Leveraging implementation science (IS) to advance adolescent immunizations

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Disclosures

• I have no conflict of interests
Disclaimer

The opinions expressed in this presentation are solely those of the presenter and do not necessarily represent the official positions of the Immunization Action Coalition, or the United States Adult and Influenza Immunization Summit.
And we are not throwing away our shots...

‘Cause we’re young, scrappy, and hungry, just like our country...
Outline

• What is Implementation Science?
• How can Implementation Science improve adolescent immunization efforts?
• Scenario exercises
What is Implementation Science (IS)?

• Implementation science is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice\(^1,2\)
  – Understand the behavior of healthcare professionals and other stakeholders as a key variable in the sustainable uptake, adoption, and implementation of evidence-based interventions.
  – Investigate and address major bottlenecks (e.g. social, behavioral, economic, management) that impede effective implementation, test new approaches to improve health programming, as well as determine a causal relationship between the intervention and its impact.

Implementation studies are different from clinical studies

- Distinguish implementation processes from the EBPs they are trying to implement\(^1\)

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Implementation studies are different from clinical studies

• Clinical research typically focuses on the health effects of an EBP; implementation studies typically focus on rates and quality of use of EBPs rather than their effects
  – Studying the effects of a program to increase effective cognitive-behavioral therapy use for bipolar disorder, the impact of cognitive-behavioral therapy on health status would be an EBP outcome (and more typically a focus for a clinical study), while measuring the proportion of clinicians providing cognitive behavioral therapy, or proportion of patients who attend a minimum level of cognitive-behavioral therapy sessions would be a more typical implementation study outcome
Interdisciplinary nature of Implementation Science

Translational Disciplines
- Social and behavioral science
- Business administration
- Economics
- Education
- Engineering

Population Sciences
- Health Policy
- Epidemiology
- Biostatistics

Clinical disciplines
- Public Health
- Medicine
- Dentistry
- Pharmacy
- Nursing

Why Implementation Science?

• Absent an implementation plan, you have no strategy. Implementation:
  – Translate the words in the plan, the intent of the plan, into ACTION
  – Identifies the IMPLICATIONS of the everyday actions
  – Evaluates its own progress and the success of the strategy. No implementation goes entirely as one expects.
  – A good implementation plan separates successful strategies from failed ones

• Especially relevant for low- and middle-income countries

• Vision without implementation is just hallucination
  - From Thomas Edison
Translating Evidence into Practice, Policy, and Public Health Improvements

An Illustration...Increase reporting to immunization registry

- Operator – Public health department (stakeholder)
  - Implements new policy that mandates practices (healthcare delivery system) to report immunizations to state IIS
  - Providers (individuals) change behavior to report to registry

- Operator – community advocacy group (stakeholder)
  - Media campaign to influence public health department (now target) to monitor and then develop policies that will increase registry reporting

- Multiple and changing actors – no fixed assignments of operator and target

Key behavior here is practice compliance with reporting

Key behavior now is state public health departments being convinced that registry participation needs policy action
Goals of Implementation Science

• Develop reliable strategies for improving health-related processes and outcomes; facilitate widespread adoption of these strategies

• Produce insights and generalizable knowledge regarding implementation processes, barriers, facilitators, strategies

• Develop, test and refine implementation theories and hypotheses; methods and measures
Implementation Science has been used to...

- Compare multiple evidence-based interventions
- Identify strategies to encourage provision and use of effective health services
- Identify strategies to promote the integration of evidence into policy and program decisions.
- Adapt interventions appropriately according to population and setting
- Identify approaches to scale-up effective interventions
- Develop innovative approaches to improve healthcare delivery
- Implement an impact evaluation for a population based intervention

Difference between quality improvement and implementation science

• Quality Improvement science generally focuses on the “here and now” – local quality problems addressed via rapid-cycle, iterative improvement
  – lead to the design and trial of strategies to improve a specific problem for that specific healthcare system

• Implementation science typically begins with an EBP that is under-utilized
  – Identifies and addresses resultant quality gaps at the provider, clinic, or healthcare system level
  – Attempts to develop, deploy and rigorously evaluate a fixed implementation strategy to close an implementation gap across multiple sites, emphasizing theory, contextual factors, (sometimes) mediators, moderators, mechanisms

• Implementation science aims to develop generalizable knowledge

Clinical and quality improvement programs are...

