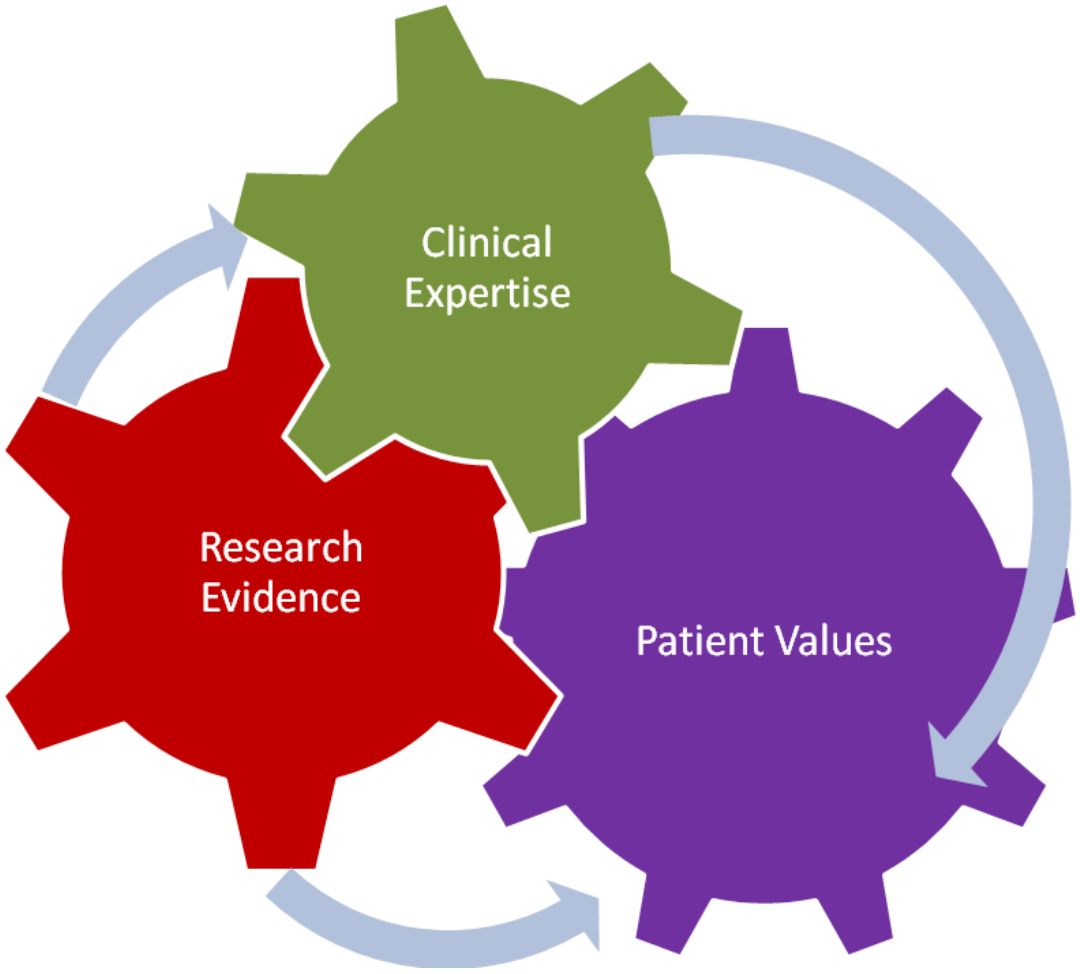
Toolkit for Nursing Evidence-Based Practice and Research



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Preamble

The Toolkit for Nursing Evidence-based Practice and Research is designed for IU Health nurses who have a question about practice and need guidance to pursue the inquiry process. The tool kit provides a brief overview of steps to find evidence and provides information about conducting research projects.

If you are a novice or advanced beginner in research and evidence-based practice, you may want more support than this toolkit offers. You can contact a clinical nurse specialist in your facility or a member of the Research-to-Practice Council in our system-wide shared governance structure (see list of members in this toolkit).

This toolkit will be revised in 2017. Until then, may it offer your spirit of inquiry a place to begin!

Research to Practice Members and Resources to You

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Introduction

Five key attributes of an IU Health nurse are:

- Possesses clinical expertise
- Embraces learning
- Has a spirit of inquiry
- Is professionally engaged
- Fosters relationships

All of these attributes are represented when clinical nurses raise important inquiries and strive to find answers through reviews of existing evidence and the conduction of research studies. This toolkit is designed as a beginning source of information for clinical nurses who want to conduct evidence reviews and research studies.

