Prioritize Prevention & Diversify Our Patient Safety Toolbox:

Decolonization is a Missing Tool We Need

Michael Craig, MPP
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
U.S. Centers for Disease Control and Prevention

August 2022

No Financial Disclosures

The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention

THE PROBLEM

The U.S. antimicrobial resistance healthcare crisis

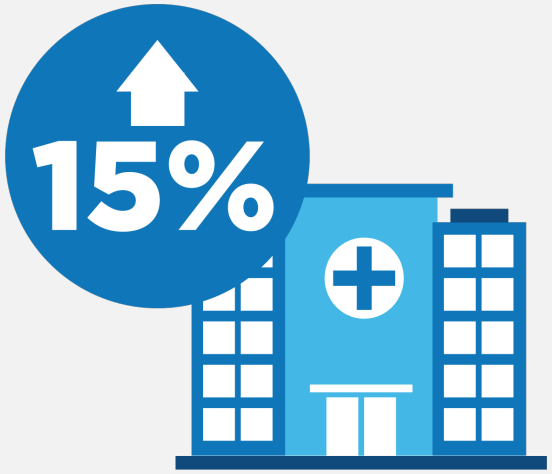
IN THE U.S., AT LEAST **2.8 million** INFECTIONS and **38,000** DEATHS per year

Deaths increase to 48,000 when *C. difficile* is factored in.[1]

On any given day, about **1 in 31 hospital patients** has at least one HAI.

- VAE (▲ 35%)
- CLABSI (▲ 24%)
- MRSA (▲ 15%)

2019 vs. 2020[3]



In U.S. hospitals, antimicrobial-resistant **infections and deaths both increased at least 15% in 2020.**[2]

Almost any infection can lead to SEPSIS. In a typical year:

- At least **1.7 million** adults in America develop sepsis.
- Nearly **270,000** Americans die as a result of sepsis.
- **1 in 3** patients who dies in a hospital has sepsis.[4]

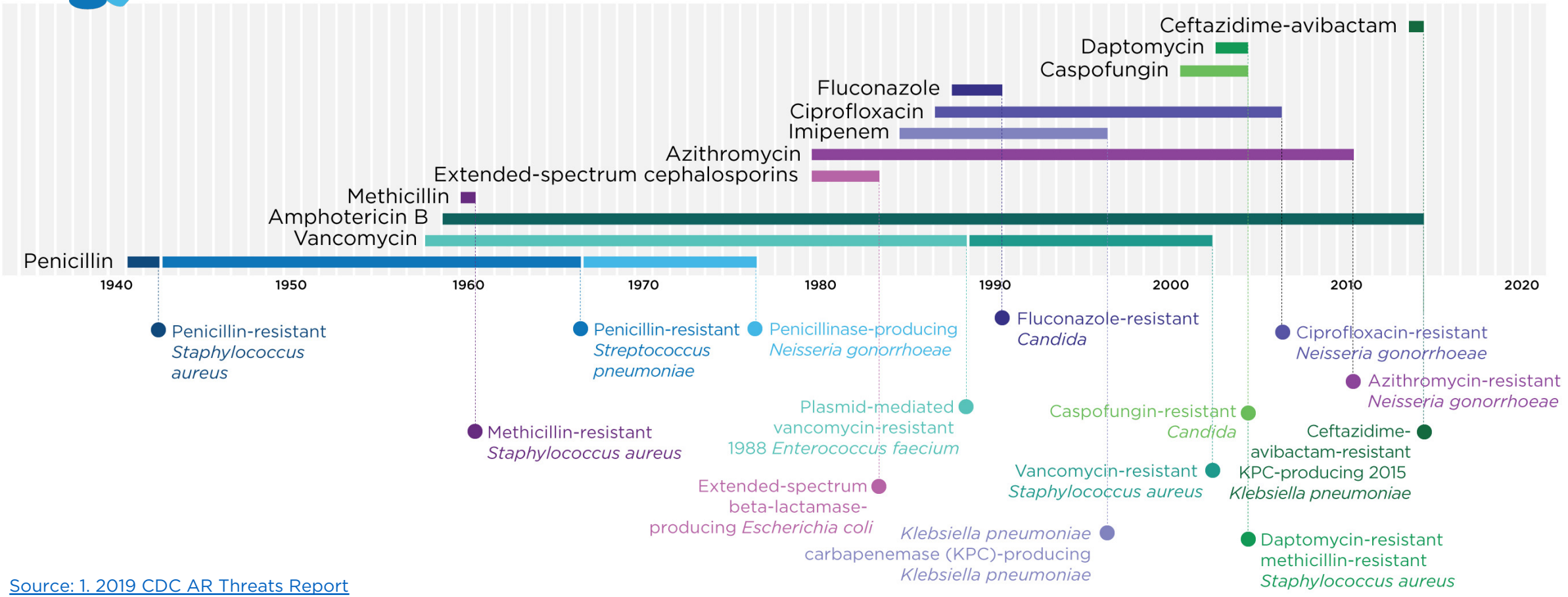
1. 2019 CDC AR Threats Report. 2. 2022 CDC COVID-19 AR Impact Report 3. CDC - HAI Data. 4. CDC - What is sepsis?

