NIH support for improving the quality of care globally

- Quality of care a major determinant of patient health outcomes and population health status

- Aligned with NIH mission:
  - “Science in pursuit of fundamental knowledge about the nature and behavior of living systems . . .
  - and the application of that knowledge to extend healthy life and reduce illness and disability.”
Supporting NIH Institutes and Centers

1. Fogarty International Center (FIC)
2. National Cancer Institute (NCI)
3. National Heart, Lung, and Blood Institute (NHLBI)
4. National Institute on Alcohol Abuse and Alcoholism (NIAAA)
5. National Institute of Allergy and Infectious Diseases (NIAID)
6. National Institute of Dental and Craniofacial Research (NIDCR)
7. National Institute of Mental Health (NIMH)
8. National Institute of Neurological Disorders and Stroke (NINDS)
9. National Institute of Nursing Research (NINR)
Crosscutting Role of Research in Improving Quality of Care

Committee tasks:

- **Illuminate** the consequences of poor quality care in low-resource areas and challenges related to mortality, morbidity, and lost productivity
- **Evaluate** the vast and complex evidence base related to safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity, with a focus on when and where quality interventions most reliably benefit health outcomes
- **Assess** current measurements of health-care quality and develop new measurements as needed
- **Create decision support frameworks** for systemic interventions and changes in delivery and patient care processes based to improve quality, for use by political, policy and clinical leadership
- **Define a research agenda** that would enable translation and broad implementation of scalable quality interventions, including issues of enrollment and financing UHC expansion

The Research Continuum: “[NHLBI] commitment of renewed emphasis on T4 translation research, including dissemination and implementation research, to maximize the clinical and public health impact of its research discoveries.”
NIH Definitions of Implementation Science – The Science of Delivery

- "Implementation research" - the scientific study of use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.

- "Dissemination research" - the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.

Glasgow RE et al Am J Public Health 2012
Example of Continuum of Care = Continuum of Quality = Continuum of Research

- Each type and transition in care offers opportunities for research on improving the quality

## Illustrative Example: Role of Research in Quality of Care

**Addressing the mental health treatment gap in Mozambique with a task-shifting strategy in primary care** – distinguishing research from monitoring and evaluation

<table>
<thead>
<tr>
<th>Research (NIH role)</th>
<th>Level</th>
<th>Actions</th>
<th>Monitoring and Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principles and knowledge that indicate what is possible across settings</td>
<td>Policy</td>
<td>Establish cadre of Psychiatric Technicians (PsyT)</td>
<td>Has new worker cadre been established in accordance with policy expectations?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expanded use of PsyTs to deliver mental health care</td>
<td></td>
</tr>
<tr>
<td>How to establish a sustainable system of mental healthcare delivered by non-specialists in low-resource settings?</td>
<td>Care Delivery</td>
<td>Train and deploy PsyT</td>
<td>How many PsyTs have been trained and deployed?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care delivered by community health workers under supervision by PsyTs</td>
<td>How much does this model expand care?</td>
</tr>
<tr>
<td>What is the optimal way to ensure high quality of care from PsyTs over time? What are key mechanisms of effective training?</td>
<td>Advocacy, Marketing</td>
<td>Create demand for mental health services</td>
<td>Reach of the advocacy campaign?</td>
</tr>
<tr>
<td>How can communities be organized to effectively advocate for community-based mental healthcare? What are key mechanisms of effective advocacy?</td>
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Opportunities for Improvement: Data Systems and Research Capacity

- Data systems:
  - Information on performance of health care workers, facilities, and systems required to assess and improve the quality of care [1]
  - Adequacy varies greatly across populations
  - Improved data collection and use can improve outcomes [2]

- Implementation science:
  - Relatively new field with few experts, mentors and programs
  - Capacity building needed [3]

- Recommended overall increase in biomedical research capacity [4]

4. NASEM. Global health and the future role of the United States. 2017
Engage Diverse Stakeholders in: 1) Committee study, 2) quality of care research, and 3) quality of care improvement

- **Rationale:**
  - Inform and validate research and research agenda
  - Multidisciplinary implementation and research
  - Connect research with implementation
  - Sustain improvements

- **Stakeholders:**
  - Researchers – multidiscipline, multisector
  - Policy Makers – Ministers of Health, health systems administrators, etc.
  - Patients and populations
  - HCW – physicians, nurses, midwives, community health workers, etc.
  - Ancillary health workers - laboratorians, social workers, physical therapists, etc.

- **Examples:**
  - PMTCT Implementation Research Alliance *(Sturke JAIDS 2016)*
  - International Cancer Screening Network (ICSN) [https://healthcaredelivery.cancer.gov/icsn/]
Linkages

- Global to local – lessons learned from abroad applicable to U.S.
  - Use of community health workers and mobile technology developed in Kenya being applied to lower infant mortality in Indiana

- Communicable to non-communicable diseases
  - “Cascade of care” for HIV as framework for hypertension:

Vital Signs: HIV Prevention Through Care and treatment — United States MMWR 2011
Summary – input from NIH

- **Research** is fundamental to improving quality of care globally
- NIH highly engaged in quality of care research and strongly supportive of Study Committee
- Opportunities to improve quality of care and conduct quality of care research at every step of care continuum
- **Implementation and dissemination research** needed (and distinct from program evaluation)
- **Data systems** and **research capacity** need strengthening
- **Diversity** is strength: involve implementation stakeholders in research and researchers in implementation
- Link: **global & local** and **communicable disease & NCD**
Thank you and good luck!

