

Antimicrobial Stewardship: Regulatory Changes Physician Engagement

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Agenda

Introduction

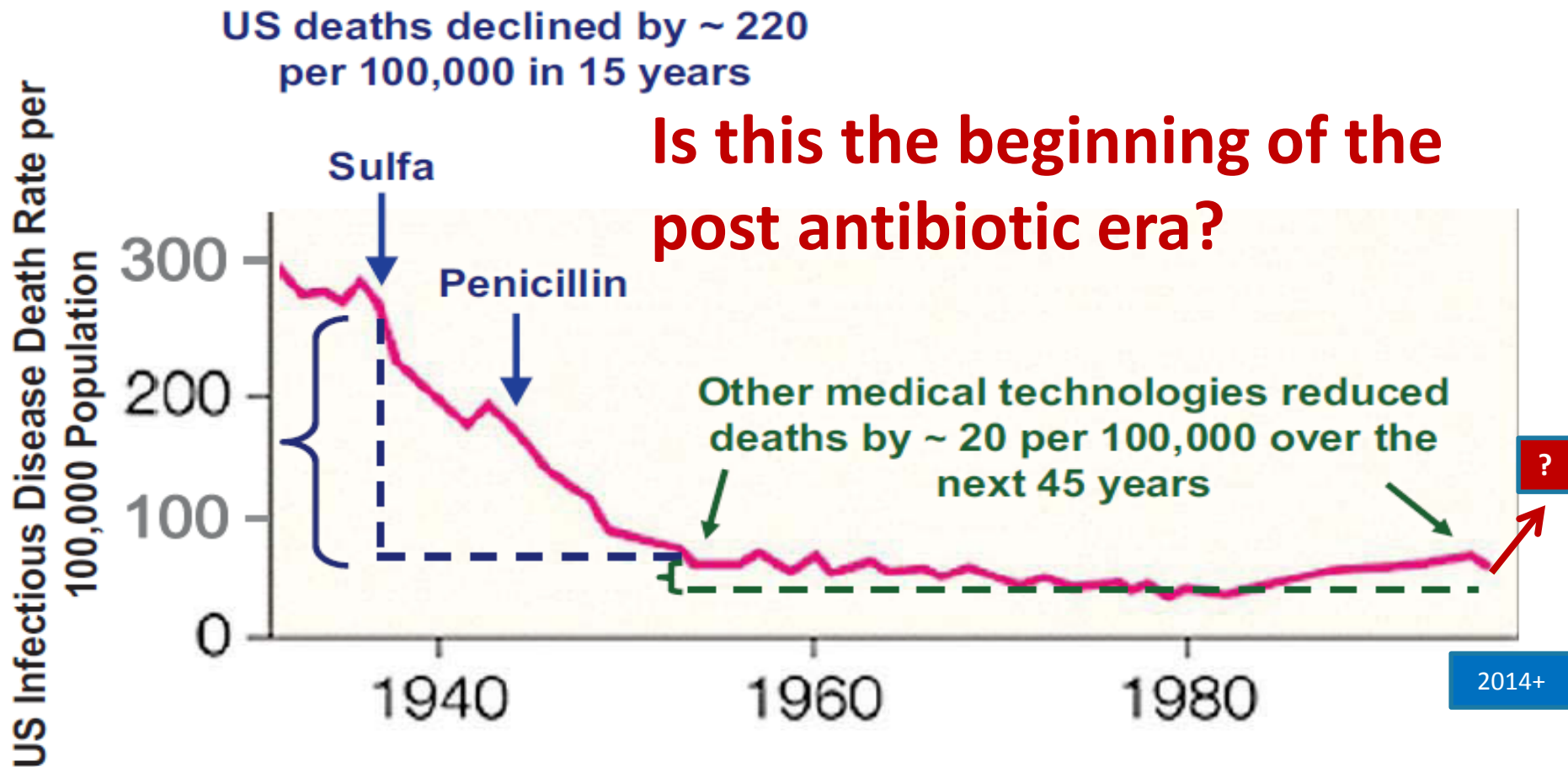
Regulatory Overview

Physician Engagement

Questions

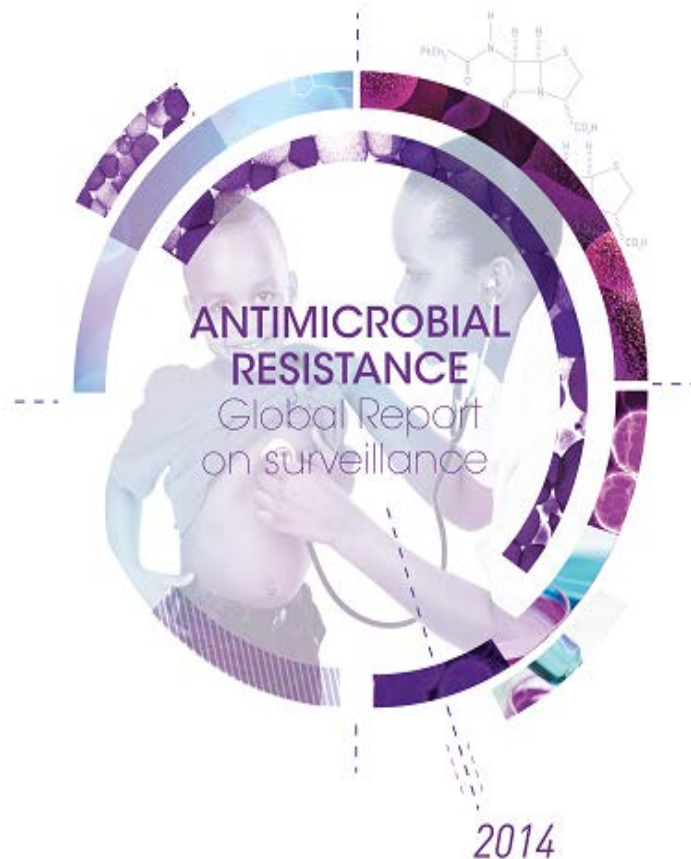
INTRODUCTION

Infectious Disease Mortality in the United States During the 20th Century



Modified from Armstrong, G. L. et al. JAMA 1999;281:61-6.

WHO Report 2014



- All regions are experiencing resistance to carbapenems
- Resistance to FQ common
- Third-generation cephalosporins ineffective to treat GC in multiple countries including US
- Key measures such as tracking and monitoring are inadequate and more needs to be done in improving appropriate antibiotic use, infection prevention, handwashing, and vaccinations

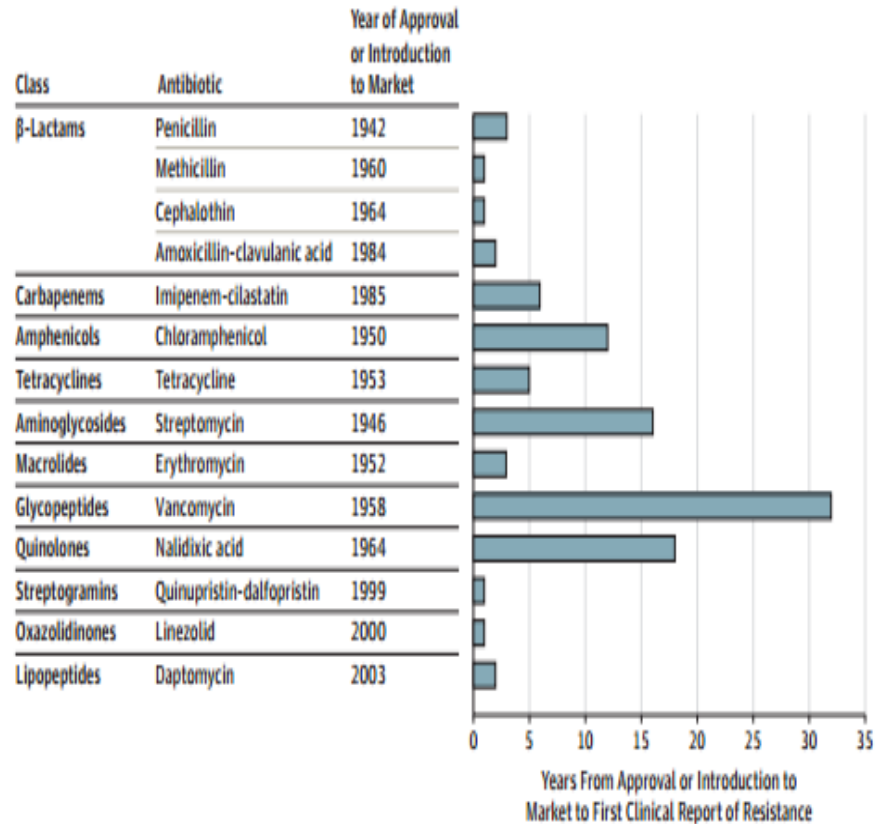
Antimicrobial Resistance

Table 1. Annual Cases and Deaths for Selected Antimicrobial-Resistant Organisms and *Clostridium difficile* Infection in the United States, 2008-2011^a

