevalence of carbapenem-resistant *Enterobacteriaceae* (CRE) over a 15-year period under three different intervention scenarios — 102-facility model, Orange County, California*

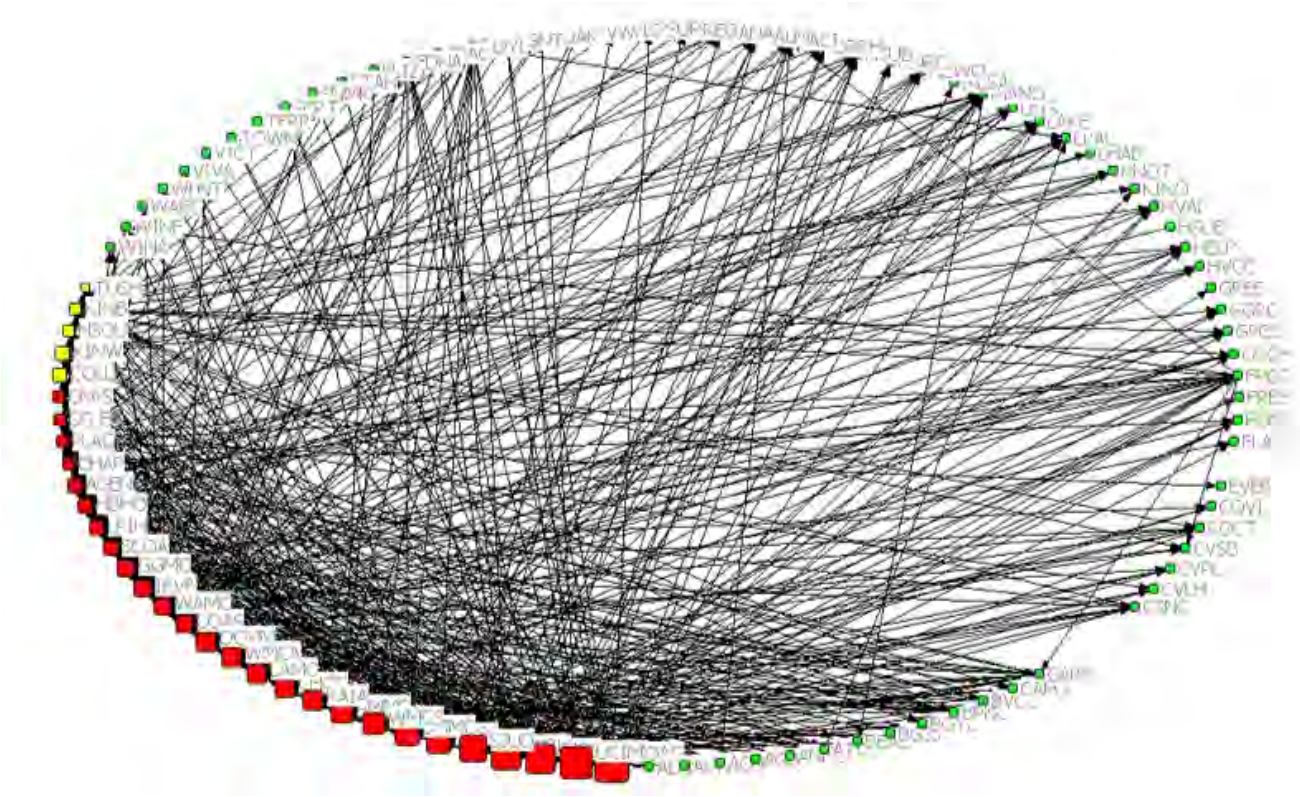


* Additional information available at http://www.cdc.gov/drugresistance/resources/publications.html.

Extent of the Problem

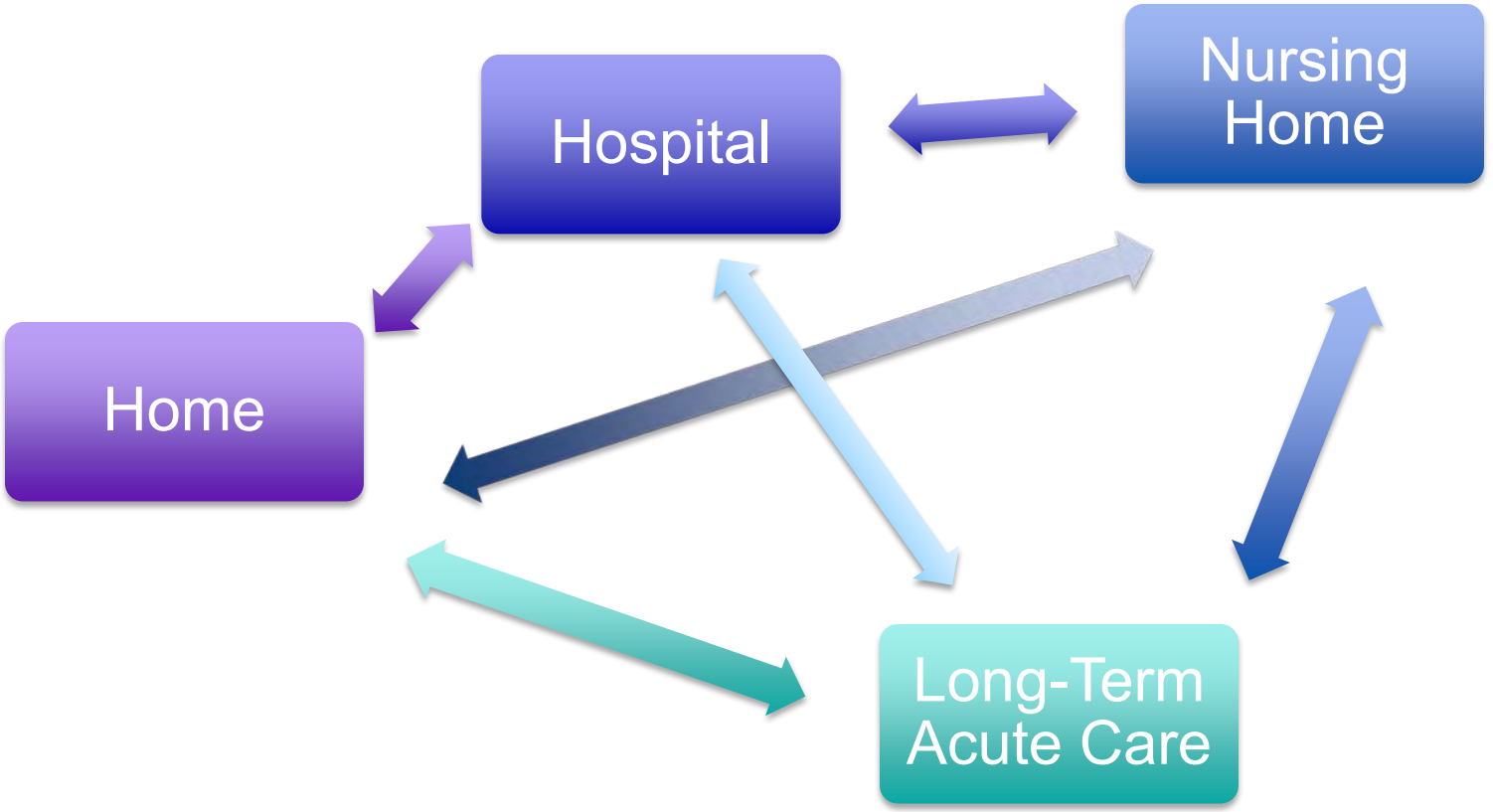
OC Hospitals and Nursing Homes

10 patients shared



Lee BY et al. Plos ONE. 2011;6(12):e29342

Extent of the Problem



Baseline MDRO Prevalence — 16 Nursing Homes

	N	Any MDRO	MRSA	VRE	ESBL	CRE
Nares	900	28%	28%	-	-	-
Axilla/Groin	900	47%	30%	10%	22%	1%
Peri-Rectal	900	52%	25%	15%	31%	1%
All Body Sites	**900**	**64%**	**42%**	**16%**	**34%**	**2%**

- 64% MDRO carriers, facility range 44–88%
- Among MDRO pathogens detected, only 14% known to facility
- Among all residents, 59% harbored ≥1 MDRO unknown to facility

Participating Health Care Facilities

16 Nursing Homes Contracted with CalOptima

- Alamitos West Health Care Center
- Anaheim Healthcare Center
- Beachside Nursing Center
- Crystal Cove Care Center
- French Park Care Center
- Garden Park Care Center
- Healthcare Center of Orange County
- Laguna Hills Health and Rehab Center
- Lake Forest Nursing Center
- Mesa Verde Post Acute Care Center
- New Orange Hills
- Orange Healthcare & Wellness Centre
- Regents Point – Windcrest
- Seal Beach Health and Rehab Center
- Town and Country Manor
- Victoria Healthcare and Rehab Center

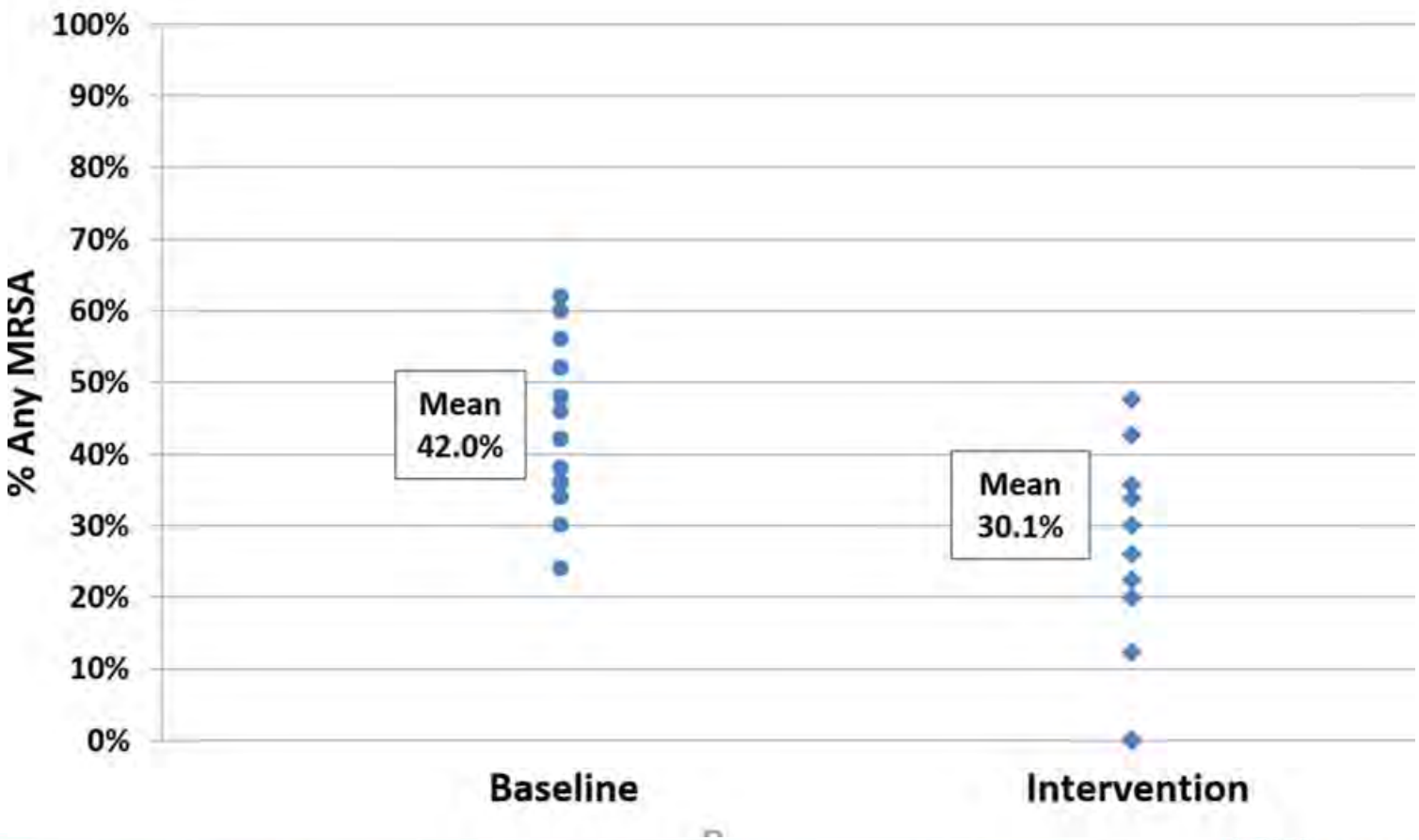
SHIELD OC Decolonization Protocol

- Nursing Homes: Decolonize All Patients
  - Replaced regular soap with chlorhexidine (CHG) antiseptic soap
  - CHG on admit and for all routine bathing/showering
  - Nasal iodophor on admit and every other week
    - https://www.cdc.gov/hai/research/cdc-mdro-project.html
- Following initial testing and training
  - Intervention timeline (22 months) July 1, 2017–May 2, 2019
- Outcome: MDRO Prevalence
  - MRSA, VRE, ESBL, CRE and any MDRO
  - By body site
    - Nasal product reduces MRSA
    - CHG bathing reduces skin carriage

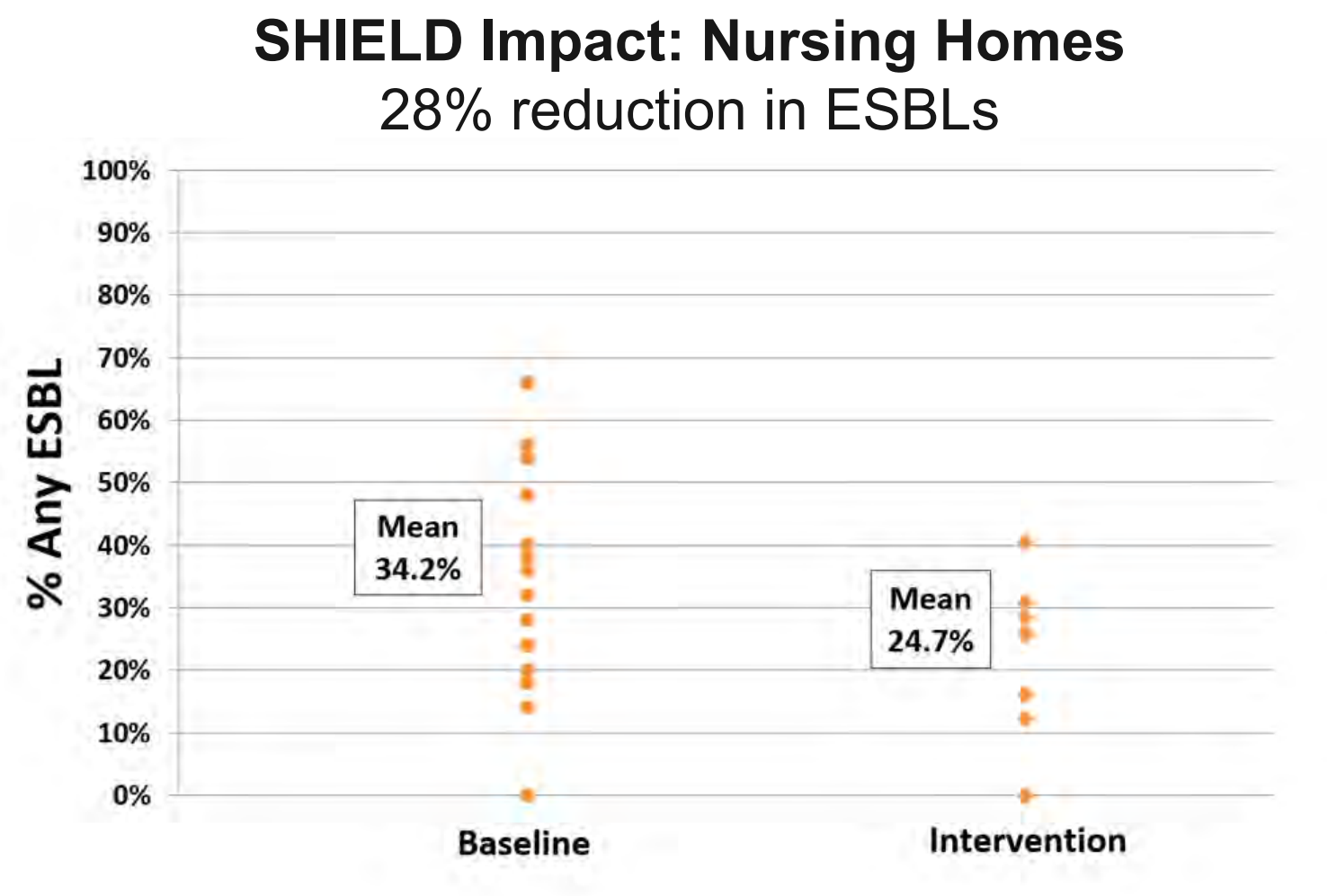
SHIELD Outcomes

SHIELD Impact: Nursing Homes

28% reduction in MRSA



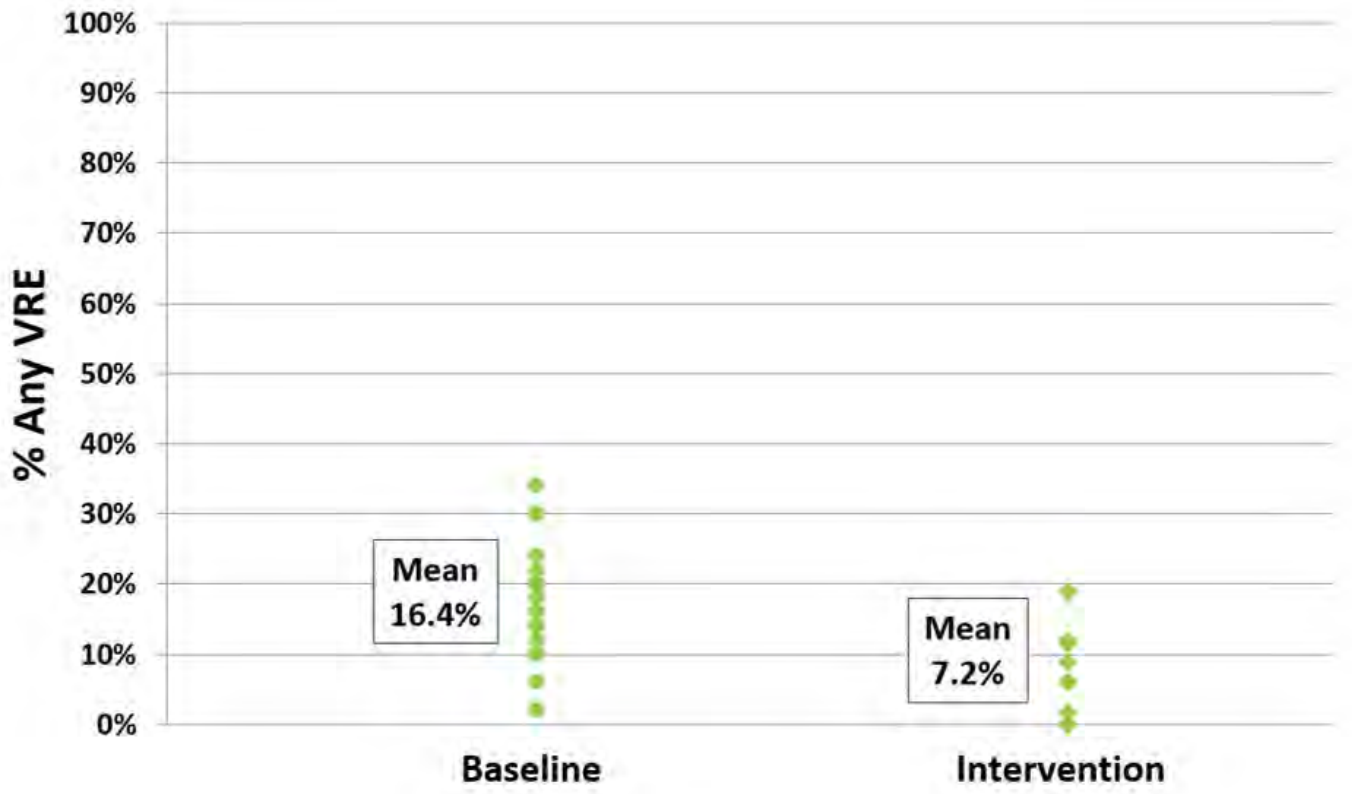
SHIELD Outcomes (cont)



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

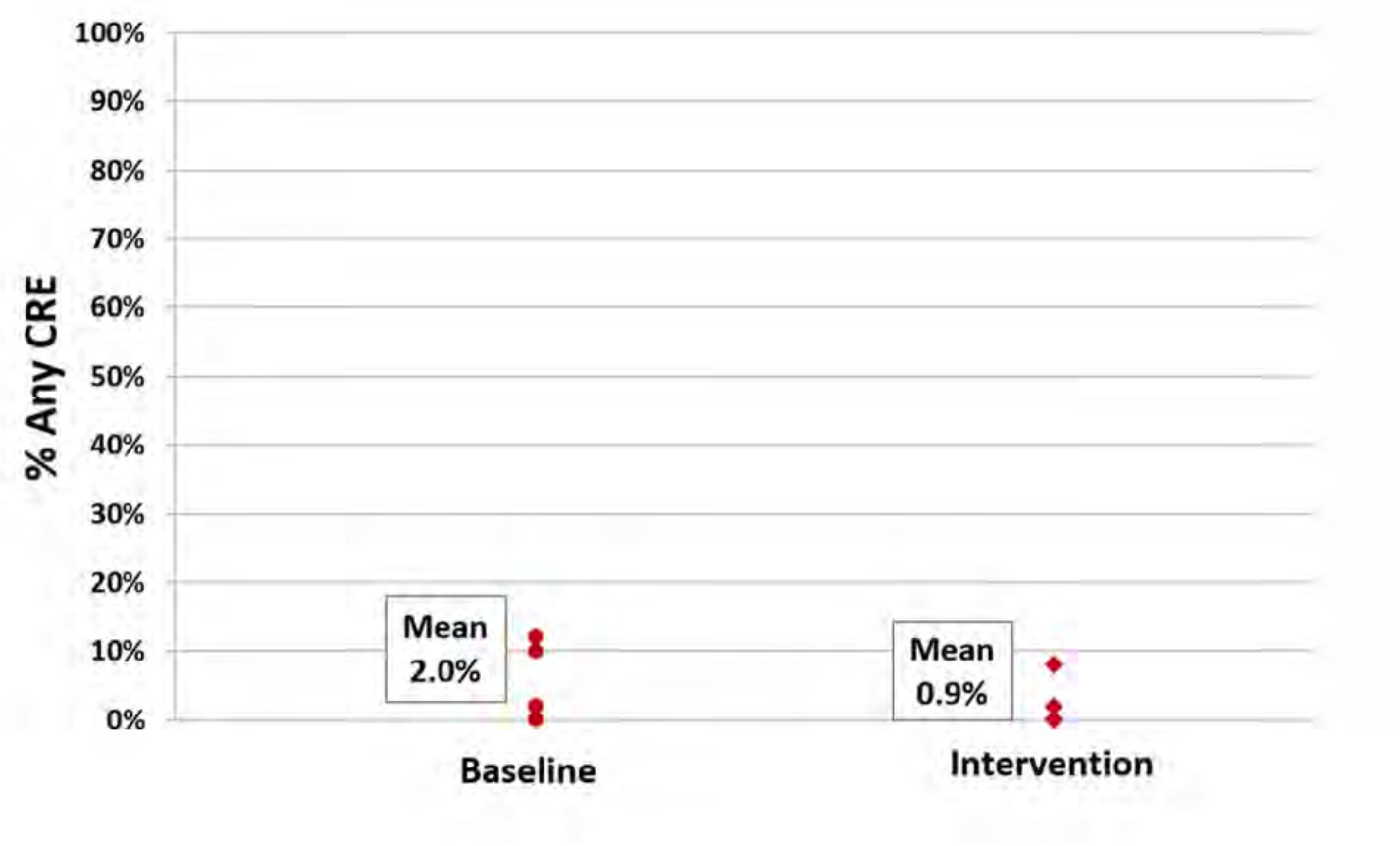
56% reduction in VRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

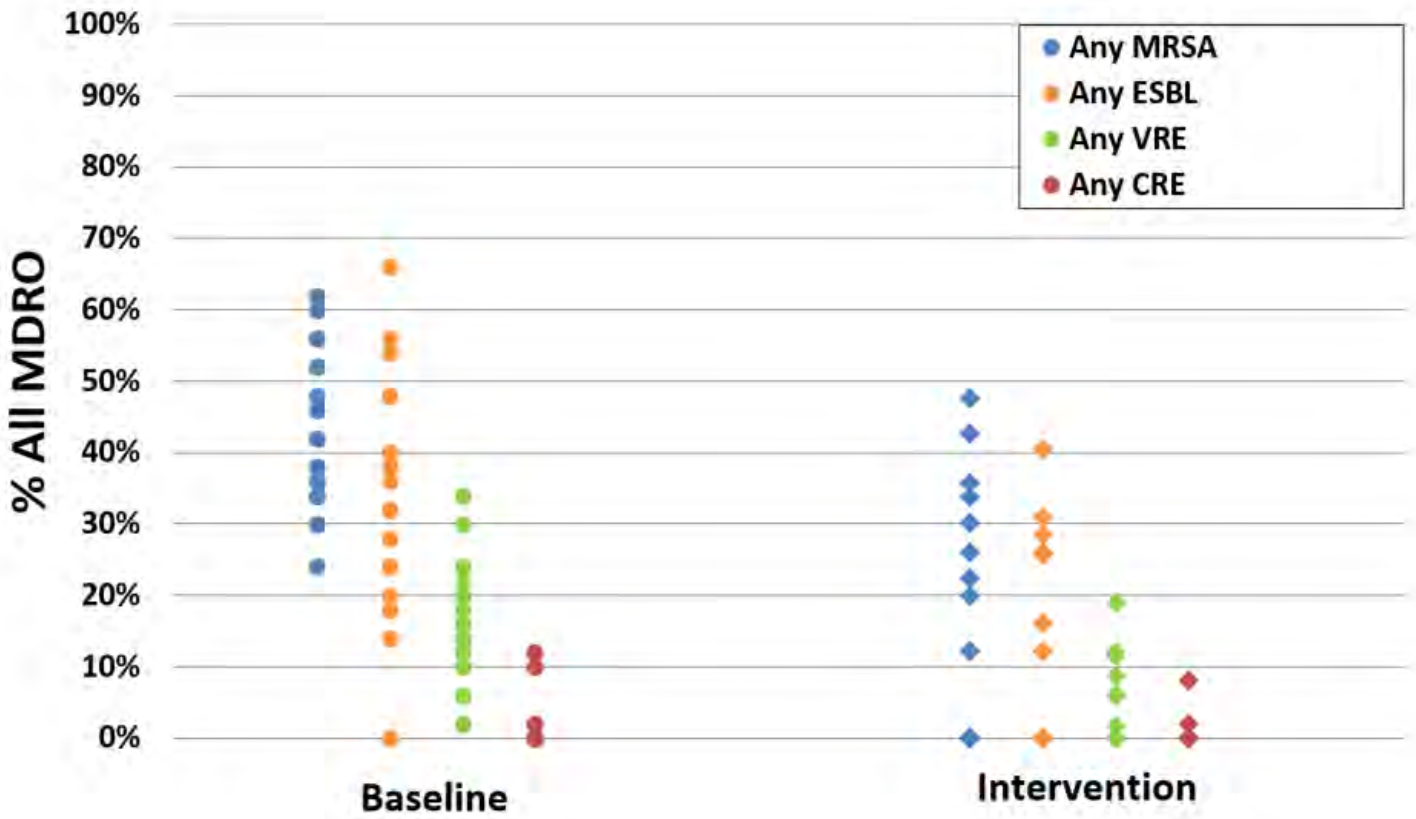
55% reduction in CRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

25% reduction in all MDROs



Quarterly Inpatient Trends

SHIELD OC Project: Quarterly Inpatient Trends

LTC Facility County: ORANGE

From: 2015-10 To: 2018-12

Category P - Primary Diagnosis

Select Year-Month Begin	Select Year-Month End	Select Category P Diagnosis Level	Select Risk Group *	Select LTC Facility County
2015-10	2018-12	Category P - Primary Diagnosis	Multiple values	ORANGE

		Before SHIELD OC						During SHIELD OC						
		2015 Q4	2016 Q1	2016 Q2	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2	2018 Q3	2018 Q4
CONTROL	Admission Count	47	61	60	51	56	65	60	49	36	46	59	48	47
	Bed Day Ct	336	383	536	383	561	570	390	376	296	377	401	456	398
	Paid Amt	$682,769	$854,676	$1,159,922	$920,317	$1,691,337	$1,231,903	$997,810	$1,236,197	$634,628	$979,762	$1,113,238	$1,176,910	$1,024,854
	Avg Mbrs	3,064	2,964	2,901	2,945	2,994	3,033	3,035	3,074	3,116	3,105	3,088	3,102	3,085
SHIELD OC	Admission Count	10	10	9	11	12	9	8	5	3	4	7	3	1
	Bed Day Ct	54	84	66	90	98	60	59	49	12	30	46	11	2
	Paid Amt	$133,362	$311,661	$124,676	$189,669	$227,224	$209,419	$175,738	$164,181	$40,354	$84,565	$127,609	$41,123	$10,177
	Avg Mbrs	590	564	564	580	576	567	581	606	625	632	641	663	652

* Risk Groups Selected: CCN - MC CCN OCC COD Admin OneCare Shared Risk - MC Shared Risk - OCC

Average member count includes all Risk Groups

Admission counts and costs significantly lower in the SHIELD OC group

Quarterly Inpatient Trends

- 16 contracted facilities utilizing the CHG program:
  - Inpatient costs for infection for 6 quarters prior to the Chlorhexidine protocol = $1,196,011
  - Inpatient costs for the last 6 quarters following training and use of CHG protocol = $468,009
    - $728,002 lowered inpatient expenditure (61%) for infection in the participating facilities

- 51 contracted facilities not utilizing the CHG program:
  - Inpatient costs for the last 6 quarters =$6,165,589
  - Potential 61% lowered inpatient expenditure for infection = $3,761,009 if the CHG protocol had been expanded

SHIELD Impact on CalOptima

- Adoption of the SHIELD protocol is well-supported by the Center for Disease Control
  - Plan for extended use of an existing trainer in OC for one year
  - Plan for extended monitoring of Orange County MDROs for one year
- 25% decrease in MDRO prevalence translates to the following for CalOptima's LTC population of 3,800 members as of December 2018:
  - Decreased infection-related hospitalizations
  - An opportunity for a significant advancement in population health management
  - Practice transformation for skilled nursing facilities in fulfillment of National Committee for Quality Assurance (NCQA) requirements
  - Continuation of cost savings

CalOptima Post-Acute Infection Prevention Quality Initiative

- Adoption of the SHIELD protocol in all 67 CalOptima post-acute contracted facilities (long-term care and subacute facilities) will:
  - Support the continuation of care in the 16 participating facilities as Phase 2 without loss of momentum
  - Initiate the chlorhexidine bathing protocol in the remaining facilities as Phase 1 utilizing the CDC-supported trainer
  - Require quarterly reporting and fulfillment of quality measures with payments proportional to compliance
  - Include a trainer provided by the CDC for one year
  - Train current CalOptima LTSS nurses to quantify best practices and oversee compliance
  - Provide consideration around adding this patient safety initiative as a Pay 4 Value (P4V) opportunity to the next quality plan

Recommended Actions

- Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
- Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner


A Public Agency
CalOptima
Better. Together.


Medi-Cal
A Public Agency
CalOptima
Better. Together.


OneCare (HMO SNP)
A Public Agency
CalOptima
Better. Together.


OneCare Connect
A Public Agency
CalOptima
Better. Together.


PACE
A Public Agency
CalOptima
Better. Together.

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs in
Orange County

SHIELD Orange County – *Together We Can Make a Difference!*

What is SHIELD Orange County?

SHIELD OC is a public health collaborative initiated by the Centers for Disease Control and Prevention (CDC) to combat the spread of endemic and emerging multi-drug resistant organisms (MDROs) across healthcare facilities in Orange County. This effort is supported by the California Department of Public Health (CDPH) and the Orange County Health Care Agency (OCHCA). This regional collaborative will implement a decolonization strategy to reduce transmission of MDROs both countywide and within healthcare facilities.

Visit our CDC webpage here!
https://www.cdc.gov/hai/research/cdc-mdro-project.html

SHIELD OC Goals:

- Reduce MDRO carriage
- Reduce countywide MDRO clinical cultures
- Assess impact in participants and non-participants

SHIELD OC is coordinated by the University of California Irvine and LA BioMed at Harbor-UCLA.

Who is participating?

38 healthcare facilities are participating in SHIELD OC. These facilities were invited to participate based on their inter-connectedness by patient sharing statistics. In total, participants include 17 hospitals, 3 long-term acute care hospitals (LTACHs), and 18 nursing homes.

What is the decolonization intervention?

In the SHIELD OC collaborative, decolonization refers to the use of topical products to reduce bacteria on the body that can produce harmful infections.

- **Hospitals (for adult patients on contact precautions)**
  - Chlorhexidine (CHG) antiseptic soap for daily bathing or showering
  - Nasal decolonization with 10% povidone-iodine
  - Continue CHG bathing for adult patients in ICU units
- **Nursing homes and LTACHs**
  - Chlorhexidine (CHG) antiseptic soap for routine bathing and showering
  - Nasal decolonization with 10% povidone-iodine on admission and every other week

All treatments used for decolonization are topical and their safety profile is excellent.

With questions, please contact the SHIELD OC Coordinating Team

(949) 824-7806 or SHIELDOrangeCounty@gmail.com

CalOptima Checklist

Nursing Home Name: _____

Month Audited (Month/year): _____/_____

Today's Date: _____/_____/_____

Completed by: _____

- ☐ Proof of product purchase
- ☐ Evidence the decolonization program handout is in admission packet
- ☐ Monitor and document compliance with bathing one day each week
- ☐ Monitor and document compliance with iodophor one day each week iodophor is used
- ☐ Conduct three peer-to-peer bathing skills assessments per month

Product Usage

PRODUCT DESCRIPTION	RECEIPT PROVIDED	QUANTITY DELIVERED	ESTIMATED MONTHLY USAGE
4% CHG Gallons	☐	_____ gallons	_____ gallons
10% Iodine Swabsticks	☐	_____ boxes	_____ boxes
		_____ swabs per box	

INTERNAL USE ONLY –APPROVAL:

Back to Agenda Back to Item

Facility Name: _____Unit: _____ Date: _____

STAFF Skills Assessment:
CHG Bed Bath Observation Checklist

Individual Giving CHG Bath

Please indicate who performed the CHG bath.

☐ **Nursing Assistant (CNA)** ☐ **Nurse** ☐ **LVN** ☐ **Other: _____**

Observed CHG Bathing Practices

Please check the appropriate response for each observation.

☐ **Y** ☐ **N** **Resident received CHG bathing handout**
☐ **Y** ☐ **N** **Resident told that no rinse bath provides protection from germs**
☐ **Y** ☐ **N** **Provided rationale to the resident for not using soap at any time while in unit**
☐ **Y** ☐ **N** **Massaged skin *firmly* with CHG cloth to ensure adequate cleansing**
☐ **Y** ☐ **N** **Cleaned face and neck well**
☐ **Y** ☐ **N** **Cleaned between fingers and toes**
☐ **Y** ☐ **N** **Cleaned between all folds**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned occlusive and semi-permeable dressings with CHG cloth**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned 6 inches of all tubes, central lines, and drains closest to body**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on superficial wounds, rash, and stage 1 & 2 decubitus ulcers**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on surgical wounds (unless primary dressing or packed)**
☐ **Y** ☐ **N** **Allowed CHG to air-dry / does not wipe off CHG**
☐ **Y** ☐ **N** **Disposed of used cloths in trash /does not flush**

Query to Bathing Assistant/Nurse

1. How many cloths were used for the bath?

_____

2. If more than 6 cloths was used, provide reason.

_____

3. Are you comfortable applying CHG to superficial wounds, including surgical wounds?

_____

4. Are you comfortable applying CHG to lines, tubes, drains and non-gauze dressings?

_____

5. Do you ever wipe off the CHG after bathing?

_____

ORIGINAL ARTICLE

Decolonization to Reduce Postdischarge Infection Risk among MRSA Carriers

S.S. Huang, R. Singh, J.A. McKinnell, S. Park, A. Gombosev, S.J. Eells, D.L. Gillen, D. Kim, S. Rashid, R. Macias-Gil, M.A. Bolaris, T. Tjoa, C. Cao, S.S. Hong, J. Lequieu, E. Cui, J. Chang, J. He, K. Evans, E. Peterson, G. Simpson, P. Robinson, C. Choi, C.C. Bailey, Jr., J.D. Leo, A. Amin, D. Goldmann, J.A. Jernigan, R. Platt, E. Septimus, R.A. Weinstein, M.K. Hayden, and L.G. Miller, for the Project CLEAR Trial

ABSTRACT

BACKGROUND

Hospitalized patients who are colonized with methicillin-resistant *Staphylococcus aureus* (MRSA) are at high risk for infection after discharge.

METHODS

We conducted a multicenter, randomized, controlled trial of postdischarge hygiene education, as compared with education plus decolonization, in patients colonized with MRSA (carriers). Decolonization involved chlorhexidine mouthwash, baths or showers with chlorhexidine, and nasal mupirocin for 5 days twice per month for 6 months. Participants were followed for 1 year. The primary outcome was MRSA infection as defined according to Centers for Disease Control and Prevention (CDC) criteria. Secondary outcomes included MRSA infection determined on the basis of clinical judgment, infection from any cause, and infection-related hospitalization. All analyses were performed with the use of proportional-hazards models in the per-protocol population (all participants who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization) and as-treated population (participants stratified according to adherence).

RESULTS

In the per-protocol population, MRSA infection occurred in 98 of 1063 participants (9.2%) in the education group and in 67 of 1058 (6.3%) in the decolonization group; 84.8% of the MRSA infections led to hospitalization. Infection from any cause occurred in 23.7% of the participants in the education group and 19.6% of those in the decolonization group; 85.8% of the infections led to hospitalization. The hazard of MRSA infection was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03; number needed to treat to prevent one infection, 30; 95% CI, 18 to 230); this lower hazard led to a lower risk of hospitalization due to MRSA infection (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The decolonization group had lower likelihoods of clinically judged infection from any cause (hazard ratio, 0.83; 95% CI, 0.70 to 0.99) and infection-related hospitalization (hazard ratio, 0.76; 95% CI, 0.62 to 0.93); treatment effects for secondary outcomes should be interpreted with caution owing to a lack of prespecified adjustment for multiple comparisons. In as-treated analyses, participants in the decolonization group who adhered fully to the regimen had 44% fewer MRSA infections than the education group (hazard ratio, 0.56; 95% CI, 0.36 to 0.86) and had 40% fewer infections from any cause (hazard ratio, 0.60; 95% CI, 0.46 to 0.78). Side effects (all mild) occurred in 4.2% of the participants.

CONCLUSIONS

Postdischarge MRSA decolonization with chlorhexidine and mupirocin led to a 30% lower risk of MRSA infection than education alone. (Funded by the AHRQ Healthcare-Associated Infections Program and others; ClinicalTrials.gov number, NCT01209234.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Huang at the University of California Irvine School of Medicine, Division of Infectious Diseases, 100 Theory, Suite 120, Irvine, CA 92617, or at sshuang@uci.edu.

N Engl J Med 2019;380:638-50.
DOI: 10.1056/NEJMoa1716771

Methicillin-resistant *Staphylococcus aureus* (MRSA) causes more than 80,000 invasive infections in the United States annually.[1] It is the most common cause of skin, soft-tissue, and procedure-related infections.[2] Rates of invasive MRSA infection are highest within 6 months after hospital discharge and do not normalize for 1 year.[1,3,4]

Approaches to MRSA have included education about both hygiene and environmental cleaning as well as decolonization with nasal mupirocin and chlorhexidine antiseptic baths to reduce carriage and prevent infection.[5,6] Decolonization has reduced the risks of surgical-site infection, recurrent skin infection, and infection in the intensive care unit (ICU).[7-10] Our goal was to evaluate whether, after hospital discharge, decolonization plus hygiene education was superior to education alone in reducing the likelihood of MRSA infection among patients colonized with MRSA (carriers).

Methods

Trial Design and Intervention

We conducted the Project CLEAR (Changing Lives by Eradicating Antibiotic Resistance) Trial as a multicenter, two-group, unblinded, randomized, controlled trial to compare the effect of hygiene education with that of education plus decolonization on the likelihood of postdischarge infection among MRSA carriers. This trial was approved by the institutional review board of the University of California Irvine. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol, available with the full text of this article at NEJM.org.

Participants were randomly assigned, in a 1:1 ratio, to the education group or the decolonization group. Randomization was performed with a randomized block design stratified according to Hispanic ethnic group and nursing home residence. In the education group, participants received and reviewed an educational binder (provided in English and Spanish) about MRSA and how it is spread and about recommendations for personal hygiene, laundry, and household cleaning (Appendix A in the Supplementary Appendix, available at NEJM.org). In the decolonization group, participants received and reviewed the identical educational binder and also underwent decolonization for 5 days twice monthly for a period of 6 months after hospital discharge (Appendix B in the Supplementary Appendix). The decolonization intervention involved the use of 4% rinse-off chlorhexidine for daily bathing or showering, 0.12% chlorhexidine mouthwash twice daily, and 2% nasal mupirocin twice daily. All products were purchased with grant funds and were provided free of charge to the participants.

Recruitment and Eligibility Criteria

Recruitment involved written informed consent provided between January 10, 2011, and January 2, 2014, during inpatient admissions in 17 hospitals and 7 nursing homes in Southern California (Table S1 in the Supplementary Appendix). Eligibility requirements included an age of 18 years or older, hospitalization within the previous 30 days, positive testing for MRSA during the enrollment hospitalization or within the 30 days before or afterward, and the ability to bathe or shower (alone or assisted by a caregiver). Key exclusion criteria were hospice care and allergy to the decolonization products at recruitment. California mandates MRSA screening at hospital admission in high-risk patients: those undergoing hemodialysis, those who had a recent hospitalization (within the preceding 30 days), those who were undergoing imminent surgery, those who were admitted to the ICU, and those who were transferred from a nursing home.

Follow-up

Participants were followed for 12 months after discharge. In-person visits at home or in a research clinic occurred at recruitment and at months 1, 3, 6, and 9. An exit interview was conducted at 12 months. The trial had a fixed end date of June 30, 2014. Participants who were enrolled after July 1, 2013, had a truncated follow-up and had their data administratively censored at that time. Loss to follow-up was defined as the inability of trial staff to contact participants for 3 months, at which point the participant was removed from the trial as of the date of last contact. Participants received escalating compensation for completing follow-up visits ($25, $30, $35, and $50).

All participants were contacted monthly and requested to report any hospitalizations or clinic visits for infection. After trial closure, medical records from reported visits were requested, double-redacted for protected health information and trial-group assignment, and reviewed for trial outcomes. Records from enrollment hospi-

talizations were requested and reviewed for characteristics of the participants and the presence or absence of MRSA infection at the enrollment hospitalization. Records were requested up to five times, with five additional attempts to address incomplete records.

TRIAL OUTCOMES

Redacted medical records from enrollment hospitalizations and all reported subsequent medical visits were reviewed in a blinded fashion, with the use of standardized forms, by two physicians with expertise in infectious diseases (five of the authors) for coexisting conditions, antibiotic agents, and infection outcomes. If consensus was not reached, discordant outcomes were adjudicated by a third physician with expertise in infectious diseases.

The primary outcome was MRSA infection according to medical-record documentation of disease-specific infection criteria (according to 2013 guidelines) from the Centers for Disease Control and Prevention (CDC) in a time-to-event analysis.[11] A priori secondary outcomes included MRSA infection defined in a time-to-event analysis according to the clinical judgment of two reviewers with expertise in infectious diseases who were unaware of the trial-group assignments, infection from any cause according to disease-specific CDC criteria in a time-to-event analysis, infection from any cause according to infectious disease clinical judgment in a time-to-event analysis, hospitalization due to infection, and new carriage of a MRSA strain that was resistant to mupirocin (evaluated by Etest, bioMérieux)[12] or that had an elevated minimum inhibitory concentration (MIC) of chlorhexidine (≥8 μg per milliliter) on microbroth dilution.[13,14] All outcomes were assessed on the basis of the first event per participant.

DATA COLLECTION

Surveys of health conditions, health care utilization, and household cleaning and bathing habits were administered during recruitment and all follow-up visits. Swabs of both nares, the throat, skin (axilla and groin), and any wounds were taken, but the results are not reported here. At each visit, participants in the decolonization group reported adherence to the intervention, and staff assessed the remaining product. Potential discrepancies were broached with the participant to obtain affirmation of actual adherence. Adherence was assessed as full (no missed doses), partial (some missed doses), and nonadherence (no doses used).

STATISTICAL ANALYSIS

The characteristics of the participants and outcomes were described by frequency and type according to trial group. Outcomes were summarized with the use of Kaplan–Meier estimates of infection-free distributions across the follow-up period and analyzed with the use of unadjusted Cox proportional-hazard models (per-protocol primary analysis) for the postdischarge trial population (all the participants who underwent randomization, met inclusion criteria, and survived beyond the recruitment hospitalization); outcomes were also analyzed according to the as-treated adherence strata (fully adherent, partially adherent, and nonadherent participant-time). In the as-treated analyses, information about participant adherence during at-risk periods before each visit was updated with the use of the adherence assessment at that visit.

The assumption of proportional hazards was assessed by means of residual diagnostic tests and formal hypothesis tests. P values are provided only for the primary outcome. Because the statistical analysis plan did not include a provision for correction for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, those results are reported as point estimates with 95% confidence intervals. The widths of the confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

In post hoc exploratory analyses, we used adjusted Cox proportional-hazard models to address potential residual imbalances in the characteristics of the participants between the two groups after randomization. The characteristics of the participants were entered into the model if they were associated with outcomes at a P value of less than 0.20 in bivariate analyses. Characteristics included demographic data; educational level; insurance type; presence of coexisting conditions, devices, or wounds at enrollment; hospitalization or residence in a nursing home in the year before enrollment; ICU admission or surgery during enrollment hospitalization; need

for assistance with bathing; frequency of bathing; and randomization strata. Adjusted models also accounted for two time-dependent covariates: receipt of anti-MRSA antibiotics and adherence to the intervention. The number needed to treat was calculated with the use of rates that accounted for participant-time that incorporated censoring due to loss to follow-up, withdrawal from the trial, or the end of the trial.[15] Full details of the trial design and analytic approach are provided in the protocol and in the Supplementary Appendix.

RESULTS

PARTICIPANTS

Figure 1 shows the randomization and follow-up of 2140 participants, of whom 19 were excluded after randomization because they did not meet inclusion criteria (6 participants did not have a positive MRSA test, and 13 died during the enrollment hospitalization). The characteristics of the final 2121 enrolled participants (per-protocol population) are provided in Table 1, and in Tables S2 through S4 in the Supplementary Appendix.

According to the randomization strata, Hispanic participants made up 31.9% of the education group (339 participants) and 32.0% of the decolonization group (339), and nursing home residents made up 11.3% of the education group (120) and 11.0% of the decolonization group (116). In a comparison of the education group with the decolonization group across the 1-year follow-up, early exit from the trial occurred in 34.9% of the participants (371 participants) and 37.0% (391), respectively ($P=0.32$); withdrawal from the trial in 6.8% (72) and 11.6% (123), respectively ($P<0.001$); loss to follow-up in 17.4% (185) and 16.1% (170), respectively ($P=0.41$); and death in 10.7% (114) and 9.3% (98), respectively ($P=0.26$). The characteristics of the participants who withdrew from the trial or were lost to follow-up and of the participants in the decolonization group according to adherence category are shown in Table S5 in the Supplementary Appendix.

OUTCOMES

A total of 8395 full-text medical records were requested, and 8067 (96.1%) were received and redacted. Charts underwent duplicate blinded review (16,134 reviews) by physicians with expertise in infectious diseases at a rate of approximately 800 charts per month for 20 months. Of the 2121 enrollment admission records, 2100 (99.0%) were received. Of the 6271 subsequent inpatient and outpatient records, 5967 (95.2%) were received for outcome assessment. The overall rate of reported hospitalizations per 365 days of follow-up was 1.97 in the education group and 1.75 in the decolonization group.

Regarding the primary outcome in the per-protocol analysis, 98 participants (9.2%) in the education group had a MRSA infection, as compared with 67 (6.3%) in the decolonization group (Table 2). This corresponded to an estimated MRSA infection rate in the education group of 0.139 infections per participant-year, as compared with 0.098 infections per participant-year in the decolonization group. Among first MRSA infections per participant, skin and soft-tissue infections and pneumonia were common. Across both groups, 84.8% (140 of 165) of the MRSA infections resulted in hospitalization, at a rate of 0.117 hospitalizations per participant-year in the education group and 0.083 per participant-year in the decolonization group. Bacteremia occurred in 28.5% (47 of 165) of all MRSA infections; the MRSA bacteremia rate was 0.040 events per participant-year in the education group and 0.028 per participant-year in the decolonization group. Findings were similar when MRSA infection was determined according to the clinical judgment of physicians with expertise in infectious diseases and according to CDC criteria (Table 2). All the MRSA infections were treated with an antibiotic, but the receipt of an antibiotic was not sufficient to render a decision of a MRSA infection.

In the analysis of infection from any cause according to CDC criteria, 23.7% of the participants in the education group (252 participants) had an infection, as compared with 19.6% of those in the decolonization group (207), which corresponded to an estimated rate of 0.407 infections per participant-year in the education group and 0.338 per participant-year in the decolonization group (Table 2). Skin and soft-tissue infections and pneumonia remained the most common infection types.

Pathogens were identified in 67.7% of the infections (Table S6 in the Supplementary Appendix). Participants in the decolonization intervention had a lower rate of infections due to gram-positive pathogens or without cultured pathogens than those in the education group. There was a

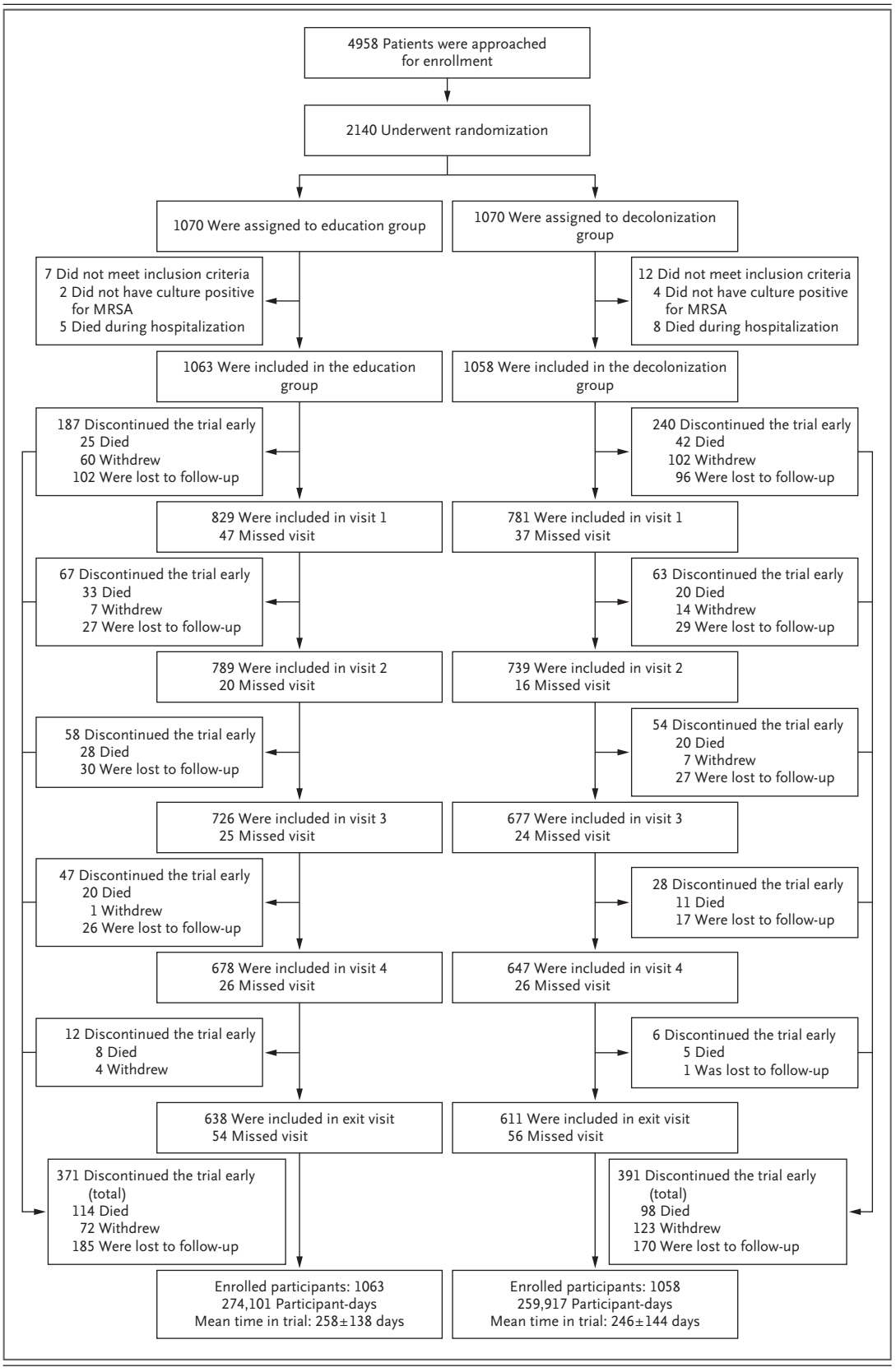


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Figure 1 (facing page). Randomization and Follow-up of the Participants.

This flow chart describes the recruitment and the four follow-up visits (at 1, 3, 6, and 9 months) for the 1-year period after hospital discharge. Recruitment occurred during hospitalization, and 19 participants were excluded from the postdischarge trial population because they did not meet inclusion criteria, leaving 2121 participants in the per-protocol population (1063 participants in the education group and 1058 in the decolonization group). Early exit from the trial was provided between each visit and included active withdrawal from the trial, loss to follow-up, and death. Active withdrawal represented situations in which participants indicated their desire to withdraw from the trial. Loss to follow-up was defined as the inability to contact the participant for 3 months, at which point the participant was removed from the trial at the time of last contact. Visits indicate both participants who successfully completed the visit and those who remained in the trial but missed that visit. The mean (±SD) time in the trial (in days) is shown for each group. All deaths were considered by the investigators to be unrelated to side effects from decolonization products. Summary boxes are provided at the bottom of the figure. MRSA denotes methicillin-resistant *Staphylococcus aureus*.

higher rate of gram-negative infection among the CDC-defined all-cause infections when participants in the decolonization intervention were compared with those in the education group, but this was not seen among clinically defined infections.

Across the two trial groups, infection from any cause led to hospitalization in 85.8% of the participants (394 of 459), and bacteremia occurred in 18.1% (83 of 459). The observed rate of hospitalization due to infection from any cause was 0.356 events per participant-year in the education group and 0.269 per participant-year in the decolonization group. The rate of bacteremia among participants with infection from any cause was 0.074 events per participant-year in the education group and 0.060 per participant-year in the decolonization group. Findings were similar when infection from any cause was determined according to clinical judgment (Table 2).

Estimates of the per-protocol treatment effects are shown in Table 3. No significant departures from proportional hazards were observed. In the main unadjusted analysis, the hazard of MRSA infection according to the CDC criteria (the primary outcome) was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03). This lower hazard of MRSA infection led to a 29% lower risk of hospitalization due to CDC-defined MRSA infection in the decolonization group than in the education group (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The effect was nearly identical for cases and hospitalizations involving clinically defined MRSA infection. Kaplan–Meier curves showing the infection-free time for the primary outcome of CDC-defined MRSA infection and the secondary outcome of infection from any cause show that the curves remained separated even after the intervention ended in month 6 (Fig. 2, and Table S7 in the Supplementary Appendix). Adjusted models showed greater MRSA infection effects that were significant (Table 3). A total of 10 participants (0.9%) in the education group and in 3 (0.3%) in the decolonization group died from MRSA infection. Results of sensitivity analyses conducted regarding death and early withdrawal from the trial are provided in Table S8 in the Supplementary Appendix.

The hazard of infection from any cause according to clinical judgment was lower in the decolonization group than in the education group (hazard ratio, 0.83; 95% CI, 0.70 to 0.99); similarly, the hazard of infection from any cause according to CDC criteria was lower in the decolonization group (hazard ratio, 0.84; 95% CI, 0.70 to 1.01) (Fig. 2B and Table 3). The risk of hospitalization due to infection from any cause was lower in the decolonization group than in the education group (hazard ratio, 0.76; 95% CI, 0.62 to 0.93). The results of the adjusted analyses were similar to those of the unadjusted analyses (Table 3). Deaths due to any infection occurred in 25 participants (2.3%) in the education group and 17 (1.6%) in the decolonization group.

EFFECT OF ADHERENCE

In as-treated analyses, 65.6% of the participant-time in the decolonization group involved full adherence; 19.6%, partial adherence; and 14.8%, nonadherence. Participants were highly consistent in adherence across the follow-up time. Increasing adherence was associated with increasingly lower rates of infection in both the adjusted and unadjusted models (Table 3). In comparisons of the adherence-category subgroups in the decolonization group with the education group overall, the likelihood of CDC-defined MRSA infection decreased 36% and 44%, respectively, as adher-

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Table 1. Characteristics of the Participants at Recruitment Hospitalization.*

Characteristic	Education Group (N=1063)	Decolonization Group (N=1058)	P Value†
Age — yr	56±17	56±17	0.78
Male sex — no. (%)	583 (54.8)	565 (53.4)	0.51
Coexisting conditions‡			
Diabetes — no./total no. (%)	424/1062 (39.9)	462/1056 (43.8)	0.08
Chronic obstructive pulmonary disease — no./total no. (%)	212/1055 (20.1)	203/1045 (19.4)	0.70
Congestive heart failure — no./total no. (%)	145/1055 (13.7)	149/1045 (14.3)	0.73
Cancer — no./total no. (%)	153/1055 (14.5)	161/1045 (15.4)	0.56
Renal disease — no./total no. (%)	140/1062 (13.2)	134/1056 (12.7)	0.74
Charlson Comorbidity Index score§	1.7±1.6	1.7±1.6	0.49
Bathe daily or every other day — no./total no. (%)¶	926/1037 (89.3)	927/1034 (89.7)	0.73
Bathing assistance needed — no./total no. (%)¶	200/1025 (19.5)	224/1013 (22.1)	0.15
MRSA source at enrollment — no. (%)			0.79
Nares‖	580 (54.6)	602 (56.9)	
Wound	320 (30.1)	305 (28.8)	
Respiratory	44 (4.1)	45 (4.3)	
Blood	43 (4.0)	31 (2.9)	
Other	76 (7.1)	75 (7.1)	
Recruitment hospitalization**			
Hospitalized in previous yr — no./total no. (%)‡	595/1046 (56.9)	598/1041 (57.4)	0.80
Nursing home stay in previous yr — no./total no. (%)‡	165/1043 (15.8)	168/1040 (16.2)	0.84
ICU stay — no./total no. (%)	188/1055 (17.8)	206/1045 (19.7)	0.27
Surgery — no./total no. (%)	392/1055 (37.2)	399/1045 (38.2)	0.63
MRSA infection — no./total no. (%)††	447/1055 (42.4)	438/1045 (41.9)	0.83
Wound at hospital discharge — no./total no. (%)	587/1055 (55.6)	588/1045 (56.3)	0.77
Medical device at hospital discharge — no./total no. (%)‡‡	320/1055 (30.3)	307/1045 (29.4)	0.63
Discharged to nursing home — no. (%)	120 (11.3)	116 (11.0)	0.81

* Plus–minus values are means ±SD. There were no significant differences between the two groups. Selected descriptive data are shown. For a full descriptive list of characteristics, see Table S2 in the Supplementary Appendix. ICU denotes intensive care unit.
† Student's t-test was performed for continuous variables, chi-square test for proportions, and Fisher's exact test for proportions if the numerator was 5 or less.
‡ Data reflect a positive response to either a survey question or chart review. Not all participants responded to every question, and not all enrollment charts were received from recruiting hospitals despite a signed release request, so data were missing for 21 participants.
§ Scores on the Charlson Comorbidity Index range from 0 to 10, with higher scores indicating more coexisting illness.
¶ Data reflect respondents to the survey question among all the participants. Not all the participants responded to every question.
‖ By law, California requires hospitals to screen five groups of patients for MRSA on hospital admission (patients who are transferred from a nursing home, who have been hospitalized in the past 30 days, who are undergoing hemodialysis, who are undergoing imminent surgery, and who are admitted to an ICU).
** Data reflect chart review from the received medical records. Not all recruiting hospitals released participants' medical records to the trial despite a signed release request, so records were missing for 21 participants.
†† Assessment of infection was based on criteria of the Centers for Disease Control and Prevention (CDC). Information regarding infection types is provided in Table S3 in the Supplementary Appendix.
‡‡ Information about medical device types is provided in Table S4 in the Supplementary Appendix.

ence increased from partial adherence (hazard ratio, 0.64; 95% CI, 0.40 to 1.00) to full adherence (hazard ratio, 0.56; 95% CI, 0.36 to 0.86). Similar effects were seen with regard to CDC-defined infection from any cause, which was 40% lower among fully adherent participants than among the participants in the education group (hazard ratio, 0.60; 95% CI, 0.46 to 0.78).

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Table 2. MRSA Infection Outcomes (First Infection per Person) per 365 Days of Follow-up, According to Trial Group.*

Variable	MRSA Infection, According to CDC Criteria†		MRSA Infection, According to Clinical Criteria		Any Infection, According to CDC Criteria		Any Infection, According to Clinical Criteria	
	Education	Decolonization	Education	Decolonization	Education	Decolonization	Education	Decolonization
All Participants								
Infection — no. of participants (no. of events/participant-yr)								
Any infection	98 (0.139)	67 (0.098)	98 (0.139)	68 (0.100)	252 (0.407)	207 (0.338)	298 (0.498)	246 (0.414)
Skin or soft-tissue infection	34 (0.048)	32 (0.047)	35 (0.050)	32 (0.047)	80 (0.129)	59 (0.096)	97 (0.162)	82 (0.138)
Pneumonia	18 (0.026)	9 (0.013)	20 (0.028)	10 (0.015)	39 (0.063)	25 (0.041)	45 (0.075)	34 (0.057)
Primary bloodstream or vascular infection	11 (0.016)	10 (0.015)	12 (0.017)	11 (0.016)	20 (0.032)	14 (0.023)	20 (0.033)	14 (0.024)
Bone or joint infection	13 (0.019)	9 (0.013)	12 (0.017)	8 (0.012)	20 (0.032)	22 (0.036)	0.18 (0.030)	17 (0.029)
Surgical-site infection	13 (0.019)	2 (0.003)	13 (0.018)	2 (0.003)	20 (0.032)	8 (0.013)	22 (0.037)	9 (0.015)
Urinary tract infection	3 (0.004)	2 (0.003)	1 (0.001)	1 (0.002)	38 (0.061)	46 (0.075)	52 (0.087)	56 (0.094)
Abdominal infection	1 (0.001)	2 (0.003)	1 (0.001)	2 (0.003)	20 (0.032)	21 (0.034)	26 (0.044)	18 (0.030)
Other infection	5 (0.007)	1 (0.002)	4 (0.006)	2 (0.003)	15 (0.024)	12 (0.020)	18 (0.030)	16 (0.027)
Infection involving bacteremia	28 (0.040)	19 (0.028)	27 (0.038)	18 (0.026)	46 (0.074)	37 (0.060)	46 (0.077)	33 (0.056)
Infection leading in hospitalization	83 (0.117)	57 (0.083)	82 (0.115)	56 (0.082)	225 (0.356)	169 (0.269)	259 (0.420)	199 (0.325)
Time to infection — days	111±91	117±93	116±94	117±95	103±87	110±91	107±91	113±94
Adherent Participants in Decolonization Group‡								
Infection — no. of participants (no. of events/participant-yr)								
Any infection		42 (0.085)		42 (0.088)		118 (0.272)		142 (0.338)
Skin or soft-tissue infection		22 (0.045)		22 (0.046)		40 (0.092)		54 (0.129)
Pneumonia		5 (0.010)		5 (0.011)		11 (0.025)		16 (0.038)
Primary bloodstream or vascular infection		5 (0.010)		6 (0.013)		8 (0.019)		8 (0.019)
Bone or joint infection		5 (0.010)		4 (0.008)		14 (0.032)		11 (0.026)
Surgical-site infection		2 (0.004)		2 (0.004)		6 (0.014)		7 (0.017)
Urinary tract infection		0		0		22 (0.051)		27 (0.064)
Abdominal infection		2 (0.004)		2 (0.004)		12 (0.028)		11 (0.026)
Other infection		1 (0.002)		1 (0.002)		5 (0.012)		8 (0.019)
Infection involving bacteremia		9 (0.019)		8 (0.017)		19 (0.045)		16 (0.039)
Infection leading to hospitalization		36 (0.075)		34 (0.071)		98 (0.226)		115 (0.274)
Time to infection — days		122±93		125±96		119±89		123±94

* Participant-day denominators were censored by the specified outcome. Dates of infection onset based on CDC criteria may differ from those based on clinical judgment.
† This was the primary outcome.
‡ A total of 546 participants were considered to have adhered fully to the decolonization intervention.

Table 3. Effect of Decolonization Plus Education, as Compared with Education Alone, According to Cox Proportional-Hazard Models.*

Variable	MRSA Infection, According to CDC Criteria	MRSA Infection, According to Clinical Criteria	Any Infection, According to CDC Criteria	Any Infection, According to Clinical Criteria
Per-protocol analysis				
Unadjusted hazard ratio (95% CI)	0.70 (0.52–0.96)†	0.71 (0.52–0.97)	0.84 (0.70–1.01)	0.83 (0.70–0.99)
Adjusted hazard ratio (95% CI)‡	0.61 (0.44–0.85)	0.61 (0.43–0.84)	0.80 (0.66–0.98)	0.81 (0.68–0.97)
As-treated analysis§				
Unadjusted hazard ratio (95% CI)				
Nonadherent	1.31 (0.72–2.38)	1.09 (0.57–2.10)	1.68 (1.19–2.36)	1.53 (1.11–2.13)
Partially adherent	0.64 (0.40–1.00)	0.72 (0.47–1.11)	0.86 (0.67–1.11)	0.92 (0.74–1.16)
Fully adherent	0.56 (0.36–0.86)	0.53 (0.34–0.83)	0.60 (0.46–0.78)	0.58 (0.45–0.74)
Adjusted hazard ratio (95% CI)¶				
Nonadherent	0.78 (0.36–1.71)	0.72 (0.37–1.41)	0.780 (0.51–1.26)	0.76 (0.40–1.45)
Partially adherent	0.75 (0.59–0.95)	0.69 (0.54–0.88)	0.78 (0.64–0.97)	0.76 (0.63–0.92)
Fully adherent	0.72 (0.57–0.92)	0.66 (0.51–0.84)	0.75 (0.60–0.94)	0.72 (0.58–0.88)

* The per-protocol population included all the participants (2121) who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization. The unadjusted analyses included all these participants. The adjusted models included the 1901 participants who provided data for all the baseline characteristics shown in Table S2 in the Supplementary Appendix.

† A P value is provided only for the primary outcome (P=0.03). Because the statistical analysis plan did not include a provision for correcting for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, these results are reported as point estimates with 95% confidence intervals. The widths of these confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

‡ Models evaluating the outcomes of MRSA infection according to CDC criteria and any infection according to clinical criteria were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, cancer, cerebrovascular disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, need for bathing assistance, and anti-MRSA antibiotics as time-varying covariates on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses. Models evaluating the outcome of MRSA infection according to clinical criteria and any infection according to CDC criteria were adjusted for the same variables with the addition of age. Resistance to mupirocin did not significantly modify the effect of the trial group.

§ The as-treated analysis assessed the effect on trial outcomes on the basis of the participant's level of adherence to the use of decolonization products as compared with the education group. Among the participants in the decolonization group, 65.6% of the participant-time involved full adherence (no missed doses); 19.6%, partial adherence (some missed doses); and 14.8%, nonadherence (no doses used). The comparator for each adherence subgroup was the overall education group.

¶ As-treated models for all outcomes were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, and need for bathing assistance on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses.

Nonadherence was associated with a higher likelihood of infection from any cause than was observed among participants in the education group.

NUMBER NEEDED TO TREAT

Overall, the estimated number needed to treat to prevent a MRSA infection was 30 (95% CI, 18 to 230) and to prevent an associated hospitalization, 34 (95% CI, 20 to 336). The number needed to treat to prevent any infection was 26 (95% CI, 13 to 212) and to prevent an associated hospitalization, 28 (95% CI, 21 to 270). Among the participants who adhered fully to the intervention (all of whom were in the decolonization group), the number needed to treat to prevent a MRSA infection was 26 (95% CI, 18 to 83) and to prevent an associated hospitalization, 27 (95% CI, 20 to 46). The number needed to treat to prevent any infection was 11 (95% CI, 8 to 21) and to prevent an associated hospitalization, 12 (95% CI, 8 to 23).

ADVERSE EVENTS

Adverse events that were associated with the topical decolonization intervention were mild and uncommon, occurring in 44 participants (4.2%) (Table S9 in the Supplementary Appendix). Local irritation occurred with mupirocin in 1.1% of the participants (12 of 1058), with chlorhexidine bathing in 2.3% (24), and with chlorhexidine mouthwash in 1.1% (12). In those respective

categories, 33% (4 of 12), 29% (7 of 24), and 50% (6 of 12) of the participants chose to continue using the product (overall, 39% of the participants with side effects).

A total of 12.6% of the 1591 participants with postrecruitment MRSA strains had high-level resistance to mupirocin (9.4% [150 participants]) or low-level resistance to mupirocin (3.1% [50]). A total of 1.9% of the participants were newly found to have a mupirocin-resistant strain at subsequent visits (1.9% [16 of 826 participants] in the education group and 2.0% [15 of 765] in the decolonization group, P=0.97). A total of 1.5% of the participants in each group were newly found to have high-level mupirocin-resistant strains (1.6% [13 of 826 participants] in the education group and 1.4% [11 of 765] in the decolonization group, P=0.82) when only sensitive strains were detected at recruitment. Chlorhexidine MICs of 8 μg or more per milliliter were rare (occurring in 2 participants overall [0.1%]). Both patients were in the intervention group, and both isolates had an MIC of 8 μg per milliliter and were negative for the *qac A/B* gene).

DISCUSSION

Infection-prevention campaigns have reduced the risks of health care–associated infections in hospitals, leaving the majority of preventable infections to the postdischarge setting.[16] MRSA carriers are an appealing population target because of their higher risks of infection and postdischarge rehospitalization and the common practice of screening selected inpatients for MRSA colonization.[1,17-19] In the CLEAR trial, topical decolonization led to lower risks of infections and readmissions than hygiene education alone among patients after the transition from hospital to home and other care settings. With a number needed to treat between 25 and 30 to prevent infection and hospitalization, this intervention is relevant to 1.8 million MRSA carriers (5% of inpatients) who are discharged from hospitals each year.[16]

Although decolonization has successfully prevented disease during temporary high-risk circumstances (e.g., recurrent skin infections, ICU care, and arthroplasty and cardiac surgery),[6-10,19-22] a single 5-day decolonization regimen produced short-lived MRSA clearance in half the carriers.[23-26] In contrast, twice-monthly decolonization provided protection for many months after discharge. The protective benefit continued after decolonization. In addition, this regimen was effective despite the greater variability in application with home bathing and showering than has occurred in previous inpatient trials that evaluated nursing-assisted chlorhexidine bath-

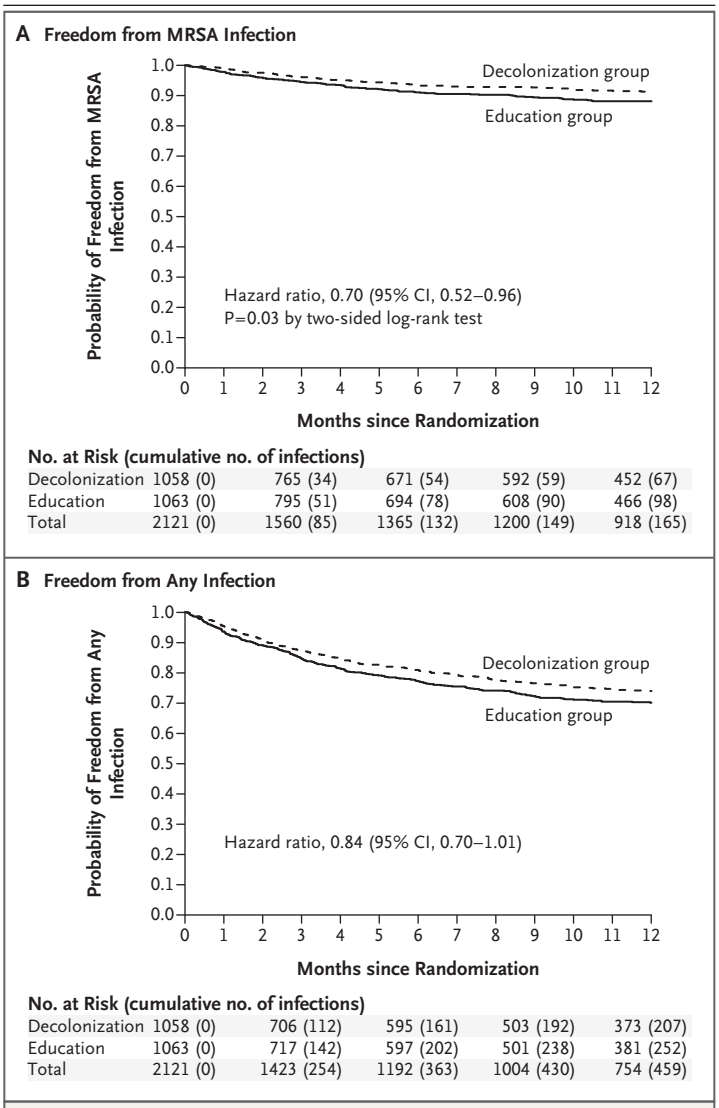

Figure 2. Kaplan–Meier Curves for Freedom from MRSA Infection and Infection from Any Cause, Assessed According to CDC Criteria.

Cases of MRSA infection and infection from any cause were assessed according to criteria of the Centers for Disease Control and Prevention (CDC). The probability of being free from MRSA infection (primary outcome) was significantly greater in the decolonization group than in the education group. The curves remained separated even though decolonization stopped at 6 months. Details regarding the numbers of patients at risk for infection and those with infection at the specific time points are provided in Table S7 in the Supplementary Appendix.

ing and mupirocin application.[8,9,22] This trial also showed that 4% rinse-off chlorhexidine was effective in a postdischarge population that typically takes showers or baths and is unlikely to use a 2% leave-on chlorhexidine product.[8,9,22]

Not surprisingly, participants who adhered fully to the decolonization intervention had rates of MRSA infection and infection from any cause that were at least 40% lower than the rates among participants in the education group, with a number needed to treat of 12 to prevent infection-related hospitalization. This finding probably is attributable to both the decolonization effect and the likelihood that these participants were more adherent to other prescribed treatments and health-promotion behavior than participants in the education group. Participants who fully adhered to the intervention had fewer coexisting conditions, had fewer devices, required less bathing assistance, and were more likely to have MRSA infection (rather than asymptomatic colonization) at the time of enrollment than either participants in the education group or participants in the decolonization group who had lower levels of adherence. These differences represent an important practical distinction. To the extent that physicians can identify patients who are able to adhere to an intervention, those patients would derive greater benefit from the recommendation to decolonize. Nonadherence was common among nursing home residents, which raises questions about research barriers in that care setting.

