Planning Effectively for Posttrial Activities

Hayden Bosworth, PhD
Duke University School of Medicine

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Panelists

- Shruti Gohil, MD
  - INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients (INSPIRE)
- Corita Grudzen, MD
  - Primary Palliative Care for Emergency Medicine (PRIM-ER)
- Stacy Sterling, DrPH, MSW
  - Guiding Good Choices for Health (GGC4H): Testing Feasibility and Effectiveness of Universal Parent-Focused Prevention in Three Healthcare Systems

Session Goals

- Discuss preparing for dissemination and sustainment or de implementation before results are known; describe considerations for when and how to share results with partners and the public
- Learn ways to share trial tools more widely, and explore Dissemination and Implementation R01s

INSPIRE Abdominal & Skin/Soft Tissue Infection Trials

INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients

NIH Collaboratory In-Person Steering Committee Meeting
Planning Effectively for Post-trial Dissemination & Implementation
May 10, 2024

Shruti K. Gohil, MD, MPH
Assistant Professor, Division of Infectious Diseases
Associate Medical Director, Epidemiology & Infection Prevention
University of California, Irvine School of Medicine

INSPIRE Trials: Purpose & Design

- **Purpose:** Reduce unnecessary empiric broad-spectrum antibiotic use
- **Design:** Cluster-randomized trials, 92 HCA Healthcare hospitals, non-ICU patients
- **Intervention:** CPOE prompts for abdominal or skin/soft tissue infections
- **Outcomes:**
  - **Effectiveness** – antibiotic use first 3 inpatient days
    - Primary – any broad-spectrum antibiotics
    - Secondary – antibiotic subsets
  - **Safety:** days to ICU transfer, hospital length of stay

Post-Trial Dissemination – Local Adoption

HCA Healthcare dissemination plan

- Prompt ready to turn on for routine care hospitals
- Centralized IT program ready to deploy for entire health system

Strong health system partnership

- Engaged during all stages of trial implementation
- Shared results early
  - Inform and influence decision to adopt
  - Allowed planning, budgeting, IT time
- Support implementation

Post-Trial Dissemination – Wider Adoption

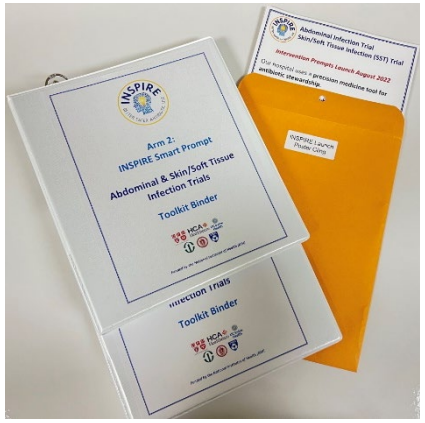
Amplify publicity

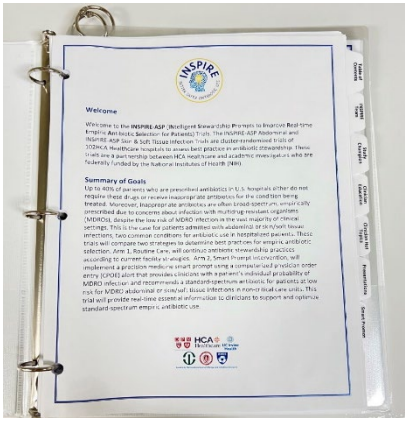
- Time release of publication with national conferences
- Leverage media/press teams
  - Multiple channels – joint release all institutions
  - Web-based opportunities for feature stories
  - Social media
- Online dissemination toolkit

Dissemination Materials – Intervention Implementation

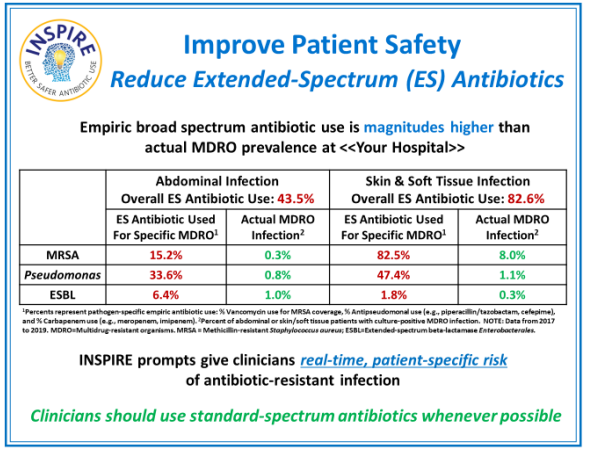
Trial implementation materials = future online dissemination toolkit