	Cases per Year	Deaths per Year
<i>Streptococcus pneumoniae</i> (resistant to clinically relevant drugs)	1.2 million	7000
Drug-resistant <i>Campylobacter</i>	310 000	28
<i>Clostridium difficile</i>	250 000	14 000
Drug-resistant <i>Neisseria gonorrhoeae</i>	246 000	< 5
Drug-resistant nontyphoidal <i>Salmonella</i>	100 000	38
Methicillin-resistant <i>Staphylococcus aureus</i>	80 461	11 285
Drug-resistant <i>Shigella</i>	27 000	40
Extended spectrum β -lactamase-producing Enterobacteriaceae	26 000	1700
Carbapenem-resistant Enterobacteriaceae	9300	610
Clindamycin-resistant group B <i>Streptococcus</i>	7600	440
Drug-resistant <i>Acinetobacter</i>	7300	500
Multidrug-resistant <i>Pseudomonas aeruginosa</i> (≥ 3 drug classes)	6700	440

^a Organisms ordered by number of cases. Methods describing figure derivation are described in the technical appendix of the Centers for Disease Control and Prevention's *Antibiotic Resistance Threats in the United States, 2013*.¹

Figure 1. Time From Antibiotic Approval or Introduction to Detection of Resistance in Clinical Samples



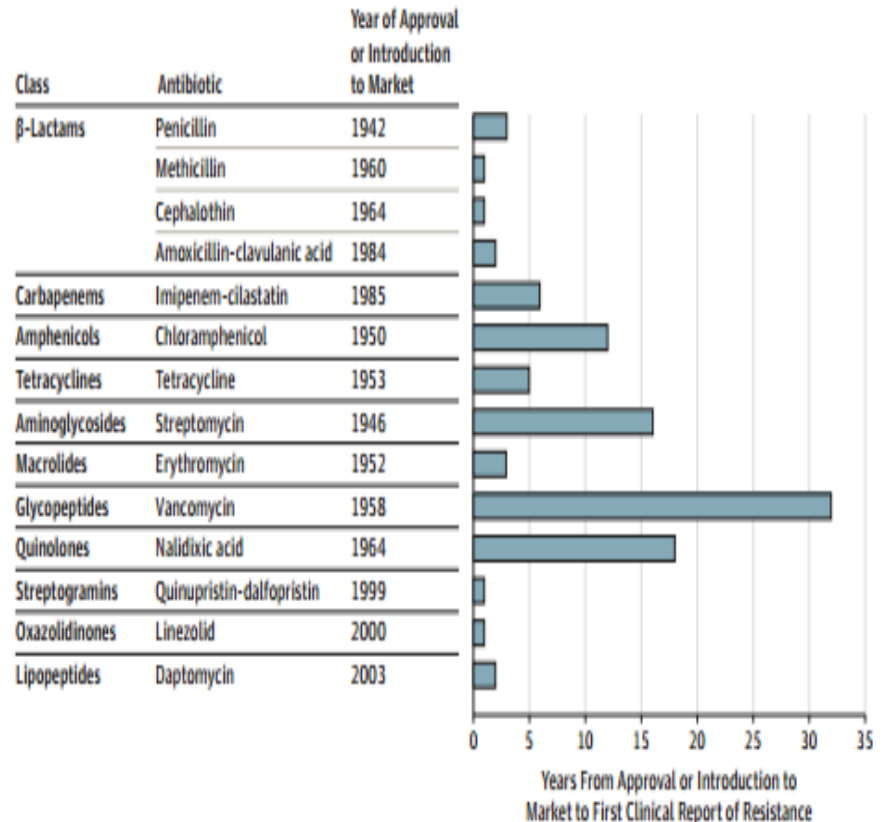
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Figure 1. Time From Antibiotic Approval or Introduction to Detection of Resistance in Clinical Samples



Death Toll of Antimicrobial Resistance

2015

2050



50,000

700,000

10,000,000

North America

317,000

Tackling Drug-Resistant Infections Globally: Final Report and Recommendations, 2016, [Online], Available at: http://amrreview.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

TURNING THE TIDE ON ANTIMICROBIAL RESISTANCE

Find it faster and more completely in	Prevent it more thoroughly with
<ul style="list-style-type: none">▪ Hospitals▪ Nursing homes▪ The community▪ Animals and food	<ul style="list-style-type: none">▪ Stewardship▪ System-wide infection control▪ Vaccination▪ Improved treatment
Stop it more quickly	Innovate for new
<ul style="list-style-type: none">▪ Surveillance and reporting▪ Outbreak control▪ Information sharing among facilities▪ Laboratory capacity and networks	<ul style="list-style-type: none">▪ Antibiotics and leverage microbiome▪ Diagnostics▪ Infection control▪ Vaccines

Tom Frieden, MD, MPH

Director, Centers for Disease Control and Prevention

October 14, 2016

REGULATORY OVERVIEW



- Executive Order: Combating Antibiotic-Resistant Bacteria
- National Strategy for Combating Antibiotic-Resistant Bacteria
- C. PCAST – Combating Antibiotic Resistance



NATIONAL ACTION
PLAN FOR COMBATING
ANTIBIOTIC-RESISTANT
BACTERIA

MARCH 2015



Section 5. Improved Antibiotic Stewardship

By January 1, 2017:

- Regulations requiring hospitals to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC
- Encourage implementation of stewardship programs in other healthcare settings (office-based, ED, LTC, correctional, dialysis facilities)

National Strategy for Combating Antibiotic-Resistant Bacteria

Goals:

- Slow the Development of Resistant Bacteria and Prevent the Spread of Resistant Infections
- **Strengthen National Surveillance** Efforts to Combat Resistance
- Advance Development and Use of **Rapid and Innovative Diagnostic Tests** for Identification and Characterization of Resistant Bacteria
- Accelerate Basic and Applied Research and Development for **New Antibiotics**, Other Therapeutics, and Vaccines
- Improve **International Collaboration** and Capacities for Antibiotics, Other Therapeutics, and Vaccines

National Strategy for Combating Antibiotic-Resistant Bacteria

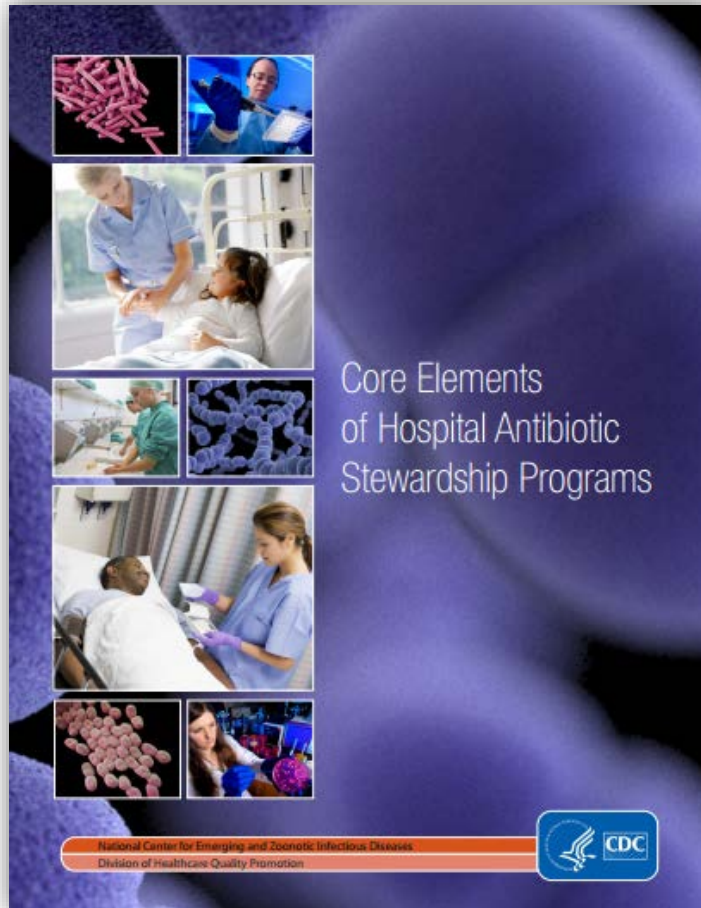
By 2020, the US will reduce:

- ↓ 50% incidence of *C.difficile* Infection
- ↓ 60% carbapenem-resistant Enterobacteriaceae (CRE)
- ↓ 35% multidrug-resistant *Pseudomonas* sp. HAI
- ↓ 50% MRSA bloodstream infections

