World Health Organization | Patient Safety

A World Alliance for Safer Health Care

Introduction to Patient Safety Research

Presentation 10 – Identifying Solutions: Randomized Clinical Trial

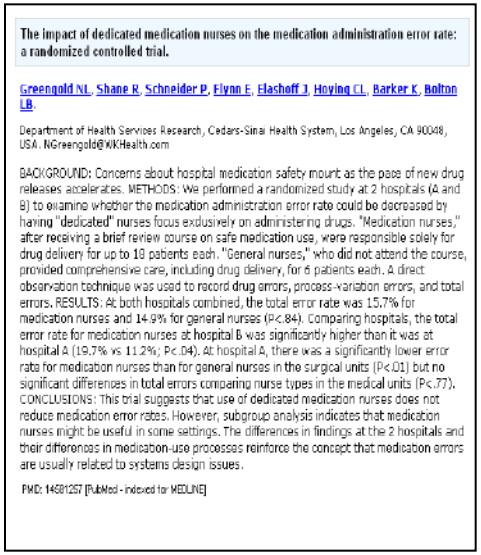
2: Overview

- **Objectives**
  - Examine whether medication administration error rates could be decreased by having "dedicated" nurses focus exclusively on administering drugs.
- **Methods**
  - A randomized study at 2 hospitals (A and B) using a direct observation technique to record drug errors, process-variation errors, and total errors.
    - "Medication nurses," after receiving a brief review course on safe medication use, responsible solely for drug delivery for up to 18 patients each.
    - "General nurses," who did not attend the course, provided comprehensive care, including drug delivery, for 6 patients each.
- **Results**
  - At both hospitals combined, the total error rate was 15.7% for medication nurses and 14.9% for general nurses.
  - Comparing hospitals, the total error rate for medication nurses at hospital B was significantly higher than it was at hospital A (19.7% vs 11.2%).
- **Conclusion**
  - Trial suggests that use of dedicated medication nurses does not reduce medication error rates, although they might be useful in some settings.

3: Introduction: Study Details

- **Full Reference**
  - **Greengold N, Shane R, Schneider P,Flynn E, Elashoff J,Hoying C, Barker K, Bolton LB. The Impact of Dedicated Medication Nurses on the Medication Administration Error Rate: A Randomized Controlled Trial. Arch Intern Med, 2003:163:2359-2367**

Link to Abstract (HTML)



The impact of dedicated medication nurses on the medication administration error rate: a randomized controlled trial.

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BACKGROUND: Concerns about hospital medication safety mount as the pace of new drug releases accelerates. METHODS: We performed a randomized study at 2 hospitals (A and B) to examine whether the medication administration error rate could be decreased by having "dedicated" nurses focus exclusively on administering drugs. "Medication nurses," after receiving a brief review course on safe medication use, were responsible solely for drug delivery for up to 10 patients each. "General nurses," who did not attend the course, provided comprehensive care, including drug delivery, for 6 patients each. A direct observation technique was used to record drug errors, process-variation errors, and total errors. RESULTS: At both hospitals combined, the total error rate was 15.7% for medication nurses and 14.9% for general nurses (P<.84). Comparing hospitals, the total error rate for medication nurses at hospital B was significantly higher than it was at hospital A (19.7% vs 11.2%; P<.04). At hospital A, there was a significantly lower error rate for medication nurses than for general nurses in the surgical units (P<.01) but no significant differences in total errors comparing nurse types in the medical units (P<.77). CONCLUSIONS: This trial suggests that use of dedicated medication nurses does not reduce medication error rates. However, subgroup analysis indicates that medication nurses might be useful in some settings. The differences in findings at the 2 hospitals and their differences in medication-use processes reinforce the concept that medication errors are usually related to systems design issues.

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ORIGINAL INVESTIGATION

The Impact of Dedicated Medication Nurses on the Medication Administration Error Rate

A Randomized Controlled Trial

Nancy L. Greengold, MD, MBA; Rita Shane, PharmD; Philip Schneider, RPh; Elizabeth Flynn, PhD; Janet Elashoff, PhD; Cheryl L. Hoying, PhD, RN; Kenneth Barker, PhD, RPh; Linda Barnes Bolton, DrPH, RN

Background: Concerns about hospital medication safety mount as the pace of new drug releases accelerates.