- Roadmap for implementation
  - FAQs
  - Recorded webinars, videos
  - Poster clings
  - Podcasts
  - Implementation tips
  - How prompt works
  - Guidance for IT teams
  - Feedback report examples





Poster Cling



Improve Patient Safety

Reduce Extended-Spectrum (ES) Antibiotics

Empiric broad spectrum antibiotic use is magnitudes higher than actual MDRO prevalence at <<Your Hospital>>

	Abdominal Infection Overall ES Antibiotic Use: 43.5%		Skin & Soft Tissue Infection Overall ES Antibiotic Use: 82.6%	
	ES Antibiotic Used For Specific MDRO[1]	Actual MDRO Infection[2]	ES Antibiotic Used For Specific MDRO[1]	Actual MDRO Infection[2]
MRSA	15.2%	0.3%	82.5%	8.0%
Pseudomonas	33.6%	0.8%	47.4%	1.1%
ESBL	6.4%	1.0%	1.8%	0.3%

[1]Percents represent pathogen-specific empiric antibiotic use: % Vancomycin use for MRSA coverage, % Antipseudomonal use (e.g., piperacillin/tazobactam, cefepime), and % Carbapenem use (e.g., meropenem, imipenem). [2]Percent of abdominal or skin/soft tissue patients with culture-positive MDRO infection. NOTE: Data from 2017 to 2019. MDRO=Multidrug-resistant organisms. MRSA = Methicillin-resistant *Staphylococcus aureus*; ESBL=Extended-spectrum beta-lactamase *Enterobacterales*.

INSPIRE prompts give clinicians *real-time, patient-specific risk* of antibiotic-resistant infection

Clinicians should use standard-spectrum antibiotics whenever possible

INSPIRE Podcast

Address Potential Avenues to Adoption

Seek opportunities to expand adoption

- Engaging EHR vendors

Planning Effectively for Post Trial Activities: Maintenance and Sustainability

Corita R. Grudzen, MD, MSHS, FACEP
Division Head, Supportive and Acute Care Services
Fern Grayer Chair in Oncology Care and Patient Experience
Director, Center for Cancer Care Innovation
Memorial Sloan Kettering Cancer Center
Professor of Emergency Medicine
Weill Cornell Medical College

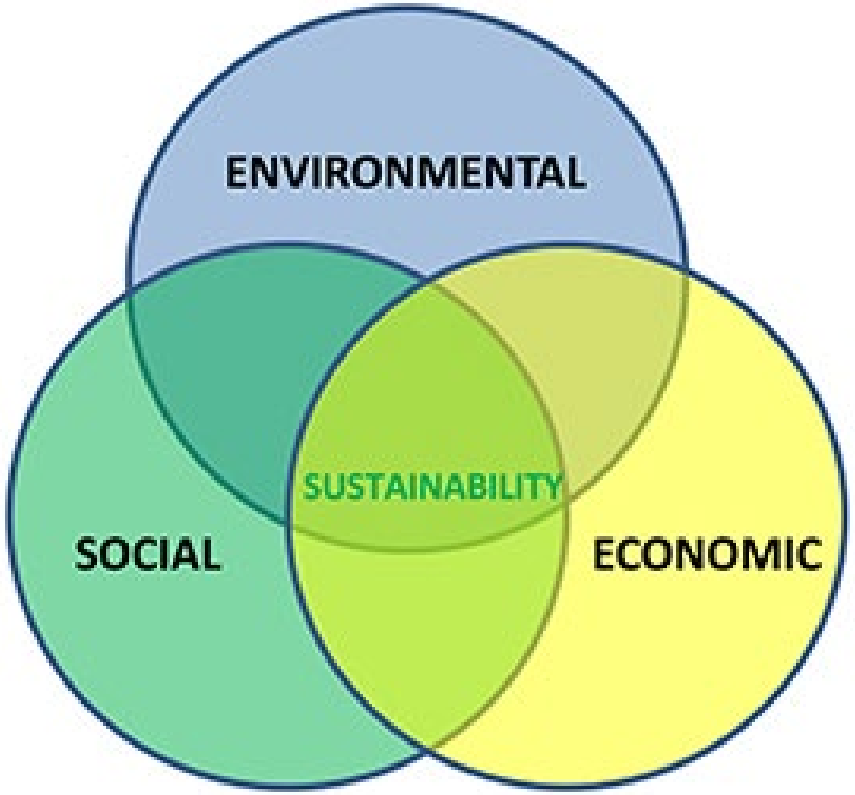
Memorial Sloan Kettering Cancer Center

Maintenance, program preservation

- Co-design and engagement
  - Patients, care partners, healthcare workers, administrators, payers, policymakers
- Context
  - +/- Champion
  - EHR or other systemwide vendor transition
- Modifications/adaptations
- Inertia
  - De-implementation is hard!