Decolonization appeared to affect the risks of skin and soft-tissue infections, surgical-site infections, pneumonia, and bacteremia, although sample-size constraints necessitate cautious speculation. Decolonization also appeared to reduce the rate of gram-positive pathogens and infections without a cultured pathogen. The higher rate of gram-negative pathogens in the decolonization group than in the education group was seen among the CDC-defined all-cause infections but not among the clinically defined infections and requires further substantiation. These observations are based on relatively small numbers; larger studies have shown that chlorhexidine can reduce the incidence of gram-negative infections and bacteriuria.[27-30]

The design of this trial did not permit us to determine the effect of hygiene education alone. Both trial groups received in-person visits and reminders about the importance of MRSA-prevention activities. In addition, the free product overcame financial disparities that could become evident with post-trial adoption of the decolonization intervention.

Some participants (<5%) in the decolonization group had mild side effects; among those participants, nearly 40% opted to continue using the agent. Resistance to chlorhexidine and mupirocin was not differentially engendered in the two groups. We defined an elevated chlorhexidine MIC as at least 8 μg per milliliter, although 4% chlorhexidine applies 40,000 μg per milliliter to the skin.

This trial is likely to be generalizable because it was inclusive. For example, the enrollment of participants with late-stage cancer contributed to the 10% anticipated mortality and the approximate 25% rate of withdrawal and loss to follow-up. These rates are similar to other postdischarge trials with shorter durations of follow-up than the durations in our trial.[31-33] It is unknown whether the participants who withdrew or were lost to follow-up had different infection rates or intervention benefits. They were more educated and less likely to be Hispanic than those who did not withdraw or were not lost to follow-up, but the percentages of participants with coexisting conditions were similar.

Limitations of this trial include the unblinded intervention, although outcomes were assessed in a blinded fashion. The trial also had substantial attrition over the 1-year follow-up, and adherence was based on reports by the participants, with spot checks of remaining product, both of which may not reflect actual use. In addition, nearly all infections led to hospitalization, which suggests that milder infections escaped detection. Most outpatient and nursing home records had insufficient documentation for the event to be deemed infection according to the CDC or clinical criteria. Thus, it remains unknown whether the observed 30% lower risk of MRSA infection or the observed 17% lower risk of infection from any cause with decolonization than with education alone would apply to less severe infections that did not lead to hospitalization. Finally, although resistance to chlorhexidine and mupirocin did not emerge during the trial, the development of resistance may take time, beyond the follow-up period of this trial.

In conclusion, inpatients with MRSA-positive

cultures who had been randomly assigned to undergo decolonization with topical chlorhexidine and mupirocin for 6 months after discharge had lower risks of MRSA infection, infection from any cause, and hospitalization over the 1 year after discharge than those who had been randomly assigned to receive hygiene education only.

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), or the Agency for Healthcare Research and Quality (AHRQ).

Supported by a grant (R01HS019388, to Dr. Huang) from the AHRQ Healthcare-Associated Infections Program and by the University of California Irvine Institute for Clinical and Translational Science, which was funded by a grant from the NIH Clinical and Translational Sciences Award program (UL1 TR000153).

Dr. Huang reports conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, Clorox, Xttrium Laboratories, and Medline; Ms. Singh, Dr. Park, and Mr. Chang, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline; Dr. McKinnell, receiving grant support and consulting fees from Achaogen and Theravance Biopharma, grant support, consulting fees, and lecture fees from Allergan, consulting fees from Cempra, Melinta Therapeutics, Menarini Group, and Thermo Fisher Scientific, and fees for serving as a research investigator from Science 37, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline, and serving as cofounder of Expert Stewardship; Ms. Gombosev, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, and Clorox; Dr. Rashid, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Clorox, and Medline; Dr. Bolaris, conducting clinical studies in which participating nursing homes received donated products from 3M and Clorox; Dr. Robinson, serving as cofounder of Expert Stewardship; Dr. Amin, receiving consulting fees from Paratek Pharmaceuticals; Dr. Septimus, conducting clinical studies in which participating hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline; Dr. Weinstein, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products) and Mölnlycke; Dr. Hayden, conducting clinical studies in which participating nursing homes and hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline and donated laboratory services from OpGen and receiving grant support and conducting clinical studies in which participating nursing homes and hospitals received donated product from Clorox; and Dr. Miller, receiving grant support from Gilead Sciences, Merck, Abbott, Cepheid, Genentech, Atox Bio, and Paratek Pharmaceuticals, grant support and fees for serving on an advisory board from Achaogen and grant support, consulting fees, and fees for serving on an advisory board from Tetraphase and conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline. No other potential conflict of interest relevant to this article was reported. Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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We thank the trial participants and their families; the trial staff (Lauren Akahoshi, Jenna Alcaron, Isabel Alegria, Stephanie Arredondo-Glacet, Elizabeth Arreola, Donald Bayley, Nelly Beltran, Barbara Bodenhoefer, Stefan Boghossian, Diane Capobianco, Claudia Cervantes, Sarah Chevallier, Heather Clayton, Ramiro Correa, Nathalia Cressey, Tiffany Dam, Rupak Datta, Jennifer Do, Phillip Duffy, Tabitha Dutciuc, Marlene Estevez, Margarita Flores, Lauren Heim, Sandra Ibarra, Usme Khusbu, Bryn Launer, Cameron Lee, Brian Lewis, Karen Lolans, Andrea Marcantonio, Donna Matsudairas, Lisa [Angie] McErlain, Maria Mejia, Job Mendez, Angela Mendoza, Melanie Meton, Nicole Mohajer, Jennifer Nam, Ann Nguyen, Hanna Owens, Jalpa Patel, Lena Portillo, Sean Prendergast, Katy Precaido, Belinda Prado, Deborah Prunean, Victor Quan, Courtney Reynolds, Diana Romero, Aubrianne Rose, Maureen Schroeder, Grace Tagudar, Cynthia Toyoshima, Ivonne Turner, Qixin Wang, Emily Wawro, and Jun Zozobrado); two physicians who actively supported and facilitated recruitment (David Petreccia and Anjali Vora); the members of our community advisory board (Patricia Cantero, Ph.D., and Jeanine Thomas); the members of our data and safety monitoring board (Honghu Liu, David Beenhouwer, and George Sakoulas); and the staff of the many hospitals and nursing homes that supported the recruitment of participants in the trial.

APPENDIX

The authors' full names and academic degrees are as follows: Susan S. Huang, M.D., M.P.H, Raveena Singh, M.A., James A. McKinnell, M.D., Steven Park, M.D., Ph.D., Adrijana Gombosev, M.S., Samantha J. Eells, M.P.H., Daniel L. Gillen, Ph.D., Diane Kim, B.S., Syma Rashid, M.D., Raul Macias-Gil, M.D., Michael A. Bolaris, M.D., Thomas Tjoa, M.P.H., M.S., Chenghua Cao, M.P.H., Suzie S. Hong, M.S., Jennifer Lequieu, B.S., Eric Cui, B.S., Justin Chang, B.S., Jiayi He, M.S., Kaye Evans, B.A., Ellena Peterson, Ph.D., Gail Simpson, M.D., Philip Robinson, M.D., Chester Choi, M.D., Charles C. Bailey, Jr., M.D., James D. Leo, M.D., Alpesh Amin, M.D., Donald Goldmann, M.D., John A. Jernigan, M.D., Richard Platt, M.D., Edward Septimus, M.D., Robert A. Weinstein, M.D., Mary K. Hayden, M.D., and Loren G. Miller, M.D., M.P.H.

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PUBLIC HEALTH

Hospitals Look To Nursing Homes To Help Stop Drug-Resistant Infections

April 2, 20195:00 AM ET

ANNA GORMAN

A certified nursing assistant wipes Neva Shinkle's face with chlorhexidine, an antimicrobial wash. Shinkle is a patient at Coventry Court Health Center, a nursing home in Anaheim, Calif., that is part of a multicenter research project aimed at stopping the spread of MRSA and CRE — two types of bacteria resistant to most antibiotics. *Heidi de Marco/KHN*

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy to stop the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government's Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

This novel collaboration recognizes that superbugs don't remain isolated in one hospital or nursing home but move quickly through a community, said Dr. John Jernigan, who directs the CDC's office on health care-acquired infection research.

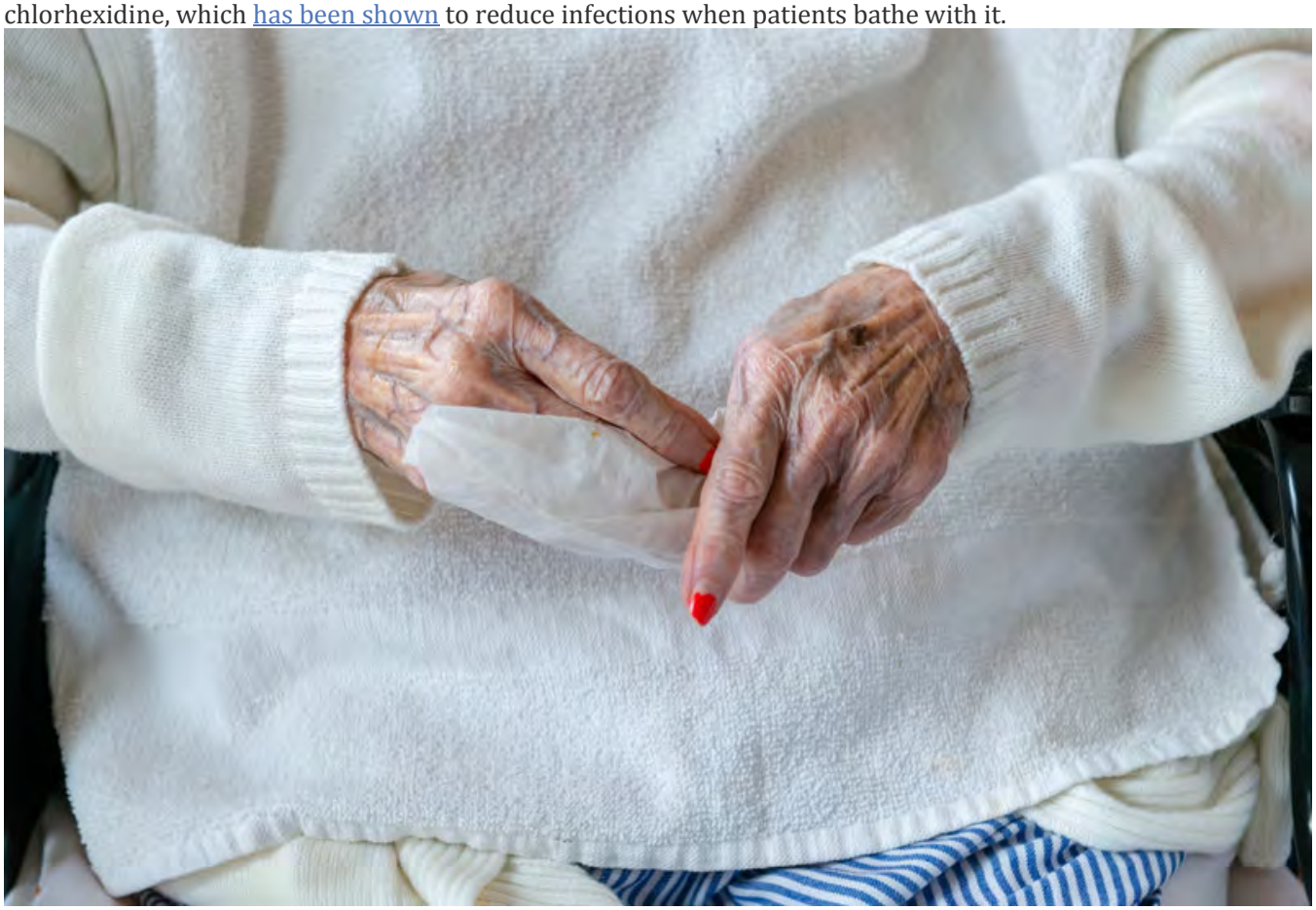
"No health care facility is an island," Jernigan says. "We all are in this complicated network."

At least 2 million people in the U.S. become infected with some type of antibiotic-resistant bacteria each year, and about 23,000 die from those infections, according to the CDC.

People in hospitals are vulnerable to these bugs, and people in nursing homes are particularly vulnerable. Up to 15 percent of hospital patients and 65 percent of nursing home residents harbor drug-resistant organisms, though not all of them will develop an infection, says Dr. Susan Huang, who specializes in infectious diseases at the University of California, Irvine.
"Superbugs are scary and they are unabated," Huang says. "They don't go away."

Some of the most common bacteria in health care facilities are methicillin-resistant *Staphylococcus aureus*, or MRSA, and carbapenem-resistant *Enterobacteriaceae*, or CRE, often called "nightmare bacteria." *E.Coli* and *Klebsiella pneumoniae* are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

CRE have "basically spread widely" among health care facilities in the Chicago region, says Dr. Michael Lin, an infectious-diseases specialist at Rush University Medical Center, who is heading the CDC-funded effort there. "If MRSA is a superbug, this is the extreme — the super superbug."
Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it.



The Centers for Disease Control and Prevention funds the project in California, based in Orange County, in which 36 hospitals and nursing homes are using an antiseptic wash, along with an iodine-based nose swab, on patients to stop the spread of deadly superbugs.
Heidi de Marco/KHN

Though hospital intensive care units frequently rely on chlorhexidine in preventing infections, it is used less commonly for bathing in nursing homes. Chlorhexidine also is sold over the counter; the FDA noted in 2017 it has caused rare but severe allergic reactions.
In Chicago, researchers are working with 14 nursing homes and long-term acute care hospitals, where staff are screening people for the CRE bacteria at admission and bathing them daily with chlorhexidine.

The Chicago project, which started in 2017 and ends in September, includes a campaign to promote hand-washing and increased communication among hospitals about which patients carry the drug-resistant organisms.

The infection-control protocol was new to many nursing homes, which don't have the same resources as hospitals, Lin says.

In fact, three-quarters of nursing homes in the U.S. received citations for infection-control problems over a four-year period, according to a Kaiser Health News analysis, and the facilities with repeat citations almost never were fined. Nursing home residents often are sent back to hospitals because of infections.
In California, health officials are closely watching the CRE bacteria, which are less prevalent there than elsewhere in the country, and they are trying to prevent CRE from taking hold, says Dr. Matthew Zahn, medical director of epidemiology at the Orange County Health Care Agency
"We don't have an infinite amount of time," Zahn says. "Taking a chance to try to make a difference in CRE's trajectory now is really important."

The CDC-funded project in California is based in Orange County, where 36 hospitals and nursing homes are using the antiseptic wash along with an iodine-based nose swab. The goal is to prevent new people from getting drug-resistant bacteria and keep the ones who already have the bacteria on their skin or elsewhere from developing infections, says Huang, who is leading the project.

Licensed vocational nurse Joana Bartolome swabs Shinkle's nose with an antibacterial, iodine-based solution at Anaheim's Coventry Court Health Center. Studies find patients can harbor drug-resistant strains in the nose that haven't yet made them sick.
Heidi de Marco/KHN

Huang kicked off the project by studying how patients move among different hospitals and nursing homes in Orange County — she discovered they do so far more than previously thought. That prompted a key question, she says: "What can we do to not just protect our patients but to protect them when they start to move all over the place?"

Her previous research showed that patients who were carriers of MRSA bacteria on their skin or in their nose, for example, who, for six months, used chlorhexidine for bathing and as a mouthwash, and swabbed their noses with a nasal antibiotic were able to reduce their risk of developing a MRSA infection by 30 percent. But all the patients in that study, published in February in the *New England Journal of Medicine*, already had been discharged from hospitals.

Now the goal is to target patients still in hospitals or nursing homes and extend the work to CRE. The traditional hospitals participating in the new project are focusing on patients in intensive care units and those who already carry drug-resistant bacteria, while the nursing homes and the long-term acute care hospitals perform the cleaning — also called "decolonizing" — on every resident.

One recent morning at Coventry Court Health Center, a nursing home in Anaheim, Calif., 94-year-old Neva Shinkle sat patiently in her wheelchair. Licensed vocational nurse Joana Bartolome swabbed her nose and asked if she remembered what it did.

"It kills germs," Shinkle responded.

"That's right. It protects you from infection."

In a nearby room, senior project coordinator Raveena Singh from UCI talked with Caridad Coca, 71, who had recently arrived at the facility. She explained that Coca would bathe with the chlorhexidine rather than regular soap. "If you have some kind of open wound or cut, it helps protect you from getting an infection," Singh said. "And we are not just protecting you, one person. We protect everybody in the nursing home."

Coca said she had a cousin who had spent months in the hospital after getting MRSA. "Luckily, I've never had it," she said.

Coventry Court administrator Shaun Dahl says he was eager to participate because people were arriving at the nursing home carrying MRSA or other bugs. "They were sick there and they are sick here," Dahl says.
Results from the Chicago project are pending. Preliminary results of the Orange County project, which ends in May, show that it seems to be working, Huang says. After 18 months, researchers saw a 25 percent decline in drug-resistant organisms in nursing home residents, 34 percent in patients of long-term acute care hospitals and 9 percent in traditional hospital patients. The most dramatic drops were in CRE, though the number of patients with that type of bacteria was smaller.

The preliminary data also show a promising ripple effect in facilities that aren't part of the effort, a sign that the project may be starting to make a difference in the county, says Zahn of the Orange County Health Care Agency.

"In our community, we have seen an increase in antimicrobial-resistant infections," he says. "This offers an opportunity to intervene and bend the curve in the right direction."

USA TODAY

How to fight ‘scary’ superbugs that kill thousands each year? Cooperation — and a special soap

Anna Gorman, Kaiser Health News Published 9:27 a.m. ET April 12, 2019 | **Updated 1:47 p.m. ET April 12, 201**

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy against the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government’s Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

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USA TODAY

Certified nursing assistant Cristina Zainos prepares a special wash using antimicrobial soap. *(Photo: Heidi de Marco, Kaiser Health News)*

“Superbugs are scary and they are unabated,” Huang said. “They don’t go away.”

Some of the most common bacteria in health care facilities are methicillin-resistant Staphylococcus aureus, or MRSA, and carbapenem-resistant Enterobacteriaceae, or CRE, often called “nightmare bacteria.” E. coli and Klebsiella pneumoniae are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

CREs have “basically spread widely” among health care facilities in the Chicago region, said Dr. Michael Lin, an infectious-diseases specialist at Rush University Medical Center, who is heading the CDC-funded effort there. “If MRSA is a superbug, this is the extreme — the super superbug.”

Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it. Though chlorhexidine is frequently used for bathing in hospital intensive care units and as a mouthwash for dental infections, it is used less commonly for bathing in nursing homes.

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In Chicago, researchers are working with 14 nursing homes and long-term acute care hospitals, where staff are screening people for the CRE bacteria at admission and bathing them daily with chlorhexidine.

The Chicago project, which started in 2017 and ends in September, includes a campaign to promote handwashing and increased communication among hospitals about which patients carry the drug-resistant organisms.

The infection-control work was new to many nursing homes, which don't have the same resources as hospitals, Lin said.

In fact, three-quarters of nursing homes in the U.S. received citations for infection-control problems over a four-year period, according to a Kaiser Health News analysis, and the facilities with repeat citations almost never were fined. Nursing home residents often are sent back to hospitals because of infections.

In California, health officials are closely watching the CRE bacteria, which are less prevalent there than elsewhere in the country, and they are trying to prevent CRE from taking hold, said Dr. Matthew Zahn, medical director of epidemiology at the Orange County Health Care Agency. "We don't have an infinite amount of time," he said. "Taking a chance to try to make a difference in CRE's trajectory now is really important."

The CDC-funded project in California is based in Orange County, where 36 hospitals and nursing homes are using the antiseptic wash along with an iodine-based nose swab. The goal is to prevent new people from getting drug-resistant bacteria and keep the ones who already have the bacteria on their skin or elsewhere from developing infections, said Huang, who is leading the project.

Huang kicked off the project by studying how patients move among different hospitals and nursing homes in Orange County, and discovered they do so far more than imagined. That prompted a key question: "What can we do to not just protect our patients but to protect them when they start to move all over the place?" she recalled.

Her previous research showed that patients with the MRSA bacteria who used chlorhexidine for bathing and as a mouthwash, and swabbed their noses with a nasal antibiotic, could reduce their risk of developing a MRSA infection by 30%. But all the patients in that study, published in February in the New England Journal of Medicine, already had been discharged from hospitals.

Now the goal is to target patients still in hospitals or nursing homes and extend the work to CRE. The traditional hospitals participating in the new project are focusing on patients in intensive care units and those who already carried drug-resistant bacteria, while the nursing homes and the

long-term acute care hospitals perform the cleaning — also called “decolonizing” — on every resident.

One recent morning at Coventry Court Health Center, a nursing home in Anaheim, Calif., 94-year-old Neva Shinkle sat patiently in her wheelchair. Licensed vocational nurse Joana Bartolome swabbed her nose and asked if she remembered what it did.

“It kills germs,” Shinkle responded.

“That’s right — it protects you from infection.”

In a nearby room, senior project coordinator Raveena Singh from UC-Irvine talked with Caridad Coca, 71, who had recently arrived at the facility. She explained that Coca would bathe with the chlorhexidine rather than regular soap. “If you have some kind of open wound or cut, it helps protect you from getting an infection,” Singh said. “And we are not just protecting you, one person. We protect everybody in the nursing home.”

Coca said she had a cousin who had spent months in the hospital after getting MRSA. “Luckily, I’ve never had it,” she said.

Coventry Court administrator Shaun Dahl said he was eager to participate because people were arriving at the nursing home carrying MRSA or other bugs. “They were sick there and they are sick here,” Dahl said.

Results from the Chicago project are pending. Preliminary results of the Orange County project, which ends in May, show that it seems to be working, Huang said. After 18 months, researchers saw a 25% decline in drug-resistant organisms in nursing home residents, 34% in patients of long-term acute care hospitals and 9% in traditional hospital patients. The most dramatic drops were in CRE, though the number of patients with that type of bacteria was smaller.

The preliminary data also shows a promising ripple effect in facilities that aren’t part of the effort, a sign that the project may be starting to make a difference in the county, said Zahn of the Orange County Health Care Agency.

“In our community, we have seen an increase in antimicrobial-resistant infections,” he said. “This offers an opportunity to intervene and bend the curve in the right direction.”

Kaiser Health News is a national health policy news service that is part of the nonpartisan Henry J. Kaiser Family Foundation.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

May 14, 2019

CalOptima Board of Directors
505 City Parkway West
Orange, CA 92868

Dear CalOptima Board of Directors:

As the Director of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC), I want to relay that CDC is very encouraged by your proposed Post-Acute Infection Prevention Quality Initiative (PIPQI). We hope that this type of insurer initiative will help protect nursing home residents from infections and hospitalization.

To combat antibiotic resistant – an important global threat – CDC has activities to prevent infections, improve antibiotic use, and detect and contain the spread of new and emerging resistant bacteria. The nursing home population is at particular risk for acquiring these bacteria and developing infections that require antibiotics and hospital admission because of their age, complex health status, frequency of wounds, and need for medical devices. Surveillance data have shown that the majority of nursing home residents currently have one of these highly antibiotic resistant bacteria on their body, and often these bacteria are spread between residents, within the nursing home, and to other healthcare facilities.

There is a need for public health agencies, insurers, and healthcare providers to forge coordinated efforts to promote evidence-based infection prevention strategies to prevent infections and save lives. We see great synergy in linking CDC's role in providing surveillance and infection prevention guidance to CalOptima's ability to protect its members by supporting patient safety initiatives to reduce infections and the hospitalizations they cause.

CDC funded the Orange County regional decolonization collaborative (SHIELD) as a demonstration project to inform broader national infection prevention guidance. The ability to maintain its resounding success in reducing antibiotic resistant bacteria and infections is critical and Orange County will benefit on initiatives such as PIPQI that provide incentives to enable its adoption into operational best practices.

CDC plans to continue transitional support for this initiative, including training support for the 16 nursing homes currently in the SHIELD collaborative for at least one year. We hope that this training effort can complement and synergize the efforts of CalOptima's education and liaison nurses. In addition, we are providing transitional support to the Orange County Health Department to continue their ongoing surveillance efforts in order that the ongoing benefits of the intervention can be captured.

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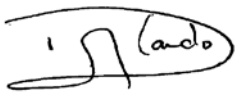
We look forward to collaborating with you. We believe this partnership is a valuable opportunity to protect highly vulnerable patients and to set an example of how insurers and public health can work together to improve healthcare quality.

Sincerely,



Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken April 2, 2020
Regular Meeting of the CalOptima Board of Directors

Report Item

26. Consider Approval of Allocation of Intergovernmental Transfer (IGT) 9 Funds

Contact

David Ramirez, Chief Medical Officer (714) 246-8400
Nancy Huang, Chief Financial Officer (714) 246-8400
Candice Gomez, Executive Director Program Implementation (714) 246-8400

Recommended Actions

1. Approve the recommended allocation of IGT 9 funds in the amount of $45 million for initiatives for quality performance, access to care, data exchange and support and other priority areas; and
2. Authorize the Chief Executive Officer, with the assistance of Legal Counsel, to take actions necessary to implement the proposed initiatives, subject to staff first returning to the Board for approval of:
    a. Additional initiative(s) related to member access and engagement; and
    b. New and/or modified policies and procedures, and contracts/contract amendments, as applicable.

Background

Intergovernmental Transfers (IGT) are transfers of public funds between eligible government entities which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has participated in eight Rate Range IGT transactions. Funds from IGTs 1 through 8 have been received and IGT 9 funds are expected from the state in the first quarter of 2020. IGTs 1 through 9 covered the applicable twelve-month state fiscal year (FY) periods (i.e., FY 2020-2011 through FY 2018-19). IGT 1 through 7 funds were retrospective payments for prior rate range years and were designated to be used to provide enhanced/additional benefits to existing Medi-Cal beneficiaries, as represented to CMS.

The IGT funds received under IGT 1 through 7 have supported special projects that address unmet healthcare needs of CalOptima members, such as vision and dental services for children, obesity prevention and intervention services, provider incentives for adolescent depression screenings, recuperative care for homeless members, and support for members through the Personal Care Coordinator (PCC) program. These funds have been best suited for one-time investments or as seed capital for enhanced health care services for the benefit of Medi-Cal beneficiaries.

Beginning with IGT 8, the IGT program covers the current fiscal year and funds are incorporated into the contract between the California Department of Health Care Services (DHCS) and CalOptima for the current fiscal year. Funds must be used for CalOptima covered Medi-Cal services per DHCS requirements. Upon Board approval, funds may be allocated and used over multiple years. IGT 8 funds have been allocated to the Homeless Health Initiative. In July 2018, CalOptima received notice from DHCS regarding the fiscal year 2018-19 Voluntary Rate Range IGT 9. While supporting documents were submitted to DHCS in August 2018, IGT 9 funds have not yet been received or allocated. Submission of documentation to participate in IGT 9 was ratified at the September 9, 2018

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Board of Directors meeting. CalOptima is expected to receive funding from DHCS in calendar year 2020. CalOptima's estimated share is expected to be approximately $45 million. Following consideration by the Quality Assurance Committee and Finance and Audit Committee at their respective February 2020 meetings and the committees' recommendations for approval by the full Board, this item was presented for approval at the March CalOptima Board meeting. At that meeting, staff was directed to conduct further study and provide additional details related to the Whole Child Model pilot program (WCM) and the program's financial performance. Details on the WCM program are provided in a separate WCM-specific Information Item.

Discussion

While IGT 1-7 funds were available to provide enhanced services to existing CalOptima Medi-Cal beneficiaries, beginning with IGT 8, the requirement is that IGT funds are to be used for Medi-Cal program covered services and operations. IGT 8 (and subsequent IGT) funds are subject to all applicable requirements set forth in the CalOptima Medi-Cal contract with DHCS and are considered part of the capitation payments CalOptima receives from DHCS and are accounted for as either medical or administrative expenses, and factor into CalOptima's Medical Loss Ratio (MLR) and Administrative Loss Ratio (ALR). As indicated, per DHCS, the use of these funds is limited to covered Medi-Cal benefits for existing CalOptima members.

While IGT 9 funds have not yet been received, CalOptima staff has begun planning to support use of the funds. CalOptima staff has considered the DHCS requirements for use of IGT 9 funds and Board approved strategic priorities and objectives in identifying the following focus areas:

- Member access and engagement
- Quality performance
- Data exchange and support
- Other priority areas

CalOptima staff has and will continue to share information about the proposed focus areas with various stakeholders.

CalOptima staff anticipates receiving approximately $45 million in IGT 9 funding. Staff has identified initiatives within four focus areas targeting $40.5 million of the anticipated $45 million. Staff proposes approval of the five initiatives and allocation of funds in the focus areas as noted below and as further described in the attached IGT Funding Proposals:

Proposals	Focus Area	Term	Amount Requested
1. Expanded Office Hours	Member access and engagement	Two–years	$2.0 million
2. Post-Acute Infection Prevention (PIPQI)	Quality performance	Three–years	$3.4 million
3. Hospital Data Exchange Incentive	Data exchange and support	One–year	$2.0 million

4. IGT Program Administration	Other priority areas	Five–years	$2.0 million
5. Whole Child Model (WCM) Program	Other priority areas	One–year	Up to $31.1 million
6. Future Request Prior to End of Fiscal Year	Member access and engagement	To be determined	$4.5 million

CalOptima staff will return to the Board with recommendations related the remaining estimated $4.5 million towards member access and engagement, as well as regarding new and/or modified policies and procedures, and contracts, if necessary.

Fiscal Impact

The recommended action has no net fiscal impact to CalOptima's operating budget over the proposed project terms. Staff estimates that IGT 9 revenue from DHCS will be sufficient to cover the allocated expenditures and initiatives recommended in this COBAR.

Rationale for Recommendation

CalOptima staff is recommending the use of IGT funds in a manner consistent with state parameters for IGT funds, identified focus areas.

Concurrence

Gary Crockett, Chief Counsel
Board of Directors' Finance and Audit Committee
Board of Directors' Quality Assurance Committee

Attachments

1. Power Point Presentation: Intergovernmental Transfer (IGT) 9 Update
2. CalOptima Board Action dated September 6, 2018, Consider and Authorize Activities to Secure Medi-Cal Funds through IGT 9
3. CalOptima Board Action dated June 6, 2019, Approve Post-Acute Infection Prevention Quality Initiative and Authorize Quality Incentive Payments
4. IGT Funding Proposals

/s/ Michael Schrader *03/26/2020*
Authorized Signature **Date**

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CalOptima
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Intergovernmental Transfer (IGT) 9 Update

Board of Directors Meeting
April 2, 2020

David Ramirez, M.D., Chief Medical Officer
Nancy Huang, Chief Financial Officer
Candice Gomez, Executive Director, Program Implementation

IGT Background

- IGT process enables CalOptima to secure additional federal revenue to increase California's low Medi-Cal managed care capitation rates
  - IGT 1–7: Funds must be used to deliver enhanced services for the Medi-Cal population
    - Funds are outside of operating income and expenses
  - IGT 8–10: Funds must be used for Medi-Cal covered services for the Medi-Cal population
    - Funds are part of operating income and expenses

IGT Funding Process

High-Level Overview
1. CalOptima receives DHCS notice announcing IGT opportunity
2. CalOptima secures funding partnership commitments (e.g., UCI, Children and Families Commission, et al.)
3. CalOptima submits Letter of Interest to DHCS listing funding partners and their respective contribution amounts
4. Funding partners wire their contributions and an additional 20% fee to DHCS
5. CMS provides matching funds to DHCS
6. DHCS sends total amount to CalOptima
7. From the total amount, CalOptima returns each funding partner's original contribution
8. From the total amount, CalOptima also reimburses each funding partner's 20% fee and where applicable, retained amount for MCO tax (IGT 1–6 only)
9. Remaining balance of the total amount is split 50/50 between CalOptima and the funding partners or their designees

CalOptima Share Totals to Date

IGTs	CalOptima Share	Date Received
IGT 1	$12.43 million	September 2012
IGT 2	$8.70 million	June 2013
IGT 3	$4.88 million	September 2014
IGT 4	$6.97 million	October 2015 (Classic)/ March 2016 (MCE)
IGT 5	$14.42 million	December 2016
IGT 6	$15.24 million	September 2017
IGT 7	$15.91 million	May 2018
IGT 8	$42.76 million	April 2019
IGT 9*	TBD	TBD (Spring 2020)
IGT 10*	TBD	TBD
Total Received	**$121.31 million**	

** Pending DHCS guidance*

IGT 9 Status

- CalOptima's estimated share is approximately $45 million
  - Expect receipt of funding in calendar year 2020
  - Funds used for Medi-Cal programs, services and operations
  - Funds are part of operating income and expenses
    - Medical Loss Ratio (MLR) and Administrative Loss Ratio (ALR) apply
    - Managed through the fiscal year budget

- Stakeholder vetting on the following focus areas
  - Member access and engagement
  - Quality performance
  - Data exchange and support
  - Other priority areas

Proposed Allocation and Initiatives

- Staff has identified initiatives targeted $40.5 million of the anticipated $45 million

Proposals	Focus Area	Term	Amount Requested
1. Expanded Office Hours	Member access and engagement	Two–years	$2.0 million
2. Post-Acute Infection Prevention (PIPQI)	Quality performance	Three–years	$3.4 million
3. Hospital Data Exchange Incentive	Data exchange and support	One–year	$2.0 million
4. IGT Program Administration	Other priority areas	Five–years	$2.0 million
5. W hole Child Model Program	Other priority areas	One–year	Up to $31.1 million
6. Future Request Prior to End of Fiscal Year	Member access and engagement	To be determined	$4.5 million

1. Member Access and Engagement: Expanded Office Hours

- Description
  - Offer additional incentives to providers and/or clinics
    - Expand office hours in the evening and weekends
    - Expand primary care services to ensure timely access
- Guidelines
  - Primary care providers in community clinics serving members in high-demand/impacted areas are eligible
  - Per-visit access incentive awarded to providers and/or clinics for members seen during expanded hours
- Key Components
  - Two-year initiative
  - Budget request of $2.0 million ($500,000 in FY 2019–20)

2. Quality Performance: Post-Acute Infection Prevention Initiative (PIPQI)

- Description
  - Expand CalOptima's PIPQI to suppress multidrug-resistant organisms in contracted skilled nursing facilities (SNFs) and decrease inpatient admissions for infection
- Guidelines
  - Phase 1: Training for 41 CalOptima-contracted SNFs not currently participating in initiative
  - Phase 2: Compliance, quality measures and performance incentives for all participating facilities
  - Two FTE to support adoption, training and monitoring
- Key Components
  - Three-year initiative
  - Budget request of $3.4 million ($1 million in FY 2019–20)

3. Data Exchange: Hospital Data Exchange Incentive

- Description
  - Support data sharing among contracted and participating hospitals via use of CalOptima selected vendors
    - Other organizations within the delivery system may also be added
  - Enhance monitoring of hospital activities for CalOptima's members, aiming to improve care management and lower costs
- Guidelines
  - Participating organizations will:
    - Work with CalOptima and vendor to facilitate sharing of ADT (Admit, Discharge, Transfer) and Electronic Health Record data
    - Be eligible for an incentive once each file exchange is in place
- Key Components
  - One-year initiative
  - Budget request of $2.0 million (CY 2020)

4. Other Priorities: IGT Program Administration

- Definition
  - Administrative support for prior, current and future IGTs
    - Continue support for two existing staff positions to manage IGT transaction process, project and expenditure oversight
    - Fund Grant Management System license, public activities and other administrative costs
- Guidelines
  - Will be consistent with CalOptima policies and procedures
  - Will provide oversight of the entire IGT process and ensure funding investments are aligned with CalOptima strategic priorities and member needs
- Key Components
  - Five years of support
  - Budget request of $2.0 million

5. Other Priorities: Whole-Child Model (WCM) Program

- Definition
  - CalOptima launched WCM on July 1, 2019
  - Based on the initial analysis, CalOptima is projecting an overall loss of up to $31.1 million in FY 2019–20
- Challenges
  - Insufficient revenue from DHCS to cover WCM services
  - Complex operations and financial reconciliation
- Key Components
  - One year
  - Budget request of up to $31.1 million to fund the deficit from WCM program in FY 2019–20

Next Steps

- Return to the Board as needed regarding
  - New or modified policy and procedures
  - Contracts
  - Additional initiatives

CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner


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CalOptima
Better. Together.


Medi-Cal
A Public Agency
CalOptima
Better. Together.


OneCare (HMO SNP)
A Public Agency
CalOptima
Better. Together.


OneCare Connect
A Public Agency
CalOptima
Better. Together.


PACE
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CalOptima
Better. Together.

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken September 6, 2018
Regular Meeting of the CalOptima Board of Directors

Report Item

14. Consider Ratification of the Pursuit of Proposals with Qualifying Funding Partners to Secure Medi-Cal Funds Through the Voluntary Rate Range Intergovernmental Transfer Program for Rate Year 2018-19 (IGT 9)

Contact

Phil Tsunoda, Executive Director, Public Policy and Public Affairs, (714) 246-8400

Recommended Actions

Ratify and authorize the following activities to secure Medi-Cal funds through the Voluntary Intergovernmental Transfer (IGT) Rate Range Program:

1. Submission of a proposal to the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range Intergovernmental Transfer Program for Rate Year 2018-19 (IGT 9);
2. Pursuit of IGT funding partnerships with the University of California-Irvine, the Children and Families Commission, the County of Orange, the City of Orange, and the City of Newport Beach to participate in the upcoming Voluntary Rate Range Intergovernmental Transfer Program for Rate Year 2018-19 (IGT 9), and;
3. Authorize the Chief Executive Officer to execute agreements with these entities and their designated providers as necessary to seek IGT 9 funds.

Background

Intergovernmental Transfers (IGT) are transfers of public funds between eligible government entities which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has participated in seven Rate Range IGT transactions. Funds from IGTs 1 – 7 have been received and IGT 8 funds are expected in the first quarter of 2019. IGT 1 – 7 funds were retrospective payments for prior rate range years and have been used to provide enhanced/additional benefits to existing Medi-Cal beneficiaries. These funds have been best suited for one-time investments or as seed capital for new services or initiatives for the benefit of Medi-Cal beneficiaries.

The IGT funds that have been received to date have supported special projects that address unmet needs for CalOptima members, such as vision and dental services for children, obesity prevention and intervention services, provider incentives for adolescent depression screenings, recuperative care for homeless members, and support for members through the Personal Care Coordinator (PCC) program. For the approved and funded IGT transactions to date, the net proceeds have been evenly divided between CalOptima and the respective funding partners, and funds retained by CalOptima have been invested in addressing unmet needs.

Discussion

Beginning with IGT 8, the IGT program covers the current fiscal year and funds will be incorporated into the contract between DHCS and CalOptima for the current fiscal year. Unlike previous IGTs (1-7), IGT funds must now be used in the current rate year for CalOptima covered

services per DHCS instructions. CalOptima may determine how to spend the IGT funds (net proceeds) as long as they are for CalOptima covered services for Medi-Cal beneficiaries.

On July 31, 2018, CalOptima received notification from DHCS regarding the State Fiscal Year (SFY) 2018-19 Voluntary Rate Range Intergovernmental Transfer Program (IGT 9). CalOptima's proposal, along with the funding entities' supporting documents were due to DHCS on August 31, 2018.

The five eligible funding entities from the previous IGT transactions were contacted regarding their interest in participation. All five funding entities have submitted letters of interest regarding participation in the IGT program this year. These entities are:

1. University of California, Irvine,
2. Children and Families Commission of Orange County,
3. County of Orange,
4. City of Orange, and
5. City of Newport Beach.

Board approval is requested to ratify the submission of the proposal letter to DHCS for participation in the 2018-19 Voluntary IGT Rate Range Program and to authorize the Chief Executive Officer to enter into agreements with the five proposed funding entities or their designated providers for the purpose of securing available IGT funds. Consistent with the eight prior IGT transactions, it is anticipated that the net proceeds will be split evenly between the respective funding entities and CalOptima.

Staff will return to your Board with more information regarding the IGT 9 transaction and an expenditure plan for CalOptima's share of the net proceeds at a later date. .

Fiscal Impact

The recommended action to ratify and authorize activities to secure Medi-Cal funds through IGT 9 will generate one-time IGT revenue that will be invested in Board-approved programs/initiatives. Expenditure of IGT funds is for restricted, one-time purposes and does not commit CalOptima to future budget allocations. As such, there is no net fiscal impact on CalOptima's current or future operating budgets as IGT funds have been accounted for separately.

Rationale for Recommendation

Consistent with the previous eight IGT transactions, ratification of the proposal and authorization of funding agreements will allow the ability to maximize Orange County's available IGT funds for Rate Year 2018-19 (IGT 9).

Concurrence

Gary Crockett, Chief Counsel

Attachment

Department of Health Care Services Voluntary IGT Rate Range Program Notification Letter

/s/ Michael Schrader — **Authorized Signature**

8/29/2018 — **Date**

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State of California—Health and Human Services Agency
Department of Health Care Services

JENNIFER KENT
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

July 31, 2018

Greg Hamblin
Chief Financial Officer
CalOptima
505 City Parkway West
Orange, CA 92868

SUBJECT: State Fiscal Year (SFY) 2018-19 Voluntary Rate Range Program – Request for Medi-Cal Managed Care Plan's (MCP) Proposal

Dear Mr. Hamblin:

The 2018-19 Voluntary Rate Range Program, authorized by Welfare and Institutions (W&I) Code sections 14164, 14301.4, and 14301.5, provides a mechanism for funding the non-federal share of the difference between the lower and upper bounds of a MCP's actuarially sound rate range, as determined by the Department of Health Care Services (DHCS). Governmental funding entities eligible to transfer the non-federal share are defined as counties, cities, special purpose districts, state university teaching hospitals, and other political subdivisions of the state, pursuant to W&I Code section 14164(a). These governmental funding entities may voluntarily transfer funds to DHCS via intergovernmental transfer (IGT). These voluntary IGTs, together with the applicable Federal Financial Participation (FFP), will be used to fund payments by DHCS to MCPs as part of the capitation rates paid for the service period of July 1, 2018 through June 30, 2019 (SFY 2018-19).

DHCS shall not direct the MCP's expenditure of payments received under the 2018-19 Voluntary Rate Range Program. These payments are subject to all applicable requirements set forth in the MCP's contract with DHCS. These payments must also be tied to covered Medi-Cal services provided on behalf of Medi-Cal beneficiaries enrolled within the MCP's rating region.

The funds transferred by an eligible governmental funding entity must qualify for FFP pursuant to Title 42 Code of Federal Regulations (CFR) Part 433, Subpart B, including the requirements that the funding source(s) shall not be derived: from impermissible sources such as recycled Medicaid payments, Federal money excluded from use as state match, impermissible taxes, and non-bona fide provider-related donations. Impermissible sources do not include patient care or other revenue received from programs such as Medicare or Medicaid to the extent that the program revenue is not obligated to the state as the source of funding.

DHCS shall continue to administer all aspects of the IGT related to the 2018-2019 Voluntary Rate Range Program, including determinations related to fees.

PROCESS FOR SFY 2018-19:

MCPs should refer to the estimated SFY 2018-19 county/region-specific non-federal share required to fund available rate range amounts for the MCP (see Attachment C). As a reminder, participation in the 2018-19 Voluntary Rate Range Program is voluntary on the part of the transferring entity and the MCP. If an MCP elect to participate in the 2018-19 Voluntary Rate Range Program, the MCP must adhere to the process for participation outlined below:

Soliciting Interest

The MCP shall contact potential governmental funding entities to determine their interest, ability, and desired level of participation in the 2018-19 Voluntary Rate Range Program. All providers and governmental funding entities who express their interest directly to DHCS will be redirected to the applicable MCP to facilitate negotiations related to participation. If, following the submission of the MCP's proposal, one or more governmental funding entities included in the MCP's proposal are unable or unwilling to participate in the Voluntary Rate Range Program, the MCP shall attempt to find other governmental funding entities able and willing to participate in their place.

The MCP must inform all participating governmental entities that, unless DHCS determines a statutory exemption applies, IGTs submitted in accordance with W&I Code section 14301.4 are subject to an additional 20 percent assessment fee (calculated on the value of their IGT contribution amount) to reimburse DHCS for the administrative costs of operating the Voluntary Rate Range Program and to support the Medi-Cal program. DHCS will determine if a fee waiver is appropriate.

Submission Requirements

Once the MCP has coordinated with the relevant governmental funding entities, the following documents must be submitted to DHCS in accordance with the requirements and procedures set forth below:

- The MCP must submit a **proposal** to DHCS. This proposal must include:

    1. A cover letter signed by the MCP's Chief Executive Officer or Chief Financial Officer on MCP letterhead.

2. The MCP's primary contact information (name, e-mail address, mailing address, and phone number).
3. County/region-specific summaries of the selected governmental funding entities, related providers, and participation levels specified for SFY 2018-19. The combined amounts or percentages must not exceed 100 percent of the estimated non-federal share of the available rate range amounts provided by DHCS. If the MCP is unable to use the entire available rate range, the MCP must indicate the unfunded amount and percentage.
4. All letters of interest (described below) and supporting documents must be attached to the proposal. If the "supplemental attachment" described below is not collected by the MCP and attached to the proposal at the time of submission, please indicate if the information will be submitted to DHCS directly by each governmental funding entity.

- The MCP must obtain a **letter of interest** (using the format provided in Attachment A) from each governmental funding entity included in the MCP's proposal to DHCS. An individual authorized to sign the certification on behalf of the governmental funding entity must sign the letter of interest. Each letter of interest must specify:

  1. The governmental funding entity's name and Federal Tax Identification Number,
  2. The dollar amount or percentage of the total available rate range the governmental funding entity will contribute for each MCP and county/region, and
  3. The governmental funding entity's primary contact information (name, e-mail address, mailing address, phone number).

- The MCP must distribute to governmental funding entities and ensure submission to DHCS of the **SFY 2018-19 Voluntary Rate Range Program Supplemental Attachment** (see Attachment B) by Friday, August 31, 2018.

- The proposals and letters of interest are due to DHCS ***by 5pm on Friday, August 31, 2018***. Please send a PDF copy of the required documents by e-mail to Sandra.Dixon@dhcs.ca.gov. ***Failure to submit all required documents by the due date may result in exclusion from the SFY 2018-19 Voluntary Rate Range Program.***

Each proposal is subject to review and approval by DHCS. The review will include an evaluation of the proposed provider participation levels in comparison to their

uncompensated contracted Medi-Cal costs and/or charges. DHCS reserves the right to approve, amend, or deny the proposal at its discretion.

Upon DHCS' approval of the governmental funding entities and non-federal share amounts for the 2018-19 Voluntary Rate Range Program, DHCS will provide the necessary funding agreement templates, forms, and related due dates to the specified governmental funding entities and MCP contacts. The governmental funding entities will be responsible for completing all necessary funding agreement documents, responding to any inquiries necessary for obtaining approval, and obtaining all required signatures.

If you have any questions regarding this letter, please contact Sandra Dixon at (916) 345-8269 or by email at Sandra.Dixon@dhcs.ca.gov.

Sincerely,

Jennifer Lopez
Division Chief
Capitated Rates Development Division

Attachments

cc: Michael Schrader, Chief Executive Officer
CalOptima
505 City Parkway West
Orange, CA 92868

Sandra Dixon
Financial Management Section
Capitated Rates Development Division
Department of Health Care Services
P.O. Box 997413, MS 4413
Sacramento, CA 95899-7413

ATTACHMENT A – LETTER OF INTEREST TEMPLATE

Jennifer Lopez
Division Chief
Capitated Rates Development Division
Department of Health Care Services
1501 Capitol Avenue, MS 4413
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Ms. Lopez:

This letter confirms the interest of [Insert Participating Funding Entity Name], a governmental entity, federal I.D. Number [Insert Federal Tax I.D. Number], in working with [Managed Care Plan's Name] (hereafter, "the MCP") and the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range Program, including providing an Intergovernmental Transfer (IGT) to DHCS to be used as a portion of the non-federal share of actuarially sound Medi-Cal managed care capitation rate payments incorporated into the contract between the MCP and DHCS for the period of July 1, 2018, to June 30, 2019. This is a non-binding letter, stating our interest in helping to finance health improvements for Medi-Cal beneficiaries receiving services in our jurisdiction. The governmental entity's funds are being provided voluntarily, and the State of California is in no way requiring the governmental entity to provide any funding.

[Insert Participating Funding Entity Name] is willing to contribute up to $_____ for the SFY 2018-19 rating period as negotiated with the MCP. We recognize that, unless a waiver is approved by DHCS, there will be an additional 20-percent assessment fee payable to DHCS on the funding amount, for the administrative costs of operating the voluntary rate range program.

The following individual from our organization will serve as the point of communication between our organization, the MCP and DHCS on this issue:

Entity Contact Information:

(Please provide complete information including name, street address, e-mail address and phone number.)

I certify that I am authorized to sign this certification on behalf of the governmental entity and that the statements in this letter are true and correct.

Sincerely,
Signature

Attachment B

SFY 2018-19 Voluntary Rate Range Program Supplemental Attachment

Provider Name:	
County:	
Health Plan:	

Instructions

Complete all yellow-highlighted fields. **Submit this completed form via e-mail to Sandra Dixon (sandra.dixon@dhcs.ca.gov) at the Department of Health Care Services (DHCS) by Friday, August 31, 2018.**

1. In the table below, report charges/costs and payments received or expected to be received from the Health Plan indicated above for Medi-Cal services (Inpatient, Outpatient, and All Other) provided to Medi-Cal beneficiaries enrolled in the Health Plan and residing in the County indicated above, for dates of service from July 1, 2016 through June 30, 2017.

	Charges	Costs	Payments Rec'd / Expected*	Uncompensated Charges / Uncompensated Costs
Inpatient				
Outpatient				
All Other				
Total	$	$	$	$

* Include payments received and anticipated to be received for service dates of July 1, 2016 through June 30, 2017.

2. Are you able to fund 100% of the higher of the uncompensated charges or uncompensated costs (as stated above)? *(Yes / No)*

   If No, please specify the amount of funding available:

3. Describe the scope of services provided to the specified Health Plan's Medi-Cal members, and if these services were provided under a contract arrangement.

4. For any capitation payments to be funded by the IGT, please provide the following:

   (i) The name of the entity transferring funds:

   (ii) The operational nature of the entity (state, county, city, other):

   (iii) The source of the funds:
   (Funds must not be derived from impermissible sources such as recycled Medicaid payments, federal funds excluded from use as State match, impermissible taxes, and non-bona fide provider-related donations.)

   (iv) Does the transferring entity have general taxing authority? *(Yes / No)*

   (v) Does the transferring entity receive appropriations from a state, county, city, or other local government jurisdiction? *(Yes / No)*

5. Comments / Notes

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ATTACHMENT C

TOTAL AVAILABLE RATE RANGE

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Orange County Organized Health System dba Cal Optima - Orange (HCP 506)
IGT - 2018/19 (July 2018 - June 2019)

	Total	50% FMAP (Non-MCHIP and OE)	88% FMAP (MCHIP)	Optional Expansion (93.5%)
Total Funds Available	$ 138,114,451	$ 68,412,249	$ 7,133,302	$ 62,568,900
Federal Match	$ 98,985,353	$ 34,206,125	$ 6,277,306	$ 58,501,922
Governmental Funding Entity's Portion	$ 39,129,098	$ 34,206,124	$ 855,996	$ 4,066,978
	28.3%	50.0%	12.0%	6.5%

Rate Categories[1]	Member Months (per Mercer est.)	Lower Bound (per Mercer Rate Worksheets)	Upper Bound (per Mercer Rate Worksheets)	Difference between Upper and Lower Bound	Other Dept. Usage[2]	Available PMPM (less Other Dept. Usage)	Estimated Available Total Fund
Child - non MCHIP	2,474,781	$ 84.85	$ 89.93	$ 5.08	$ -	$ 5.08	$ 12,571,887
Child - MCHIP	1,273,587	$ 84.85	$ 89.93	$ 5.08	$ -	$ 5.08	$ 6,469,822
Adult - non MCHIP	1,082,406	$ 299.18	$ 316.64	$ 17.46	$ -	$ 17.46	$ 18,898,809
Adult - MCHIP	38,000	$ 299.18	$ 316.64	$ 17.46	$ -	$ 17.46	$ 663,480
SPD	466,754	$ 755.18	$ 798.48	$ 43.30	$ -	$ 43.30	$ 20,210,448
SPD/Full-Dual	22,704	$ 219.25	$ 229.52	$ 10.27	$ -	$ 10.27	$ 233,170
BCCTP	7,156	$ 1,225.69	$ 1,296.82	$ 71.13	$ -	$ 71.13	$ 509,006
LTC	14,686	$ 10,472.34	$ 10,858.28	$ 385.94	$ -	$ 385.94	$ 5,667,915
LTC/Full-Dual	0	$ 6,036.73	$ 6,235.58	$ 198.85	$ -	$ 198.85	$ -
OBRA	0	$ -	$ -	$ -	$ -	$ -	$ -
Whole Child Model	74,642	$ 1,824.65	$ 1,962.92	$ 138.27	$ -	$ 138.27	$ 10,321,014
Optional Expansion	2,853,119	$ 442.21	$ 471.45	$ 29.24	$ 7.31	$ 21.93	$ 62,568,900
	8,307,835	$ 309.49	$ 328.62	$ 19.14	$ 2.51	$ 16.62	$ 138,114,451

[1]The supplemental payments (Maternity, BHT and HEP C) are not included in the rate range calculation.
[2]Other Departmental Usages decreases available rate range funding.

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CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken June 6, 2019
Regular Meeting of the CalOptima Board of Directors

Report Item

33. Consider Approval of Quality Initiative Related to Post-Acute Infection Prevention and Authorization of Related Funding for Quality Initiative Payments

Contact

David Ramirez, M.D., Chief Medical Officer, (714) 246-8400
Emily Fonda, M.D., MMM, CHCQM, Medical Director, (714) 246-8400
Ladan Khamseh, Chief Operating Officer, (714) 246-8400

Recommended Actions

1. Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
2. Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

Background

The Centers for Disease Control and Prevention (CDC) and the University of California-Irvine (UCI) recently collaborated on an extensive study in 2017 through 2019 to suppress the spread of Multi-Drug-Resistant Organisms (MDRO) in Skilled Nursing Facilities (SNFs) across Orange County. The ambitious study also garnered the support of the California Department of Public Health as well as the Orange County Health Care Agency. This regional collaborative established a structured "…decolonization strategy to reduce the transmission of MDROs both countywide and within healthcare facilities." The name of the collaborative is SHIELD OC.

SHIELD OC is comprised of intervention protocols for both hospitals and nursing homes. There were 16 Orange County SNFs contracted with CalOptima that participated through to the conclusion of the study.

The study was focused on MDRO decolonization through "…the use of topical products to reduce bacteria on the body that can produce harmful infections." In SNFs, the study protocol involved the implementation of two interventions: (1) the consistent use of Chlorhexidine (CHG) antiseptic soap for routine bathing and showering of residents, and (2) the scheduled use of povidone-iodine nasal swabs on residents.

The preliminary study outcomes were very promising and gained the close attention of CDC senior leadership, who have reached out to CalOptima regarding the project on more than one occasion. Long term care (LTC) residents in facilities following the study protocol showed markedly lower rates of MDRO colonization, which translated into lower rates of hospital admissions and lower utilization costs for CalOptima members. The implications of the study, as well as the innovative regional collaboration model, have also garnered the interest of the press. News regarding the collaborative recently aired on National Public Radio and appeared in *USA Today* articles. The lead author in the study, Dr. Susan Huang, was also recently interviewed in a local news radio segment on KNX 1070.

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The study concluded on May 2, 2019. At the SHIELD OC Wrap Up Event, concerns were expressed by facility participants as well as the CDC that the end of the project funding would prevent the SNFs in the study from continuing the study protocol efforts. Without continuation of the interventions, the momentum of the efforts by the participating SNFs would be interrupted, and the considerable gains made in regional decolonization could potentially be unraveled. While the responsibility of infection prevention in post-acute settings is not solely the responsibility of CalOptima, the extensive project has provided significant safety and health benefits to CalOptima members who reside in these facilities. After the conclusion of the study, the collaborative will face an absence of funding and direction. This presents an opportunity for CalOptima to take a leadership role in supporting the care delivery system by offering value-based quality incentives to facilities that follow evidence-based patient safety practices in the institutionalized population segment which are congruent with CalOptima's mission as well as the National Quality Assurance Committee (NCQA) Population Health Management Standards of Delivery System Support.

Discussion

As proposed, the Post-Acute Infection Prevention Quality Initiative will provide an avenue through which CalOptima can incentivize SNFs to provide the study protocol interventions. The study protocols have been recognized to meaningfully suppress the spread of MDROs and will support the safety and health of CalOptima members receiving skilled interventions at or residing in SNFs. Implementation of the quality initiative is in line with CalOptima's commitment to continuous quality improvement.

The initiative would be comprised of two separate phases. Summarily, in Phase I, CalOptima-contracted SNFs in Orange County could initiate a commitment to implementing the study protocol and CalOptima would respond by providing funding to the facility for setup and protocol training. For each participating SNF, Phase I would last for two quarters. In Phase II of the quality initiative, after the SNF has been trained and can demonstrate successful adoption of the protocol, each SNF would be required to demonstrate consistent adherence to the study protocol as well as meet defined quality measures in order to be eligible to continue receiving the quality initiative payments on a retrospective quarterly basis.

Phase I

CalOptima to provide quality initiative funding to SNFs demonstrating a commitment to implementing the SHIELD OC study protocol. The quality initiative is intended to support start up and training for implementation of the protocols not currently in standard use in SNFs but, as per the SHIELD OC study, have been demonstrated to effectively suppress the spread of MDROs.

Contracted SNFs in Orange County must complete an Intent to Implement MDRO Suppression form, signed by both its Administrator and Director of Nursing.

CalOptima will then initiate payment for the first quarter of setting up and training. Payment will be based on an average expected usage cost per resident, to be determined by CalOptima for application across all participating facilities, so the amount of payment for each facility will be dependent on its size. These payments are intended to incentivize the facilities to meet the protocol requirements. The facility must demonstrate use of the supplies and the appropriate

application of the study protocol to the assigned CalOptima staff to qualify for the second quarterly Phase I payment.

The following supplies are required of the facility:

- 4% Chlorohexidine Soap
- 10% Iodine Swab Sticks

The following activities will be required of the facility:

- Proof of appropriate product usage.
- Acceptance of training and monitoring of infection prevention protocol by CalOptima and/or CDC/UCI staff.
- Evidence the decolonization program handouts are in admission packets.
- Monitoring and documentation of compliance with CHG bathing.
- Monitoring and documentation of compliance with iodophor nasal swab.
- Documentation of three peer-to-peer bathing skills assessments per month.

Phase II

CalOptima will provide retrospective quality initiative payments on a quarterly basis for facilities that completed Phase I and meet Phase II criteria outlined below. The amount of each Phase II facility payment will reflect the methodology used in Phase I, accounting for facility size at the average expected usage cost. These payments are intended to support facilities in sustaining the quality practices they adopted during Phase I to suppress MDRO infections.

To qualify for Phase II quality initiative payments, the participating facility must continue demonstrating adherence to the study protocol through the requirements as outlined above for Phase I.

In addition, the facility must also meet minimum quality measures representative of effective decolonization and infection prevention efforts, to be further defined with the guidance of the UCI and CDC project leads. The facilities in Phase II of the initiative must meet these measures each quarter to be eligible for retrospective payment.

The 16 SNFs that participated in SHIELD OC would be eligible for Phase II of the quality initiative at implementation of this quality initiative since they have already been trained in the project and demonstrated adherence to the study protocol. Other contracted SNFs in Orange County not previously in SHILED OC and beginning participation in the quality initiative would be eligible for Phase I.

The proposed implementation of the quality initiative is Q3 2019.

Fiscal Impact

The recommended action to implement a Post-Acute Infection Prevention Quality Initiative program and make payments to qualifying SMFs, beginning in FY 2019-20 to CalOptima-contracted SNFs in Orange County is projected to cost up to and not to exceed $2.3 million annually. Management plans to include projected expenses associated with the quality initiative in the upcoming CalOptima FY 2019-20 Operating Budget.

Rationale for Recommendation

The quality initiative presents an avenue for CalOptima to actively support an innovative regional collaborative of high visibility that has been widely recognized to support the safety and health of individuals receiving care in SNFs.

Concurrence

Gary Crockett, Chief Counsel

Attachment

1. PowerPoint Presentation
2. SHIELD OC Flyer
3. Letter of Support

/s/ Michael Schrader *5/29/2019*
Authorized Signature **Date**

Post-Acute Infection Prevention Quality Initiative

Regular Meeting of the Board of Directors

June 6, 2019

Dr. Emily Fonda, MD, MMM, CHCQM

Medical Director

Care Management, Long-Term Services and Supports and Senior Programs

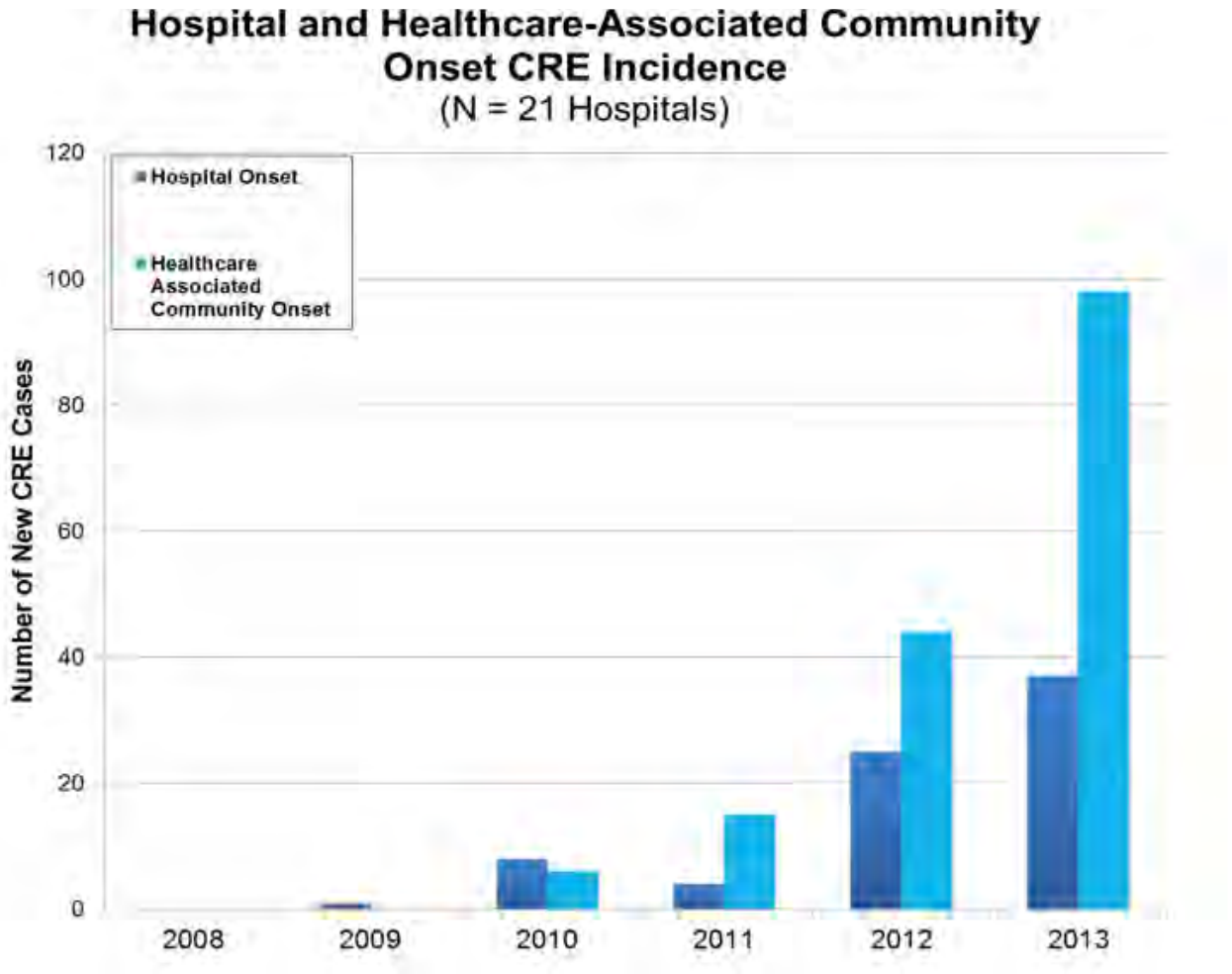
Background

- Efforts to lower hospitalization rates from long-term care (LTC) placed us in contact with Dr. Huang and her study
  - Through the Long-Term Services and Supports (LTSS) Quality Improvement Subcommittee
- Susan Huang, MD, MPH, Professor, Division of Infectious Diseases at U.C. Irvine — lead investigator for Project SHIELD Orange County (OC)
  - 36 facility decolonization intervention protocol supported by the Center for Disease Control and Prevention (CDC)
  - 16 of those facilities are CalOptima-contracted skilled nursing facilities
- Early results at wrap-up event on 1/30/19 ➔ overall 25 percent lower colonization rate of multidrug resistant organisms in OC skilled nursing facilities

Background

- Rise of Multi-Drug Resistant Organisms (MDROs)
  - Methicillin Resistant *Staphylococcus aureus* (MRSA)
  - Vancomycin Resistant Enterococcus (VRE)
  - Multi-Drug Resistant Pseudomonas
  - Multi-Drug Resistant Acinetobacter
  - Extended Spectrum Beta Lactamase Producers (ESBLs)
  - Carbapenem Resistant Enterobacteriaceae (CRE)
  - Hypervirulent KPC (NDM)
  - *Candida auris*
- **10–15%of hospital patients harbor at least one of the above**
- **65% of nursing home residents harbor at least one of the above**

CRE Trends in Orange County, CA



Gohil S. AJIC 2017; 45:1177-82

CDC Interest

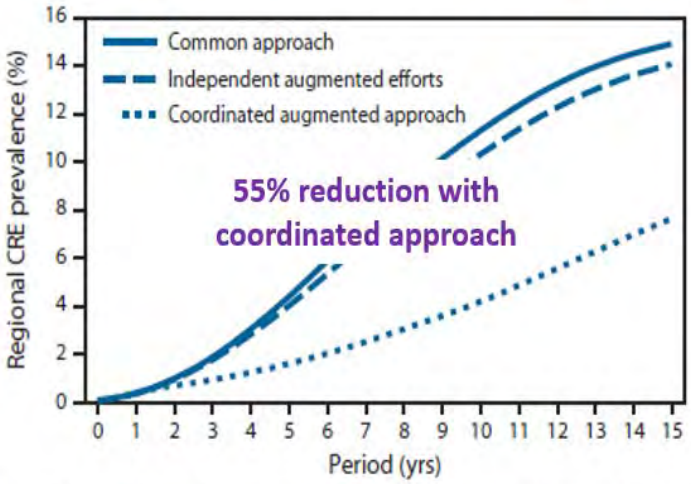
Orange County has historically had one of the highest carbapenem-resistant enterobacteriaceae (CRE) rates in California according to the OC Health Care Agency

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 64
August 4, 2015

Vital Signs: Estimated Effects of a Coordinated Approach for Action to Reduce Antibiotic-Resistant Infections in Health Care Facilities — United States

Rachel B. Slayton, PhD[1]; Damon Toth, PhD[2]; Bruce Y. Lee, MD[3]; Windy Tanner, PhD[2]; Sarah M. Bartsch, MPH[3]; Karim Khader, PhD[2]; Kim Wong, PhD[4]; Kevin Brown, PhD[2]; James A. McKinnell, MD[5]; William Ray[2]; Loren G. Miller, MD[6]; Michael Rubin, MD, PhD[2]; Diane S. Kim[7]; Fred Adler, PhD[8]; Chenghua Cao, MPH[7]; Lacey Avery, MA[1]; Nathan T.B. Stone, PhD[8]; Alexander Kallen, MD[1]; Matthew Samore, MD[2]; Susan S. Huang, MD[7]; Scott Fridkin, MD[1]; John A. Jernigan, MD[1]

FIGURE 3. Projected countywide prevalence of carbapenem-resistant *Enterobacteriaceae* (CRE) over a 15-year period under three different intervention scenarios — 102-facility model, Orange County, California*

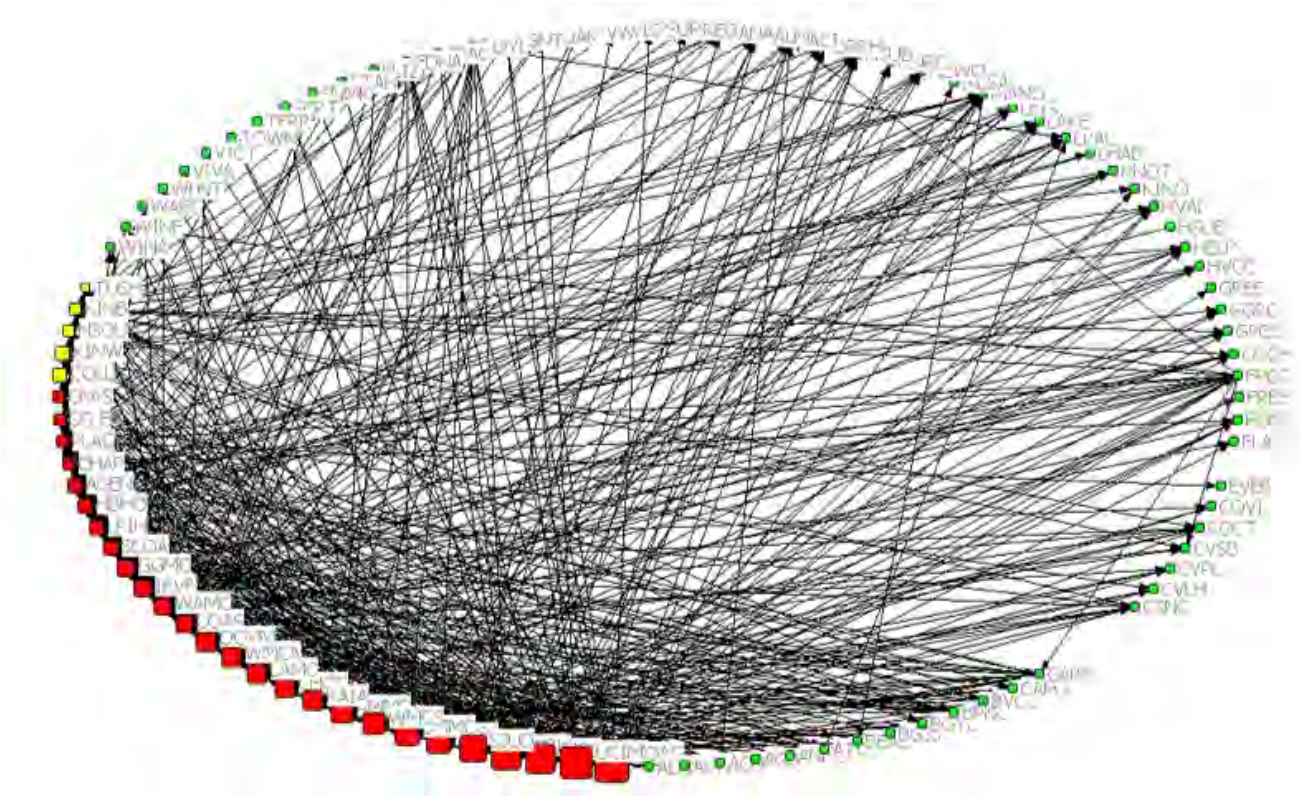


* Additional information available at http://www.cdc.gov/drugresistance/resources/publications.html.

