Translational Research: How Research Informs Evidence-Based Practice and Practice Change

2014 Nursing Research Symposium: Improving Patient Outcomes through Quality Improvement, Evidence-Based Practice and Research

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Program Director
National Institute of Nursing Research
Overview

- Introduction to the structure of NIH and NINR
- Generate a discussion surrounding the meaning of translation and how we can move translation into a transformative approach for active implementation.
- Real world translation….a story
The NIH Mission

Science in pursuit of fundamental knowledge about the nature & behavior of living systems & the application of that knowledge to enhance health, lengthen life, & reduce illness & disability.

www.nih.gov/about/mission.htm
FY 2014
Budget Mechanisms
(Dollars in Thousands)

- Research Project Grants: $818,631 (69%)
- Research Centers: $88,906 (7%)
- Other Research: $36,864 (3%)
- Research Training: $24,756 (2%)
- Intramural Research: $118,601 (10%)
- RMS: $42,373 (4%)
- R&D Contracts: $63,239 (5%)

Celebrating 60 years at the NIH Clinical Center
The National Institutes of Health (NIH)
November 1985  
Formal authorization of NCNR at NIH

April 1986  
NCNR established at NIH

December 1986  
Members of the NCNR Advisory Council appointed

February 1987  
1st meeting of the NCNR Advisory Council

June 1993  
NCNR officially elevated to Institute status
NINR Mission

To promote and improve the health of individuals, families, and communities.
NINR science offers unique expertise within the NIH with our focus on the science of health:

- Inclusive of full life-course through end-of-life
- Encompasses spectrum of health & settings of care
- Promotes multi/interdisciplinary & team science
- Person- & family-centered
- Community-engaged research
- Cultivates partnerships, collaboration & leadership
NINR and Nursing Research

NINR Strategic Plan: Meeting the Challenges

Science that invests in:
• Health Promotion and Disease Prevention
• Advancing the Quality of Life: Symptom Management
• Palliative and End-of-Life Care
• Innovation
• Training Nurse Scientists

Patricia A. Grady, PhD, RN, FAAN
Scientific Focus Areas to Implement NINR’s Strategic Plan

- Symptom Science
- Wellness
- Self-Management
- End-of-Life & Palliative Care
NINR’s Areas of Research

NINR Extramural Research

- Primarily at universities and health science centers
- Cross-cutting, interdisciplinary research

http://www.ninr.nih.gov/ResearchAndFunding/DEA/

NINR Intramural Research

- On the NIH campus in Bethesda, Maryland
- Collaborative research in symptom management, TBI, and genomics
- Training at all career levels

http://www.ninr.nih.gov/ResearchAndFunding/dir/
What If………

You could translate the evidence from a research question into practice that improves health outcomes of individuals and/or their families?

Translation is a process not an event…..
What is Translation?
“Bench to Bedside?”

Translational Research?
Translation is NOT........
“Translational research means different things to different people, but it seems important to almost everyone”.
Steve Woolf, 2008

“It appears that translation in the 1970s morphed into research utilization in the 1980s and into evidence-based practice in the 1990s, with some re-acquaintance with translation again in the first years of the 21st century”.
Pam Mitchell, 2004
The Quality of Health Care Delivered to Adults in the United States

Elizabeth A. McGlynn, Ph.D., Steven M. Asch, M.D., M.P.H., John Adams, Ph.D., Joan Keesey, B.A., Jennifer Hicks, M.P.H., Ph.D., Alison DeCristofaro, M.P.H., and Eve A. Kerr, M.D., M.P.H.

Abstract

Background

We have little systematic information about the extent to which standard processes involved in health care — a key element of quality — are delivered in the United States.

Methods

We telephoned a random sample of adults living in 12 metropolitan areas in the United States and asked them about selected health care experiences. We also received written...
Basing nursing practice on research findings is essential and not new to nursing.

Almost 140 years ago Florence Nightingale stressed translation (the use of evidence).
It was not until the 1950’s and 1960’s that nursing research became a priority.

- Introduced to the undergraduate level
- *Nursing Research* was first published in 1952
In 1956 the editor of *Nursing Research*, Virginia Henderson, was quoted:

“It must be assumed by the researcher who must make known the results of research; by professional organizations through periodicals, meetings, and conferences; by faculties of schools where students expect to find curricula based on the latest research findings; by officials of nursing services who are responsible for seeing that patient care is based on the latest and most accurate knowledge concerning nursing; and by every individual professional nurse whose responsibility it is to use reported research to improve her own work”.

*That was almost 60 years ago…..*
Translating Research to Practice

Jean E. Johnson, Ph.D., R.N., F.A.A.N.

The translation of research to practice is a responsibility of practitioners. The responsibility for nursing care and whether or not that care is influenced by knowledge from scientific investigations rests with each practitioner. A practitioner as a professional person is accountable for the quality of her or his practice; a nurse researcher as a professional is accountable for the quality of her or his research. The researcher is held accountable by scientific criteria and for the potential relevance of the research to nursing functions. The researcher cannot be held accountable for the use or misuse of the new knowledge generated. However, retrospective evaluation of the contribution of research to nursing will be influenced by both the quality of the research and whether the knowledge influenced the quality of nursing care provided to the public.