And resistance isn't slowing down.

Antibiotics are one of the few drugs that are readily available everywhere

Antibiotics are still used inappropriately, even when alternatives are available

Many perceive antibiotics "do no harm" but they cause side effects and can lead to patient harm



Source: 1. 2019 CDC AR Threats Report

Sepsis Treatment

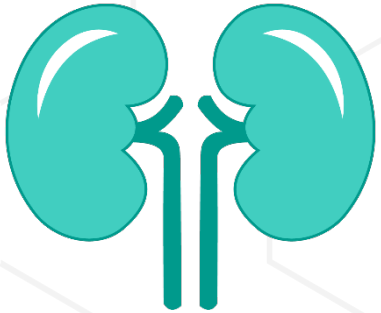
Surgery

Chronic Conditions

If we do not seriously invest in PREVENTING INFECTIONS, we will lose modern health care.

Organ Transplants

Dialysis for Advanced Kidney Disease



Cancer Care

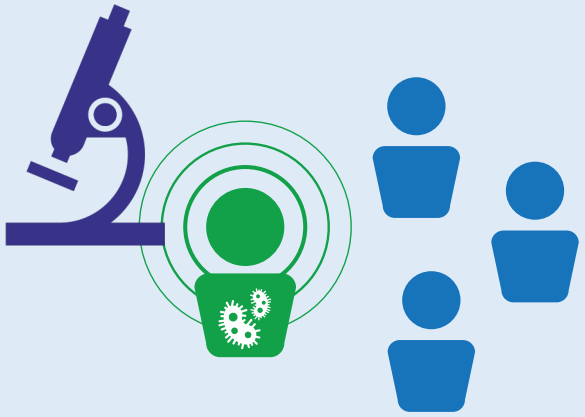
WHERE WE ARE TODAY
What we know, what we have

Prevention lessons (hopefully) learned.

- **We cannot treat our way out** of a pandemic, epidemic, or outbreak.
- **We cannot rely on one tool.** We need a comprehensive approach that accounts for limitations of human behavior, resources, and unknown threats.
- **We get what we pay for now.** If we don't invest in effective public health capacity and prevention today, we will not have these when we need them most:
  - Early detection and containment;
  - Infection prevention to stop transmission;
  - Evidence based prevention interventions including vaccines and preventatives.