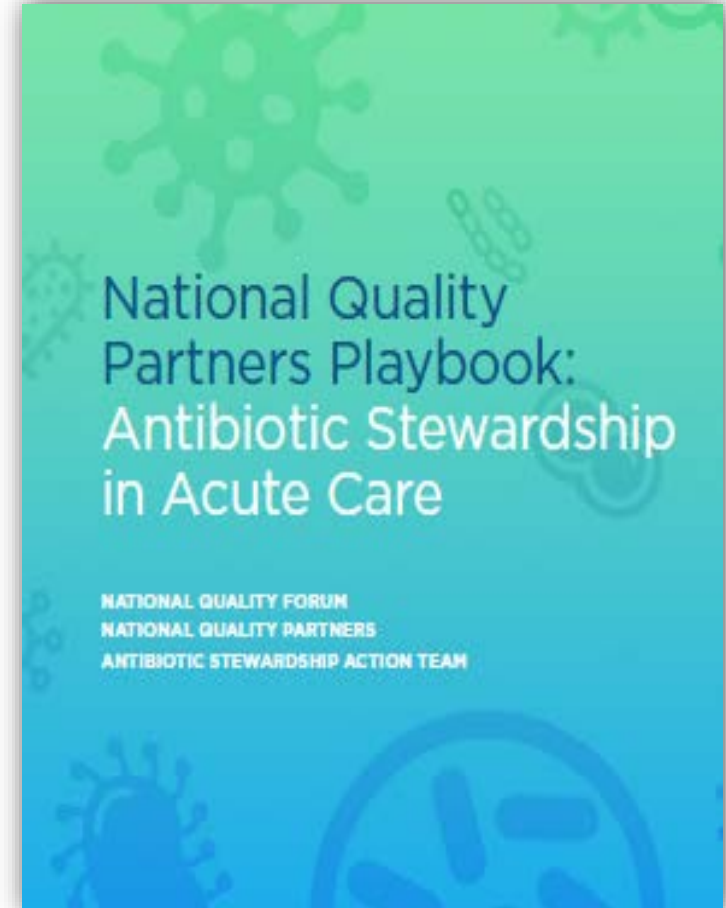
PCAST – Combating Antibiotic Resistance

- **End of 2017, CMS will require** (Conditions of Participation)
“U.S. hospitals, critical access hospitals, and long-term care and nursing home facilities to have in place robust ASP that adhere to best practices (CDC Core Elements)”
- Joint Commission accreditation standards start **January 2017**
- NIH prize of up to \$20 million
“to the first group(s) to develop a rapid diagnostic test to be used by health care providers to identify highly resistant bacterial infections at the point of patient care”

Regulatory Overview

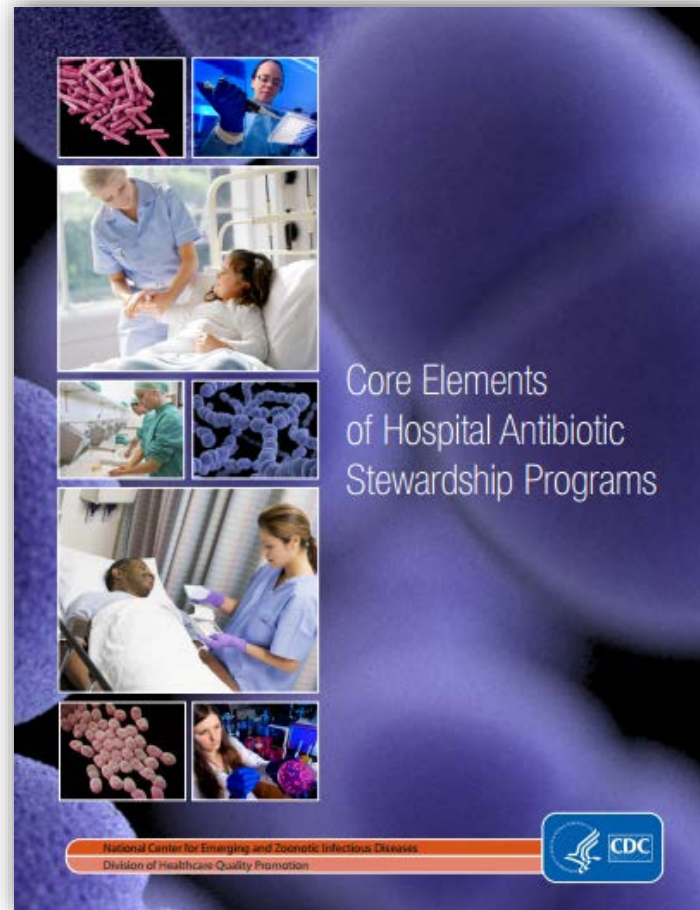


2014



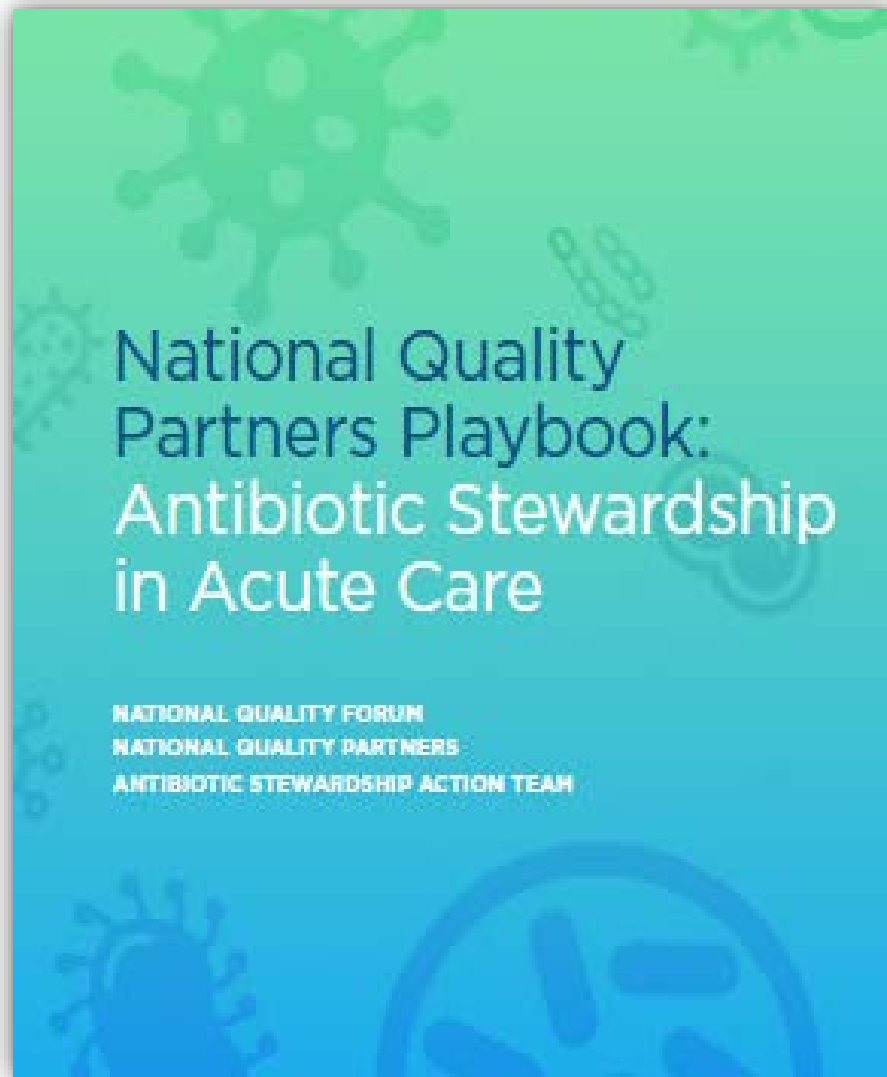
2016

Recap of Regulatory Core Elements



CDC Antibiotic Treatment in Hospitals: Core Elements

1. **Leadership commitment:** Dedicate necessary human, financial, and IT resources
2. **Accountability:** Appoint a single leader responsible for program outcomes-this is usually a physician
3. **Drug expertise:** Appoint a single pharmacist leader to support improved prescribing
4. **Act:** Take at least one prescribing improvement action, such as “antibiotic timeout”
5. **Track:** Monitor prescribing and antibiotic resistance patterns
6. **Report:** Regularly report to interdisciplinary team the prescribing and resistance patterns, and steps to improve
7. **Educate:** Offer team education about antibiotic resistance and improving prescribing practice



Infection Prevention and Epidemiology

Value of the Playbook

- Impressive list of national experts with diverse healthcare backgrounds and leading organizations reinforces that antibiotic stewardship is a national priority
- Indispensable tool that aligns perfectly with the CDC's Core Elements and new Joint Commission Accreditation Standards and proposed CMS Conditions for Participation
- Provides examples and suggestions for action for organizations regardless of size or resources
 - Basic > Intermediate > Advanced
 - Barriers and suggested solutions

The Antimicrobial Stewardship Playbook is a key resource. In addition to distributing the document to 15,000+ individuals and facilities, we hope it will actively integrate it into all acute care hospitals through antimicrobial stewardship collaboratives and with individual hospitals/health systems that are starting or enhancing their ASP program.

