Clinical Research Nursing and Nursing Science: A Perfect Partnership

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Objectives

• To explore the roles of clinical research nurses and nurse scientists and the synergy that exists between the two roles
• To provide exemplars of collaborations throughout the translational continuum from bench to bedside and back.
• To introduce a process model, INSPIRE, to encourage innovation and discovery in nursing practice.
• To describe the essential role that mentorship plays in the development of clinical research nurses and nurse scientists.
Defining the Roles

Nursing care is patient-focused, and is driven by clinical and research requirements. Workload based on clinical needs/protocol requirements. Supervision/ allocation of work by nursing management.

Clinical Research Nurse (Case Manager)

Clinical Research Nurse (Staff Nurse)

Nurse Practitioner (Research focus)

Study Coordinator / Research Nurse

Nursing care is independent of direct patient requirements and is investigator focused. Workload requirements research based. Daily supervision and allocation of work done by PI.

Funded by Clinical Site

Funded by Study
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Funded by Study
Translational Science Continuum

WHERE DOES NURSING INNOVATION START?

BENCH

BEDSIDE

COMMUNITY
Exemplar 1: Bedside to Bench

• We have poor and/or inconsistent mouth care in the ICU. Why?

• Does systematic oral care improve outcomes (e.g. ventilator associated pneumonia) in critically ill patients?

• Are there changes in the oral microbiome of critically ill patients?
The Human Microbiome—Distinct Sites

[Graph showing distinct sites: Gastrointestinal, Urogenital, Skin, Nasal, Oral]

Role of the Oral Microbiome in VAP

- 500-700 bacterial species estimated
- ~200 species in each person
- Fifty percent of oral bacteria are uncultivable
- Next-generation sequencing
- Culture-independent methods are required

Effects of Systematic Oral Care in Critically Ill Patients: A Multicenter Study

By Nancy J. Ames, RN, PhD, CCRN, Pawel Sulima, PhD, Jan M. Yates, RN, PhD, Linda McCullagh, RN, MPH, Sherri L. Collins, RHN, BS,D, Karen Soden, PhD, and Gwene R. Wallen, RN, PhD

Background: No standard oral assessment tools are available for determining frequency of oral care in critical care patients, and the method of providing oral care is controversial.

Objectives: To examine the effects of a systematic program of oral care on oral assessment scores in critically ill intubated and nonintubated patients.

Methods: Clinical data were collected 3 times during critical care admissions before and after institution of a systematic program of oral care in 2 different medical centers. The oral care education program consisted of instruction from a dentist or dental hygienist and a clear procedure outlining systematic oral care. The Beck Oral Assessment Scale and the mucosal-plaque score were used to assess the oral cavity. Data were analyzed by using linear mixed modeling with controls for severity of illness.

Results: Scores on the Beck Scale differed significantly (F = 4.75, P = .01) in the pattern of scores across the 3 days and between the control group (before oral education) and the systematic oral care group. Unlike the control group, the treatment group had decreasing scores on the Beck Scale from day 1 to day 5. The mucosal-plaque score and the Beck scale scores had strong correlations throughout the study; the highest correlation was on day 5 (r = 0.781, P < .001, n = 436).

Clinical Study: The Effect of a Systematic Oral Care Program on Reducing Exposure to Oropharyngeal Pathogens in Critically Ill Patients

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>Day 3</th>
<th>Day 5</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>10.9 (0.39)</td>
<td>11.9 (0.38)</td>
<td>11.0 (0.51)</td>
<td>11.3 (0.33)</td>
</tr>
<tr>
<td>Treatment</td>
<td>9.5 (0.35)</td>
<td>9.2 (0.36)</td>
<td>7.7 (0.58)</td>
<td>8.8 (0.32)</td>
</tr>
<tr>
<td>Overall</td>
<td>10.2 (0.26)</td>
<td>10.5 (0.26)</td>
<td>9.4 (0.38)</td>
<td>8.8 (0.32)</td>
</tr>
</tbody>
</table>

Beck Oral Assessment Scale

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>Day 3</th>
<th>Day 5</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>4.1 (0.19)</td>
<td>4.3 (0.16)</td>
<td>4.0 (0.25)</td>
<td>4.2 (0.16)</td>
</tr>
<tr>
<td>Treatment</td>
<td>3.8 (0.16)</td>
<td>3.3 (0.16)</td>
<td>2.6 (0.28)</td>
<td>3.3 (0.15)</td>
</tr>
<tr>
<td>Overall</td>
<td>4.0 (0.12)</td>
<td>3.8 (0.11)</td>
<td>3.2 (0.19)</td>
<td>3.3 (0.15)</td>
</tr>
</tbody>
</table>