Extent of the Problem

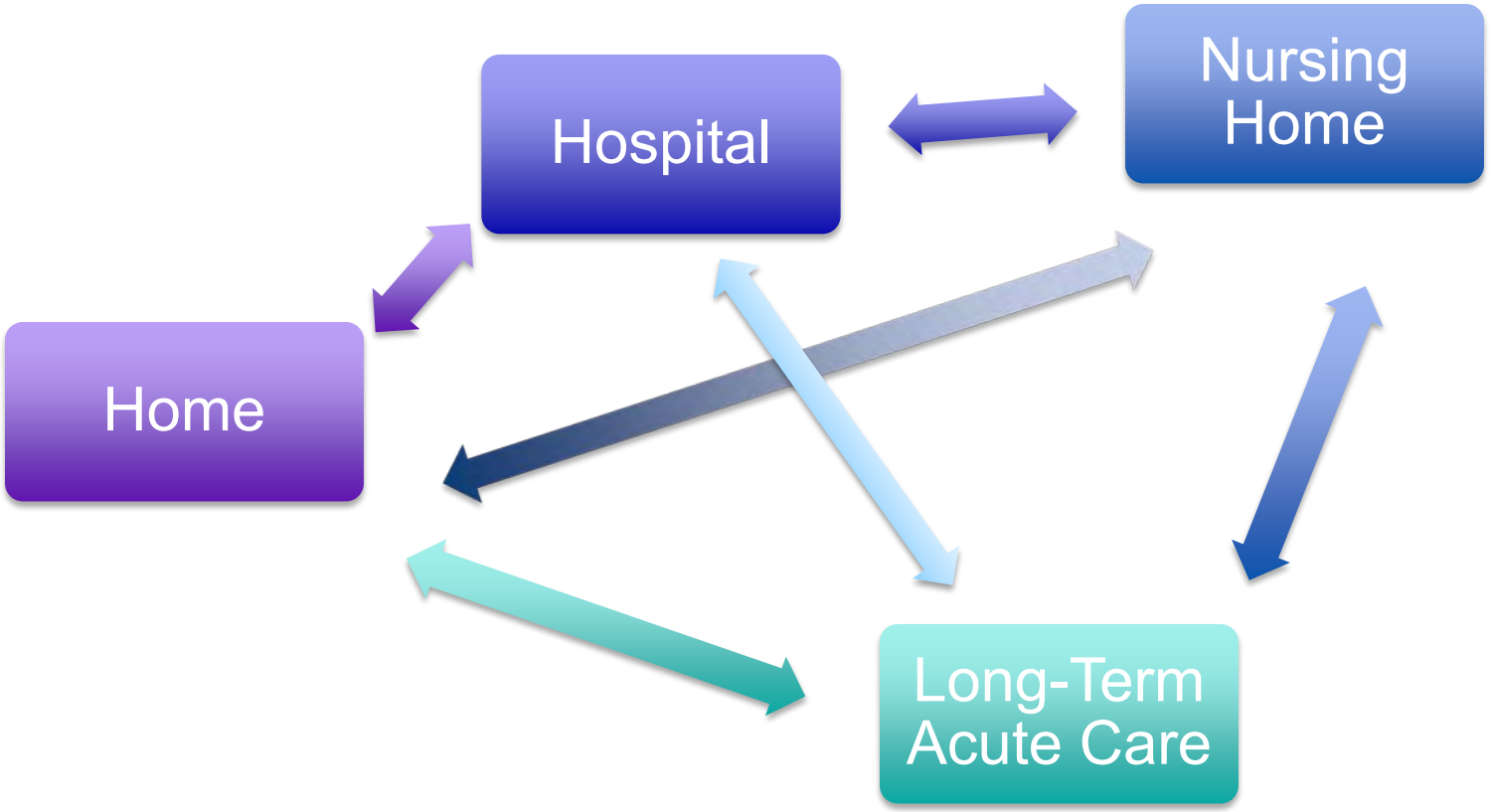
OC Hospitals and Nursing Homes

10 patients shared



Lee BY et al. Plos ONE. 2011;6(12):e29342

Extent of the Problem



Baseline MDRO Prevalence — 16 Nursing Homes

	N	Any MDRO	MRSA	VRE	ESBL	CRE
Nares	900	28%	28%	-	-	-
Axilla/Groin	900	47%	30%	10%	22%	1%
Peri-Rectal	900	52%	25%	15%	31%	1%
All Body Sites	**900**	**64%**	**42%**	**16%**	**34%**	**2%**

- 64% MDRO carriers, facility range 44–88%
- Among MDRO pathogens detected, only 14% known to facility
- Among all residents, 59% harbored ≥1 MDRO unknown to facility

Participating Health Care Facilities

16 Nursing Homes Contracted with CalOptima

- Alamitos West Health Care Center
- Anaheim Healthcare Center
- Beachside Nursing Center
- Crystal Cove Care Center
- French Park Care Center
- Garden Park Care Center
- Healthcare Center of Orange County
- Laguna Hills Health and Rehab Center
- Lake Forest Nursing Center
- Mesa Verde Post Acute Care Center
- New Orange Hills
- Orange Healthcare & Wellness Centre
- Regents Point – Windcrest
- Seal Beach Health and Rehab Center
- Town and Country Manor
- Victoria Healthcare and Rehab Center

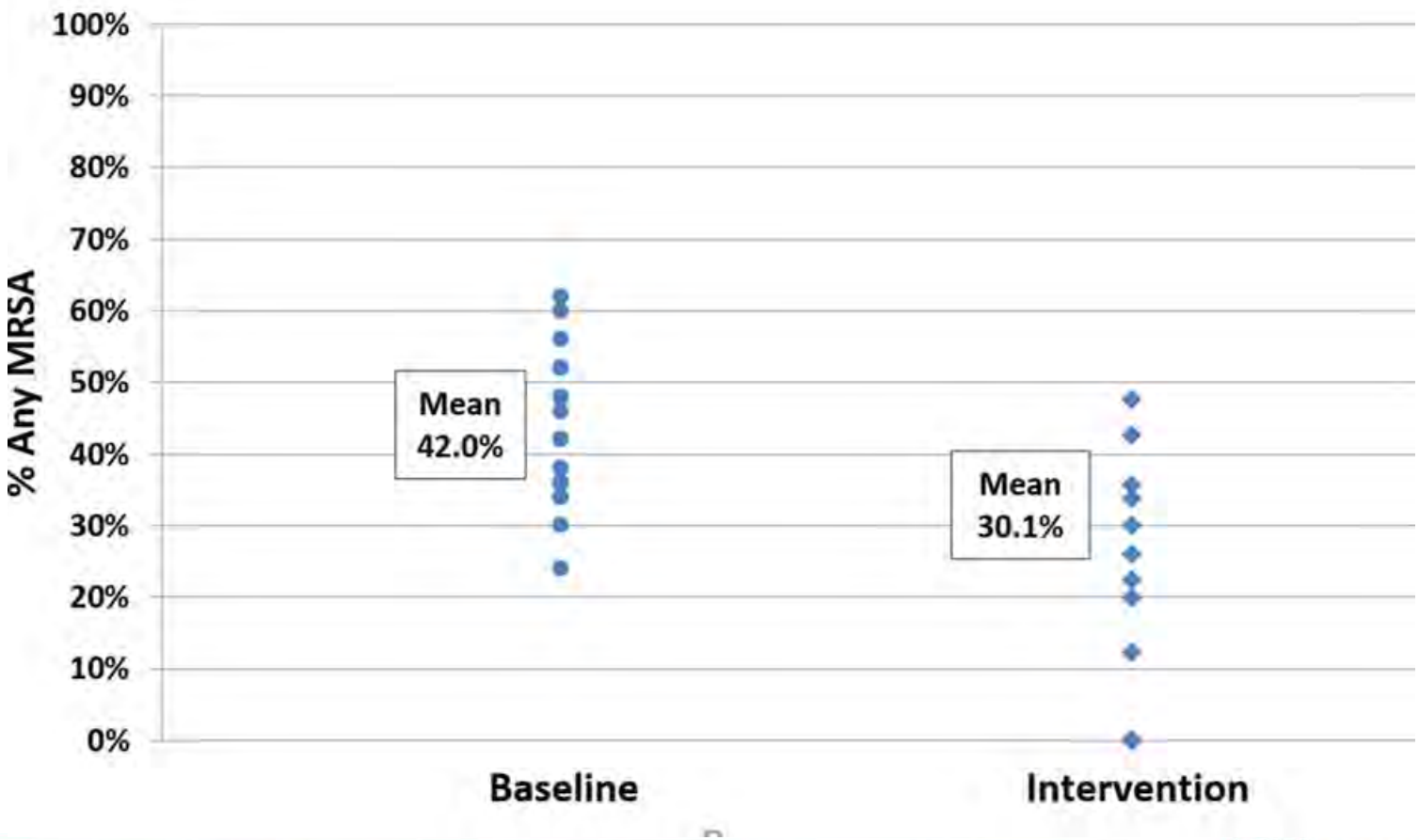
SHIELD OC Decolonization Protocol

- Nursing Homes: Decolonize All Patients
  - Replaced regular soap with chlorhexidine (CHG) antiseptic soap
  - CHG on admit and for all routine bathing/showering
  - Nasal iodophor on admit and every other week
    - https://www.cdc.gov/hai/research/cdc-mdro-project.html
- Following initial testing and training
  - Intervention timeline (22 months) July 1, 2017–May 2, 2019
- Outcome: MDRO Prevalence
  - MRSA, VRE, ESBL, CRE and any MDRO
  - By body site
    - Nasal product reduces MRSA
    - CHG bathing reduces skin carriage

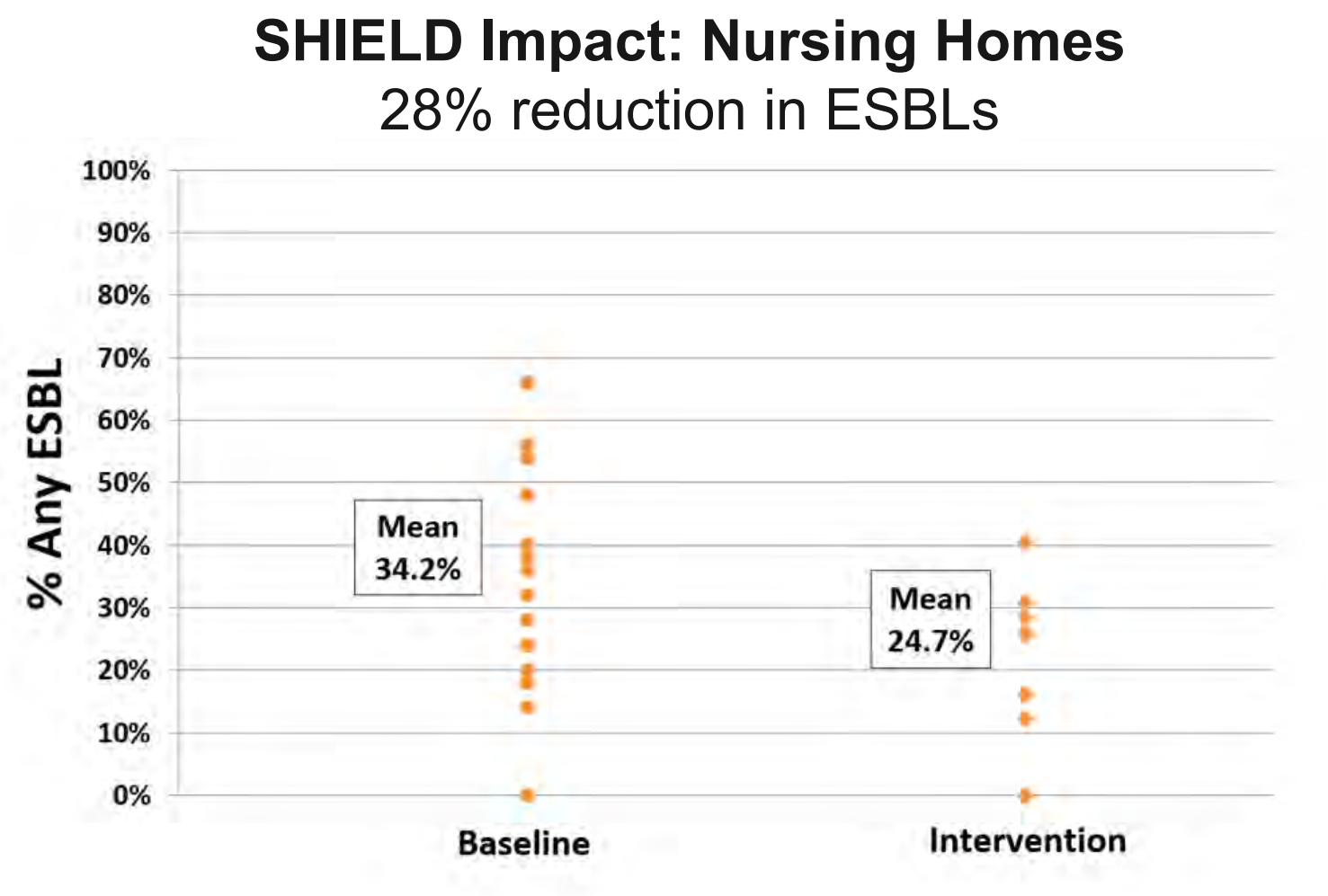
SHIELD Outcomes

SHIELD Impact: Nursing Homes

28% reduction in MRSA



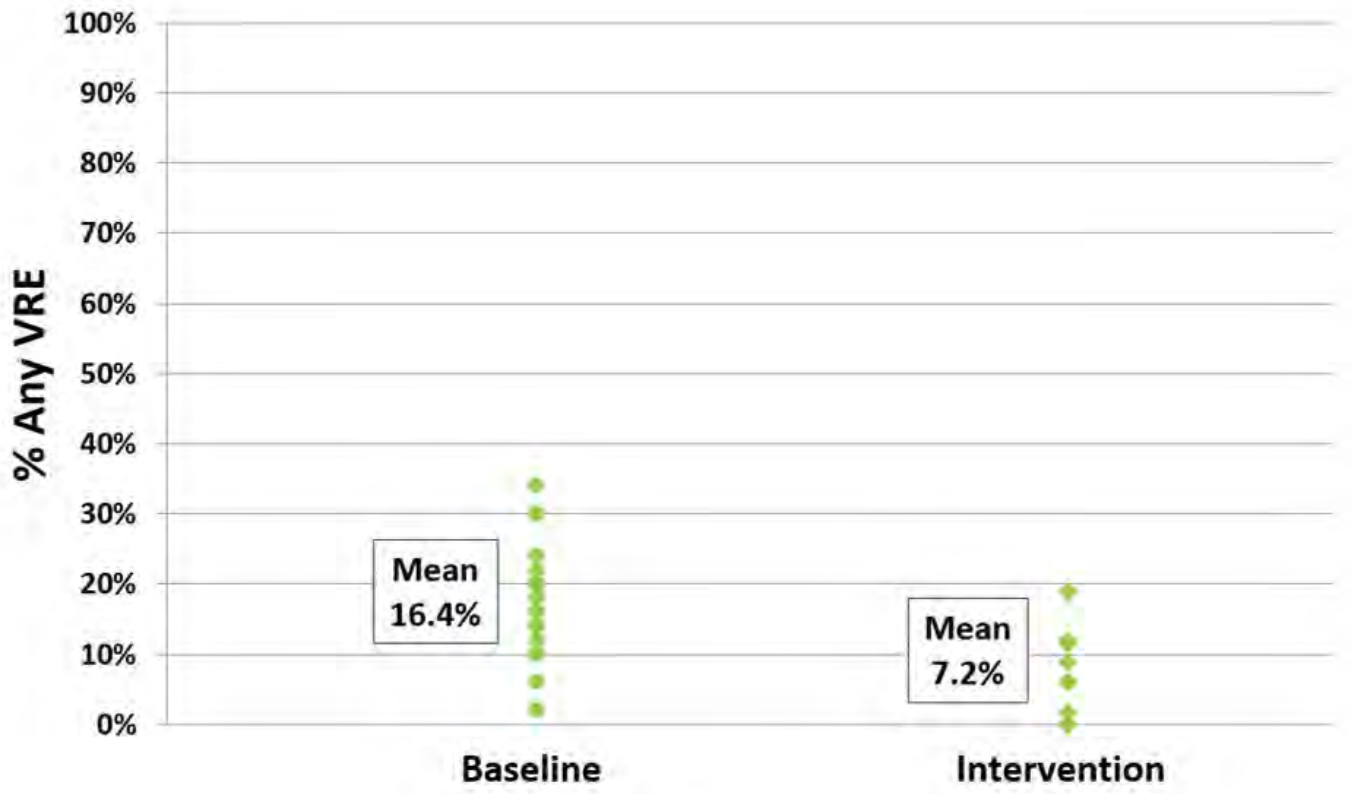
SHIELD Outcomes (cont)



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

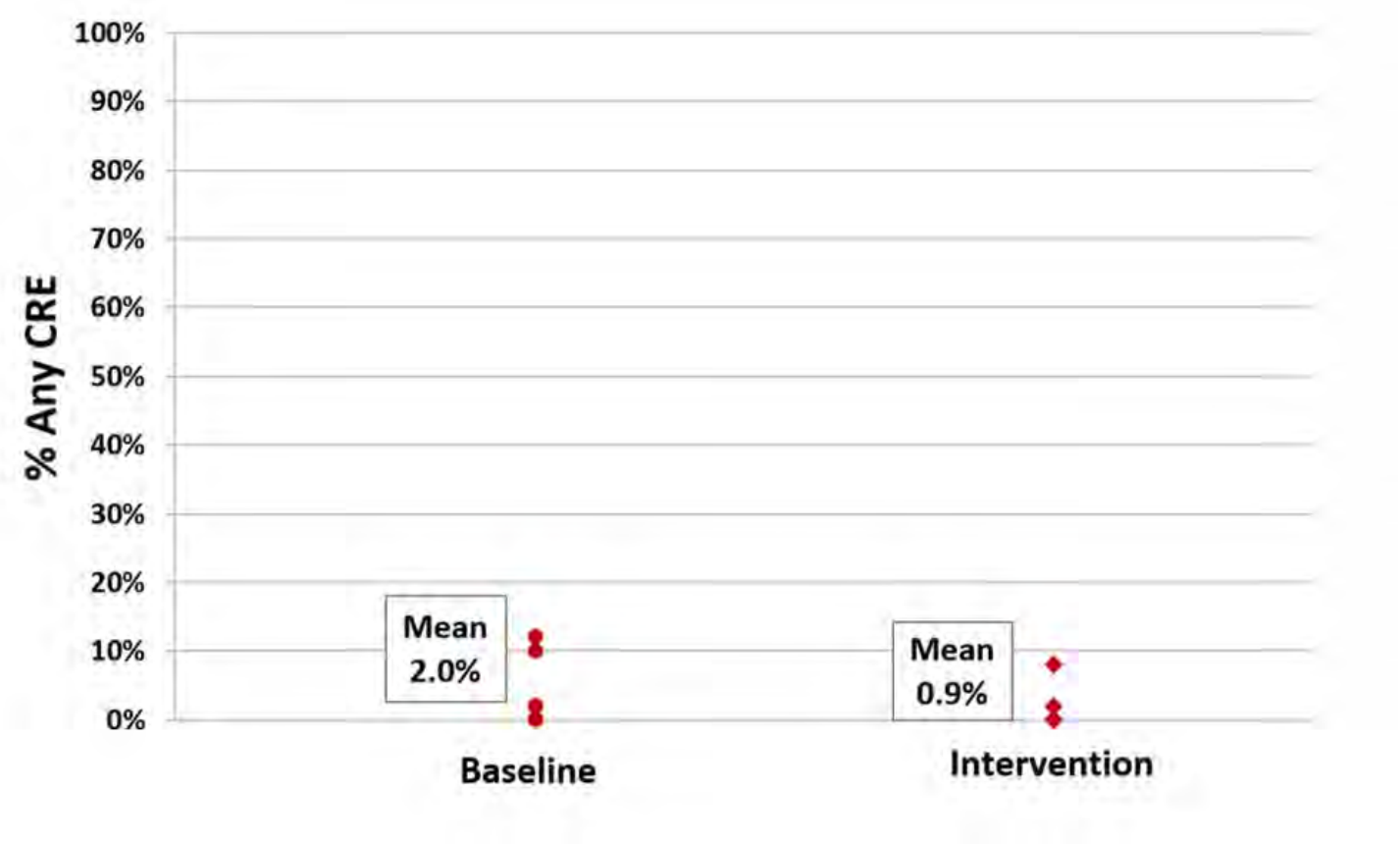
56% reduction in VRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

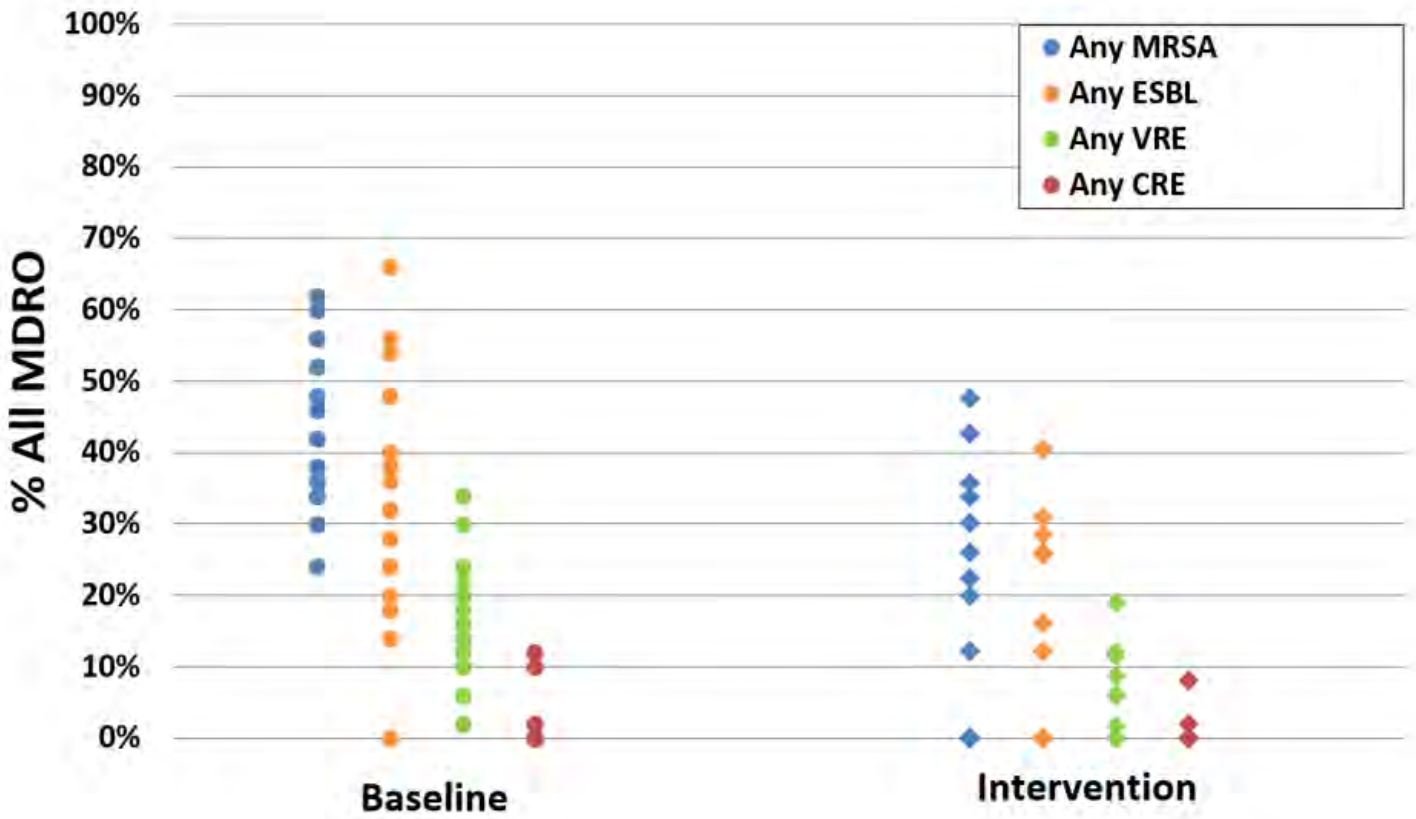
55% reduction in CRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

25% reduction in all MDROs



Quarterly Inpatient Trends

SHIELD OC Project: Quarterly Inpatient Trends

LTC Facility County: ORANGE

From: 2015-10 To: 2018-12

Category P - Primary Diagnosis

Select Year-Month Begin	Select Year-Month End	Select Category P Diagnosis Level	Select Risk Group *	Select LTC Facility County
2015-10	2018-12	Category P - Primary Diagnosis	Multiple values	ORANGE

		Before SHIELD OC						During SHIELD OC						
		2015 Q4	2016 Q1	2016 Q2	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2	2018 Q3	2018 Q4
CONTROL	Admission Count	47	61	60	51	56	65	60	49	36	46	59	48	47
	Bed Day Ct	336	383	536	383	561	570	390	376	296	377	401	456	398
	Paid Amt	$682,769	$854,676	$1,159,922	$920,317	$1,691,337	$1,231,903	$997,810	$1,236,197	$634,628	$979,762	$1,113,238	$1,176,910	$1,024,854
	Avg Mbrs	3,064	2,964	2,901	2,945	2,994	3,033	3,035	3,074	3,116	3,105	3,088	3,102	3,085
SHIELD OC	Admission Count	10	10	9	11	12	9	8	5	3	4	7	3	1
	Bed Day Ct	54	84	66	90	98	60	59	49	12	30	46	11	2
	Paid Amt	$133,362	$311,661	$124,676	$189,669	$227,224	$209,419	$175,738	$164,181	$40,354	$84,565	$127,609	$41,123	$10,177
	Avg Mbrs	590	564	564	580	576	567	581	606	625	632	641	663	652

* Risk Groups Selected: CCN - MC CCN OCC COD Admin OneCare Shared Risk - MC Shared Risk - OCC

Average member count includes all Risk Groups

Admission counts and costs significantly lower in the SHIELD OC group

Quarterly Inpatient Trends

- 16 contracted facilities utilizing the CHG program:
  - Inpatient costs for infection for 6 quarters prior to the Chlorhexidine protocol = $1,196,011
  - Inpatient costs for the last 6 quarters following training and use of CHG protocol = $468,009
    - $728,002 lowered inpatient expenditure (61%) for infection in the participating facilities

- 51 contracted facilities not utilizing the CHG program:
  - Inpatient costs for the last 6 quarters =$6,165,589
  - Potential 61% lowered inpatient expenditure for infection = $3,761,009 if the CHG protocol had been expanded

SHIELD Impact on CalOptima

- Adoption of the SHIELD protocol is well-supported by the Center for Disease Control
  - Plan for extended use of an existing trainer in OC for one year
  - Plan for extended monitoring of Orange County MDROs for one year
- 25% decrease in MDRO prevalence translates to the following for CalOptima's LTC population of 3,800 members as of December 2018:
  - Decreased infection-related hospitalizations
  - An opportunity for a significant advancement in population health management
  - Practice transformation for skilled nursing facilities in fulfillment of National Committee for Quality Assurance (NCQA) requirements
  - Continuation of cost savings

CalOptima Post-Acute Infection Prevention Quality Initiative

- Adoption of the SHIELD protocol in all 67 CalOptima post-acute contracted facilities (long-term care and subacute facilities) will:
  - Support the continuation of care in the 16 participating facilities as Phase 2 without loss of momentum
  - Initiate the chlorhexidine bathing protocol in the remaining facilities as Phase 1 utilizing the CDC-supported trainer
  - Require quarterly reporting and fulfillment of quality measures with payments proportional to compliance
  - Include a trainer provided by the CDC for one year
  - Train current CalOptima LTSS nurses to quantify best practices and oversee compliance
  - Provide consideration around adding this patient safety initiative as a Pay 4 Value (P4V) opportunity to the next quality plan

Recommended Actions

- Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
- Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner


A Public Agency
CalOptima
Better. Together.


Medi-Cal
A Public Agency
CalOptima
Better. Together.


OneCare (HMO SNP)
A Public Agency
CalOptima
Better. Together.


OneCare Connect
A Public Agency
CalOptima
Better. Together.


PACE
A Public Agency
CalOptima
Better. Together.

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs in
Orange County

SHIELD Orange County – *Together We Can Make a Difference!*

What is SHIELD Orange County?

SHIELD OC is a public health collaborative initiated by the Centers for Disease Control and Prevention (CDC) to combat the spread of endemic and emerging multi-drug resistant organisms (MDROs) across healthcare facilities in Orange County. This effort is supported by the California Department of Public Health (CDPH) and the Orange County Health Care Agency (OCHCA). This regional collaborative will implement a decolonization strategy to reduce transmission of MDROs both countywide and within healthcare facilities.

Visit our CDC webpage here!
https://www.cdc.gov/hai/research/cdc-mdro-project.html

SHIELD OC Goals:

- Reduce MDRO carriage
- Reduce countywide MDRO clinical cultures
- Assess impact in participants and non-participants

SHIELD OC is coordinated by the University of California Irvine and LA BioMed at Harbor-UCLA.

Who is participating?

38 healthcare facilities are participating in SHIELD OC. These facilities were invited to participate based on their inter-connectedness by patient sharing statistics. In total, participants include 17 hospitals, 3 long-term acute care hospitals (LTACHs), and 18 nursing homes.

What is the decolonization intervention?

In the SHIELD OC collaborative, decolonization refers to the use of topical products to reduce bacteria on the body that can produce harmful infections.

- **Hospitals (for adult patients on contact precautions)**
  - Chlorhexidine (CHG) antiseptic soap for daily bathing or showering
  - Nasal decolonization with 10% povidone-iodine
  - Continue CHG bathing for adult patients in ICU units
- **Nursing homes and LTACHs**
  - Chlorhexidine (CHG) antiseptic soap for routine bathing and showering
  - Nasal decolonization with 10% povidone-iodine on admission and every other week

All treatments used for decolonization are topical and their safety profile is excellent.

With questions, please contact the SHIELD OC Coordinating Team

(949) 824-7806 or SHIELDOrangeCounty@gmail.com

CalOptima Checklist

Nursing Home Name: _____

Month Audited (Month/year): _____/_____

Today's Date: _____/_____/_____

Completed by: _____

- ☐ Proof of product purchase
- ☐ Evidence the decolonization program handout is in admission packet
- ☐ Monitor and document compliance with bathing one day each week
- ☐ Monitor and document compliance with iodophor one day each week iodophor is used
- ☐ Conduct three peer-to-peer bathing skills assessments per month

Product Usage

PRODUCT DESCRIPTION	RECEIPT PROVIDED	QUANTITY DELIVERED	ESTIMATED MONTHLY USAGE
4% CHG Gallons	☐	_____ gallons	_____ gallons
10% Iodine Swabsticks	☐	_____ boxes	_____ boxes
		_____ swabs per box	

INTERNAL USE ONLY –APPROVAL:

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Facility Name: _____Unit: _____ Date: _____

STAFF Skills Assessment:
CHG Bed Bath Observation Checklist

Individual Giving CHG Bath

Please indicate who performed the CHG bath.

☐ **Nursing Assistant (CNA)** ☐ **Nurse** ☐ **LVN** ☐ **Other: _____**

Observed CHG Bathing Practices

Please check the appropriate response for each observation.

☐ **Y** ☐ **N** **Resident received CHG bathing handout**
☐ **Y** ☐ **N** **Resident told that no rinse bath provides protection from germs**
☐ **Y** ☐ **N** **Provided rationale to the resident for not using soap at any time while in unit**
☐ **Y** ☐ **N** **Massaged skin *firmly* with CHG cloth to ensure adequate cleansing**
☐ **Y** ☐ **N** **Cleaned face and neck well**
☐ **Y** ☐ **N** **Cleaned between fingers and toes**
☐ **Y** ☐ **N** **Cleaned between all folds**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned occlusive and semi-permeable dressings with CHG cloth**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned 6 inches of all tubes, central lines, and drains closest to body**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on superficial wounds, rash, and stage 1 & 2 decubitus ulcers**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on surgical wounds (unless primary dressing or packed)**
☐ **Y** ☐ **N** **Allowed CHG to air-dry / does not wipe off CHG**
☐ **Y** ☐ **N** **Disposed of used cloths in trash /does not flush**

Query to Bathing Assistant/Nurse

1. How many cloths were used for the bath?

_____

2. If more than 6 cloths was used, provide reason.

_____

3. Are you comfortable applying CHG to superficial wounds, including surgical wounds?

_____

4. Are you comfortable applying CHG to lines, tubes, drains and non-gauze dressings?

_____

5. Do you ever wipe off the CHG after bathing?

_____

ORIGINAL ARTICLE

Decolonization to Reduce Postdischarge Infection Risk among MRSA Carriers

S.S. Huang, R. Singh, J.A. McKinnell, S. Park, A. Gombosev, S.J. Eells, D.L. Gillen, D. Kim, S. Rashid, R. Macias-Gil, M.A. Bolaris, T. Tjoa, C. Cao, S.S. Hong, J. Lequieu, E. Cui, J. Chang, J. He, K. Evans, E. Peterson, G. Simpson, P. Robinson, C. Choi, C.C. Bailey, Jr., J.D. Leo, A. Amin, D. Goldmann, J.A. Jernigan, R. Platt, E. Septimus, R.A. Weinstein, M.K. Hayden, and L.G. Miller, for the Project CLEAR Trial

ABSTRACT

BACKGROUND

Hospitalized patients who are colonized with methicillin-resistant *Staphylococcus aureus* (MRSA) are at high risk for infection after discharge.

METHODS

We conducted a multicenter, randomized, controlled trial of postdischarge hygiene education, as compared with education plus decolonization, in patients colonized with MRSA (carriers). Decolonization involved chlorhexidine mouthwash, baths or showers with chlorhexidine, and nasal mupirocin for 5 days twice per month for 6 months. Participants were followed for 1 year. The primary outcome was MRSA infection as defined according to Centers for Disease Control and Prevention (CDC) criteria. Secondary outcomes included MRSA infection determined on the basis of clinical judgment, infection from any cause, and infection-related hospitalization. All analyses were performed with the use of proportional-hazards models in the per-protocol population (all participants who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization) and as-treated population (participants stratified according to adherence).

RESULTS

In the per-protocol population, MRSA infection occurred in 98 of 1063 participants (9.2%) in the education group and in 67 of 1058 (6.3%) in the decolonization group; 84.8% of the MRSA infections led to hospitalization. Infection from any cause occurred in 23.7% of the participants in the education group and 19.6% of those in the decolonization group; 85.8% of the infections led to hospitalization. The hazard of MRSA infection was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03; number needed to treat to prevent one infection, 30; 95% CI, 18 to 230); this lower hazard led to a lower risk of hospitalization due to MRSA infection (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The decolonization group had lower likelihoods of clinically judged infection from any cause (hazard ratio, 0.83; 95% CI, 0.70 to 0.99) and infection-related hospitalization (hazard ratio, 0.76; 95% CI, 0.62 to 0.93); treatment effects for secondary outcomes should be interpreted with caution owing to a lack of prespecified adjustment for multiple comparisons. In as-treated analyses, participants in the decolonization group who adhered fully to the regimen had 44% fewer MRSA infections than the education group (hazard ratio, 0.56; 95% CI, 0.36 to 0.86) and had 40% fewer infections from any cause (hazard ratio, 0.60; 95% CI, 0.46 to 0.78). Side effects (all mild) occurred in 4.2% of the participants.

CONCLUSIONS

Postdischarge MRSA decolonization with chlorhexidine and mupirocin led to a 30% lower risk of MRSA infection than education alone. (Funded by the AHRQ Healthcare-Associated Infections Program and others; ClinicalTrials.gov number, NCT01209234.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Huang at the University of California Irvine School of Medicine, Division of Infectious Diseases, 100 Theory, Suite 120, Irvine, CA 92617, or at sshuang@uci.edu.

N Engl J Med 2019;380:638-50.
DOI: 10.1056/NEJMoa1716771

Methicillin-resistant *Staphylococcus aureus* (MRSA) causes more than 80,000 invasive infections in the United States annually.[1] It is the most common cause of skin, soft-tissue, and procedure-related infections.[2] Rates of invasive MRSA infection are highest within 6 months after hospital discharge and do not normalize for 1 year.[1,3,4]

Approaches to MRSA have included education about both hygiene and environmental cleaning as well as decolonization with nasal mupirocin and chlorhexidine antiseptic baths to reduce carriage and prevent infection.[5,6] Decolonization has reduced the risks of surgical-site infection, recurrent skin infection, and infection in the intensive care unit (ICU).[7-10] Our goal was to evaluate whether, after hospital discharge, decolonization plus hygiene education was superior to education alone in reducing the likelihood of MRSA infection among patients colonized with MRSA (carriers).

Methods

Trial Design and Intervention

We conducted the Project CLEAR (Changing Lives by Eradicating Antibiotic Resistance) Trial as a multicenter, two-group, unblinded, randomized, controlled trial to compare the effect of hygiene education with that of education plus decolonization on the likelihood of postdischarge infection among MRSA carriers. This trial was approved by the institutional review board of the University of California Irvine. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol, available with the full text of this article at NEJM.org.

Participants were randomly assigned, in a 1:1 ratio, to the education group or the decolonization group. Randomization was performed with a randomized block design stratified according to Hispanic ethnic group and nursing home residence. In the education group, participants received and reviewed an educational binder (provided in English and Spanish) about MRSA and how it is spread and about recommendations for personal hygiene, laundry, and household cleaning (Appendix A in the Supplementary Appendix, available at NEJM.org). In the decolonization group, participants received and reviewed the identical educational binder and also underwent decolonization for 5 days twice monthly for a period of 6 months after hospital discharge (Appendix B in the Supplementary Appendix). The decolonization intervention involved the use of 4% rinse-off chlorhexidine for daily bathing or showering, 0.12% chlorhexidine mouthwash twice daily, and 2% nasal mupirocin twice daily. All products were purchased with grant funds and were provided free of charge to the participants.

Recruitment and Eligibility Criteria

Recruitment involved written informed consent provided between January 10, 2011, and January 2, 2014, during inpatient admissions in 17 hospitals and 7 nursing homes in Southern California (Table S1 in the Supplementary Appendix). Eligibility requirements included an age of 18 years or older, hospitalization within the previous 30 days, positive testing for MRSA during the enrollment hospitalization or within the 30 days before or afterward, and the ability to bathe or shower (alone or assisted by a caregiver). Key exclusion criteria were hospice care and allergy to the decolonization products at recruitment. California mandates MRSA screening at hospital admission in high-risk patients: those undergoing hemodialysis, those who had a recent hospitalization (within the preceding 30 days), those who were undergoing imminent surgery, those who were admitted to the ICU, and those who were transferred from a nursing home.

Follow-up

Participants were followed for 12 months after discharge. In-person visits at home or in a research clinic occurred at recruitment and at months 1, 3, 6, and 9. An exit interview was conducted at 12 months. The trial had a fixed end date of June 30, 2014. Participants who were enrolled after July 1, 2013, had a truncated follow-up and had their data administratively censored at that time. Loss to follow-up was defined as the inability of trial staff to contact participants for 3 months, at which point the participant was removed from the trial as of the date of last contact. Participants received escalating compensation for completing follow-up visits ($25, $30, $35, and $50).

All participants were contacted monthly and requested to report any hospitalizations or clinic visits for infection. After trial closure, medical records from reported visits were requested, double-redacted for protected health information and trial-group assignment, and reviewed for trial outcomes. Records from enrollment hospi-

talizations were requested and reviewed for characteristics of the participants and the presence or absence of MRSA infection at the enrollment hospitalization. Records were requested up to five times, with five additional attempts to address incomplete records.

TRIAL OUTCOMES

Redacted medical records from enrollment hospitalizations and all reported subsequent medical visits were reviewed in a blinded fashion, with the use of standardized forms, by two physicians with expertise in infectious diseases (five of the authors) for coexisting conditions, antibiotic agents, and infection outcomes. If consensus was not reached, discordant outcomes were adjudicated by a third physician with expertise in infectious diseases.

The primary outcome was MRSA infection according to medical-record documentation of disease-specific infection criteria (according to 2013 guidelines) from the Centers for Disease Control and Prevention (CDC) in a time-to-event analysis.[11] A priori secondary outcomes included MRSA infection defined in a time-to-event analysis according to the clinical judgment of two reviewers with expertise in infectious diseases who were unaware of the trial-group assignments, infection from any cause according to disease-specific CDC criteria in a time-to-event analysis, infection from any cause according to infectious disease clinical judgment in a time-to-event analysis, hospitalization due to infection, and new carriage of a MRSA strain that was resistant to mupirocin (evaluated by Etest, bioMérieux)[12] or that had an elevated minimum inhibitory concentration (MIC) of chlorhexidine (≥8 μg per milliliter) on microbroth dilution.[13,14] All outcomes were assessed on the basis of the first event per participant.

DATA COLLECTION

Surveys of health conditions, health care utilization, and household cleaning and bathing habits were administered during recruitment and all follow-up visits. Swabs of both nares, the throat, skin (axilla and groin), and any wounds were taken, but the results are not reported here. At each visit, participants in the decolonization group reported adherence to the intervention, and staff assessed the remaining product. Potential discrepancies were broached with the participant to obtain affirmation of actual adherence. Adherence was assessed as full (no missed doses), partial (some missed doses), and nonadherence (no doses used).

STATISTICAL ANALYSIS

The characteristics of the participants and outcomes were described by frequency and type according to trial group. Outcomes were summarized with the use of Kaplan–Meier estimates of infection-free distributions across the follow-up period and analyzed with the use of unadjusted Cox proportional-hazard models (per-protocol primary analysis) for the postdischarge trial population (all the participants who underwent randomization, met inclusion criteria, and survived beyond the recruitment hospitalization); outcomes were also analyzed according to the as-treated adherence strata (fully adherent, partially adherent, and nonadherent participant-time). In the as-treated analyses, information about participant adherence during at-risk periods before each visit was updated with the use of the adherence assessment at that visit.

The assumption of proportional hazards was assessed by means of residual diagnostic tests and formal hypothesis tests. P values are provided only for the primary outcome. Because the statistical analysis plan did not include a provision for correction for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, those results are reported as point estimates with 95% confidence intervals. The widths of the confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

In post hoc exploratory analyses, we used adjusted Cox proportional-hazard models to address potential residual imbalances in the characteristics of the participants between the two groups after randomization. The characteristics of the participants were entered into the model if they were associated with outcomes at a P value of less than 0.20 in bivariate analyses. Characteristics included demographic data; educational level; insurance type; presence of coexisting conditions, devices, or wounds at enrollment; hospitalization or residence in a nursing home in the year before enrollment; ICU admission or surgery during enrollment hospitalization; need

for assistance with bathing; frequency of bathing; and randomization strata. Adjusted models also accounted for two time-dependent covariates: receipt of anti-MRSA antibiotics and adherence to the intervention. The number needed to treat was calculated with the use of rates that accounted for participant-time that incorporated censoring due to loss to follow-up, withdrawal from the trial, or the end of the trial.[15] Full details of the trial design and analytic approach are provided in the protocol and in the Supplementary Appendix.

RESULTS

PARTICIPANTS

Figure 1 shows the randomization and follow-up of 2140 participants, of whom 19 were excluded after randomization because they did not meet inclusion criteria (6 participants did not have a positive MRSA test, and 13 died during the enrollment hospitalization). The characteristics of the final 2121 enrolled participants (per-protocol population) are provided in Table 1, and in Tables S2 through S4 in the Supplementary Appendix.

According to the randomization strata, Hispanic participants made up 31.9% of the education group (339 participants) and 32.0% of the decolonization group (339), and nursing home residents made up 11.3% of the education group (120) and 11.0% of the decolonization group (116). In a comparison of the education group with the decolonization group across the 1-year follow-up, early exit from the trial occurred in 34.9% of the participants (371 participants) and 37.0% (391), respectively ($P=0.32$); withdrawal from the trial in 6.8% (72) and 11.6% (123), respectively ($P<0.001$); loss to follow-up in 17.4% (185) and 16.1% (170), respectively ($P=0.41$); and death in 10.7% (114) and 9.3% (98), respectively ($P=0.26$). The characteristics of the participants who withdrew from the trial or were lost to follow-up and of the participants in the decolonization group according to adherence category are shown in Table S5 in the Supplementary Appendix.

OUTCOMES

A total of 8395 full-text medical records were requested, and 8067 (96.1%) were received and redacted. Charts underwent duplicate blinded review (16,134 reviews) by physicians with expertise in infectious diseases at a rate of approximately 800 charts per month for 20 months. Of the 2121 enrollment admission records, 2100 (99.0%) were received. Of the 6271 subsequent inpatient and outpatient records, 5967 (95.2%) were received for outcome assessment. The overall rate of reported hospitalizations per 365 days of follow-up was 1.97 in the education group and 1.75 in the decolonization group.

Regarding the primary outcome in the per-protocol analysis, 98 participants (9.2%) in the education group had a MRSA infection, as compared with 67 (6.3%) in the decolonization group (Table 2). This corresponded to an estimated MRSA infection rate in the education group of 0.139 infections per participant-year, as compared with 0.098 infections per participant-year in the decolonization group. Among first MRSA infections per participant, skin and soft-tissue infections and pneumonia were common. Across both groups, 84.8% (140 of 165) of the MRSA infections resulted in hospitalization, at a rate of 0.117 hospitalizations per participant-year in the education group and 0.083 per participant-year in the decolonization group. Bacteremia occurred in 28.5% (47 of 165) of all MRSA infections; the MRSA bacteremia rate was 0.040 events per participant-year in the education group and 0.028 per participant-year in the decolonization group. Findings were similar when MRSA infection was determined according to the clinical judgment of physicians with expertise in infectious diseases and according to CDC criteria (Table 2). All the MRSA infections were treated with an antibiotic, but the receipt of an antibiotic was not sufficient to render a decision of a MRSA infection.

In the analysis of infection from any cause according to CDC criteria, 23.7% of the participants in the education group (252 participants) had an infection, as compared with 19.6% of those in the decolonization group (207), which corresponded to an estimated rate of 0.407 infections per participant-year in the education group and 0.338 per participant-year in the decolonization group (Table 2). Skin and soft-tissue infections and pneumonia remained the most common infection types.

Pathogens were identified in 67.7% of the infections (Table S6 in the Supplementary Appendix). Participants in the decolonization intervention had a lower rate of infections due to gram-positive pathogens or without cultured pathogens than those in the education group. There was a

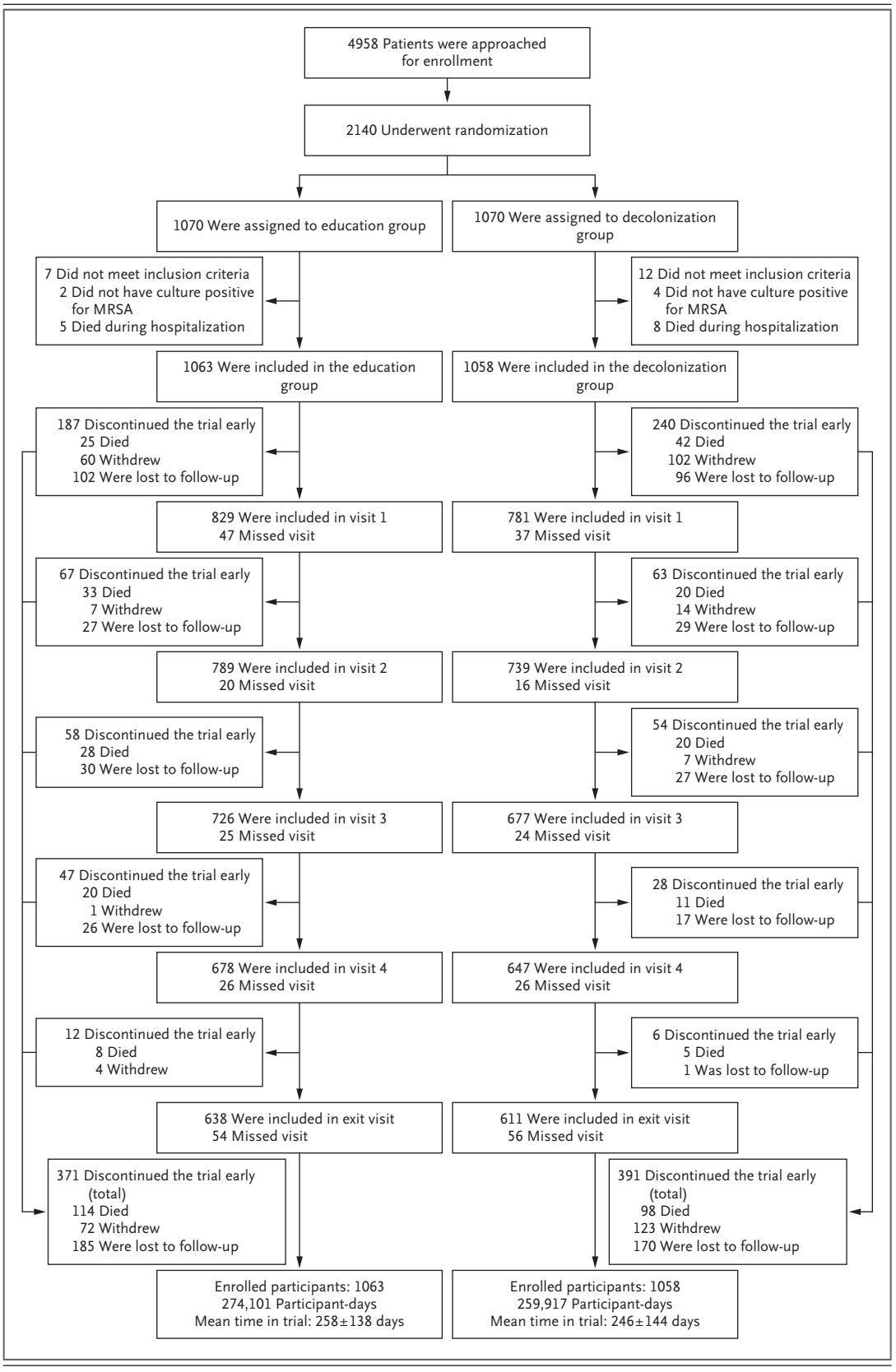

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Figure 1 (facing page). Randomization and Follow-up of the Participants.

This flow chart describes the recruitment and the four follow-up visits (at 1, 3, 6, and 9 months) for the 1-year period after hospital discharge. Recruitment occurred during hospitalization, and 19 participants were excluded from the postdischarge trial population because they did not meet inclusion criteria, leaving 2121 participants in the per-protocol population (1063 participants in the education group and 1058 in the decolonization group). Early exit from the trial was provided between each visit and included active withdrawal from the trial, loss to follow-up, and death. Active withdrawal represented situations in which participants indicated their desire to withdraw from the trial. Loss to follow-up was defined as the inability to contact the participant for 3 months, at which point the participant was removed from the trial at the time of last contact. Visits indicate both participants who successfully completed the visit and those who remained in the trial but missed that visit. The mean (±SD) time in the trial (in days) is shown for each group. All deaths were considered by the investigators to be unrelated to side effects from decolonization products. Summary boxes are provided at the bottom of the figure. MRSA denotes methicillin-resistant *Staphylococcus aureus*.

higher rate of gram-negative infection among the CDC-defined all-cause infections when participants in the decolonization intervention were compared with those in the education group, but this was not seen among clinically defined infections.

Across the two trial groups, infection from any cause led to hospitalization in 85.8% of the participants (394 of 459), and bacteremia occurred in 18.1% (83 of 459). The observed rate of hospitalization due to infection from any cause was 0.356 events per participant-year in the education group and 0.269 per participant-year in the decolonization group. The rate of bacteremia among participants with infection from any cause was 0.074 events per participant-year in the education group and 0.060 per participant-year in the decolonization group. Findings were similar when infection from any cause was determined according to clinical judgment (Table 2).

Estimates of the per-protocol treatment effects are shown in Table 3. No significant departures from proportional hazards were observed. In the main unadjusted analysis, the hazard of MRSA infection according to the CDC criteria (the primary outcome) was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03). This lower hazard of MRSA infection led to a 29% lower risk of hospitalization due to CDC-defined MRSA infection in the decolonization group than in the education group (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The effect was nearly identical for cases and hospitalizations involving clinically defined MRSA infection. Kaplan–Meier curves showing the infection-free time for the primary outcome of CDC-defined MRSA infection and the secondary outcome of infection from any cause show that the curves remained separated even after the intervention ended in month 6 (Fig. 2, and Table S7 in the Supplementary Appendix). Adjusted models showed greater MRSA infection effects that were significant (Table 3). A total of 10 participants (0.9%) in the education group and in 3 (0.3%) in the decolonization group died from MRSA infection. Results of sensitivity analyses conducted regarding death and early withdrawal from the trial are provided in Table S8 in the Supplementary Appendix.

The hazard of infection from any cause according to clinical judgment was lower in the decolonization group than in the education group (hazard ratio, 0.83; 95% CI, 0.70 to 0.99); similarly, the hazard of infection from any cause according to CDC criteria was lower in the decolonization group (hazard ratio, 0.84; 95% CI, 0.70 to 1.01) (Fig. 2B and Table 3). The risk of hospitalization due to infection from any cause was lower in the decolonization group than in the education group (hazard ratio, 0.76; 95% CI, 0.62 to 0.93). The results of the adjusted analyses were similar to those of the unadjusted analyses (Table 3). Deaths due to any infection occurred in 25 participants (2.3%) in the education group and 17 (1.6%) in the decolonization group.

EFFECT OF ADHERENCE

In as-treated analyses, 65.6% of the participant-time in the decolonization group involved full adherence; 19.6%, partial adherence; and 14.8%, nonadherence. Participants were highly consistent in adherence across the follow-up time. Increasing adherence was associated with increasingly lower rates of infection in both the adjusted and unadjusted models (Table 3). In comparisons of the adherence-category subgroups in the decolonization group with the education group overall, the likelihood of CDC-defined MRSA infection decreased 36% and 44%, respectively, as adher-

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Table 1. Characteristics of the Participants at Recruitment Hospitalization.*

Characteristic	Education Group (N=1063)	Decolonization Group (N=1058)	P Value†
Age — yr	56±17	56±17	0.78
Male sex — no. (%)	583 (54.8)	565 (53.4)	0.51
Coexisting conditions‡			
Diabetes — no./total no. (%)	424/1062 (39.9)	462/1056 (43.8)	0.08
Chronic obstructive pulmonary disease — no./total no. (%)	212/1055 (20.1)	203/1045 (19.4)	0.70
Congestive heart failure — no./total no. (%)	145/1055 (13.7)	149/1045 (14.3)	0.73
Cancer — no./total no. (%)	153/1055 (14.5)	161/1045 (15.4)	0.56
Renal disease — no./total no. (%)	140/1062 (13.2)	134/1056 (12.7)	0.74
Charlson Comorbidity Index score§	1.7±1.6	1.7±1.6	0.49
Bathe daily or every other day — no./total no. (%)¶	926/1037 (89.3)	927/1034 (89.7)	0.73
Bathing assistance needed — no./total no. (%)¶	200/1025 (19.5)	224/1013 (22.1)	0.15
MRSA source at enrollment — no. (%)			0.79
Nares‖	580 (54.6)	602 (56.9)	
Wound	320 (30.1)	305 (28.8)	
Respiratory	44 (4.1)	45 (4.3)	
Blood	43 (4.0)	31 (2.9)	
Other	76 (7.1)	75 (7.1)	
Recruitment hospitalization**			
Hospitalized in previous yr — no./total no. (%)‡	595/1046 (56.9)	598/1041 (57.4)	0.80
Nursing home stay in previous yr — no./total no. (%)‡	165/1043 (15.8)	168/1040 (16.2)	0.84
ICU stay — no./total no. (%)	188/1055 (17.8)	206/1045 (19.7)	0.27
Surgery — no./total no. (%)	392/1055 (37.2)	399/1045 (38.2)	0.63
MRSA infection — no./total no. (%)††	447/1055 (42.4)	438/1045 (41.9)	0.83
Wound at hospital discharge — no./total no. (%)	587/1055 (55.6)	588/1045 (56.3)	0.77
Medical device at hospital discharge — no./total no. (%)‡‡	320/1055 (30.3)	307/1045 (29.4)	0.63
Discharged to nursing home — no. (%)	120 (11.3)	116 (11.0)	0.81

* Plus–minus values are means ±SD. There were no significant differences between the two groups. Selected descriptive data are shown. For a full descriptive list of characteristics, see Table S2 in the Supplementary Appendix. ICU denotes intensive care unit.
† Student's t-test was performed for continuous variables, chi-square test for proportions, and Fisher's exact test for proportions if the numerator was 5 or less.
‡ Data reflect a positive response to either a survey question or chart review. Not all participants responded to every question, and not all enrollment charts were received from recruiting hospitals despite a signed release request, so data were missing for 21 participants.
§ Scores on the Charlson Comorbidity Index range from 0 to 10, with higher scores indicating more coexisting illness.
¶ Data reflect respondents to the survey question among all the participants. Not all the participants responded to every question.
‖ By law, California requires hospitals to screen five groups of patients for MRSA on hospital admission (patients who are transferred from a nursing home, who have been hospitalized in the past 30 days, who are undergoing hemodialysis, who are undergoing imminent surgery, and who are admitted to an ICU).
** Data reflect chart review from the received medical records. Not all recruiting hospitals released participants' medical records to the trial despite a signed release request, so records were missing for 21 participants.
†† Assessment of infection was based on criteria of the Centers for Disease Control and Prevention (CDC). Information regarding infection types is provided in Table S3 in the Supplementary Appendix.
‡‡ Information about medical device types is provided in Table S4 in the Supplementary Appendix.

ence increased from partial adherence (hazard ratio, 0.64; 95% CI, 0.40 to 1.00) to full adherence (hazard ratio, 0.56; 95% CI, 0.36 to 0.86). Similar effects were seen with regard to CDC-defined infection from any cause, which was 40% lower among fully adherent participants than among the participants in the education group (hazard ratio, 0.60; 95% CI, 0.46 to 0.78).

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Table 2. MRSA Infection Outcomes (First Infection per Person) per 365 Days of Follow-up, According to Trial Group.*

Variable	MRSA Infection, According to CDC Criteria†		MRSA Infection, According to Clinical Criteria		Any Infection, According to CDC Criteria		Any Infection, According to Clinical Criteria	
	Education	Decolonization	Education	Decolonization	Education	Decolonization	Education	Decolonization
All Participants								
Infection — no. of participants (no. of events/participant-yr)								
Any infection	98 (0.139)	67 (0.098)	98 (0.139)	68 (0.100)	252 (0.407)	207 (0.338)	298 (0.498)	246 (0.414)
Skin or soft-tissue infection	34 (0.048)	32 (0.047)	35 (0.050)	32 (0.047)	80 (0.129)	59 (0.096)	97 (0.162)	82 (0.138)
Pneumonia	18 (0.026)	9 (0.013)	20 (0.028)	10 (0.015)	39 (0.063)	25 (0.041)	45 (0.075)	34 (0.057)
Primary bloodstream or vascular infection	11 (0.016)	10 (0.015)	12 (0.017)	11 (0.016)	20 (0.032)	14 (0.023)	20 (0.033)	14 (0.024)
Bone or joint infection	13 (0.019)	9 (0.013)	12 (0.017)	8 (0.012)	20 (0.032)	22 (0.036)	0.18 (0.030)	17 (0.029)
Surgical-site infection	13 (0.019)	2 (0.003)	13 (0.018)	2 (0.003)	20 (0.032)	8 (0.013)	22 (0.037)	9 (0.015)
Urinary tract infection	3 (0.004)	2 (0.003)	1 (0.001)	1 (0.002)	38 (0.061)	46 (0.075)	52 (0.087)	56 (0.094)
Abdominal infection	1 (0.001)	2 (0.003)	1 (0.001)	2 (0.003)	20 (0.032)	21 (0.034)	26 (0.044)	18 (0.030)
Other infection	5 (0.007)	1 (0.002)	4 (0.006)	2 (0.003)	15 (0.024)	12 (0.020)	18 (0.030)	16 (0.027)
Infection involving bacteremia	28 (0.040)	19 (0.028)	27 (0.038)	18 (0.026)	46 (0.074)	37 (0.060)	46 (0.077)	33 (0.056)
Infection leading in hospitalization	83 (0.117)	57 (0.083)	82 (0.115)	56 (0.082)	225 (0.356)	169 (0.269)	259 (0.420)	199 (0.325)
Time to infection — days	111±91	117±93	116±94	117±95	103±87	110±91	107±91	113±94
Adherent Participants in Decolonization Group‡								
Infection — no. of participants (no. of events/participant-yr)								
Any infection		42 (0.085)		42 (0.088)		118 (0.272)		142 (0.338)
Skin or soft-tissue infection		22 (0.045)		22 (0.046)		40 (0.092)		54 (0.129)
Pneumonia		5 (0.010)		5 (0.011)		11 (0.025)		16 (0.038)
Primary bloodstream or vascular infection		5 (0.010)		6 (0.013)		8 (0.019)		8 (0.019)
Bone or joint infection		5 (0.010)		4 (0.008)		14 (0.032)		11 (0.026)
Surgical-site infection		2 (0.004)		2 (0.004)		6 (0.014)		7 (0.017)
Urinary tract infection		0		0		22 (0.051)		27 (0.064)
Abdominal infection		2 (0.004)		2 (0.004)		12 (0.028)		11 (0.026)
Other infection		1 (0.002)		1 (0.002)		5 (0.012)		8 (0.019)
Infection involving bacteremia		9 (0.019)		8 (0.017)		19 (0.045)		16 (0.039)
Infection leading to hospitalization		36 (0.075)		34 (0.071)		98 (0.226)		115 (0.274)
Time to infection — days		122±93		125±96		119±89		123±94

* Participant-day denominators were censored by the specified outcome. Dates of infection onset based on CDC criteria may differ from those based on clinical judgment.
† This was the primary outcome.
‡ A total of 546 participants were considered to have adhered fully to the decolonization intervention.

Table 3. Effect of Decolonization Plus Education, as Compared with Education Alone, According to Cox Proportional-Hazard Models.*

Variable	MRSA Infection, According to CDC Criteria	MRSA Infection, According to Clinical Criteria	Any Infection, According to CDC Criteria	Any Infection, According to Clinical Criteria
Per-protocol analysis				
Unadjusted hazard ratio (95% CI)	0.70 (0.52–0.96)†	0.71 (0.52–0.97)	0.84 (0.70–1.01)	0.83 (0.70–0.99)
Adjusted hazard ratio (95% CI)‡	0.61 (0.44–0.85)	0.61 (0.43–0.84)	0.80 (0.66–0.98)	0.81 (0.68–0.97)
As-treated analysis§				
Unadjusted hazard ratio (95% CI)				
Nonadherent	1.31 (0.72–2.38)	1.09 (0.57–2.10)	1.68 (1.19–2.36)	1.53 (1.11–2.13)
Partially adherent	0.64 (0.40–1.00)	0.72 (0.47–1.11)	0.86 (0.67–1.11)	0.92 (0.74–1.16)
Fully adherent	0.56 (0.36–0.86)	0.53 (0.34–0.83)	0.60 (0.46–0.78)	0.58 (0.45–0.74)
Adjusted hazard ratio (95% CI)¶				
Nonadherent	0.78 (0.36–1.71)	0.72 (0.37–1.41)	0.780 (0.51–1.26)	0.76 (0.40–1.45)
Partially adherent	0.75 (0.59–0.95)	0.69 (0.54–0.88)	0.78 (0.64–0.97)	0.76 (0.63–0.92)
Fully adherent	0.72 (0.57–0.92)	0.66 (0.51–0.84)	0.75 (0.60–0.94)	0.72 (0.58–0.88)

* The per-protocol population included all the participants (2121) who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization. The unadjusted analyses included all these participants. The adjusted models included the 1901 participants who provided data for all the baseline characteristics shown in Table S2 in the Supplementary Appendix.

† A P value is provided only for the primary outcome (P=0.03). Because the statistical analysis plan did not include a provision for correcting for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, these results are reported as point estimates with 95% confidence intervals. The widths of these confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

‡ Models evaluating the outcomes of MRSA infection according to CDC criteria and any infection according to clinical criteria were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, cancer, cerebrovascular disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, need for bathing assistance, and anti-MRSA antibiotics as time-varying covariates on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses. Models evaluating the outcome of MRSA infection according to clinical criteria and any infection according to CDC criteria were adjusted for the same variables with the addition of age. Resistance to mupirocin did not significantly modify the effect of the trial group.

§ The as-treated analysis assessed the effect on trial outcomes on the basis of the participant's level of adherence to the use of decolonization products as compared with the education group. Among the participants in the decolonization group, 65.6% of the participant-time involved full adherence (no missed doses); 19.6%, partial adherence (some missed doses); and 14.8%, nonadherence (no doses used). The comparator for each adherence subgroup was the overall education group.

¶ As-treated models for all outcomes were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, and need for bathing assistance on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses.

Nonadherence was associated with a higher likelihood of infection from any cause than was observed among participants in the education group.

NUMBER NEEDED TO TREAT

Overall, the estimated number needed to treat to prevent a MRSA infection was 30 (95% CI, 18 to 230) and to prevent an associated hospitalization, 34 (95% CI, 20 to 336). The number needed to treat to prevent any infection was 26 (95% CI, 13 to 212) and to prevent an associated hospitalization, 28 (95% CI, 21 to 270). Among the participants who adhered fully to the intervention (all of whom were in the decolonization group), the number needed to treat to prevent a MRSA infection was 26 (95% CI, 18 to 83) and to prevent an associated hospitalization, 27 (95% CI, 20 to 46). The number needed to treat to prevent any infection was 11 (95% CI, 8 to 21) and to prevent an associated hospitalization, 12 (95% CI, 8 to 23).

ADVERSE EVENTS

Adverse events that were associated with the topical decolonization intervention were mild and uncommon, occurring in 44 participants (4.2%) (Table S9 in the Supplementary Appendix). Local irritation occurred with mupirocin in 1.1% of the participants (12 of 1058), with chlorhexidine bathing in 2.3% (24), and with chlorhexidine mouthwash in 1.1% (12). In those respective

categories, 33% (4 of 12), 29% (7 of 24), and 50% (6 of 12) of the participants chose to continue using the product (overall, 39% of the participants with side effects).

A total of 12.6% of the 1591 participants with postrecruitment MRSA strains had high-level resistance to mupirocin (9.4% [150 participants]) or low-level resistance to mupirocin (3.1% [50]). A total of 1.9% of the participants were newly found to have a mupirocin-resistant strain at subsequent visits (1.9% [16 of 826 participants] in the education group and 2.0% [15 of 765] in the decolonization group, P=0.97). A total of 1.5% of the participants in each group were newly found to have high-level mupirocin-resistant strains (1.6% [13 of 826 participants] in the education group and 1.4% [11 of 765] in the decolonization group, P=0.82) when only sensitive strains were detected at recruitment. Chlorhexidine MICs of 8 μg or more per milliliter were rare (occurring in 2 participants overall [0.1%]). Both patients were in the intervention group, and both isolates had an MIC of 8 μg per milliliter and were negative for the *qac A/B* gene).

DISCUSSION

Infection-prevention campaigns have reduced the risks of health care–associated infections in hospitals, leaving the majority of preventable infections to the postdischarge setting.[16] MRSA carriers are an appealing population target because of their higher risks of infection and postdischarge rehospitalization and the common practice of screening selected inpatients for MRSA colonization.[1,17-19] In the CLEAR trial, topical decolonization led to lower risks of infections and readmissions than hygiene education alone among patients after the transition from hospital to home and other care settings. With a number needed to treat between 25 and 30 to prevent infection and hospitalization, this intervention is relevant to 1.8 million MRSA carriers (5% of inpatients) who are discharged from hospitals each year.[16]

Although decolonization has successfully prevented disease during temporary high-risk circumstances (e.g., recurrent skin infections, ICU care, and arthroplasty and cardiac surgery),[6-10,19-22] a single 5-day decolonization regimen produced short-lived MRSA clearance in half the carriers.[23-26] In contrast, twice-monthly decolonization provided protection for many months after discharge. The protective benefit continued after decolonization. In addition, this regimen was effective despite the greater variability in application with home bathing and showering than has occurred in previous inpatient trials that evaluated nursing-assisted chlorhexidine bath-

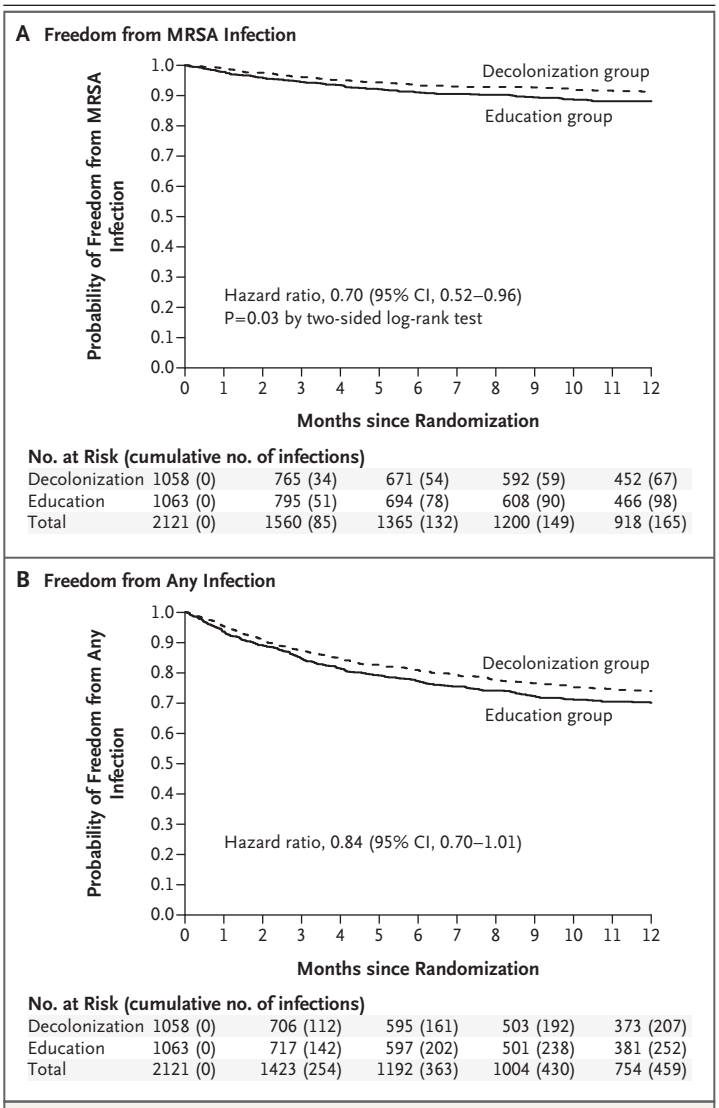

Figure 2. Kaplan–Meier Curves for Freedom from MRSA Infection and Infection from Any Cause, Assessed According to CDC Criteria.

Cases of MRSA infection and infection from any cause were assessed according to criteria of the Centers for Disease Control and Prevention (CDC). The probability of being free from MRSA infection (primary outcome) was significantly greater in the decolonization group than in the education group. The curves remained separated even though decolonization stopped at 6 months. Details regarding the numbers of patients at risk for infection and those with infection at the specific time points are provided in Table S7 in the Supplementary Appendix.

ing and mupirocin application.[8,9,22] This trial also showed that 4% rinse-off chlorhexidine was effective in a postdischarge population that typically takes showers or baths and is unlikely to use a 2% leave-on chlorhexidine product.[8,9,22]

Not surprisingly, participants who adhered fully to the decolonization intervention had rates of MRSA infection and infection from any cause that were at least 40% lower than the rates among participants in the education group, with a number needed to treat of 12 to prevent infection-related hospitalization. This finding probably is attributable to both the decolonization effect and the likelihood that these participants were more adherent to other prescribed treatments and health-promotion behavior than participants in the education group. Participants who fully adhered to the intervention had fewer coexisting conditions, had fewer devices, required less bathing assistance, and were more likely to have MRSA infection (rather than asymptomatic colonization) at the time of enrollment than either participants in the education group or participants in the decolonization group who had lower levels of adherence. These differences represent an important practical distinction. To the extent that physicians can identify patients who are able to adhere to an intervention, those patients would derive greater benefit from the recommendation to decolonize. Nonadherence was common among nursing home residents, which raises questions about research barriers in that care setting.

Decolonization appeared to affect the risks of skin and soft-tissue infections, surgical-site infections, pneumonia, and bacteremia, although sample-size constraints necessitate cautious speculation. Decolonization also appeared to reduce the rate of gram-positive pathogens and infections without a cultured pathogen. The higher rate of gram-negative pathogens in the decolonization group than in the education group was seen among the CDC-defined all-cause infections but not among the clinically defined infections and requires further substantiation. These observations are based on relatively small numbers; larger studies have shown that chlorhexidine can reduce the incidence of gram-negative infections and bacteriuria.[27-30]

The design of this trial did not permit us to determine the effect of hygiene education alone. Both trial groups received in-person visits and reminders about the importance of MRSA-prevention activities. In addition, the free product overcame financial disparities that could become evident with post-trial adoption of the decolonization intervention.

Some participants (<5%) in the decolonization group had mild side effects; among those participants, nearly 40% opted to continue using the agent. Resistance to chlorhexidine and mupirocin was not differentially engendered in the two groups. We defined an elevated chlorhexidine MIC as at least 8 μg per milliliter, although 4% chlorhexidine applies 40,000 μg per milliliter to the skin.

This trial is likely to be generalizable because it was inclusive. For example, the enrollment of participants with late-stage cancer contributed to the 10% anticipated mortality and the approximate 25% rate of withdrawal and loss to follow-up. These rates are similar to other postdischarge trials with shorter durations of follow-up than the durations in our trial.[31-33] It is unknown whether the participants who withdrew or were lost to follow-up had different infection rates or intervention benefits. They were more educated and less likely to be Hispanic than those who did not withdraw or were not lost to follow-up, but the percentages of participants with coexisting conditions were similar.

Limitations of this trial include the unblinded intervention, although outcomes were assessed in a blinded fashion. The trial also had substantial attrition over the 1-year follow-up, and adherence was based on reports by the participants, with spot checks of remaining product, both of which may not reflect actual use. In addition, nearly all infections led to hospitalization, which suggests that milder infections escaped detection. Most outpatient and nursing home records had insufficient documentation for the event to be deemed infection according to the CDC or clinical criteria. Thus, it remains unknown whether the observed 30% lower risk of MRSA infection or the observed 17% lower risk of infection from any cause with decolonization than with education alone would apply to less severe infections that did not lead to hospitalization. Finally, although resistance to chlorhexidine and mupirocin did not emerge during the trial, the development of resistance may take time, beyond the follow-up period of this trial.

In conclusion, inpatients with MRSA-positive

cultures who had been randomly assigned to undergo decolonization with topical chlorhexidine and mupirocin for 6 months after discharge had lower risks of MRSA infection, infection from any cause, and hospitalization over the 1 year after discharge than those who had been randomly assigned to receive hygiene education only.

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), or the Agency for Healthcare Research and Quality (AHRQ).

Supported by a grant (R01HS019388, to Dr. Huang) from the AHRQ Healthcare-Associated Infections Program and by the University of California Irvine Institute for Clinical and Translational Science, which was funded by a grant from the NIH Clinical and Translational Sciences Award program (UL1 TR000153).

Dr. Huang reports conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, Clorox, Xttrium Laboratories, and Medline; Ms. Singh, Dr. Park, and Mr. Chang, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline; Dr. McKinnell, receiving grant support and consulting fees from Achaogen and Theravance Biopharma, grant support, consulting fees, and lecture fees from Allergan, consulting fees from Cempra, Melinta Therapeutics, Menarini Group, and Thermo Fisher Scientific, and fees for serving as a research investigator from Science 37, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline, and serving as cofounder of Expert Stewardship; Ms. Gombosev, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, and Clorox; Dr. Rashid, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Clorox, and Medline; Dr. Bolaris, conducting clinical studies in which participating nursing homes received donated products from 3M and Clorox; Dr. Robinson, serving as cofounder of Expert Stewardship; Dr. Amin, receiving consulting fees from Paratek Pharmaceuticals; Dr. Septimus, conducting clinical studies in which participating hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline; Dr. Weinstein, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products) and Mölnlycke; Dr. Hayden, conducting clinical studies in which participating nursing homes and hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline and donated laboratory services from OpGen and receiving grant support and conducting clinical studies in which participating nursing homes and hospitals received donated product from Clorox; and Dr. Miller, receiving grant support from Gilead Sciences, Merck, Abbott, Cepheid, Genentech, Atox Bio, and Paratek Pharmaceuticals, grant support and fees for serving on an advisory board from Achaogen and grant support, consulting fees, and fees for serving on an advisory board from Tetraphase and conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline. No other potential conflict of interest relevant to this article was reported. Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank the trial participants and their families; the trial staff (Lauren Akahoshi, Jenna Alcaron, Isabel Alegria, Stephanie Arredondo-Glacet, Elizabeth Arreola, Donald Bayley, Nelly Beltran, Barbara Bodenhoefer, Stefan Boghossian, Diane Capobianco, Claudia Cervantes, Sarah Chevallier, Heather Clayton, Ramiro Correa, Nathalia Cressey, Tiffany Dam, Rupak Datta, Jennifer Do, Phillip Duffy, Tabitha Dutciuc, Marlene Estevez, Margarita Flores, Lauren Heim, Sandra Ibarra, Usme Khusbu, Bryn Launer, Cameron Lee, Brian Lewis, Karen Lolans, Andrea Marcantonio, Donna Matsudairas, Lisa [Angie] McErlain, Maria Mejia, Job Mendez, Angela Mendoza, Melanie Meton, Nicole Mohajer, Jennifer Nam, Ann Nguyen, Hanna Owens, Jalpa Patel, Lena Portillo, Sean Prendergast, Katy Precaido, Belinda Prado, Deborah Prunean, Victor Quan, Courtney Reynolds, Diana Romero, Aubrianne Rose, Maureen Schroeder, Grace Tagudar, Cynthia Toyoshima, Ivonne Turner, Qixin Wang, Emily Wawro, and Jun Zozobrado); two physicians who actively supported and facilitated recruitment (David Petreccia and Anjali Vora); the members of our community advisory board (Patricia Cantero, Ph.D., and Jeanine Thomas); the members of our data and safety monitoring board (Honghu Liu, David Beenhouwer, and George Sakoulas); and the staff of the many hospitals and nursing homes that supported the recruitment of participants in the trial.

APPENDIX

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PUBLIC HEALTH

Hospitals Look To Nursing Homes To Help Stop Drug-Resistant Infections

April 2, 20195:00 AM ET

ANNA GORMAN

A certified nursing assistant wipes Neva Shinkle's face with chlorhexidine, an antimicrobial wash. Shinkle is a patient at Coventry Court Health Center, a nursing home in Anaheim, Calif., that is part of a multicenter research project aimed at stopping the spread of MRSA and CRE — two types of bacteria resistant to most antibiotics. *Heidi de Marco/KHN*

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy to stop the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government's Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

This novel collaboration recognizes that superbugs don't remain isolated in one hospital or nursing home but move quickly through a community, said Dr. John Jernigan, who directs the CDC's office on health care-acquired infection research.