- NIH appreciates opportunity to engage with Study Committee
  - Keen to provide additional subject matter expertise as appropriate
  - Eagerly await recommendations, particularly on defining a research agenda
Additional Slides
Select Examples of Quality of Care in NIH Strategic Plans

- **NIMH [1]:**
  - Develop assessment platforms within service systems that allow ongoing monitoring of mental illness prevalence, service access, quality, efficiency of care, and outcomes in diverse populations and settings
  - Develop valid and reliable measures of treatment quality and outcomes that can be feasibly applied at the person, clinic, system, and population levels

- **NHLBI [2]:** Develop multidisciplinary, multinational partnerships needed to develop effective and sustainable strategies for combating chronic HLBS disorders in developing nations, which take into account the highly variable local epidemiology of HLBS disorders, the need for novel approaches to reducing disease burden, and the challenges of implementation in developing countries.

- **NINR [3]:** In promoting symptom and symptom management science, NINR supports research focused on understanding the biological and behavioral aspects of symptoms, with the goal of developing and testing new interventions to reduce the disabling effects of symptoms and improving patient health outcomes and quality of life.

2. [https://www.nhlbi.nih.gov/about/documents/strategic-vision](https://www.nhlbi.nih.gov/about/documents/strategic-vision)
Context Matters: Consolidated Framework For Implementation Research (CFIR)

Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science

Laura J Damschroder\(^1\), David C Aron\(^2\), Rosalind E Keith\(^1\), Susan R Kirsh\(^2\), Jeffery A Alexander\(^3\) and Julie C Lowery\(^1\)

*Implementation Science*, 2009, 4:50

Care is Complex: The multilevel context of care

Taplin SH, Rodgers AB. Toward improving the quality of cancer care: addressing the interfaces of primary and oncology-related subspecialty care. J Natl Cancer Inst Monogr. 2010;
Evolution of International Cancer Screening Network (ICSN)

1988
International Breast Cancer Screening Database Project
- 11 volunteer groups, each from a different country
- Focus on creating a common international database to facilitate comparative research on screening mammography
- A group of about 30 junior investigators and 2 or three senior researchers

1997
International Breast Cancer Screening Network (IBSN)
- Membership represented 33 countries
- Refocused on understanding how to:
  - Use and compare data from screening mammography programs internationally, and
  - Develop methods for evaluating the impact of population-based breast cancer screening programs.
  - Report specific studies of evaluations and interventions

2008 – 2017
International Cancer Screening Network (ICSN)
- Scope expanded to include colorectal and cervical cancer screening, as well as lung
- Evolved into a full fledged conference (300+ participants, Rotterdam 2015; up from 150 in Oxford, 2010, 256 in Bethesda, 2017)
- Audience now includes senior professors and PhD candidates

THE LATEST CHANGE WE MUST CHANGE TO RESPOND TO:
The growing cancer burden in LMICs creates a need for screening infrastructure and evaluation. How can we leverage ICSN to contribute?
GOAL: Improve the quality of the cancer screening process

AIM: Study the comparative effectiveness of screening processes across recognized human risk levels and consider the benefits and harms

PROSPR applicants address this aim differentially across the continuum of care

- **Recruitment**: Evaluate factors affecting adoption of proven recruitment strategies
- **Detection**: Comparative effectiveness of technology and its consequences
  - Breast: MRI, Digital Mammography, tomosynthesis
  - Cervical: Pap, HPV
  - Colorectal: Colonoscopy, FIT, FOBT
- **Diagnosis**: Evaluation of failures in follow-up, failures in diagnosis
- **Synthesize findings through modeling, simulation, and specific studies**
  - Compare the false positive rates of 3D vs. 2D digital mammography
  - Test impact of risk stratified screening for colorectal cancer and FIT vs. colonoscopy
  - Evaluate the potential mortality impact of risk-based screening

NIH-Funded Research to Improve Patient Outcomes – Retention in Care

- Same-day HIV testing and initiation of antiretroviral therapy increased retention vs. standard care for persons living with HIV in a randomized trial in Haiti.

Retention at 12 months with HIV-1 RNA <50 copies/ml was RR 1.21 (95% CI: 1.04, 1.38; p = 0.015) for the same-day ART group vs. standard ART group.

Koenig SP et al. PLoS Med 2017
Falsified Drugs: A Pandemic

“An epidemic occurring over a very wide area, crossing international boundaries, and usually affecting a large number of people”

(Dictionary of Epidemiology, 2014)

Falsified Drugs and Supply Chain Breaches: Pfizer Global Security

<table>
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<tr>
<td>Falsified drugs</td>
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<td>Countries</td>
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<td>Products</td>
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<td>78</td>
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Supply chain breaches

<table>
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<tr>
<th></th>
<th>2008</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries</td>
<td>25</td>
<td>60</td>
</tr>
<tr>
<td>Medicines</td>
<td>8</td>
<td>26</td>
</tr>
</tbody>
</table>


- System commenced roll out July 2013
- 113 Member States trained in 11 regional workshops
- Over 300 Regulatory personnel trained
- 18 large procurement agencies trained
- Over 900 Suspect Products Reported
- Incidents occurred in 80 countries
- 12 WHO Global Drug alerts and numerous warnings
- Technical support provided in over 50 incidents


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THE GLOBAL PANDEMIC OF FALSIFIED MEDICINES:
Laboratory and Field Innovations and Policy Perspectives

Guest Editors:
James E. Herrington, Gaurvika M. L. Nayyar, and Joel G. Breman

June 3, 2015