This Toolkit for Nursing Evidence-based Practice and Research aims to aid the learner in reviewing published evidence on a clinical topic and beginning to think about the design of a research study. Evidence practice reviews and the conduction of research studies are not solitary activities; many people are required for the process to be successful.

Research studies have found that evidence-based practice (EBP) enhances healthcare quality, reduces costs and improves patient outcomes. However, the majority of clinicians are not enlisting this evidence into practice. To reach the Institute of Medicine (IOM) goal that, by 2020, 90 percent of healthcare decisions are evidence-based, intense efforts will need to be made to enhance and sustain EBP in healthcare systems across the United States. *(Melynk & Fineout-Overholt, 2011)*

The EBP process contains seven steps that range from igniting inquiry to sharing results of practice changes, large and small, with others who can benefit from them. For the EBP process to fully impact practice, this seven-step conceptual framework must be in place. Clinicians must blend current research evidence, their own nursing expertise, and the patients' values and preferences into daily clinical decision making for the purpose of achieving the agreed upon outcome. Otherwise, the EBP process becomes just a process and is not sustainable. *(Melynk & Fineout-Overholt, 2011)*

The Seven Steps of the EBP Process

Step 0: Cultivate a spirit of inquiry

Step 1: Ask the clinical question in PICOT format (patient population; intervention or area of interest; comparison intervention or group; outcome; time/format)

Step 2: Search for and collect the most relevant and best evidence to answer the clinical question

Step 3: Critically appraise the evidence. First, rapidly appraise the evidence that has been collected for its validity, reliability, and applicability; then evaluate it for how it best answers the questions; then synthesize that evidence to determine what is known from that body of evidence

Step 4: Integrate the evidence with one's clinical expertise and the patient's preferences and values to implement a clinical decision

Step 5: Evaluate the outcomes of the practice decision or change based on evidence

Step 6: Disseminate the outcomes of the EBP decision or change

Step 0: Cultivate a spirit of inquiry

When clinicians have a spirit of inquiry, they are constantly asking questions about the care they are providing to patients, the outcomes it achieves, and the evidence to support that care.

(Melynk & Fineout-Overholt, 2011)

Tips:

Look at your current practice. What questions do you have about your practice?

Step 1: Ask the clinical question in PICOT format

Questions that are searchable tend to:

1. Be specific
2. Designate the intervention or area of interest
3. Delineate the intervention or area of interest
4. Identify the comparison intervention if applicable or the comparison status
5. Designate measurable outcomes

Why PICOT?

- To get the question clear in your mind
- To identify the information you need to answer the question
- To translate the question into searchable terms
- To develop and refine your search approach

P = patient or **p**atient group:
What characteristics of your patient/s are important?

Age
Gender
Condition

I = intervention or **i**ndicator:
Defining the intervention is often the central part of PICOT, for example:
What intervention or indicator (therapy, diagnostic test or exposure) are you interested in?

C = compare:
You might want to compare the chosen intervention to another intervention or to no intervention. What alternative or different option do you want to compare you intervention to?

O = outcome:
Outcome is the final aspect of PICOT. Outcomes expected from therapy, accuracy of diagnosis, and rate of occurrence of adverse outcome (e.g., death)

T = time or format:
The time involved to demonstrate an outcome.
What is your study design (resources available on pages 28 & 32)?

(Melynk & Fineout-Overholt, 2010)

Examples of PICOT questions:

Intervention
In _____ (P), how does _____ (I) compared to_____(C) affect _____ (O) within _____ (T)?

Prognosis/Prediction
In _____ (P), how does _____ (I) compared to _____(C) influence/predict _____ (O) over _____ (T)?

Diagnosis or Diagnostic Test
In _____ (P), are/is _____ (I) compared with _____(C) more accurate in diagnosing _____ (O)?

Etiology
Are _____ (P), who have _____ (I) compared with those without _____(C) at _____risk for/of _____ (O) over_____ (T)?

Meaning
How do _____ (P) with _____ (I) perceive _____ (O) during _____ (T)?