Methods: We performed a randomized study at 2 hospitals (A and B) to examine whether the medication administration error rate could be decreased by having "dedicated" nurses focus exclusively on administering drugs. "Medication nurses," after receiving a brief review course on safe medication use, were responsible solely for drug delivery for up to 10 patients each. "General nurses," who did not attend the course, provided comprehensive care, including drug delivery, for 6 patients each. A direct observation technique was used to record drug errors, process-variation errors, and total errors.

Results: At both hospitals combined, the total error rate was 15.7% for medication nurses and 14.9% for general nurses (P<.84). Comparing hospitals, the total error rate for medication nurses at hospital B was significantly higher than it was at hospital A (19.7% vs 11.2%; P<.04). At hospital A, there was a significantly lower error rate for medication nurses than for general nurses in the surgical units (P<.01) but no significant differences in total errors comparing nurse types in the medical units (P<.77).

Conclusions: This trial suggests that use of dedicated medication nurses does not reduce medication error rates. However, subgroup analysis indicates that medication nurses might be useful in some settings. The differences in findings at the 2 hospitals and their differences in medication-use processes reinforce the concept that medication errors are usually related to systems design issues.

Arch Intern Med. 2003;163:2359-2367

From the Department of Health Services Research (Dr Greengold) and Pharmacy Services (Dr Shane), the Biostatistics Core, Burns and Allen Research Institute (Dr Elashoff), and Clinical Care Services (Dr Barnes Bolton), Cedars-Sinai Health System, Los Angeles, Calif; David Geffen School of Medicine at UCLA (Drs Greengold and Elashoff); the University of California San Francisco School of Pharmacy (Dr Shane); the Latrobe Leadership Program, College of Pharmacy (Mr Schneider); and the Department of Nursing (Dr Hoying), The Ohio State University Medical Center, Columbus; the Center for Pharmacy Operations and Design, Harrison School of Pharmacy, Auburn University, Auburn, Ala (Drs Flynn and Barker); and the University of California Los Angeles School of Nursing (Dr Barnes Bolton). The authors' financial disclosures are given at the end of the article.

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4: Introduction: Patient Safety Research Team

- **Lead researcher – Nancy L. Greengold, MD, MBA**
  - Associate Clinical Professor of Medicine, UCLA
  - Assistant Director of Health Services Research, Cedars-Sinai Health System in Los Angeles, California, USA
- **Other team members**
  - Rita Shane, PharmD
  - Philip Schneider, RPh
  - Elizabeth Flynn, PhD
  - Janet Elashoff, PhD
  - Cheryl L. Hoying, PhD, RN
  - Kenneth Barker, PhD, RPh
  - Linda Burnes Bolton, DrPH, RN

5: Background: Opening Points

- Previous study found that prescribing errors represented 56% of preventable adverse drug events
  - Errors in medication administration were the second most frequent type, accounting for 34% of preventable events
- Observation technique for studying medication administration errors, first developed in 1962, used in more than 40 studies
  - Consistently demonstrated to be the most accurate for detecting drug administration errors

6: Background: Study Rationale

- Nurses have primary responsibility for medication administration as part of a disparate and demanding set of patient care duties
  - Medication administration is prone to errors, in part because of the proliferation of new devices and new drug products
- Despite the impressive statistics about adverse drug events it is believed that the percentages reported actually underestimate the problem because it is known that most errors go unreported
  - *"I had been discussing various patient safety issues with our Director of Pharmacy and we both felt that this would be an important issue to study."*

7: Background: Setting Up the Research Team

- **Selecting collaborators**
  - ***"We wanted to pull together a multi-disciplinary team so we invited the Chief Nursing Officer at our institution, who is an experienced researcher, to join us.***
  - ***We also solicited the services of an expert statistician at our institution who contributed greatly to the project.***
  - ***Because we wanted to examine the issue at two academic medical centers, we invited a prominent pharmacist and his nurse colleague at the Ohio State University to join us, as well.***
  - ***Finally, we wanted to employ an observation technique pioneered by researchers at Auburn University so we invited two leaders from this institution to be part of our team."***