Johnson, J., 1979, Journal of Professional Nursing
• Pursue new ways of thinking and working.
• Pay attention to the interface
• Educate, educate, educate
“It took 264 years to implement the use of citrus juice on British ships from the time it was discovered as a prevention for scurvy”

# Research Utilization Gap

## Time span between Research and Utilization

<table>
<thead>
<tr>
<th>Research</th>
<th>Year idea generated</th>
<th>Year 1(^{st}) realization</th>
<th>Duration in Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemaker</td>
<td>1928</td>
<td>1960</td>
<td>32</td>
</tr>
<tr>
<td>Electrophotography</td>
<td>1937</td>
<td>1959</td>
<td>22</td>
</tr>
<tr>
<td>Oral Contraceptive</td>
<td>1951</td>
<td>1960</td>
<td>9</td>
</tr>
<tr>
<td>Hybrid Corn</td>
<td>1908</td>
<td>1933</td>
<td>28</td>
</tr>
</tbody>
</table>

## Research Utilization

Comparison of a replicated study to the original study

<table>
<thead>
<tr>
<th>Position for IM Injections</th>
<th>Brett, 1987 (n=216)</th>
<th>Coyle &amp; Sokop, 1990 (n=113)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aware of findings</td>
<td>44%</td>
<td>34%</td>
</tr>
<tr>
<td>Persuaded that the finding was useful</td>
<td>34%</td>
<td>21%</td>
</tr>
<tr>
<td>Sometimes used intervention</td>
<td>29%</td>
<td>4%</td>
</tr>
<tr>
<td>Always used intervention</td>
<td>10%</td>
<td>22%</td>
</tr>
</tbody>
</table>

“...effective translation of the new knowledge, mechanisms, and techniques generated by advances in basic science research into new approaches for prevention, diagnosis, and treatment of disease is essential for improving health”

Source: Fontanarosa PB, DeAngelis CD. Basic science and translational research in JAMA. JAMA 2002;287:1728.
Translational Research

From: **Practice-Based Research—“Blue Highways” on the NIH Roadmap**

NCATS defines translational research broadly to include the early steps necessary to develop new therapeutics, devices and diagnostics from basic discoveries, the steps necessary to establish real world efficacy, and the research needed to improve the practical implementation and dissemination of improved approaches to care. This breadth is sometimes described as T1 through T4.
From: Blumberg, et Al., Nature Medicine Volume: 18, Pages: 35–41 Year published: (2012) DOI: doi:10.1038/nm.2632 Published online 06 January 2012
T1 and T2, T3 4, 5, 6

- Goals
- Settings
- Study designs
- Investigators
The Traditional Laboratory of T1/T2
Laboratory of T2
The Traditional “Laboratory” of T3/T4
What are the Challenges?
The “Ecology” of Medical Care US

The “Ecology” of Medical Care Sweden

Ferro; Scandinavian Journal of Primary Health Care, 2011; 29: 187–192

Figure 1. Number of people per 1000 inhabitants who had at least one appointment with a physician in an average month by the different health care settings.
Resources Needed for T1/T2

- Mastery of molecular biology, genetics, and other basic sciences
- Appropriately trained clinical scientists
- Strong laboratories
- Cutting-edge technology
- Supportive infrastructure within the institution
“Implementation science”: evaluating interventions in real-world settings

- Clinical epidemiology and evidence synthesis
- Communication theory
- Behavioral science
- Public policy
- Financing
- Organizational theory
- System redesign
- Informatics
- Mixed methods/qualitative research
The Dominant Challenges

- Biological and technological mysteries
- Trial recruitment
- Regulatory concerns
- Human behavior
- Infrastructure and resource constraints
- Messiness of “moving targets” and conditions that investigators cannot fully control
System Challenge

“My personal opinion is that all this “tracking” system is completely wrong and badly designed destroying the career of very good researchers with great potential to develop and discover important things in science. I am using this blog to say that the scientific community needs to re-evaluate this whole system.

– the scientific community somehow decides who stays and who doesn’t. But, isn’t that the same way in everything in life?; such as the way evolution works – the more adapted and fit stay and the weakest ones have to give up or “die”.
Challenges: The Conventional “Afferent” Model

Community practitioners → Subject recruitment → Clinical Trials
If you build it, they will come.
Solution?

Formulating research questions

- Generalizable populations
- Evaluations of effectiveness
- Develop Sustainability Strategies

Evaluation of systems for delivering interventions
What T3/T4 Needs

- A new name? “translational research” is too vague
- Not using the same label for the T’s would reduce confusion
- Policymakers need to understand distinction between inventing treatments and getting them used
Better Labels..... Just Translation?