Joint Commission (TJC)

The Joint Commission has approved the following elements of performance (EPs), to take effect **January 1, 2017**:

- EP 1** Leaders establish antimicrobial stewardship as an organizational priority
- EP 2** The hospital educates staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire or granting of initial privileges and periodically thereafter, based on organizational need.
- EP 3** The hospital educates patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics
- EP 4** The hospital has an antimicrobial stewardship multidisciplinary team that includes the following members, when available: infectious diseases physician, pharmacy, infection prevention, other practitioners

Joint Commission (TJC)

The Joint Commission has approved the following elements of performance (EPs), to take effect **January 1, 2017**:

The hospital's antimicrobial stewardship program includes the following core elements:

- **Leadership commitment:** Dedicating necessary human, financial, and information technology resources.
- **Accountability:** Appointing a single leader responsible for program outcomes.
- **Drug expertise:** Appointing a single pharmacist leader responsible for working to improve antibiotic use.
- **Action:** Implementing recommended actions, such as systemic evaluation of ongoing treatment need, after a set period of initial treatment (for example, *S aureus* bacteremia, de-escalation, 72 hour time-out).
- **Tracking:** Monitoring the antimicrobial stewardship program, which may include information on antibiotic prescribing and resistance patterns
- **Reporting:** Regularly reporting information on the antimicrobial stewardship program, which may include information on antibiotic use and resistance, to doctors, nurses, and relevant staff
- **Education:** Educating practitioners, staff, and patients on the antimicrobial program, which may include information about resistance and optimal prescribing.

EP 5

Joint Commission (TJC)

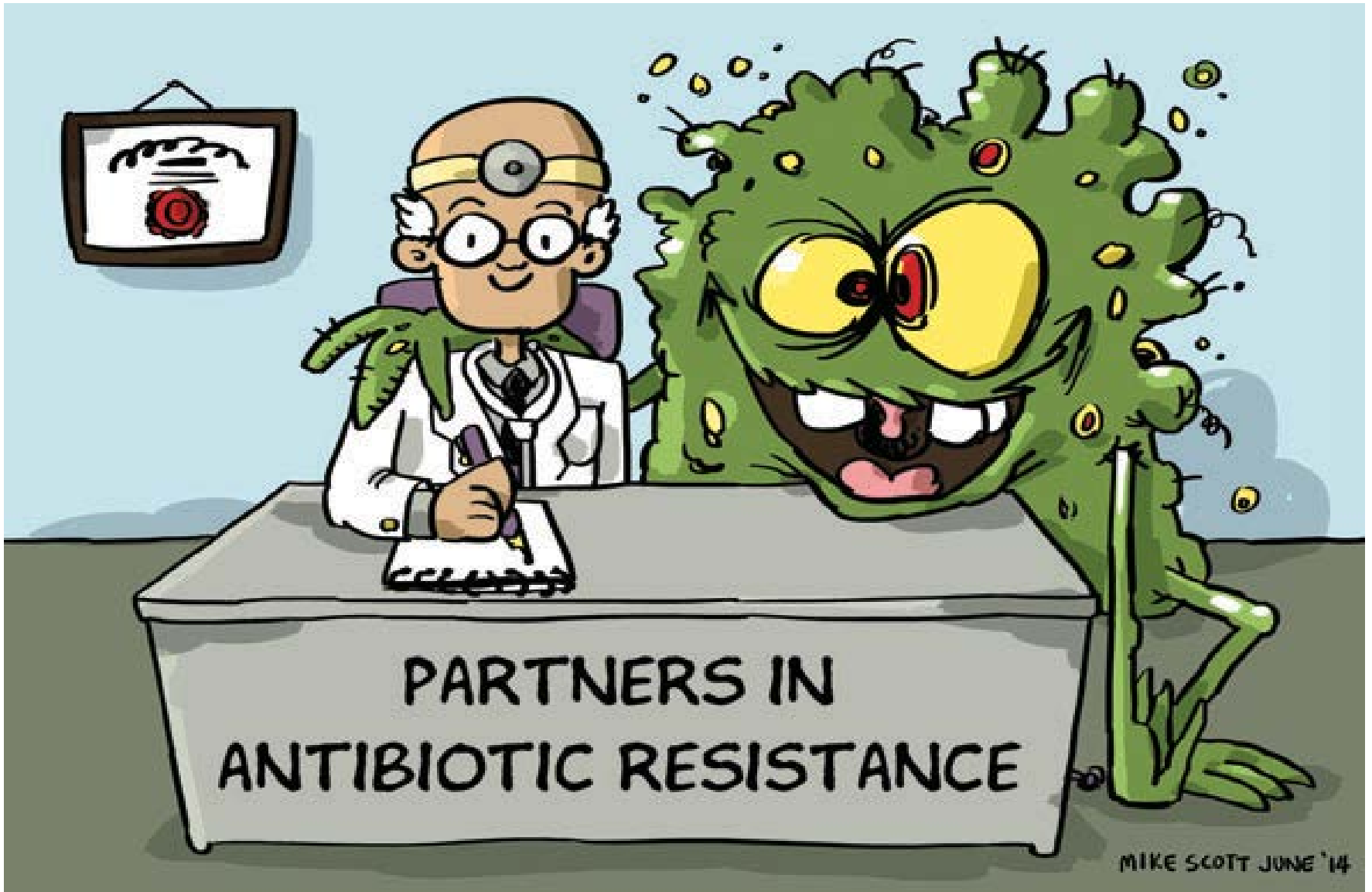
The Joint Commission has approved the following elements of performance (EPs), to take effect **January 1, 2017**:

- EP 6** The hospital's antimicrobial stewardship program uses organization-approved multidisciplinary protocols (for example, policies and procedures).
- EP 7** The hospital collects, analyzes, and reports data on its antimicrobial stewardship program.
- EP 8** The hospital takes action on improvement opportunities identified in its antimicrobial stewardship program.