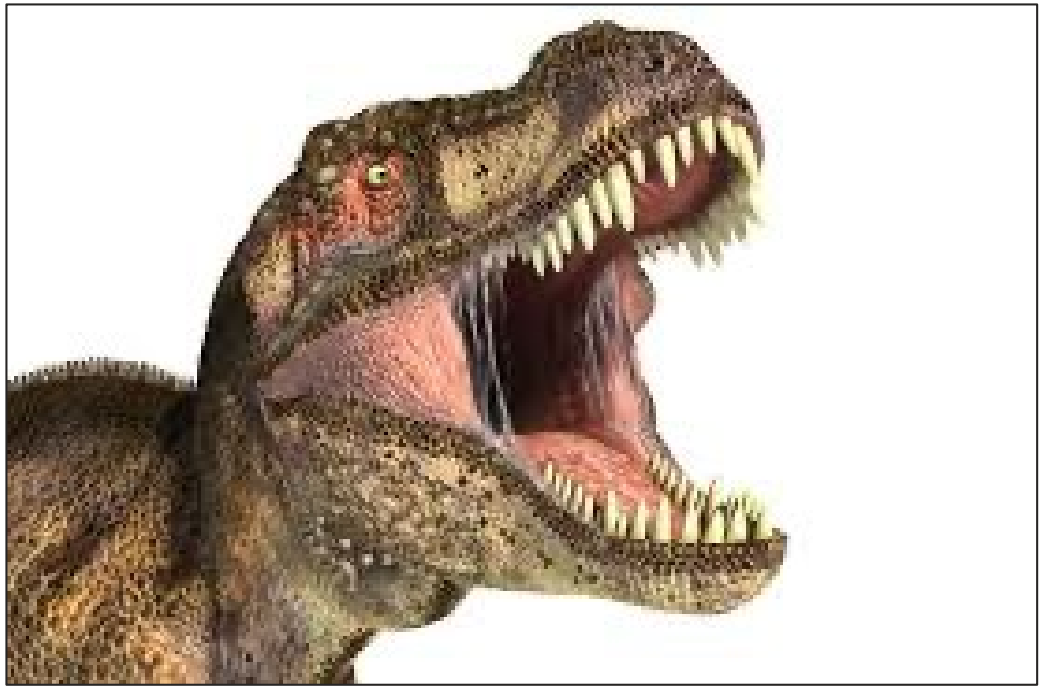
Sustainability, meeting needs of present without compromising future resources

- Value-based care versus Fee-for-service
- Revenue-generating, cost-saving, cost-neutral
- Incremental FTEs
- Perceived value to patients, care partners, and healthcare workers



Survival, versus extinction

445 million years
“living fossil”



3 million years

Memorial Sloan Kettering
Cancer Center

Guiding Good Choices for Health

Stacy Sterling, DrPH, MSW, Margaret Kuklinski, PhD, Jordan Braciszewski, PhD, Arne Beck, PhD, Jennifer Boggs, PhD, MSW

NIH Collaboratory Steering Committee, May 10, 2024

- **6- Session virtual Universal Prevention program for all parents of adolescents ages 11-14**
- **Evaluated in previous RCTs**
  - ✓ Affects **Parenting Behavior** regardless of family risk (Spoth et al., 1998)
  - ✓ Reduced Growth in **Substance Use, Delinquency; Depressive Symptoms** (Mason et al., 2003, 2007)
  - ✓ **Cost-beneficial:** Benefit-Cost Ratio: $2.77 (WSIPP, 2018)

SOCIAL DEVELOPMENT RESEARCH GROUP, University of Washington

KAISER PERMANENTE® Northern California

Henry Ford Health System

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Challenges

1. Competing priorities – both clinically and organizationally
2. Staffing and Resources – personnel, space, time…
3. Who owns this?
4. Overarching challenge of implementation of primary prevention interventions: ***“It's difficult to create the case for urgency, when there's no burning platform, right?”***

"Dig where the hole is"

1. **KPCO:** Looking to train the cadres of Psychology Interns who come in each year, in how to deliver GGC
2. **UW:** 1) Working with team at Yale to implement in Federally Qualified Health Center settings; 2) Adapting GGC for high school population, to include focus on social media use
3. **KPNC:** New state mandate to provide dyadic behavioral health care to Medicaid Managed Care beneficiary children and their caregivers – GGC might meet a need of health system

Thank You!

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Questions