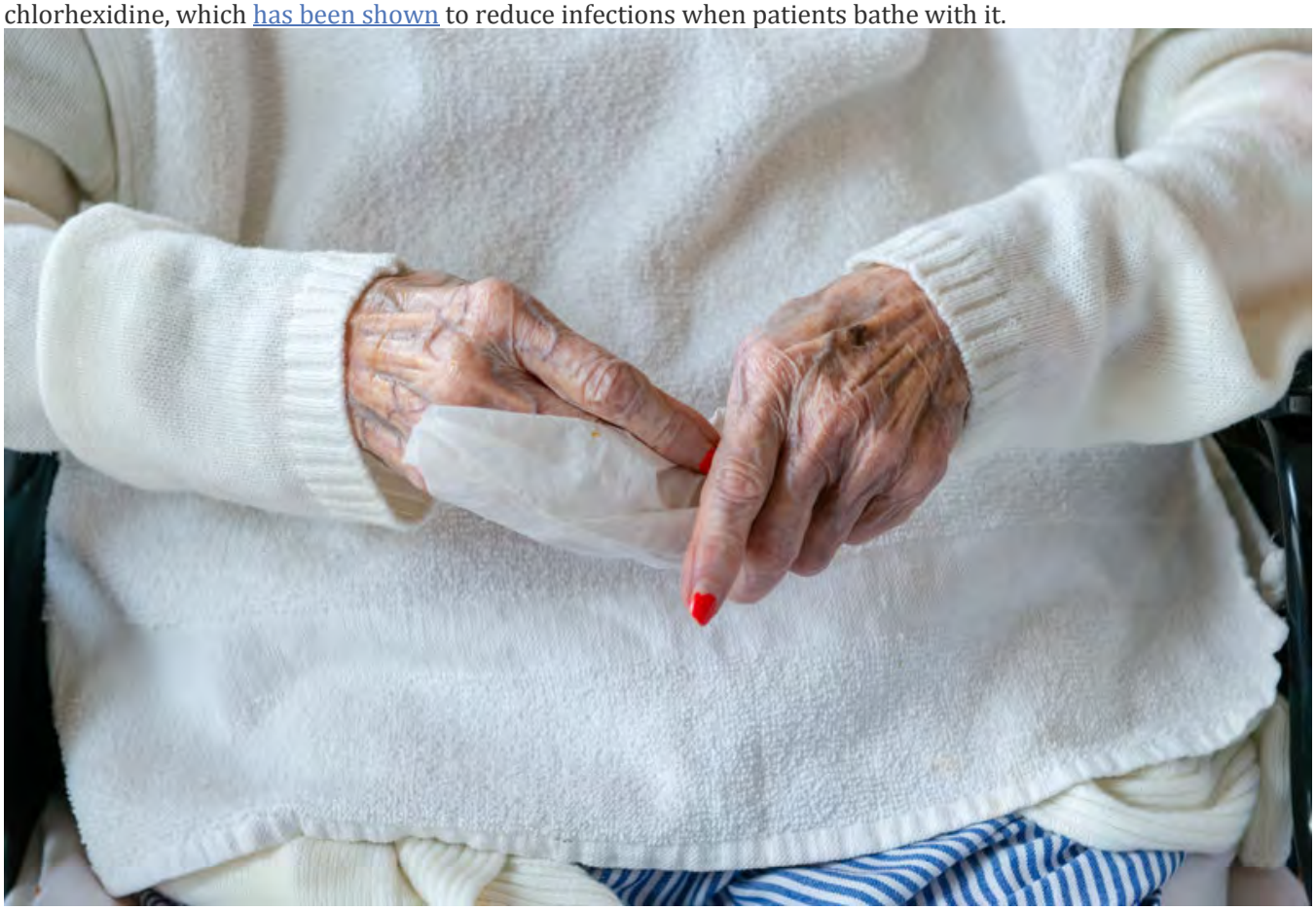
"No health care facility is an island," Jernigan says. "We all are in this complicated network."

At least 2 million people in the U.S. become infected with some type of antibiotic-resistant bacteria each year, and about 23,000 die from those infections, according to the CDC.

People in hospitals are vulnerable to these bugs, and people in nursing homes are particularly vulnerable. Up to 15 percent of hospital patients and 65 percent of nursing home residents harbor drug-resistant organisms, though not all of them will develop an infection, says Dr. Susan Huang, who specializes in infectious diseases at the University of California, Irvine.
"Superbugs are scary and they are unabated," Huang says. "They don't go away."

Some of the most common bacteria in health care facilities are methicillin-resistant *Staphylococcus aureus*, or MRSA, and carbapenem-resistant *Enterobacteriaceae*, or CRE, often called "nightmare bacteria." *E.Coli* and *Klebsiella pneumoniae* are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

CRE have "basically spread widely" among health care facilities in the Chicago region, says Dr. Michael Lin, an infectious-diseases specialist at Rush University Medical Center, who is heading the CDC-funded effort there. "If MRSA is a superbug, this is the extreme — the super superbug."
Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it.



The Centers for Disease Control and Prevention funds the project in California, based in Orange County, in which 36 hospitals and nursing homes are using an antiseptic wash, along with an iodine-based nose swab, on patients to stop the spread of deadly superbugs.
Heidi de Marco/KHN

Though hospital intensive care units frequently rely on chlorhexidine in preventing infections, it is used less commonly for bathing in nursing homes. Chlorhexidine also is sold over the counter; the FDA noted in 2017 it has caused rare but severe allergic reactions.
In Chicago, researchers are working with 14 nursing homes and long-term acute care hospitals, where staff are screening people for the CRE bacteria at admission and bathing them daily with chlorhexidine.

The Chicago project, which started in 2017 and ends in September, includes a campaign to promote hand-washing and increased communication among hospitals about which patients carry the drug-resistant organisms.

The infection-control protocol was new to many nursing homes, which don't have the same resources as hospitals, Lin says.

In fact, three-quarters of nursing homes in the U.S. received citations for infection-control problems over a four-year period, according to a Kaiser Health News analysis, and the facilities with repeat citations almost never were fined. Nursing home residents often are sent back to hospitals because of infections.
In California, health officials are closely watching the CRE bacteria, which are less prevalent there than elsewhere in the country, and they are trying to prevent CRE from taking hold, says Dr. Matthew Zahn, medical director of epidemiology at the Orange County Health Care Agency
"We don't have an infinite amount of time," Zahn says. "Taking a chance to try to make a difference in CRE's trajectory now is really important."

The CDC-funded project in California is based in Orange County, where 36 hospitals and nursing homes are using the antiseptic wash along with an iodine-based nose swab. The goal is to prevent new people from getting drug-resistant bacteria and keep the ones who already have the bacteria on their skin or elsewhere from developing infections, says Huang, who is leading the project.

Licensed vocational nurse Joana Bartolome swabs Shinkle's nose with an antibacterial, iodine-based solution at Anaheim's Coventry Court Health Center. Studies find patients can harbor drug-resistant strains in the nose that haven't yet made them sick.
Heidi de Marco/KHN

Huang kicked off the project by studying how patients move among different hospitals and nursing homes in Orange County — she discovered they do so far more than previously thought. That prompted a key question, she says: "What can we do to not just protect our patients but to protect them when they start to move all over the place?"

Her previous research showed that patients who were carriers of MRSA bacteria on their skin or in their nose, for example, who, for six months, used chlorhexidine for bathing and as a mouthwash, and swabbed their noses with a nasal antibiotic were able to reduce their risk of developing a MRSA infection by 30 percent. But all the patients in that study, published in February in the *New England Journal of Medicine*, already had been discharged from hospitals.

Now the goal is to target patients still in hospitals or nursing homes and extend the work to CRE. The traditional hospitals participating in the new project are focusing on patients in intensive care units and those who already carry drug-resistant bacteria, while the nursing homes and the long-term acute care hospitals perform the cleaning — also called "decolonizing" — on every resident.

One recent morning at Coventry Court Health Center, a nursing home in Anaheim, Calif., 94-year-old Neva Shinkle sat patiently in her wheelchair. Licensed vocational nurse Joana Bartolome swabbed her nose and asked if she remembered what it did.

"It kills germs," Shinkle responded.

"That's right. It protects you from infection."

In a nearby room, senior project coordinator Raveena Singh from UCI talked with Caridad Coca, 71, who had recently arrived at the facility. She explained that Coca would bathe with the chlorhexidine rather than regular soap. "If you have some kind of open wound or cut, it helps protect you from getting an infection," Singh said. "And we are not just protecting you, one person. We protect everybody in the nursing home."

Coca said she had a cousin who had spent months in the hospital after getting MRSA. "Luckily, I've never had it," she said.

Coventry Court administrator Shaun Dahl says he was eager to participate because people were arriving at the nursing home carrying MRSA or other bugs. "They were sick there and they are sick here," Dahl says.
Results from the Chicago project are pending. Preliminary results of the Orange County project, which ends in May, show that it seems to be working, Huang says. After 18 months, researchers saw a 25 percent decline in drug-resistant organisms in nursing home residents, 34 percent in patients of long-term acute care hospitals and 9 percent in traditional hospital patients. The most dramatic drops were in CRE, though the number of patients with that type of bacteria was smaller.

The preliminary data also show a promising ripple effect in facilities that aren't part of the effort, a sign that the project may be starting to make a difference in the county, says Zahn of the Orange County Health Care Agency.

"In our community, we have seen an increase in antimicrobial-resistant infections," he says. "This offers an opportunity to intervene and bend the curve in the right direction."

USA TODAY

How to fight ‘scary’ superbugs that kill thousands each year? Cooperation — and a special soap

Anna Gorman, Kaiser Health News Published 9:27 a.m. ET April 12, 2019 | **Updated 1:47 p.m. ET April 12, 201**

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy against the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government’s Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

This novel approach recognizes that superbugs don’t remain isolated in one hospital or nursing home but move quickly through a community, said Dr. John Jernigan, who directs the CDC’s office on health care-acquired infection research.

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USA TODAY

Certified nursing assistant Cristina Zainos prepares a special wash using antimicrobial soap. *(Photo: Heidi de Marco, Kaiser Health News)*

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Some of the most common bacteria in health care facilities are methicillin-resistant Staphylococcus aureus, or MRSA, and carbapenem-resistant Enterobacteriaceae, or CRE, often called “nightmare bacteria.” E. coli and Klebsiella pneumoniae are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

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Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it. Though chlorhexidine is frequently used for bathing in hospital intensive care units and as a mouthwash for dental infections, it is used less commonly for bathing in nursing homes.

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Kaiser Health News is a national health policy news service that is part of the nonpartisan Henry J. Kaiser Family Foundation.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

May 14, 2019

CalOptima Board of Directors
505 City Parkway West
Orange, CA 92868

Dear CalOptima Board of Directors:

As the Director of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC), I want to relay that CDC is very encouraged by your proposed Post-Acute Infection Prevention Quality Initiative (PIPQI). We hope that this type of insurer initiative will help protect nursing home residents from infections and hospitalization.

To combat antibiotic resistant – an important global threat – CDC has activities to prevent infections, improve antibiotic use, and detect and contain the spread of new and emerging resistant bacteria. The nursing home population is at particular risk for acquiring these bacteria and developing infections that require antibiotics and hospital admission because of their age, complex health status, frequency of wounds, and need for medical devices. Surveillance data have shown that the majority of nursing home residents currently have one of these highly antibiotic resistant bacteria on their body, and often these bacteria are spread between residents, within the nursing home, and to other healthcare facilities.

There is a need for public health agencies, insurers, and healthcare providers to forge coordinated efforts to promote evidence-based infection prevention strategies to prevent infections and save lives. We see great synergy in linking CDC's role in providing surveillance and infection prevention guidance to CalOptima's ability to protect its members by supporting patient safety initiatives to reduce infections and the hospitalizations they cause.

CDC funded the Orange County regional decolonization collaborative (SHIELD) as a demonstration project to inform broader national infection prevention guidance. The ability to maintain its resounding success in reducing antibiotic resistant bacteria and infections is critical and Orange County will benefit on initiatives such as PIPQI that provide incentives to enable its adoption into operational best practices.

CDC plans to continue transitional support for this initiative, including training support for the 16 nursing homes currently in the SHIELD collaborative for at least one year. We hope that this training effort can complement and synergize the efforts of CalOptima's education and liaison nurses. In addition, we are providing transitional support to the Orange County Health Department to continue their ongoing surveillance efforts in order that the ongoing benefits of the intervention can be captured.

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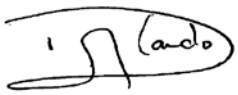
We look forward to collaborating with you. We believe this partnership is a valuable opportunity to protect highly vulnerable patients and to set an example of how insurers and public health can work together to improve healthcare quality.

Sincerely,



Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Attachment 4: IGT Funding Proposals

Proposal 1: Expanded Office Hours

Initiative Description: The Member Access and Engagement: Expanded Office Hours (Expanded Office Hours) is a two-year program to incentivize primary care providers and/or clinics for providing after-hour primary care services to CalOptima members in highly demanded and highly impacted areas. The Expanded Office Hours aims to improve member experience, timely access to needed care, and achieve positive population health outcomes.

Target Population(s): Primary care providers serving CalOptima's Medi-Cal members in highly demanded/impacted areas

Plan of Action/Key Milestones:
High level actions of how CalOptima will invest financial and staff resources to support the Expanded Office Hours initiative, such as:

1. Provider Data Gathering and Internal System Configuration
    - Identify primary care providers in community clinics who serve members in highly demanded and impacted areas
    - Configure the internal system (using codes 99050 and 99051) so claims can be adjudicated, and providers can receive expanded office hour incentives.
        - CPT code descriptions:
            - 99050: Services provided in the office at times other than regularly scheduled office hours, or days when the office is normally closed (e.g., holidays, Saturday or Sunday), in addition to basic service
            - 99051: Service(s) provided in the office during regularly scheduled evening, weekend, or holiday office hours, in addition to basic service
2. Provider Outreach
    - Collaborate with Provider Relations and Health Network Relations to promote the opportunity and encourage providers to provide these services.
    - $125 per member per visit incentive
3. Announce the Expanded Office Hours initiative to impacted Members
    - Call Center and frontline staff training
4. Monitor utilization of the expanded office hour services
    - Monitor and report claims and encounter for identification and linkage to primary care providers providing expanded office hour services

5. Evaluation
    - Conduct evaluation after pilot to see if member access has improved and depending on the outcome, consider expanding the initiative.

Estimated Budget: Total $2 million (up to $500,000 for FY2019/20, remaining amounts from FY2019/20 and $750,000 for FY2020/21, $750,000 FY2021/22)

Project Timeframe: April 2020 – March 2022

IGT 9 Focus Area: Member access and engagement

Strategic Plan Priority/Objectives: Expand CalOptima's Member-Centric Focus

- Focus on Population Health
- Strengthen Provider Network and Access to Care
- Enhance Member Experience and Customer Service

Participating/Collaborating Partners/Vendors/Covered Entities: Participating providers

Proposal 2: Post-Acute Infection Prevention Initiative (PIPQI)

Initiative Description: Expand CalOptima's program to suppress Multi Drug Resistant Organisms (MDROs) in CalOptima's contracted nursing facilities and decrease inpatient admissions due to infection. The pilot program was approved by CalOptima's Board of Directors on June 6, 2019.

Benefits of the Initiative:

- Member-centric focus: avoid MDRO colonization and inpatient admissions
- Potential cost savings from decreased antibiotic utilization
- Decreased demand for antibiotic-related c. difficile isolation beds
- Decreased Healthcare Acquired Infection rates (HAI):
    - Potential improved Star ratings
    - Strengthens community and national partnerships:
        - UCI (Professor Susan Huang -Department of Infectious Diseases)
        - Matthew Zahn, MD, Orange County Health Care Agency-Division of Epidemiology, CDC
        - (John A. Jernigan, MD, MS, Director, Office of Prevention Research and Evaluation Division of Healthcare Quality Promotion Centers for Disease Control and Prevention)
        - contracted nursing facilities
        - members/families
- Increased value and improved care delivery
- Enhanced operational excellence and efficiency

*Please note that there is currently an outbreak of a fungal infection called C. auris in Orange County LTACHs and NFs. It's a costly and virulent infection and the Public Health Department is involved. There are currently 160 cases in OC (need updated numbers). Chlorhexidine eradicates and protects against this fungus as well as Multi Drug Resistant Organisms (MDROs)

Target Member Population(s): CalOptima Members receiving services at contracted nursing facilities

Plan of Action/Key Milestones:

A. Teleconference requested by the CDC scheduled for April 2, 2020, as CalOptima is the only County in the U.S. that is an early adopter of CHG/Iodophor in NFs to lower MDRO colonization rates

B. Dedicate two Long Term Support Services Nurses to:

1) Provide training for newly participating facilities,
2) Provide ongoing support and compliance monitoring* at all participating facilities,
3) Develop additional informing, training and monitoring materials.

C. Promote the expansion of the Post-Acute of Infection Prevention Program and engage nursing facility administration and staff at the March 20, 202 LTSS Workshop.

*Monitoring includes monthly random testing (five patients per facility confirming presence of Chlorhexidine, invoices /delivery receipt for Chlorhexidine and Iodophor). Additional metrics: acute inpatient admission rates due to infection, Hospital Acquired Infection (HAI) rates.

Estimated Budget: Total budgeted amount $3.4 million over 3 fiscal years ($1 million for FY2019/20, $1.2 million for FY 2020/21 and $1.2 million for FY 2021/22)

Project Timeframe: Three years FY 2019/20– 2021/22

IGT 9 Focus Area: Quality performance and data exchange and support

Strategic Plan Priority/Objectives: Innovate and Be Proactive, Expand CalOptima's Member-Centric Focus, Strengthen Community Partnerships, Increase Value and Improve Care Delivery, Enhance Operational Excellence and Efficiency.

Participating/Collaborating Partners/Vendors/Covered Entities: University of California Irvine Medical Center, Department of Infectious Disease, Dr. Susan Huang; Orange County Health Care Agency-Division of Epidemiology, Centers for Disease Control (CDC); John A. Jernigan, MD, MS, Director, Office of Prevention Research and Evaluation Division of Healthcare Quality Promotion Centers for Disease Control and Prevention; CalOptima contracted nursing facilities.

Proposal 3: Hospital Data Sharing Initiative

Initiative Description: Establish incentives for implementation of a data sharing solution for Admit, Discharge, Transfer (ADT) and Electronic Health Record data to support alerting of hospital activities for CalOptima members for the purposes of improving care management. Participating entity will be eligible for incentive once each file exchange is in place. The overall goal is to improve costs, quality, care, and satisfaction.

Target Population(s): Contracted and participating Orange County hospitals serving CalOptima members and, potentially, other Community Based Organizations within the delivery system

Plan of Action/Key Milestones: Staff will obtain Board of Directors approval, contract with selected vendors, implement the solutions, establish an incentive plan and details, and work with the vendors and the hospitals to establish the means of sharing data.

Estimated Budget: $2 million to be exhausted by end of FY 2020-2021

Project Timeframe: Until end of FY 2020-2021

IGT 9 Focus Area: Data exchange and support

Strategic Plan Priority/Objectives: Expand CalOptima's Member-Centric Focus and Increase Value and Improve Care Delivery

Participating/Collaborating Partners/Vendors/Covered Entities: Hospitals providing the requested data

Proposal 4: Intergovernmental Transfer (IGT) Program Administration

Initiative Description: Administrative support activities related to prior, current and future IGTs opportunities, grants, internal initiatives. This will continue support for management of the IGT transaction process, project and expenditure oversight related to prior IGTs (outstanding grants and internal projects), as well as current IGTs in progress (i.e., IGTs 9 and 10) and oversight. Administration will be consistent with CalOptima standard policies, procedures and practices and will ensure funding investments are aligned with CalOptima's strategic priorities and member needs. Two staff positions, the Grant Management System license, public activities and other administrative costs are included.

Target Member Population(s): NA

Plan of Action/Key Milestones: NA

Estimated Budget: $2,000,000

Project Timeframe: Five–years

IGT 9 Focus Area: Other priority areas

Strategic Plan Priority/Objectives: Innovate and Be Proactive, Strengthen Community Partnerships, Increase Value and Improve Care Delivery

Participating/Collaborating Partners/Vendors/Covered Entities: NA

Proposal 5: Whole Child Model (WCM) Program

Initiative Description: To fund WCM program deficit in year one

Target Member Population(s): WCM eligible members (12,000 to 13,000)

Plan of Action/Key Milestones: N/A

Estimated Budget: Total $31.1 million for FY 2019-20

Project Timeframe: FY 2019-20 (July 1, 2019 to June 30, 2020)

IGT 9 Focus Area: Other priority areas

Strategic Plan Priority/Objectives:
To Support care delivery for WCM population in FY 2019-20

1) Insufficient revenue from DHCS
2) Complexity in operation and financial reconciliation

Participating/Collaborating Partners/Vendors/Covered Entities: N/A

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken April 16, 2020
Special Meeting of the CalOptima Board of Directors

Report Item

3. Consider Authorizing Modifications to the Post-Acute Infection Prevention Quality Initiative During the Coronavirus Disease (COVID-19) Crisis

Contact

David Ramirez, MD, Chief Medical Officer, 714-246-8400
Emily Fonda, M.D., MMM, CHCQM, Deputy Chief Medical Officer, 714-246-8400

Recommended Actions

Authorize the Chief Executive Officer (CEO) to temporarily modify the Post-Acute Infection Prevention Quality Initiative (PIPQI) by:

1. Suspending skin testing requirements during the Coronavirus Disease (COVID-19) pandemic, and
2. Allowing early disbursement of the first quarterly incentive payment (January – March 2020) and prepayment of the second quarterly payment (April – June 2020) due to added Personal Protective Equipment (PPE) and personnel costs in participating skilled nursing facilities.

Background/Discussion

The PIPQI program for contracted skilled nursing facilities (SNFs) was approved by the Board in June of 2019 as a means of infection prevention by replacing liquid soap with Chlorhexidine (CHG) soap for bathing and using Iodophor nasal swabs every other week. This protocol had been successful in demonstrating a significant reduction in Multi Drug Resistant Organisms (MDROs) on the skin of patients in 16 CalOptima contracted SNFs in a two-year study conducted by UCI Infectious Disease Professor, Dr. Susan Huang, from 2017–2019. Over the same time period, CalOptima data showed a 61% reduction in inpatient hospital costs for infection in patients from the same 16 SNFs. The combination of achievements has gained strong endorsement from the Centers for Disease Control and Prevention (CDC).

Over the past six months, the CDC has been funding CalOptima's PIPQI trainer from University of California, Irvine, since the CDC has been fully engaged and supportive of the PIPQI program at CalOptima. Dr. John Jernigan, the Director of the Office of Healthcare-Associated Infections Prevention Research and Evaluation of the CDC's Division of Healthcare Quality Promotion, and his team have been following CalOptima's progress since the PIPQI program recently put the Plan on the national radar as the only county in the U.S. attempting such infection prevention.

Compliance from the current 24 participating contracted SNFs has been managed by tracking product invoices for Chlorhexidine (CHG) and Iodophor along with Hospital Acquired Infection (HAI) rates, which is ongoing. Added funding was recently requested in order to expand the program to include more SNFs and to retain two of CalOptima's Long Term Services and Supports (LTSS) nurses as full-time compliance officers, promoters, and trainers. Furthermore, the funding is currently available to provide quarterly financial incentives to the participating facilities with proven program adherence. The initial plan was to add random CHG skin testing in order to qualify for a $7,500 quarterly incentive for each facility. At its April 2, 2020, meeting, the Board approved allocation of Intergovernmental Transfer

(IGT) 9 funds for certain initiatives. Included in this approval was $3.4 million in additional funding over a three (3) year period for the expansion of the PIPQI.

However, due to the current COVID-19 precautions and social distancing requirements, CalOptima's LTSS nurses are currently performing their functions remotely since entrance to SNFs has been curtailed in the interest of patient safety. CalOptima's LTSS nurses are also not currently allowed access to the facilities to collect CHG skin testing samples; nevertheless, our belief is that participating contracted SNF partners are continuing to perform infection control and have been successful in preventing a large outbreak of COVID-19, with the extra burden of PPE costs and personnel overtime. Under these extraordinary circumstances it is important to note that CHG's anti-viral, anti-bacterial, and anti-fungal properties have been emphasized to all the facility medical directors.

In view of the temporary constraints that preclude skin testing in order to qualify for financial incentives, a suspension of the skin testing requirement is proposed for the duration of the national emergency, along with release of the quarterly incentive funds to our participating SNF partners, who are safeguarding the health and safety of a vulnerable population. The CHG skin testing protocol will be re-implemented when safety permits and the national emergency has come to an end.

Fiscal Impact

The recommended action to temporarily modify the PIPQI by suspending skin testing requirements during the Coronavirus Disease pandemic and early disbursement of quarterly payments to qualifying SNFs has no additional fiscal impact to CalOptima's operating budget. Staff anticipates that IGT 9 revenue from the State will be sufficient to cover the expenditures for the PIPQI.

Rationale for Recommendation

The recommended actions will support CalOptima's efforts to continue providing quality healthcare to our members residing at SNFs during the COVID-19 public health crisis and allow CalOptima to continue its robust partnership with participating SNFs after the current pandemic.

Concurrence

Gary Crockett, Chief Counsel

Attachments

1. Board Action dated June 6, 2019, Consider Approval of Quality Initiative Related to Post-Acute Infection Prevention and Authorization of Related Funding for Quality Initiative Payments
2. Board Action dated April 2, 2020, Consider Approval of Allocation of Intergovernmental Transfer (IGT) 9 Funds
3. PIPQI Presentation

/s/ Richard Sanchez — *04/10/2020*

Authorized Signature — **Date**

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken June 6, 2019
Regular Meeting of the CalOptima Board of Directors

Report Item

33. Consider Approval of Quality Initiative Related to Post-Acute Infection Prevention and Authorization of Related Funding for Quality Initiative Payments

Contact

David Ramirez, M.D., Chief Medical Officer, (714) 246-8400
Emily Fonda, M.D., MMM, CHCQM, Medical Director, (714) 246-8400
Ladan Khamseh, Chief Operating Officer, (714) 246-8400

Recommended Actions

1. Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
2. Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

Background

The Centers for Disease Control and Prevention (CDC) and the University of California-Irvine (UCI) recently collaborated on an extensive study in 2017 through 2019 to suppress the spread of Multi-Drug-Resistant Organisms (MDRO) in Skilled Nursing Facilities (SNFs) across Orange County. The ambitious study also garnered the support of the California Department of Public Health as well as the Orange County Health Care Agency. This regional collaborative established a structured "…decolonization strategy to reduce the transmission of MDROs both countywide and within healthcare facilities." The name of the collaborative is SHIELD OC.

SHIELD OC is comprised of intervention protocols for both hospitals and nursing homes. There were 16 Orange County SNFs contracted with CalOptima that participated through to the conclusion of the study.

The study was focused on MDRO decolonization through "…the use of topical products to reduce bacteria on the body that can produce harmful infections." In SNFs, the study protocol involved the implementation of two interventions: (1) the consistent use of Chlorhexidine (CHG) antiseptic soap for routine bathing and showering of residents, and (2) the scheduled use of povidone-iodine nasal swabs on residents.

The preliminary study outcomes were very promising and gained the close attention of CDC senior leadership, who have reached out to CalOptima regarding the project on more than one occasion. Long term care (LTC) residents in facilities following the study protocol showed markedly lower rates of MDRO colonization, which translated into lower rates of hospital admissions and lower utilization costs for CalOptima members. The implications of the study, as well as the innovative regional collaboration model, have also garnered the interest of the press. News regarding the collaborative recently aired on National Public Radio and appeared in *USA Today* articles. The lead author in the study, Dr. Susan Huang, was also recently interviewed in a local news radio segment on KNX 1070.

Back to Agenda Back to Item

The study concluded on May 2, 2019. At the SHIELD OC Wrap Up Event, concerns were expressed by facility participants as well as the CDC that the end of the project funding would prevent the SNFs in the study from continuing the study protocol efforts. Without continuation of the interventions, the momentum of the efforts by the participating SNFs would be interrupted, and the considerable gains made in regional decolonization could potentially be unraveled. While the responsibility of infection prevention in post-acute settings is not solely the responsibility of CalOptima, the extensive project has provided significant safety and health benefits to CalOptima members who reside in these facilities. After the conclusion of the study, the collaborative will face an absence of funding and direction. This presents an opportunity for CalOptima to take a leadership role in supporting the care delivery system by offering value-based quality incentives to facilities that follow evidence-based patient safety practices in the institutionalized population segment which are congruent with CalOptima's mission as well as the National Quality Assurance Committee (NCQA) Population Health Management Standards of Delivery System Support.

Discussion

As proposed, the Post-Acute Infection Prevention Quality Initiative will provide an avenue through which CalOptima can incentivize SNFs to provide the study protocol interventions. The study protocols have been recognized to meaningfully suppress the spread of MDROs and will support the safety and health of CalOptima members receiving skilled interventions at or residing in SNFs. Implementation of the quality initiative is in line with CalOptima's commitment to continuous quality improvement.

The initiative would be comprised of two separate phases. Summarily, in Phase I, CalOptima-contracted SNFs in Orange County could initiate a commitment to implementing the study protocol and CalOptima would respond by providing funding to the facility for setup and protocol training. For each participating SNF, Phase I would last for two quarters. In Phase II of the quality initiative, after the SNF has been trained and can demonstrate successful adoption of the protocol, each SNF would be required to demonstrate consistent adherence to the study protocol as well as meet defined quality measures in order to be eligible to continue receiving the quality initiative payments on a retrospective quarterly basis.

Phase I

CalOptima to provide quality initiative funding to SNFs demonstrating a commitment to implementing the SHIELD OC study protocol. The quality initiative is intended to support start up and training for implementation of the protocols not currently in standard use in SNFs but, as per the SHIELD OC study, have been demonstrated to effectively suppress the spread of MDROs.

Contracted SNFs in Orange County must complete an Intent to Implement MDRO Suppression form, signed by both its Administrator and Director of Nursing.

CalOptima will then initiate payment for the first quarter of setting up and training. Payment will be based on an average expected usage cost per resident, to be determined by CalOptima for application across all participating facilities, so the amount of payment for each facility will be dependent on its size. These payments are intended to incentivize the facilities to meet the protocol requirements. The facility must demonstrate use of the supplies and the appropriate

application of the study protocol to the assigned CalOptima staff to qualify for the second quarterly Phase I payment.

The following supplies are required of the facility:

- 4% Chlorohexidine Soap
- 10% Iodine Swab Sticks

The following activities will be required of the facility:

- Proof of appropriate product usage.
- Acceptance of training and monitoring of infection prevention protocol by CalOptima and/or CDC/UCI staff.
- Evidence the decolonization program handouts are in admission packets.
- Monitoring and documentation of compliance with CHG bathing.
- Monitoring and documentation of compliance with iodophor nasal swab.
- Documentation of three peer-to-peer bathing skills assessments per month.

Phase II

CalOptima will provide retrospective quality initiative payments on a quarterly basis for facilities that completed Phase I and meet Phase II criteria outlined below. The amount of each Phase II facility payment will reflect the methodology used in Phase I, accounting for facility size at the average expected usage cost. These payments are intended to support facilities in sustaining the quality practices they adopted during Phase I to suppress MDRO infections.

To qualify for Phase II quality initiative payments, the participating facility must continue demonstrating adherence to the study protocol through the requirements as outlined above for Phase I.

In addition, the facility must also meet minimum quality measures representative of effective decolonization and infection prevention efforts, to be further defined with the guidance of the UCI and CDC project leads. The facilities in Phase II of the initiative must meet these measures each quarter to be eligible for retrospective payment.

The 16 SNFs that participated in SHIELD OC would be eligible for Phase II of the quality initiative at implementation of this quality initiative since they have already been trained in the project and demonstrated adherence to the study protocol. Other contracted SNFs in Orange County not previously in SHILED OC and beginning participation in the quality initiative would be eligible for Phase I.

The proposed implementation of the quality initiative is Q3 2019.

Fiscal Impact

The recommended action to implement a Post-Acute Infection Prevention Quality Initiative program and make payments to qualifying SMFs, beginning in FY 2019-20 to CalOptima-contracted SNFs in Orange County is projected to cost up to and not to exceed $2.3 million annually. Management plans to include projected expenses associated with the quality initiative in the upcoming CalOptima FY 2019-20 Operating Budget.

Rationale for Recommendation

The quality initiative presents an avenue for CalOptima to actively support an innovative regional collaborative of high visibility that has been widely recognized to support the safety and health of individuals receiving care in SNFs.

Concurrence

Gary Crockett, Chief Counsel

Attachment

1. PowerPoint Presentation
2. SHIELD OC Flyer
3. Letter of Support

/s/ Michael Schrader *5/29/2019*
Authorized Signature **Date**

Post-Acute Infection Prevention Quality Initiative

Regular Meeting of the Board of Directors

June 6, 2019

Dr. Emily Fonda, MD, MMM, CHCQM

Medical Director

Care Management, Long-Term Services and Supports and Senior Programs

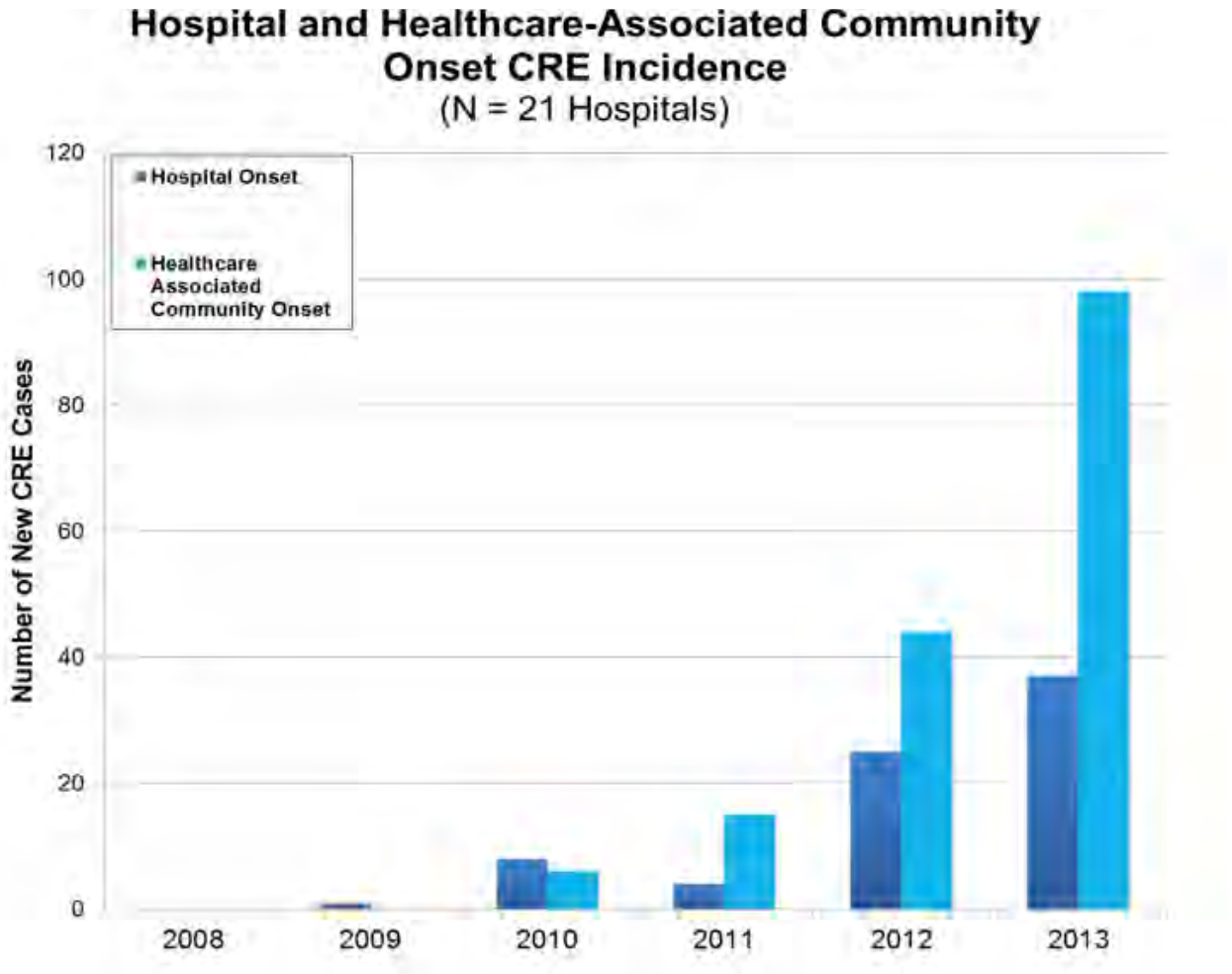
Background

- Efforts to lower hospitalization rates from long-term care (LTC) placed us in contact with Dr. Huang and her study
  - Through the Long-Term Services and Supports (LTSS) Quality Improvement Subcommittee
- Susan Huang, MD, MPH, Professor, Division of Infectious Diseases at U.C. Irvine — lead investigator for Project SHIELD Orange County (OC)
  - 36 facility decolonization intervention protocol supported by the Center for Disease Control and Prevention (CDC)
  - 16 of those facilities are CalOptima-contracted skilled nursing facilities
- Early results at wrap-up event on 1/30/19 ➔ overall 25 percent lower colonization rate of multidrug resistant organisms in OC skilled nursing facilities

Background

- Rise of Multi-Drug Resistant Organisms (MDROs)
  - Methicillin Resistant *Staphylococcus aureus* (MRSA)
  - Vancomycin Resistant Enterococcus (VRE)
  - Multi-Drug Resistant Pseudomonas
  - Multi-Drug Resistant Acinetobacter
  - Extended Spectrum Beta Lactamase Producers (ESBLs)
  - Carbapenem Resistant Enterobacteriaceae (CRE)
  - Hypervirulent KPC (NDM)
  - *Candida auris*
- **10–15%of hospital patients harbor at least one of the above**
- **65% of nursing home residents harbor at least one of the above**

CRE Trends in Orange County, CA



Gohil S. AJIC 2017; 45:1177-82

CDC Interest

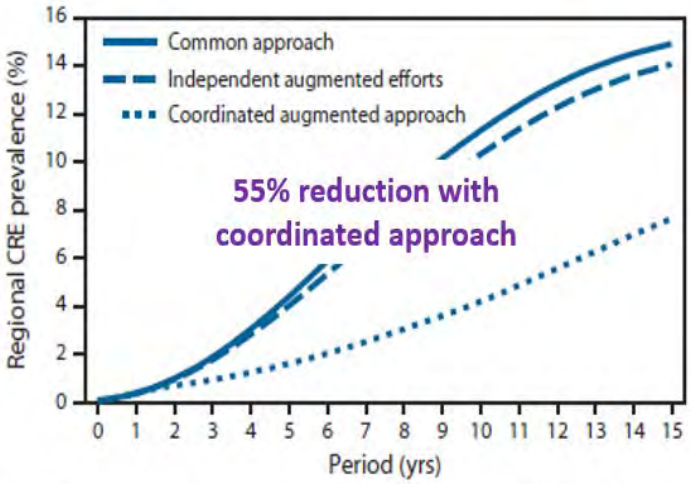
Orange County has historically had one of the highest carbapenem-resistant enterobacteriaceae (CRE) rates in California according to the OC Health Care Agency

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 64
August 4, 2015

Vital Signs: Estimated Effects of a Coordinated Approach for Action to Reduce Antibiotic-Resistant Infections in Health Care Facilities — United States

Rachel B. Slayton, PhD[1]; Damon Toth, PhD[2]; Bruce Y. Lee, MD[3]; Windy Tanner, PhD[2]; Sarah M. Bartsch, MPH[3]; Karim Khader, PhD[2]; Kim Wong, PhD[4]; Kevin Brown, PhD[2]; James A. McKinnell, MD[5]; William Ray[2]; Loren G. Miller, MD[6]; Michael Rubin, MD, PhD[2]; Diane S. Kim[7]; Fred Adler, PhD[8]; Chenghua Cao, MPH[7]; Lacey Avery, MA[1]; Nathan T.B. Stone, PhD[8]; Alexander Kallen, MD[1]; Matthew Samore, MD[2]; Susan S. Huang, MD[7]; Scott Fridkin, MD[1]; John A. Jernigan, MD[1]

FIGURE 3. Projected countywide prevalence of carbapenem-resistant *Enterobacteriaceae* (CRE) over a 15-year period under three different intervention scenarios — 102-facility model, Orange County, California*

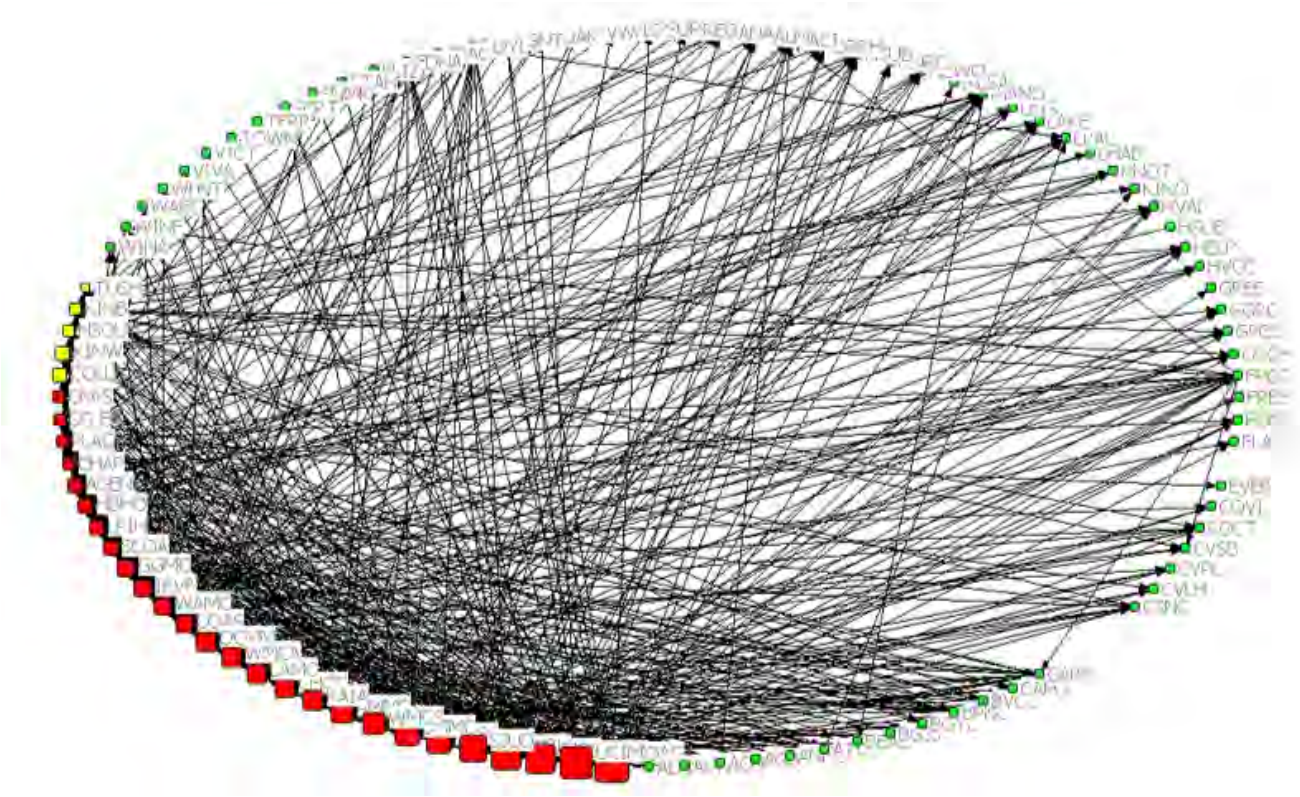


* Additional information available at http://www.cdc.gov/drugresistance/resources/publications.html.

Extent of the Problem

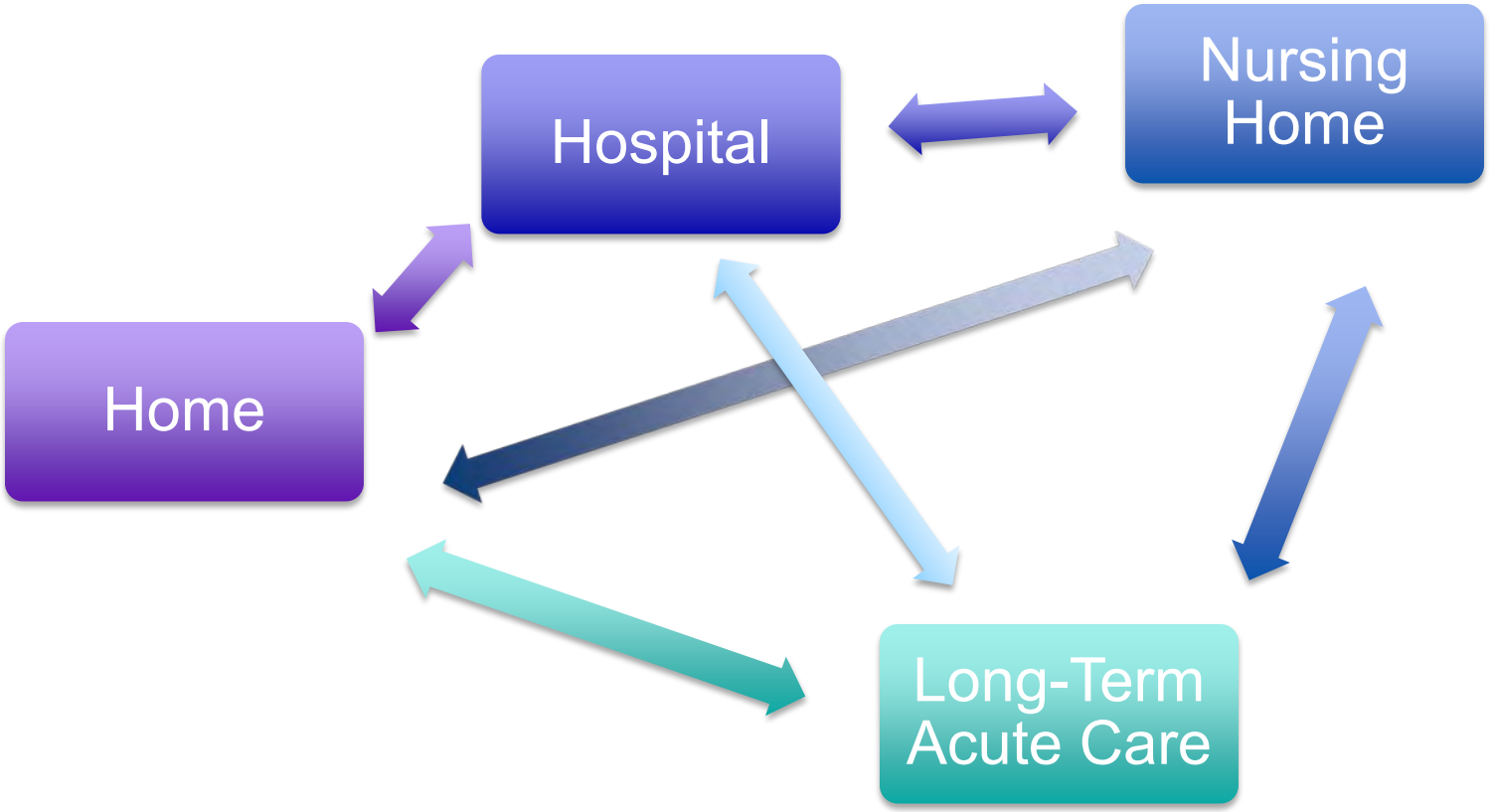
OC Hospitals and Nursing Homes

10 patients shared



Lee BY et al. Plos ONE. 2011;6(12):e29342

Extent of the Problem



Baseline MDRO Prevalence — 16 Nursing Homes

	N	Any MDRO	MRSA	VRE	ESBL	CRE
Nares	900	28%	28%	-	-	-
Axilla/Groin	900	47%	30%	10%	22%	1%
Peri-Rectal	900	52%	25%	15%	31%	1%
All Body Sites	**900**	**64%**	**42%**	**16%**	**34%**	**2%**

- 64% MDRO carriers, facility range 44–88%
- Among MDRO pathogens detected, only 14% known to facility
- Among all residents, 59% harbored ≥1 MDRO unknown to facility

Participating Health Care Facilities

16 Nursing Homes Contracted with CalOptima

- Alamitos West Health Care Center
- Anaheim Healthcare Center
- Beachside Nursing Center
- Crystal Cove Care Center
- French Park Care Center
- Garden Park Care Center
- Healthcare Center of Orange County
- Laguna Hills Health and Rehab Center
- Lake Forest Nursing Center
- Mesa Verde Post Acute Care Center
- New Orange Hills
- Orange Healthcare & Wellness Centre
- Regents Point – Windcrest
- Seal Beach Health and Rehab Center
- Town and Country Manor
- Victoria Healthcare and Rehab Center

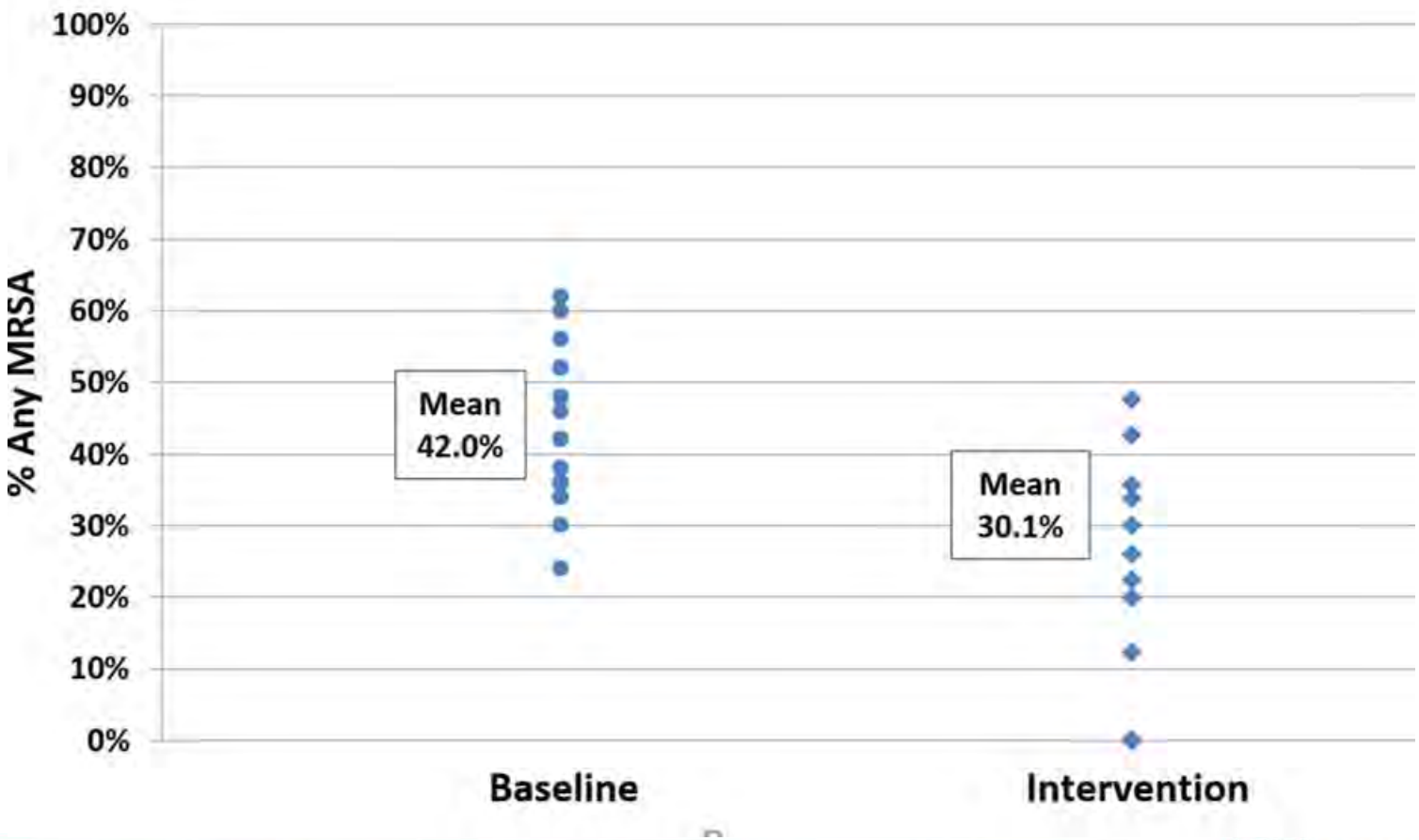
SHIELD OC Decolonization Protocol

- Nursing Homes: Decolonize All Patients
  - Replaced regular soap with chlorhexidine (CHG) antiseptic soap
  - CHG on admit and for all routine bathing/showering
  - Nasal iodophor on admit and every other week
    - https://www.cdc.gov/hai/research/cdc-mdro-project.html
- Following initial testing and training
  - Intervention timeline (22 months) July 1, 2017–May 2, 2019
- Outcome: MDRO Prevalence
  - MRSA, VRE, ESBL, CRE and any MDRO
  - By body site
    - Nasal product reduces MRSA
    - CHG bathing reduces skin carriage

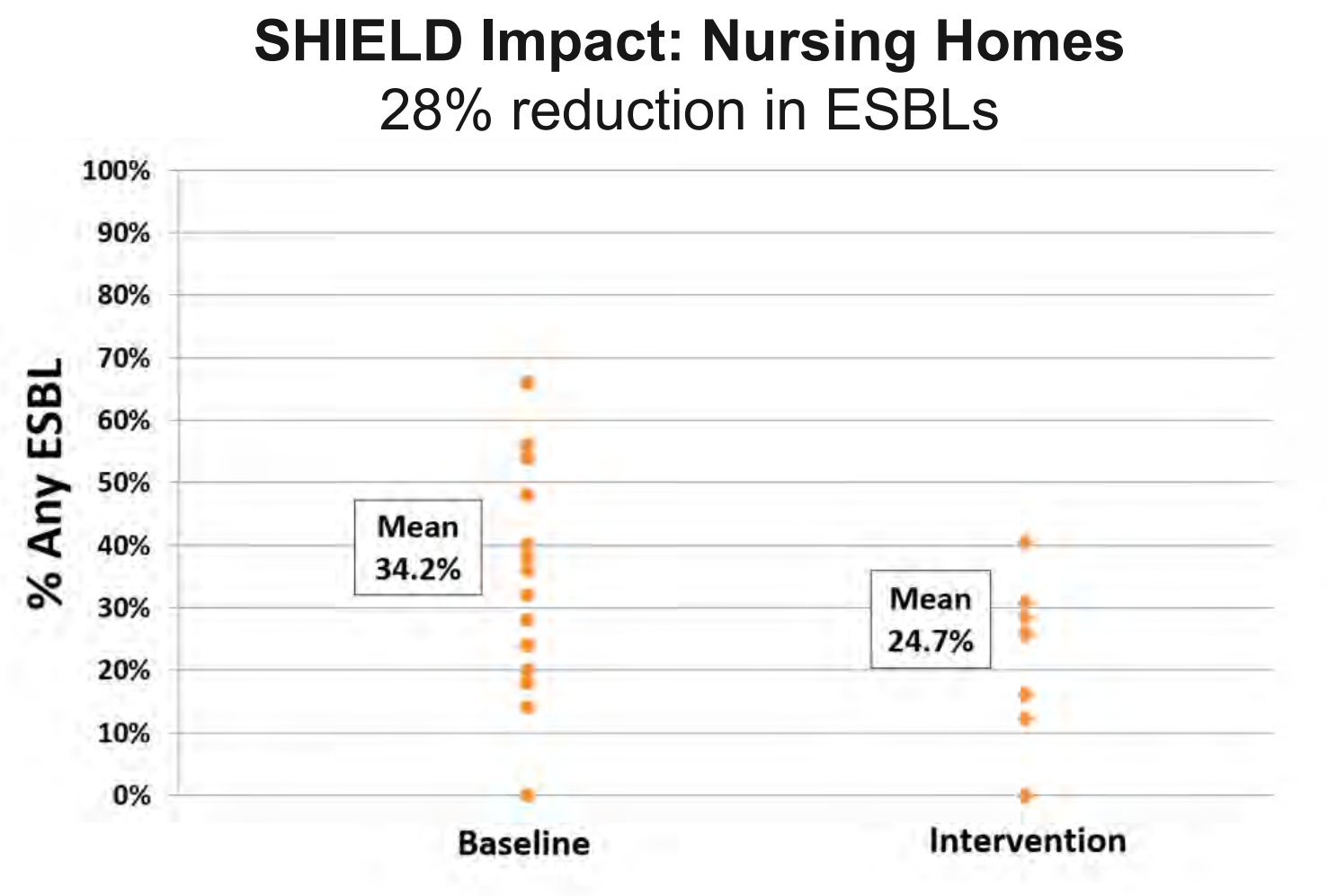
SHIELD Outcomes

SHIELD Impact: Nursing Homes

28% reduction in MRSA



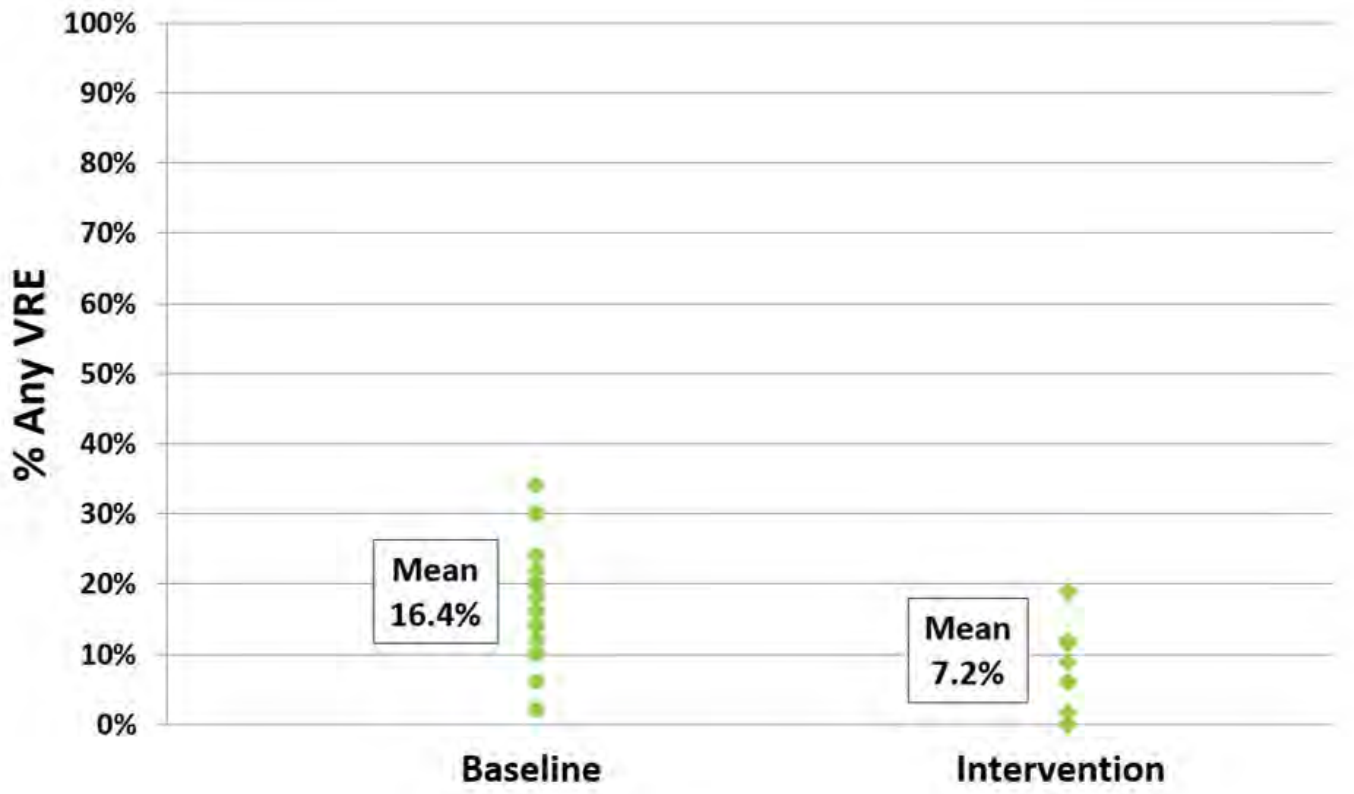
SHIELD Outcomes (cont)



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

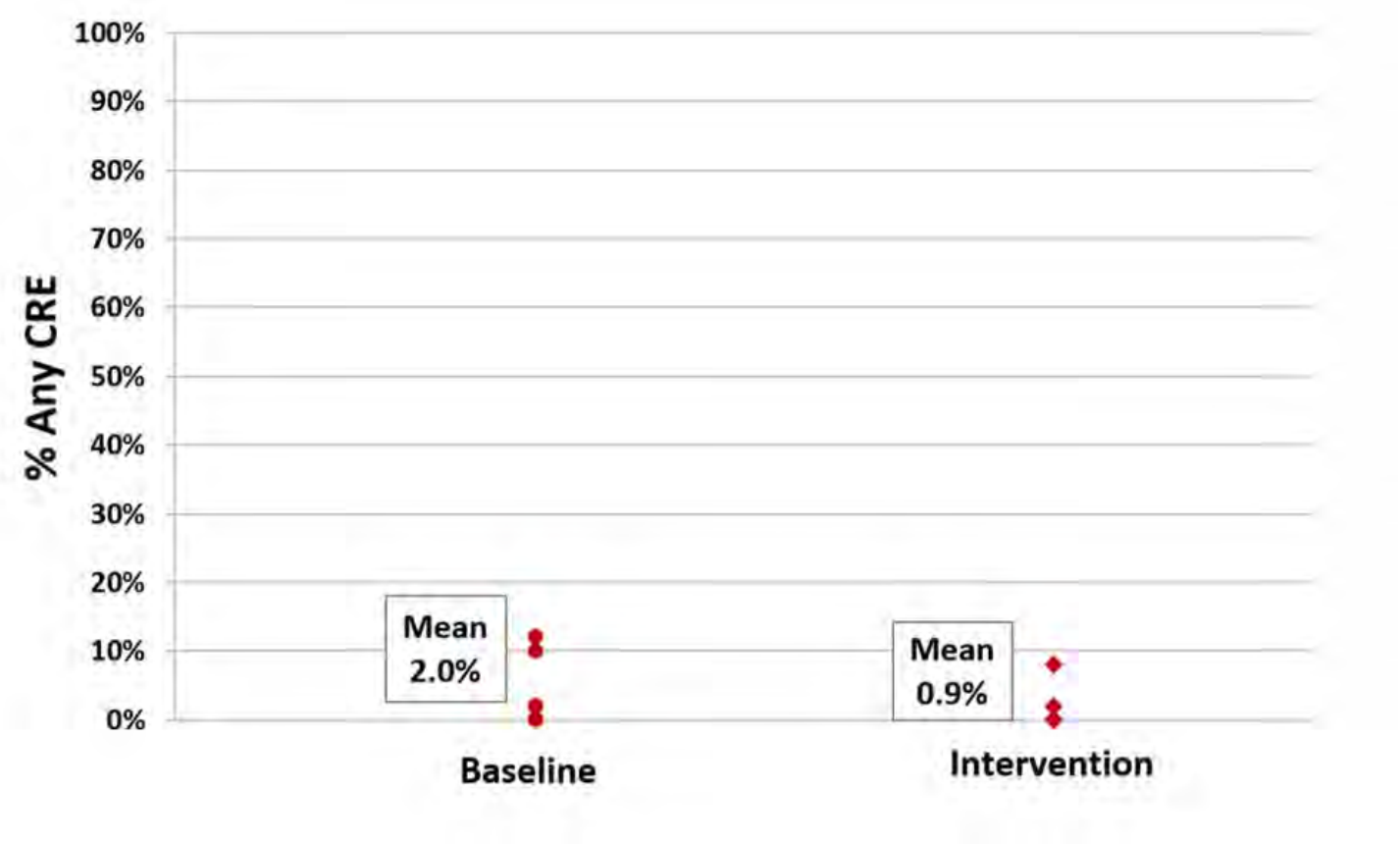
56% reduction in VRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

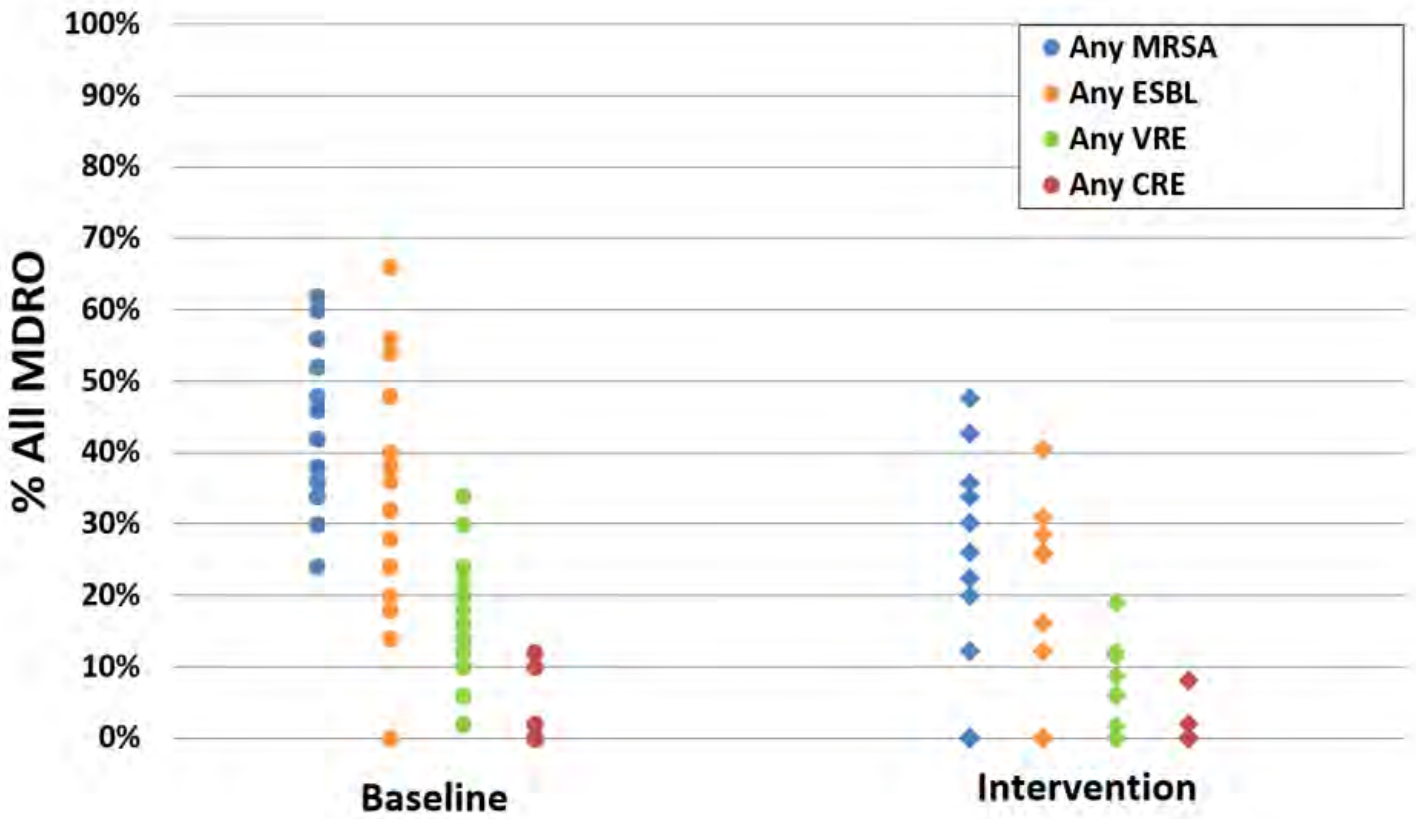
55% reduction in CRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

25% reduction in all MDROs



Quarterly Inpatient Trends

SHIELD OC Project: Quarterly Inpatient Trends

LTC Facility County: ORANGE

From: 2015-10 To: 2018-12

Category P - Primary Diagnosis

Select Year-Month Begin	Select Year-Month End	Select Category P Diagnosis Level	Select Risk Group *	Select LTC Facility County
2015-10	2018-12	Category P - Primary Diagnosis	Multiple values	ORANGE

		Before SHIELD OC						During SHIELD OC						
		2015 Q4	2016 Q1	2016 Q2	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2	2018 Q3	2018 Q4
CONTROL	Admission Count	47	61	60	51	56	65	60	49	36	46	59	48	47
	Bed Day Ct	336	383	536	383	561	570	390	376	296	377	401	456	398
	Paid Amt	$682,769	$854,676	$1,159,922	$920,317	$1,691,337	$1,231,903	$997,810	$1,236,197	$634,628	$979,762	$1,113,238	$1,176,910	$1,024,854
	Avg Mbrs	3,064	2,964	2,901	2,945	2,994	3,033	3,035	3,074	3,116	3,105	3,088	3,102	3,085
SHIELD OC	Admission Count	10	10	9	11	12	9	8	5	3	4	7	3	1
	Bed Day Ct	54	84	66	90	98	60	59	49	12	30	46	11	2
	Paid Amt	$133,362	$311,661	$124,676	$189,669	$227,224	$209,419	$175,738	$164,181	$40,354	$84,565	$127,609	$41,123	$10,177
	Avg Mbrs	590	564	564	580	576	567	581	606	625	632	641	663	652

* Risk Groups Selected: CCN - MC CCN OCC COD Admin OneCare Shared Risk - MC Shared Risk - OCC

Average member count includes all Risk Groups

Admission counts and costs significantly lower in the SHIELD OC group

Quarterly Inpatient Trends

- 16 contracted facilities utilizing the CHG program:
  - Inpatient costs for infection for 6 quarters prior to the Chlorhexidine protocol = $1,196,011
  - Inpatient costs for the last 6 quarters following training and use of CHG protocol = $468,009
    - $728,002 lowered inpatient expenditure (61%) for infection in the participating facilities

- 51 contracted facilities not utilizing the CHG program:
  - Inpatient costs for the last 6 quarters =$6,165,589
  - Potential 61% lowered inpatient expenditure for infection = $3,761,009 if the CHG protocol had been expanded

SHIELD Impact on CalOptima

- Adoption of the SHIELD protocol is well-supported by the Center for Disease Control
  - Plan for extended use of an existing trainer in OC for one year
  - Plan for extended monitoring of Orange County MDROs for one year
- 25% decrease in MDRO prevalence translates to the following for CalOptima's LTC population of 3,800 members as of December 2018:
  - Decreased infection-related hospitalizations
  - An opportunity for a significant advancement in population health management
  - Practice transformation for skilled nursing facilities in fulfillment of National Committee for Quality Assurance (NCQA) requirements
  - Continuation of cost savings

CalOptima Post-Acute Infection Prevention Quality Initiative

- Adoption of the SHIELD protocol in all 67 CalOptima post-acute contracted facilities (long-term care and subacute facilities) will:
  - Support the continuation of care in the 16 participating facilities as Phase 2 without loss of momentum
  - Initiate the chlorhexidine bathing protocol in the remaining facilities as Phase 1 utilizing the CDC-supported trainer
  - Require quarterly reporting and fulfillment of quality measures with payments proportional to compliance
  - Include a trainer provided by the CDC for one year
  - Train current CalOptima LTSS nurses to quantify best practices and oversee compliance
  - Provide consideration around adding this patient safety initiative as a Pay 4 Value (P4V) opportunity to the next quality plan

Recommended Actions

- Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
- Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner


A Public Agency
CalOptima
Better. Together.


Medi-Cal
A Public Agency
CalOptima
Better. Together.


OneCare (HMO SNP)
A Public Agency
CalOptima
Better. Together.


OneCare Connect
A Public Agency
CalOptima
Better. Together.


PACE
A Public Agency
CalOptima
Better. Together.

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs in
Orange County

SHIELD Orange County – *Together We Can Make a Difference!*

What is SHIELD Orange County?

SHIELD OC is a public health collaborative initiated by the Centers for Disease Control and Prevention (CDC) to combat the spread of endemic and emerging multi-drug resistant organisms (MDROs) across healthcare facilities in Orange County. This effort is supported by the California Department of Public Health (CDPH) and the Orange County Health Care Agency (OCHCA). This regional collaborative will implement a decolonization strategy to reduce transmission of MDROs both countywide and within healthcare facilities.

Visit our CDC webpage here!
https://www.cdc.gov/hai/research/cdc-mdro-project.html

SHIELD OC Goals:

- Reduce MDRO carriage
- Reduce countywide MDRO clinical cultures
- Assess impact in participants and non-participants

SHIELD OC is coordinated by the University of California Irvine and LA BioMed at Harbor-UCLA.

Who is participating?

38 healthcare facilities are participating in SHIELD OC. These facilities were invited to participate based on their inter-connectedness by patient sharing statistics. In total, participants include 17 hospitals, 3 long-term acute care hospitals (LTACHs), and 18 nursing homes.

What is the decolonization intervention?

In the SHIELD OC collaborative, decolonization refers to the use of topical products to reduce bacteria on the body that can produce harmful infections.

- **Hospitals (for adult patients on contact precautions)**
  - Chlorhexidine (CHG) antiseptic soap for daily bathing or showering
  - Nasal decolonization with 10% povidone-iodine
  - Continue CHG bathing for adult patients in ICU units
- **Nursing homes and LTACHs**
  - Chlorhexidine (CHG) antiseptic soap for routine bathing and showering
  - Nasal decolonization with 10% povidone-iodine on admission and every other week

All treatments used for decolonization are topical and their safety profile is excellent.

With questions, please contact the SHIELD OC Coordinating Team

(949) 824-7806 or SHIELDOrangeCounty@gmail.com

CalOptima Checklist

Nursing Home Name: _____

Month Audited (Month/year): _____/_____

Today's Date: _____/_____/_____

Completed by: _____

- ☐ Proof of product purchase
- ☐ Evidence the decolonization program handout is in admission packet
- ☐ Monitor and document compliance with bathing one day each week
- ☐ Monitor and document compliance with iodophor one day each week iodophor is used
- ☐ Conduct three peer-to-peer bathing skills assessments per month

Product Usage

PRODUCT DESCRIPTION	RECEIPT PROVIDED	QUANTITY DELIVERED	ESTIMATED MONTHLY USAGE
4% CHG Gallons	☐	_____ gallons	_____ gallons
10% Iodine Swabsticks	☐	_____ boxes	_____ boxes
		_____ swabs per box	

INTERNAL USE ONLY –APPROVAL:

Back to Agenda Back to Item

Facility Name: _____Unit: _____ Date: _____

STAFF Skills Assessment:
CHG Bed Bath Observation Checklist

Individual Giving CHG Bath

Please indicate who performed the CHG bath.

☐ **Nursing Assistant (CNA)** ☐ **Nurse** ☐ **LVN** ☐ **Other: _____**

Observed CHG Bathing Practices

Please check the appropriate response for each observation.

☐ **Y** ☐ **N** **Resident received CHG bathing handout**
☐ **Y** ☐ **N** **Resident told that no rinse bath provides protection from germs**
☐ **Y** ☐ **N** **Provided rationale to the resident for not using soap at any time while in unit**
☐ **Y** ☐ **N** **Massaged skin *firmly* with CHG cloth to ensure adequate cleansing**
☐ **Y** ☐ **N** **Cleaned face and neck well**
☐ **Y** ☐ **N** **Cleaned between fingers and toes**
☐ **Y** ☐ **N** **Cleaned between all folds**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned occlusive and semi-permeable dressings with CHG cloth**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned 6 inches of all tubes, central lines, and drains closest to body**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on superficial wounds, rash, and stage 1 & 2 decubitus ulcers**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on surgical wounds (unless primary dressing or packed)**
☐ **Y** ☐ **N** **Allowed CHG to air-dry / does not wipe off CHG**
☐ **Y** ☐ **N** **Disposed of used cloths in trash /does not flush**

Query to Bathing Assistant/Nurse

1. How many cloths were used for the bath?

_____

2. If more than 6 cloths was used, provide reason.

_____

3. Are you comfortable applying CHG to superficial wounds, including surgical wounds?

_____

4. Are you comfortable applying CHG to lines, tubes, drains and non-gauze dressings?

_____

5. Do you ever wipe off the CHG after bathing?

_____

ORIGINAL ARTICLE

Decolonization to Reduce Postdischarge Infection Risk among MRSA Carriers

S.S. Huang, R. Singh, J.A. McKinnell, S. Park, A. Gombosev, S.J. Eells, D.L. Gillen, D. Kim, S. Rashid, R. Macias-Gil, M.A. Bolaris, T. Tjoa, C. Cao, S.S. Hong, J. Lequieu, E. Cui, J. Chang, J. He, K. Evans, E. Peterson, G. Simpson, P. Robinson, C. Choi, C.C. Bailey, Jr., J.D. Leo, A. Amin, D. Goldmann, J.A. Jernigan, R. Platt, E. Septimus, R.A. Weinstein, M.K. Hayden, and L.G. Miller, for the Project CLEAR Trial

ABSTRACT

BACKGROUND

Hospitalized patients who are colonized with methicillin-resistant *Staphylococcus aureus* (MRSA) are at high risk for infection after discharge.