Mucosal-Plaque Score

The difference in BOAS scores was statistically significant over time, day 1, 3, or 5 (F = 5.1; P = .009), and between groups, treatment or control, (F = 29.05; P < .001)

One Good Clinical Question Leads to Another...
Clinical Study: A Description of the Oral Microbiome of Patients with Severe Aplastic Anemia (SAA)

PI: Nancy Ames, RN, PhD

Aims:

• Compare oral microbiomes of SAA patients before treatment (baseline) and after treatment (3 months/engraftment)

• Compare the oral microbiome of SAA patients who are treated with immunosuppressive agents with those patients who receive an ASCT

• Compare the oral microbiome of SAA patients require intubation to SAA patients who do not develop this complication

• Identify potential respiratory pathogens in the oral microbiome and develop a database of bacterial organisms identified


http://sustainablebalance.ca/microbes-over-medicine/
Exemplar 2: Bedside to the Community and then Back to the Bench

• Our alcohol use disorder (AUD) patients say they have trouble sleeping but every time we go into their rooms they are asleep. Why?

• We want to deliver an evidence-based practice approach but we don’t know the prevalence of sleep disturbance in our patient population.

• What is the prevalence of sleep disturbance in AUD patients seeking treatment?

• How does sleep disturbance change post-discharge
Alcohol Dependence and Sleep

- Clinical Research Nursing led amendment for sleep and actigraphy in treatment seeking individuals with alcohol dependence (n=164)
- Evaluating sleep and relapse rates in alcohol dependent individuals (n=125 to date).
- RCT with customized sleep intervention APP (CBT-I plus)
Nursing-led amendment to 05-AA-0121 (Screening / Treatment Protocol)

- Objective (actigraphy) and subjective (PROs) measures of sleep quantity & quality collected on 164 individuals undergoing alcohol detoxification
- High prevalence of sleep disturbance found in this sample: sleep quality improved by week four but continued to be altered
- Signals a target area for recovery management
- Sub-analyses demonstrated correlates of improved sleep across inpatient treatment (females, higher levels of dependence)


One Good Clinical Question Leads to Another...
Clinical Study: Sleep disturbance and relapse in individuals with alcohol dependence: an exploratory mixed methods study (n=126)
PI: Gwenyth R. Wallen

- Mixed-methods approach used to assess experiences with sleep throughout the process of alcohol rehabilitation pre- and post-discharge from inpatient facility
- Self-efficacy: important predictor of sleep quality
- Thematic analysis of participants’ interview transcripts yield overarching themes of sleep-related beliefs, sleeping environments, and sleep-related behaviors
- Highlights need for behavioral sleep intervention efforts to improve outcomes
...And Yet Another...
The Gut Microbiome

• About 99% of the microbiome located in the gut
  • Tens of trillions of bacteria

• Individuals possess unique microbiota fingerprints that change in response to diet, immune system changes

• “Gut-brain axis:” connection between anxiety, mood, depression and intestinal microflora
  • Emerging area of psychomicrobiotics for treatment of psychiatric disorders

Clinical Study: Longitudinal changes in the oral and gut microbiome of individuals with alcohol dependence

Aims:

• Characterize oral and gut microbiome in patients with severe alcohol use disorder throughout an inpatient detoxification treatment period

• Compare and contrast the gut and oral microbiomes

• Compare microbial flora of individuals undergoing inpatient detoxification to healthy volunteer data from the Human Microbiome Project

• Correlate changes to psychosocial measures

PI: Nancy Ames, RN, PhD

http://sayostudio.com/inside-the-body-health-disease-cancer
Exemplar 3: Bedside to the Community

- We have a new urban clinic serving Spanish speaking Hispanic and African American patients with rheumatic diseases. We think they are practicing a number of alternative therapies that may be contraindicated. How can we assess this?

- Are there evidence-based modalities that would be acceptable as adjunct therapies in these underserved populations?
Health Disparities in Chronic Disease

Health Behaviors and Outcomes in Rheumatic Diseases

- **Community Based Participatory Research (CBPR)**
  - Engaged a community partnership to sustain research and improve practice in patients with rheumatic diseases

- **Cognitive Interviews**
  - Developed and validated a quantitative inventory to evaluate complementary and alternative practices in English and Spanish speaking arthritis patients

- **Patient Reported Outcomes (PROs)**
  - Evaluated pain, depressive symptoms, functional status, social support and shared decision-making which supported the yoga feasibility and acceptability study

- **Intervention Study**
  - Community-based Yoga Pilot Study to test for feasibility and acceptability in Hispanic and African American Patients with Arthritis
Community Study: Health Beliefs and Health Behavior Practices, Including Complementary and Alternative Medicine Use, Among Minorities With Rheumatic Disease. PI: Gwenyth R. Wallen

- Trust, patient-provider relationships, and access to healthcare were identified as key issues to consider in moving forward with research in this predominately Hispanic and African American community.