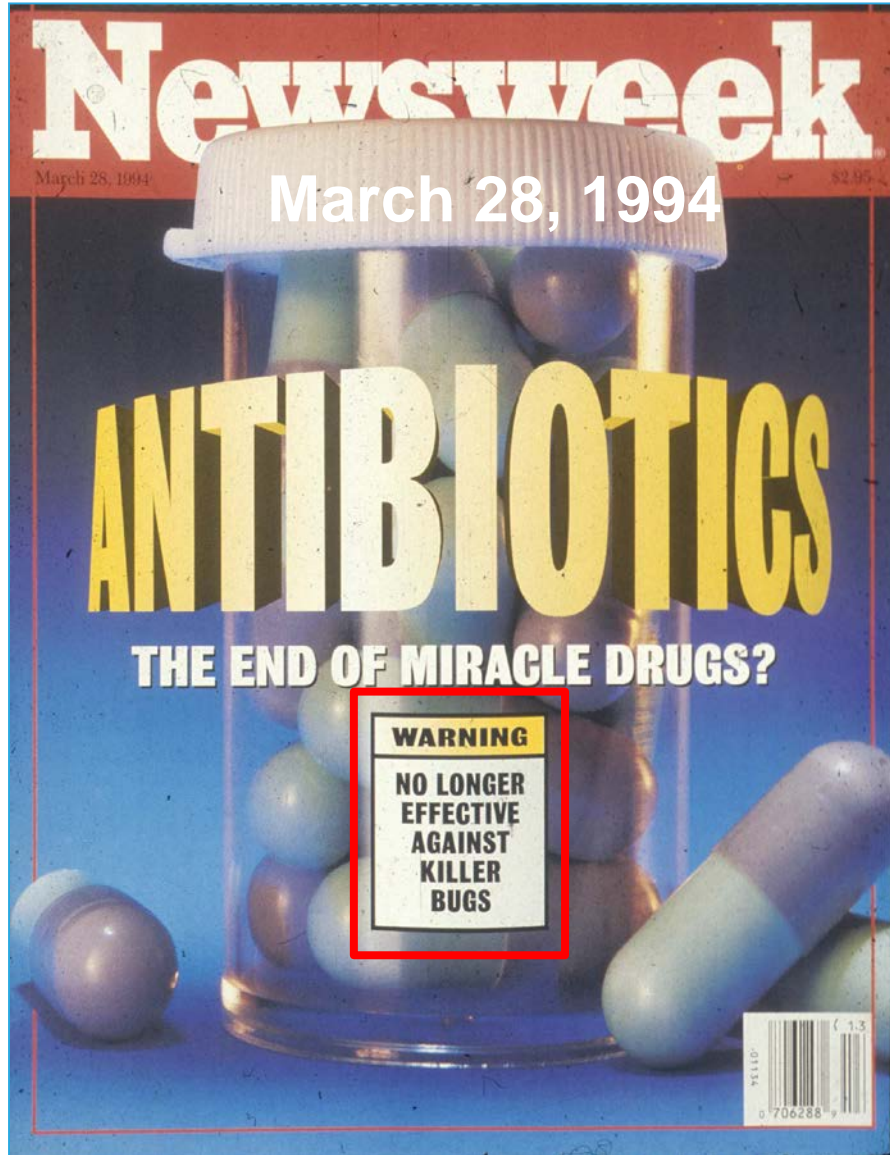
PHYSICIAN ENGAGEMENT

**WE HAVE MET THE ENEMY
AND HE IS US**

Walt Kelly



1994



2015



Infection Prevention Approaches

Vertical: Substantially reduces a pathogen specific

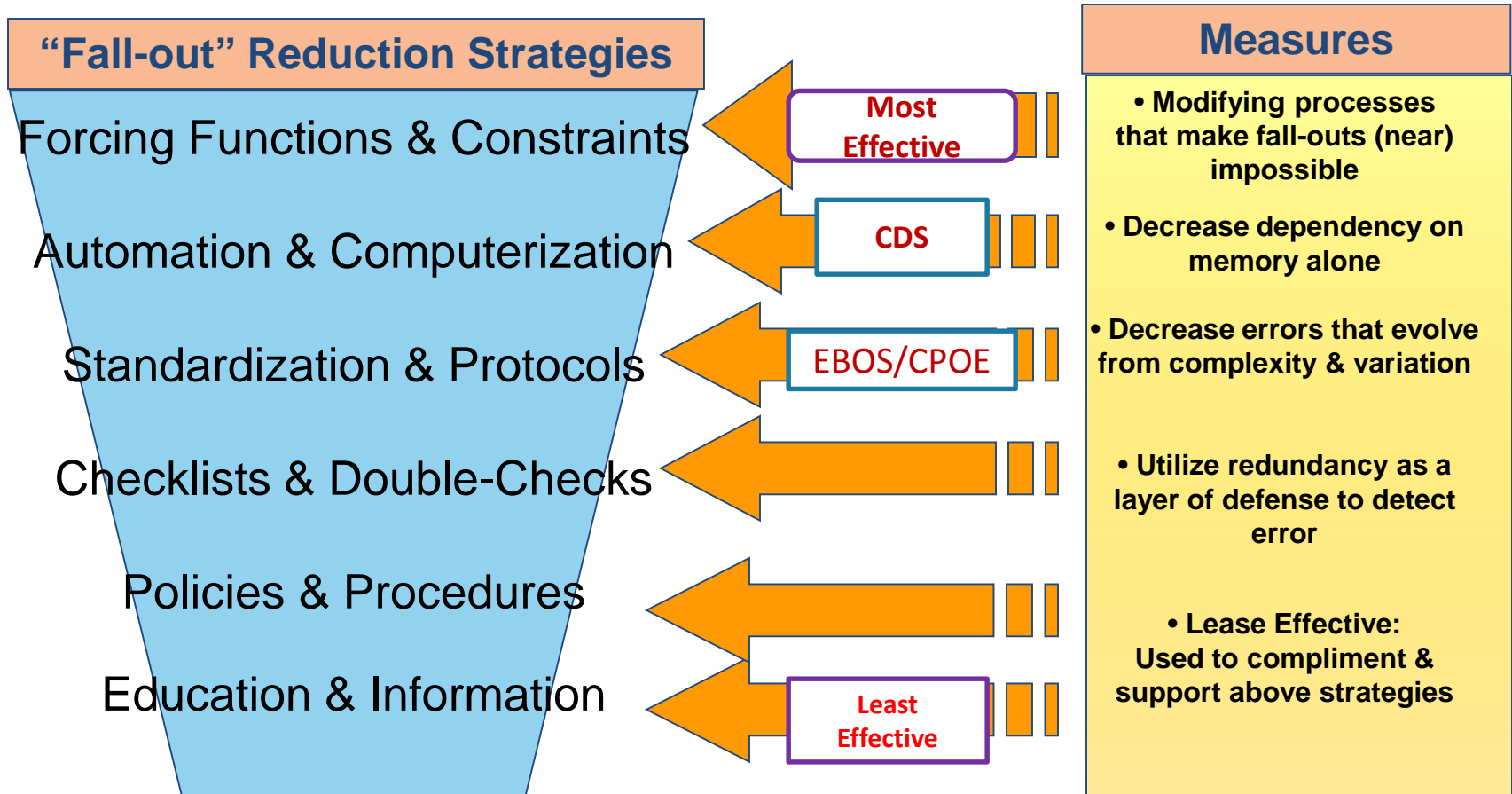
- Active surveillance(e.g. MRSA, *C. difficile*, MDRO)
- Contact precautions(e.g. MRSA colonization or MRSA, *C. difficile* infection, MDRO)
- Decolonization (e.g. MRSA)
- Vaccination (e.g. influenza, Tdap)

Horizontal: Substantially reduces all infections and is not pathogen specific

- Standard precautions (HH, cough etiquette, PPE)
- Environmental cleaning and disinfection
- **Antimicrobial stewardship**
- Bundles of care (e.g. CLABSI, SCIP, Vent)
- Normothermia and glucose control in surgery
- CHG bathing
- **Behavior modification**

Modified Int J of Infect Dis. 1 4S4;2010: S3

Strategies to Improve Results



ISMP Medication Safety Alert! Medication Error Prevention Toolbox from the June 2, 1999 issue
 Smetzer, et al. *Jt Comm J Qual Patient Saf* 2010; 36(4): 152-163

Antimicrobial Stewardship Team

Multidisciplinary Team Approach to Optimizing Clinical Outcomes*



Clin Infect Dis 2007;44:159-177.

*based on local resources

Antimicrobial Stewardship and Behavior Change

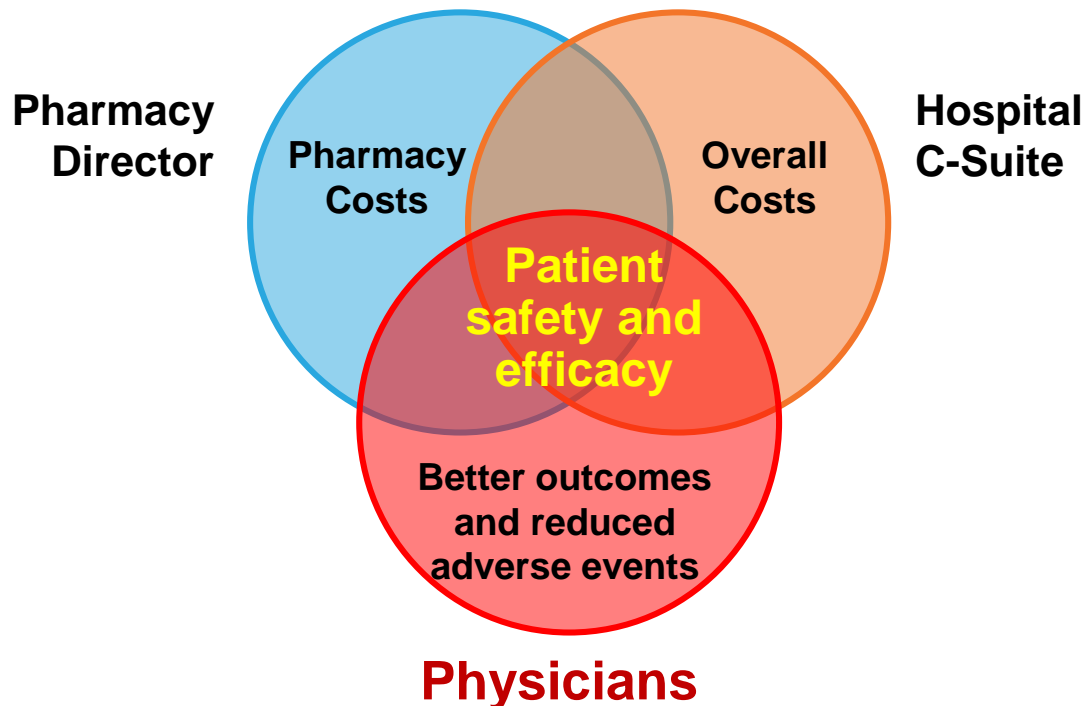
- Antimicrobial stewardship (AS) aims to facilitate appropriate use of antimicrobials
- AS interventions use different strategies (both persuasive and restrictive) to change the prescribing behaviors of frontline clinicians
 - Passive education
 - Audit and Feedback-
 - with and without real-time “academic detailing”
 - Restricted Formularies
 - Prior Approval
 - CDS
- Prescribing behavior is complex, multifactorial process
- The decision to use an antimicrobial is influenced by a host of factors