METHODS

We conducted a multicenter, randomized, controlled trial of postdischarge hygiene education, as compared with education plus decolonization, in patients colonized with MRSA (carriers). Decolonization involved chlorhexidine mouthwash, baths or showers with chlorhexidine, and nasal mupirocin for 5 days twice per month for 6 months. Participants were followed for 1 year. The primary outcome was MRSA infection as defined according to Centers for Disease Control and Prevention (CDC) criteria. Secondary outcomes included MRSA infection determined on the basis of clinical judgment, infection from any cause, and infection-related hospitalization. All analyses were performed with the use of proportional-hazards models in the per-protocol population (all participants who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization) and as-treated population (participants stratified according to adherence).

RESULTS

In the per-protocol population, MRSA infection occurred in 98 of 1063 participants (9.2%) in the education group and in 67 of 1058 (6.3%) in the decolonization group; 84.8% of the MRSA infections led to hospitalization. Infection from any cause occurred in 23.7% of the participants in the education group and 19.6% of those in the decolonization group; 85.8% of the infections led to hospitalization. The hazard of MRSA infection was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03; number needed to treat to prevent one infection, 30; 95% CI, 18 to 230); this lower hazard led to a lower risk of hospitalization due to MRSA infection (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The decolonization group had lower likelihoods of clinically judged infection from any cause (hazard ratio, 0.83; 95% CI, 0.70 to 0.99) and infection-related hospitalization (hazard ratio, 0.76; 95% CI, 0.62 to 0.93); treatment effects for secondary outcomes should be interpreted with caution owing to a lack of prespecified adjustment for multiple comparisons. In as-treated analyses, participants in the decolonization group who adhered fully to the regimen had 44% fewer MRSA infections than the education group (hazard ratio, 0.56; 95% CI, 0.36 to 0.86) and had 40% fewer infections from any cause (hazard ratio, 0.60; 95% CI, 0.46 to 0.78). Side effects (all mild) occurred in 4.2% of the participants.

CONCLUSIONS

Postdischarge MRSA decolonization with chlorhexidine and mupirocin led to a 30% lower risk of MRSA infection than education alone. (Funded by the AHRQ Healthcare-Associated Infections Program and others; ClinicalTrials.gov number, NCT01209234.)

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N Engl J Med 2019;380:638-50.
DOI: 10.1056/NEJMoa1716771

Methicillin-resistant *Staphylococcus aureus* (MRSA) causes more than 80,000 invasive infections in the United States annually.[1] It is the most common cause of skin, soft-tissue, and procedure-related infections.[2] Rates of invasive MRSA infection are highest within 6 months after hospital discharge and do not normalize for 1 year.[1,3,4]

Approaches to MRSA have included education about both hygiene and environmental cleaning as well as decolonization with nasal mupirocin and chlorhexidine antiseptic baths to reduce carriage and prevent infection.[5,6] Decolonization has reduced the risks of surgical-site infection, recurrent skin infection, and infection in the intensive care unit (ICU).[7-10] Our goal was to evaluate whether, after hospital discharge, decolonization plus hygiene education was superior to education alone in reducing the likelihood of MRSA infection among patients colonized with MRSA (carriers).

Methods

Trial Design and Intervention

We conducted the Project CLEAR (Changing Lives by Eradicating Antibiotic Resistance) Trial as a multicenter, two-group, unblinded, randomized, controlled trial to compare the effect of hygiene education with that of education plus decolonization on the likelihood of postdischarge infection among MRSA carriers. This trial was approved by the institutional review board of the University of California Irvine. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol, available with the full text of this article at NEJM.org.

Participants were randomly assigned, in a 1:1 ratio, to the education group or the decolonization group. Randomization was performed with a randomized block design stratified according to Hispanic ethnic group and nursing home residence. In the education group, participants received and reviewed an educational binder (provided in English and Spanish) about MRSA and how it is spread and about recommendations for personal hygiene, laundry, and household cleaning (Appendix A in the Supplementary Appendix, available at NEJM.org). In the decolonization group, participants received and reviewed the identical educational binder and also underwent decolonization for 5 days twice monthly for a period of 6 months after hospital discharge (Appendix B in the Supplementary Appendix). The decolonization intervention involved the use of 4% rinse-off chlorhexidine for daily bathing or showering, 0.12% chlorhexidine mouthwash twice daily, and 2% nasal mupirocin twice daily. All products were purchased with grant funds and were provided free of charge to the participants.

Recruitment and Eligibility Criteria

Recruitment involved written informed consent provided between January 10, 2011, and January 2, 2014, during inpatient admissions in 17 hospitals and 7 nursing homes in Southern California (Table S1 in the Supplementary Appendix). Eligibility requirements included an age of 18 years or older, hospitalization within the previous 30 days, positive testing for MRSA during the enrollment hospitalization or within the 30 days before or afterward, and the ability to bathe or shower (alone or assisted by a caregiver). Key exclusion criteria were hospice care and allergy to the decolonization products at recruitment. California mandates MRSA screening at hospital admission in high-risk patients: those undergoing hemodialysis, those who had a recent hospitalization (within the preceding 30 days), those who were undergoing imminent surgery, those who were admitted to the ICU, and those who were transferred from a nursing home.

Follow-up

Participants were followed for 12 months after discharge. In-person visits at home or in a research clinic occurred at recruitment and at months 1, 3, 6, and 9. An exit interview was conducted at 12 months. The trial had a fixed end date of June 30, 2014. Participants who were enrolled after July 1, 2013, had a truncated follow-up and had their data administratively censored at that time. Loss to follow-up was defined as the inability of trial staff to contact participants for 3 months, at which point the participant was removed from the trial as of the date of last contact. Participants received escalating compensation for completing follow-up visits ($25, $30, $35, and $50).

All participants were contacted monthly and requested to report any hospitalizations or clinic visits for infection. After trial closure, medical records from reported visits were requested, double-redacted for protected health information and trial-group assignment, and reviewed for trial outcomes. Records from enrollment hospi-

talizations were requested and reviewed for characteristics of the participants and the presence or absence of MRSA infection at the enrollment hospitalization. Records were requested up to five times, with five additional attempts to address incomplete records.

TRIAL OUTCOMES

Redacted medical records from enrollment hospitalizations and all reported subsequent medical visits were reviewed in a blinded fashion, with the use of standardized forms, by two physicians with expertise in infectious diseases (five of the authors) for coexisting conditions, antibiotic agents, and infection outcomes. If consensus was not reached, discordant outcomes were adjudicated by a third physician with expertise in infectious diseases.

The primary outcome was MRSA infection according to medical-record documentation of disease-specific infection criteria (according to 2013 guidelines) from the Centers for Disease Control and Prevention (CDC) in a time-to-event analysis.[11] A priori secondary outcomes included MRSA infection defined in a time-to-event analysis according to the clinical judgment of two reviewers with expertise in infectious diseases who were unaware of the trial-group assignments, infection from any cause according to disease-specific CDC criteria in a time-to-event analysis, infection from any cause according to infectious disease clinical judgment in a time-to-event analysis, hospitalization due to infection, and new carriage of a MRSA strain that was resistant to mupirocin (evaluated by Etest, bioMérieux)[12] or that had an elevated minimum inhibitory concentration (MIC) of chlorhexidine (≥8 μg per milliliter) on microbroth dilution.[13,14] All outcomes were assessed on the basis of the first event per participant.

DATA COLLECTION

Surveys of health conditions, health care utilization, and household cleaning and bathing habits were administered during recruitment and all follow-up visits. Swabs of both nares, the throat, skin (axilla and groin), and any wounds were taken, but the results are not reported here. At each visit, participants in the decolonization group reported adherence to the intervention, and staff assessed the remaining product. Potential discrepancies were broached with the participant to obtain affirmation of actual adherence. Adherence was assessed as full (no missed doses), partial (some missed doses), and nonadherence (no doses used).

STATISTICAL ANALYSIS

The characteristics of the participants and outcomes were described by frequency and type according to trial group. Outcomes were summarized with the use of Kaplan–Meier estimates of infection-free distributions across the follow-up period and analyzed with the use of unadjusted Cox proportional-hazard models (per-protocol primary analysis) for the postdischarge trial population (all the participants who underwent randomization, met inclusion criteria, and survived beyond the recruitment hospitalization); outcomes were also analyzed according to the as-treated adherence strata (fully adherent, partially adherent, and nonadherent participant-time). In the as-treated analyses, information about participant adherence during at-risk periods before each visit was updated with the use of the adherence assessment at that visit.

The assumption of proportional hazards was assessed by means of residual diagnostic tests and formal hypothesis tests. P values are provided only for the primary outcome. Because the statistical analysis plan did not include a provision for correction for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, those results are reported as point estimates with 95% confidence intervals. The widths of the confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

In post hoc exploratory analyses, we used adjusted Cox proportional-hazard models to address potential residual imbalances in the characteristics of the participants between the two groups after randomization. The characteristics of the participants were entered into the model if they were associated with outcomes at a P value of less than 0.20 in bivariate analyses. Characteristics included demographic data; educational level; insurance type; presence of coexisting conditions, devices, or wounds at enrollment; hospitalization or residence in a nursing home in the year before enrollment; ICU admission or surgery during enrollment hospitalization; need

for assistance with bathing; frequency of bathing; and randomization strata. Adjusted models also accounted for two time-dependent covariates: receipt of anti-MRSA antibiotics and adherence to the intervention. The number needed to treat was calculated with the use of rates that accounted for participant-time that incorporated censoring due to loss to follow-up, withdrawal from the trial, or the end of the trial.[15] Full details of the trial design and analytic approach are provided in the protocol and in the Supplementary Appendix.

RESULTS

PARTICIPANTS

Figure 1 shows the randomization and follow-up of 2140 participants, of whom 19 were excluded after randomization because they did not meet inclusion criteria (6 participants did not have a positive MRSA test, and 13 died during the enrollment hospitalization). The characteristics of the final 2121 enrolled participants (per-protocol population) are provided in Table 1, and in Tables S2 through S4 in the Supplementary Appendix.

According to the randomization strata, Hispanic participants made up 31.9% of the education group (339 participants) and 32.0% of the decolonization group (339), and nursing home residents made up 11.3% of the education group (120) and 11.0% of the decolonization group (116). In a comparison of the education group with the decolonization group across the 1-year follow-up, early exit from the trial occurred in 34.9% of the participants (371 participants) and 37.0% (391), respectively ($P=0.32$); withdrawal from the trial in 6.8% (72) and 11.6% (123), respectively ($P<0.001$); loss to follow-up in 17.4% (185) and 16.1% (170), respectively ($P=0.41$); and death in 10.7% (114) and 9.3% (98), respectively ($P=0.26$). The characteristics of the participants who withdrew from the trial or were lost to follow-up and of the participants in the decolonization group according to adherence category are shown in Table S5 in the Supplementary Appendix.

OUTCOMES

A total of 8395 full-text medical records were requested, and 8067 (96.1%) were received and redacted. Charts underwent duplicate blinded review (16,134 reviews) by physicians with expertise in infectious diseases at a rate of approximately 800 charts per month for 20 months. Of the 2121 enrollment admission records, 2100 (99.0%) were received. Of the 6271 subsequent inpatient and outpatient records, 5967 (95.2%) were received for outcome assessment. The overall rate of reported hospitalizations per 365 days of follow-up was 1.97 in the education group and 1.75 in the decolonization group.

Regarding the primary outcome in the per-protocol analysis, 98 participants (9.2%) in the education group had a MRSA infection, as compared with 67 (6.3%) in the decolonization group (Table 2). This corresponded to an estimated MRSA infection rate in the education group of 0.139 infections per participant-year, as compared with 0.098 infections per participant-year in the decolonization group. Among first MRSA infections per participant, skin and soft-tissue infections and pneumonia were common. Across both groups, 84.8% (140 of 165) of the MRSA infections resulted in hospitalization, at a rate of 0.117 hospitalizations per participant-year in the education group and 0.083 per participant-year in the decolonization group. Bacteremia occurred in 28.5% (47 of 165) of all MRSA infections; the MRSA bacteremia rate was 0.040 events per participant-year in the education group and 0.028 per participant-year in the decolonization group. Findings were similar when MRSA infection was determined according to the clinical judgment of physicians with expertise in infectious diseases and according to CDC criteria (Table 2). All the MRSA infections were treated with an antibiotic, but the receipt of an antibiotic was not sufficient to render a decision of a MRSA infection.

In the analysis of infection from any cause according to CDC criteria, 23.7% of the participants in the education group (252 participants) had an infection, as compared with 19.6% of those in the decolonization group (207), which corresponded to an estimated rate of 0.407 infections per participant-year in the education group and 0.338 per participant-year in the decolonization group (Table 2). Skin and soft-tissue infections and pneumonia remained the most common infection types.

Pathogens were identified in 67.7% of the infections (Table S6 in the Supplementary Appendix). Participants in the decolonization intervention had a lower rate of infections due to gram-positive pathogens or without cultured pathogens than those in the education group. There was a

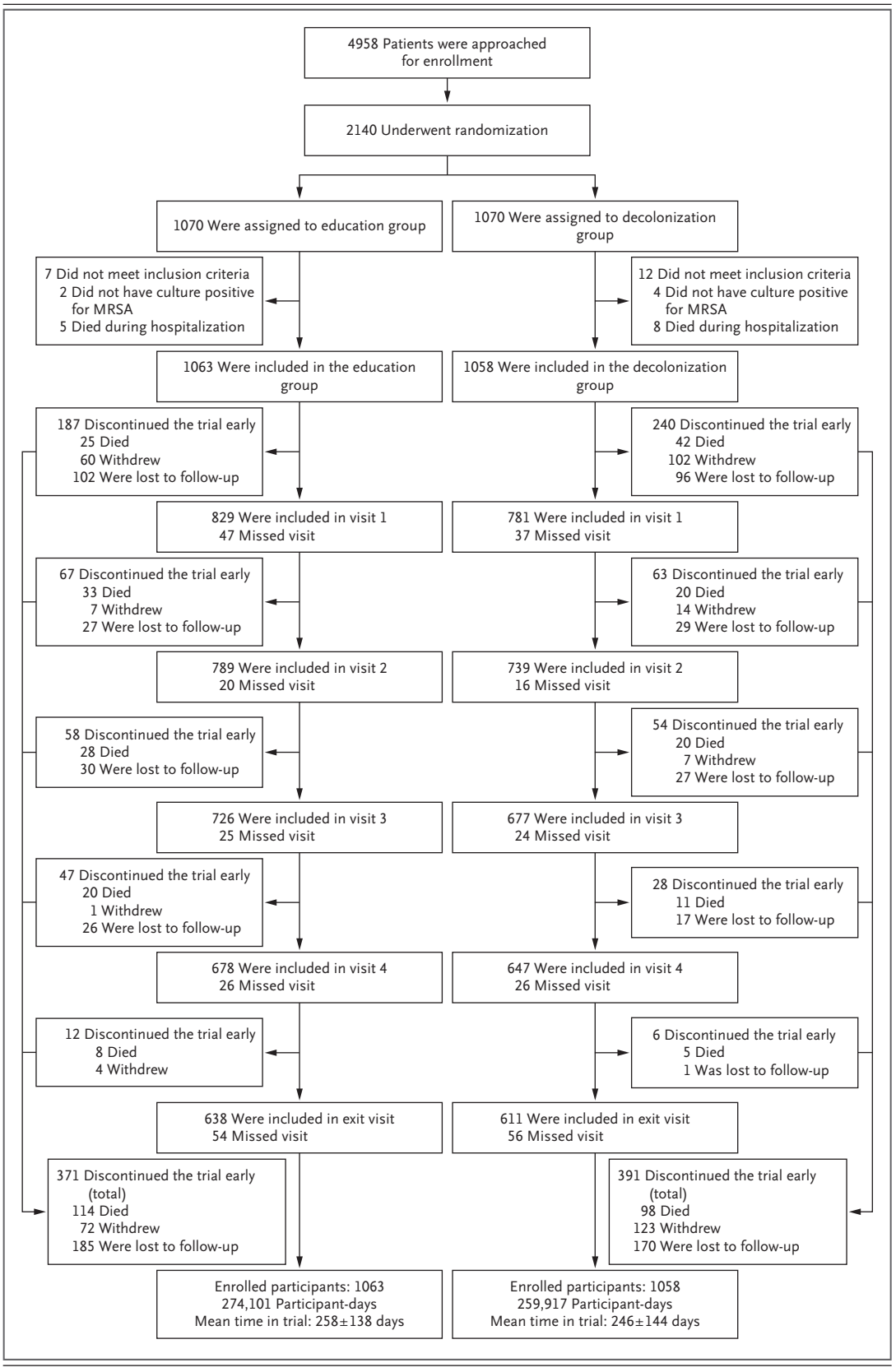

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Figure 1 (facing page). Randomization and Follow-up of the Participants.

This flow chart describes the recruitment and the four follow-up visits (at 1, 3, 6, and 9 months) for the 1-year period after hospital discharge. Recruitment occurred during hospitalization, and 19 participants were excluded from the postdischarge trial population because they did not meet inclusion criteria, leaving 2121 participants in the per-protocol population (1063 participants in the education group and 1058 in the decolonization group). Early exit from the trial was provided between each visit and included active withdrawal from the trial, loss to follow-up, and death. Active withdrawal represented situations in which participants indicated their desire to withdraw from the trial. Loss to follow-up was defined as the inability to contact the participant for 3 months, at which point the participant was removed from the trial at the time of last contact. Visits indicate both participants who successfully completed the visit and those who remained in the trial but missed that visit. The mean (±SD) time in the trial (in days) is shown for each group. All deaths were considered by the investigators to be unrelated to side effects from decolonization products. Summary boxes are provided at the bottom of the figure. MRSA denotes methicillin-resistant *Staphylococcus aureus*.

higher rate of gram-negative infection among the CDC-defined all-cause infections when participants in the decolonization intervention were compared with those in the education group, but this was not seen among clinically defined infections.

Across the two trial groups, infection from any cause led to hospitalization in 85.8% of the participants (394 of 459), and bacteremia occurred in 18.1% (83 of 459). The observed rate of hospitalization due to infection from any cause was 0.356 events per participant-year in the education group and 0.269 per participant-year in the decolonization group. The rate of bacteremia among participants with infection from any cause was 0.074 events per participant-year in the education group and 0.060 per participant-year in the decolonization group. Findings were similar when infection from any cause was determined according to clinical judgment (Table 2).

Estimates of the per-protocol treatment effects are shown in Table 3. No significant departures from proportional hazards were observed. In the main unadjusted analysis, the hazard of MRSA infection according to the CDC criteria (the primary outcome) was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03). This lower hazard of MRSA infection led to a 29% lower risk of hospitalization due to CDC-defined MRSA infection in the decolonization group than in the education group (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The effect was nearly identical for cases and hospitalizations involving clinically defined MRSA infection. Kaplan–Meier curves showing the infection-free time for the primary outcome of CDC-defined MRSA infection and the secondary outcome of infection from any cause show that the curves remained separated even after the intervention ended in month 6 (Fig. 2, and Table S7 in the Supplementary Appendix). Adjusted models showed greater MRSA infection effects that were significant (Table 3). A total of 10 participants (0.9%) in the education group and in 3 (0.3%) in the decolonization group died from MRSA infection. Results of sensitivity analyses conducted regarding death and early withdrawal from the trial are provided in Table S8 in the Supplementary Appendix.

The hazard of infection from any cause according to clinical judgment was lower in the decolonization group than in the education group (hazard ratio, 0.83; 95% CI, 0.70 to 0.99); similarly, the hazard of infection from any cause according to CDC criteria was lower in the decolonization group (hazard ratio, 0.84; 95% CI, 0.70 to 1.01) (Fig. 2B and Table 3). The risk of hospitalization due to infection from any cause was lower in the decolonization group than in the education group (hazard ratio, 0.76; 95% CI, 0.62 to 0.93). The results of the adjusted analyses were similar to those of the unadjusted analyses (Table 3). Deaths due to any infection occurred in 25 participants (2.3%) in the education group and 17 (1.6%) in the decolonization group.

EFFECT OF ADHERENCE

In as-treated analyses, 65.6% of the participant-time in the decolonization group involved full adherence; 19.6%, partial adherence; and 14.8%, nonadherence. Participants were highly consistent in adherence across the follow-up time. Increasing adherence was associated with increasingly lower rates of infection in both the adjusted and unadjusted models (Table 3). In comparisons of the adherence-category subgroups in the decolonization group with the education group overall, the likelihood of CDC-defined MRSA infection decreased 36% and 44%, respectively, as adher-

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Table 1. Characteristics of the Participants at Recruitment Hospitalization.*

Characteristic	Education Group (N=1063)	Decolonization Group (N=1058)	P Value†
Age — yr	56±17	56±17	0.78
Male sex — no. (%)	583 (54.8)	565 (53.4)	0.51
Coexisting conditions‡			
Diabetes — no./total no. (%)	424/1062 (39.9)	462/1056 (43.8)	0.08
Chronic obstructive pulmonary disease — no./total no. (%)	212/1055 (20.1)	203/1045 (19.4)	0.70
Congestive heart failure — no./total no. (%)	145/1055 (13.7)	149/1045 (14.3)	0.73
Cancer — no./total no. (%)	153/1055 (14.5)	161/1045 (15.4)	0.56
Renal disease — no./total no. (%)	140/1062 (13.2)	134/1056 (12.7)	0.74
Charlson Comorbidity Index score§	1.7±1.6	1.7±1.6	0.49
Bathe daily or every other day — no./total no. (%)¶	926/1037 (89.3)	927/1034 (89.7)	0.73
Bathing assistance needed — no./total no. (%)¶	200/1025 (19.5)	224/1013 (22.1)	0.15
MRSA source at enrollment — no. (%)			0.79
Nares‖	580 (54.6)	602 (56.9)	
Wound	320 (30.1)	305 (28.8)	
Respiratory	44 (4.1)	45 (4.3)	
Blood	43 (4.0)	31 (2.9)	
Other	76 (7.1)	75 (7.1)	
Recruitment hospitalization**			
Hospitalized in previous yr — no./total no. (%)‡	595/1046 (56.9)	598/1041 (57.4)	0.80
Nursing home stay in previous yr — no./total no. (%)‡	165/1043 (15.8)	168/1040 (16.2)	0.84
ICU stay — no./total no. (%)	188/1055 (17.8)	206/1045 (19.7)	0.27
Surgery — no./total no. (%)	392/1055 (37.2)	399/1045 (38.2)	0.63
MRSA infection — no./total no. (%)††	447/1055 (42.4)	438/1045 (41.9)	0.83
Wound at hospital discharge — no./total no. (%)	587/1055 (55.6)	588/1045 (56.3)	0.77
Medical device at hospital discharge — no./total no. (%)‡‡	320/1055 (30.3)	307/1045 (29.4)	0.63
Discharged to nursing home — no. (%)	120 (11.3)	116 (11.0)	0.81

* Plus–minus values are means ±SD. There were no significant differences between the two groups. Selected descriptive data are shown. For a full descriptive list of characteristics, see Table S2 in the Supplementary Appendix. ICU denotes intensive care unit.
† Student's t-test was performed for continuous variables, chi-square test for proportions, and Fisher's exact test for proportions if the numerator was 5 or less.
‡ Data reflect a positive response to either a survey question or chart review. Not all participants responded to every question, and not all enrollment charts were received from recruiting hospitals despite a signed release request, so data were missing for 21 participants.
§ Scores on the Charlson Comorbidity Index range from 0 to 10, with higher scores indicating more coexisting illness.
¶ Data reflect respondents to the survey question among all the participants. Not all the participants responded to every question.
‖ By law, California requires hospitals to screen five groups of patients for MRSA on hospital admission (patients who are transferred from a nursing home, who have been hospitalized in the past 30 days, who are undergoing hemodialysis, who are undergoing imminent surgery, and who are admitted to an ICU).
** Data reflect chart review from the received medical records. Not all recruiting hospitals released participants' medical records to the trial despite a signed release request, so records were missing for 21 participants.
†† Assessment of infection was based on criteria of the Centers for Disease Control and Prevention (CDC). Information regarding infection types is provided in Table S3 in the Supplementary Appendix.
‡‡ Information about medical device types is provided in Table S4 in the Supplementary Appendix.

ence increased from partial adherence (hazard ratio, 0.64; 95% CI, 0.40 to 1.00) to full adherence (hazard ratio, 0.56; 95% CI, 0.36 to 0.86). Similar effects were seen with regard to CDC-defined infection from any cause, which was 40% lower among fully adherent participants than among the participants in the education group (hazard ratio, 0.60; 95% CI, 0.46 to 0.78).

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Table 2. MRSA Infection Outcomes (First Infection per Person) per 365 Days of Follow-up, According to Trial Group.*

Variable	MRSA Infection, According to CDC Criteria†		MRSA Infection, According to Clinical Criteria		Any Infection, According to CDC Criteria		Any Infection, According to Clinical Criteria	
	Education	Decolonization	Education	Decolonization	Education	Decolonization	Education	Decolonization
All Participants								
Infection — no. of participants (no. of events/participant-yr)								
Any infection	98 (0.139)	67 (0.098)	98 (0.139)	68 (0.100)	252 (0.407)	207 (0.338)	298 (0.498)	246 (0.414)
Skin or soft-tissue infection	34 (0.048)	32 (0.047)	35 (0.050)	32 (0.047)	80 (0.129)	59 (0.096)	97 (0.162)	82 (0.138)
Pneumonia	18 (0.026)	9 (0.013)	20 (0.028)	10 (0.015)	39 (0.063)	25 (0.041)	45 (0.075)	34 (0.057)
Primary bloodstream or vascular infection	11 (0.016)	10 (0.015)	12 (0.017)	11 (0.016)	20 (0.032)	14 (0.023)	20 (0.033)	14 (0.024)
Bone or joint infection	13 (0.019)	9 (0.013)	12 (0.017)	8 (0.012)	20 (0.032)	22 (0.036)	0.18 (0.030)	17 (0.029)
Surgical-site infection	13 (0.019)	2 (0.003)	13 (0.018)	2 (0.003)	20 (0.032)	8 (0.013)	22 (0.037)	9 (0.015)
Urinary tract infection	3 (0.004)	2 (0.003)	1 (0.001)	1 (0.002)	38 (0.061)	46 (0.075)	52 (0.087)	56 (0.094)
Abdominal infection	1 (0.001)	2 (0.003)	1 (0.001)	2 (0.003)	20 (0.032)	21 (0.034)	26 (0.044)	18 (0.030)
Other infection	5 (0.007)	1 (0.002)	4 (0.006)	2 (0.003)	15 (0.024)	12 (0.020)	18 (0.030)	16 (0.027)
Infection involving bacteremia	28 (0.040)	19 (0.028)	27 (0.038)	18 (0.026)	46 (0.074)	37 (0.060)	46 (0.077)	33 (0.056)
Infection leading in hospitalization	83 (0.117)	57 (0.083)	82 (0.115)	56 (0.082)	225 (0.356)	169 (0.269)	259 (0.420)	199 (0.325)
Time to infection — days	111±91	117±93	116±94	117±95	103±87	110±91	107±91	113±94
Adherent Participants in Decolonization Group‡								
Infection — no. of participants (no. of events/participant-yr)								
Any infection		42 (0.085)		42 (0.088)		118 (0.272)		142 (0.338)
Skin or soft-tissue infection		22 (0.045)		22 (0.046)		40 (0.092)		54 (0.129)
Pneumonia		5 (0.010)		5 (0.011)		11 (0.025)		16 (0.038)
Primary bloodstream or vascular infection		5 (0.010)		6 (0.013)		8 (0.019)		8 (0.019)
Bone or joint infection		5 (0.010)		4 (0.008)		14 (0.032)		11 (0.026)
Surgical-site infection		2 (0.004)		2 (0.004)		6 (0.014)		7 (0.017)
Urinary tract infection		0		0		22 (0.051)		27 (0.064)
Abdominal infection		2 (0.004)		2 (0.004)		12 (0.028)		11 (0.026)
Other infection		1 (0.002)		1 (0.002)		5 (0.012)		8 (0.019)
Infection involving bacteremia		9 (0.019)		8 (0.017)		19 (0.045)		16 (0.039)
Infection leading to hospitalization		36 (0.075)		34 (0.071)		98 (0.226)		115 (0.274)
Time to infection — days		122±93		125±96		119±89		123±94

* Participant-day denominators were censored by the specified outcome. Dates of infection onset based on CDC criteria may differ from those based on clinical judgment.
† This was the primary outcome.
‡ A total of 546 participants were considered to have adhered fully to the decolonization intervention.

Table 3. Effect of Decolonization Plus Education, as Compared with Education Alone, According to Cox Proportional-Hazard Models.*

Variable	MRSA Infection, According to CDC Criteria	MRSA Infection, According to Clinical Criteria	Any Infection, According to CDC Criteria	Any Infection, According to Clinical Criteria
Per-protocol analysis				
Unadjusted hazard ratio (95% CI)	0.70 (0.52–0.96)†	0.71 (0.52–0.97)	0.84 (0.70–1.01)	0.83 (0.70–0.99)
Adjusted hazard ratio (95% CI)‡	0.61 (0.44–0.85)	0.61 (0.43–0.84)	0.80 (0.66–0.98)	0.81 (0.68–0.97)
As-treated analysis§				
Unadjusted hazard ratio (95% CI)				
Nonadherent	1.31 (0.72–2.38)	1.09 (0.57–2.10)	1.68 (1.19–2.36)	1.53 (1.11–2.13)
Partially adherent	0.64 (0.40–1.00)	0.72 (0.47–1.11)	0.86 (0.67–1.11)	0.92 (0.74–1.16)
Fully adherent	0.56 (0.36–0.86)	0.53 (0.34–0.83)	0.60 (0.46–0.78)	0.58 (0.45–0.74)
Adjusted hazard ratio (95% CI)¶				
Nonadherent	0.78 (0.36–1.71)	0.72 (0.37–1.41)	0.780 (0.51–1.26)	0.76 (0.40–1.45)
Partially adherent	0.75 (0.59–0.95)	0.69 (0.54–0.88)	0.78 (0.64–0.97)	0.76 (0.63–0.92)
Fully adherent	0.72 (0.57–0.92)	0.66 (0.51–0.84)	0.75 (0.60–0.94)	0.72 (0.58–0.88)

* The per-protocol population included all the participants (2121) who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization. The unadjusted analyses included all these participants. The adjusted models included the 1901 participants who provided data for all the baseline characteristics shown in Table S2 in the Supplementary Appendix.

† A P value is provided only for the primary outcome (P=0.03). Because the statistical analysis plan did not include a provision for correcting for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, these results are reported as point estimates with 95% confidence intervals. The widths of these confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

‡ Models evaluating the outcomes of MRSA infection according to CDC criteria and any infection according to clinical criteria were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, cancer, cerebrovascular disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, need for bathing assistance, and anti-MRSA antibiotics as time-varying covariates on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses. Models evaluating the outcome of MRSA infection according to clinical criteria and any infection according to CDC criteria were adjusted for the same variables with the addition of age. Resistance to mupirocin did not significantly modify the effect of the trial group.

§ The as-treated analysis assessed the effect on trial outcomes on the basis of the participant's level of adherence to the use of decolonization products as compared with the education group. Among the participants in the decolonization group, 65.6% of the participant-time involved full adherence (no missed doses); 19.6%, partial adherence (some missed doses); and 14.8%, nonadherence (no doses used). The comparator for each adherence subgroup was the overall education group.

¶ As-treated models for all outcomes were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, and need for bathing assistance on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses.

Nonadherence was associated with a higher likelihood of infection from any cause than was observed among participants in the education group.

NUMBER NEEDED TO TREAT

Overall, the estimated number needed to treat to prevent a MRSA infection was 30 (95% CI, 18 to 230) and to prevent an associated hospitalization, 34 (95% CI, 20 to 336). The number needed to treat to prevent any infection was 26 (95% CI, 13 to 212) and to prevent an associated hospitalization, 28 (95% CI, 21 to 270). Among the participants who adhered fully to the intervention (all of whom were in the decolonization group), the number needed to treat to prevent a MRSA infection was 26 (95% CI, 18 to 83) and to prevent an associated hospitalization, 27 (95% CI, 20 to 46). The number needed to treat to prevent any infection was 11 (95% CI, 8 to 21) and to prevent an associated hospitalization, 12 (95% CI, 8 to 23).

ADVERSE EVENTS

Adverse events that were associated with the topical decolonization intervention were mild and uncommon, occurring in 44 participants (4.2%) (Table S9 in the Supplementary Appendix). Local irritation occurred with mupirocin in 1.1% of the participants (12 of 1058), with chlorhexidine bathing in 2.3% (24), and with chlorhexidine mouthwash in 1.1% (12). In those respective

categories, 33% (4 of 12), 29% (7 of 24), and 50% (6 of 12) of the participants chose to continue using the product (overall, 39% of the participants with side effects).

A total of 12.6% of the 1591 participants with postrecruitment MRSA strains had high-level resistance to mupirocin (9.4% [150 participants]) or low-level resistance to mupirocin (3.1% [50]). A total of 1.9% of the participants were newly found to have a mupirocin-resistant strain at subsequent visits (1.9% [16 of 826 participants] in the education group and 2.0% [15 of 765] in the decolonization group, P=0.97). A total of 1.5% of the participants in each group were newly found to have high-level mupirocin-resistant strains (1.6% [13 of 826 participants] in the education group and 1.4% [11 of 765] in the decolonization group, P=0.82) when only sensitive strains were detected at recruitment. Chlorhexidine MICs of 8 μg or more per milliliter were rare (occurring in 2 participants overall [0.1%]). Both patients were in the intervention group, and both isolates had an MIC of 8 μg per milliliter and were negative for the *qac A/B* gene).

DISCUSSION

Infection-prevention campaigns have reduced the risks of health care–associated infections in hospitals, leaving the majority of preventable infections to the postdischarge setting.[16] MRSA carriers are an appealing population target because of their higher risks of infection and postdischarge rehospitalization and the common practice of screening selected inpatients for MRSA colonization.[1,17-19] In the CLEAR trial, topical decolonization led to lower risks of infections and readmissions than hygiene education alone among patients after the transition from hospital to home and other care settings. With a number needed to treat between 25 and 30 to prevent infection and hospitalization, this intervention is relevant to 1.8 million MRSA carriers (5% of inpatients) who are discharged from hospitals each year.[16]

Although decolonization has successfully prevented disease during temporary high-risk circumstances (e.g., recurrent skin infections, ICU care, and arthroplasty and cardiac surgery),[6-10,19-22] a single 5-day decolonization regimen produced short-lived MRSA clearance in half the carriers.[23-26] In contrast, twice-monthly decolonization provided protection for many months after discharge. The protective benefit continued after decolonization. In addition, this regimen was effective despite the greater variability in application with home bathing and showering than has occurred in previous inpatient trials that evaluated nursing-assisted chlorhexidine bath-

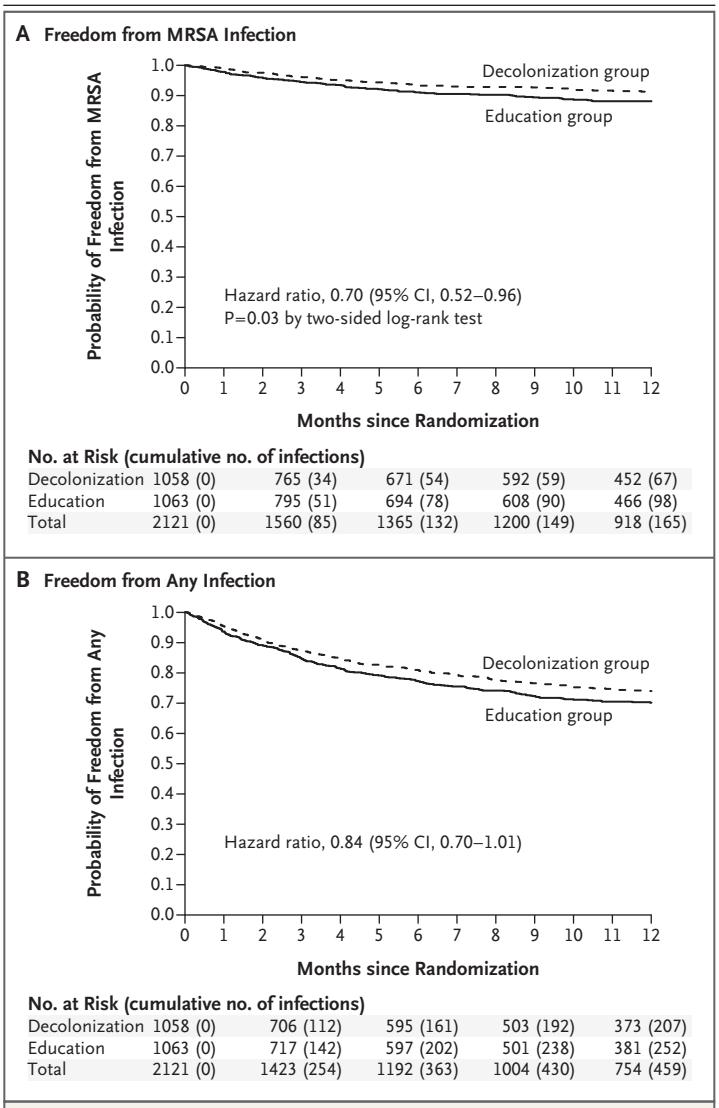

Figure 2. Kaplan–Meier Curves for Freedom from MRSA Infection and Infection from Any Cause, Assessed According to CDC Criteria.

Cases of MRSA infection and infection from any cause were assessed according to criteria of the Centers for Disease Control and Prevention (CDC). The probability of being free from MRSA infection (primary outcome) was significantly greater in the decolonization group than in the education group. The curves remained separated even though decolonization stopped at 6 months. Details regarding the numbers of patients at risk for infection and those with infection at the specific time points are provided in Table S7 in the Supplementary Appendix.

ing and mupirocin application.[8,9,22] This trial also showed that 4% rinse-off chlorhexidine was effective in a postdischarge population that typically takes showers or baths and is unlikely to use a 2% leave-on chlorhexidine product.[8,9,22]

Not surprisingly, participants who adhered fully to the decolonization intervention had rates of MRSA infection and infection from any cause that were at least 40% lower than the rates among participants in the education group, with a number needed to treat of 12 to prevent infection-related hospitalization. This finding probably is attributable to both the decolonization effect and the likelihood that these participants were more adherent to other prescribed treatments and health-promotion behavior than participants in the education group. Participants who fully adhered to the intervention had fewer coexisting conditions, had fewer devices, required less bathing assistance, and were more likely to have MRSA infection (rather than asymptomatic colonization) at the time of enrollment than either participants in the education group or participants in the decolonization group who had lower levels of adherence. These differences represent an important practical distinction. To the extent that physicians can identify patients who are able to adhere to an intervention, those patients would derive greater benefit from the recommendation to decolonize. Nonadherence was common among nursing home residents, which raises questions about research barriers in that care setting.

Decolonization appeared to affect the risks of skin and soft-tissue infections, surgical-site infections, pneumonia, and bacteremia, although sample-size constraints necessitate cautious speculation. Decolonization also appeared to reduce the rate of gram-positive pathogens and infections without a cultured pathogen. The higher rate of gram-negative pathogens in the decolonization group than in the education group was seen among the CDC-defined all-cause infections but not among the clinically defined infections and requires further substantiation. These observations are based on relatively small numbers; larger studies have shown that chlorhexidine can reduce the incidence of gram-negative infections and bacteriuria.[27-30]

The design of this trial did not permit us to determine the effect of hygiene education alone. Both trial groups received in-person visits and reminders about the importance of MRSA-prevention activities. In addition, the free product overcame financial disparities that could become evident with post-trial adoption of the decolonization intervention.

Some participants (<5%) in the decolonization group had mild side effects; among those participants, nearly 40% opted to continue using the agent. Resistance to chlorhexidine and mupirocin was not differentially engendered in the two groups. We defined an elevated chlorhexidine MIC as at least 8 μg per milliliter, although 4% chlorhexidine applies 40,000 μg per milliliter to the skin.

This trial is likely to be generalizable because it was inclusive. For example, the enrollment of participants with late-stage cancer contributed to the 10% anticipated mortality and the approximate 25% rate of withdrawal and loss to follow-up. These rates are similar to other postdischarge trials with shorter durations of follow-up than the durations in our trial.[31-33] It is unknown whether the participants who withdrew or were lost to follow-up had different infection rates or intervention benefits. They were more educated and less likely to be Hispanic than those who did not withdraw or were not lost to follow-up, but the percentages of participants with coexisting conditions were similar.

Limitations of this trial include the unblinded intervention, although outcomes were assessed in a blinded fashion. The trial also had substantial attrition over the 1-year follow-up, and adherence was based on reports by the participants, with spot checks of remaining product, both of which may not reflect actual use. In addition, nearly all infections led to hospitalization, which suggests that milder infections escaped detection. Most outpatient and nursing home records had insufficient documentation for the event to be deemed infection according to the CDC or clinical criteria. Thus, it remains unknown whether the observed 30% lower risk of MRSA infection or the observed 17% lower risk of infection from any cause with decolonization than with education alone would apply to less severe infections that did not lead to hospitalization. Finally, although resistance to chlorhexidine and mupirocin did not emerge during the trial, the development of resistance may take time, beyond the follow-up period of this trial.

In conclusion, inpatients with MRSA-positive

cultures who had been randomly assigned to undergo decolonization with topical chlorhexidine and mupirocin for 6 months after discharge had lower risks of MRSA infection, infection from any cause, and hospitalization over the 1 year after discharge than those who had been randomly assigned to receive hygiene education only.

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), or the Agency for Healthcare Research and Quality (AHRQ).

Supported by a grant (R01HS019388, to Dr. Huang) from the AHRQ Healthcare-Associated Infections Program and by the University of California Irvine Institute for Clinical and Translational Science, which was funded by a grant from the NIH Clinical and Translational Sciences Award program (UL1 TR000153).

Dr. Huang reports conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, Clorox, Xttrium Laboratories, and Medline; Ms. Singh, Dr. Park, and Mr. Chang, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline; Dr. McKinnell, receiving grant support and consulting fees from Achaogen and Theravance Biopharma, grant support, consulting fees, and lecture fees from Allergan, consulting fees from Cempra, Melinta Therapeutics, Menarini Group, and Thermo Fisher Scientific, and fees for serving as a research investigator from Science 37, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline, and serving as cofounder of Expert Stewardship; Ms. Gombosev, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, and Clorox; Dr. Rashid, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Clorox, and Medline; Dr. Bolaris, conducting clinical studies in which participating nursing homes received donated products from 3M and Clorox; Dr. Robinson, serving as cofounder of Expert Stewardship; Dr. Amin, receiving consulting fees from Paratek Pharmaceuticals; Dr. Septimus, conducting clinical studies in which participating hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline; Dr. Weinstein, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products) and Mölnlycke; Dr. Hayden, conducting clinical studies in which participating nursing homes and hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline and donated laboratory services from OpGen and receiving grant support and conducting clinical studies in which participating nursing homes and hospitals received donated product from Clorox; and Dr. Miller, receiving grant support from Gilead Sciences, Merck, Abbott, Cepheid, Genentech, Atox Bio, and Paratek Pharmaceuticals, grant support and fees for serving on an advisory board from Achaogen and grant support, consulting fees, and fees for serving on an advisory board from Tetraphase and conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline. No other potential conflict of interest relevant to this article was reported. Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank the trial participants and their families; the trial staff (Lauren Akahoshi, Jenna Alcaron, Isabel Alegria, Stephanie Arredondo-Glacet, Elizabeth Arreola, Donald Bayley, Nelly Beltran, Barbara Bodenhoefer, Stefan Boghossian, Diane Capobianco, Claudia Cervantes, Sarah Chevallier, Heather Clayton, Ramiro Correa, Nathalia Cressey, Tiffany Dam, Rupak Datta, Jennifer Do, Phillip Duffy, Tabitha Dutciuc, Marlene Estevez, Margarita Flores, Lauren Heim, Sandra Ibarra, Usme Khusbu, Bryn Launer, Cameron Lee, Brian Lewis, Karen Lolans, Andrea Marcantonio, Donna Matsudairas, Lisa [Angie] McErlain, Maria Mejia, Job Mendez, Angela Mendoza, Melanie Meton, Nicole Mohajer, Jennifer Nam, Ann Nguyen, Hanna Owens, Jalpa Patel, Lena Portillo, Sean Prendergast, Katy Precaido, Belinda Prado, Deborah Prunean, Victor Quan, Courtney Reynolds, Diana Romero, Aubrianne Rose, Maureen Schroeder, Grace Tagudar, Cynthia Toyoshima, Ivonne Turner, Qixin Wang, Emily Wawro, and Jun Zozobrado); two physicians who actively supported and facilitated recruitment (David Petreccia and Anjali Vora); the members of our community advisory board (Patricia Cantero, Ph.D., and Jeanine Thomas); the members of our data and safety monitoring board (Honghu Liu, David Beenhouwer, and George Sakoulas); and the staff of the many hospitals and nursing homes that supported the recruitment of participants in the trial.

APPENDIX

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PUBLIC HEALTH

Hospitals Look To Nursing Homes To Help Stop Drug-Resistant Infections

April 2, 20195:00 AM ET

ANNA GORMAN

A certified nursing assistant wipes Neva Shinkle's face with chlorhexidine, an antimicrobial wash. Shinkle is a patient at Coventry Court Health Center, a nursing home in Anaheim, Calif., that is part of a multicenter research project aimed at stopping the spread of MRSA and CRE — two types of bacteria resistant to most antibiotics. *Heidi de Marco/KHN*

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy to stop the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government's Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

This novel collaboration recognizes that superbugs don't remain isolated in one hospital or nursing home but move quickly through a community, said Dr. John Jernigan, who directs the CDC's office on health care-acquired infection research.

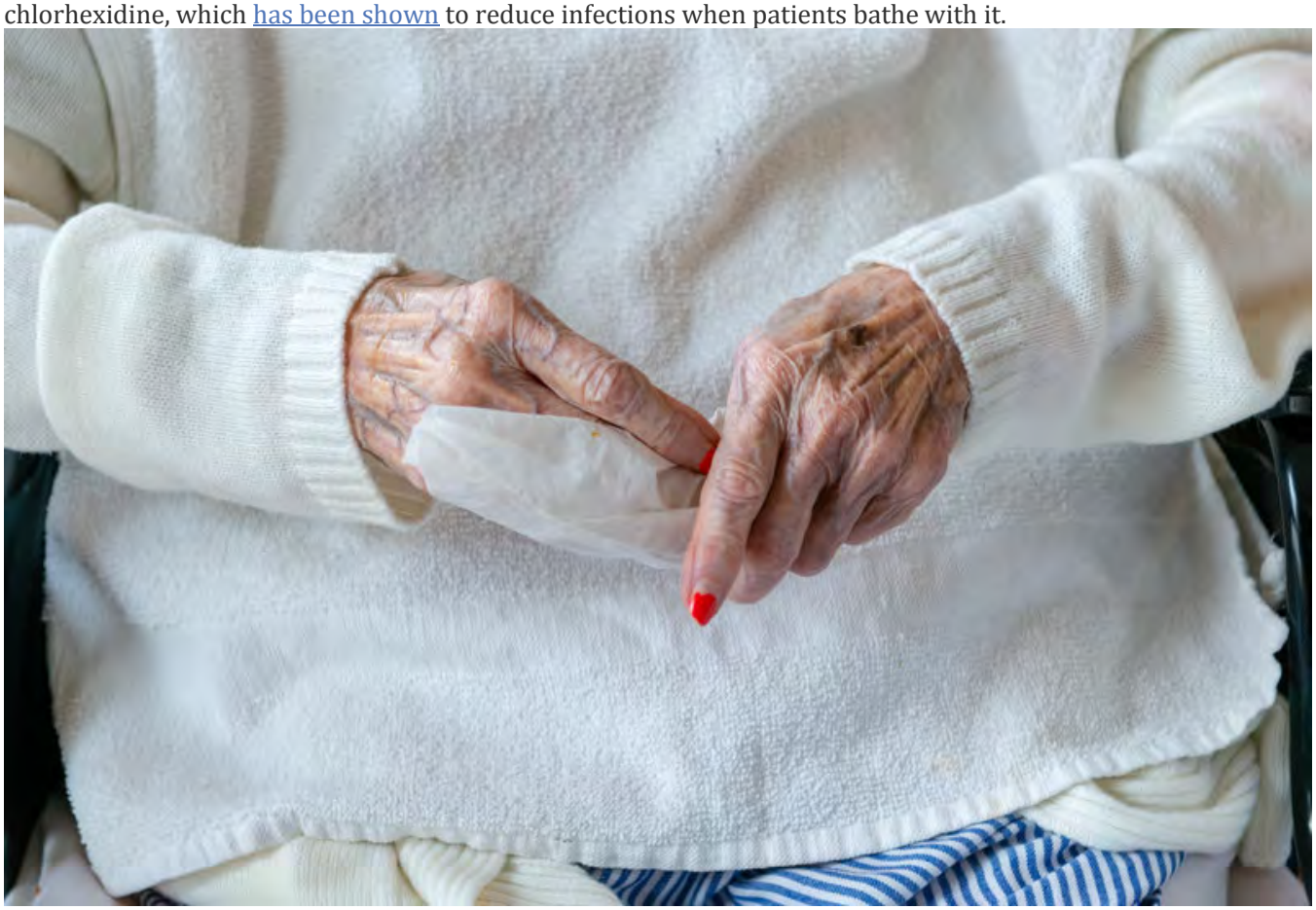
"No health care facility is an island," Jernigan says. "We all are in this complicated network."

At least 2 million people in the U.S. become infected with some type of antibiotic-resistant bacteria each year, and about 23,000 die from those infections, according to the CDC.

People in hospitals are vulnerable to these bugs, and people in nursing homes are particularly vulnerable. Up to 15 percent of hospital patients and 65 percent of nursing home residents harbor drug-resistant organisms, though not all of them will develop an infection, says Dr. Susan Huang, who specializes in infectious diseases at the University of California, Irvine.
"Superbugs are scary and they are unabated," Huang says. "They don't go away."

Some of the most common bacteria in health care facilities are methicillin-resistant *Staphylococcus aureus*, or MRSA, and carbapenem-resistant *Enterobacteriaceae*, or CRE, often called "nightmare bacteria." *E.Coli* and *Klebsiella pneumoniae* are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

CRE have "basically spread widely" among health care facilities in the Chicago region, says Dr. Michael Lin, an infectious-diseases specialist at Rush University Medical Center, who is heading the CDC-funded effort there. "If MRSA is a superbug, this is the extreme — the super superbug."
Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it.



The Centers for Disease Control and Prevention funds the project in California, based in Orange County, in which 36 hospitals and nursing homes are using an antiseptic wash, along with an iodine-based nose swab, on patients to stop the spread of deadly superbugs.
Heidi de Marco/KHN

Though hospital intensive care units frequently rely on chlorhexidine in preventing infections, it is used less commonly for bathing in nursing homes. Chlorhexidine also is sold over the counter; the FDA noted in 2017 it has caused rare but severe allergic reactions.
In Chicago, researchers are working with 14 nursing homes and long-term acute care hospitals, where staff are screening people for the CRE bacteria at admission and bathing them daily with chlorhexidine.

The Chicago project, which started in 2017 and ends in September, includes a campaign to promote hand-washing and increased communication among hospitals about which patients carry the drug-resistant organisms.

The infection-control protocol was new to many nursing homes, which don't have the same resources as hospitals, Lin says.

In fact, three-quarters of nursing homes in the U.S. received citations for infection-control problems over a four-year period, according to a Kaiser Health News analysis, and the facilities with repeat citations almost never were fined. Nursing home residents often are sent back to hospitals because of infections.
In California, health officials are closely watching the CRE bacteria, which are less prevalent there than elsewhere in the country, and they are trying to prevent CRE from taking hold, says Dr. Matthew Zahn, medical director of epidemiology at the Orange County Health Care Agency
"We don't have an infinite amount of time," Zahn says. "Taking a chance to try to make a difference in CRE's trajectory now is really important."

The CDC-funded project in California is based in Orange County, where 36 hospitals and nursing homes are using the antiseptic wash along with an iodine-based nose swab. The goal is to prevent new people from getting drug-resistant bacteria and keep the ones who already have the bacteria on their skin or elsewhere from developing infections, says Huang, who is leading the project.

Licensed vocational nurse Joana Bartolome swabs Shinkle's nose with an antibacterial, iodine-based solution at Anaheim's Coventry Court Health Center. Studies find patients can harbor drug-resistant strains in the nose that haven't yet made them sick.
Heidi de Marco/KHN

Huang kicked off the project by studying how patients move among different hospitals and nursing homes in Orange County — she discovered they do so far more than previously thought. That prompted a key question, she says: "What can we do to not just protect our patients but to protect them when they start to move all over the place?"

Her previous research showed that patients who were carriers of MRSA bacteria on their skin or in their nose, for example, who, for six months, used chlorhexidine for bathing and as a mouthwash, and swabbed their noses with a nasal antibiotic were able to reduce their risk of developing a MRSA infection by 30 percent. But all the patients in that study, published in February in the *New England Journal of Medicine*, already had been discharged from hospitals.

Now the goal is to target patients still in hospitals or nursing homes and extend the work to CRE. The traditional hospitals participating in the new project are focusing on patients in intensive care units and those who already carry drug-resistant bacteria, while the nursing homes and the long-term acute care hospitals perform the cleaning — also called "decolonizing" — on every resident.

One recent morning at Coventry Court Health Center, a nursing home in Anaheim, Calif., 94-year-old Neva Shinkle sat patiently in her wheelchair. Licensed vocational nurse Joana Bartolome swabbed her nose and asked if she remembered what it did.

"It kills germs," Shinkle responded.

"That's right. It protects you from infection."

In a nearby room, senior project coordinator Raveena Singh from UCI talked with Caridad Coca, 71, who had recently arrived at the facility. She explained that Coca would bathe with the chlorhexidine rather than regular soap. "If you have some kind of open wound or cut, it helps protect you from getting an infection," Singh said. "And we are not just protecting you, one person. We protect everybody in the nursing home."

Coca said she had a cousin who had spent months in the hospital after getting MRSA. "Luckily, I've never had it," she said.

Coventry Court administrator Shaun Dahl says he was eager to participate because people were arriving at the nursing home carrying MRSA or other bugs. "They were sick there and they are sick here," Dahl says.
Results from the Chicago project are pending. Preliminary results of the Orange County project, which ends in May, show that it seems to be working, Huang says. After 18 months, researchers saw a 25 percent decline in drug-resistant organisms in nursing home residents, 34 percent in patients of long-term acute care hospitals and 9 percent in traditional hospital patients. The most dramatic drops were in CRE, though the number of patients with that type of bacteria was smaller.

The preliminary data also show a promising ripple effect in facilities that aren't part of the effort, a sign that the project may be starting to make a difference in the county, says Zahn of the Orange County Health Care Agency.

"In our community, we have seen an increase in antimicrobial-resistant infections," he says. "This offers an opportunity to intervene and bend the curve in the right direction."

USA TODAY

How to fight ‘scary’ superbugs that kill thousands each year? Cooperation — and a special soap

Anna Gorman, Kaiser Health News Published 9:27 a.m. ET April 12, 2019 | **Updated 1:47 p.m. ET April 12, 201**

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy against the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government’s Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

This novel approach recognizes that superbugs don’t remain isolated in one hospital or nursing home but move quickly through a community, said Dr. John Jernigan, who directs the CDC’s office on health care-acquired infection research.

“No health care facility is an island,” Jernigan said. “We all are in this complicated network.”

At least 2 million people in the U.S. become infected with an antibiotic-resistant bacterium each year, and about 23,000 die from those infections, according to the CDC.

People in hospitals are vulnerable to these bugs, and people in nursing homes are particularly vulnerable. Up to 15% of hospital patients and 65% of nursing home residents harbor drug-resistant organisms, though not all of them will develop an infection, said Dr. Susan Huang, who specializes in infectious diseases at the University of California-Irvine.

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USA TODAY

Certified nursing assistant Cristina Zainos prepares a special wash using antimicrobial soap. *(Photo: Heidi de Marco, Kaiser Health News)*

“Superbugs are scary and they are unabated,” Huang said. “They don’t go away.”

Some of the most common bacteria in health care facilities are methicillin-resistant Staphylococcus aureus, or MRSA, and carbapenem-resistant Enterobacteriaceae, or CRE, often called “nightmare bacteria.” E. coli and Klebsiella pneumoniae are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

CREs have “basically spread widely” among health care facilities in the Chicago region, said Dr. Michael Lin, an infectious-diseases specialist at Rush University Medical Center, who is heading the CDC-funded effort there. “If MRSA is a superbug, this is the extreme — the super superbug.”

Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it. Though chlorhexidine is frequently used for bathing in hospital intensive care units and as a mouthwash for dental infections, it is used less commonly for bathing in nursing homes.

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In Chicago, researchers are working with 14 nursing homes and long-term acute care hospitals, where staff are screening people for the CRE bacteria at admission and bathing them daily with chlorhexidine.

The Chicago project, which started in 2017 and ends in September, includes a campaign to promote handwashing and increased communication among hospitals about which patients carry the drug-resistant organisms.

The infection-control work was new to many nursing homes, which don't have the same resources as hospitals, Lin said.

In fact, three-quarters of nursing homes in the U.S. received citations for infection-control problems over a four-year period, according to a Kaiser Health News analysis, and the facilities with repeat citations almost never were fined. Nursing home residents often are sent back to hospitals because of infections.

In California, health officials are closely watching the CRE bacteria, which are less prevalent there than elsewhere in the country, and they are trying to prevent CRE from taking hold, said Dr. Matthew Zahn, medical director of epidemiology at the Orange County Health Care Agency. "We don't have an infinite amount of time," he said. "Taking a chance to try to make a difference in CRE's trajectory now is really important."

The CDC-funded project in California is based in Orange County, where 36 hospitals and nursing homes are using the antiseptic wash along with an iodine-based nose swab. The goal is to prevent new people from getting drug-resistant bacteria and keep the ones who already have the bacteria on their skin or elsewhere from developing infections, said Huang, who is leading the project.

Huang kicked off the project by studying how patients move among different hospitals and nursing homes in Orange County, and discovered they do so far more than imagined. That prompted a key question: "What can we do to not just protect our patients but to protect them when they start to move all over the place?" she recalled.

Her previous research showed that patients with the MRSA bacteria who used chlorhexidine for bathing and as a mouthwash, and swabbed their noses with a nasal antibiotic, could reduce their risk of developing a MRSA infection by 30%. But all the patients in that study, published in February in the New England Journal of Medicine, already had been discharged from hospitals.

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Kaiser Health News is a national health policy news service that is part of the nonpartisan Henry J. Kaiser Family Foundation.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

May 14, 2019

CalOptima Board of Directors
505 City Parkway West
Orange, CA 92868

Dear CalOptima Board of Directors:

As the Director of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC), I want to relay that CDC is very encouraged by your proposed Post-Acute Infection Prevention Quality Initiative (PIPQI). We hope that this type of insurer initiative will help protect nursing home residents from infections and hospitalization.

To combat antibiotic resistant – an important global threat – CDC has activities to prevent infections, improve antibiotic use, and detect and contain the spread of new and emerging resistant bacteria. The nursing home population is at particular risk for acquiring these bacteria and developing infections that require antibiotics and hospital admission because of their age, complex health status, frequency of wounds, and need for medical devices. Surveillance data have shown that the majority of nursing home residents currently have one of these highly antibiotic resistant bacteria on their body, and often these bacteria are spread between residents, within the nursing home, and to other healthcare facilities.

There is a need for public health agencies, insurers, and healthcare providers to forge coordinated efforts to promote evidence-based infection prevention strategies to prevent infections and save lives. We see great synergy in linking CDC's role in providing surveillance and infection prevention guidance to CalOptima's ability to protect its members by supporting patient safety initiatives to reduce infections and the hospitalizations they cause.

CDC funded the Orange County regional decolonization collaborative (SHIELD) as a demonstration project to inform broader national infection prevention guidance. The ability to maintain its resounding success in reducing antibiotic resistant bacteria and infections is critical and Orange County will benefit on initiatives such as PIPQI that provide incentives to enable its adoption into operational best practices.

CDC plans to continue transitional support for this initiative, including training support for the 16 nursing homes currently in the SHIELD collaborative for at least one year. We hope that this training effort can complement and synergize the efforts of CalOptima's education and liaison nurses. In addition, we are providing transitional support to the Orange County Health Department to continue their ongoing surveillance efforts in order that the ongoing benefits of the intervention can be captured.

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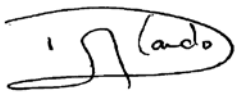
We look forward to collaborating with you. We believe this partnership is a valuable opportunity to protect highly vulnerable patients and to set an example of how insurers and public health can work together to improve healthcare quality.

Sincerely,



Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken April 2, 2020
Regular Meeting of the CalOptima Board of Directors

Report Item

26. Consider Approval of Allocation of Intergovernmental Transfer (IGT) 9 Funds

Contact

David Ramirez, Chief Medical Officer (714) 246-8400
Nancy Huang, Chief Financial Officer (714) 246-8400
Candice Gomez, Executive Director Program Implementation (714) 246-8400

Recommended Actions

1. Approve the recommended allocation of IGT 9 funds in the amount of $45 million for initiatives for quality performance, access to care, data exchange and support and other priority areas; and
2. Authorize the Chief Executive Office, with the assistance of Legal Counsel, to take actions necessary to implement the proposed initiatives, subject to staff first returning to the Board for approval of:
    a. Additional initiative(s) related to member access and engagement; and
    b. New and/or modified policies and procedures, and contracts/contract amendments, as applicable.

Background

Intergovernmental Transfers (IGT) are transfers of public funds between eligible government entities which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has participated in eight Rate Range IGT transactions. Funds from IGTs 1 through 8 have been received and IGT 9 funds are expected from the state in the first quarter of 2020. IGTs 1 through 9 covered the applicable twelve-month state fiscal year (FY) periods (i.e., FY 2020-2011 through FY 2018-19). IGT 1 through 7 funds were retrospective payments for prior rate range years and were designated to be used to provide enhanced/additional benefits to existing Medi-Cal beneficiaries, as represented to CMS.

The IGT funds received under IGT 1 through 7 have supported special projects that address unmet healthcare needs of CalOptima members, such as vision and dental services for children, obesity prevention and intervention services, provider incentives for adolescent depression screenings, recuperative care for homeless members, and support for members through the Personal Care Coordinator (PCC) program. These funds have been best suited for one-time investments or as seed capital for enhanced health care services for the benefit of Medi-Cal beneficiaries.

Beginning with IGT 8, the IGT program covers the current fiscal year and funds are incorporated into the contract between the California Department of Health Care Services (DHCS) and CalOptima for the current fiscal year. Funds must be used for CalOptima covered Medi-Cal services per DHCS requirements. Upon Board approval, funds may be allocated and used over multiple years. IGT 8 funds have been allocated to the Homeless Health Initiative. In July 2018, CalOptima received notice from DHCS regarding the fiscal year 2018-19 Voluntary Rate Range IGT 9. While supporting documents were submitted to DHCS in August 2018, IGT 9 funds have not yet been received or allocated. Submission of documentation to participate in IGT 9 was ratified at the September 9, 2018

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Board of Directors meeting. CalOptima is expected to receive funding from DHCS in calendar year 2020. CalOptima's estimated share is expected to be approximately $45 million. Following consideration by the Quality Assurance Committee and Finance and Audit Committee at their respective February 2020 meetings and the committees' recommendations for approval by the full Board, this item was presented for approval at the March CalOptima Board meeting. At that meeting, staff was directed to conduct further study and provide additional details related to the Whole Child Model pilot program (WCM) and the program's financial performance. Details on the WCM program are provided in a separate WCM-specific Information Item.

Discussion

While IGT 1-7 funds were available to provide enhanced services to existing CalOptima Medi-Cal beneficiaries, beginning with IGT 8, the requirement is that IGT funds are to be used for Medi-Cal program covered services and operations. IGT 8 (and subsequent IGT) funds are subject to all applicable requirements set forth in the CalOptima Medi-Cal contract with DHCS and are considered part of the capitation payments CalOptima receives from DHCS and are accounted for as either medical or administrative expenses, and factor into CalOptima's Medical Loss Ratio (MLR) and Administrative Loss Ratio (ALR). As indicated, per DHCS, the use of these funds is limited to covered Medi-Cal benefits for existing CalOptima members.

While IGT 9 funds have not yet been received, CalOptima staff has begun planning to support use of the funds. CalOptima staff has considered the DHCS requirements for use of IGT 9 funds and Board approved strategic priorities and objectives in identifying the following focus areas:

- Member access and engagement
- Quality performance
- Data exchange and support
- Other priority areas

CalOptima staff has and will continue to share information about the proposed focus areas with various stakeholders.

CalOptima staff anticipates receiving approximately $45 million in IGT 9 funding. Staff has identified initiatives within four focus areas targeting $40.5 million of the anticipated $45 million. Staff proposes approval of the five initiatives and allocation of funds in the focus areas as noted below and as further described in the attached IGT Funding Proposals:

Proposals	Focus Area	Term	Amount Requested
1. Expanded Office Hours	Member access and engagement	Two–years	$2.0 million
2. Post-Acute Infection Prevention (PIPQI)	Quality performance	Three–years	$3.4 million
3. Hospital Data Exchange Incentive	Data exchange and support	One–year	$2.0 million

4. IGT Program Administration	Other priority areas	Five–years	$2.0 million
5. Whole Child Model (WCM) Program	Other priority areas	One–year	Up to $31.1 million
6. Future Request Prior to End of Fiscal Year	Member access and engagement	To be determined	$4.5 million

CalOptima staff will return to the Board with recommendations related the remaining estimated $4.5 million towards member access and engagement, as well as regarding new and/or modified policies and procedures, and contracts, if necessary.

Fiscal Impact

The recommended action has no net fiscal impact to CalOptima's operating budget over the proposed project terms. Staff estimates that IGT 9 revenue from DHCS will be sufficient to cover the allocated expenditures and initiatives recommended in this COBAR.

Rationale for Recommendation

CalOptima staff is recommending the use of IGT funds in a manner consistent with state parameters for IGT funds, identified focus areas.

Concurrence

Gary Crockett, Chief Counsel
Board of Directors' Finance and Audit Committee
Board of Directors' Quality Assurance Committee

Attachments

1. Power Point Presentation: Intergovernmental Transfer (IGT) 9 Update
2. CalOptima Board Action dated September 6, 2018, Consider and Authorize Activities to Secure Medi-Cal Funds through IGT 9
3. CalOptima Board Action dated June 6, 2019, Approve Post-Acute Infection Prevention Quality Initiative and Authorize Quality Incentive Payments
4. IGT Funding Proposals

/s/ Michael Schrader *03/26/2020*
Authorized Signature **Date**

CalOptima
A Public Agency
Better. Together.

Intergovernmental Transfer (IGT) 9 Update

Board of Directors Meeting
April 2, 2020

David Ramirez, M.D., Chief Medical Officer
Nancy Huang, Chief Financial Officer
Candice Gomez, Executive Director, Program Implementation

IGT Background

- IGT process enables CalOptima to secure additional federal revenue to increase California's low Medi-Cal managed care capitation rates
  - IGT 1–7: Funds must be used to deliver enhanced services for the Medi-Cal population
    - Funds are outside of operating income and expenses
  - IGT 8–10: Funds must be used for Medi-Cal covered services for the Medi-Cal population
    - Funds are part of operating income and expenses

IGT Funding Process

High-Level Overview
1. CalOptima receives DHCS notice announcing IGT opportunity
2. CalOptima secures funding partnership commitments (e.g., UCI, Children and Families Commission, et al.)
3. CalOptima submits Letter of Interest to DHCS listing funding partners and their respective contribution amounts
4. Funding partners wire their contributions and an additional 20% fee to DHCS
5. CMS provides matching funds to DHCS
6. DHCS sends total amount to CalOptima
7. From the total amount, CalOptima returns each funding partner's original contribution
8. From the total amount, CalOptima also reimburses each funding partner's 20% fee and where applicable, retained amount for MCO tax (IGT 1–6 only)
9. Remaining balance of the total amount is split 50/50 between CalOptima and the funding partners or their designees

CalOptima Share Totals to Date

IGTs	CalOptima Share	Date Received
IGT 1	$12.43 million	September 2012
IGT 2	$8.70 million	June 2013
IGT 3	$4.88 million	September 2014
IGT 4	$6.97 million	October 2015 (Classic)/ March 2016 (MCE)
IGT 5	$14.42 million	December 2016
IGT 6	$15.24 million	September 2017
IGT 7	$15.91 million	May 2018
IGT 8	$42.76 million	April 2019
IGT 9*	TBD	TBD (Spring 2020)
IGT 10*	TBD	TBD
Total Received	**$121.31 million**	

** Pending DHCS guidance*

IGT 9 Status

- CalOptima's estimated share is approximately $45 million
  - Expect receipt of funding in calendar year 2020
  - Funds used for Medi-Cal programs, services and operations
  - Funds are part of operating income and expenses
    - Medical Loss Ratio (MLR) and Administrative Loss Ratio (ALR) apply
    - Managed through the fiscal year budget

- Stakeholder vetting on the following focus areas
  - Member access and engagement
  - Quality performance
  - Data exchange and support
  - Other priority areas

Proposed Allocation and Initiatives

- Staff has identified initiatives targeted $40.5 million of the anticipated $45 million

Proposals	Focus Area	Term	Amount Requested
1. Expanded Office Hours	Member access and engagement	Two–years	$2.0 million
2. Post-Acute Infection Prevention (PIPQI)	Quality performance	Three–years	$3.4 million
3. Hospital Data Exchange Incentive	Data exchange and support	One–year	$2.0 million
4. IGT Program Administration	Other priority areas	Five–years	$2.0 million
5. W hole Child Model Program	Other priority areas	One–year	Up to $31.1 million
6. Future Request Prior to End of Fiscal Year	Member access and engagement	To be determined	$4.5 million

1. Member Access and Engagement: Expanded Office Hours

- Description
  - Offer additional incentives to providers and/or clinics
    - Expand office hours in the evening and weekends
    - Expand primary care services to ensure timely access
- Guidelines
  - Primary care providers in community clinics serving members in high-demand/impacted areas are eligible
  - Per-visit access incentive awarded to providers and/or clinics for members seen during expanded hours
- Key Components
  - Two-year initiative
  - Budget request of $2.0 million ($500,000 in FY 2019–20)

2. Quality Performance: Post-Acute Infection Prevention Initiative (PIPQI)

- Description
  - Expand CalOptima's PIPQI to suppress multidrug-resistant organisms in contracted skilled nursing facilities (SNFs) and decrease inpatient admissions for infection
- Guidelines
  - Phase 1: Training for 41 CalOptima-contracted SNFs not currently participating in initiative
  - Phase 2: Compliance, quality measures and performance incentives for all participating facilities
  - Two FTE to support adoption, training and monitoring
- Key Components
  - Three-year initiative
  - Budget request of $3.4 million ($1 million in FY 2019–20)

3. Data Exchange: Hospital Data Exchange Incentive

- Description
  - Support data sharing among contracted and participating hospitals via use of CalOptima selected vendors
    - Other organizations within the delivery system may also be added
  - Enhance monitoring of hospital activities for CalOptima's members, aiming to improve care management and lower costs
- Guidelines
  - Participating organizations will:
    - Work with CalOptima and vendor to facilitate sharing of ADT (Admit, Discharge, Transfer) and Electronic Health Record data
    - Be eligible for an incentive once each file exchange is in place
- Key Components
  - One-year initiative
  - Budget request of $2.0 million (CY 2020)

4. Other Priorities: IGT Program Administration

- Definition
  - Administrative support for prior, current and future IGTs
    - Continue support for two existing staff positions to manage IGT transaction process, project and expenditure oversight
    - Fund Grant Management System license, public activities and other administrative costs
- Guidelines
  - Will be consistent with CalOptima policies and procedures
  - Will provide oversight of the entire IGT process and ensure funding investments are aligned with CalOptima strategic priorities and member needs
- Key Components
  - Five years of support
  - Budget request of $2.0 million

5. Other Priorities: Whole-Child Model (WCM) Program

- Definition
  - CalOptima launched WCM on July 1, 2019
  - Based on the initial analysis, CalOptima is projecting an overall loss of up to $31.1 million in FY 2019–20
- Challenges
  - Insufficient revenue from DHCS to cover WCM services
  - Complex operations and financial reconciliation
- Key Components
  - One year
  - Budget request of up to $31.1 million to fund the deficit from WCM program in FY 2019–20

Next Steps

- Return to the Board as needed regarding
  - New or modified policy and procedures
  - Contracts
  - Additional initiatives

CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner


A Public Agency
CalOptima
Better. Together.


Medi-Cal
A Public Agency
CalOptima
Better. Together.


OneCare (HMO SNP)
A Public Agency
CalOptima
Better. Together.


OneCare Connect
A Public Agency
CalOptima
Better. Together.


PACE
A Public Agency
CalOptima
Better. Together.

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken September 6, 2018
Regular Meeting of the CalOptima Board of Directors

Report Item

14. Consider Ratification of the Pursuit of Proposals with Qualifying Funding Partners to Secure Medi-Cal Funds Through the Voluntary Rate Range Intergovernmental Transfer Program for Rate Year 2018-19 (IGT 9)

Contact

Phil Tsunoda, Executive Director, Public Policy and Public Affairs, (714) 246-8400

Recommended Actions

Ratify and authorize the following activities to secure Medi-Cal funds through the Voluntary Intergovernmental Transfer (IGT) Rate Range Program:

1. Submission of a proposal to the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range Intergovernmental Transfer Program for Rate Year 2018-19 (IGT 9);
2. Pursuit of IGT funding partnerships with the University of California-Irvine, the Children and Families Commission, the County of Orange, the City of Orange, and the City of Newport Beach to participate in the upcoming Voluntary Rate Range Intergovernmental Transfer Program for Rate Year 2018-19 (IGT 9), and;
3. Authorize the Chief Executive Officer to execute agreements with these entities and their designated providers as necessary to seek IGT 9 funds.

Background

Intergovernmental Transfers (IGT) are transfers of public funds between eligible government entities which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has participated in seven Rate Range IGT transactions. Funds from IGTs 1 – 7 have been received and IGT 8 funds are expected in the first quarter of 2019. IGT 1 – 7 funds were retrospective payments for prior rate range years and have been used to provide enhanced/additional benefits to existing Medi-Cal beneficiaries. These funds have been best suited for one-time investments or as seed capital for new services or initiatives for the benefit of Medi-Cal beneficiaries.

The IGT funds that have been received to date have supported special projects that address unmet needs for CalOptima members, such as vision and dental services for children, obesity prevention and intervention services, provider incentives for adolescent depression screenings, recuperative care for homeless members, and support for members through the Personal Care Coordinator (PCC) program. For the approved and funded IGT transactions to date, the net proceeds have been evenly divided between CalOptima and the respective funding partners, and funds retained by CalOptima have been invested in addressing unmet needs.