8: Background: Setting Up a Research Team (2)

- **Obtaining funding**
  - ***"We applied for a grant from the National Patient Safety Foundation. The process was competitive, especially because the principal investigator (yours truly) had never obtained a grant previously."***

9: Background: Objectives

- **Objectives**
  - To determine if medication administration errors can be decreased by using a more focused human approach to medication delivery
  - To test the hypothesis that the drug administration could be decreased by having "dedicated medication nurses" who:
    - have received a brief review course on pharmacology and safe medication use, and
    - focus exclusively on administering drugs during their nursing shifts without increasing the existing complement of nurse staffing

10: Methods: Study Design

- Design: randomized clinical trial
  - *"We felt that a randomized design represented the crème-de-la-crème in research design, and sought to generate results that would be having the least amount of bias."*
- Examined whether the medication administration error rate could be decreased by having "dedicated" nurses focus exclusively on administering drugs
  - A direct observation technique was used to record drug errors, process variation errors, and total errors

11: Methods: Study Population and Setting

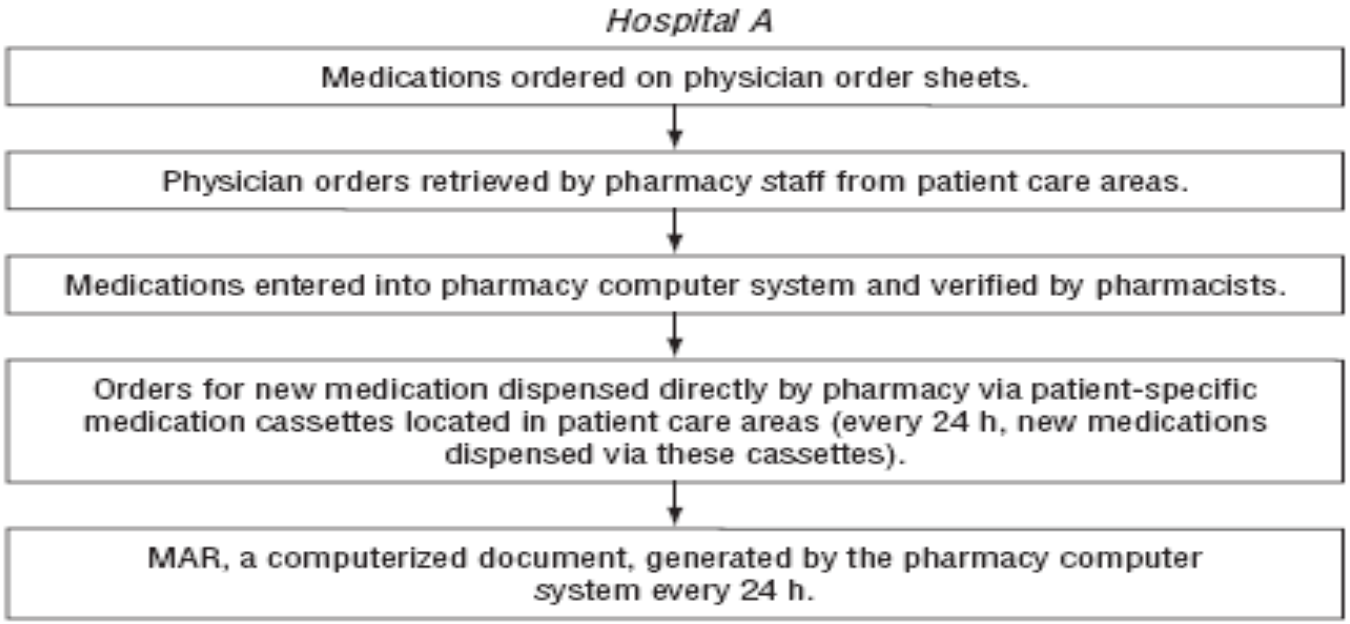
- Setting: study conducted simultaneously at two academic hospitals in two contiguous 6-week blocks for 12 weeks
  - An academic community hospital on the West Coast (Hospital A)
  - A university teaching hospital in the Midwest (Hospital B)
- Population: registered nurses who had at least 1 year of acute care nursing experience and a minimum of 6 months of fulltime employment at the hospital
  - "Medication nurses," after receiving a brief review course on safe medication use, responsible solely for drug delivery for up to 18 patients each
  - "General nurses," who did not attend the course, provided comprehensive care, including drug delivery, for 6 patients each