Physician Barriers

- Physician accountability and acceptance of need for improvement
- Misperceptions
- Misalignment of incentives
- Lack of definition of appropriate use of antimicrobial agents
- Lack of standardized, risk-adjusted measures
- Adaptive/behavioral changes needed to change prescribing practices

Some Stakeholders Do Not Align

- Pharmacy director, physician, and hospital goals should align on patient safety and efficacy of treatments
- However, they approach that mutual goal from different points of view



A Collaborative Approach to Treatment Algorithms and Align Stakeholders' Goals

(Mis)Perception of the Problem

- Numerous survey studies find that clinicians perceive antimicrobial overuse is a problem generally, but not locally^{1,2}
- Other medical specialties responsible for overuse³
- Antimicrobial resistance is a macro problem but of limited concern at the bedside
 - Resistance is a “theoretical”⁴ or “intellectual”⁵ concern, not a practical one

1. Giblin et al. Arch Intern Med 2004:164
2. Wood et al. J Antimicrob Chemother 2013:68
3. Szymczak et al. ICHE 2014:35
4. Bjorkman et al. Qual Saf Health Care 2010:19

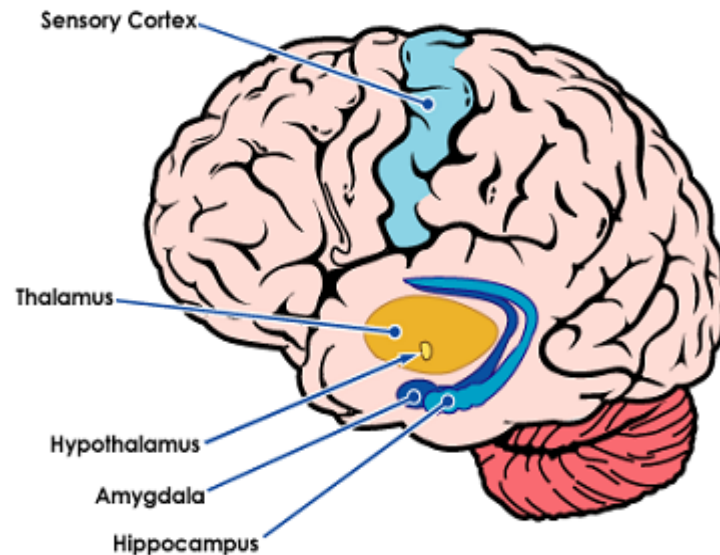
Factors Influencing Antibiotic-Prescribing Decisions Among Inpatient Physicians: A Qualitative Investigation

- Antibiotic overuse is recognized but generally accepted
- Potential adverse effects of antibiotics have a limited influence on physician decision making
- Physician-in-training are strongly influenced by the antibiotic prescribing behavior of their supervising staff physicians
- Prescribing decisions of other physicians are questioned, but there is reluctance to provide critique, feedback, or advice

Infect Control Hosp Epidemiol 2015; 36:1065-1072

Much antibiotic use is based on **fear** of missing a diagnosis

Parts of the Brain Involved in Fear Response



©2005 HowStuffWorks

- Fear factors:
 - missing an infection (80%)¹
 - criticism by peers
 - patient complaints
 - law suits
 - Only 13% of doctors feel they overprescribe¹
 - Fear of C. difficile is low
 - Only 30%¹
1. Abbo L, et al. ICHE 2011;32;714-8
Physicians' attitudes about antibiotic use.

The Chagrin Factor



The Chagrin Factor

- A physician is seeing a patient whose clinical picture and culture results could represent infection. Which outcome would a physician most like to avoid?



The Chagrin Factor

A) Antibiotics are withheld. The patient develops sepsis, shock, and requires transfer to the ICU.

B) Antibiotics are given. The patient does well, but develops a rash, and *C. difficile* requiring PO vancomycin and an ICU admission. No infection was identified.



Risk, Fear and Emotion

- Perception that risk of under-treating is greater than individual patient risk associated with receiving unnecessary antimicrobials^{1,2}
 - Residents perceive overly dire consequences for initiating coverage this is too narrow, broad spectrum drugs feel “safe,” overarching goal is “prevention of disaster in next 24 hrs”³
- Emotional desire to provide all immediate therapeutic options regardless of wider population consequences⁴
 - “My relationship with my patient is much stronger than my relationship with the hospital inpatient population and the microbial ether that we live in. You’ve got an emotional bond with that patient.”

1. May et al. ICHE 2014:35
2. Bjorkman et al. Qual Saf Health Care 2010:19
3. Laake et al. IDWeek 2013
4. Broom et al. Soc Sci Med 2014:110

Understanding the Determinants of Antimicrobial Prescribing Within Hospitals: The Role of “Prescribing Etiquette”

- Qualitative semi-structured interviews with doctors, pharmacists, nurses/midwives in 4 teaching hospitals (n=39)
- Three themes related to prescribing etiquette:
 - Decision-making autonomy**
 - Senior doctors make whatever decisions they want and no one questions it
 - One doctor does not want to interfere with another doctor’s decision

Clin Infect Dis. 2013; 57:188.

Understanding the Determinants of Antimicrobial Prescribing Within Hospitals: The Role of “Prescribing Etiquette”

- Limitations of local evidence-based policies
 - Doctors frequently consider their patients to be outside the boundaries of local guidelines
 - Doctors are “above” the guidelines because of experience and expertise-
“cook book medicine”
- Culture of hierarchy
 - Senior doctors decide what is prescribed and junior doctors do not challenge it

Contextual and Environmental Factors

- Time pressures
 - Pressure to discharge quickly discourages a “watch and wait” approach¹
 - Practice volume and throughput pressures discourage adequate communication with patients
- Ease of accessing diagnostic testing systems and acting on results ²
 - Diagnostic uncertainty is a key driver for drug use and overuse³

1. Avorn et al. Ann Intern Med 2000;133

2. May et al. ICHE 2014;35

3. Harbarth et al. Emerg Infect Dis 2005; 11

Patient Demand

- Clinicians identify patient pressure for antimicrobials as major barrier to more judicious prescribing^{1,2,3}
 - Especially in ambulatory settings and pediatrics
- Why capitulate to patient pressure? ^{4,5}
 - Want to please patient
 - Explaining why antimicrobials are not necessary is too time-consuming and fear of losing patient
 - Fear medicolegal sanctions

(1) Bauchner et al. Pediatrics 1999:103
(2) Brookes-Howell et al. BMJ Open 2012:2
(3) Vazquez-Lago et al. Fam Pract 2012:29
(4) Butler et al. BMJ 1998:317
(5) Shapiro Clin Ther 2002:24

Patient Demand, Cont'd.

- Evidence to suggest that clinicians overestimate patient demand for antimicrobials^{1,2}
- Patients becoming more aware of antimicrobial overuse³
- Clinicians prescribe on the basis of perceived rather than actual patient expectations^{4,5}

1. Mangione-Smith et al. Pediatrics 1999:103
2. Stivers et al. J Fam Pract 2003:52
3. Finkelstein et al. Clin Pediatr (Phila) 2014:53
4. Mangione-Smith et al. Arch Pediatr Adolesc Med 2006:160
5. Ong et al. Ann Emerg Med 2007:50

Current Challenges: What is not happening reliably?

- Obtaining appropriate cultures and other tests before starting antibiotics
- Review of prior culture results / antibiograms
- Antibiotic restraint
 - Double coverage
 - Treatment of asymptomatic bacteriuria
 - Treatment of colonizing organisms
 - Treatment of noninfectious fever
- Re-consideration of the diagnosis; A “72 hour time-out”
- Narrowing coverage at 48-72 hours(de-escalate)
- Treating for an appropriate duration

Driving Appropriate Use

De-escalation Barriers:

- All cultures are negative and....
- “The patient improved on all 3 antibiotics, so they need all 3”
- The patient does not improve
- Patient is being treated for more than 1 infection
 - Pneumonia and UTI
 - CLABSI and UTI

What Works?



Reassessment of IV Antibiotic Therapy Using a Reminder of Direct Counseling

J Antimicrob Chemother 2010; 65:789

- Before and after study to evaluate support to clinicians to de-escalate-perspective audit and feedback
- 3 strategies were implemented over 3 consecutive 8-week periods
 - Conventional management by attending physician (control group)
 - Distribution of a questionnaire to physician (questionnaire group)
 - Distribution of questionnaire followed by advise from an ID physician(Q-IDP)-“academic detailing”

YOUR PATIENT HAS BEEN RECEIVING AN INTRAVENOUS ANTIBIOTIC THERAPY FOR 72 HOURS

At this point in time, you should consider adapting the therapy based on your clinical observations and results of cultures available on Mediweb. Possible modifications include:

- 1) modification of antibiotic therapy by targeting the documented pathogen,
- 2) and/or switch to oral therapy,
- 3) or discontinuation of an empirical treatment no longer necessary

Inappropriate use of antibiotics contributes to therapeutic failures, emergence of bacterial resistance and avoidable drug reactions. Intravenous treatment may expose your patient to specific complications such as thrombophlebitis or bacteremia.