Discussion

Beginning with IGT 8, the IGT program covers the current fiscal year and funds will be incorporated into the contract between DHCS and CalOptima for the current fiscal year. Unlike previous IGTs (1-7), IGT funds must now be used in the current rate year for CalOptima covered

services per DHCS instructions. CalOptima may determine how to spend the IGT funds (net proceeds) as long as they are for CalOptima covered services for Medi-Cal beneficiaries.

On July 31, 2018, CalOptima received notification from DHCS regarding the State Fiscal Year (SFY) 2018-19 Voluntary Rate Range Intergovernmental Transfer Program (IGT 9). CalOptima's proposal, along with the funding entities' supporting documents were due to DHCS on August 31, 2018.

The five eligible funding entities from the previous IGT transactions were contacted regarding their interest in participation. All five funding entities have submitted letters of interest regarding participation in the IGT program this year. These entities are:

1. University of California, Irvine,
2. Children and Families Commission of Orange County,
3. County of Orange,
4. City of Orange, and
5. City of Newport Beach.

Board approval is requested to ratify the submission of the proposal letter to DHCS for participation in the 2018-19 Voluntary IGT Rate Range Program and to authorize the Chief Executive Officer to enter into agreements with the five proposed funding entities or their designated providers for the purpose of securing available IGT funds. Consistent with the eight prior IGT transactions, it is anticipated that the net proceeds will be split evenly between the respective funding entities and CalOptima.

Staff will return to your Board with more information regarding the IGT 9 transaction and an expenditure plan for CalOptima's share of the net proceeds at a later date. .

Fiscal Impact

The recommended action to ratify and authorize activities to secure Medi-Cal funds through IGT 9 will generate one-time IGT revenue that will be invested in Board-approved programs/initiatives. Expenditure of IGT funds is for restricted, one-time purposes and does not commit CalOptima to future budget allocations. As such, there is no net fiscal impact on CalOptima's current or future operating budgets as IGT funds have been accounted for separately.

Rationale for Recommendation

Consistent with the previous eight IGT transactions, ratification of the proposal and authorization of funding agreements will allow the ability to maximize Orange County's available IGT funds for Rate Year 2018-19 (IGT 9).

Concurrence

Gary Crockett, Chief Counsel

Attachment

Department of Health Care Services Voluntary IGT Rate Range Program Notification Letter

/s/ Michael Schrader — **Authorized Signature**

8/29/2018 — **Date**

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State of California—Health and Human Services Agency
Department of Health Care Services

JENNIFER KENT
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

July 31, 2018

Greg Hamblin
Chief Financial Officer
CalOptima
505 City Parkway West
Orange, CA 92868

SUBJECT: State Fiscal Year (SFY) 2018-19 Voluntary Rate Range Program – Request for Medi-Cal Managed Care Plan's (MCP) Proposal

Dear Mr. Hamblin:

The 2018-19 Voluntary Rate Range Program, authorized by Welfare and Institutions (W&I) Code sections 14164, 14301.4, and 14301.5, provides a mechanism for funding the non-federal share of the difference between the lower and upper bounds of a MCP's actuarially sound rate range, as determined by the Department of Health Care Services (DHCS). Governmental funding entities eligible to transfer the non-federal share are defined as counties, cities, special purpose districts, state university teaching hospitals, and other political subdivisions of the state, pursuant to W&I Code section 14164(a). These governmental funding entities may voluntarily transfer funds to DHCS via intergovernmental transfer (IGT). These voluntary IGTs, together with the applicable Federal Financial Participation (FFP), will be used to fund payments by DHCS to MCPs as part of the capitation rates paid for the service period of July 1, 2018 through June 30, 2019 (SFY 2018-19).

DHCS shall not direct the MCP's expenditure of payments received under the 2018-19 Voluntary Rate Range Program. These payments are subject to all applicable requirements set forth in the MCP's contract with DHCS. These payments must also be tied to covered Medi-Cal services provided on behalf of Medi-Cal beneficiaries enrolled within the MCP's rating region.

The funds transferred by an eligible governmental funding entity must qualify for FFP pursuant to Title 42 Code of Federal Regulations (CFR) Part 433, Subpart B, including the requirements that the funding source(s) shall not be derived: from impermissible sources such as recycled Medicaid payments, Federal money excluded from use as state match, impermissible taxes, and non-bona fide provider-related donations. Impermissible sources do not include patient care or other revenue received from programs such as Medicare or Medicaid to the extent that the program revenue is not obligated to the state as the source of funding.

DHCS shall continue to administer all aspects of the IGT related to the 2018-2019 Voluntary Rate Range Program, including determinations related to fees.

PROCESS FOR SFY 2018-19:

MCPs should refer to the estimated SFY 2018-19 county/region-specific non-federal share required to fund available rate range amounts for the MCP (see Attachment C). As a reminder, participation in the 2018-19 Voluntary Rate Range Program is voluntary on the part of the transferring entity and the MCP. If an MCP elect to participate in the 2018-19 Voluntary Rate Range Program, the MCP must adhere to the process for participation outlined below:

Soliciting Interest

The MCP shall contact potential governmental funding entities to determine their interest, ability, and desired level of participation in the 2018-19 Voluntary Rate Range Program. All providers and governmental funding entities who express their interest directly to DHCS will be redirected to the applicable MCP to facilitate negotiations related to participation. If, following the submission of the MCP's proposal, one or more governmental funding entities included in the MCP's proposal are unable or unwilling to participate in the Voluntary Rate Range Program, the MCP shall attempt to find other governmental funding entities able and willing to participate in their place.

The MCP must inform all participating governmental entities that, unless DHCS determines a statutory exemption applies, IGTs submitted in accordance with W&I Code section 14301.4 are subject to an additional 20 percent assessment fee (calculated on the value of their IGT contribution amount) to reimburse DHCS for the administrative costs of operating the Voluntary Rate Range Program and to support the Medi-Cal program. DHCS will determine if a fee waiver is appropriate.

Submission Requirements

Once the MCP has coordinated with the relevant governmental funding entities, the following documents must be submitted to DHCS in accordance with the requirements and procedures set forth below:

- The MCP must submit a **proposal** to DHCS. This proposal must include:

    1. A cover letter signed by the MCP's Chief Executive Officer or Chief Financial Officer on MCP letterhead.

2. The MCP's primary contact information (name, e-mail address, mailing address, and phone number).
3. County/region-specific summaries of the selected governmental funding entities, related providers, and participation levels specified for SFY 2018-19. The combined amounts or percentages must not exceed 100 percent of the estimated non-federal share of the available rate range amounts provided by DHCS. If the MCP is unable to use the entire available rate range, the MCP must indicate the unfunded amount and percentage.
4. All letters of interest (described below) and supporting documents must be attached to the proposal. If the "supplemental attachment" described below is not collected by the MCP and attached to the proposal at the time of submission, please indicate if the information will be submitted to DHCS directly by each governmental funding entity.

- The MCP must obtain a **letter of interest** (using the format provided in Attachment A) from each governmental funding entity included in the MCP's proposal to DHCS. An individual authorized to sign the certification on behalf of the governmental funding entity must sign the letter of interest. Each letter of interest must specify:

  1. The governmental funding entity's name and Federal Tax Identification Number,
  2. The dollar amount or percentage of the total available rate range the governmental funding entity will contribute for each MCP and county/region, and
  3. The governmental funding entity's primary contact information (name, e-mail address, mailing address, phone number).

- The MCP must distribute to governmental funding entities and ensure submission to DHCS of the **SFY 2018-19 Voluntary Rate Range Program Supplemental Attachment** (see Attachment B) by Friday, August 31, 2018.

- The proposals and letters of interest are due to DHCS ***by 5pm on Friday, August 31, 2018***. Please send a PDF copy of the required documents by e-mail to Sandra.Dixon@dhcs.ca.gov. ***Failure to submit all required documents by the due date may result in exclusion from the SFY 2018-19 Voluntary Rate Range Program.***

Each proposal is subject to review and approval by DHCS. The review will include an evaluation of the proposed provider participation levels in comparison to their

uncompensated contracted Medi-Cal costs and/or charges. DHCS reserves the right to approve, amend, or deny the proposal at its discretion.

Upon DHCS' approval of the governmental funding entities and non-federal share amounts for the 2018-19 Voluntary Rate Range Program, DHCS will provide the necessary funding agreement templates, forms, and related due dates to the specified governmental funding entities and MCP contacts. The governmental funding entities will be responsible for completing all necessary funding agreement documents, responding to any inquiries necessary for obtaining approval, and obtaining all required signatures.

If you have any questions regarding this letter, please contact Sandra Dixon at (916) 345-8269 or by email at Sandra.Dixon@dhcs.ca.gov.

Sincerely,

Jennifer Lopez
Division Chief
Capitated Rates Development Division

Attachments

cc: Michael Schrader, Chief Executive Officer
CalOptima
505 City Parkway West
Orange, CA 92868

Sandra Dixon
Financial Management Section
Capitated Rates Development Division
Department of Health Care Services
P.O. Box 997413, MS 4413
Sacramento, CA 95899-7413

ATTACHMENT A – LETTER OF INTEREST TEMPLATE

Jennifer Lopez
Division Chief
Capitated Rates Development Division
Department of Health Care Services
1501 Capitol Avenue, MS 4413
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Ms. Lopez:

This letter confirms the interest of [Insert Participating Funding Entity Name], a governmental entity, federal I.D. Number [Insert Federal Tax I.D. Number], in working with [Managed Care Plan's Name] (hereafter, "the MCP") and the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range Program, including providing an Intergovernmental Transfer (IGT) to DHCS to be used as a portion of the non-federal share of actuarially sound Medi-Cal managed care capitation rate payments incorporated into the contract between the MCP and DHCS for the period of July 1, 2018, to June 30, 2019. This is a non-binding letter, stating our interest in helping to finance health improvements for Medi-Cal beneficiaries receiving services in our jurisdiction. The governmental entity's funds are being provided voluntarily, and the State of California is in no way requiring the governmental entity to provide any funding.

[Insert Participating Funding Entity Name] is willing to contribute up to $_____ for the SFY 2018-19 rating period as negotiated with the MCP. We recognize that, unless a waiver is approved by DHCS, there will be an additional 20-percent assessment fee payable to DHCS on the funding amount, for the administrative costs of operating the voluntary rate range program.

The following individual from our organization will serve as the point of communication between our organization, the MCP and DHCS on this issue:

Entity Contact Information:

(Please provide complete information including name, street address, e-mail address and phone number.)

I certify that I am authorized to sign this certification on behalf of the governmental entity and that the statements in this letter are true and correct.

Sincerely,
Signature

Attachment B

SFY 2018-19 Voluntary Rate Range Program Supplemental Attachment

Provider Name:	
County:	
Health Plan:	

Instructions

Complete all yellow-highlighted fields. **Submit this completed form via e-mail to Sandra Dixon (sandra.dixon@dhcs.ca.gov) at the Department of Health Care Services (DHCS) by Friday, August 31, 2018.**

1. In the table below, report charges/costs and payments received or expected to be received from the Health Plan indicated above for Medi-Cal services (Inpatient, Outpatient, and All Other) provided to Medi-Cal beneficiaries enrolled in the Health Plan and residing in the County indicated above, for dates of service from July 1, 2016 through June 30, 2017.

	Charges	Costs	Payments from Health Plan*	Uncompensated Charges / Uncompensated Costs
Inpatient				
Outpatient				
All Other				
Total	$	$	$	

* Include payments received and anticipated to be received for service dates of July 1, 2016 through June 30, 2017.

2. Are you able to fund 100% of the higher of the uncompensated charges or uncompensated costs (as stated above)? *(Yes / No)*

   If No, please specify the amount of funding available:

3. Describe the scope of services provided to the specified Health Plan's Medi-Cal members, and if these services were provided under a contract arrangement.

4. For any capitation payments to be funded by the IGT, please provide the following:

   (i) The name of the entity transferring funds:

   (ii) The operational nature of the entity (state, county, city, other):

   (iii) The source of the funds:
   (Funds must not be derived from impermissible sources such as recycled Medicaid payments, federal funds excluded from use as State match, impermissible taxes, and non-bona fide provider-related donations.)

   (iv) Does the transferring entity have general taxing authority? *(Yes / No)*

   (v) Does the transferring entity receive appropriations from a state, county, city, or other local government jurisdiction? *(Yes / No)*

5. Comments / Notes

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ATTACHMENT C

TOTAL AVAILABLE RATE RANGE

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Orange County Organized Health System dba Cal Optima - Orange (HCP 506)
IGT - 2018/19 (July 2018 - June 2019)

	Total	50% FMAP (Non-MCHIP and OE)	88% FMAP (MCHIP)	Optional Expansion (93.5%)
Total Funds Available	$ 138,114,451	$ 68,412,249	$ 7,133,302	$ 62,568,900
Federal Match	$ 98,985,353	$ 34,206,125	$ 6,277,306	$ 58,501,922
Governmental Funding Entity's Portion	$ 39,129,098	$ 34,206,124	$ 855,996	$ 4,066,978
	28.3%	50.0%	12.0%	6.5%

Rate Categories[1]	Member Months (per Mercer est.)	Lower Bound (per Mercer Rate Worksheets)	Upper Bound (per Mercer Rate Worksheets)	Difference between Upper and Lower Bound	Other Dept. Usage[2]	Available PMPM (less Other Dept. Usage)	Estimated Available Total Fund
Child - non MCHIP	2,474,781	$ 84.85	$ 89.93	$ 5.08	$ -	$ 5.08	$ 12,571,887
Child - MCHIP	1,273,587	$ 84.85	$ 89.93	$ 5.08	$ -	$ 5.08	$ 6,469,822
Adult - non MCHIP	1,082,406	$ 299.18	$ 316.64	$ 17.46	$ -	$ 17.46	$ 18,898,809
Adult - MCHIP	38,000	$ 299.18	$ 316.64	$ 17.46	$ -	$ 17.46	$ 663,480
SPD	466,754	$ 755.18	$ 798.48	$ 43.30	$ -	$ 43.30	$ 20,210,448
SPD/Full-Dual	22,704	$ 219.25	$ 229.52	$ 10.27	$ -	$ 10.27	$ 233,170
BCCTP	7,156	$ 1,225.69	$ 1,296.82	$ 71.13	$ -	$ 71.13	$ 509,006
LTC	14,686	$ 10,472.34	$ 10,858.28	$ 385.94	$ -	$ 385.94	$ 5,667,915
LTC/Full-Dual	0	$ 6,036.73	$ 6,235.58	$ 198.85	$ -	$ 198.85	$ -
OBRA	0	$ -	$ -	$ -	$ -	$ -	$ -
Whole Child Model	74,642	$ 1,824.65	$ 1,962.92	$ 138.27	$ -	$ 138.27	$ 10,321,014
Optional Expansion	2,853,119	$ 442.21	$ 471.45	$ 29.24	$ 7.31	$ 21.93	$ 62,568,900
	8,307,835	$ 309.49	$ 328.62	$ 19.14	$ 2.51	$ 16.62	$ 138,114,451

[1]The supplemental payments (Maternity, BHT and HEP C) are not included in the rate range calculation.
[2]Other Departmental Usages decreases available rate range funding.

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CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken June 6, 2019
Regular Meeting of the CalOptima Board of Directors

Report Item

33. Consider Approval of Quality Initiative Related to Post-Acute Infection Prevention and Authorization of Related Funding for Quality Initiative Payments

Contact

David Ramirez, M.D., Chief Medical Officer, (714) 246-8400
Emily Fonda, M.D., MMM, CHCQM, Medical Director, (714) 246-8400
Ladan Khamseh, Chief Operating Officer, (714) 246-8400

Recommended Actions

1. Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
2. Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

Background

The Centers for Disease Control and Prevention (CDC) and the University of California-Irvine (UCI) recently collaborated on an extensive study in 2017 through 2019 to suppress the spread of Multi-Drug-Resistant Organisms (MDRO) in Skilled Nursing Facilities (SNFs) across Orange County. The ambitious study also garnered the support of the California Department of Public Health as well as the Orange County Health Care Agency. This regional collaborative established a structured "…decolonization strategy to reduce the transmission of MDROs both countywide and within healthcare facilities." The name of the collaborative is SHIELD OC.

SHIELD OC is comprised of intervention protocols for both hospitals and nursing homes. There were 16 Orange County SNFs contracted with CalOptima that participated through to the conclusion of the study.

The study was focused on MDRO decolonization through "…the use of topical products to reduce bacteria on the body that can produce harmful infections." In SNFs, the study protocol involved the implementation of two interventions: (1) the consistent use of Chlorhexidine (CHG) antiseptic soap for routine bathing and showering of residents, and (2) the scheduled use of povidone-iodine nasal swabs on residents.

The preliminary study outcomes were very promising and gained the close attention of CDC senior leadership, who have reached out to CalOptima regarding the project on more than one occasion. Long term care (LTC) residents in facilities following the study protocol showed markedly lower rates of MDRO colonization, which translated into lower rates of hospital admissions and lower utilization costs for CalOptima members. The implications of the study, as well as the innovative regional collaboration model, have also garnered the interest of the press. News regarding the collaborative recently aired on National Public Radio and appeared in *USA Today* articles. The lead author in the study, Dr. Susan Huang, was also recently interviewed in a local news radio segment on KNX 1070.

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The study concluded on May 2, 2019. At the SHIELD OC Wrap Up Event, concerns were expressed by facility participants as well as the CDC that the end of the project funding would prevent the SNFs in the study from continuing the study protocol efforts. Without continuation of the interventions, the momentum of the efforts by the participating SNFs would be interrupted, and the considerable gains made in regional decolonization could potentially be unraveled. While the responsibility of infection prevention in post-acute settings is not solely the responsibility of CalOptima, the extensive project has provided significant safety and health benefits to CalOptima members who reside in these facilities. After the conclusion of the study, the collaborative will face an absence of funding and direction. This presents an opportunity for CalOptima to take a leadership role in supporting the care delivery system by offering value-based quality incentives to facilities that follow evidence-based patient safety practices in the institutionalized population segment which are congruent with CalOptima's mission as well as the National Quality Assurance Committee (NCQA) Population Health Management Standards of Delivery System Support.

Discussion

As proposed, the Post-Acute Infection Prevention Quality Initiative will provide an avenue through which CalOptima can incentivize SNFs to provide the study protocol interventions. The study protocols have been recognized to meaningfully suppress the spread of MDROs and will support the safety and health of CalOptima members receiving skilled interventions at or residing in SNFs. Implementation of the quality initiative is in line with CalOptima's commitment to continuous quality improvement.

The initiative would be comprised of two separate phases. Summarily, in Phase I, CalOptima-contracted SNFs in Orange County could initiate a commitment to implementing the study protocol and CalOptima would respond by providing funding to the facility for setup and protocol training. For each participating SNF, Phase I would last for two quarters. In Phase II of the quality initiative, after the SNF has been trained and can demonstrate successful adoption of the protocol, each SNF would be required to demonstrate consistent adherence to the study protocol as well as meet defined quality measures in order to be eligible to continue receiving the quality initiative payments on a retrospective quarterly basis.

Phase I

CalOptima to provide quality initiative funding to SNFs demonstrating a commitment to implementing the SHIELD OC study protocol. The quality initiative is intended to support start up and training for implementation of the protocols not currently in standard use in SNFs but, as per the SHIELD OC study, have been demonstrated to effectively suppress the spread of MDROs.

Contracted SNFs in Orange County must complete an Intent to Implement MDRO Suppression form, signed by both its Administrator and Director of Nursing.

CalOptima will then initiate payment for the first quarter of setting up and training. Payment will be based on an average expected usage cost per resident, to be determined by CalOptima for application across all participating facilities, so the amount of payment for each facility will be dependent on its size. These payments are intended to incentivize the facilities to meet the protocol requirements. The facility must demonstrate use of the supplies and the appropriate

application of the study protocol to the assigned CalOptima staff to qualify for the second quarterly Phase I payment.

The following supplies are required of the facility:

- 4% Chlorohexidine Soap
- 10% Iodine Swab Sticks

The following activities will be required of the facility:

- Proof of appropriate product usage.
- Acceptance of training and monitoring of infection prevention protocol by CalOptima and/or CDC/UCI staff.
- Evidence the decolonization program handouts are in admission packets.
- Monitoring and documentation of compliance with CHG bathing.
- Monitoring and documentation of compliance with iodophor nasal swab.
- Documentation of three peer-to-peer bathing skills assessments per month.

Phase II

CalOptima will provide retrospective quality initiative payments on a quarterly basis for facilities that completed Phase I and meet Phase II criteria outlined below. The amount of each Phase II facility payment will reflect the methodology used in Phase I, accounting for facility size at the average expected usage cost. These payments are intended to support facilities in sustaining the quality practices they adopted during Phase I to suppress MDRO infections.

To qualify for Phase II quality initiative payments, the participating facility must continue demonstrating adherence to the study protocol through the requirements as outlined above for Phase I.

In addition, the facility must also meet minimum quality measures representative of effective decolonization and infection prevention efforts, to be further defined with the guidance of the UCI and CDC project leads. The facilities in Phase II of the initiative must meet these measures each quarter to be eligible for retrospective payment.

The 16 SNFs that participated in SHIELD OC would be eligible for Phase II of the quality initiative at implementation of this quality initiative since they have already been trained in the project and demonstrated adherence to the study protocol. Other contracted SNFs in Orange County not previously in SHILED OC and beginning participation in the quality initiative would be eligible for Phase I.

The proposed implementation of the quality initiative is Q3 2019.

Fiscal Impact
The recommended action to implement a Post-Acute Infection Prevention Quality Initiative program and make payments to qualifying SMFs, beginning in FY 2019-20 to CalOptima-contracted SNFs in Orange County is projected to cost up to and not to exceed $2.3 million annually. Management plans to include projected expenses associated with the quality initiative in the upcoming CalOptima FY 2019-20 Operating Budget.

Rationale for Recommendation
The quality initiative presents an avenue for CalOptima to actively support an innovative regional collaborative of high visibility that has been widely recognized to support the safety and health of individuals receiving care in SNFs.

Concurrence
Gary Crockett, Chief Counsel

Attachment
1. PowerPoint Presentation
2. SHIELD OC Flyer
3. Letter of Support

/s/ Michael Schrader *5/29/2019*
Authorized Signature **Date**

Post-Acute Infection Prevention Quality Initiative

Regular Meeting of the Board of Directors

June 6, 2019

Dr. Emily Fonda, MD, MMM, CHCQM

Medical Director

Care Management, Long-Term Services and Supports and Senior Programs

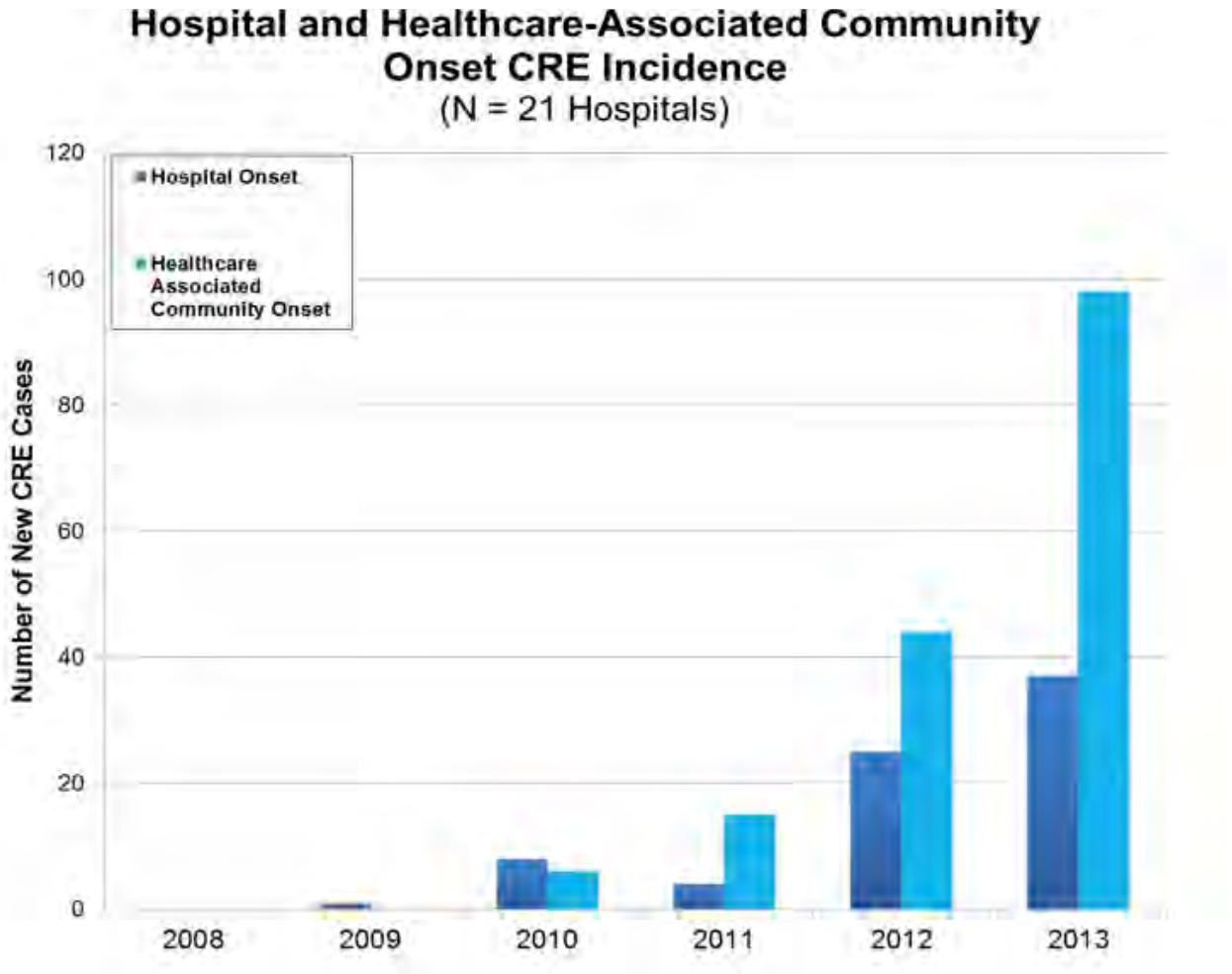
Background

- Efforts to lower hospitalization rates from long-term care (LTC) placed us in contact with Dr. Huang and her study
  - Through the Long-Term Services and Supports (LTSS) Quality Improvement Subcommittee
- Susan Huang, MD, MPH, Professor, Division of Infectious Diseases at U.C. Irvine — lead investigator for Project SHIELD Orange County (OC)
  - 36 facility decolonization intervention protocol supported by the Center for Disease Control and Prevention (CDC)
  - 16 of those facilities are CalOptima-contracted skilled nursing facilities
- Early results at wrap-up event on 1/30/19 ➔ overall 25 percent lower colonization rate of multidrug resistant organisms in OC skilled nursing facilities

Background

- Rise of Multi-Drug Resistant Organisms (MDROs)
  - Methicillin Resistant *Staphylococcus aureus* (MRSA)
  - Vancomycin Resistant Enterococcus (VRE)
  - Multi-Drug Resistant Pseudomonas
  - Multi-Drug Resistant Acinetobacter
  - Extended Spectrum Beta Lactamase Producers (ESBLs)
  - Carbapenem Resistant Enterobacteriaceae (CRE)
  - Hypervirulent KPC (NDM)
  - *Candida auris*
- **10–15%of hospital patients harbor at least one of the above**
- **65% of nursing home residents harbor at least one of the above**

CRE Trends in Orange County, CA



Gohil S. AJIC 2017; 45:1177-82

CDC Interest

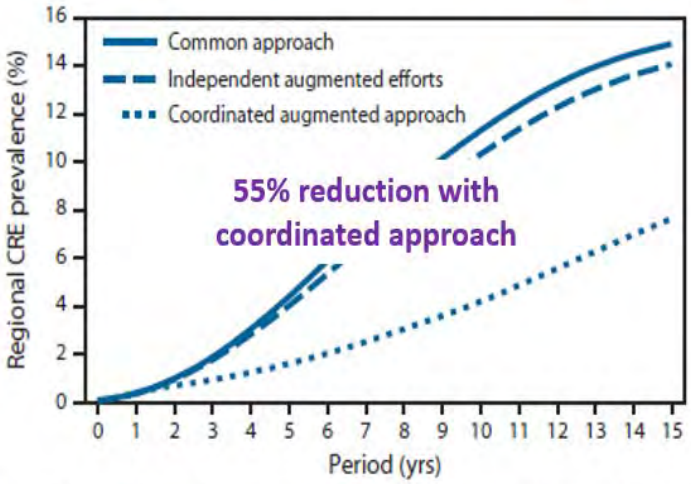
Orange County has historically had one of the highest carbapenem-resistant enterobacteriaceae (CRE) rates in California according to the OC Health Care Agency

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 64
August 4, 2015

Vital Signs: Estimated Effects of a Coordinated Approach for Action to Reduce Antibiotic-Resistant Infections in Health Care Facilities — United States

Rachel B. Slayton, PhD[1]; Damon Toth, PhD[2]; Bruce Y. Lee, MD[3]; Windy Tanner, PhD[2]; Sarah M. Bartsch, MPH[3]; Karim Khader, PhD[2]; Kim Wong, PhD[4]; Kevin Brown, PhD[2]; James A. McKinnell, MD[5]; William Ray[2]; Loren G. Miller, MD[6]; Michael Rubin, MD, PhD[2]; Diane S. Kim[7]; Fred Adler, PhD[8]; Chenghua Cao, MPH[7]; Lacey Avery, MA[1]; Nathan T.B. Stone, PhD[8]; Alexander Kallen, MD[1]; Matthew Samore, MD[2]; Susan S. Huang, MD[7]; Scott Fridkin, MD[1]; John A. Jernigan, MD[1]

FIGURE 3. Projected countywide prevalence of carbapenem-resistant *Enterobacteriaceae* (CRE) over a 15-year period under three different intervention scenarios — 102-facility model, Orange County, California*

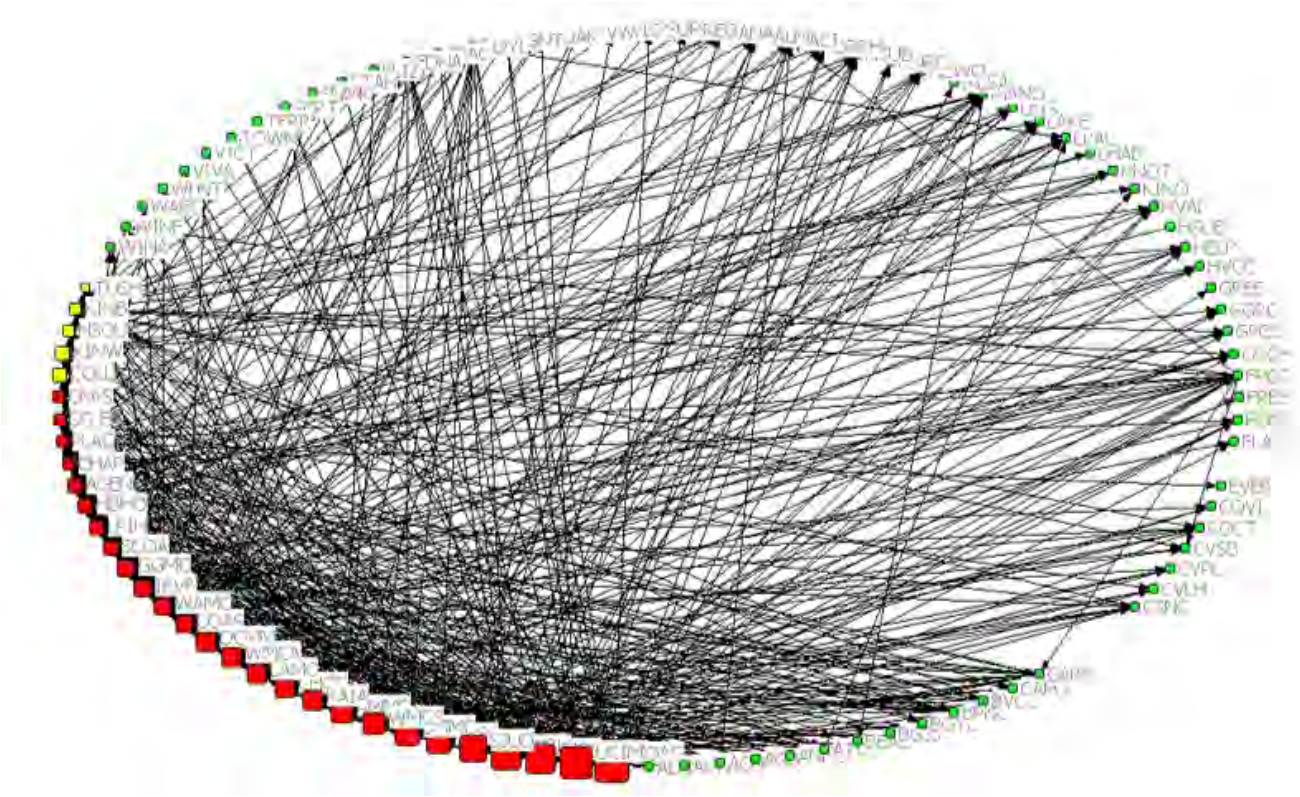


* Additional information available at http://www.cdc.gov/drugresistance/resources/publications.html.

Extent of the Problem

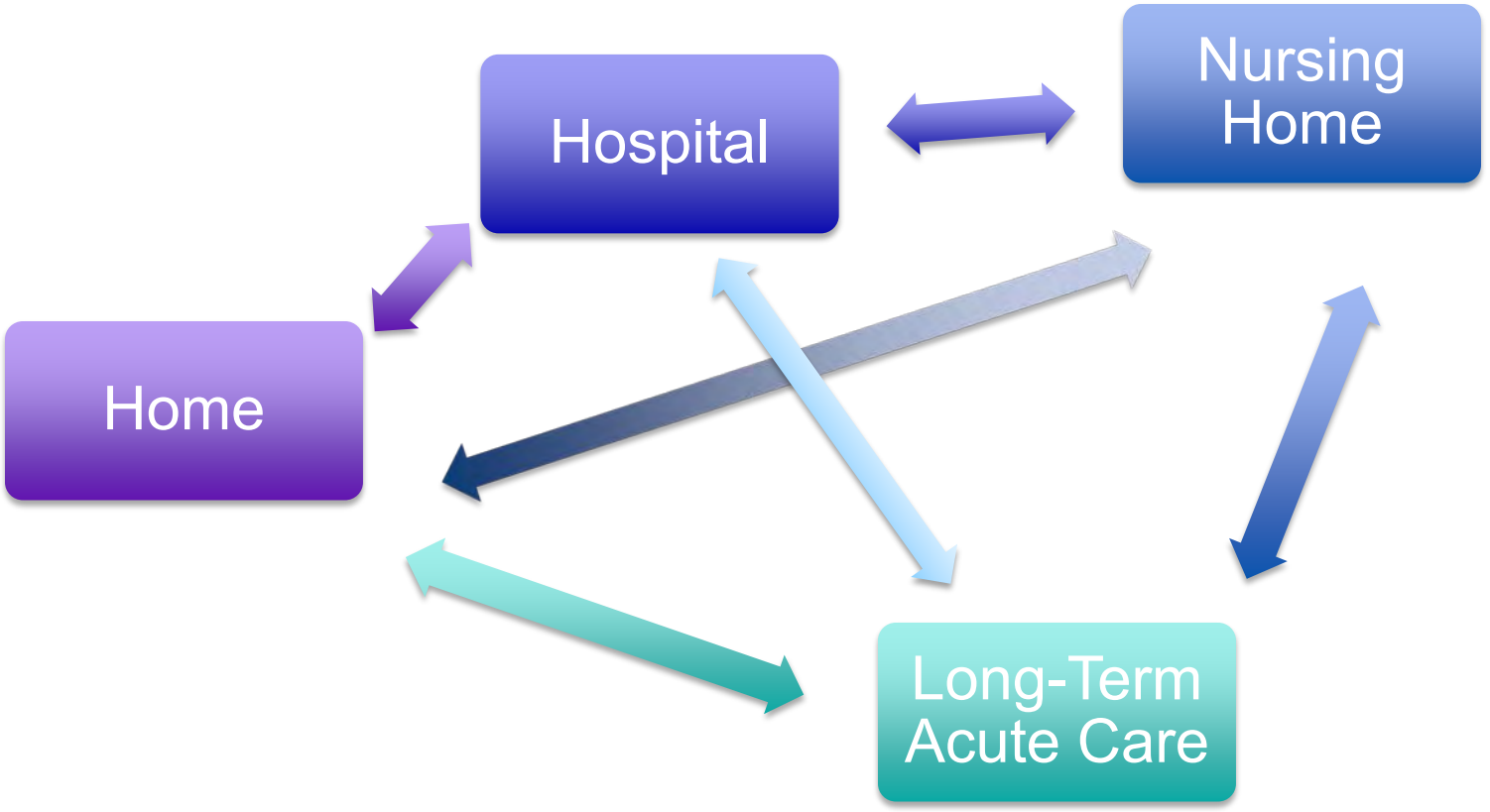
OC Hospitals and Nursing Homes

10 patients shared



Lee BY et al. Plos ONE. 2011;6(12):e29342

Extent of the Problem



Baseline MDRO Prevalence — 16 Nursing Homes

	N	Any MDRO	MRSA	VRE	ESBL	CRE
Nares	900	28%	28%	-	-	-
Axilla/Groin	900	47%	30%	10%	22%	1%
Peri-Rectal	900	52%	25%	15%	31%	1%
All Body Sites	**900**	**64%**	**42%**	**16%**	**34%**	**2%**

- 64% MDRO carriers, facility range 44–88%
- Among MDRO pathogens detected, only 14% known to facility
- Among all residents, 59% harbored ≥1 MDRO unknown to facility

Participating Health Care Facilities

16 Nursing Homes Contracted with CalOptima

- Alamitos West Health Care Center
- Anaheim Healthcare Center
- Beachside Nursing Center
- Crystal Cove Care Center
- French Park Care Center
- Garden Park Care Center
- Healthcare Center of Orange County
- Laguna Hills Health and Rehab Center
- Lake Forest Nursing Center
- Mesa Verde Post Acute Care Center
- New Orange Hills
- Orange Healthcare & Wellness Centre
- Regents Point – Windcrest
- Seal Beach Health and Rehab Center
- Town and Country Manor
- Victoria Healthcare and Rehab Center

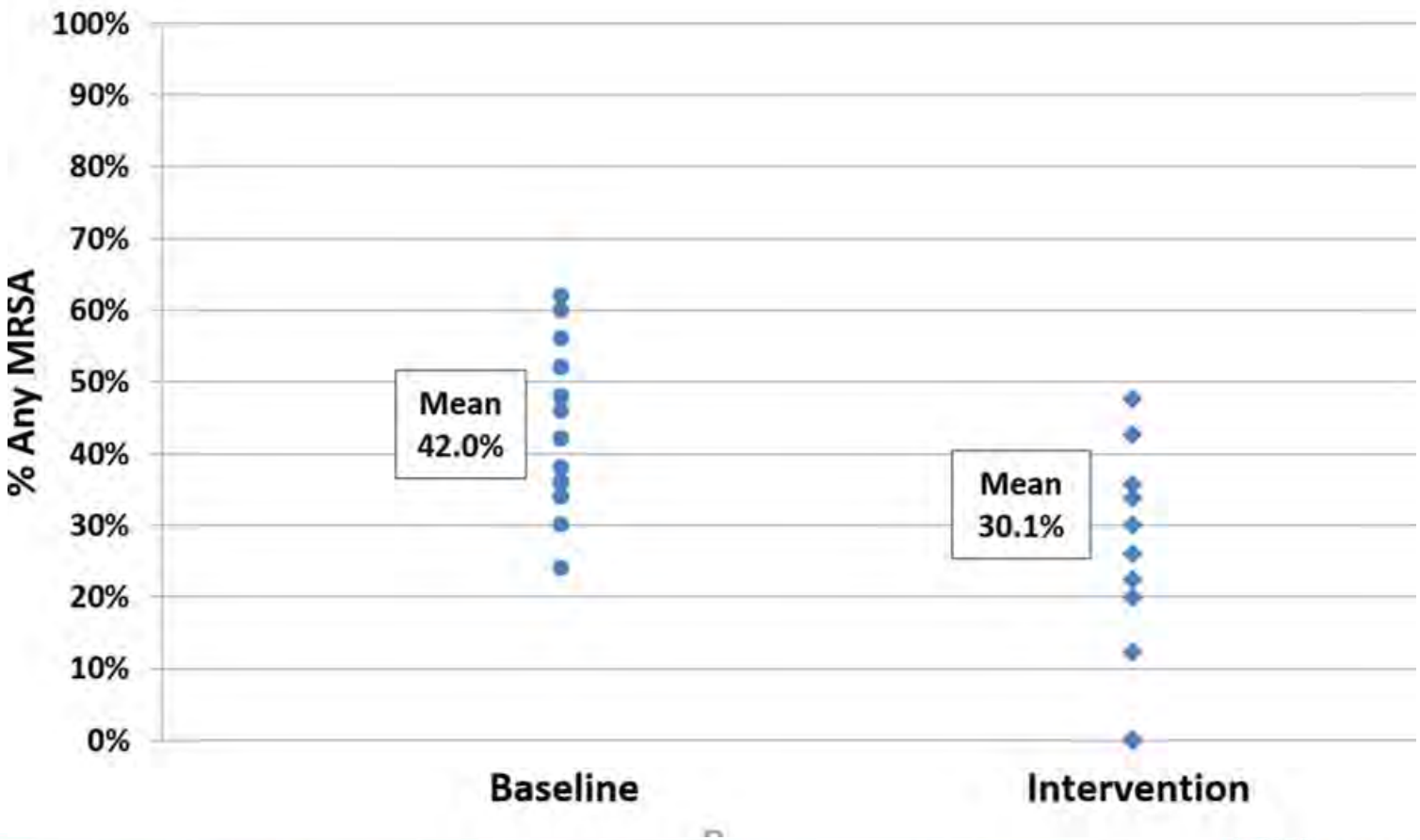
SHIELD OC Decolonization Protocol

- Nursing Homes: Decolonize All Patients
  - Replaced regular soap with chlorhexidine (CHG) antiseptic soap
  - CHG on admit and for all routine bathing/showering
  - Nasal iodophor on admit and every other week
    - https://www.cdc.gov/hai/research/cdc-mdro-project.html
- Following initial testing and training
  - Intervention timeline (22 months) July 1, 2017–May 2, 2019
- Outcome: MDRO Prevalence
  - MRSA, VRE, ESBL, CRE and any MDRO
  - By body site
    - Nasal product reduces MRSA
    - CHG bathing reduces skin carriage

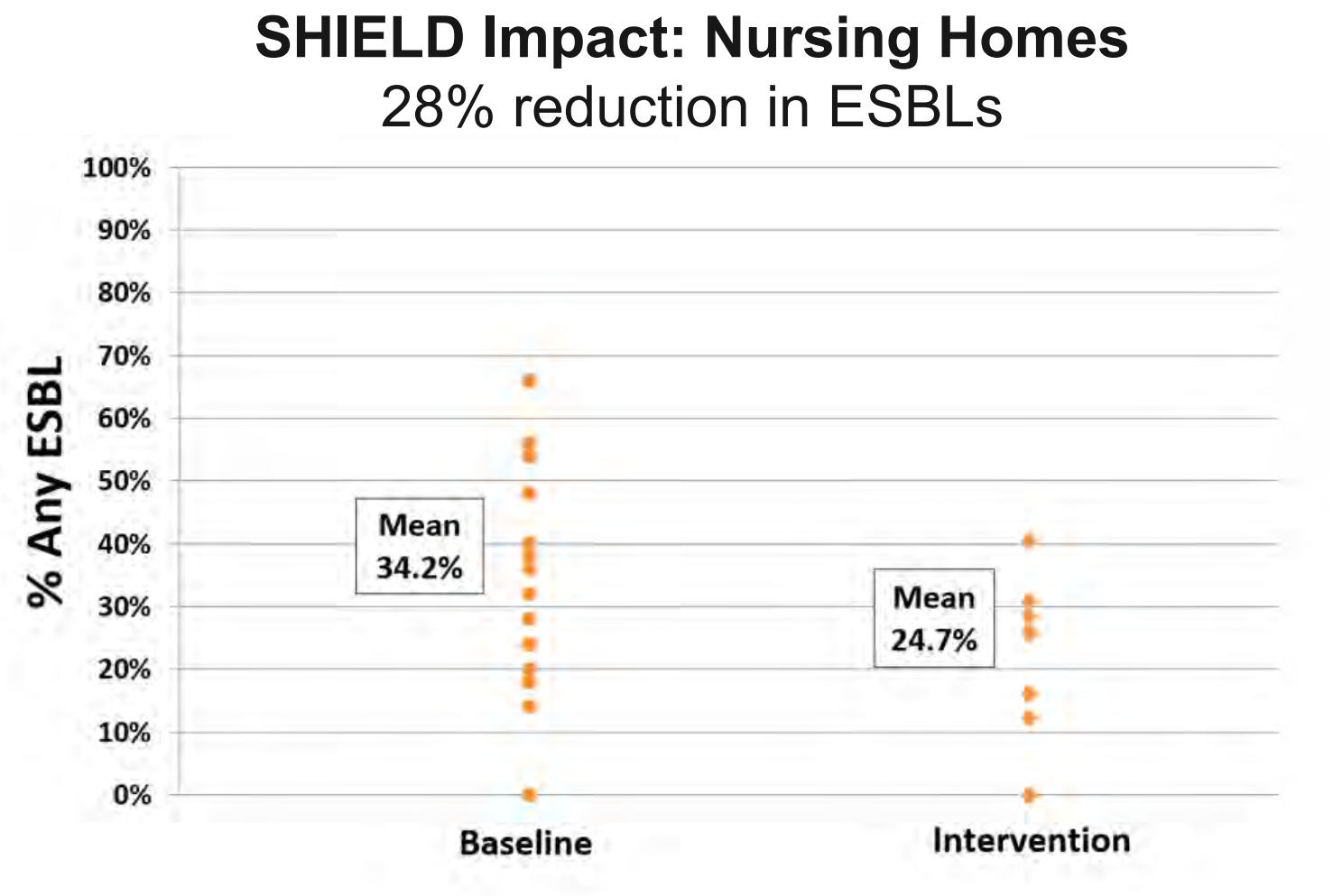
SHIELD Outcomes

SHIELD Impact: Nursing Homes

28% reduction in MRSA



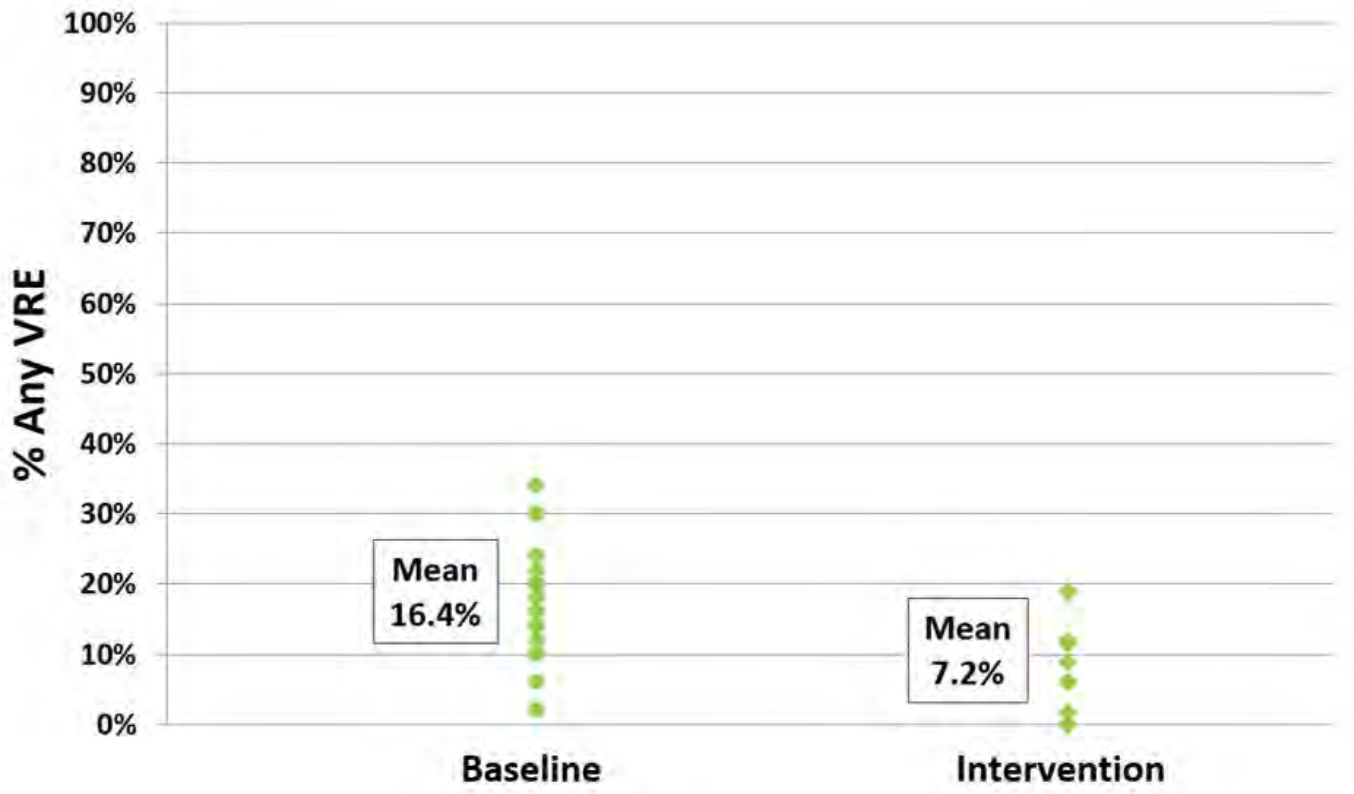
SHIELD Outcomes (cont)



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

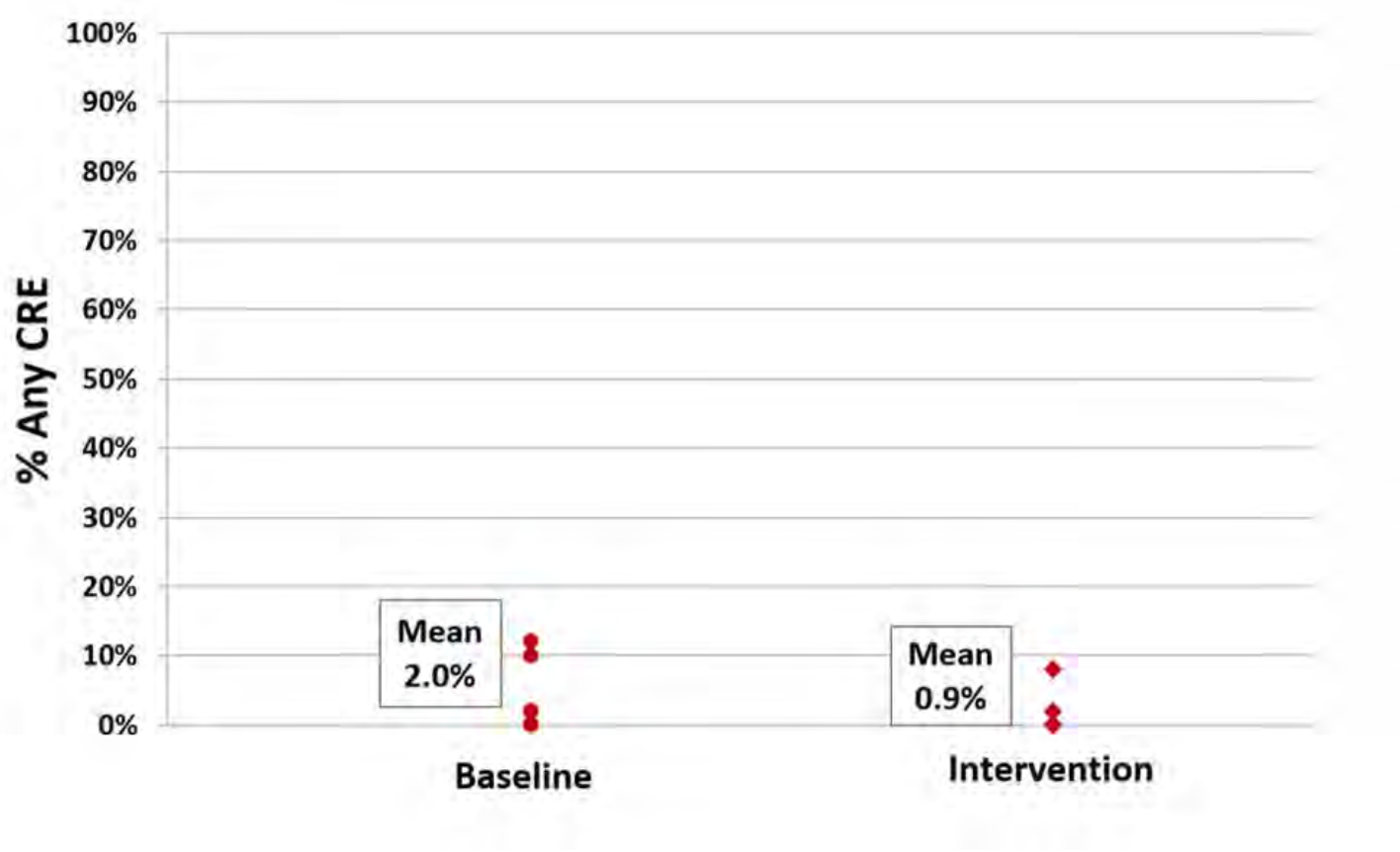
56% reduction in VRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

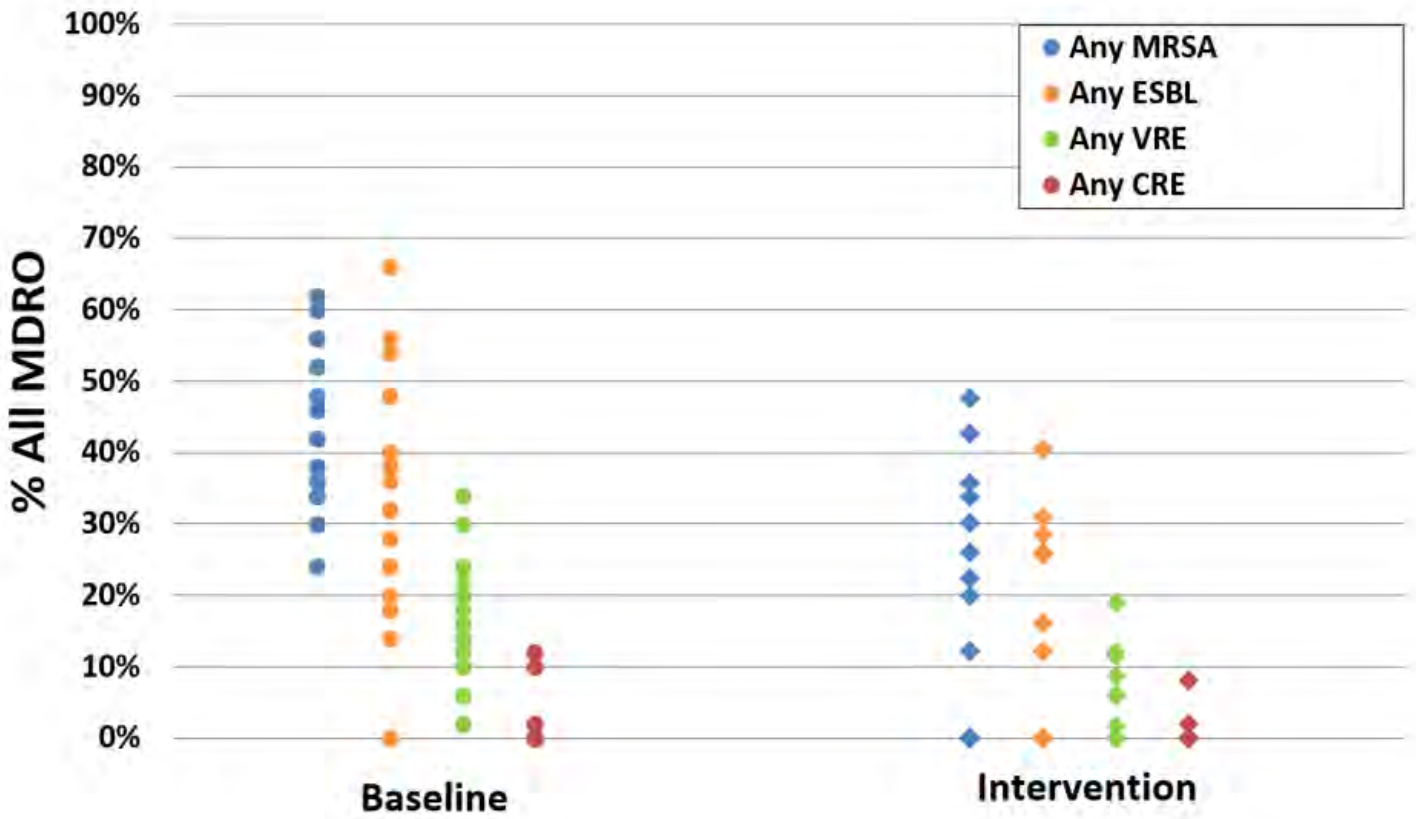
55% reduction in CRE



SHIELD Outcomes (cont)

SHIELD Impact: Nursing Homes

25% reduction in all MDROs



Quarterly Inpatient Trends

SHIELD OC Project: Quarterly Inpatient Trends

LTC Facility County: ORANGE

From: 2015-10 To: 2018-12

Category P - Primary Diagnosis

Select Year-Month Begin	Select Year-Month End	Select Category P Diagnosis Level	Select Risk Group *	Select LTC Facility County
2015-10	2018-12	Category P - Primary Diagnosis	Multiple values	ORANGE

		Before SHIELD OC						During SHIELD OC						
		2015 Q4	2016 Q1	2016 Q2	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2	2018 Q3	2018 Q4
CONTROL	Admission Count	47	61	60	51	56	65	60	49	36	46	59	48	47
	Bed Day Ct	336	383	536	383	561	570	390	376	296	377	401	456	398
	Paid Amt	$682,769	$854,676	$1,159,922	$920,317	$1,691,337	$1,231,903	$997,810	$1,236,197	$634,628	$979,762	$1,113,238	$1,176,910	$1,024,854
	Avg Mbrs	3,064	2,964	2,901	2,945	2,994	3,033	3,035	3,074	3,116	3,105	3,088	3,102	3,085
SHIELD OC	Admission Count	10	10	9	11	12	9	8	5	3	4	7	3	1
	Bed Day Ct	54	84	66	90	98	60	59	49	12	30	46	11	2
	Paid Amt	$133,362	$311,661	$124,676	$189,669	$227,224	$209,419	$175,738	$164,181	$40,354	$84,565	$127,609	$41,123	$10,177
	Avg Mbrs	590	564	564	580	576	567	581	606	625	632	641	663	652

* Risk Groups Selected: CCN - MC CCN OCC COD Admin OneCare Shared Risk - MC Shared Risk - OCC

Average member count includes all Risk Groups

Admission counts and costs significantly lower in the SHIELD OC group

Quarterly Inpatient Trends

- 16 contracted facilities utilizing the CHG program:
  - Inpatient costs for infection for 6 quarters prior to the Chlorhexidine protocol = $1,196,011
  - Inpatient costs for the last 6 quarters following training and use of CHG protocol = $468,009
    - $728,002 lowered inpatient expenditure (61%) for infection in the participating facilities

- 51 contracted facilities not utilizing the CHG program:
  - Inpatient costs for the last 6 quarters =$6,165,589
  - Potential 61% lowered inpatient expenditure for infection = $3,761,009 if the CHG protocol had been expanded

SHIELD Impact on CalOptima

- Adoption of the SHIELD protocol is well-supported by the Center for Disease Control
  - Plan for extended use of an existing trainer in OC for one year
  - Plan for extended monitoring of Orange County MDROs for one year
- 25% decrease in MDRO prevalence translates to the following for CalOptima's LTC population of 3,800 members as of December 2018:
  - Decreased infection-related hospitalizations
  - An opportunity for a significant advancement in population health management
  - Practice transformation for skilled nursing facilities in fulfillment of National Committee for Quality Assurance (NCQA) requirements
  - Continuation of cost savings

CalOptima Post-Acute Infection Prevention Quality Initiative

- Adoption of the SHIELD protocol in all 67 CalOptima post-acute contracted facilities (long-term care and subacute facilities) will:
  - Support the continuation of care in the 16 participating facilities as Phase 2 without loss of momentum
  - Initiate the chlorhexidine bathing protocol in the remaining facilities as Phase 1 utilizing the CDC-supported trainer
  - Require quarterly reporting and fulfillment of quality measures with payments proportional to compliance
  - Include a trainer provided by the CDC for one year
  - Train current CalOptima LTSS nurses to quantify best practices and oversee compliance
  - Provide consideration around adding this patient safety initiative as a Pay 4 Value (P4V) opportunity to the next quality plan

Recommended Actions

- Authorize establishment of a Multi-Drug-Resistant Organisms (MDRO) suppression quality initiative; and
- Authorize the distribution of up to $2.3 million in FY 2019-20 CalOptima Medi-Cal funds in payments to providers meeting criteria for payment under this MDRO suppression quality initiative.

CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner


A Public Agency
CalOptima
Better. Together.


Medi-Cal
A Public Agency
CalOptima
Better. Together.


OneCare (HMO SNP)
A Public Agency
CalOptima
Better. Together.


OneCare Connect
A Public Agency
CalOptima
Better. Together.


PACE
A Public Agency
CalOptima
Better. Together.

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs in
Orange County

SHIELD Orange County – *Together We Can Make a Difference!*

What is SHIELD Orange County?

SHIELD OC is a public health collaborative initiated by the Centers for Disease Control and Prevention (CDC) to combat the spread of endemic and emerging multi-drug resistant organisms (MDROs) across healthcare facilities in Orange County. This effort is supported by the California Department of Public Health (CDPH) and the Orange County Health Care Agency (OCHCA). This regional collaborative will implement a decolonization strategy to reduce transmission of MDROs both countywide and within healthcare facilities.

Visit our CDC webpage here!
https://www.cdc.gov/hai/research/cdc-mdro-project.html

SHIELD OC Goals:

- Reduce MDRO carriage
- Reduce countywide MDRO clinical cultures
- Assess impact in participants and non-participants

SHIELD OC is coordinated by the University of California Irvine and LA BioMed at Harbor-UCLA.

Who is participating?

38 healthcare facilities are participating in SHIELD OC. These facilities were invited to participate based on their inter-connectedness by patient sharing statistics. In total, participants include 17 hospitals, 3 long-term acute care hospitals (LTACHs), and 18 nursing homes.

What is the decolonization intervention?

In the SHIELD OC collaborative, decolonization refers to the use of topical products to reduce bacteria on the body that can produce harmful infections.

- **Hospitals (for adult patients on contact precautions)**
  - Chlorhexidine (CHG) antiseptic soap for daily bathing or showering
  - Nasal decolonization with 10% povidone-iodine
  - Continue CHG bathing for adult patients in ICU units
- **Nursing homes and LTACHs**
  - Chlorhexidine (CHG) antiseptic soap for routine bathing and showering
  - Nasal decolonization with 10% povidone-iodine on admission and every other week

All treatments used for decolonization are topical and their safety profile is excellent.

With questions, please contact the SHIELD OC Coordinating Team

(949) 824-7806 or SHIELDOrangeCounty@gmail.com

CalOptima Checklist

Nursing Home Name: _____

Month Audited (Month/year): _____/_____

Today's Date: _____/_____/_____

Completed by: _____

- ☐ Proof of product purchase
- ☐ Evidence the decolonization program handout is in admission packet
- ☐ Monitor and document compliance with bathing one day each week
- ☐ Monitor and document compliance with iodophor one day each week iodophor is used
- ☐ Conduct three peer-to-peer bathing skills assessments per month

Product Usage

PRODUCT DESCRIPTION	RECEIPT PROVIDED	QUANTITY DELIVERED	ESTIMATED MONTHLY USAGE
4% CHG Gallons	☐	_____ gallons	_____ gallons
10% Iodine Swabsticks	☐	_____ boxes	_____ boxes
		_____ swabs per box	

INTERNAL USE ONLY –APPROVAL:

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Facility Name: _____Unit: _____ Date: _____

STAFF Skills Assessment:
CHG Bed Bath Observation Checklist

Individual Giving CHG Bath

Please indicate who performed the CHG bath.

☐ **Nursing Assistant (CNA)** ☐ **Nurse** ☐ **LVN** ☐ **Other: _____**

Observed CHG Bathing Practices

Please check the appropriate response for each observation.

☐ **Y** ☐ **N** **Resident received CHG bathing handout**
☐ **Y** ☐ **N** **Resident told that no rinse bath provides protection from germs**
☐ **Y** ☐ **N** **Provided rationale to the resident for not using soap at any time while in unit**
☐ **Y** ☐ **N** **Massaged skin *firmly* with CHG cloth to ensure adequate cleansing**
☐ **Y** ☐ **N** **Cleaned face and neck well**
☐ **Y** ☐ **N** **Cleaned between fingers and toes**
☐ **Y** ☐ **N** **Cleaned between all folds**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned occlusive and semi-permeable dressings with CHG cloth**
☐ **Y** ☐ **N** ☐ **N/A** **Cleaned 6 inches of all tubes, central lines, and drains closest to body**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on superficial wounds, rash, and stage 1 & 2 decubitus ulcers**
☐ **Y** ☐ **N** ☐ **N/A** **Used CHG on surgical wounds (unless primary dressing or packed)**
☐ **Y** ☐ **N** **Allowed CHG to air-dry / does not wipe off CHG**
☐ **Y** ☐ **N** **Disposed of used cloths in trash /does not flush**

Query to Bathing Assistant/Nurse

1. How many cloths were used for the bath?

_____

2. If more than 6 cloths was used, provide reason.

_____

3. Are you comfortable applying CHG to superficial wounds, including surgical wounds?

_____

4. Are you comfortable applying CHG to lines, tubes, drains and non-gauze dressings?

_____

5. Do you ever wipe off the CHG after bathing?

_____

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ORIGINAL ARTICLE

Decolonization to Reduce Postdischarge Infection Risk among MRSA Carriers

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ABSTRACT

BACKGROUND

Hospitalized patients who are colonized with methicillin-resistant *Staphylococcus aureus* (MRSA) are at high risk for infection after discharge.

METHODS

We conducted a multicenter, randomized, controlled trial of postdischarge hygiene education, as compared with education plus decolonization, in patients colonized with MRSA (carriers). Decolonization involved chlorhexidine mouthwash, baths or showers with chlorhexidine, and nasal mupirocin for 5 days twice per month for 6 months. Participants were followed for 1 year. The primary outcome was MRSA infection as defined according to Centers for Disease Control and Prevention (CDC) criteria. Secondary outcomes included MRSA infection determined on the basis of clinical judgment, infection from any cause, and infection-related hospitalization. All analyses were performed with the use of proportional-hazards models in the per-protocol population (all participants who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization) and as-treated population (participants stratified according to adherence).

RESULTS

In the per-protocol population, MRSA infection occurred in 98 of 1063 participants (9.2%) in the education group and in 67 of 1058 (6.3%) in the decolonization group; 84.8% of the MRSA infections led to hospitalization. Infection from any cause occurred in 23.7% of the participants in the education group and 19.6% of those in the decolonization group; 85.8% of the infections led to hospitalization. The hazard of MRSA infection was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03; number needed to treat to prevent one infection, 30; 95% CI, 18 to 230); this lower hazard led to a lower risk of hospitalization due to MRSA infection (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The decolonization group had lower likelihoods of clinically judged infection from any cause (hazard ratio, 0.83; 95% CI, 0.70 to 0.99) and infection-related hospitalization (hazard ratio, 0.76; 95% CI, 0.62 to 0.93); treatment effects for secondary outcomes should be interpreted with caution owing to a lack of prespecified adjustment for multiple comparisons. In as-treated analyses, participants in the decolonization group who adhered fully to the regimen had 44% fewer MRSA infections than the education group (hazard ratio, 0.56; 95% CI, 0.36 to 0.86) and had 40% fewer infections from any cause (hazard ratio, 0.60; 95% CI, 0.46 to 0.78). Side effects (all mild) occurred in 4.2% of the participants.

CONCLUSIONS

Postdischarge MRSA decolonization with chlorhexidine and mupirocin led to a 30% lower risk of MRSA infection than education alone. (Funded by the AHRQ Healthcare-Associated Infections Program and others; ClinicalTrials.gov number, NCT01209234.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Huang at the University of California Irvine School of Medicine, Division of Infectious Diseases, 100 Theory, Suite 120, Irvine, CA 92617, or at sshuang@uci.edu.

N Engl J Med 2019;380:638-50.
DOI: 10.1056/NEJMoa1716771

Methicillin-resistant *Staphylococcus aureus* (MRSA) causes more than 80,000 invasive infections in the United States annually.[1] It is the most common cause of skin, soft-tissue, and procedure-related infections.[2] Rates of invasive MRSA infection are highest within 6 months after hospital discharge and do not normalize for 1 year.[1,3,4]

Approaches to MRSA have included education about both hygiene and environmental cleaning as well as decolonization with nasal mupirocin and chlorhexidine antiseptic baths to reduce carriage and prevent infection.[5,6] Decolonization has reduced the risks of surgical-site infection, recurrent skin infection, and infection in the intensive care unit (ICU).[7-10] Our goal was to evaluate whether, after hospital discharge, decolonization plus hygiene education was superior to education alone in reducing the likelihood of MRSA infection among patients colonized with MRSA (carriers).

Methods

Trial Design and Intervention

We conducted the Project CLEAR (Changing Lives by Eradicating Antibiotic Resistance) Trial as a multicenter, two-group, unblinded, randomized, controlled trial to compare the effect of hygiene education with that of education plus decolonization on the likelihood of postdischarge infection among MRSA carriers. This trial was approved by the institutional review board of the University of California Irvine. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol, available with the full text of this article at NEJM.org.

Participants were randomly assigned, in a 1:1 ratio, to the education group or the decolonization group. Randomization was performed with a randomized block design stratified according to Hispanic ethnic group and nursing home residence. In the education group, participants received and reviewed an educational binder (provided in English and Spanish) about MRSA and how it is spread and about recommendations for personal hygiene, laundry, and household cleaning (Appendix A in the Supplementary Appendix, available at NEJM.org). In the decolonization group, participants received and reviewed the identical educational binder and also underwent decolonization for 5 days twice monthly for a period of 6 months after hospital discharge (Appendix B in the Supplementary Appendix). The decolonization intervention involved the use of 4% rinse-off chlorhexidine for daily bathing or showering, 0.12% chlorhexidine mouthwash twice daily, and 2% nasal mupirocin twice daily. All products were purchased with grant funds and were provided free of charge to the participants.

Recruitment and Eligibility Criteria

Recruitment involved written informed consent provided between January 10, 2011, and January 2, 2014, during inpatient admissions in 17 hospitals and 7 nursing homes in Southern California (Table S1 in the Supplementary Appendix). Eligibility requirements included an age of 18 years or older, hospitalization within the previous 30 days, positive testing for MRSA during the enrollment hospitalization or within the 30 days before or afterward, and the ability to bathe or shower (alone or assisted by a caregiver). Key exclusion criteria were hospice care and allergy to the decolonization products at recruitment. California mandates MRSA screening at hospital admission in high-risk patients: those undergoing hemodialysis, those who had a recent hospitalization (within the preceding 30 days), those who were undergoing imminent surgery, those who were admitted to the ICU, and those who were transferred from a nursing home.

Follow-up

Participants were followed for 12 months after discharge. In-person visits at home or in a research clinic occurred at recruitment and at months 1, 3, 6, and 9. An exit interview was conducted at 12 months. The trial had a fixed end date of June 30, 2014. Participants who were enrolled after July 1, 2013, had a truncated follow-up and had their data administratively censored at that time. Loss to follow-up was defined as the inability of trial staff to contact participants for 3 months, at which point the participant was removed from the trial as of the date of last contact. Participants received escalating compensation for completing follow-up visits ($25, $30, $35, and $50).

All participants were contacted monthly and requested to report any hospitalizations or clinic visits for infection. After trial closure, medical records from reported visits were requested, double-redacted for protected health information and trial-group assignment, and reviewed for trial outcomes. Records from enrollment hospi-

talizations were requested and reviewed for characteristics of the participants and the presence or absence of MRSA infection at the enrollment hospitalization. Records were requested up to five times, with five additional attempts to address incomplete records.

TRIAL OUTCOMES

Redacted medical records from enrollment hospitalizations and all reported subsequent medical visits were reviewed in a blinded fashion, with the use of standardized forms, by two physicians with expertise in infectious diseases (five of the authors) for coexisting conditions, antibiotic agents, and infection outcomes. If consensus was not reached, discordant outcomes were adjudicated by a third physician with expertise in infectious diseases.

The primary outcome was MRSA infection according to medical-record documentation of disease-specific infection criteria (according to 2013 guidelines) from the Centers for Disease Control and Prevention (CDC) in a time-to-event analysis.[11] A priori secondary outcomes included MRSA infection defined in a time-to-event analysis according to the clinical judgment of two reviewers with expertise in infectious diseases who were unaware of the trial-group assignments, infection from any cause according to disease-specific CDC criteria in a time-to-event analysis, infection from any cause according to infectious disease clinical judgment in a time-to-event analysis, hospitalization due to infection, and new carriage of a MRSA strain that was resistant to mupirocin (evaluated by Etest, bioMérieux)[12] or that had an elevated minimum inhibitory concentration (MIC) of chlorhexidine (≥8 μg per milliliter) on microbroth dilution.[13,14] All outcomes were assessed on the basis of the first event per participant.

DATA COLLECTION

Surveys of health conditions, health care utilization, and household cleaning and bathing habits were administered during recruitment and all follow-up visits. Swabs of both nares, the throat, skin (axilla and groin), and any wounds were taken, but the results are not reported here. At each visit, participants in the decolonization group reported adherence to the intervention, and staff assessed the remaining product. Potential discrepancies were broached with the participant to obtain affirmation of actual adherence. Adherence was assessed as full (no missed doses), partial (some missed doses), and nonadherence (no doses used).

STATISTICAL ANALYSIS

The characteristics of the participants and outcomes were described by frequency and type according to trial group. Outcomes were summarized with the use of Kaplan–Meier estimates of infection-free distributions across the follow-up period and analyzed with the use of unadjusted Cox proportional-hazard models (per-protocol primary analysis) for the postdischarge trial population (all the participants who underwent randomization, met inclusion criteria, and survived beyond the recruitment hospitalization); outcomes were also analyzed according to the as-treated adherence strata (fully adherent, partially adherent, and nonadherent participant-time). In the as-treated analyses, information about participant adherence during at-risk periods before each visit was updated with the use of the adherence assessment at that visit.

The assumption of proportional hazards was assessed by means of residual diagnostic tests and formal hypothesis tests. P values are provided only for the primary outcome. Because the statistical analysis plan did not include a provision for correction for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, those results are reported as point estimates with 95% confidence intervals. The widths of the confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

In post hoc exploratory analyses, we used adjusted Cox proportional-hazard models to address potential residual imbalances in the characteristics of the participants between the two groups after randomization. The characteristics of the participants were entered into the model if they were associated with outcomes at a P value of less than 0.20 in bivariate analyses. Characteristics included demographic data; educational level; insurance type; presence of coexisting conditions, devices, or wounds at enrollment; hospitalization or residence in a nursing home in the year before enrollment; ICU admission or surgery during enrollment hospitalization; need

for assistance with bathing; frequency of bathing; and randomization strata. Adjusted models also accounted for two time-dependent covariates: receipt of anti-MRSA antibiotics and adherence to the intervention. The number needed to treat was calculated with the use of rates that accounted for participant-time that incorporated censoring due to loss to follow-up, withdrawal from the trial, or the end of the trial.[15] Full details of the trial design and analytic approach are provided in the protocol and in the Supplementary Appendix.