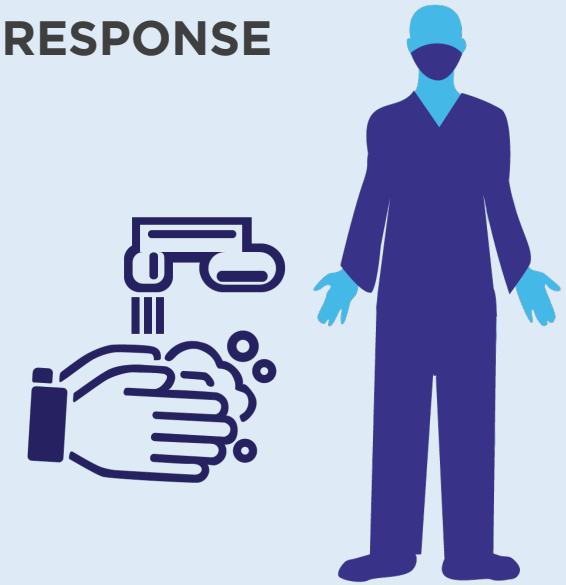
CDC needs more in our patient safety toolbox.

1 DETECTION



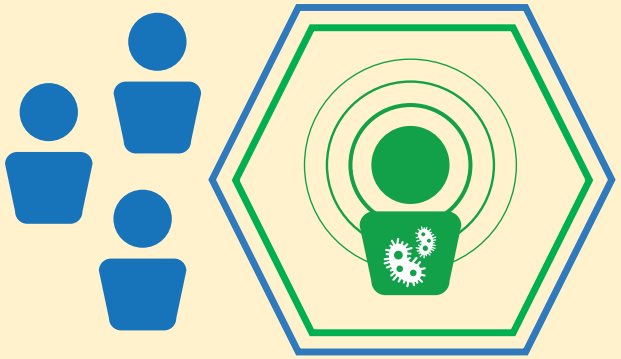
When unusual resistance emerges, screening identifies spread and cues prevention. **CDC's AR Lab Network can screen for threats like *C. auris* and CRE.**

2 PREVENTION & RESPONSE



CDC infection prevention guidance can reduce the risk of spread and risk of infection— **but IPC relies on consistency and accuracy.**