(Melynk & Fineout-Overholt, 2010)

Tips:
You may change your question many times before you narrow down exactly what you are looking for. Do not be discouraged. This is an important part of the process. Different types of questions are best answered by different types of studies. Not every clinical inquiry will neatly fit into the PICOT format.

To provide accurate and reliable information, studies are developed using many methods. The gold standard for accuracy and reliability is the **systematic review**, sometimes referred to as Level 1 evidence.

Systematic reviews are a synthesis from all of the available studies under the subject matter you are researching. A systematic review has many qualities:

- Addresses a focused, clearly formulated question
- Uses systematic and explicit methods of inquiry to:
  - ✓ Identify, select and critically appraise relevant research
  - ✓ Collect and analyze data from the studies that are included in the review

If one research study or clinical trial provides good evidence, several studies with similar results may provide even stronger evidence or negate previous findings. This logic is applied by researchers to systematically identify, appraise and synthesize evidence from individual studies on a particular topic.

Systematic reviews are not available for every clinical question. Look to other types of studies that may be a little lower on the level of evidence chart. Refer to page 24 for levels of evidence chart.

Narrative reviews are not systematic reviews, they may be useful for background information, and should not be mistaken as useful or used as Level 1 evidence. They also are prone to bias. Narrative reviews include published papers that support an author's particular point of view and usually serves as general background discussion of a particular issue. An explicit and systematic approach to searching for and evaluating papers in usually not used.

Meta-analysis is a statistical approach to synthesizing the results of a number of studies that produces a larger sample size, thus greater power to determine the true magnitude of an effect. This type of review is used to obtain a single-effect measure (i.e., summary statistic) of the results of all studies included in a systematic review.

Integrative reviews do not have a summary statistic because of limitations in the studies found (usually due to heterogeneous studies or samples).

(Melynk & Fineout-Overholt, 2010)

Example:
If your study is about therapy, diagnosis/screening and prognosis, what type of study design would you look for to answer this question? Review the information on page 29 and check the appropriate box.

	Randomized controlled trial
	Controlled trial
	Cohort study
	Case-control study
	Case series
	Case study
	Other

Step 2: Search for and collect the most relevant and best evidence

Navigating the literature

Seven essential steps of a search strategy

1. Formulate a clear clinical question without jargon or ambiguity.
2. Determine the databases you will use from the list below. Determine the type of study design that would best answer the question using the information on page 29 of this Toolkit.
3. Enter a subject heading and/or text word search into the database(s) you have selected. Use your PICOT question components to identify the search terms that will form the basis of your search strategy. (PICOT tools on pages 6 & 7).
4. Keep trialing search words to find relevant evidence.
5. Refine searches to match your study design and key variables in your question. Consider limiting the search to English or human, not another language and not animal, depending on the question.
6. Apply inclusion and exclusion criteria (such as original research only or no qualitative methods) to prioritize the studies gathered by the search and focus on the best available evidence for your question.

Best Databases to Begin Your Literature Search:

- Cochrane Database of Systematic Reviews http://www.cochranelibrary.com/cochrane-database-of-systematic-reviews/
- The Cochrane Collaboration http://www.cochrane.org
- Joanna Briggs Institute http://joannabriggs.org/
- Agency for Healthcare Research and Quality (AHRQ) http://www.ahrq.gov/clinic/epcix.htm
- National Guideline Clearinghouse http://www.guideline.gov/
- Nursing OVID www.ovid.com/webapp/wcs/stores/servlet/ProductDisplay?storeId
- MEDLINE http://www.ncbi.nlm.nih.gov/pubmed
- CINAHL http://www.ebscohost.com/cinahl/

Additional resources for literature searching are available for IU Health Employees via Pulse via links to the Medical Library. Phone number for the Methodist Medical Library is (317) 962-8021.

Searching tools:

To combine search terms use the **Boolean operators** "AND" and "OR." These terms affect the way the database retrieves records.

- **"OR" will broaden your search by** returning any records that contain either one of your terms e.g. cancer OR neoplasm.
- **"AND" will restrict your search** by only returning records that contain both terms e.g. stroke AND aspirin.

In the box below, use "AND" and "OR" to combine your search terms into a search phrase that includes all your PICOT elements and their alternatives.

P
AND/OR
I
AND/OR
C
AND/OR
O
AND/OR
T

(Melynk & Fineout-Overholt, 2010)

Focus and explode:

Focusing is a technique that searches and retrieves only articles that contain the identifiable subject heading as a major emphasis of the article.