RESULTS

PARTICIPANTS

Figure 1 shows the randomization and follow-up of 2140 participants, of whom 19 were excluded after randomization because they did not meet inclusion criteria (6 participants did not have a positive MRSA test, and 13 died during the enrollment hospitalization). The characteristics of the final 2121 enrolled participants (per-protocol population) are provided in Table 1, and in Tables S2 through S4 in the Supplementary Appendix.

According to the randomization strata, Hispanic participants made up 31.9% of the education group (339 participants) and 32.0% of the decolonization group (339), and nursing home residents made up 11.3% of the education group (120) and 11.0% of the decolonization group (116). In a comparison of the education group with the decolonization group across the 1-year follow-up, early exit from the trial occurred in 34.9% of the participants (371 participants) and 37.0% (391), respectively ($P=0.32$); withdrawal from the trial in 6.8% (72) and 11.6% (123), respectively ($P<0.001$); loss to follow-up in 17.4% (185) and 16.1% (170), respectively ($P=0.41$); and death in 10.7% (114) and 9.3% (98), respectively ($P=0.26$). The characteristics of the participants who withdrew from the trial or were lost to follow-up and of the participants in the decolonization group according to adherence category are shown in Table S5 in the Supplementary Appendix.

OUTCOMES

A total of 8395 full-text medical records were requested, and 8067 (96.1%) were received and redacted. Charts underwent duplicate blinded review (16,134 reviews) by physicians with expertise in infectious diseases at a rate of approximately 800 charts per month for 20 months. Of the 2121 enrollment admission records, 2100 (99.0%) were received. Of the 6271 subsequent inpatient and outpatient records, 5967 (95.2%) were received for outcome assessment. The overall rate of reported hospitalizations per 365 days of follow-up was 1.97 in the education group and 1.75 in the decolonization group.

Regarding the primary outcome in the per-protocol analysis, 98 participants (9.2%) in the education group had a MRSA infection, as compared with 67 (6.3%) in the decolonization group (Table 2). This corresponded to an estimated MRSA infection rate in the education group of 0.139 infections per participant-year, as compared with 0.098 infections per participant-year in the decolonization group. Among first MRSA infections per participant, skin and soft-tissue infections and pneumonia were common. Across both groups, 84.8% (140 of 165) of the MRSA infections resulted in hospitalization, at a rate of 0.117 hospitalizations per participant-year in the education group and 0.083 per participant-year in the decolonization group. Bacteremia occurred in 28.5% (47 of 165) of all MRSA infections; the MRSA bacteremia rate was 0.040 events per participant-year in the education group and 0.028 per participant-year in the decolonization group. Findings were similar when MRSA infection was determined according to the clinical judgment of physicians with expertise in infectious diseases and according to CDC criteria (Table 2). All the MRSA infections were treated with an antibiotic, but the receipt of an antibiotic was not sufficient to render a decision of a MRSA infection.

In the analysis of infection from any cause according to CDC criteria, 23.7% of the participants in the education group (252 participants) had an infection, as compared with 19.6% of those in the decolonization group (207), which corresponded to an estimated rate of 0.407 infections per participant-year in the education group and 0.338 per participant-year in the decolonization group (Table 2). Skin and soft-tissue infections and pneumonia remained the most common infection types.

Pathogens were identified in 67.7% of the infections (Table S6 in the Supplementary Appendix). Participants in the decolonization intervention had a lower rate of infections due to gram-positive pathogens or without cultured pathogens than those in the education group. There was a

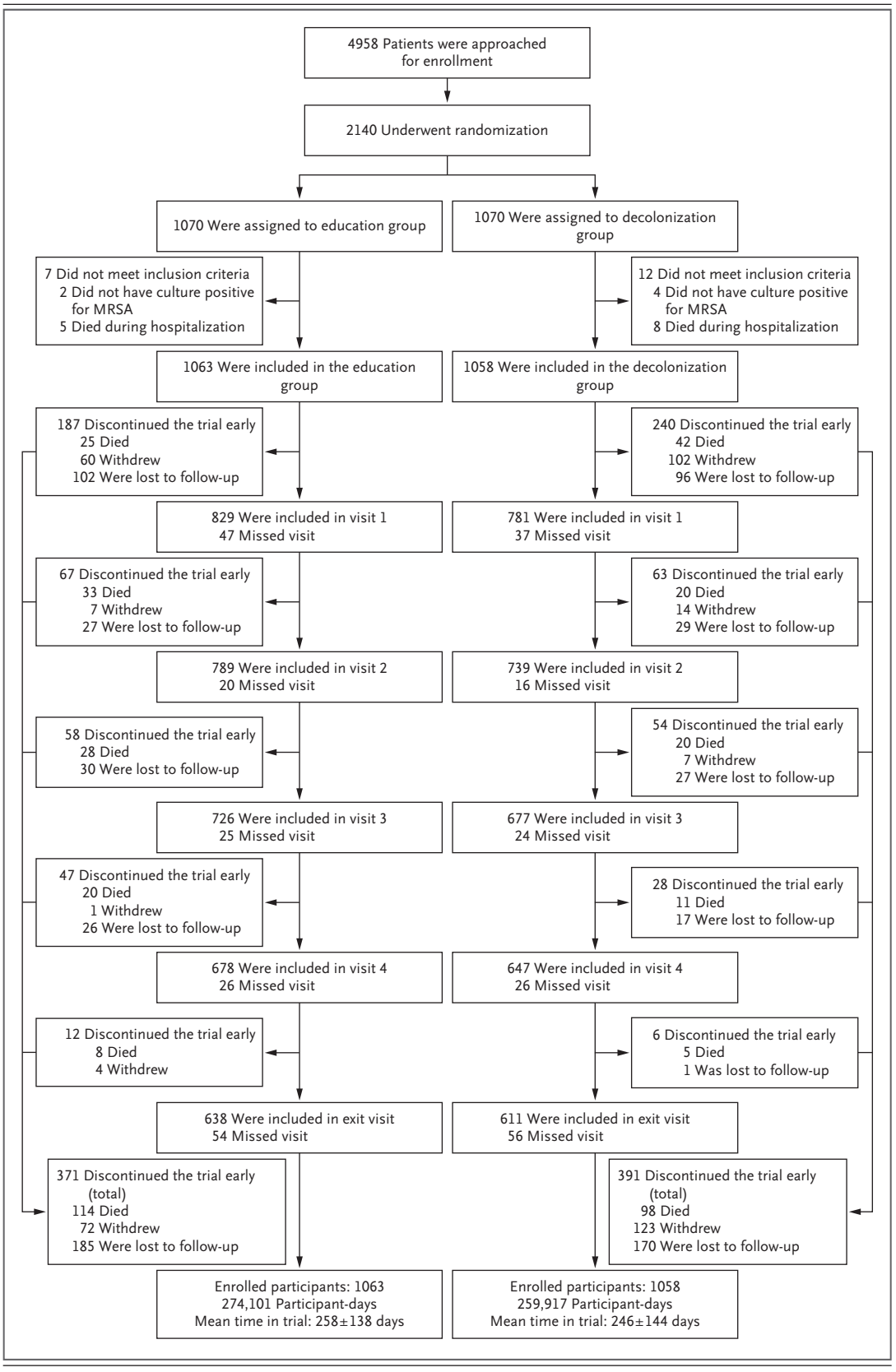

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Figure 1 (facing page). Randomization and Follow-up of the Participants.

This flow chart describes the recruitment and the four follow-up visits (at 1, 3, 6, and 9 months) for the 1-year period after hospital discharge. Recruitment occurred during hospitalization, and 19 participants were excluded from the postdischarge trial population because they did not meet inclusion criteria, leaving 2121 participants in the per-protocol population (1063 participants in the education group and 1058 in the decolonization group). Early exit from the trial was provided between each visit and included active withdrawal from the trial, loss to follow-up, and death. Active withdrawal represented situations in which participants indicated their desire to withdraw from the trial. Loss to follow-up was defined as the inability to contact the participant for 3 months, at which point the participant was removed from the trial at the time of last contact. Visits indicate both participants who successfully completed the visit and those who remained in the trial but missed that visit. The mean (±SD) time in the trial (in days) is shown for each group. All deaths were considered by the investigators to be unrelated to side effects from decolonization products. Summary boxes are provided at the bottom of the figure. MRSA denotes methicillin-resistant *Staphylococcus aureus*.

higher rate of gram-negative infection among the CDC-defined all-cause infections when participants in the decolonization intervention were compared with those in the education group, but this was not seen among clinically defined infections.

Across the two trial groups, infection from any cause led to hospitalization in 85.8% of the participants (394 of 459), and bacteremia occurred in 18.1% (83 of 459). The observed rate of hospitalization due to infection from any cause was 0.356 events per participant-year in the education group and 0.269 per participant-year in the decolonization group. The rate of bacteremia among participants with infection from any cause was 0.074 events per participant-year in the education group and 0.060 per participant-year in the decolonization group. Findings were similar when infection from any cause was determined according to clinical judgment (Table 2).

Estimates of the per-protocol treatment effects are shown in Table 3. No significant departures from proportional hazards were observed. In the main unadjusted analysis, the hazard of MRSA infection according to the CDC criteria (the primary outcome) was significantly lower in the decolonization group than in the education group (hazard ratio, 0.70; 95% confidence interval [CI], 0.52 to 0.96; P=0.03). This lower hazard of MRSA infection led to a 29% lower risk of hospitalization due to CDC-defined MRSA infection in the decolonization group than in the education group (hazard ratio, 0.71; 95% CI, 0.51 to 0.99). The effect was nearly identical for cases and hospitalizations involving clinically defined MRSA infection. Kaplan–Meier curves showing the infection-free time for the primary outcome of CDC-defined MRSA infection and the secondary outcome of infection from any cause show that the curves remained separated even after the intervention ended in month 6 (Fig. 2, and Table S7 in the Supplementary Appendix). Adjusted models showed greater MRSA infection effects that were significant (Table 3). A total of 10 participants (0.9%) in the education group and in 3 (0.3%) in the decolonization group died from MRSA infection. Results of sensitivity analyses conducted regarding death and early withdrawal from the trial are provided in Table S8 in the Supplementary Appendix.

The hazard of infection from any cause according to clinical judgment was lower in the decolonization group than in the education group (hazard ratio, 0.83; 95% CI, 0.70 to 0.99); similarly, the hazard of infection from any cause according to CDC criteria was lower in the decolonization group (hazard ratio, 0.84; 95% CI, 0.70 to 1.01) (Fig. 2B and Table 3). The risk of hospitalization due to infection from any cause was lower in the decolonization group than in the education group (hazard ratio, 0.76; 95% CI, 0.62 to 0.93). The results of the adjusted analyses were similar to those of the unadjusted analyses (Table 3). Deaths due to any infection occurred in 25 participants (2.3%) in the education group and 17 (1.6%) in the decolonization group.

EFFECT OF ADHERENCE

In as-treated analyses, 65.6% of the participant-time in the decolonization group involved full adherence; 19.6%, partial adherence; and 14.8%, nonadherence. Participants were highly consistent in adherence across the follow-up time. Increasing adherence was associated with increasingly lower rates of infection in both the adjusted and unadjusted models (Table 3). In comparisons of the adherence-category subgroups in the decolonization group with the education group overall, the likelihood of CDC-defined MRSA infection decreased 36% and 44%, respectively, as adher-

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Table 1. Characteristics of the Participants at Recruitment Hospitalization.*

Characteristic	Education Group (N=1063)	Decolonization Group (N=1058)	P Value†
Age — yr	56±17	56±17	0.78
Male sex — no. (%)	583 (54.8)	565 (53.4)	0.51
Coexisting conditions‡			
Diabetes — no./total no. (%)	424/1062 (39.9)	462/1056 (43.8)	0.08
Chronic obstructive pulmonary disease — no./total no. (%)	212/1055 (20.1)	203/1045 (19.4)	0.70
Congestive heart failure — no./total no. (%)	145/1055 (13.7)	149/1045 (14.3)	0.73
Cancer — no./total no. (%)	153/1055 (14.5)	161/1045 (15.4)	0.56
Renal disease — no./total no. (%)	140/1062 (13.2)	134/1056 (12.7)	0.74
Charlson Comorbidity Index score§	1.7±1.6	1.7±1.6	0.49
Bathe daily or every other day — no./total no. (%)¶	926/1037 (89.3)	927/1034 (89.7)	0.73
Bathing assistance needed — no./total no. (%)¶	200/1025 (19.5)	224/1013 (22.1)	0.15
MRSA source at enrollment — no. (%)			0.79
Nares‖	580 (54.6)	602 (56.9)	
Wound	320 (30.1)	305 (28.8)	
Respiratory	44 (4.1)	45 (4.3)	
Blood	43 (4.0)	31 (2.9)	
Other	76 (7.1)	75 (7.1)	
Recruitment hospitalization**			
Hospitalized in previous yr — no./total no. (%)‡	595/1046 (56.9)	598/1041 (57.4)	0.80
Nursing home stay in previous yr — no./total no. (%)‡	165/1043 (15.8)	168/1040 (16.2)	0.84
ICU stay — no./total no. (%)	188/1055 (17.8)	206/1045 (19.7)	0.27
Surgery — no./total no. (%)	392/1055 (37.2)	399/1045 (38.2)	0.63
MRSA infection — no./total no. (%)††	447/1055 (42.4)	438/1045 (41.9)	0.83
Wound at hospital discharge — no./total no. (%)	587/1055 (55.6)	588/1045 (56.3)	0.77
Medical device at hospital discharge — no./total no. (%)‡‡	320/1055 (30.3)	307/1045 (29.4)	0.63
Discharged to nursing home — no. (%)	120 (11.3)	116 (11.0)	0.81

* Plus–minus values are means ±SD. There were no significant differences between the two groups. Selected descriptive data are shown. For a full descriptive list of characteristics, see Table S2 in the Supplementary Appendix. ICU denotes intensive care unit.
† Student's t-test was performed for continuous variables, chi-square test for proportions, and Fisher's exact test for proportions if the numerator was 5 or less.
‡ Data reflect a positive response to either a survey question or chart review. Not all participants responded to every question, and not all enrollment charts were received from recruiting hospitals despite a signed release request, so data were missing for 21 participants.
§ Scores on the Charlson Comorbidity Index range from 0 to 10, with higher scores indicating more coexisting illness.
¶ Data reflect respondents to the survey question among all the participants. Not all the participants responded to every question.
‖ By law, California requires hospitals to screen five groups of patients for MRSA on hospital admission (patients who are transferred from a nursing home, who have been hospitalized in the past 30 days, who are undergoing hemodialysis, who are undergoing imminent surgery, and who are admitted to an ICU).
** Data reflect chart review from the received medical records. Not all recruiting hospitals released participants' medical records to the trial despite a signed release request, so records were missing for 21 participants.
†† Assessment of infection was based on criteria of the Centers for Disease Control and Prevention (CDC). Information regarding infection types is provided in Table S3 in the Supplementary Appendix.
‡‡ Information about medical device types is provided in Table S4 in the Supplementary Appendix.

ence increased from partial adherence (hazard ratio, 0.64; 95% CI, 0.40 to 1.00) to full adherence (hazard ratio, 0.56; 95% CI, 0.36 to 0.86). Similar effects were seen with regard to CDC-defined infection from any cause, which was 40% lower among fully adherent participants than among the participants in the education group (hazard ratio, 0.60; 95% CI, 0.46 to 0.78).

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Table 2. MRSA Infection Outcomes (First Infection per Person) per 365 Days of Follow-up, According to Trial Group.*

Variable	MRSA Infection, According to CDC Criteria†		MRSA Infection, According to Clinical Criteria		Any Infection, According to CDC Criteria		Any Infection, According to Clinical Criteria	
	Education	Decolonization	Education	Decolonization	Education	Decolonization	Education	Decolonization
All Participants								
Infection — no. of participants (no. of events/participant-yr)								
Any infection	98 (0.139)	67 (0.098)	98 (0.139)	68 (0.100)	252 (0.407)	207 (0.338)	298 (0.498)	246 (0.414)
Skin or soft-tissue infection	34 (0.048)	32 (0.047)	35 (0.050)	32 (0.047)	80 (0.129)	59 (0.096)	97 (0.162)	82 (0.138)
Pneumonia	18 (0.026)	9 (0.013)	20 (0.028)	10 (0.015)	39 (0.063)	25 (0.041)	45 (0.075)	34 (0.057)
Primary bloodstream or vascular infection	11 (0.016)	10 (0.015)	12 (0.017)	11 (0.016)	20 (0.032)	14 (0.023)	20 (0.033)	14 (0.024)
Bone or joint infection	13 (0.019)	9 (0.013)	12 (0.017)	8 (0.012)	20 (0.032)	22 (0.036)	0.18 (0.030)	17 (0.029)
Surgical-site infection	13 (0.019)	2 (0.003)	13 (0.018)	2 (0.003)	20 (0.032)	8 (0.013)	22 (0.037)	9 (0.015)
Urinary tract infection	3 (0.004)	2 (0.003)	1 (0.001)	1 (0.002)	38 (0.061)	46 (0.075)	52 (0.087)	56 (0.094)
Abdominal infection	1 (0.001)	2 (0.003)	1 (0.001)	2 (0.003)	20 (0.032)	21 (0.034)	26 (0.044)	18 (0.030)
Other infection	5 (0.007)	1 (0.002)	4 (0.006)	2 (0.003)	15 (0.024)	12 (0.020)	18 (0.030)	16 (0.027)
Infection involving bacteremia	28 (0.040)	19 (0.028)	27 (0.038)	18 (0.026)	46 (0.074)	37 (0.060)	46 (0.077)	33 (0.056)
Infection leading in hospitalization	83 (0.117)	57 (0.083)	82 (0.115)	56 (0.082)	225 (0.356)	169 (0.269)	259 (0.420)	199 (0.325)
Time to infection — days	111±91	117±93	116±94	117±95	103±87	110±91	107±91	113±94
Adherent Participants in Decolonization Group‡								
Infection — no. of participants (no. of events/participant-yr)								
Any infection		42 (0.085)		42 (0.088)		118 (0.272)		142 (0.338)
Skin or soft-tissue infection		22 (0.045)		22 (0.046)		40 (0.092)		54 (0.129)
Pneumonia		5 (0.010)		5 (0.011)		11 (0.025)		16 (0.038)
Primary bloodstream or vascular infection		5 (0.010)		6 (0.013)		8 (0.019)		8 (0.019)
Bone or joint infection		5 (0.010)		4 (0.008)		14 (0.032)		11 (0.026)
Surgical-site infection		2 (0.004)		2 (0.004)		6 (0.014)		7 (0.017)
Urinary tract infection		0		0		22 (0.051)		27 (0.064)
Abdominal infection		2 (0.004)		2 (0.004)		12 (0.028)		11 (0.026)
Other infection		1 (0.002)		1 (0.002)		5 (0.012)		8 (0.019)
Infection involving bacteremia		9 (0.019)		8 (0.017)		19 (0.045)		16 (0.039)
Infection leading to hospitalization		36 (0.075)		34 (0.071)		98 (0.226)		115 (0.274)
Time to infection — days		122±93		125±96		119±89		123±94

* Participant-day denominators were censored by the specified outcome. Dates of infection onset based on CDC criteria may differ from those based on clinical judgment.
† This was the primary outcome.
‡ A total of 546 participants were considered to have adhered fully to the decolonization intervention.

Table 3. Effect of Decolonization Plus Education, as Compared with Education Alone, According to Cox Proportional-Hazard Models.*

Variable	MRSA Infection, According to CDC Criteria	MRSA Infection, According to Clinical Criteria	Any Infection, According to CDC Criteria	Any Infection, According to Clinical Criteria
Per-protocol analysis				
Unadjusted hazard ratio (95% CI)	0.70 (0.52–0.96)†	0.71 (0.52–0.97)	0.84 (0.70–1.01)	0.83 (0.70–0.99)
Adjusted hazard ratio (95% CI)‡	0.61 (0.44–0.85)	0.61 (0.43–0.84)	0.80 (0.66–0.98)	0.81 (0.68–0.97)
As-treated analysis§				
Unadjusted hazard ratio (95% CI)				
Nonadherent	1.31 (0.72–2.38)	1.09 (0.57–2.10)	1.68 (1.19–2.36)	1.53 (1.11–2.13)
Partially adherent	0.64 (0.40–1.00)	0.72 (0.47–1.11)	0.86 (0.67–1.11)	0.92 (0.74–1.16)
Fully adherent	0.56 (0.36–0.86)	0.53 (0.34–0.83)	0.60 (0.46–0.78)	0.58 (0.45–0.74)
Adjusted hazard ratio (95% CI)¶				
Nonadherent	0.78 (0.36–1.71)	0.72 (0.37–1.41)	0.780 (0.51–1.26)	0.76 (0.40–1.45)
Partially adherent	0.75 (0.59–0.95)	0.69 (0.54–0.88)	0.78 (0.64–0.97)	0.76 (0.63–0.92)
Fully adherent	0.72 (0.57–0.92)	0.66 (0.51–0.84)	0.75 (0.60–0.94)	0.72 (0.58–0.88)

* The per-protocol population included all the participants (2121) who underwent randomization, met the inclusion criteria, and survived beyond the recruitment hospitalization. The unadjusted analyses included all these participants. The adjusted models included the 1901 participants who provided data for all the baseline characteristics shown in Table S2 in the Supplementary Appendix.

† A P value is provided only for the primary outcome (P=0.03). Because the statistical analysis plan did not include a provision for correcting for multiple comparisons when tests for prespecified secondary outcomes or post hoc exploratory outcomes were conducted, these results are reported as point estimates with 95% confidence intervals. The widths of these confidence intervals were not adjusted for multiple comparisons, so intervals should not be used to infer definitive treatment effects within subgroups or for secondary outcomes.

‡ Models evaluating the outcomes of MRSA infection according to CDC criteria and any infection according to clinical criteria were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, cancer, cerebrovascular disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, need for bathing assistance, and anti-MRSA antibiotics as time-varying covariates on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses. Models evaluating the outcome of MRSA infection according to clinical criteria and any infection according to CDC criteria were adjusted for the same variables with the addition of age. Resistance to mupirocin did not significantly modify the effect of the trial group.

§ The as-treated analysis assessed the effect on trial outcomes on the basis of the participant's level of adherence to the use of decolonization products as compared with the education group. Among the participants in the decolonization group, 65.6% of the participant-time involved full adherence (no missed doses); 19.6%, partial adherence (some missed doses); and 14.8%, nonadherence (no doses used). The comparator for each adherence subgroup was the overall education group.

¶ As-treated models for all outcomes were adjusted for randomization strata, sex, primary insurance type, diabetes, renal disease, liver disease, hospitalization within 12 months before enrollment hospitalization, medical device on discharge from enrollment hospitalization, bathing frequency, and need for bathing assistance on the basis of variables associated with outcomes at a P value of less than 0.20 in bivariate analyses.

Nonadherence was associated with a higher likelihood of infection from any cause than was observed among participants in the education group.

NUMBER NEEDED TO TREAT

Overall, the estimated number needed to treat to prevent a MRSA infection was 30 (95% CI, 18 to 230) and to prevent an associated hospitalization, 34 (95% CI, 20 to 336). The number needed to treat to prevent any infection was 26 (95% CI, 13 to 212) and to prevent an associated hospitalization, 28 (95% CI, 21 to 270). Among the participants who adhered fully to the intervention (all of whom were in the decolonization group), the number needed to treat to prevent a MRSA infection was 26 (95% CI, 18 to 83) and to prevent an associated hospitalization, 27 (95% CI, 20 to 46). The number needed to treat to prevent any infection was 11 (95% CI, 8 to 21) and to prevent an associated hospitalization, 12 (95% CI, 8 to 23).

ADVERSE EVENTS

Adverse events that were associated with the topical decolonization intervention were mild and uncommon, occurring in 44 participants (4.2%) (Table S9 in the Supplementary Appendix). Local irritation occurred with mupirocin in 1.1% of the participants (12 of 1058), with chlorhexidine bathing in 2.3% (24), and with chlorhexidine mouthwash in 1.1% (12). In those respective

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categories, 33% (4 of 12), 29% (7 of 24), and 50% (6 of 12) of the participants chose to continue using the product (overall, 39% of the participants with side effects).

A total of 12.6% of the 1591 participants with postrecruitment MRSA strains had high-level resistance to mupirocin (9.4% [150 participants]) or low-level resistance to mupirocin (3.1% [50]). A total of 1.9% of the participants were newly found to have a mupirocin-resistant strain at subsequent visits (1.9% [16 of 826 participants] in the education group and 2.0% [15 of 765] in the decolonization group, P=0.97). A total of 1.5% of the participants in each group were newly found to have high-level mupirocin-resistant strains (1.6% [13 of 826 participants] in the education group and 1.4% [11 of 765] in the decolonization group, P=0.82) when only sensitive strains were detected at recruitment. Chlorhexidine MICs of 8 μg or more per milliliter were rare (occurring in 2 participants overall [0.1%]). Both patients were in the intervention group, and both isolates had an MIC of 8 μg per milliliter and were negative for the *qac A/B* gene).

DISCUSSION

Infection-prevention campaigns have reduced the risks of health care–associated infections in hospitals, leaving the majority of preventable infections to the postdischarge setting.[16] MRSA carriers are an appealing population target because of their higher risks of infection and postdischarge rehospitalization and the common practice of screening selected inpatients for MRSA colonization.[1,17-19] In the CLEAR trial, topical decolonization led to lower risks of infections and readmissions than hygiene education alone among patients after the transition from hospital to home and other care settings. With a number needed to treat between 25 and 30 to prevent infection and hospitalization, this intervention is relevant to 1.8 million MRSA carriers (5% of inpatients) who are discharged from hospitals each year.[16]

Although decolonization has successfully prevented disease during temporary high-risk circumstances (e.g., recurrent skin infections, ICU care, and arthroplasty and cardiac surgery),[6-10,19-22] a single 5-day decolonization regimen produced short-lived MRSA clearance in half the carriers.[23-26] In contrast, twice-monthly decolonization provided protection for many months after discharge. The protective benefit continued after decolonization. In addition, this regimen was effective despite the greater variability in application with home bathing and showering than has occurred in previous inpatient trials that evaluated nursing-assisted chlorhexidine bath-

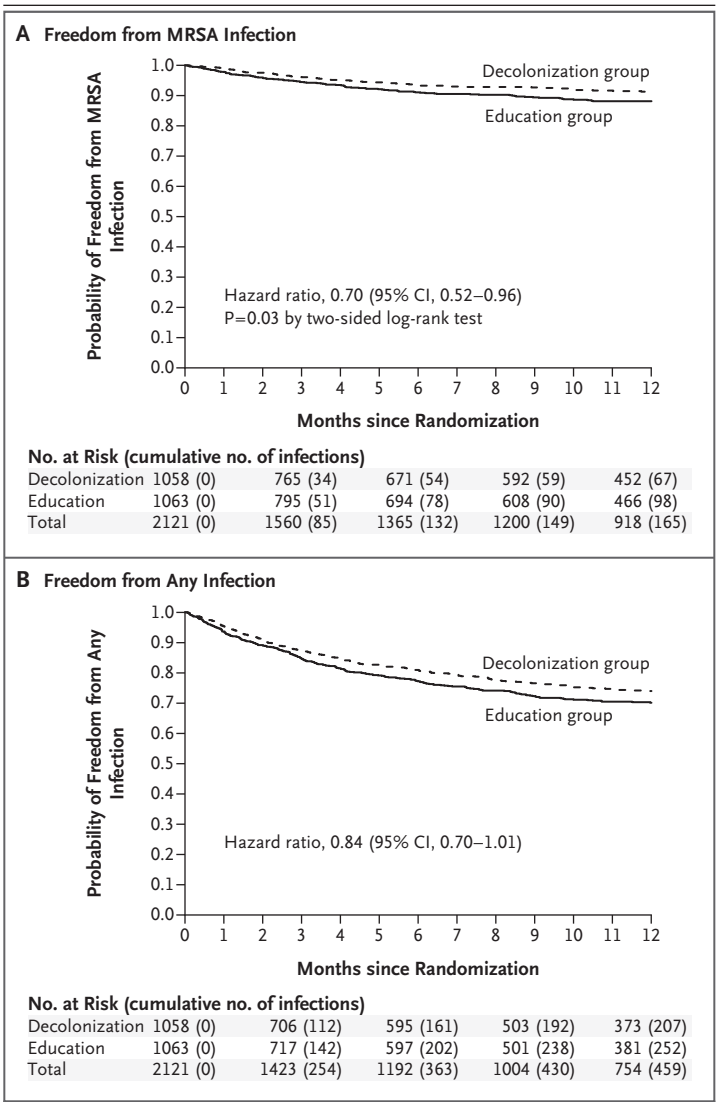

Figure 2. Kaplan–Meier Curves for Freedom from MRSA Infection and Infection from Any Cause, Assessed According to CDC Criteria.

Cases of MRSA infection and infection from any cause were assessed according to criteria of the Centers for Disease Control and Prevention (CDC). The probability of being free from MRSA infection (primary outcome) was significantly greater in the decolonization group than in the education group. The curves remained separated even though decolonization stopped at 6 months. Details regarding the numbers of patients at risk for infection and those with infection at the specific time points are provided in Table S7 in the Supplementary Appendix.

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ing and mupirocin application.[8,9,22] This trial also showed that 4% rinse-off chlorhexidine was effective in a postdischarge population that typically takes showers or baths and is unlikely to use a 2% leave-on chlorhexidine product.[8,9,22]

Not surprisingly, participants who adhered fully to the decolonization intervention had rates of MRSA infection and infection from any cause that were at least 40% lower than the rates among participants in the education group, with a number needed to treat of 12 to prevent infection-related hospitalization. This finding probably is attributable to both the decolonization effect and the likelihood that these participants were more adherent to other prescribed treatments and health-promotion behavior than participants in the education group. Participants who fully adhered to the intervention had fewer coexisting conditions, had fewer devices, required less bathing assistance, and were more likely to have MRSA infection (rather than asymptomatic colonization) at the time of enrollment than either participants in the education group or participants in the decolonization group who had lower levels of adherence. These differences represent an important practical distinction. To the extent that physicians can identify patients who are able to adhere to an intervention, those patients would derive greater benefit from the recommendation to decolonize. Nonadherence was common among nursing home residents, which raises questions about research barriers in that care setting.

Decolonization appeared to affect the risks of skin and soft-tissue infections, surgical-site infections, pneumonia, and bacteremia, although sample-size constraints necessitate cautious speculation. Decolonization also appeared to reduce the rate of gram-positive pathogens and infections without a cultured pathogen. The higher rate of gram-negative pathogens in the decolonization group than in the education group was seen among the CDC-defined all-cause infections but not among the clinically defined infections and requires further substantiation. These observations are based on relatively small numbers; larger studies have shown that chlorhexidine can reduce the incidence of gram-negative infections and bacteriuria.[27-30]

The design of this trial did not permit us to determine the effect of hygiene education alone. Both trial groups received in-person visits and reminders about the importance of MRSA-prevention activities. In addition, the free product overcame financial disparities that could become evident with post-trial adoption of the decolonization intervention.

Some participants (<5%) in the decolonization group had mild side effects; among those participants, nearly 40% opted to continue using the agent. Resistance to chlorhexidine and mupirocin was not differentially engendered in the two groups. We defined an elevated chlorhexidine MIC as at least 8 μg per milliliter, although 4% chlorhexidine applies 40,000 μg per milliliter to the skin.

This trial is likely to be generalizable because it was inclusive. For example, the enrollment of participants with late-stage cancer contributed to the 10% anticipated mortality and the approximate 25% rate of withdrawal and loss to follow-up. These rates are similar to other postdischarge trials with shorter durations of follow-up than the durations in our trial.[31-33] It is unknown whether the participants who withdrew or were lost to follow-up had different infection rates or intervention benefits. They were more educated and less likely to be Hispanic than those who did not withdraw or were not lost to follow-up, but the percentages of participants with coexisting conditions were similar.

Limitations of this trial include the unblinded intervention, although outcomes were assessed in a blinded fashion. The trial also had substantial attrition over the 1-year follow-up, and adherence was based on reports by the participants, with spot checks of remaining product, both of which may not reflect actual use. In addition, nearly all infections led to hospitalization, which suggests that milder infections escaped detection. Most outpatient and nursing home records had insufficient documentation for the event to be deemed infection according to the CDC or clinical criteria. Thus, it remains unknown whether the observed 30% lower risk of MRSA infection or the observed 17% lower risk of infection from any cause with decolonization than with education alone would apply to less severe infections that did not lead to hospitalization. Finally, although resistance to chlorhexidine and mupirocin did not emerge during the trial, the development of resistance may take time, beyond the follow-up period of this trial.

In conclusion, inpatients with MRSA-positive

cultures who had been randomly assigned to undergo decolonization with topical chlorhexidine and mupirocin for 6 months after discharge had lower risks of MRSA infection, infection from any cause, and hospitalization over the 1 year after discharge than those who had been randomly assigned to receive hygiene education only.

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), or the Agency for Healthcare Research and Quality (AHRQ).

Supported by a grant (R01HS019388, to Dr. Huang) from the AHRQ Healthcare-Associated Infections Program and by the University of California Irvine Institute for Clinical and Translational Science, which was funded by a grant from the NIH Clinical and Translational Sciences Award program (UL1 TR000153).

Dr. Huang reports conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, Clorox, Xttrium Laboratories, and Medline; Ms. Singh, Dr. Park, and Mr. Chang, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline; Dr. McKinnell, receiving grant support and consulting fees from Achaogen and Theravance Biopharma, grant support, consulting fees, and lecture fees from Allergan, consulting fees from Cempra, Melinta Therapeutics, Menarini Group, and Thermo Fisher Scientific, and fees for serving as a research investigator from Science 37, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline, and serving as cofounder of Expert Stewardship; Ms. Gombosev, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Mölnlycke, 3M, and Clorox; Dr. Rashid, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), Clorox, and Medline; Dr. Bolaris, conducting clinical studies in which participating nursing homes received donated products from 3M and Clorox; Dr. Robinson, serving as cofounder of Expert Stewardship; Dr. Amin, receiving consulting fees from Paratek Pharmaceuticals; Dr. Septimus, conducting clinical studies in which participating hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline; Dr. Weinstein, conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products) and Mölnlycke; Dr. Hayden, conducting clinical studies in which participating nursing homes and hospitals received donated product from Stryker (Sage Products), Mölnlycke, and Medline and donated laboratory services from OpGen and receiving grant support and conducting clinical studies in which participating nursing homes and hospitals received donated product from Clorox; and Dr. Miller, receiving grant support from Gilead Sciences, Merck, Abbott, Cepheid, Genentech, Atox Bio, and Paratek Pharmaceuticals, grant support and fees for serving on an advisory board from Achaogen and grant support, consulting fees, and fees for serving on an advisory board from Tetraphase and conducting clinical studies in which participating nursing homes and hospitals received donated products from Stryker (Sage Products), 3M, Clorox, Xttrium Laboratories, and Medline. No other potential conflict of interest relevant to this article was reported. Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank the trial participants and their families; the trial staff (Lauren Akahoshi, Jenna Alcaron, Isabel Alegria, Stephanie Arredondo-Glacet, Elizabeth Arreola, Donald Bayley, Nelly Beltran, Barbara Bodenhoefer, Stefan Boghossian, Diane Capobianco, Claudia Cervantes, Sarah Chevallier, Heather Clayton, Ramiro Correa, Nathalia Cressey, Tiffany Dam, Rupak Datta, Jennifer Do, Phillip Duffy, Tabitha Dutciuc, Marlene Estevez, Margarita Flores, Lauren Heim, Sandra Ibarra, Usme Khusbu, Bryn Launer, Cameron Lee, Brian Lewis, Karen Lolans, Andrea Marcantonio, Donna Matsudairas, Lisa [Angie] McErlain, Maria Mejia, Job Mendez, Angela Mendoza, Melanie Meton, Nicole Mohajer, Jennifer Nam, Ann Nguyen, Hanna Owens, Jalpa Patel, Lena Portillo, Sean Prendergast, Katy Precaido, Belinda Prado, Deborah Prunean, Victor Quan, Courtney Reynolds, Diana Romero, Aubrianne Rose, Maureen Schroeder, Grace Tagudar, Cynthia Toyoshima, Ivonne Turner, Qixin Wang, Emily Wawro, and Jun Zozobrado); two physicians who actively supported and facilitated recruitment (David Petreccia and Anjali Vora); the members of our community advisory board (Patricia Cantero, Ph.D., and Jeanine Thomas); the members of our data and safety monitoring board (Honghu Liu, David Beenhouwer, and George Sakoulas); and the staff of the many hospitals and nursing homes that supported the recruitment of participants in the trial.

APPENDIX

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PUBLIC HEALTH

Hospitals Look To Nursing Homes To Help Stop Drug-Resistant Infections

April 2, 20195:00 AM ET

ANNA GORMAN

A certified nursing assistant wipes Neva Shinkle's face with chlorhexidine, an antimicrobial wash. Shinkle is a patient at Coventry Court Health Center, a nursing home in Anaheim, Calif., that is part of a multicenter research project aimed at stopping the spread of MRSA and CRE — two types of bacteria resistant to most antibiotics. *Heidi de Marco/KHN*

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy to stop the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government's Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

This novel collaboration recognizes that superbugs don't remain isolated in one hospital or nursing home but move quickly through a community, said Dr. John Jernigan, who directs the CDC's office on health care-acquired infection research.

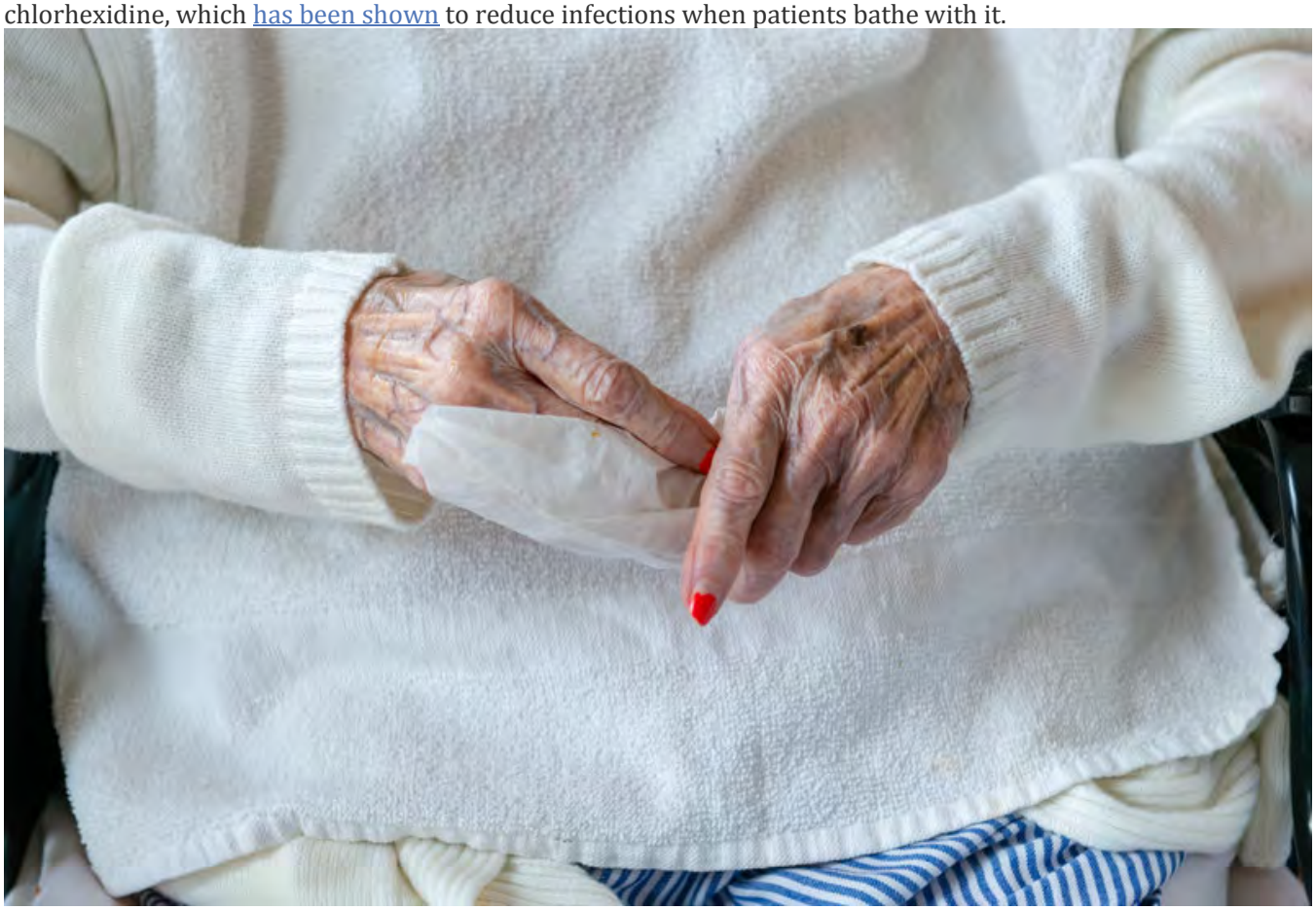
"No health care facility is an island," Jernigan says. "We all are in this complicated network."

At least 2 million people in the U.S. become infected with some type of antibiotic-resistant bacteria each year, and about 23,000 die from those infections, according to the CDC.

People in hospitals are vulnerable to these bugs, and people in nursing homes are particularly vulnerable. Up to 15 percent of hospital patients and 65 percent of nursing home residents harbor drug-resistant organisms, though not all of them will develop an infection, says Dr. Susan Huang, who specializes in infectious diseases at the University of California, Irvine.
"Superbugs are scary and they are unabated," Huang says. "They don't go away."

Some of the most common bacteria in health care facilities are methicillin-resistant *Staphylococcus aureus*, or MRSA, and carbapenem-resistant *Enterobacteriaceae*, or CRE, often called "nightmare bacteria." *E.Coli* and *Klebsiella pneumoniae* are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

CRE have "basically spread widely" among health care facilities in the Chicago region, says Dr. Michael Lin, an infectious-diseases specialist at Rush University Medical Center, who is heading the CDC-funded effort there. "If MRSA is a superbug, this is the extreme — the super superbug."
Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it.



The Centers for Disease Control and Prevention funds the project in California, based in Orange County, in which 36 hospitals and nursing homes are using an antiseptic wash, along with an iodine-based nose swab, on patients to stop the spread of deadly superbugs.
Heidi de Marco/KHN

Though hospital intensive care units frequently rely on chlorhexidine in preventing infections, it is used less commonly for bathing in nursing homes. Chlorhexidine also is sold over the counter; the FDA noted in 2017 it has caused rare but severe allergic reactions.
In Chicago, researchers are working with 14 nursing homes and long-term acute care hospitals, where staff are screening people for the CRE bacteria at admission and bathing them daily with chlorhexidine.

The Chicago project, which started in 2017 and ends in September, includes a campaign to promote hand-washing and increased communication among hospitals about which patients carry the drug-resistant organisms.

The infection-control protocol was new to many nursing homes, which don't have the same resources as hospitals, Lin says.

In fact, three-quarters of nursing homes in the U.S. received citations for infection-control problems over a four-year period, according to a Kaiser Health News analysis, and the facilities with repeat citations almost never were fined. Nursing home residents often are sent back to hospitals because of infections.
In California, health officials are closely watching the CRE bacteria, which are less prevalent there than elsewhere in the country, and they are trying to prevent CRE from taking hold, says Dr. Matthew Zahn, medical director of epidemiology at the Orange County Health Care Agency
"We don't have an infinite amount of time," Zahn says. "Taking a chance to try to make a difference in CRE's trajectory now is really important."

The CDC-funded project in California is based in Orange County, where 36 hospitals and nursing homes are using the antiseptic wash along with an iodine-based nose swab. The goal is to prevent new people from getting drug-resistant bacteria and keep the ones who already have the bacteria on their skin or elsewhere from developing infections, says Huang, who is leading the project.

Licensed vocational nurse Joana Bartolome swabs Shinkle's nose with an antibacterial, iodine-based solution at Anaheim's Coventry Court Health Center. Studies find patients can harbor drug-resistant strains in the nose that haven't yet made them sick.
Heidi de Marco/KHN

Huang kicked off the project by studying how patients move among different hospitals and nursing homes in Orange County — she discovered they do so far more than previously thought. That prompted a key question, she says: "What can we do to not just protect our patients but to protect them when they start to move all over the place?"

Her previous research showed that patients who were carriers of MRSA bacteria on their skin or in their nose, for example, who, for six months, used chlorhexidine for bathing and as a mouthwash, and swabbed their noses with a nasal antibiotic were able to reduce their risk of developing a MRSA infection by 30 percent. But all the patients in that study, published in February in the *New England Journal of Medicine*, already had been discharged from hospitals.

Now the goal is to target patients still in hospitals or nursing homes and extend the work to CRE. The traditional hospitals participating in the new project are focusing on patients in intensive care units and those who already carry drug-resistant bacteria, while the nursing homes and the long-term acute care hospitals perform the cleaning — also called "decolonizing" — on every resident.

One recent morning at Coventry Court Health Center, a nursing home in Anaheim, Calif., 94-year-old Neva Shinkle sat patiently in her wheelchair. Licensed vocational nurse Joana Bartolome swabbed her nose and asked if she remembered what it did.

"It kills germs," Shinkle responded.

"That's right. It protects you from infection."

In a nearby room, senior project coordinator Raveena Singh from UCI talked with Caridad Coca, 71, who had recently arrived at the facility. She explained that Coca would bathe with the chlorhexidine rather than regular soap. "If you have some kind of open wound or cut, it helps protect you from getting an infection," Singh said. "And we are not just protecting you, one person. We protect everybody in the nursing home."

Coca said she had a cousin who had spent months in the hospital after getting MRSA. "Luckily, I've never had it," she said.

Coventry Court administrator Shaun Dahl says he was eager to participate because people were arriving at the nursing home carrying MRSA or other bugs. "They were sick there and they are sick here," Dahl says.
Results from the Chicago project are pending. Preliminary results of the Orange County project, which ends in May, show that it seems to be working, Huang says. After 18 months, researchers saw a 25 percent decline in drug-resistant organisms in nursing home residents, 34 percent in patients of long-term acute care hospitals and 9 percent in traditional hospital patients. The most dramatic drops were in CRE, though the number of patients with that type of bacteria was smaller.

The preliminary data also show a promising ripple effect in facilities that aren't part of the effort, a sign that the project may be starting to make a difference in the county, says Zahn of the Orange County Health Care Agency.

"In our community, we have seen an increase in antimicrobial-resistant infections," he says**.** "This offers an opportunity to intervene and bend the curve in the right direction."

USA TODAY

How to fight ‘scary’ superbugs that kill thousands each year? Cooperation — and a special soap

Anna Gorman, Kaiser Health News Published 9:27 a.m. ET April 12, 2019 | **Updated 1:47 p.m. ET April 12, 201**

Hospitals and nursing homes in California and Illinois are testing a surprisingly simple strategy against the dangerous, antibiotic-resistant superbugs that kill thousands of people each year: washing patients with a special soap.

The efforts — funded with roughly $8 million from the federal government’s Centers for Disease Control and Prevention — are taking place at 50 facilities in those two states.

This novel approach recognizes that superbugs don’t remain isolated in one hospital or nursing home but move quickly through a community, said Dr. John Jernigan, who directs the CDC’s office on health care-acquired infection research.

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At least 2 million people in the U.S. become infected with an antibiotic-resistant bacterium each year, and about 23,000 die from those infections, according to the CDC.

People in hospitals are vulnerable to these bugs, and people in nursing homes are particularly vulnerable. Up to 15% of hospital patients and 65% of nursing home residents harbor drug-resistant organisms, though not all of them will develop an infection, said Dr. Susan Huang, who specializes in infectious diseases at the University of California-Irvine.

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USA TODAY

Certified nursing assistant Cristina Zainos prepares a special wash using antimicrobial soap. *(Photo: Heidi de Marco, Kaiser Health News)*

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Some of the most common bacteria in health care facilities are methicillin-resistant Staphylococcus aureus, or MRSA, and carbapenem-resistant Enterobacteriaceae, or CRE, often called “nightmare bacteria.” E. coli and Klebsiella pneumoniae are two common germs that can fall into this category when they become resistant to last-resort antibiotics known as carbapenems. CRE bacteria cause an estimated 600 deaths each year, according to the CDC.

CREs have “basically spread widely” among health care facilities in the Chicago region, said Dr. Michael Lin, an infectious-diseases specialist at Rush University Medical Center, who is heading the CDC-funded effort there. “If MRSA is a superbug, this is the extreme — the super superbug.”

Containing the dangerous bacteria has been a challenge for hospitals and nursing homes. As part of the CDC effort, doctors and health care workers in Chicago and Southern California are using the antimicrobial soap chlorhexidine, which has been shown to reduce infections when patients bathe with it. Though chlorhexidine is frequently used for bathing in hospital intensive care units and as a mouthwash for dental infections, it is used less commonly for bathing in nursing homes.

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Kaiser Health News is a national health policy news service that is part of the nonpartisan Henry J. Kaiser Family Foundation.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

May 14, 2019

CalOptima Board of Directors
505 City Parkway West
Orange, CA 92868

Dear CalOptima Board of Directors:

As the Director of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC), I want to relay that CDC is very encouraged by your proposed Post-Acute Infection Prevention Quality Initiative (PIPQI). We hope that this type of insurer initiative will help protect nursing home residents from infections and hospitalization.

To combat antibiotic resistant – an important global threat – CDC has activities to prevent infections, improve antibiotic use, and detect and contain the spread of new and emerging resistant bacteria. The nursing home population is at particular risk for acquiring these bacteria and developing infections that require antibiotics and hospital admission because of their age, complex health status, frequency of wounds, and need for medical devices. Surveillance data have shown that the majority of nursing home residents currently have one of these highly antibiotic resistant bacteria on their body, and often these bacteria are spread between residents, within the nursing home, and to other healthcare facilities.

There is a need for public health agencies, insurers, and healthcare providers to forge coordinated efforts to promote evidence-based infection prevention strategies to prevent infections and save lives. We see great synergy in linking CDC's role in providing surveillance and infection prevention guidance to CalOptima's ability to protect its members by supporting patient safety initiatives to reduce infections and the hospitalizations they cause.

CDC funded the Orange County regional decolonization collaborative (SHIELD) as a demonstration project to inform broader national infection prevention guidance. The ability to maintain its resounding success in reducing antibiotic resistant bacteria and infections is critical and Orange County will benefit on initiatives such as PIPQI that provide incentives to enable its adoption into operational best practices.

CDC plans to continue transitional support for this initiative, including training support for the 16 nursing homes currently in the SHIELD collaborative for at least one year. We hope that this training effort can complement and synergize the efforts of CalOptima's education and liaison nurses. In addition, we are providing transitional support to the Orange County Health Department to continue their ongoing surveillance efforts in order that the ongoing benefits of the intervention can be captured.

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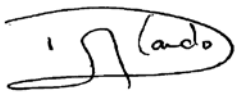
We look forward to collaborating with you. We believe this partnership is a valuable opportunity to protect highly vulnerable patients and to set an example of how insurers and public health can work together to improve healthcare quality.

Sincerely,



Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Attachment 4: IGT Funding Proposals

Proposal 1: Expanded Office Hours

Initiative Description: The Member Access and Engagement: Expanded Office Hours (Expanded Office Hours) is a two-year program to incentivize primary care providers and/or clinics for providing after-hour primary care services to CalOptima members in highly demanded and highly impacted areas. The Expanded Office Hours aims to improve member experience, timely access to needed care, and achieve positive population health outcomes.

Target Population(s): Primary care providers serving CalOptima's Medi-Cal members in highly demanded/impacted areas

Plan of Action/Key Milestones:
High level actions of how CalOptima will invest financial and staff resources to support the Expanded Office Hours initiative, such as:

1. Provider Data Gathering and Internal System Configuration
    - Identify primary care providers in community clinics who serve members in highly demanded and impacted areas
    - Configure the internal system (using codes 99050 and 99051) so claims can be adjudicated, and providers can receive expanded office hour incentives.
        - CPT code descriptions:
            - 99050: Services provided in the office at times other than regularly scheduled office hours, or days when the office is normally closed (e.g., holidays, Saturday or Sunday), in addition to basic service
            - 99051: Service(s) provided in the office during regularly scheduled evening, weekend, or holiday office hours, in addition to basic service
2. Provider Outreach
    - Collaborate with Provider Relations and Health Network Relations to promote the opportunity and encourage providers to provide these services.
    - $125 per member per visit incentive
3. Announce the Expanded Office Hours initiative to impacted Members
    - Call Center and frontline staff training
4. Monitor utilization of the expanded office hour services
    - Monitor and report claims and encounter for identification and linkage to primary care providers providing expanded office hour services

5. Evaluation
    - Conduct evaluation after pilot to see if member access has improved and depending on the outcome, consider expanding the initiative.

Estimated Budget: Total $2 million (up to $500,000 for FY2019/20, remaining amounts from FY2019/20 and $750,000 for FY2020/21, $750,000 FY2021/22)

Project Timeframe: April 2020 – March 2022

IGT 9 Focus Area: Member access and engagement

Strategic Plan Priority/Objectives: Expand CalOptima's Member-Centric Focus

- Focus on Population Health
- Strengthen Provider Network and Access to Care
- Enhance Member Experience and Customer Service

Participating/Collaborating Partners/Vendors/Covered Entities: Participating providers

Proposal 2: Post-Acute Infection Prevention Initiative (PIPQI)

Initiative Description: Expand CalOptima's program to suppress Multi Drug Resistant Organisms (MDROs) in CalOptima's contracted nursing facilities and decrease inpatient admissions due to infection. The pilot program was approved by CalOptima's Board of Directors on June 6, 2019.

Benefits of the Initiative:

- Member-centric focus: avoid MDRO colonization and inpatient admissions
- Potential cost savings from decreased antibiotic utilization
- Decreased demand for antibiotic-related c. difficile isolation beds
- Decreased Healthcare Acquired Infection rates (HAI):
    - Potential improved Star ratings
    - Strengthens community and national partnerships:
        - UCI (Professor Susan Huang -Department of Infectious Diseases)
        - Matthew Zahn, MD, Orange County Health Care Agency-Division of Epidemiology, CDC
        - (John A. Jernigan, MD, MS, Director, Office of Prevention Research and Evaluation Division of Healthcare Quality Promotion Centers for Disease Control and Prevention)
        - contracted nursing facilities
        - members/families
- Increased value and improved care delivery
- Enhanced operational excellence and efficiency

*Please note that there is currently an outbreak of a fungal infection called C. auris in Orange County LTACHs and NFs. It's a costly and virulent infection and the Public Health Department is involved. There are currently 160 cases in OC (need updated numbers). Chlorhexidine eradicates and protects against this fungus as well as Multi Drug Resistant Organisms (MDROs)

Target Member Population(s): CalOptima Members receiving services at contracted nursing facilities

Plan of Action/Key Milestones:

A. Teleconference requested by the CDC scheduled for April 2, 2020, as CalOptima is the only County in the U.S. that is an early adopter of CHG/Iodophor in NFs to lower MDRO colonization rates

B. Dedicate two Long Term Support Services Nurses to:

1) Provide training for newly participating facilities,
2) Provide ongoing support and compliance monitoring* at all participating facilities,
3) Develop additional informing, training and monitoring materials.

C. Promote the expansion of the Post-Acute of Infection Prevention Program and engage nursing facility administration and staff at the March 20, 202 LTSS Workshop.

*Monitoring includes monthly random testing (five patients per facility confirming presence of Chlorhexidine, invoices /delivery receipt for Chlorhexidine and Iodophor). Additional metrics: acute inpatient admission rates due to infection, Hospital Acquired Infection (HAI) rates.

Estimated Budget: Total budgeted amount $3.4 million over 3 fiscal years ($1 million for FY2019/20, $1.2 million for FY 2020/21 and $1.2 million for FY 2021/22)

Project Timeframe: Three years FY 2019/20– 2021/22

IGT 9 Focus Area: Quality performance and data exchange and support

Strategic Plan Priority/Objectives: Innovate and Be Proactive, Expand CalOptima's Member-Centric Focus, Strengthen Community Partnerships, Increase Value and Improve Care Delivery, Enhance Operational Excellence and Efficiency.

Participating/Collaborating Partners/Vendors/Covered Entities: University of California Irvine Medical Center, Department of Infectious Disease, Dr. Susan Huang; Orange County Health Care Agency-Division of Epidemiology, Centers for Disease Control (CDC); John A. Jernigan, MD, MS, Director, Office of Prevention Research and Evaluation Division of Healthcare Quality Promotion Centers for Disease Control and Prevention; CalOptima contracted nursing facilities.

Proposal 3: Hospital Data Sharing Initiative

Initiative Description: Establish incentives for implementation of a data sharing solution for Admit, Discharge, Transfer (ADT) and Electronic Health Record data to support alerting of hospital activities for CalOptima members for the purposes of improving care management. Participating entity will be eligible for incentive once each file exchange is in place. The overall goal is to improve costs, quality, care, and satisfaction.

Target Population(s): Contracted and participating Orange County hospitals serving CalOptima members and, potentially, other Community Based Organizations within the delivery system

Plan of Action/Key Milestones: Staff will obtain Board of Directors approval, contract with selected vendors, implement the solutions, establish an incentive plan and details, and work with the vendors and the hospitals to establish the means of sharing data.

Estimated Budget: $2 million to be exhausted by end of FY 2020-2021

Project Timeframe: Until end of FY 2020-2021

IGT 9 Focus Area: Data exchange and support

Strategic Plan Priority/Objectives: Expand CalOptima's Member-Centric Focus and Increase Value and Improve Care Delivery

Participating/Collaborating Partners/Vendors/Covered Entities: Hospitals providing the requested data

Proposal 4: Intergovernmental Transfer (IGT) Program Administration

Initiative Description: Administrative support activities related to prior, current and future IGTs opportunities, grants, internal initiatives. This will continue support for management of the IGT transaction process, project and expenditure oversight related to prior IGTs (outstanding grants and internal projects), as well as current IGTs in progress (i.e., IGTs 9 and 10) and oversight. Administration will be consistent with CalOptima standard policies, procedures and practices and will ensure funding investments are aligned with CalOptima's strategic priorities and member needs. Two staff positions, the Grant Management System license, public activities and other administrative costs are included.

Target Member Population(s): NA

Plan of Action/Key Milestones: NA

Estimated Budget: $2,000,000

Project Timeframe: Five–years

IGT 9 Focus Area: Other priority areas

Strategic Plan Priority/Objectives: Innovate and Be Proactive, Strengthen Community Partnerships, Increase Value and Improve Care Delivery

Participating/Collaborating Partners/Vendors/Covered Entities: NA

Proposal 5: Whole Child Model (WCM) Program

Initiative Description: To fund WCM program deficit in year one

Target Member Population(s): WCM eligible members (12,000 to 13,000)

Plan of Action/Key Milestones: N/A

Estimated Budget: Total $31.1 million for FY 2019-20

Project Timeframe: FY 2019-20 (July 1, 2019 to June 30, 2020)

IGT 9 Focus Area: Other priority areas

Strategic Plan Priority/Objectives:
To Support care delivery for WCM population in FY 2019-20

1) Insufficient revenue from DHCS
2) Complexity in operation and financial reconciliation

Participating/Collaborating Partners/Vendors/Covered Entities: N/A

CalOptima
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Post-Acute Infection Prevention Quality Initiative (PIPQI)

Special Board of Directors Meeting

April 16, 2020

David Ramirez, M.D., Chief Medical Officer
Emily Fonda, M.D., MMM, CHCQM, Deputy Chief Medical Officer

Post-Acute Infection Prevention Quality Initiative (PIPQI) Program

- Since October 2019, 24 participating skilled nursing facilities (SNFs) substitute Chlorhexidine (CHG) soap for liquid soap along with use of Iodophor nasal swabs to decrease skin colonization of Multi-Drug Resistant Organisms, which leads to decreased infection rates.
- CHG has anti-viral, anti-bacterial and anti-fungal properties.
- CHG has been proven to significantly decrease inpatient hospitalization for infection.
- The Centers for Disease Control and Prevention (CDC) has funded a nurse trainer in Orange County and strongly endorses CalOptima's PIPQI, the only such program in the country.
- CalOptima proposes to provide a quarterly incentive ($7,500 per SNF) for program adherence. Following the COVID-19 crisis — as safety permits — will skin test for CHG.

December 28, 2020

OC Nursing Home COVID Prevention Team: Urgent Expansion Proposal for Vaccine Uptake

Title: OC Nursing Home COVID Prevention Team: Vaccine Uptake

Purpose: Increase knowledge and uptake of COVID vaccine among OC nursing home staff and residents

Project Leader:

Susan Huang, MD MPH
Professor, Division of Infectious Diseases
Medical Director, Epidemiology & Infection Prevention
UC Irvine Health
sshuang@hs.uci.edu
Cell: 617-921-9103

Team Expertise:

Member	Experience
Susan Huang, MD MPH Professor Division of Infectious Diseases Medical Director, Epidemiology & Infection Prevention (EIP) UCI Health	15+ years of infectious diseases and infection prevention leadership and innovation. 12y of nursing home experience for infection prevention campaigns, studies, and trials. CDC-CMS Task Force on transitions of care. Prior member of CDC guidelines committee for infection prevention (HICPAC). Longstanding partnership with public health. Conducted SHIELD OC initiative, which led to a 44% decrease in hospitalizations for infection and a 53% reduction in expenditures among participating nursing homes.
Shruti Gohil, MD MPH Assistant Professor, Infectious Diseases Associate Medical Director, EIP UCI Health	Infectious diseases, infection prevention, including device care and telehealth/mobile applications. 5 yrs experience in nursing home campaigns, including SHIELD OC
Raveena Singh, MA Project Manager	Masters in Sociology. 12y experience in health behavior change, including 10+ years in post-discharge area and nursing homes using prevention strategies to reduce infection. Conducted projects in over 50 nursing homes
Gabrielle Gussin, MS Graduate Student	Epidemiology, and logistical expertise for healthcare facilities focusing on infection prevention and social determinants of health

Goals

- **#1:** Increase knowledge and dispel myths about the COVID-19 vaccine to increase vaccine uptake in nursing home staff and residents
- **#2:** Enable tracking of COVID-19 vaccination among nursing home staff and residents

Expansion Project Dates: February 1, 2021 – May 31, 2021

December 28, 2020

Expansion Project 1: Increase knowledge and dispel myths about the COVID-19 vaccine to increase vaccine uptake in nursing home staff and residents

Mass media about COVID-19 vaccines have caused the spread of both true and false information about the COVID-19 vaccines currently authorized in the United States. Nursing home staff are particularly subject to influence by media sentiments because they do not have ready access to scientific experts to refute or support these notions. Available knowledge in the form of complex FDA briefings or scientific publications are generally inaccessible to nursing home staff due to lack of knowledge base in epidemiology, immunology, or infectious diseases to read and process highly scientific journals, lack of time due to working multiple jobs and being limited staffing during the pandemic surge, and language barriers. These impediments have led to the influence of circulating myths about COVID-19 vaccines causing cancer, causing harm to unborn children, and implanting controlling microchips during the vaccination process. These myths are highly detrimental in fueling vaccine hesitancy in nursing homes staff with reported rates of 15-30% intended vaccine uptake, far from the >70% necessary to provide herd immunity and protection in nursing homes, or in the population-at-large to end the pandemic.

We will provide the following to increase the knowledge-base of nursing home staff and residents related to COVID-19 vaccines

- Provide informative vaccine webinar to OC nursing homes
- Offer in person training and Q&A with infectious diseases experts to OC nursing homes
- Provide a helpline for vaccine questions in English, Spanish
- Provide and update FAQs for staff on vaccine myths and questions in English, Spanish
- Provide and update FAQs for residents on vaccine myths and questions in English, Spanish
- Provide posters and laminated information sheets for breakrooms to address vaccine hesitancy
- Provide advocacy through co-branded CalOptima-UCI communication for COVID vaccine uptake (supported by Brian O'Dea, Executive Director, UCI Health Marketing and Communications)

Expansion Project 2: Enable tracking of COVID-19 vaccination among nursing home staff and residents

An easy and efficient way to track COVID-19 vaccination among nursing home staff is needed for three main reasons: 1) to measure vaccine uptake and respond to vaccination statistics, 2) to understand impact to vaccination proportion given the high rate of staff turnover (e.g. estimate the need for ongoing vaccine uptake efforts to meet goal of >70% vaccination to end the pandemic), and 3) to provide an alternative to existing mobile apps which require a comfort with technology that is uncommon in nursing homes.

We will provide the following:

- Creation of a roster-based tracker to identify vaccine uptake by type of healthcare personnel
- Reminders and support for monthly vaccine point-prevalence tracking assessments
- Progress reports on the trajectory of vaccine uptake among participating nursing homes

Vaccine Expansion SubBudget: $315,250

December 28, 2020

OC Nursing Home COVID Prevention Team: Extension of Infection Prevention Activities

Title: OC Nursing Home COVID Prevention Team: Infection Prevention

Purpose: Educate and Reinforce OC Nursing Homes on COVID-19 Infection Prevention Practices

Project Leader:

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Team Expertise:

Member	Experience
Susan Huang, MD MPH Professor Division of Infectious Diseases Medical Director, Epidemiology & Infection Prevention (EIP) UCI Health	15+ years of infectious diseases and infection prevention leadership and innovation. 12y of nursing home experience for infection prevention campaigns, studies, and trials. CDC-CMS Task Force on transitions of care. Prior member of CDC guidelines committee for infection prevention (HICPAC). Longstanding partnership with public health. Conducted SHIELD OC initiative which led to a 44% decrease in hospitalizations for infection and a 53% reduction in expenditures among participating nursing homes.
Shruti Gohil, MD MPH Assistant Professor, Infectious Diseases Assoc Medical Director, EIP UCI Health	Infectious diseases, infection prevention, including device care and telehealth/mobile applications. 5 yrs experience in nursing home campaigns, including SHIELD OC
Cassiana Bittencourt, MD Assistant Professor, Pathology and Laboratory Medicine Medical Director, Clinical Microbiology Laboratory, UCI Health	Microbiology, including antibiotic resistant pathogens. Has worked with Dr. Huang on nursing home projects processing thousands of laboratory samples for many years. Also, oversees all COVID validation and testing platforms at UCI Health.
Raveena Singh, MA Project Manager	Masters in Sociology. 12y experience in health behavior change, including 10+ years in post-discharge area and nursing homes using prevention strategies to reduce infection. Conducted projects in over 50 nursing homes
Raheeb Saavedra, AS Clinical Coordinator	Extensive fieldwork experience in hospitals and nursing homes. Active in previous public health collaborative (SHIELD OC) including implementing decolonization in 17 nursing homes, now supports training for PIPQI decolonization program in nursing homes
Paula Pedrani, BS Assistant Clinical Coordinator	Extensive field experience in environmental cleaning interventions in nursing homes
Gabrielle Gussin, MS Graduate Student	Epidemiology, microbiome, and logistical expertise for healthcare facilities focusing on infection prevention and social determinants of health
Video Reviewers (2)	Supporting staff

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December 28, 2020

Goals

- **#1:** Address critical gaps in COVID infection prevention until the pandemic ends
- **#2**: Ongoing support of 12 nursing homes in initial intensive COVID-19 infection prevention training program to address environmental cleaning and other infection prevention gaps to enable these nursing homes to serve as an ongoing high fidelity resource for culture change
- **#3:** Monitor for COVID re-emergence during 2021 winter cold/flu season
- **#4:** Assess COVID impact on expansion of multidrug-resistant organisms (MDROs)/emerging pathogen threats

COVID NH Prevention Team Extension Period: 6/1/21-5/31/22

Extension Project 1: Address critical gaps in COVID infection prevention until the pandemic ends

The initial project provided urgently needed training, webinars and an extensive COVID toolkit for infection prevention during a rapidly expanding pandemic. This training uncovered critical gaps in knowledge, acceptance, and practice that need to be shored up, and assessed for post-pandemic long-term value to reduce future endemic spread of cold and flu viruses, including COVID-19.

To this end, we will provide the following found in Table 1.

Table 1: Extended COVID Infection Prevention Plan for Nursing Homes

Element	Value for Maintenance or Improvement
Webinars	Online informational webinars for OC nursing homes using CalOptima communication channels were successfully used in the initial program plan. This extension program will add webinars on lessons learned to prevent COVID-19 transmission (infection prevention pearls), major environmental cleaning gaps, and infection prevention activities to retain post-pandemic
Posters	Poster reminders of essential COVID-19 infection prevention protocols and policies to reinforce behavior
Helpline	Helpline to address pressing COVID-19 concerns, including ongoing infection prevention or vaccination concerns beyond the expanded vaccine uptake period. When pressing concerns are addressed, adopt periodic marketing to call for specific issues (e.g. if vaccines become annual/seasonal, seasonal prevention if COVID becomes endemic)
Toolkit Conversion	Preparation for post-vaccine and, eventually, post-pandemic reality. Convert current COVID toolkit created in initial program plan to a stratified toolkit – 1) add reminders about post-vaccine policies and protocols for COVID care, and eventually stratify into A) archived information for pandemic resurgence or preparedness, and B) protocols and policies of continued value, for example to mitigate spread of cold and flu during the winter season, or maintenance of infection prevention tenets that continue to be universally applicable in nursing homes
Cleaning Training: Dos & Don'ts	Update common mistakes and gaps based upon lessons learned in initial program
Skills Assessment Tools	Update tools to check appropriate training with interactive feedback based upon lessons learned in initial program

Extension Project 2: Ongoing support of 12 nursing homes in initial intensive COVID-19 infection prevention training program to address environmental cleaning and other infection prevention gaps to enable these nursing homes to serve as an ongoing high fidelity resource for culture change

The 12 nursing homes that underwent high intensity COVID-19 prevention training identified key gaps in infection prevention that require ongoing feedback, monitoring, and training. This will be maintained to promote culture change and adoption of appropriate protocols.

We will reinforce pandemic infection prevention practices and post-pandemic maintenance of hand hygiene, avoiding working while ill, and improving environmental cleaning. Specifically, the following will be maintained:

- Use of invisible black light (UV) marker to provide feedback on environmental cleaning gaps
- Video assisted support, including maintenance of streaming video in common areas (not resident rooms) such as hallways, nursing stations, and breakrooms/conference rooms to evaluate PPE and infection prevention behavior (e.g. failure to distance, touching masks with unclean hands, wearing PPE like second skin in common areas)
- Biweekly video montages and quantified tracking of infection prevention practices for the 12 nursing homes to feedback opportunities for improvement and hardwire prevention practices

Extension Project 3: Monitor for COVID re-emergence during 2021 winter cold/flu season

Current efforts for weekly surveillance of nursing home staff and residents are unlikely to retained when COVID-19 vaccine uptake demonstrates containment of the pandemic. Given the known seasonality of COVID-19, weekly surveillance is unlikely to be retained by early fall 2021. To account for possible re-emergence of COVID-19 during the 2021 winter cold/flu season, periodic sampling for COVID-19 among staff and residents is wise.

To this end, we will conduct a point prevalence sweep of staff and residents from 5 nursing homes during the 2021 winter cold/flu season to detect any resurgence of COVID-19. With a mean staff size of 175 and mean residents of 100, that would be 275 samples for 5 nursing homes = 1375 samples at $65 each. Selection of the 5 nursing homes will consider data on COVID-19 vaccine uptake among staff and, if available, residents.

Extension Project 4: Assess COVID impact on expansion of multidrug-resistant organisms (MDROs)/emerging pathogen threats

The efforts to cohort COVID-19 residents in nursing homes has led to the discovery of increased transmission of multidrug-resistant organisms (MDROs), such as *Candida auris* (a highly resistant emerging fungal pathogen of public health import), in Los Angeles and Orange Counties due to the shortage of PPE and the cohorted use of gowns and other PPE elements between patients cohorted for COVID-19. This is important because 65% of nursing home residents harbor an MDRO. This raises serious concerns about whether the COVID-19 pandemic has worsened the MDRO/*C. auris* situation.

Due to prior studies in OC (e.g. SHIELD OC and others), we have relatively recent baseline data on MDRO prevalence in OC nursing homes. We propose to conduct a point prevalence sweep of a representative sample of 50 residents in 5 nursing homes to understand the public health implications of cohorting COVID-19 patients without consideration of other MDROs they may harbor. We will specifically evaluate the body sites known to harbor MDROs (nares, axilla/groin, and peri-rectal) similar to prior interventions like SHIELD OC, for methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococcus (VRE), extended-spectrum beta-lactamase producers (ESBL), carbapenem-resistant

enterobacteriaeceae (CRE), and *C. auris*. If expansion of these organisms is seen, this will raise awareness for the importance of sufficient supplies of PPE, particularly gowns and gloves for the care of person in nursing homes during a pandemic crisis.

Extension SubBudget: $945,750

Total Budget (Expansion and Extension): $1,261,000

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken January 7, 2021
Special Meeting of the CalOptima Board of Directors

Report Item

4. Consider Authorizing Homeless Health Initiative Vaccination Intervention and Member Incentive Strategy in Response to the Coronavirus Pandemic

Contacts

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Betsy Ha, Executive Director, Quality and Population Health Management, (714) 246-8574
Ladan Khamseh, Chief Operating Officer (714) 246-8866

Recommended Actions

1. Authorize development and implementation of a Homeless Health Initiative (HHI) – Vaccination Intervention and Member Incentive Strategy, as described, to increase member participation and ensure community safety amid the COVID-19 pandemic, subject to approval of the California Department of Health Care Services (DHCS);
2. Approve an allocation of HHI funds not to exceed $400,000 to provide two $25 nonmonetary gift cards for members experiencing homelessness who are ages 14 and older for receiving the required two doses of the COVID-19 vaccine; and
3. Authorize the Chief Executive Officer, with the assistance of Legal Counsel, to enter into contracts/contract amendments with the Orange County Health Care Agency (OCHCA) and/or other entity/entities as appropriate for administration and implementation of this initiative program.

Background

Although the COVID-19 pandemic threatens everyone, CalOptima members experiencing homelessness may be at greater risk of being exposed to this deadly virus. As the population experiencing homelessness has increased significantly over the past few years in Orange County, and in response to the critical needs of this population, CalOptima, in partnership with the OCHCA and other community stakeholders, has focused on developing a system of care that uses a multifaceted approach to respond to the unique needs of members experiencing homelessness.

The economic downturn stemming from the COVID-19 pandemic has exacerbated the problem, causing more people to experience housing insecurity or become homeless for the first time. To continue providing access to quality health care and ensure safety of unsheltered members amid COVID-19, staff proposes a 1-year Homeless Health Initiative (HHI) that provides nonmonetary member incentives to promote COVID-19 vaccination while addressing Social Determinants of Health (SDOH), such as food insecurity. Public health experts have indicated that at least 70% of the overall population needs to get vaccinated to build herd immunity that will help end the pandemic, and the same percentage applies to those experiencing homelessness.

CalOptima has launched various initiatives to provide clinical care for CalOptima Medi-Cal members who are experiencing homelessness through a series of actions approved by the CalOptima Board of Directors (Board). On April 4, 2019, the Board approved the establishment of a restricted Homeless Health Reserve in the amount of $100 million that included: $24 million in previously approved initiatives using IGT 1-7 funds, and $76 million in IGT 8 funds (approximately $43 million), with the

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balance from Fiscal Year (FY) 2018-19 operating funds. These funds have been designated by the Board to address the healthcare needs of members experiencing homelessness.