12: Methods: Study Population and Setting (2)

- Four nursing units at each hospital were selected to participate and consent was acquired from nurse volunteers
  - Hospital A: nursing units aggregated to focus on either medical or surgical patients
  - Hospital B: all nursing units involved were mixed medical and surgical units
- Nurses randomly assigned using a random-number generator to one of two groups: "medication" or "general" nurses
  - 8 medication nurses and 8 general nurses were randomized to participate as principal study participants
  - 7 medication nurses and 3 general nurses were randomized to participate as backup study participants to fill in as needed

13: Methods: Medication Use Process

- **Medication-use processes differed between the two hospitals:**



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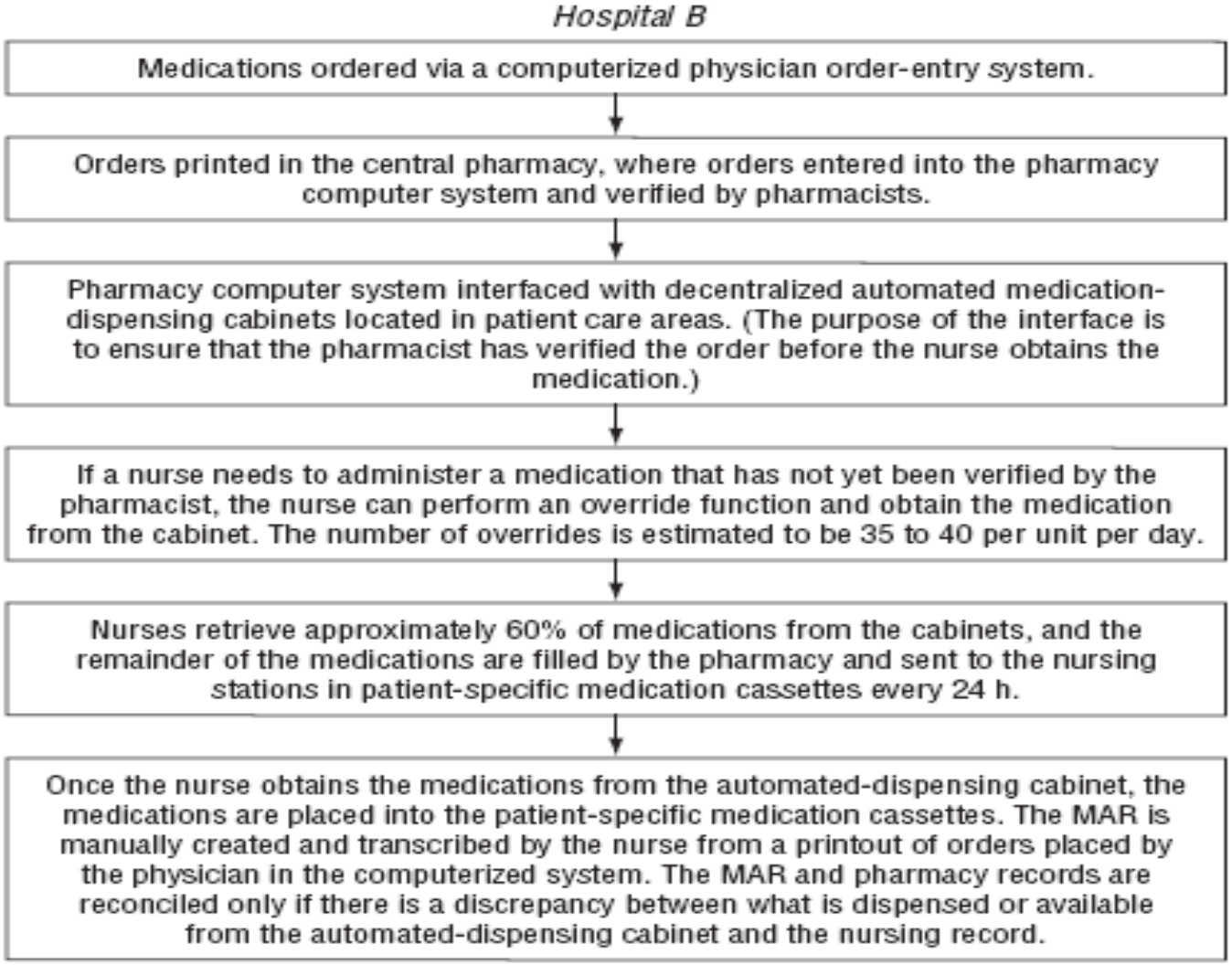
14: Methods: Medication Use Process (2)