The Translational Continuum

- **Basic Science Discovery**
  - Promising molecule or gene target
  - Candidate protein biomarker
  - Basic epidemiologic finding

- **Early Translation**
  - Partnerships and collaboration (academia, government, industry)
  - Intervention development
  - Phase I/II trials

- **Late Translation**
  - Phase III trials
  - Regulatory approval
  - Partnerships
  - Production & commercialization
  - Phase IV trials – approval for additional uses

- **Dissemination**
  - (new drug, assay, device, behavioral intervention, educational materials, training)
  - To community health providers
  - To patients and public

- **Adoption**
  - Adoption of advance by providers, patients, public
  - Payment mechanisms (s) in place to enable adoption

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From the President’s Cancer Panel’s 2004-2005 Report Translating Research into Cancer Care: Delivering on the Promise
Lost In Translation
Community Hospital
Translational Science: Research Example

Thrombotic complications of venous access devices

Discovery of Persistent Withdrawal Occlusion

Thrombosis of Subclavian Vein from VAD

Chemotherapy Extravasation
Persistent Withdrawal Occlusion

Groshong Port Catheter Tip Design

valve open-infusion
(+ pressure)

valve open-aspiration
(- pressure)

catheter tip

valve closed

pressure = neutral

inner lumen
Persistent Withdrawal Occlusion
**Pilot study:** Quasi experimental design using a historical control group

All adult patients with newly inserted Groshong® catheters

Population consisted of adult oncology patients
The use of heparinized saline flush solution in Groshong® catheters will decrease the incidence of PWO when compared to Groshong® catheters flushed with normal saline alone.
Results: Persistent Withdrawal Occlusion

<table>
<thead>
<tr>
<th>Patients</th>
<th>Saline Flush</th>
<th>Heparin Flush</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malfunction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Needed</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Still In Place</td>
<td>2</td>
<td>8</td>
</tr>
</tbody>
</table>

Legend:
- Infection
- Malfunction
- Not Needed
- Still In Place
## Results: Persistent Withdrawal Occlusion

<table>
<thead>
<tr>
<th></th>
<th>Saline Flush</th>
<th>Heparin Flush</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Catheter Days</strong></td>
<td>3,420 days</td>
<td>3,095 days</td>
</tr>
<tr>
<td><strong>Vials of UK</strong></td>
<td>94 vials</td>
<td>14 vials</td>
</tr>
<tr>
<td><strong>Cost of UK and/or Heparin</strong></td>
<td>$4,396</td>
<td>$507</td>
</tr>
<tr>
<td></td>
<td>$1.29/day</td>
<td>$0.33</td>
</tr>
<tr>
<td><strong>Total Maint. Cost</strong></td>
<td>$154.80</td>
<td>$38.40</td>
</tr>
</tbody>
</table>

**Based on the Ave. Catheter Longevity of 120 days**
The addition of heparin flush to maintain Groshong® catheters appeared to decrease the presence of intraluminal blood and clot and improves catheter function.

The effects of heparin flush on patency of the Groshong catheter: a pilot study.

Mayo DJ Jr, Horne MK 3rd, Summers BL, Pearson DC, Helsabeck CB.

Author information

Abstract

PURPOSE/OBJECTIVES: To determine whether the addition or a heparinized saline flush would decrease clot formation and persistent withdrawal occlusion (PWO) in Groshong (Bard Access Systems, Salt Lake City, UT) catheters.

DESIGN: A prospective, nonrandomized study using a historical control group of patients with Groshong catheters that had been flushed weekly with 5 ml normal saline compared to data from patients with Groshong catheters flushed weekly with 2.5 ml heparinized saline (100 U/ml). A retrospective chart review was performed to determine the incidence of PWO. In both groups, the presence of liquid blood and adherent or nonadherent clot in explanted catheters was recorded.
Fibrin Sheath Formation

- Venotomy Site
- Fibrin Sheath
Translational Science: Research Example
Background: Case report

- 56 year old woman getting treatment for breast cancer
- Catheter inserted for treatment management (Groshong)
- 3-months after insertion– PWO and treated with UK
- Sluggish blood return after UK but deemed ok to administer chemo
- Because of the PWO and suspected extravasation a cathetergram was done
Translational Science: Research Example

Chemotherapy extravasation: a consequence of fibrin sheath formation around venous access devices.

Mayo DJ¹, Pearson DC.

© Springer-Verlag 1998

Fibrin sheath formation and chemotherapy extravasation: a case report

PMID: 7675669 [PubMed - indexed for MEDLINE]
Case Report

- Male patient with diagnosis of lymphoma
- Hickman catheter inserted via SC Vein
- Symptoms of arm swelling and pain
- Subclavian vein thrombosis diagnosed by arm venogram
- Treated with lytic therapy (t-PA)
- Vascular patency achieved in 24 hours
Translational Science: Subclavian Vein Thrombosis
Current treatment options for catheter-related thrombosis

Donna Jo Mayo, RN, MA

DOI: 10.2309/108300800775897980
Questions?