  Wallen, et al., *Progress in Community Health Partnerships*, 2012

- An *Inventory of Complementary and Alternative Medicine Practices (ICAMP)* was developed as a measure for CAM assessment in Spanish and English in a community setting.


- Shared decision-making (SDM) played a significant role in whether patients used CAM and disclosed CAM use to their providers. We found that gender, ethnicity and SDM significantly (p=.001) predicted CAM disclosure.

One Good Clinical Question Leads to Another...
Community-Based Study: Pilot Study of Yoga Self-Care in Minority Communities

PI: Kimberly Middleton

- To further test the feasibility of yoga as a self-care strategy to reduce chronic pain, improve functional capacity and enhance sleep hygiene in arthritis patients.
- Pilot study was developed to examine the feasibility of yoga acceptability of providing yoga to an urban, minority population with arthritis.
- Arthritis patients attending a community clinic are amenable to enrolling in a study evaluating the feasibility and acceptability of yoga classes taught in English and Spanish as a self-care strategy.

Middleton, et al., (2013). Health and Quality of Life Outcomes,

Middleton, et al., International Journal of Yoga Therapy,

INSPIRE
Innovation for Nursing Sensitive Practice in a Research Environment
INSPIRE Model

Setting Priorities

Innovation for **Nursing Sensitive Practice In a Research Environment**
QI/PI, EBP, or Research

Selecting an Approach To Improve Care

Determine Which Improvement Process To Use
Implementation
Committee Purpose

- *Forum for initial dialogue* on innovative ideas generated from clinical staff
- Way to engage clinical staff in building and sustaining a culture of EBP, QI/patient safety, and research by:
  - Providing resources and consultation re: best methods to approach improvement ideas
  - Facilitating consultation with *experts in methods* and/or other topics based on the scope of the initiative
Committee Purpose

- Coordinating INSPIRE Committee review process
- Tracking progress and communicating overall number of projects and topic areas via INSPIRE website and updates at CCND meetings (e.g., leadership, NPC)

- The goal is **not**
  - To track all department initiatives
  - To be a gatekeeper
“INSPIRE-ation” Request

- Review idea with immediate supervisor who will seek support and agreement from the respective Service Chief
  - Goal is to facilitate communication to ensure success
Roles

- Leadership Point of Contact
  - Member of program leadership (facilitate the work of the project)
- Methods Expert/Consultant
  - Involved in at least one meeting
  - Engaged intermittently at the discretion of the requestee over the course of the project (start up through dissemination)
Embracing a Culture of Innovation

• Engaging staff to bring innovative idea forward despite uncertainty. Set a culture that is open to early idea generation.

• Consider: quarterly ‘open forum’ innovative idea generation sessions
  - Staff who have ideas but aren’t sure how to present to leadership or narrow down
  - Rapid fire ideas & brainstorming (e.g., 15 minutes of agenda time)
  - All leadership would be encouraged to attend (maybe based on agenda/topic)
  - Brainstorming, no judgement; no pre-approval required
INSPIREd Projects

- Initiated by staff from both outpatient and inpatient areas
  - 8 QI
  - 4 EBP
  - 4 Research
  - 2 Unit-based Clinical Projects
Examples

• QI: Alaris Guardrails
  ➢ Alaris guardrail drug library usage on all inpatient units

• EBP: Distress Screening
  ➢ Routine screening for distress in adult oncology clinics

• RESEARCH: Authorized Deception
  ➢ Exploring participants attitudes and perceptions (OP4) enrolled on studies using authorized deception
Practice Innovation and Good Science Requires Good Mentorship
Personal Characteristics in a Research Mentor

- Enthusiasm
- Sensitivity
- Appreciating individual differences
- Respect
- Unselfishness
- Support for other than one’s own
- Teaching and communication

Growth Through Challenges

Micromanagement  Sink or Swim  Guided independence and scientific creativity

"The delicate balance of mentoring someone is not creating them in your own image, but giving them the opportunity to create themselves." Steven Spielberg
Acknowledgment

I am grateful for the invaluable insight that clinical research nurses, nurse scientists and patient-participants have provided during the process of innovation development and scientific inquiry.