3 MISSING: PATHOGEN REDUCTION

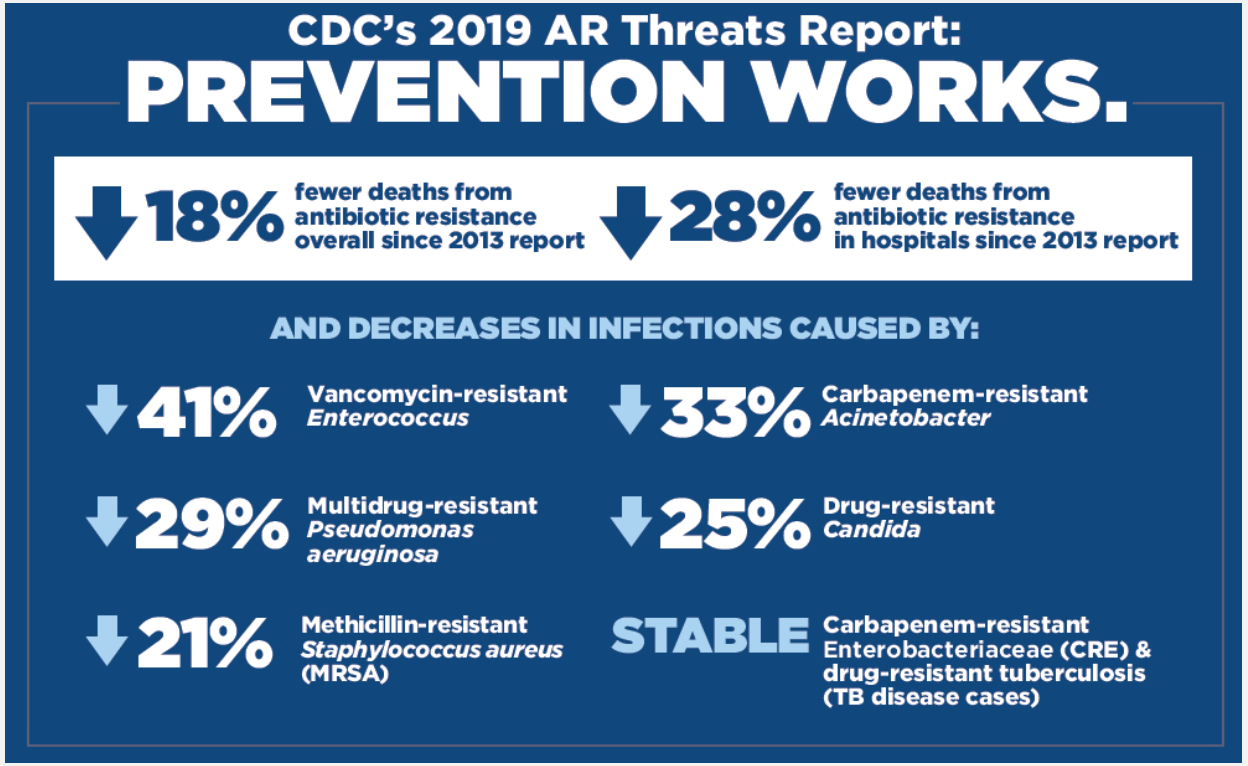


Novel decolonization agents could make colonized patients **less-infectious and slow the development of resistance.**

Patients need more products approved for prevention.

- In 2019, CDC showed that preventing AR infections, AR transmission, and deaths was not only possible, but a reality.
- The best infection is the one that never happens.
- Prevention saves lives and reduces antibiotic and antifungal use.
- Even if someone survives an infection, there are often lasting and long-term consequences from antibiotic/antifungal use.

2017 data in the 2019 AR Threats Report showed prevention was working.[1]



However, in 2020, resistant hospital-onset infections and deaths both increased at least 15% from 2019 levels.[2]

1. 2019 CDC AR Threats Report. 2. 2022 CDC COVID-19 AR Impact Report.

Development pathways need “prevention mindset,” too.

- Antibiotics approved to **TREAT** infections are already being used “off label” to **PREVENT** colonization and subsequent infection
  - Development pathways could allow products (new and existing) to be approved for prevention
- **Other products** (not antibiotic or antifungals) could help reduce the pressure for new drugs and prolong the life of drug treatments
- **We need evidence** for both indications to benefit a larger patient population. Ideally, data would also show how the product may:
  - Help protect the patient’s microbiome
  - Combat antimicrobial resistance (or not speed up development)
  - Benefit an individual patient and larger population

Prevention products could benefit:

~5x-10X[1]
number of colonized patients vs. infected patients

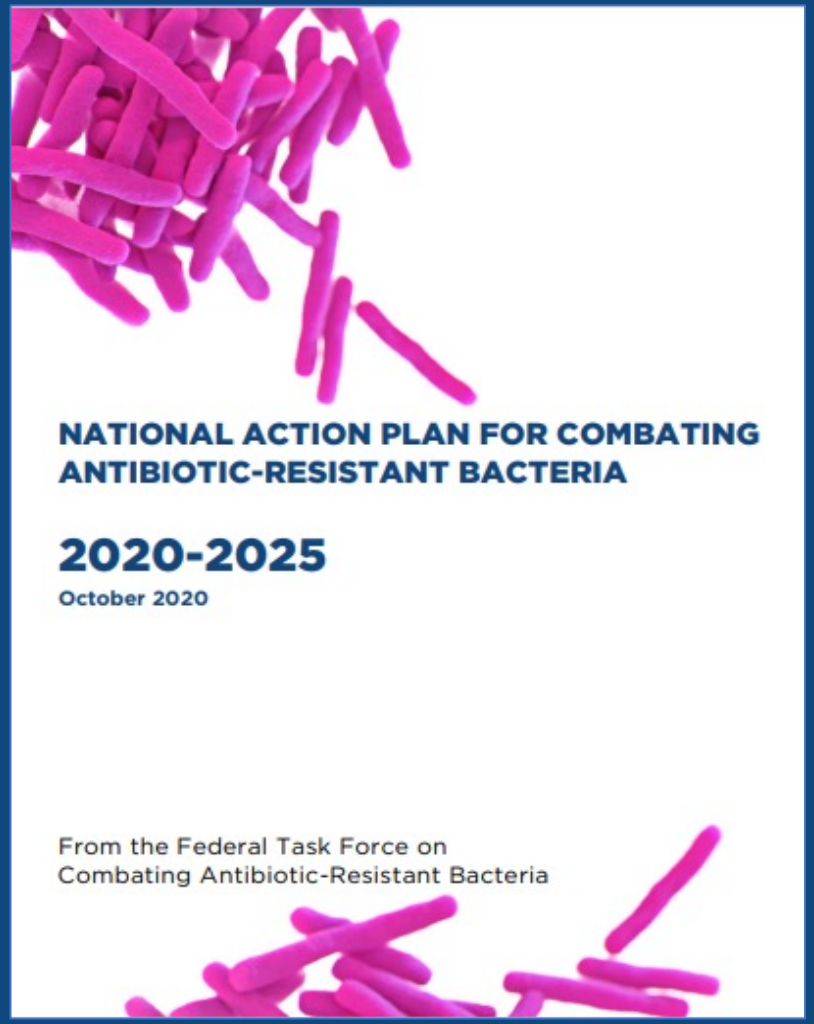
5 million[2]
patients admitted to U.S. ICUs annually

1.3 million[3]
nursing home residents in the U.S.

1.27-5 million[4]
resistant deaths worldwide (2019), including 2.8 million resistant infections in the U.S. each year

1. Tischendorf, Am J Infect Control.
2. Critical Care Statistics - SCCM
3. FastStats - Nursing Home Care (cdc.gov)
4. AR Collaborators, Lancet

Prevention is at the center of the national action plan directives.



Objective 3:

Intensify basic, translational, and clinical research to support the discovery and development of new preventative products or strategies

Objective 3.2:

Clarify pathways for new pharmaceutical preventatives by defining appropriate clinical trial designs, including end points.

CDC, FDA, NIH, DoD

Convene two meetings to discuss developmental pathways and regulatory considerations, including clinical trial designs, by 2023

WHAT WE NEED

CDC's priorities for preventative products or strategies

1. **Prevent recurrence and do more than "decontaminate," such as protecting and/or restoring the microbiome**

2. **Reduce pathogen burden (load) and/or eliminate pathogens completely, even better if it has a targeted application (body site, pathogen)**
   - Products that will not drive or increase antimicrobial resistance should be prioritized

3. **Benefit both individuals (the patient or "source") and populations**

EXPECTED CHALLENGES

- The multi-year process to develop new antibiotics, therapeutics, and vaccines includes a high rate of attrition within the discovery pipeline
- Development pathways for most nonantibiotic therapeutics remain uncharted
- Lag time between completing and publishing the results of basic and applied research studies can delay their real-world impact

Today's objectives from CDC & FDA

- The current state of development of pathogen-directed products used to prevent healthcare-associated infections
- Evidence supporting decolonization and pathogen reduction (in colonized patients) as a strategy to prevent infection and transmission of antimicrobial-resistant healthcare-associated pathogens
- Antimicrobial resistance threats as potential targets for decolonization and pathogen reduction
- Challenges and potential approaches to drug development and registration of products for the prevention of healthcare-associated infections

FOR DISCUSSION

- What are greatest needs for product development for HAI prevention?
- What study designs could provide best evidence for these products?
- What clinical endpoints would be most relevant for evaluating efficacy?

Stay up to date with the latest AR information and events

@CDC_AR

Join our email distribution list
—search "Antibiotic Resistance" at bit.ly/CDC-email-listserv

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Read more about Pathogen Reduction & Decolonization | CDC

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.