Please answer the following questions and leave the completed questionnaire in the medical chart of your patient (it will be collected tomorrow):

1. At the time you are reading this message the antibiotic therapy:

- A. Has been interrupted or will be interrupted in the following 24 hours
- B. Will be continued

If your answer is B:

2. Give the reason for continuing the antibiotic therapy:

- A. Prophylaxis
- B. Treatment of a documented infection
- C. Empirical treatment

3. Will you consider one of the modifications mentioned below in the following 24 hours?

- A. Switching to oral therapy
- B. De-escalating therapy to target the documented pathogen
- C. Decreasing the planned duration of therapy

J Antimicrob Chemother 2010; 65:789

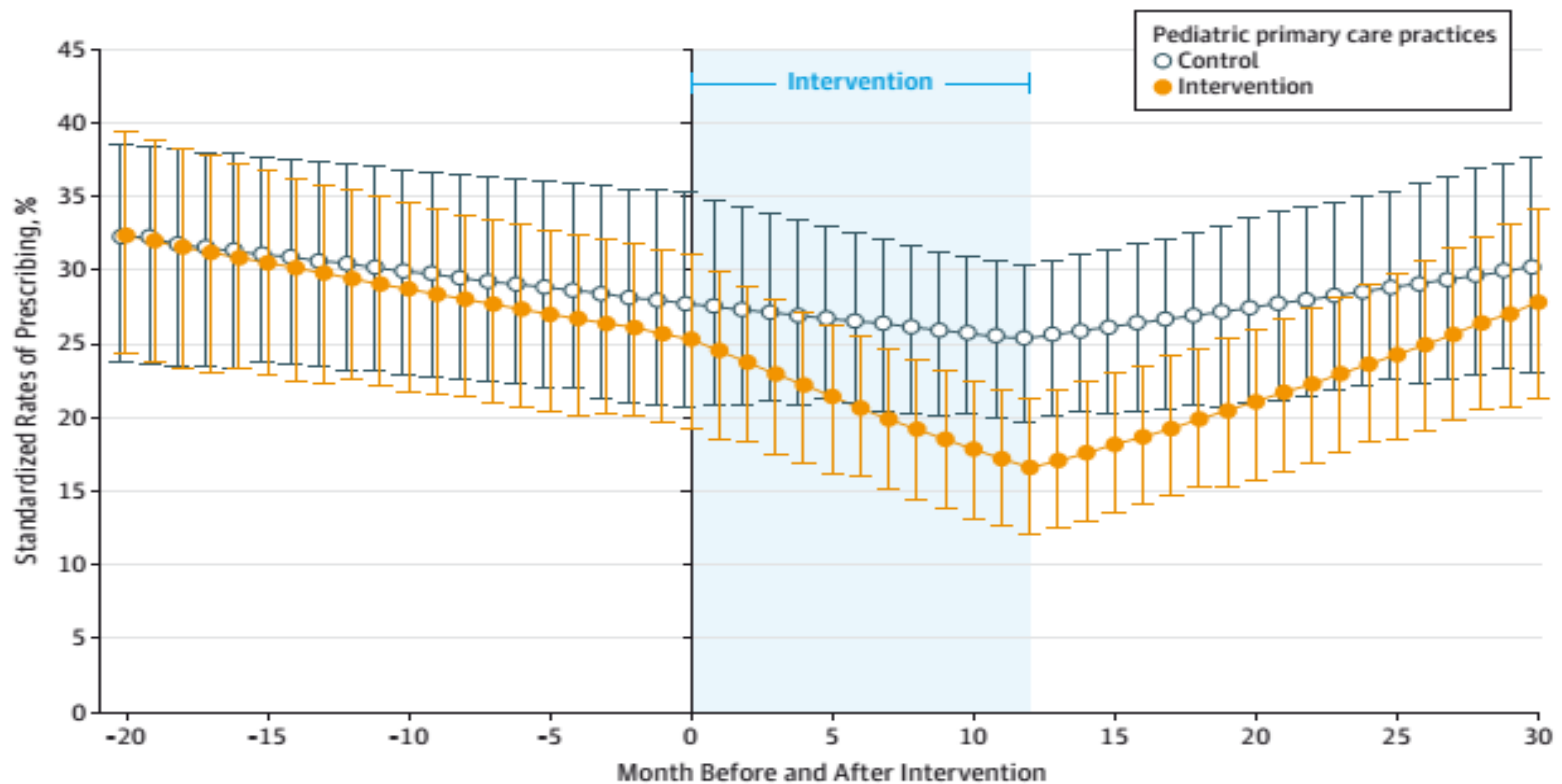
Reassessment of IV Antibiotic therapy Using a Reminder of Direct Counseling-Results

J Antimicrob Chemother 2010; 65:789

- At day 4: 49% and 55% of prescriptions were modified in the control group and the questionnaire group respectively ($P=0.35$)
- In contrast more prescriptions (66%) were modified in Q-IDP group compared to controls ($P=0.004$)
- Stopping therapy in absence of bacterial infection occurred significantly more often in Q-IDP group than control ($P=0.0001$) or questionnaire group ($P=0.002$)

Durability of Benefits of an Outpatient Antimicrobial Stewardship Intervention After Discontinuation of Audit and Feedback

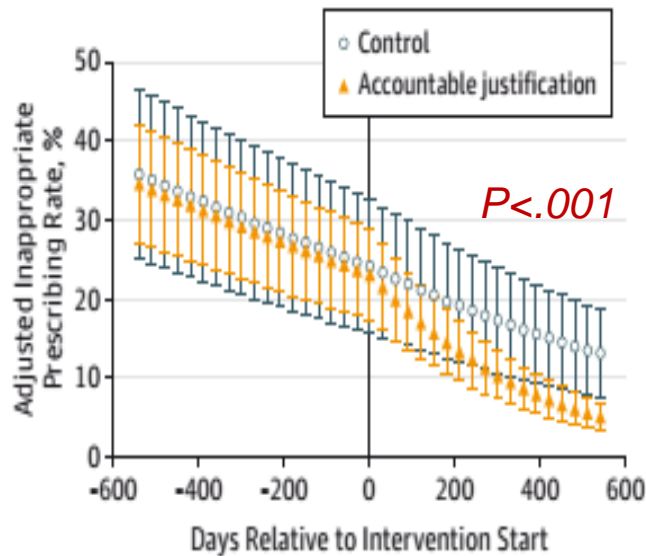
Figure. Standardized Rates of Broad-Spectrum Antibiotic Prescribing Before, During, and After Audit and Feedback



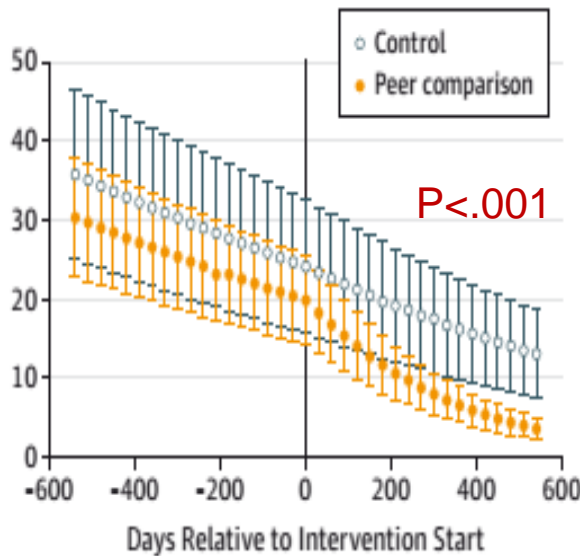
JAMA Published online October 10, 2014

Effect of Behavioral Interventions on Inappropriate Antibiotic Prescribing Among Primary Care Practices