- Highly stable and slow to change; clinical inertia, conservatism
  - With notable exceptions (CT scans, robotic surgery)
- Variable and heterogeneous (across time, place, problem)
- Multi-faceted, multi-level
- Not responsive to simple practice change strategies
  - “Intervention physicians displayed improved knowledge and attitudes but no change in clinical practices”

Selected barriers to implementation

- Insufficient information, knowledge, skill, time
- Too much information
- Evidence is not accepted as legitimate
- Implementation gaps not recognized
- Misaligned financial incentives
- Insufficient staff or systems support
- Lack of external pressure, expectations

Where can you impact clinical practice?

- Point of care (MD knowledge, patient demand)
- Microsystem, team (norms, culture)
- Clinic, hospital (policies, leadership)
- Delivery system (organizational/fiscal policies, leadership, resources)
- Professional norms (local, regional, national)
- Patients, businesses, other stakeholders (community, region, province/state, nation)
- Local, regional, national regulations

The lack of adequately defined programs is an impediment to implementation with good outcomes

• Clear description of the program
  – Clear Philosophy, Values, and Principles
    • The philosophy, values, and principles that underlie the program provide guidance for all treatment decisions, program decisions, and evaluations; and are used to promote consistency, integrity, and sustainable effort across all provider organization units.
  – Clear inclusion and exclusion criteria that define the population for which the program is intended
    • The criteria define who is most likely to benefit when the program is used as intended

The lack of adequately defined programs is an impediment to implementation with good outcomes

• Clear description of the essential functions that define the program
  – Clear description of the features that must be present to say that a program exists in a given location (essential functions sometimes are called core intervention components, active ingredients, or practice elements)

• Operational definitions of the essential functions
  – Practice profiles describe the core activities that allow a program to be teachable, learnable, and doable in practice; and promote consistency across practitioners at the level of actual service delivery

The lack of adequately defined programs is an impediment to implementation with good outcomes

- A practical assessment of the performance of practitioners who are using the program
  - The performance assessment relates to the program philosophy, values, and principles; essential functions; and core activities specified in the practice profiles; and is practical and can be done repeatedly in the context of typical human service systems.
  - Evidence that the program is effective when used as intended.
  - The performance assessment (often referred to as “fidelity”) is highly correlated (e.g. 0.50 or better) with intended outcomes for children, families, individuals, and society.

### Studies to address blockages in your implementation process

Table 2: Types of Studies to Address Blockages in the Implementation Process

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<thead>
<tr>
<th>Implementation Process Gap</th>
<th>Types of Studies</th>
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<tbody>
<tr>
<td>Limited external validity of efficacy/effectiveness studies</td>
<td>- Design clinical interventions ready for implementation earlier in the research pipeline, emphasizing tools, products, and strategies that mitigate variations in uptake across consumer, provider, and or organizational contexts</td>
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<td>Quality gaps across systems due to variations in organizational capacity (e.g., resources, leadership)</td>
<td>- Assess variations and customize implementation strategies based on organizational context</td>
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<td>- Data infrastructure development to routinely capture or assess implementation fidelity, patient-level processes/outcomes of care, and value/return-on-investment measures</td>
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<td>- Further refinement of implementation strategies involving organizational and/or provider behavior change</td>
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<td>Frontline provider competing demands (e.g., multiple clinical reminders)</td>
<td>- Development of provider/practice networks to conduct implementation studies or evaluation of national programs</td>
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<td>- Refinement of implementation strategies using cross-disciplinary methods that address provider behavior/organizational change (e.g., business, economics, policy, operations research, etc.)</td>
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<td>- Positive deviation or adaptation studies especially to improve implementation at lower-resourced, later-adopter sites</td>
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<td>Misalignment with national or regional priorities</td>
<td>- National policy/practice roll-outs</td>
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<td>- Randomized evaluations of national programs or policies</td>
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Implementation Science Identifies these EIGHT Requirements for Behavior Change

1. Valid, legitimate, accepted evidence
   – Appropriately endorsed
   – Consistent with prevailing beliefs or compelling enough to change minds – so not dismissible

2. Clinician/staff knowledge, skill
   – Requires education and training
   – BUT, education is necessary but not sufficient

3. Supportive professional norms
   – Non-adherence is improper, unacceptable, counter normative

Implementation Science Identifies these EIGHT Requirements for Behavior Change (cont.)