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15: Methods: Data Collection (1)

- Trained observer responsible for following the study participants unobtrusively during the medication administration process
  - In the interests of patient safety, observers intervened if a serious error with potential for patient harm was expected to occur
- At the conclusion of each observation shift, observers performed a "reconciliation" of their observations
  - Compared medication administration information recorded during the shift with the physicians' orders in the medical records

16: Methods: Data Collection (2)

- A data collection form was developed to record all observations during the medication administration process
  - All aspects of drug retrieval, preparation and administration
  - Variations from safe medication practices
- Medication errors were recorded by the observers
  - For drugs: dose, dosage form, route, rate of administration
  - For intravenous drugs: dose preparation, administration
  - Technique
  - Omitted drugs

17: Methods: Data Analysis and Interpretation

- Error rate was computed for each nursing unit for each hospital by study week for each nurse type (medication or general)
  - Statistical significance assessed using the sign test (a test of the null hypothesis that the probability of a positive difference is 50%)
  - P values were computed based on the binomial distribution
- Conclusions based on the consistency of differences across the 12-week period

18: Results: Demographics

- Two medication nurses dropped out of the study and were replaced by randomized backup medication nurses
- Occasionally necessary to recruit nurses to serve as general nurses when the randomized backup general nurses unavailable
  - Occurred 12% of the time for total days worked by general nurses
  - These nurses not randomized

Table 1. Characteristics of Registered Nurses Studied at Each Hospital*

	Medication Nurses			General Nurses		
Characteristic	Hospital A (n = 5)	Hospital B (n = 5)	Total (N = 10)	Hospital A (n = 5)	Hospital B (n = 13)	Total (N = 18)
Age, mean, y	37	32	35	41	30	33
Women, No. (%)	3 (60)	5 (100)	8 (80)	4 (80)	13 (100)	17 (94)
Acute care nursing, mean, y	10	5	7	13	5	7
Worked at current hospital, mean, y	7	4	6	8	4	5
Previous experience as a medication nurse of those who worked, No. (%)	1 (20)	1 (20)	2 (20)	1 (20)	0	1 (6)

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19: Results: Key Findings

- At both hospitals, the combined total error rate was 15.7% for medication nurses and 14.9% for general nurses
- Total error rate for medication nurses at Hospital B (19.7%) was significantly higher than at Hospital A (11.2%)

Table 3. Total Error Rates, by Study Site and Nurse Type

Study Site	Medication Nurses		General Nurses		Medication Nurse Errors > General Nurse Errors, wk	*P* Value (Medication vs General Nurses)*
	Errors, No. (%)	Opportunities for Error, No.	Errors, No. (%)	Opportunities for Error, No.		
Hospital A						
Medical units	224 (13.6)	1644	121 (12.4)	975	7/12	<.77
Surgical units	78 (7.4)	1052	134 (17.7)	756	1/12	<.01
Subtotal	**302** (11.2)	**2696**	**255** (14.7)	**1731**	**4/12**	**<.39**
Hospital B (all units)	610 (19.7)	3096	290 (15.0)	1930	9/12	<.15
Total	**912** (15.7)	**5792**	**545** (14.9)	**3661**	**13/24**	**<.84**

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20: Results: Key Findings (2)

- **Unit and nurse type comparison within Hospital A**
  - Significantly lower error rate for medication nurses (7.4%) than for general nurses (17.7%) in the surgical units BUT
  - No significant differences in total errors comparing nurse types in the medical units (13.6 vs. 12.4%)