Beginning with IGT 8, the IGT program covers the current fiscal year and funds are incorporated into the contract between DHCS and CalOptima. Unlike previous IGT funds (i.e., IGTs 1-7) that could be used to provide enhanced services to existing CalOptima Medi-Cal members, beginning with IGT 8, IGT funds are paid through capitation, and as such, may only be used in the same way that CalOptima uses its primary capitation funds; that is, for covered Medi-Cal medically necessary services for CalOptima members and for administration expense. These IGT capitation payments are also subject to all applicable requirements as set forth in CalOptima's contract with DHCS. In other words, the unallocated funds remaining in the Reserve are IGT 8 and FY 2018-19 operating funds. Based on state requirements, use of these funds is limited to covered, medically necessary Medi-Cal services for CalOptima members and administrative expense.

Subject to DHCS approval, staff proposes use of HHI funds allocated from IGT 8 to support vaccine acceptance by CalOptima members experiencing homelessness.

Discussion

CalOptima staff recommends implementing a one-year public health focused intervention to support vaccination and public health awareness to mitigate COVID-19 exposure and infection for individuals experiencing homelessness. CalOptima will work collaboratively with community partners, such as the OCHCA, shelter operators and clinics to support COVID-19 vaccination events at shelters, hotspots and other identified locations in the community; CalOptima staff will also encourage vaccination by providing nonmonetary incentives (such as food vouchers at nearly local fast food chains such as Subway, Burger King, etc.) in an amount not to exceed $50 (two $25 gift cards) to members experiencing homelessness and receiving the two required doses of the COVID-19 vaccines (i.e., one $25 gift card per shot, with a limit of two gift cards per member). Total incentive cost will not exceed $400,000.

Staff projects that approximately 8,000 members experiencing homelessness age 14 and older would participate in this initiative. CalOptima staff will work collaboratively with OCHCA (or other organizations, as appropriate) to develop a process to obtain confirmation that eligible individuals (i.e., CalOptima members experiencing homelessness who have received both of their COVID-19 vaccine shots) are provided with these incentives.

Fiscal Impact

The estimated fiscal impact of the HHI - Vaccination Intervention and Member Incentive Strategy is $400,000. A previous Board action on April 4, 2019, to Consider Actions Related to Delivery of Care for Homeless CalOptima Members, established a restricted Homeless Health Reserve in the amount of $100 million. Staff recommends the allocation of HHI funding from the remaining balance of $57 million of this reserve for the proposed initiative.

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Rationale for Recommendation

The recommended action is to provide food vouchers for CalOptima members experiencing homelessness, who received COVID-19 vaccines identified under the HHI. This initiative will support CalOptima's efforts to address SDOH, prevent spread of COVID-19, ensure community immunity, and continue providing access to quality health care for members experiencing homelessness during the COVID-19 public health crisis.

Concurrence

Gary Crockett, Chief Counsel

Attachments

1. Entities Covered by this Recommended Action
2. CalOptima Board Action dated April 4, 2019, Consider Actions Related to Delivery of Care for Homeless CalOptima Members

/s/ Richard Sanchez *12/31/2020*
Authorized Signature **Date**

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ENTITITES COVERED BY THIS RECOMMENDED ACTION

Legal Name	Address	City	State	Zip code
Central City Community Health Center	1000 San Gabriel Boulevard	Rosemead	CA	91770
Families Together of Orange County	661 W 1st St Suite G	Tustin	CA	92780
Hurtt Family Health Clinic, Inc.	One Hope Drive	Tustin	CA	92782
Korean Community Services, Inc. dba Korean Community Services Health Center	8633 Knott Ave.	Buena Park	CA	90620
Serve the People Community Health Center	1206 E. 17th St., Ste 101	Santa Ana	CA	92701
AltaMed Health Services Corporation	2040 Camfield Ave	Los Angeles	CA	90040
Share Our Selves Corporation	1550 Superior Avenue	Costa Mesa	CA	92627
St Jude Neighborhood Health Centers	731 S Highland Ave	Fullerton	CA	92832
County of Orange	405 W. 5th Street, Suite 756	Santa Ana	CA	92701

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Homeless Health Care Update

Board of Directors Meeting
April 4, 2019

Michael Schrader
Chief Executive Officer

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Impetus for Action in Orange County

- Address homeless crisis with urgency and commitment
- Address trend of homeless deaths
- Build a better system of care for members who are homeless that is long-lasting and becomes part of established delivery system
- Prioritize population health for this group

Homeless Deaths

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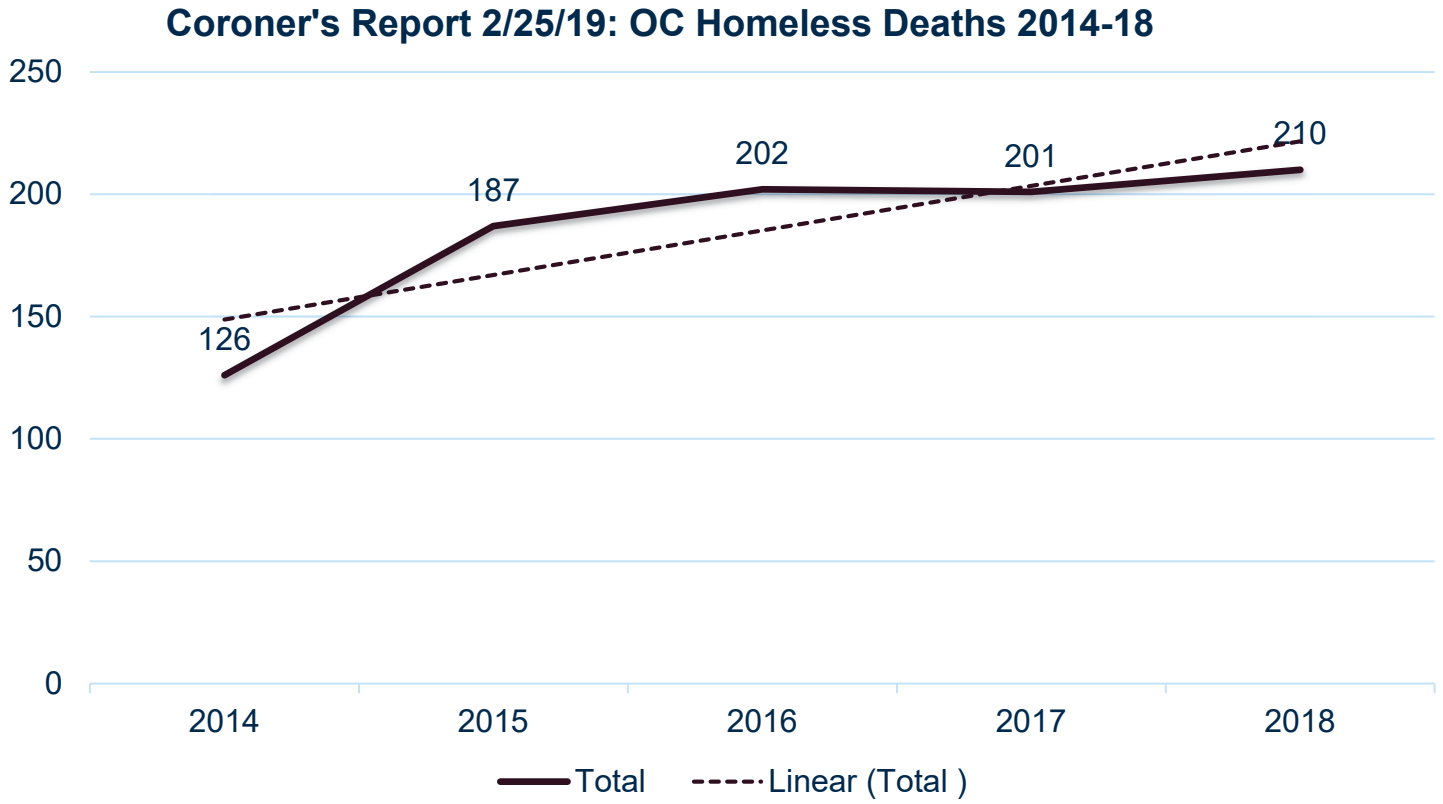
Coroner's Report on Homeless Deaths



- Includes all homeless deaths in Orange County, not limited to CalOptima members
- Methodology of reporting and identification of homeless may vary by county
- Increased homeless death rates over the past five years reported in the media statewide

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Coroner's Report on Homeless Deaths And Possible Interventions

- Natural causes (42% homeless v. 83% total OC population)
  - Clinical field teams (CalOptima)
  - CalOptima Homeless Response Team (CalOptima)
  - Recuperative care (County and CalOptima)
- Overdose (24% homeless v. 5% total OC population)
  - Opioid prescribing interventions (CalOptima)
  - Medication-assisted treatment (County and CalOptima)
  - Substance use disorder centers (County)
  - Medical detox (CalOptima)
  - Social model detox (County)
  - Naloxone (County and CalOptima)
  - Needle exchange (County)

Coroner's Report on Homeless Deaths And Possible Interventions (cont.)

- Traffic accidents (12% homeless v. 3% total OC population)
- Suicide (7% homeless v. 4% total OC population)
  - Moderate-severe behavioral health (County)
    - Crisis intervention
    - Post-acute transitions
    - Intensive outpatient treatment programs
  - Mild-moderate behavioral health (CalOptima)
    - Screening
    - Early treatment
- Homicide (6% homeless v. 1% total OC population)
- Other accidents (5% homeless v. 5% total OC population)
- Undetermined (3% homeless v. 1% total OC population)

Quality Assurance Committee
Further Clinical Analysis

- Deeper analysis into causes of deaths and interventions
- Case studies for each cause of homeless death
- Benchmarks and comparison with interventions and resources in other counties
- Presentations from partnering organizations

Better System of Care

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Ad Hoc Recommendations

- Take action to commit $100 million for homeless health
  - ➢ Create a restricted homeless health reserve
  - ➢ Stipulate that funds can only be used for homeless health

New Initiatives/Projects	BOD Approved	Pending BOD Approval	Funding Category
Be Well OC	$11.4 million		IGT 1–7 ($24 million total)
Recuperative Care	$11 million		
Clinical Field Team Startup	$1.6 million		
CalOptima Homeless Response Team ($1.2 million/year x 5 years)	$1.2 million	$4.8 million	IGT 8 and FY 2018–19 operating funds ($76 million total)
Homeless Coordination at Hospitals ($2 million/year x 5 years)		$10 million	
New Initiatives		$60 million	
Total Reserve: $100 million	**$25.2 million**	**$74.8 million**	

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Clinical Field Team Structure

- Team Components
  - Includes clinical and support staff
  - Vehicle for transportation of staff and equipment
  - Internet connectivity and use of Whole-Person Care (WPC) Connect
- Clinical Services
  - Urgent care, wound care, vaccinations, health screening and point-of-care labs
  - Prescriptions and immediate dispensing of commonly used medications
  - Video consults, referrals, appointment scheduling and care transitions

Clinical Field Team Structure (cont.)

- Referrals and Coordination
  - Coordination with CalOptima Homeless Response Team
  - Coordination with providers
  - Referrals for behavioral health, substance abuse, recuperative care and social services
- Availability and Coverage
  - Regular hours at shelters/hot spots
  - Rotation for on-call services from 8 a.m.–9 p.m. seven days a week, with response time of less than 90 minutes

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Clinical Field Team Partnerships

- Five FQHCs have received contract amendments
  - AltaMed
  - Central City Community Health Center*
  - Hurtt Family Health Clinic*
  - Korean Community Services*
  - Serve the People*
- Contract amendments to be authorized/ratified at April Board meeting, per Board direction
- Go-live
  - Deploy on a phased basis, based on FQHC readiness

** Signed contract amendment*

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CalOptima Homeless Response Team

- Phone line and daily hours (8 a.m.–9 p.m.) established
  - Available to Blue Shirts and CHAT-H nurses
  - Primary point of contact at CalOptima for rapid response
- Coordinate and dispatch clinical field teams
- Serve as liaisons with regular field visits to shelters/hot spots in the county and recuperative care facilities
  - Establish working in-person relationships with collaborating partners
  - Assess and coordinate physical health needs for CalOptima members

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Homeless Population in CalOptima Direct

- Pursue moving members who are homeless to CalOptima Direct, subject to regulatory approval
  - Maximum flexibility with access to any provider (no PCP assignment)
  - Fast-tracked authorization processing
  - Direct medical management in collaboration with clinical field teams, CalOptima Homeless Response Team, and County Blue Shirts and CHAT-H nurses
  - Connectivity with WPC Connect and CalOptima population health platform
- In the interim, move members identified in the field based on choice
- Obtain stakeholder input
  - County, PAC, MAC and health networks

Homeless Coordination at Hospitals

- COBAR in April
- Help hospitals meet SB 1152 requirements for homeless-specific discharge planning and care coordination, effective July 1, 2019
- Utilization by hospitals of data sharing technology to help facilitate coordination of services for CalOptima members who are homeless
- Proposing 2 percent increase to the inpatient Classic rates for Medi-Cal contracted hospitals
  - $2 million financial impact per year
  - Distributes funding based on volume of services provided to members

Medical Respite Program

- Recuperative care beyond 90 days
  - Reallocate $250,000 of the $10 million in IGT6/7 already allocated to the County's WPC program for recuperative care
  - Leverage existing process
    - County to coordinate and pay recuperative care vendor
    - CalOptima to reimburse County for 100 percent of cost
  - COBAR in April
  - Return to CalOptima Board for ratification of associated policy

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WPC Connect

- Data-sharing tool for coordinating care used by the Whole-Person Care collaborative
  - Specifically used for homeless individuals
  - Includes social supports and referrals to services
  - Includes community partners (e.g., Illumination Foundation, 211, Lestonnac, Health Care Agency, Social Services Agency, hospitals, community clinics, health networks and CalOptima)
- WPC Connect workflow
  - Community partners can, with consent, add individuals into WPC Connect system once identified as homeless
  - WPC Connect sends an email notification and/or text message to identified care team for homeless individuals seen in ER, admitted to hospital or discharged

WPC Connect (cont.)

- CalOptima use of WPC Connect
  - Case management staff is trained and actively uses the system
    - Identify members enrolled in WPC
    - Coordinate with other partners caring for members
    - Access information from other partners

- Status of WPC Connect
  - Five hospitals are currently connected
  - COBAR to amend hospital contracts to support a discharge process for members experiencing homelessness, including the utilization by hospitals of data-sharing technology to help facilitate coordination of services with other providers and community partners

Better System of Care: Future Planning

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Evolving Strategy and Homeless Health Needs

- Propose and respond to changes
  - Regulatory and legislative
  - Available permanent supportive housing and shelters
  - State programs (e.g., expanded WPC funding and Housing for a Healthy California Program)
- Identify other potential uses for committed funds to optimize the delivery system, subject to Board consideration, for example:
  - Enrollment assistance
  - Enhanced data connectivity technology
  - Housing supportive services
  - Other physical health services
  - Rental assistance and shelter, if permissible

Recommended Actions

- Separate COBARs
  - Clinical field team implementation
  - Medical respite program
  - Homeless coordination at hospitals

- Additional action recommended by Board Ad Hoc
  - Create a restricted homeless health reserve in the amount of $100 million
    - $24 million – previously approved initiatives using IGT 1–7 funds
    - $76 million – all IGT 8 funds (approximately $43 million) with balance from FY 2018–19 operating funds
  - Stipulate that funds can only be used for homeless health

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CalOptima's Mission

To provide members with access to quality health care services delivered in a cost-effective and compassionate manner

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Medi-Cal
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OneCare (HMO SNP)
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OneCare Connect
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PACE
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CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken January 7, 2021
Special Meeting of the CalOptima Board of Directors

Report Item

5. Consider Authorizing Coronavirus (COVID-19) Vaccination Member Incentive Program for Calendar Year 2021

Contacts

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Betsy Ha, Executive Director, Quality and Population Health Management, 714-246-8574
Ladan Khamseh, Chief Operating Officer, (714) 246-8866

Recommended Actions

1. Authorize the development and implementation of a COVID-19 Vaccination Incentive Program (VIP) for Calendar Year (CY) 2021, as described below, to increase member participation and ensure community safety amid the COVID-19 pandemic, subject to DHCS approval prior to implementation;
2. Approve the recommended allocation of Intergovernmental Transfer (IGT) 10 funds, not to exceed ~~$20 million~~ $35 million, to provide two $25 nonmonetary gift cards to individual Medi-Cal members ~~age 14 and older~~ for receiving the two required doses of the COVID-19 vaccine (one gift card per shot); and *Rev. 1/7/21*
3. Authorize implementation of the VIP prior to CalOptima's receipt of IGT 10 funds from the State of California.
4. Authorize the Chief Executive Officer, with the assistance of Legal Counsel, to enter into an Memorandum of Understanding (MOU), and/or contract or contract amendment with the Orange County Health Care Agency (OCHCA) as appropriate for administration and implementation of the VIP.

Background

In late December 2020, the first doses of the COVID-19 vaccines arrived in Orange County. Vaccines will be distributed according to a phased approach, with high-priority groups vaccinated first and eventually the general public as determined by the California Department of Public Health and local health department. The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the Pfizer-BioNTech and Moderna vaccines, both of which offer more than 94% protection against COVID-19 when two doses are taken. Public health experts recommend that at least 70% of the population needs to get vaccinated to develop herd community, which can bring an end to the pandemic.

As the only Medi-Cal plan serving Orange County's most vulnerable residents, CalOptima is responding in collaboration with the Orange County Health Care Agency (OCHCA) to support the community in achieving herd immunity. The first step is a strategy that promotes COVID-19 vaccination, including tailoring member education on the importance of vaccination, dispelling misconceptions, and providing nonmonetary member incentives to ensure health equity across race, ethnicity and socioeconomic status. To support this effort, CalOptima staff is seeking an allocation of IGT 10 funds.

Intergovernmental Transfers (IGT) are transfers of public funds between eligible government entities, which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has

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participated in ten Voluntary Rate Range IGT transactions. Funds from IGTs 1 through 9 have been received, and IGT 10 funds will be distributed in two separate installments, which are expected from the state in 2021.

Discussion

Subject to state approval, staff will work with various internal and external partners on a member outreach program that provides COVID-19 vaccine information. The proposed program includes:

1. A mailing to all members with information about the vaccine.
2. A targeted text messaging campaign. When different priority groups are permitted to be vaccinated, CalOptima will send out targeted text messages to these members letting them know the following:
    a. They are now eligible to be vaccinated.
    b. Where they need to go to be vaccinated. (This information is not yet available, but staff continue to work with OCHCA to establish vaccine events in targeted geographic locations within the county. The vaccine events are likely to begin in Spring 2021, but may extend into the fall, depending on the vaccine distribution timeline as established by OCHCA.)
3. A targeted phone call campaign to population segments who are at high risk for not getting vaccinated. This will begin once the vaccine is widely available to at least essential workers, according to the phased approach.

Staff projects that as many as 400,000 members will participate in this program. To encourage members to participate in vaccination, staff proposes to provide two $25 nonmonetary gift cards for Medi-Cal members age 14 and older for receiving each of two doses of the COVID-19 vaccine, for a total of $50. Members will be encouraged to sign up with the OCHCA's app, Othena, at no cost, to receive the gift card incentives, one gift card for each shot received. The app is being developed to help healthcare providers track vaccine recipients to ensure they get a booster shot and to monitor for side effects. Staff is also seeking authority to enter into a Memorandum of Understanding (MOU) and/or contract or contract amendment with the County as necessary to implement the program. If it is subsequently determined that agreements with other entities, organizations or vendors are necessary, staff will return to the Board with further recommendations for consideration at a later date.

The targeted timeframe for the COVID-19 nonmonetary incentive is CY 2021. IGT 10 funds have not yet been received. For the approved and funded IGT transactions to date, the net proceeds have been evenly divided between CalOptima and the respective funding partners, and funds retained by CalOptima have been invested in addressing member's unmet health care needs. It is anticipated that CalOptima's share of IGT 10 funds will be approximately $66 million ($43.3 million in Spring 2021 and $22.7 million in Fall 2021).

Due to timing issues, staff requests that the Board authorize the CEO to implement the COVID-19 Vaccination Incentive Program for CY 2021 prior to CalOptima's receipt of IGT 10 funds from DHCS. Providing the nonmonetary incentive to coincide with the availability of the COVID-19 vaccination to members will support CalOptima's health promotion efforts in our community.

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It should be noted that since IGT 10 funds are accounted for in the same fashion as the Medi-Cal capitation revenue CalOptima receives from DHCS, to the extent that these funds are not expended on covered, medically necessary Medi-Cal services or qualifying quality initiatives, the expenditures would be charged to CalOptima's administrative loss ratio (ALR), rather than the medical loss ratio (MLR).

Fiscal Impact

The recommended action to allocate up to ~~$20 million~~ $35 million in IGT 10 funds to support the COVID-19 Vaccination Member Incentive Program has no net fiscal impact to CalOptima's Fiscal Year 2020-21 Operating Budget approved by the Board on June 4, 2020. Staff anticipates any cash expended to implement the program will be replenished when IGT 10 funds are received from DHCS. Expenditure of IGT funds is for restricted one-time purposes for covered Medi-Cal services to CalOptima members and does not commit CalOptima to future budget allocations.

Rationale for Recommendation

Staff recommends adding a COVID-19 vaccination member incentive component to CalOptima's preventive initiatives to educate and encourage member participation. The recommended actions will support CalOptima's efforts to help the community reach herd immunity, address health disparities, and continue providing access to quality health care for members during the COVID-19 public health crisis.

Concurrence

Gary Crockett, Chief Counsel

Attachments

1. Entities Covered by this Recommended Action
2. CalOptima Board Action dated February 6, 2020, Consider Pursuit of Proposals with Qualifying Funding Partners to Secure Medi-Cal Funds Through the Voluntary Rate Range Intergovernmental Transfer Program for Rating Period 2019-20 (IGT 10)

/s/ Richard Sanchez — *12/31/2020*

Authorized Signature — **Date**

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ENTITITES COVERED BY THIS RECOMMENDED ACTION

Legal Name	Address	City	State	Zip code
County of Orange	405 W. 5th Street, Suite 756	Santa Ana	CA	92701

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CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken February 6, 2020
Regular Meeting of the CalOptima Board of Directors

Report Item

15. Consider Pursuit of Proposals with Qualifying Funding Partners to Secure Medi-Cal Funds Through the Voluntary Rate Range Intergovernmental Transfer Program for Rating Period 2019-20 (IGT 10)

Contact

Candice Gomez, Executive Director, Program Implementation, (714) 246-8400

Recommended Actions

Authorize the following activities to secure Medi-Cal funds through the Voluntary Intergovernmental Transfer (IGT) Rate Range Program:

1. Submission of a proposal to the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range IGT Program for Rating Period 2019-20 (IGT 10);
2. Pursuit of IGT funding partnerships with the University of California-Irvine, the Children and Families Commission, the County of Orange, the City of Orange, and the City of Newport Beach to participate in the upcoming Voluntary Rate Range IGT Program for Rating Period 2019-20 (IGT 10); and,
3. Authorize the Chief Executive Officer to execute agreements with these entities and their designated providers as necessary to seek IGT 10 funds.

Background

Intergovernmental Transfers (IGT) are transfers of public funds between eligible government entities which are used to draw down federal funds for the Medi-Cal program. To date, CalOptima has participated in eight Rate Range IGT transactions. Funds from IGTs 1 through 8 have been received and IGT 9 funds are expected from the state in the first quarter of 2020. IGTs 1 through 9 covered the applicable twelve-month state fiscal year (FY) periods (i.e., FY 2010-11 through FY 2018-19). IGT 1 through 7 funds were retrospective payments for prior rate range years and were designated to be used to provide enhanced/additional benefits to existing Medi-Cal beneficiaries, as represented to CMS. These funds have been best suited for one-time investments or as seed capital for enhanced health care services for the benefit of Medi-Cal beneficiaries.

The IGT funds received under IGTs 1 through 7 have supported special projects that address unmet healthcare needs of CalOptima members, such as vision and dental services for children, obesity prevention and intervention services, provider incentives for adolescent depression screenings, recuperative care for homeless members, and support for members through the Personal Care Coordinator (PCC) program.

Beginning with IGT 8, the IGT program covers the current fiscal year and funds will be incorporated into the contract between DHCS and CalOptima for the current fiscal year. Unlike previous IGTs (1-7), beginning with IGT 8 funds must be used in the current rate year for CalOptima covered Medi-Cal services per DHCS direction. IGT 8 funds have been allocated to the Homeless Health Initiative. IGT 9 funds have not yet been received, nor allocated; CalOptima staff anticipates returning with recommendations on an allocation plan in a separate Board action; however, as indicated,

per DHCS, the use of these funds is limited to covered Medi-Cal benefits for existing CalOptima members.

For the approved and funded IGT transactions to date, the net proceeds have been evenly divided between CalOptima and the respective funding partners, and funds retained by CalOptima have been invested in addressing Member's unmet healthcare needs.

Discussion

On December 20, 2019, CalOptima received notification from DHCS regarding the Rating Period 2019 - 20 Voluntary Rate Range IGT Program (IGT 10). Unlike the prior IGTs, which covered the applicable twelve-month state fiscal year, IGT 10 covers eighteen months including the periods of July 1, 2019 through June 30, 2020 and July 1, 2020. through December 31, 2020. CalOptima's proposal, along with the funding entities' supporting documents are due to DHCS no later than February 19, 2020.

The five eligible funding entities from the previous IGT transactions have been contacted regarding their interest in participation in IGT 10. All five funding entities have informally indicated that they are interested in participation in the IGT program this year. The formal DHCS required Letter of Interest is due to CalOptima by February 14, 2020 for delivery to DHCS by February 19, 2020. These entities are:

1. University of California, Irvine,
2. Children and Families Commission of Orange County,
3. County of Orange,
4. City of Orange, and
5. City of Newport Beach.

Board approval is requested to authorize staff to submit the proposal letter to DHCS for participation in the 2019-20 Voluntary IGT Rate Range Program and to authorize the Chief Executive Officer to enter into agreements with each of the five proposed funding entities submitting a letter of interest (or their designated providers) for the purpose of securing available IGT funds. Consistent with the nine prior IGT transactions, it is anticipated that the net proceeds will be split evenly between the respective funding entities and CalOptima.

Staff will return to the Board with additional information regarding the IGT 10 transaction and a proposed expenditure plan for CalOptima's share of the net proceeds at a later date.

Fiscal Impact

The recommended actions to submit a proposal to DHCS and pursue IGT funding partnerships with five governmental funding entities for IGT 10 is expected to generate one-time IGT revenue that will be invested in covered Medi-Cal services for CalOptima members. As such, there is no net fiscal impact on CalOptima's current and future operating budgets.

Rationale for Recommendation

Consistent with the previous nine IGT transactions, submission of the proposal and authorization of funding agreements will allow the ability to maximize Orange County's available IGT funds for Rate Year 2019-20 (IGT 10). Also, consistent with the 2020-22 Strategic Plan, it would increase funding to support delivery of covered Medi-Cal services for CalOptima members.

Concurrence

Gary Crockett, Chief Counsel

Attachment

1. Entities Covered by this Recommended Board Action
2. Department of Health Care Services Voluntary IGT Rate Range Program Notification Letter

/s/ Michael Schrader — *01/28/2020*

Authorized Signature — **Date**

Attachment 1 to February 6, 2020 Board of Directors Meeting – Agenda Item 15

ENTITIES COVERED BY THIS RECOMMENDED BOARD ACTION

Legal Name	Address	City	State	Zip code
Children and Families Commission of Orange County	1505 E. 17th Street, 230	Santa Ana	CA	92705
City of Newport Beach	100 Civic Center Drive	Newport Beach	CA	92660
City of Orange	300 E. Chapman Avenue	Orange	CA	92866
Orange County Health Care Agency	405 W. 5th Street, 7th Floor	Santa Ana	CA	92701
University of California, Irvine UCI Health	333 City Blvd. West, Suite 200	Orange	CA	92868

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State of California—Health and Human Services Agency
Department of Health Care Services

RICHARD FIGUEROA
ACTING DIRECTOR

GAVIN NEWSOME
GOVERNOR

DEC 2 0 2019

Nancy Huang
Interim Chief Financial Officer
CalOptima
505 City Parkway West
Orange, CA 92868

SUBJECT: Rating Period 2019–20 (July 1, 2019 through December 31, 2020) Voluntary Rate Range Program – Request for Medi-Cal Managed Care Plan's (MCP) Proposal

Dear Ms. Nancy Huang:

The Rating Period 2019-20 Voluntary Rate Range Program, authorized by Welfare and Institutions (W&I) Code sections 14164, 14301.4, and 14301.5, provides a mechanism for funding the non-federal share of the difference between the lower and upper bounds of a MCP's actuarially sound rate range, as determined by the Department of Health Care Services (DHCS). Governmental funding entities eligible to transfer the non-federal share are defined as counties, cities, special purpose districts, state university teaching hospitals, and other political subdivisions of the state, pursuant to W&I Code section 14164(a). These governmental funding entities may voluntarily transfer funds to DHCS via intergovernmental transfer (IGT). These voluntary IGTs, together with the applicable Federal Financial Participation (FFP), will be used to fund payments by DHCS to MCPs as part of the capitation rates paid for the service periods of July 1, 2019 through June 30, 2020, and July 1, 2020 through December 31, 2020.

DHCS shall not direct the MCP's expenditure of payments received under the Rating Period 2019-20 Voluntary Rate Range Program. These payments are subject to all applicable requirements set forth in the MCP's contract with DHCS. These payments must also be tied to covered Medi-Cal services provided on behalf of Medi-Cal beneficiaries enrolled within the MCP's rating region.

The funds transferred by an eligible governmental funding entity must qualify for FFP pursuant to Title 42 Code of Federal Regulations (CFR) Part 433, Subpart B, including the requirements that the funding source(s) shall not be derived: from impermissible sources such as recycled Medicaid payments, Federal money excluded from use as state match, impermissible taxes, and non-bona fide provider-related donations. Impermissible sources do not include patient care or other revenue received from

programs such as Medicare or Medicaid to the extent that the program revenue is not obligated to the state as the source of funding.

DHCS shall continue to administer all aspects of the IGT related to the Rating Period 2019-20 Voluntary Rate Range Program, including determinations related to fees.

PROCESS FOR RATING PERIOD 2019-20:

MCPs should refer to the estimated Rating Period 2019-20 (service periods July 1, 2019 through June 30, 2020, and July 1, 2020 through December 31, 2020) county/region-specific non-federal share required to fund available rate range amounts for the MCP (see Attachment C). As a reminder, participation in the Rating Period 2019-20 Voluntary Rate Range Program is voluntary on the part of the transferring entity and the MCP. Note that for service periods July 1, 2019 through June 30, 2020 and July 1, 2020 through December 31, 2020, the Contribution (Non-Federal Share) amounts are based on Estimated Member Months, and the actual amounts may change based on actual enrollment. Note that for service period July 1, 2020 through December 31, 2020, the Contribution (Non-Federal Share) amounts are based on Projected Contribution PMPMs, and the actual amounts may change based on the risk adjustment process that DHCS uses as part of its rate development methodology.

If an MCP elect to participate in the Rating Period 2019-20 Voluntary Rate Range Program, the MCP must adhere to the process for participation outlined below:

Soliciting Interest

The MCP shall contact potential governmental funding entities to determine their interest, ability, and desired level of participation in the Rating Period 2019-20 Voluntary Rate Range Program. All providers and governmental funding entities who express their interest directly to DHCS will be redirected to the applicable MCP to facilitate negotiations related to participation. If, following the submission of the MCP's proposal, one or more governmental funding entities included in the MCP's proposal are unable or unwilling to participate in the Voluntary Rate Range Program, the MCP shall attempt to find other governmental funding entities able and willing to participate in their place.

The MCP must inform all participating governmental entities that, unless DHCS determines a statutory exemption applies, IGTs submitted in accordance with W&I Code section 14301.4 are subject to an additional 20 percent assessment fee (calculated on the value of their IGT contribution amount) to reimburse DHCS for the administrative costs of operating the Voluntary Rate Range Program and to support the Medi-Cal program. DHCS will determine if a fee waiver is appropriate.

Submission Requirements

Once the MCP has coordinated with the relevant governmental funding entities, the following documents must be submitted to DHCS in accordance with the requirements and procedures set forth below:

- The MCP must submit a **proposal** to DHCS. This proposal must include:

    1. A cover letter signed by the MCP's Chief Executive Officer or Chief Financial Officer on MCP letterhead.
    2. The MCP's primary contact information (name, e-mail address, mailing address, and phone number).
    3. County/region-specific summaries of the selected governmental funding entities, related providers, and participation levels specified for Rating Period 2019-20. The combined amounts or percentages must not exceed 100 percent of the estimated non-federal share of the available rate range amounts provided by DHCS. If the MCP is unable to use the entire available rate range, the MCP must indicate the unfunded amount and percentage.
    4. All letters of interest (described below) and supporting documents must be attached to the proposal. If the Rating Period 2019-20 Voluntary Rate Range Program Supplemental Attachment described below is not collected by the MCP and attached to the proposal at the time of submission, please indicate if the information will be submitted to DHCS directly by each governmental funding entity.

- The MCP must obtain a **letter of interest** from each governmental funding entity included in the MCP's proposal to DHCS. The highlighted sections in the letter of interest form provided in Attachment A must be filled out completely and printed on the participating governmental funding entity's letterhead. A separate letter of interest must be provided for each county or rating region. An individual who is authorized to sign the certification on behalf of the governmental funding entity must sign the letter of interest.

- The MCP must distribute to governmental funding entities and ensure submission to DHCS, either by the MCP or the governmental funding entity, of the **Rating Period 2019-20 Voluntary Rate Range Program Supplemental Attachment** (see Attachment B) by Wednesday, February 19, 2020.

- The proposals and letters of interest are due to DHCS ***by 5pm on* Wednesday, February 19, 2020**. Please send a PDF copy of the required documents by e-

mail to Sandra.Dixon@dhcs.ca.gov. ***Failure to submit all required documents by the due date may result in exclusion from the Rating Period 2019-20 Voluntary Rate Range Program.***

Each proposal is subject to review and approval by DHCS. The review will include an evaluation of the proposed provider participation levels in comparison to their uncompensated contracted Medi-Cal costs and/or charges. DHCS reserves the right to approve, amend, or deny the proposal at its discretion.

Upon DHCS' approval of the governmental funding entities and non-federal share amounts for the Rating Period 2019-20 Voluntary Rate Range Program, DHCS will provide the necessary funding agreement templates, forms, and related due dates to the specified governmental funding entities and MCP contacts. The governmental funding entities will be responsible for completing all necessary funding agreement documents, responding to any inquiries necessary for obtaining approval, and obtaining all required signatures.

If you have any questions regarding this letter, please contact Sandra Dixon at (916) 345-8269 or by email at Sandra.Dixon@dhcs.ca.gov.

Sincerely,

Jennifer Lopez
Division Chief
Capitated Rates Development Division

Attachments

cc: Michael Schrader
CalOptima
505 City Parkway West
Orange, CA 92868

Sandra Dixon
Capitated Rates Development Division
Department of Health Care Services
1501 Capitol Avenue, MS 4413
P.O. Box 997413
Sacramento, CA 95899-7413

ATTACHMENT A – LETTER OF INTEREST

Jennifer Lopez
Division Chief
Capitated Rates Development Division
Department of Health Care Services
1501 Capitol Avenue, MS 4413
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Ms. Lopez:

This letter confirms the interest of _Insert Participating Funding Entity Name, a governmental entity, federal I.D. Number _Insert Federal Tax I.D. Number, in working with Managed Care Plan's Name (hereafter, "the MCP") and the California Department of Health Care Services (DHCS) to participate in the Voluntary Rate Range Program, including providing an Intergovernmental Transfer (IGT) to DHCS to be used as a portion of the non-federal share of actuarially sound Medi-Cal managed care capitation rate payments incorporated into the contract between the MCP and DHCS for the service periods of July 1, 2019 through June 30, 2020, and July 1, 2020 through December 31, 2020. This is a non-binding letter, stating our interest in helping to finance health improvements for Medi-Cal beneficiaries receiving services in our jurisdiction. The governmental entity's funds are being provided voluntarily, and the State of California is in no way requiring the governmental entity to provide any funding.

_Insert Participating Funding Entity Name is willing to contribute approximately $_____ for the Rating Period 2019-20 (July 1, 2019 through December 31, 2020) as negotiated with the MCP. We recognize that, unless a waiver is approved by DHCS, there will be an additional 20-percent assessment fee payable to DHCS on the funding amount, for the administrative costs of operating the voluntary rate range program.

The following individual from our organization will serve as the point of communication between our organization, the MCP and DHCS on this issue:

Entity Contact Information:

(Please provide complete information including name, street address, e-mail address and phone number.)

I certify that I am authorized to sign this certification on behalf of the governmental entity and that the statements in this letter are true and correct.

Sincerely,

Signature

Attachment B

Voluntary Rate Range Program Supplemental Attachment
Rating Period 2019-20 (July 1, 2019 through December 31, 2020)

Provider Name:	
County:	
Health Plan:	

Instructions

Complete all yellow-highlighted fields. **Submit this completed form via e-mail to Sandra Dixon (sandra.dixon@dhcs.ca.gov) at the Department of Health Care Services (DHCS) by no later than February 19, 2020.**

1. In the table below, report charges/costs and payments received or expected to be received from the Health Plan indicated above for Medi-Cal services (Inpatient, Outpatient, and All Other) provided to Medi-Cal beneficiaries enrolled in the Health Plan and residing in the County indicated above, for dates of service from July 1, 2018 - June 30, 2019.

	Charges	Costs	Payments from Health Plan*	Uncompensated Chares (charges less payments)	Uncompensated Costs (Costs less payments)
Inpatient				$	$
Outpatient				$	$
All Other				$	$
Total	$	$	$	$	$

* Include payments received and anticipated to be received for service dates of July 1, 2018 through June 30, 2019.

2. Are you able to fund 100% of the higher of the uncompensated charges or uncompensated costs (as stated above)? *(Yes / No)*

If No, please specify the amount of funding available:

3. Describe the scope of services provided to the specified Health Plan's Medi-Cal members, and if these services were provided under a contract arrangement.

4. Please provide the following information:

(i) The name of the entity transferring funds:

(ii) The operational nature of the entity (county, city, special purpose district, state university teaching hospitals or other political subdivisions of the state) transferring funding:

(iii) The source of the funds:
(Funds must not be derived from impermissible sources such as recycled Medicaid payments, federal funds excluded from use as State match, impermissible taxes, and non-bona fide provider-related donations. Impermissible sources do not include patient care or other revenue received from programs such as Medicare or Medicaid to the extent that the program revenue is not obligated to the State as the source of

(iv) Does the transferring entity have general taxing authority? *(Yes / No)*

If No, does the transferring entity receive State appropriations (identify level of appropriation)? This may include, but not limited to, annual State appropriations for various programs, or realignment funds to support programs transferred by State Law to local control. *(Yes / No)*

5. Comments / Notes

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ATTACHMENT C

TOTAL AVAILABLE RATE RANGE

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CalOptima - Orange (HCP 506)
IGT - 2019/20 (July 2019 - June 2020)

	Total	50% FFP (Non-MCHIP,SPD and LTC)	88% FFP (MCHIP - 7/2019 to 9/2019)	76.5% FFP (MCHIP - 10/2019 to 6/2020)	BCCTP[3]	WCM[4]	93% FFP Optional Expansion (7/2019 - 12/2019)	90% FFP Optional Expansion (1/2020 - 6/2020)
Total Funds Available	$ 143,831,947	$ 60,609,553	$ 2,248,273	$ 6,744,806	$ 567,560	$ 20,884,320	$ 26,388,727	$ 26,388,708
Federal Match	$ 98,389,329	$ 30,304,777	$ 1,978,480	$ 5,159,777	$ 189,344	$ 12,465,598	$ 24,541,516	$ 23,749,837
Governmental Funding Entity's Portion	$ 45,442,618	$ 30,304,776	$ 269,793	$ 1,585,029	$ 378,216	$ 8,418,722	$ 1,847,211	$ 2,638,871
	31.6%	50.0%	12.0%	23.5%	66.6%	40.3%	7.0%	10.0%

Rate Categories[1]	Member Months (per Mercer est.)	Lower Bound (per Mercer Rate Worksheets)	Upper Bound (per Mercer Rate Worksheets)	Difference between Upper and Lower Bound	Other Departmental Usage[2]	Available PMPM (less Other Dept. Usage)	Estimated Available Total Fund
Child - non MCHIP	2,271,664	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 15,356,449
Child - MCHIP 7/2019 - 9/2019	303,510	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 2,051,728
Child - MCHIP 10/2019 - 6/2020	910,531	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 6,155,190
Adult - non MCHIP	1,007,518	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 19,948,856
Adult - MCHIP 7/2019 - 9/2019	9,788	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 193,802
Adult - MCHIP 10/2019 - 6/2020	29,363	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 581,387
SPD	448,861	$ 814.48	$ 859.81	$ 45.33	$ -	$ 45.33	$ 20,346,869
SPD/Full-Dual	24,336	$ 205.34	$ 215.02	$ 9.68	$ -	$ 9.68	$ 235,572
BCCTP	7,026	$ 1,430.69	$ 1,511.47	$ 80.78	$ -	$ 80.78	$ 567,560
LTC	15,492	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 4,721,807
LTC - MCHIP 7/2019 - 9/2019	9	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,743
LTC - MCHIP 10/2019 - 6/2020	27	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 8,229
LTC/Full-Dual	0	$ 6,630.57	$ 6,780.31	$ 149.74	$ -	$ 149.74	$ -
WCM	146,382	$ 1,876.85	$ 2,019.52	$ 142.67	$ -	$ 142.67	$ 20,884,320
Optional Expansion 7/2019 - 12/2019	1,394,753	$ 424.87	$ 450.10	$ 25.23	$ 6.31	$ 18.92	$ 26,388,727
Optional Expansion 1/2020 - 6/2020	1,394,752	$ 424.87	$ 450.10	$ 25.23	$ 6.31	$ 18.92	$ 26,388,708
	7,964,012	$ 333.59	$ 353.87	$ 20.27	$ 2.21	$ 18.06	$ 143,831,947

[1] The supplemental payments (Maternity, BHT and HEP C) and CCI population are not included in the rate range calculation.

[2] Other Departmental Usages decreases available rate range funding.

[3] BCCTP Federal Match is based on the portion of the population enrolleed in a BCCTP aid code associated with a FFP percentage of 65%.

[4] WCM Federal Match is based on the FFP percentage associated with the aid codes within each rating categories.

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CalOptima - Orange (HCP 506)
IGT - 2019/20 (July 2020 - December 2020)

	Total	50% FFP (Non-MCHIP and SPD)	76.5% FFP (MCHIP - 7/2020 to 9/2020)	65% FFP (MCHIP - 10/2020 to 12/2020)	BCCTP [3]	WCM [4]	90% FFP Optional Expansion
Total Funds Available	$ 71,458,138	$ 30,053,529	$ 2,227,321	$ 2,227,321	$ 282,165	$ 10,402,926	$ 26,264,876
Federal Match	$ 47,878,762	$ 15,026,765	$ 1,703,901	$ 1,447,759	$ 94,133	$ 5,967,816	$ 23,638,388
Governmental Funding Entity's Portion	$ 23,579,376	$ 15,026,764	$ 523,420	$ 779,562	$ 188,032	$ 4,435,110	$ 2,626,488
	33.0%	50.0%	23.5%	35.0%	66.6%	42.6%	10.0%

Rate Categories [1]	Member Months (per Mercer est.)	Lower Bound (per Mercer Rate Worksheets)	Upper Bound (per Mercer Rate Worksheets)	Difference between Upper and Lower Bound	Other Departmental Usage [2]	Available PMPM (less Other Dept. Usage)	Estimated Available Total Fund
Child - non MCHIP	1,126,338	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 7,614,045
Child - MCHIP 7/2020 - 9/2020	300,973	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 2,034,577
Child - MCHIP 10/2020 - 12/2020	300,973	$ 87.64	$ 94.40	$ 6.76	$ -	$ 6.76	$ 2,034,577
Adult - non MCHIP	493,892	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 9,779,062
Adult - MCHIP 7/2020 - 9/2020	9,596	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 190,001
Adult - MCHIP 10/2020 - 12/2020	9,596	$ 324.35	$ 344.15	$ 19.80	$ -	$ 19.80	$ 190,001
SPD	224,524	$ 814.48	$ 859.81	$ 45.33	$ -	$ 45.33	$ 10,177,673
SPD/Full-Dual	12,241	$ 205.34	$ 215.02	$ 9.68	$ -	$ 9.68	$ 118,493
BCCTP	3,493	$ 1,430.69	$ 1,511.47	$ 80.78	$ -	$ 80.78	$ 282,165
LTC	7,757	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,364,256
LTC - MCHIP 7/2020 - 9/2020	9	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,743
LTC - MCHIP 10/2020 - 12/2020	9	$ 11,026.93	$ 11,331.72	$ 304.79	$ -	$ 304.79	$ 2,743
LTC/Full-Dual	0	$ 6,630.57	$ 6,780.31	$ 149.74	$ -	$ 149.74	$ -
WCM	72,916	$ 1,876.85	$ 2,019.52	$ 142.67	$ -	$ 142.67	$ 10,402,926
Optional Expansion	1,388,207	$ 424.87	$ 450.10	$ 25.23	$ 6.31	$ 18.92	$ 26,264,876
	3,950,524	$ 334.30	$ 354.61	$ 20.31	$ 2.22	$ 18.09	$ 71,458,138

[1] The supplemental payments (Maternity, BHT and HEP C) and CCI population are not included in the rate range calculation.

[2] Other Departmental Usages decreases available rate range funding.

[3] BCCTP Federal Match is based on the portion of the population enrolleed in a BCCTP aid code associated with a FFP percentage of 65%.

[4] WCM Federal Match is based on the FFP percentage associated with the aid codes within each rating categories.

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken January 7, 2021
Special Meeting of the CalOptima Board of Directors

Report

6. Consider Ratifying a Letter of Agreement for Emergency Transition of Tustin Care Center Residents and Authorization of an Amendment to the Professional Services Contract with GN Medical Associates dba CareConnect Medical Group for Future Emergency Transition Care Coordination Services

Contacts

Richard Sanchez, Chief Executive Officer, (657) 900-1481
Ladan Khamseh, Chief Operating Officer, (714) 246-8866

Recommended Actions

1. Ratify Letter of Agreement (LOA) with GN Medical Associates dba CareConnect Medical Group (CareConnect) to provide emergency transition care coordination services for certain categories of CalOptima Members residing at Tustin Care Center; and
2. Authorize the Chief Executive Officer, with the assistance of Legal Counsel, to amend the Professional Services Contract with CareConnect to furnish future emergency transition care coordination services for certain categories of CalOptima Members residing at skilled nursing facilities providing long term care, where the Members' current placement is medically contraindicated and/or due to the immediate, unexpected closure of the current facility due to any cause.

Background

CalOptima received an urgent request in early December 2020 from the California Department of Public Health (CDPH) and the Orange County Health Care Agency (HCA) to provide assistance to address emergency events at the Tustin Care Center Facility resulting from a severe COVID-19 outbreak. The COVID-19 outbreak impacted both facility staff and patients, a significant number of whom were Medi-Medi Members, with CalOptima Medi-Cal as secondary coverage.

CalOptima currently contracts with CareConnect to provide specialist physician and other services in skilled nursing facilities (SNF). These physician services are also sometimes referred to as a "SNFist" services. CalOptima also has a separate contract with CareConnect for primary care physician (PCP) services. CareConnect's providers are registered to provide services through both the Medicare and Medi-Cal programs, including CalOptima Medi-Cal. In response to the urgent request, CalOptima staff was able to immediately engage CareConnect to provide case management support to facilitate the transition of CalOptima Members to other licensed Medi-Cal facilities.

Notably, Tustin Care Center's residents generally have Medicare as their primary health care coverage and CalOptima Medi-Cal as secondary insurance coverage, such that CalOptima would solely be providing reimbursement for their long-term care room and board. Since the facility had not been ordered closed, relocation required an order by each individual resident's physician. However, some of the facility's staff tested positive for COVID-19, while others were disengaged with providing medical and other assistance to the residents due to the COVID-19 crisis. CareConnect, as a Medicare provider, was able to step in to fill the needed physician services, filling that void for these resident patients,

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including CalOptima Members, who did not have a physician to provide the necessary orders to relocate them outside of Tustin Care Center.

Due to COVID-19, Tustin Care Center was impacted by staff illness, staffing shortages and other serious patient care issues such that all Tustin Care Center residents needed to be relocated to other facilities, including acute care hospitals for those individuals in medical distress. As medically appropriate, some residents were able to be transferred to other nursing facilities in coordination with the residents' families, with consideration given to the Members' cultural and language preferences. CareConnect communicated with the Member's families to ensure smooth transitions to other licensed Medi-Cal facilities. In addition, CalOptima provided Medi-Cal-covered non-emergency medical transportation benefits not covered by Medicare in order to accomplish timely and safe transitions to new facilities.

Discussion

CalOptima Case Management and Medical Staff worked on a daily basis in concert with the CDPH and HCA over the course of an approximate two-week period to address the care of CalOptima members. As discussed above, staff engaged CareConnect to coordinate the relocation of CalOptima Members from Tustin Care Center to other facilities for those Members without a Primary Care Physician (PCP) to coordinate their transition. CareConnect coordinated the physical transfer of the Members, the transfer of medical records for those Members, completed the transfer paperwork, including physician orders necessary for the transfer, and coordinated the transportation of the Members to other skilled nursing facilities or acute care hospitals. Staff now requests that the Board ratify the Letter of Agreement providing for payment at a per Member case rate for care coordination services rendered by CareConnect to assist with the emergency COVID-19 crisis at Tustin Care Center.

With the COVID-19 surge in Orange County, and its continuing impact on SNFs providing skilled and other long term care services, CalOptima staff also seeks to contract with CareConnect to continue to provide emergency transition care coordination services on an as needed basis. CareConnect would coordinate, at the direction of CalOptima, the care and transfer of certain CalOptima Members (CalOptima Medi-Medi Members not enrolled in OneCare or OneCare Connect, or Medi-Cal Members without a PCP) when the current resident placement is medically contraindicated due to events related to the COVID-19 Public Health Emergency and/or due to the immediate, unexpected closures of their current SNF or other Medi-Cal facility for whatever cause.

The emergency transition care coordination services would include the following and collectively would be paid at a per Member case rate:

- Collection, reproduction, and review of Members' medical records for transfer to the new facility
- Seeking and procuring placement at an alternate, Medi-Cal licensed facility at the medically necessary level of care for the Member

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- Communicating with the primary care provider, Member and family about the transition and transfer

- Arranging with a CalOptima-contracted transportation provider for appropriate transportation of the Member to the accepting facility

- Timely reporting to CalOptima

If Medi-Cal Members without a Primary Care Provider require additional primary care services, such services would be provided by CareConnect based on their existing PCP Contract, even if the Medi-Cal Member is not otherwise assigned to them. For Medi-Medi Members (not enrolled in OneCare or OneCare Connect), Primary Care Physician services are the responsibility of Traditional Medicare (also called Fee-for-Service Medicare), and would be billed accordingly.

Fiscal Impact

The recommended action to ratify the LOA with CareConnect to provide emergency transition care coordination services for Medi-Cal as secondary coverage for Members at Tustin Care Center is an unbudgeted item. The total cost related to transition services provided for the Tustin Care Center relocations was $15,600. Staff anticipates the fiscal impact will be budget neutral, as decreased utilization of certain services within the Medi-Cal program will offset the additional costs in unbudgeted medical services related to the LOA.

The recommended action to amend the Professional Services Contract with CareConnect to provide future emergency transition care coordination services is an unbudgeted item. The estimated cost for transition services is $175 per Member. Under extreme circumstances, CareConnect may have to provide authorized extended services which will be billed additionally but will not exceed $300 per Member. At this time, it is difficult to predict the number of transitions that will occur pursuant to the contract provisions. However, staff anticipates the fiscal impact will be budget neutral, as decreased utilization of certain services within the Medi-Cal program will offset the additional costs in unbudgeted medical services related to the contract amendment. Staff will closely monitor utilization levels to ensure offsetting funds are sufficient to support the contract amendment.

Rationale for Recommendation

Under certain circumstances, especially those related to the spread of the COVID-19 virus, a skilled nursing or similar facility may suddenly and unexpectedly become unable to safely provide its normal services to Members. This occurred in early December 2020 with the Tustin Care Center and could occur again at any time in the future. Staff undertook urgent action to address the health and safety of CalOptima Members at the Tustin Care Center, and safely relocate them to other facilities. In order to address this and possible future situations, staff is seeking Board ratification of the LOA to reimburse CareConnect for actions undertaken with regard to the Tustin Care Center, and authorization to amend the CareConnect Contract to address the services and payments for future similar services made necessary due to COVID-19 or other unforeseen emergency circumstances.

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Concurrence
Gary Crockett, Chief Counsel

Attachment
1. Entities Covered by this Recommended Action

/s/ Richard Sanchez *12/31/2020*
Authorized Signature **Date**

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ENTITIES COVERED BY THIS RECOMMENDED BOARD ACTION

Name	Address	City	State	Zip Code
CareConnect Health Services (GeriNet)	16162 Beach Blvd. Ste. 250	Huntington Beach	CA	92647

CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken January 7, 2021
Special Meeting of the CalOptima Board of Directors

Report Item

7. Authorize Health Network Medi-Cal Capitation Rate Increases for the Period of January 1, 2021, through June 30, 2021, due to COVID-Related Expenses

Contacts

Richard Sanchez, Chief Executive Officer, (657) 900-1481
Nancy Huang, Chief Financial Officer, (657) 235-6935

Recommended Actions

1. Authorize Health Network Medi-Cal capitation rate increases for contracted Physician Hospital Consortia (PHC), Shared Risk Group (SRG), and Health Maintenance Organizations (HMO), except Kaiser Foundation Health Plan, Inc.(Kaiser), on Child, Adult and Seniors and Persons with Disabilities (SPD) Categories of Aid (COA), by 5.0% from current levels for the period of January 1, 2021 through June 30, 2021;
2. Authorize unbudgeted expenditures up to $9 million to provide funding for Health Network capitation rate adjustments; and
3. Authorize the Chief Executive Officer, with the assistance of Legal Counsel, to amend the Medi-Cal PHC, SRG, and HMO Health Network contracts, except Kaiser, to implement the Health Network capitation rate adjustments.

Background

On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency under section 319, of the Public Health Service Act (42 U.S.C. 247d) in response to a novel coronavirus known as SARS-CoV-2 (coronavirus). On March 13, 2020, the President of the United States declared a national emergency based on the spread of this coronavirus. Subsequently, the Governor and the Orange County Health Officer have similarly taken steps to slow the spread of the coronavirus and protect the public. As with federal, state, and local agencies, CalOptima is taking action to continue efforts to support providers serving CalOptima members during the pandemic.

At its April 2, 2020, meeting, the Board authorized a 5% health network Medi-Cal capitation rate increase from reserve for contracted PHCs, SRGs and HMOs for the period of April 1, 2020, through June 30, 2020 to support CalOptima's provider networks and ensure member access proactively in the beginning of pandemic.

On December 23, 2020, CalOptima received final Calendar Year 2021 Medi-Cal capitation rates from the California Department of Health Care Services (DHCS). The final rates included an update rate component for COVID-related adjustments.

Discussion

Management recognizes that the coronavirus pandemic has placed significant stress on healthcare providers and on the delivery system serving CalOptima members. Consistent with DHCS's rate adjustment methodology, staff has included COVID-related testing and treatment costs, as well as potential changes in utilization in the evaluation. As such, in order to support the viability of our contracted health networks, Management requests authority to:

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1. Provide a 5.0% increase from current levels to contracted PHC, SRG and HMO Medi-Cal capitation rates, and shared risk pool funding on Child, Adult and SPD COAs, for the period of January 1, 2021, through June 30, 2021, except Kaiser. The estimated aggregate monthly fiscal impact is approximately $1.5 million.

2. Amend the Medi-Cal PHC, SRG, and HMO Health Network contracts, except Kaiser, to reflect this increase for the period stated above.

Fiscal Impact
The total funds for the Health Network Medi-Cal capitation rates for contracted PHCs, SRGs and HMOs will not exceed 5.0% of total medical capitation expenditures, on Child, Adult and SPD COAs, in the CalOptima Fiscal Year (FY) 2020-21 Operating Budget. The projected aggregate monthly fiscal impact is approximately $1.5 million or up to $9 million for the period of January 1, 2021, through June 30, 2021. It will be net budget neutral since additional funding from DHCS is anticipated to be sufficient to cover the unbudgeted Medi-Cal capitation rate increase.

Rationale for Recommendation
Providing additional provider payments during the coronavirus pandemic will ensure providers remain viable and accessible to our members, as well as increased financial security for the Orange County safety net system.

Concurrence
Gary Crockett, Chief Counsel

Attachments
1. Entities Covered by this Recommended Action
2. Board Action Dated April 2, 2020: Consider Actions Related to Coronavirus (COVID-19) Pandemic

/s/ Richard Sanchez — *12/31/2020*
Authorized Signature — **Date**

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ENTITIES COVERED BY THIS RECOMMENDED BOARD ACTION

Name	Address	City	State	Zip Code
Heritage Provider Network, Inc.	8510 Balboa Blvd., Ste. 285	Northridge	CA	91325
Monarch Health Plan, Inc.	11 Technology Dr.	Irvine	CA	92618
Prospect Health Plan, Inc.	600 City Parkway West, Ste. 800	Orange	CA	92868
CHOC Physicians Network and Children's Hospital of Orange County	1120 West La Veta Ave., Ste. 450	Orange	CA	92868
Family Choice Medical Group, Inc.	7631 Wyoming St., Ste. 202	Westminster	CA	92683
Fountain Valley Regional Hospital and Medical Center	17100 Euclid St.	Fountain Valley	CA	92708
AMVI Care Health Network	600 City Parkway West, Ste. 800	Orange	CA	92868
Orange County Physicians IPA Medical Group, Inc dba Noble Community Medical Associates, Inc.	10855 Business Center Dr., Ste. C	Cypress	CA	90630
Talbert Medical Group, P.C.	2175 Park Place	El Segundo	CA	90245
ARTA Western California, Inc.	2175 Park Place	El Segundo	CA	90245
United Care Medical Group, Inc.	600 City Parkway West	Orange	CA	92868
AltaMed Health Services Corporation	2040 Camfield Ave.	Los Angeles	CA	90040

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CALOPTIMA BOARD ACTION AGENDA REFERRAL

Action To Be Taken April 2, 2020
Regular Meeting of the CalOptima Board of Directors

Report Item

4. Consider Actions Related to Coronavirus (COVID-19) Pandemic

Contact

Nancy Huang, Chief Financial Officer (714) 246-8400
Michelle Laughlin, Executive Director Network Operations (714) 246-8400

Recommended Actions

1. Authorize Health Network Medi-Cal capitation rate increases for contracted Physician Hospital Consortia (PHC), Shared Risk Group (SRG), and Health Maintenance Organizations (HMO) by 5% from current levels for the period of April 1, 2020, through June 30, 2020;

2. Authorize waiver of the minimum stay requirement and expand types of services eligible for per diem payments for contracted Community-Based Adult Services (CBAS) providers for Medi-Cal and OneCare Connect;

3. Authorize unbudgeted expenditures from existing reserves of up to $14 million to provide funding for rates adjustments for Health Network capitation rates;

~~4. Authorize interim Medi-Cal rate for coronavirus testing for dates of service on or after February 4, 2020;~~ Amended 4/2/20

5. Authorize the Chief Executive Officer (CEO), with the assistance of Legal Counsel, to:

    a. Amend the Medi-Cal PHC, SRG, and HMO Health Network contracts to implement the 5% capitation rate increase; and
    b. Amend Medi-Cal and OneCare Connect contracts with CBAS providers effective March 13, 2020 to provide flexibility for services, in accordance with the Department of Health Care Services' (DHCS) section 1135 Waiver application.

Background

On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency under section 319, of the Public Health Service Act (42 U.S.C. 247d) in response to a novel coronavirus known as SARS-CoV-2 (coronavirus). On March 13, 2020, the President of the United States declared a national emergency based on the spread of this coronavirus. Along with federal, state, and local agencies, CalOptima is taking action to continue efforts to protect the health and safety of our providers and members.

As an unprecedented safety measure, the state has issued self-quarantine and social distancing requirements for an unknown period of time. These requirements have and continue to affect CalOptima's provider networks as the coronavirus pandemic develops. One immediate downstream effect of these measures has been CBAS closures as a result of a reduction of in-person utilization. Left

unaddressed, this can rapidly jeopardize the viability of CalOptima's CBAS provider network. Moreover, it underscores the need for CalOptima to take necessary measures to ensure there is limited disruption of care and access to services for our members, which includes vulnerable individuals.

Discussion

CalOptima management recognizes that healthcare service delivery to our members has undergone significant changes during the coronavirus pandemic. Management recommends the following actions in order to provide immediate aid and service authorization flexibilities to CalOptima's provider network in order to ensure that members received access to covered, medically necessary health care services:

Medi-Cal Rate Enhancement for Health Networks

To provide immediate aid and support and maintain the viability of the health networks, Management proposes to:

1. Provide a 5% increase from current levels to contracted PHC, SRG and HMO Medi-Cal capitation rates for the period of April 1, 2020, through June 30, 2020. The estimated aggregate monthly fiscal impact is approximately $4.4 million.

2. Amend the Medi-Cal Health Network contracts to reflect this increase for the period stated above.

Special Reimbursement to CBAS providers

Staff anticipates face-to-face visits at CBAS centers to continue decreasing due to the Governor's stay at home executive order issued on March 19, 2020, and the County of Orange's social distancing requirements. CalOptima currently holds contracts with 31 CBAS centers, serving approximately 2,580 members. Preventing this is critical at this time, as CBAS centers serve CalOptima's most vulnerable senior members On March 19, 2020, the California Department of Health Care Services (DHCS) submitted a request for additional Section 1135 Waiver flexibilities related to coronavirus. This request included additional flexibilities related to the CBAS benefit and individual plan of care. In order to continue uninterrupted access to CBAS services, effective March 13, 2020, Management proposes to:

1. Waive the 1115 waiver requirement of a minimum of a four-hour stay at the center. This change will enable CalOptima members to receive appropriate services at home and remove barriers to access.

2. Expand the types of services eligible for per diem payments. Pursuant to DHCS' 1135 Waiver request, CalOptima will provide per diem payments to CBAS providers who provide:
   - Telephonic or live video interactions in lieu of face-to-face social/therapeutic visits and/or assessments;
   - Arrange for home delivered meals in absence of meals provided at the CBAS center; and/or
   - Provide physical therapy or occupational therapy in the home

3. Amend CBAS contracts to reflect the waiver of the minimum four-hour stay requirement and expansion of services pursuant to DHCS 1135 Waiver request.

~~Interim Medi-Cal Rate for Coronavirus Testing~~

~~The Centers for Medicare & Medicaid Services (CMS) established, for the Medicare program, procedure codes and provider reimbursement rates for coronavirus testing conducted on or after February 4, 2020. DHCS adopted these same procedure codes for the Medi-Cal program effective February 4, 2020. As of this writing, DHCS has not established Medi-Cal reimbursement rates for coronavirus testing.~~ Amended 4/2/20

~~Management proposes to adopt the Medicare provider reimbursement rates on an interim basis for CalOptima's Medi-Cal program for dates of service on or after February 4, 2020. Once DHCS establishes Medi-Cal reimbursement rates for coronavirus testing, CalOptima will make retroactive adjustments to Medi-Cal claims, as appropriate.~~ Amended 4/2/20

Fiscal Impact

The total funds for the Health Network Medi-Cal capitation rates for contracted PHCs, SRGs and HMOs will not exceed 5% of total medical capitation expenditures, in aggregate, in the CalOptima Fiscal Year (FY) 2019-20 Operating Budget. Staff projects the monthly incremental funding at approximately $4.4 million. An allocation of up to $14 million from existing reserves will fund this action.

The CalOptima FY 2019-20 Operating Budget includes funding for Professional medical expenditures for contracted CBAS providers. Currently, the net fiscal impact for the recommended action is unknown. However, assuming current utilization levels will continue, Staff anticipates the recommended action will not have an additional fiscal impact to the operating budget.

~~The fiscal impact for the recommended action to authorize an interim Medi-Cal rate for coronavirus testing is unknown at this time, since both utilization and costs estimates are difficult to quantify. However, Staff anticipates future funding received from DHCS for this purpose will fully offset expenses incurred by CalOptima.~~ Amended 4/2/20

Rationale for Recommendation

Providing additional provider payments during the coronavirus pandemic will ensure providers remain viable and accessible to our members, as well as increased financial security for the Orange County safety net system.

Concurrence

Gary Crockett, Chief Counsel

Attachments

1. DHCS Request for Additional Section 1135 Waiver Flexibilities Related to Novel Coronavirus Disease (COVID-19) National Emergency/Public Health Emergency dated March 19, 2020

/s/ Michael Schrader — **Authorized Signature**

03/26/2020 — **Date**

State of California—Health and Human Services Agency
Department of Health Care Services

BRADLEY P. GILBERT, MD, MPP
DIRECTOR

GAVIN NEWSOM
GOVERNOR

March 19, 2020

Jackie Glaze
CMS Acting Director
Medicaid & CHIP Operations Group Center for Medicaid & CHIP
Services 7500 Security Boulevard
Baltimore, MD 21244
Jackie.Glaze@cms.hhs.gov

REQUEST FOR ADDITIONAL SECTION 1135 WAIVER FLEXIBILITIES RELATED TO NOVEL CORONAVIRUS DISEASE (COVID-19) NATIONAL EMERGENCY/PUBLIC HEALTH EMERGENCY

Dear Ms. Glaze:

The Department of Health Care Services (DHCS) writes to request approval for the below-detailed additional flexibilities under Section 1135 of the Social Security Act (42 U.S.C. § 1320b-5) as related to the Novel Coronavirus Disease (COVID-19). These flexibilities are in addition to the request submitted from DHCS on March 16, 2020. As you know, the COVID-19 outbreak was declared a national emergency on March 13, 2020, and was previously declared a nationwide public health emergency on January 31, 2020 (retroactive to January 27, 2020).

The below list represents California's additional requested flexibilities under the Section 1135 authority in connection with the COVID-19 outbreak and emergency based on further exploration of need. Because circumstances surrounding the COVID-19 emergency remain quite fluid, DHCS may subsequently request approval for additional flexibilities, which we can commit to doing promptly as soon as the need is discovered. Consistent with Section 1 of the President's March 13, 2020, national emergency declaration, DHCS requests a retroactive effective date of January 27, 2020, for the requested Section 1135 flexibilities to coincide with the effective start date of the Public Health Emergency, unless otherwise specified. In the event a requested flexibility below is not approvable under the Section 1135 authority, DHCS requests CMS technical assistance to identify any other authority (e.g. under the State Plan or Section 1115) for which approval may be available. Per our discussion with CMS on March 19, 2020, DHCS will request the flexibilities associated with Inmate and Institutions for Mental Disease (IMD) funding exclusions in the Section 1115 context (according to the forthcoming CMS instructions/Section 1115 template).

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In addition, DHCS requests confirmation that any approved flexibility granted with respect to fee-for-service Medi-Cal benefits and providers would apply equally, to the extent applicable, to our various federally approved delivery systems, such as Medi-Cal managed care plans (MCPs), county organized health systems, county mental health plans, and Drug Medi-Cal organized delivery systems (DMC-ODS) and to the State's standalone Children's Health Insurance Program.

1. **Service authorization and utilization controls**, including but not necessarily limited to:

- Waiver of Attachment 3.1 – A.1, page 2 of the State Plan, exclusion of adult receipt of acetaminophen-containing and cough/cold products.

- For individuals with developmental disabilities receiving services under the State Plan 1915(i) authority, the state requests retainer payments. Retainer payments are available only for absences (maximum 30 consecutive days) in excess of the average number of absences experienced by the provider during the 12 month period prior to 2020.

- For Community-Based Adult Services (CBAS) – CBAS Benefit and Individual Plan of Care (IPC), the state requests:
    - Flexibility to reduce day center activities/gatherings and limit exposure to vulnerable populations.
    - Flexibility to utilize telephonic or live video interactions in lieu of face-to-face social/therapeutic visits.
    - Flexibility to utilize telephonic or live video interactions in lieu of face-to-face assessments.
    - Flexibility to allow following services to be provided at a beneficiary's home:
        - Physical Therapy
        - Occupational Therapy
    - Flexibility to provide or arrange for home delivered meals in absence of meals provided at the CBAS Center.
    - Flexibility for DHCS and MCPs to provide per diem payments to CBAS providers who provide telephonic or live video interactions in lieu of face-to-face social/therapeutic visits and/or assessments, arrange for home delivered meals in absence of meals provided at the CBAS Center, and/or provide physical therapy or occupational therapy in the home.

2. **Eligibility Flexibilities**, including but not necessarily limited to:

    - Flexibility in the hospital presumptive eligibility (HPE) program to cover more than one HPE period in a given 12-month timeframe. To the extent a beneficiary seeks care for coronavirus but has already used an HPE period in the last 12 months, or tests negative and then seeks care for a suspected episode later in the same 12-month period, HPE can provide a fast, low-barrier way to provide immediate, temporary coverage during the emergency period.

3. **Telehealth/Telephonic/Virtual Visits**, including but not necessarily limited to:

    - Waiver of 42 C.F.R. §438.6(c)(1), as necessary, to permit the State to direct MCO and PIHP payments to network providers, where telehealth/telephonic service is medically appropriate and feasible, at the same rate the MCO or PIHP would pay if the service was provided in person, unless the MCO/PIHP and the provider otherwise agree to a different rate for the telehealth modality.

    - Similar to flexibility granted at the federal level, DHCS requests authority for the State not to impose penalties for noncompliance with the regulatory requirements under the Health Insurance Portability and Accountability Act (HIPAA) against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 emergency.

4. **Administrative Activities**, regarding deadlines and timetables for performance of required activities, DHCS requests extension of time for activities conducted by the state, MCPs, and/or county mental health and substance use disorder prepaid inpatient health plans (PIHPs), as applicable, due to social distancing to reduce the spread of COVID-19 and to allow the state, MCP, and/or PIHP resources to prioritize COVID-19 response efforts including:

    - Waiver of the two-year claiming submission limit (42 USC §1320b-2; 45 CFR §95.1, et seq.) for federal financial participation or claiming adjustments with respect to medical assistance and administrative expenditures.

    - Waiver of the requirement in 42 CFR §447.45(d)(1), that DHCS require providers to submit all claims no later than 12 months from the date of service. DHCS is requesting authority to extend the 12-month timeframe for services provided with dates of service during this emergency.

    - Modification of the federal deadlines for submission of cost reports for Medicare and Medicaid (currently due Nov. 2020) by at least 6 months, with no late penalties, so that providers have time to file the appropriate documents. Many provider and hospital staff have been told to work remotely or have been reassigned to

emergency response activities, which will cause delays in meeting reporting timelines.

- Waiver of the timeframe required for financial oversight and medical compliance audits for PIHPs and State Plan Drug Medi-Cal counties. DHCS requests this waiver to allow flexibility regarding deploying staff resources to manage the emergency.

5. **Payment Rates**, including but not necessarily limited to:

- Waiver of the county interim rate setting methodology described beginning on page 10 of the Certified Public Expenditure (CPE) protocol approved through the 1915(b) waiver. The CPE protocol requires DHCS to calculate county interim rates using prior year cost reports trended forward using the Home Health Agency Market Basket Index or a CMS approved cost of living index. As utilization drops and costs increase during this emergency, DHCS is requesting authority to use alternative methodologies, at DHCS's discretion, to temporarily increase county interim rates.

- Waiver of the interim rate setting methodology described on page 5 and 6 of the Drug Medi-Cal Organized Delivery System (DMC ODS) Certified Public Expenditure protocol approved through the 1115 demonstration. The CPE protocol requires DHCS to reimburse DMC ODS counties on an interim basis pursuant to county developed and DHCS approved interim rates for each service, which are expected to be based upon the most recently calculated or estimated county costs for the specific service. DHCS is requesting authority, if counties reimburse DMC providers up to actual cost, to reimburse counties the federal and state share of their certified public expenditures for services rendered during this emergency.

- Waiver of the Statewide Maximum Allowance (SMA) rate limitation on interim reimbursement and final settlement for Drug Medi-Cal (DMC) services provided in state plan counties. California's State Plan describes the reimbursement methodology for DMC services in Attachment 4.19-B, pages 38-41b (SPA 09-022 and SPA 15-013), which limits interim payments to DMC providers to the lower of the SMA or the USDR (Section E.1, page 41). Furthermore, the Medicaid State Plan also limits final reimbursement to lower of actual cost, usual and customary charges, or the SMA for DMC providers. DHCS is requesting authority to waive the SMA and usual and customary charge limitations on interim and final reimbursement for DMC state plan services.

6. **Clarification of Previous Requests**:

- Item 2 in the March 16, 2020 1135 Waiver requested to waive various federal and State Plan requirements pertaining to service authorization and utilization controls

imposed on covered benefits. DHCS seeks to clarify that the requested waivers would extend to any limitations for elective procedures and informed consent (including, but not necessarily limited, to 42 C.F.R. § 441.253) to enable provider to postpone elective procedures to prioritize COVID-19 response activities. DHCS suggests extending the current 180-day limit for beneficiary informed consent to 360 days.

- Item 5 in the March 16, 2020 1135 Waiver requested to waive restrictions existing restrictions on individual counseling sessions under the Drug Medi-Cal state plan. DHCS wants to clarify that we are requesting to waive Supplement 3 to Attachment 3.1-B, to allow individual visits in lieu of group visits, and that these visits may be conducted by telephone, telehealth, and/or in-person. Waive the current restriction on individual visits (only allowed for intake, crisis intervention, collateral services, and treatment and discharge planning). Allow individual visits to be used for counseling focused on short-term personal, family, job/school and other problems and their relationship to substance use. This waiver is needed so the services previously provided in groups can be done in individual sessions during the emergency, to prevent COVID-19 exposure.

- Item 6 in the March 16, 2020 1135 Waiver requested to waive State Plan Attachment 4.19-D, including any applicable Supplements, which establishes the payment methodology for Intermediate Care Facilities for the Developmentally Disabled (ICF-DD) and skilled nursing facilities (SNFs). The state wanted to clarify that the waiver being requested would apply to all SNF and ICF-DD facility types and the reimbursement flexibilities would not be limited solely to the costs associated with suspension of Day Programs. SNFs and ICF-DDs are experiencing increased cost pressures in a variety of areas as a result of the COVID-19 response and the state is seeking flexibility to allow consideration of all costs being incurred by facilities to ensure the health and safety of residents.

7. Flexibilities to be Requested under Section 1115 Authority (according to forthcoming CMS guidance):

- Waiver of the inmate exclusion (42 U.S.C. §1396d(a)(30)(A)) to allow for Medi-Cal claiming for services provided ***in*** jails and prisons for the testing, diagnosis and treatment of COVID-19 or services to ensure other care is provided in a safe way without transporting individuals to acute care facilities.

- Waiver of the 16-bed limitation/prohibition on receipt of federal financial participation for patients residing in Institutions for Mental Disease (IMD) pursuant to 42 U.S.C. §1396d(a)(30)(B). DHCS believes waiver of the IMD exclusion is necessary to temporarily increase bed capacity for affected beneficiaries and to allow facilities to claim for services provided for these

additional beds. Evaluation of less restritictive settings would be completed prior to placement.

During such difficult times for California and the nation, DHCS greatly appreciates the prompt attention exhibited by CMS to these matters and we look forward to the continued partnership.

Sincerely,
Original Signed By:

Jacey Cooper
Chief Deputy Director
Health Care Programs
State Medicaid Director

cc: Bradley P. Gilbert, MD, MPP
Director
Department of Health Care Services

Erika Sperbeck
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