4. External expectations, monitoring, pressure/incentives
   – Has to be adequate to overcome competing demands and to focus attention/interest
   – Meaningful consequences; requires measurement, reporting
   – Need broad buy-in

5. Patient Acceptance
   – Meet patient expectations and demand

6. Evidence of quality gaps
   – Is the evidence of deviation from recommendations valid?
   – Is it credible and acceptable? Relevant?

Implementation Science Identifies these EIGHT Requirements for Behavior Change (cont.)

7. Understand the etiology of practices, quality gaps
   – Why did the gap occur? What were the causes, influences, or barriers? What were the facilitators?
   – Reliable broad spectrum practice-change interventions do not exist

8. Feasible methods/systems
   – It has to be supported logistically
   – There needs to be thought of how to remove of the financial, organizational and operational constraints

Implementation Science Identifies these EIGHT Requirements for Behavior Change

1. Valid, legitimate, accepted evidence
2. Clinician/staff knowledge, skill
3. Supportive professional norms
4. External expectations, monitoring, pressure/incentives
5. Patient acceptance
6. Evidence of quality gaps
7. Etiology of practices, quality gaps
8. Feasible methods/systems

Mittman, B. 2015. Presentation to the National Adult and Influenza Immunization Summit.  
Scenarios
Implement an adolescent immunization program in your country

- #1, 7 - What evidence gaps are there?
  - Surveillance and disease epidemiology gaps
  - Cost data gaps?
- #2 – #6 - How to focus the activities?
  - Which vaccines?
  - Are the targets the same for chosen vaccines?
  - With the same messaging?
  - Is there evidence for your plan?
- #8 - What existing programs can you leverage?

1. Valid, legitimate, accepted evidence
2. Clinician/staff knowledge, skill
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6. Evidence of quality gaps
7. Etiology of practices, quality gaps
8. Feasible methods/systems
Integrate a new adolescent IZ program into existing pregnancy prevention program

• Is there evidence for adolescent IZ?
  – Disease burden?
  – Cost effectiveness gaps?
• Will current healthcare professionals accept it?
  – If not, are there skills/education that can be provided?
• Will patients accept IZ discussion in combination with pregnancy counseling?
• Can logistics of IZ fit into current pregnancy counseling infrastructure?

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3. Supportive professional norms
4. External expectations, monitoring, pressure/incentives
5. Patient acceptance
6. Evidence of quality gaps
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8. Feasible methods/systems
Health department asked to work with specific at-risk populations in their communities

- No additional resources
- Is there evidence that this makes a difference (YES!)
- Is there patient acceptance (here the community itself)?
- What is a legitimate gap to address? IZ rates too low?
  - Need evidence to convince
  - Need etiology of the quality gap
- What’s feasible?
  - Forming partnerships with organizations with reach?

1. Valid, legitimate, accepted evidence
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Health department asked to improve protection against pertussis by vaccination with Tdap

- No additional resources
- What’s your evidence base of what is best?
- Cocooning? Does it work?
- Maternal immunization?
- What is feasible?
  - New partners? Lamaze?
- Do patient-directed strategies consider acceptance?

1. Valid, legitimate, accepted evidence
2. Clinician/staff knowledge, skill
3. Supportive professional norms
4. External expectations, monitoring, pressure/incentives
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6. Evidence of quality gaps
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8. Feasible methods/systems
Some Implementation Science Resources

- National Implementation Research Network
- Journals: Implementation Science, Translational Behavioral Medicine, special issues of general and specialty journals
- NIH CTSAs (selected), PBRNs (AHRQ, other), VA QUERI
- Patient-Centered Outcomes Research Institute (PCORI), AAMC Research on Care Community (ROCC)
- WHO. A guide to implementation research in the prevention and control of NCDs
- Knowledge Translation Canada, Kings College London Centre for Implementation Science, etc.
Thank You!