Exploding is a technique that searches and retrieves articles with all of the more specific elements of the identified heading, that is, it takes all more specific headings that are under it in the hierarchical thesaurus and makes them available by using one exploded heading.

Combine and limit:

Combine at the start of your search by individually entering key concepts from the PICOT components of the question into the search field.

Limitations can be applied to the final grouping of articles to help reduce the less relevant evidence.

Inclusion and exclusion criteria:

Once a search yields a number of potential matches or" hits," it is wise to have established specific conditions beforehand that will assist in determining which hits are "keepers" and which will be discarded. These conditions are called **inclusion and exclusion criteria**.

Reliable resources:

Research studies and clinical trials published in the journal literature form the foundation of scientific evidence, but not all research meets the highest standard of quality. The following resources provide access to high quality, synthesized research on medical and nursing topics.

Meta-analyses

A rigorous review process with standardized protocols is applied to multiple studies, often utilizing meta-analysis of data from several studies, combined with statistical analyses techniques to minimize the bias of the conclusion. These processes translate into the literature as systematic reviews and summaries of evidence. Meta-analyses are the highest level of evidence available. If you find some in your search process, be sure to keep them and inspect them closely for possible translation into practice.

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Step 3: Critically appraise the evidence

Not all literature is evidence based. Look at the article with a critical eye. Is the information valid and reliable? Are there primary references? Is the study funded and by whom? Resources for critical appraisal are located on pages 29 and thereafter.

Process for appraisal:

Why was the study done?

What was the research question?

What type of study design was used?

Was the design the most appropriate for the research question posed?

What are the study characteristics?

Patient or population	
Intervention	
Comparison	
Outcomes	
Time	

Are these characteristics compatible with my question?

- ☐ Yes
- ☐ Maybe
- ☐ No ⟶ stop reading now, this article will not answer your question

Are the results valid?

Was the study carried out in an appropriate way, and was the study designed to minimize the opportunity for bias to affect the results? Refer to the study prompts in Tables 1 and 2.

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Types of bias:

- Selection bias - how subjects were selected or allocated for the study
- Information bias - the impact of inaccurate or incomplete measurement of the data about the subjects

Minimizing opportunity for bias is the aim of good research design.
Resource for critiquing an article is located on page 32.

What weaknesses (opportunities for bias) exist in this study?

What effect would this have on outcomes?

Why was the study done?

What was the research question?

What type of study design was used?

Was the design the most appropriate for the question posed?

Were there other factors that would impact the study? Was it funded and by whom, what were the inclusion and exclusion criteria for the participants, was there financial conflict of interest for the author, how many participants were in the study, where was the study conducted?

Compose a brief synopsis of the literature you found related to your clinical question. (See template and guidelines, pg. 34?)