Table 3. Total Error Rates, by Study Site and Nurse Type

Study Site	Medication Nurses		General Nurses		Medication Nurse Errors > General Nurse Errors, wk	*P* Value (Medication vs General Nurses)*
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21: Conclusion: Main Points

- This trial suggests that use of dedicated medication nurses does not reduce medication error rates.
  - However, subgroup analysis indicates that medication nurses might be useful in certain settings.
- Differences in findings at the two hospitals and differences in medication-use processes reinforce the concept that medication errors are usually related to systems design issues

22: Conclusion: Discussion

- Simple changes in work design and modest education intervention do not seem to decrease medication error rates
  - Not sufficient in diverse hospital populations with complicated medication-use systems
- Likely that more substantive system changed to medication-use systems and trains are required to reduce medication error rates
  - Attempting to reduce medication error rates through comprehensive educational programs requires further study

23: Conclusion: Discussion (2)

- **Study limitations**
  - Medication nurses received little training (1 day only); results may be different if given further training and time to develop expertise
  - Nurses observed between 8AM and 1PM only and hours and shifts worked by nurses different at each institution
  - Due to different medication-use processes at each hospital, observers used different methods in recording errors

24: Conclusion: Practical Considerations

- Study duration: approximately one year
- Cost: about $99,000 USD
- Additional resources
  - Designed own data collection forms and used paper to record the "observation" data
  - One computer to transfer the paper information into a database file (all of this work was done by one individual)
  - Statistics programs to analyze the data
- Competencies needed
  - Trained observers (nurses at one institution, pharmacy technicians at another)
  - Statistician
  - Nurses to fill the roles of "medication nurse" and "general nurse"
- Ethical approval: took several months to obtain

25: Conclusion: Study Impact

- **Academic impact**
  - *"The article appeared to be of interest primarily to the academic world.*
  - *However, because the results were mostly negative (the trial did not find a statistically significant difference between total error rate for so-called medication nurses compared with total error rate for so-called general nurses), the research did not generate the type of excitement it might have had we found a statistically significant difference in error rates."*

26: Conclusion: Study Impact (2)

- **Policy impact**
  - *"It's hard to know if there was any effect on policy. I suppose that the absence of an effect may have led to a decreased interest in establishing dedicated medication nurses in hospitals.*
  - *That is, had our results demonstrated improved patient safety from use of medication nurses, institutions might have pressed for changes in their facilities in this regard."*

27: Conclusion: Study Impact (3)

- **Practice impact**
  - *"There may have been an increased awareness of patient safety issues (and thus improved safety practices) by the nurses who participated in our study.*
  - *Anecdotally, several of them remarked that they paid closer attention to drug administration when they knew they were being observed.*
  - *But I cannot claim that there was any impact upon patient safety at these institutions or at institutions that were not part of the study."*

28: Author Reflections: Lessons and Advice

- **If you could do one thing differently in this study what would it be?**
  - ***"I would have made it less complex. There were far too many variables that muddied the waters – different nurse types, different care units, different hospitals, different medication use processes at each hospital, different backgrounds for the observers, too many definitions of "error." And I'm only scratching the surface!"***

29: Author Reflections: Overcoming Barriers

- **What barriers or problematic issues did you encounter when setting up your research and how did you overcome these?**
  - ***"We encountered many barriers, but the one that stands out in my mind is trying to conduct a clean research study with very busy study subjects, nurses, whose first priority (appropriately) is trying to take care of patients.***
  - ***It is very difficult to adhere to all of the rules and regulations of research in a real-world setting, such as keeping the intervention and control groups the same size when the clinical staffing fluctuates day by day.***
  - ***Also, on some days our research subjects (the nurses) were unable to work for one reason or another and we had to scramble to get replacements (including obtaining informed consent)."***

30: Author Reflections: Ideas for Future Research

- **What message do you have for future researchers from developing countries?**
  - ***"Research is challenging. It tends to look clean and logical on paper, but when you are actually conducting it, it is messy and sometimes confusing."***
- **What would be an important research project you recommend that they do?**
  - ***"Any type of research would serve as a learning experience.***
  - ***I would recommend that new researchers start by doing some "retrospective" research involving analysis of chart or other data.***
  - ***Researchers should then build slowly upon their experiences, advancing to more complicated trial designs as they learn new lessons."***