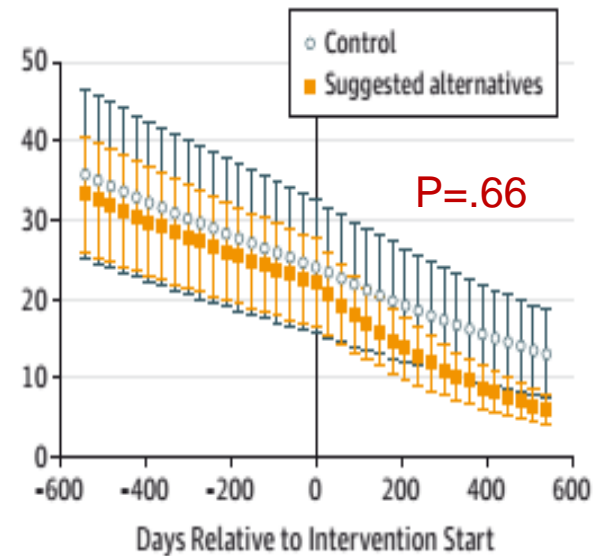
A Accountable justification



B Peer comparison



C Suggested alternatives

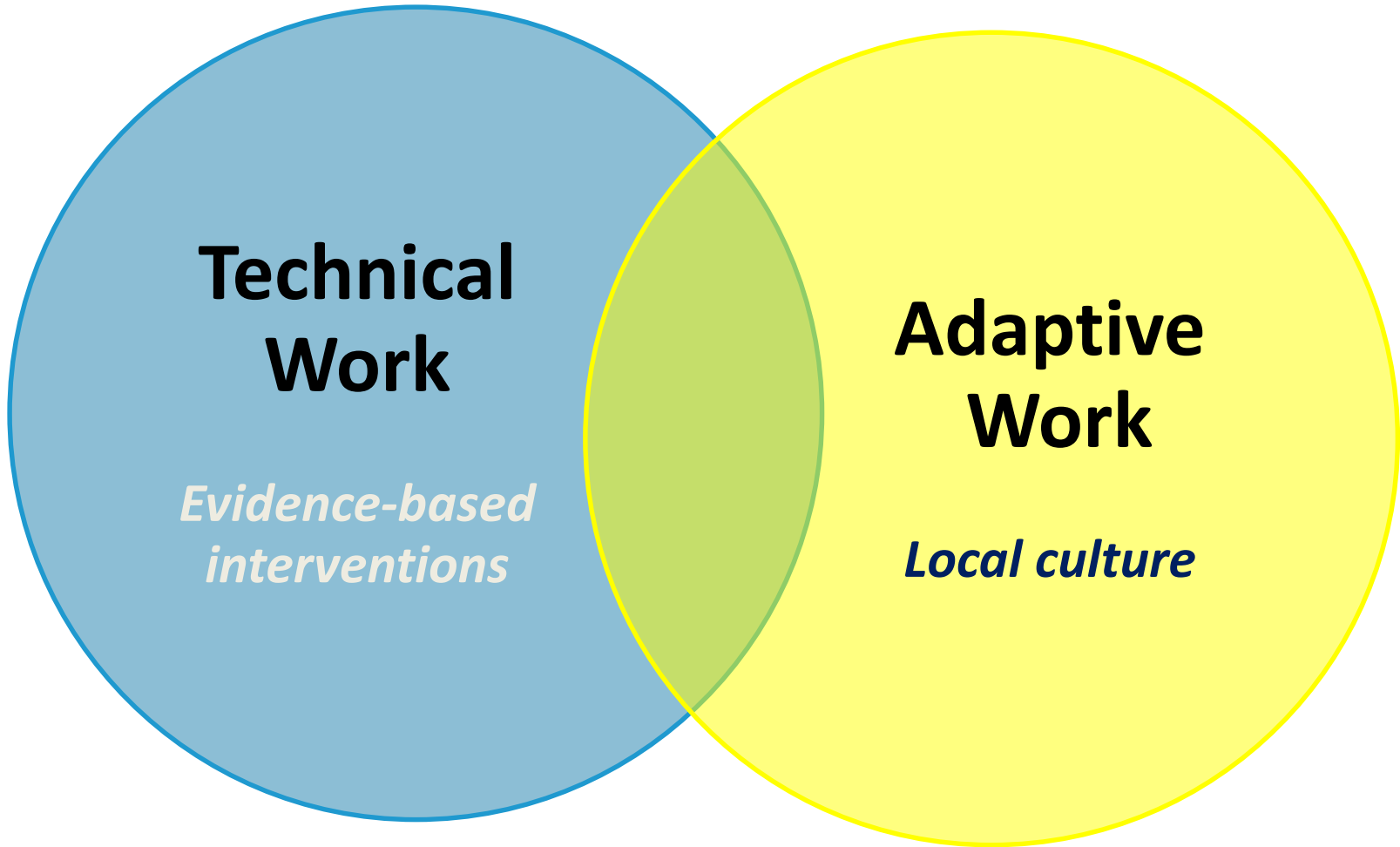


Accountable=prompts clinicians to enter text justifying for prescribing antibiotics
Peer comparison=sends e-mails to clinicians that compare their rates with “top performers”
Suggested=with electronic orders suggesting nonantibiotic treatments

Elements of Safer Care

- Must contain all three
 - Summarize and simplify what to do (KISS)
 - Measure and feedback on outcomes
 - Improve culture by building expectations of performance standards into work processes
 - Need appreciation of how or why components work

How Will We Get There?



Why does Culture Matter?

- Safety culture influences the effectiveness of other safety and quality interventions
 - Can enhance or inhibit effects of other interventions
- Safety culture can change through intervention
 - Best evidence so far for culture interventions that use multiple components (e.g.: CUSP, Positive Deviance)

Haynes et al., 2011; Morello et al., 2012; Van Nord et al., 2010;
Weaver et al. Ann Intern Med. 2013;158:369-374.

How Will We Get There?

TECHNICAL WORK	ADAPTIVE WORK
<p>Work that we know we <i>should do</i>: <i>Right diagnosis, right drug, right dose, right duration, and right de-escalation</i></p>	<p>The intangible components of work, like ensuring team members speak up with concerns and hold each other accountable</p>
<p>Work that lends itself to standardization (e.g., measurement, audit and feedback, EBOS/CPOE, CDS, clinical pathways) Build an effective antimicrobial stewardship team</p>	<p>Work that shapes the attitudes, beliefs, and values of clinicians, so they consistently perform tasks the way they know they <i>should</i></p>
<p>Evidence-based treatment</p>	<p>Local culture</p>

Changing Prescriber Behavior

- Engagement of senior physician leadership (clinical and administrative) is critical
- Address stewardship message to the clinical leadership within existing clinical groups (rather than just the trainees or the ID doctors)
- ID should not be excluded from stewardship process
- Understand local culture and patient population

Lessons Learned for Successful Stewardship (ASP)

- Although ASP interventions have had limited success at some facilities, we can do better
 - Direct (passive)educational approaches generally do not result in sustained reductions in prescribing ¹
 - Restrictive policies can be circumvented
 - “Stealth dosing”²
 - Misrepresenting clinical information ^{3,4}
 - Audits can be “gamed” ⁵
- To bring about lasting change, clinicians need to hard wire new culture about what is considered prudent antimicrobial prescribing⁶

1. Arnold et al. Cochrane Database of Systematic Reviews 2005:4

2. LaRosa et al. ICHE 2007:28

3. Calfee et al. J Hosp Infect 2003:55

4. Linkin et al. ICHE 2007:28

5. Szymczak et al. ICHE 2014:35

6. Bosk et al. Lancet 2009:374

Lessons Learned for Successful Stewardship (ASP) cont'd.

- Prescribing drivers
 - Lack of conclusive microbiology
 - Diagnostic uncertainty
 - Insecurity

Lessons Learned for Successful Stewardship (ASP) cont'd.

- When developing any quality improvement intervention, we need to understand attitudes, motivation and intentions of those whose behavior we wish to change¹ and the local social/environmental context²
- Despite evidence to suggest the importance of social and behavioral factors, this is frequently overlooked in design and implementation of AS interventions³

1. Pronovost BMJ 2011:20
2. Aveling et al. J Health Organ Manag 2012:26
3. Charani et al. Clin Infect Dis 2011:53

Physician To Do List

- Stewardship is every physician's responsibility
- Select physician champion
- Develop an effective antimicrobial stewardship team
- Educate the medical staff and administration about the urgency and value of an effective antimicrobial stewardship team
- Program must be approved by the Physician Executive Committee
- Comply with infection prevention especially hand hygiene
- Assure that microbiology is aware of how to detect new resistance mechanisms (e.g. CREs, NDM1) and new CLSI break points
- Understand how to appropriately obtain cultures and other diagnostic testing including rapid diagnostic tests and acting and interpreting results

Summary

- Changing prescriber behavior is a key factor in improving antibiotic use in the long term
 - Need to evolve from top down stewardship approach to a bottom up approach
- But, changing behavior is hard and the solution most likely multi-factorial
 - More emphasis on shorter duration and de-escalation given expanding evidence base
- Enhancing comfort level with new rapid microbiology approaches-results must be actionable and add value
- Ongoing benchmarking and feedback at institutional and provider level
 - Need to engage senior leadership
 - Need to engage physician leadership-must be physician directed

Questions