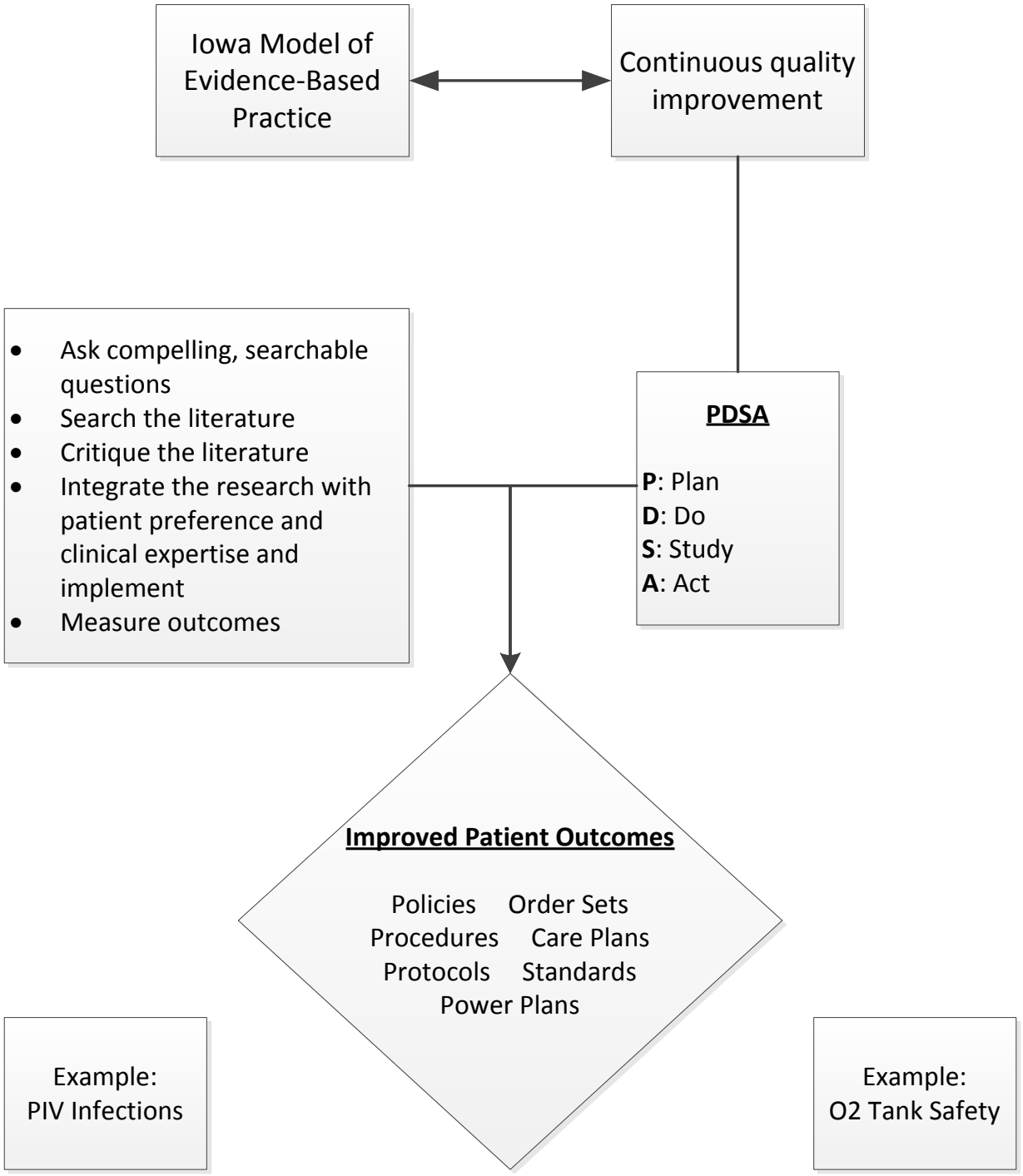
Step 4: Integrate the evidence into practice as appropriate

If the clinical question is answered through your literature search and there are implications for practice, consult with your nursing leaders and experts to plan next steps in practice changes.

- A successful evidence-based practice project will be integrated into practice most effectively when your nurses and leaders have: Strong beliefs that the EBP improves care and patient outcomes
- Knowledge and skills in EBP
- EBP mentors, such as Clinical Nurse Specialists, nurse researchers and research council members in your facility
- EBP resources and tools
- Administrators who support and model EBP

Your evidence-based practice project can bring innovations in care on your unit or in your facility. Innovation is an idea that becomes a sustainable reality. Ongoing innovation is the consistent introduction of something radical or new that leads to positive change. Innovation is needed in the current health system to enhance the quality of care and for the ultimate purpose of improving patient outcomes. Sustainability of best practice innovations will only occur within cultures that support innovative evidence-based practice *(Melynk & Fineout-Overholt, 2011)*.

If your clinical question is not answered from your literature search, consider conducting an original research study or performance improvement project to create new evidence or test existing evidence. The Iowa Model for Evidence-based Practice (pg. 25) parallels the performance improvement process and can be a starting point for an original research study.


Iowa Model of Evidence-Based Practice
Continuous quality improvement
Ask compelling, searchable questions
Search the literature
Critique the literature
Integrate the research with patient preference and clinical expertise and implement
Measure outcomes
PDSA
P: Plan
D: Do
S: Study
A: Act
Improved Patient Outcomes
Policies
Order Sets
Procedures
Care Plans
Protocols
Standards
Power Plans
Example:
PIV Infections
Example:
O2 Tank Safety

Step 5: Evaluate the outcomes

After you find evidence that is ready to integrate into practice and initiate a new practice, you will measure the results of the practice change

Were the outcome measures you used relevant and comprehensive?

If you measured outcomes with statistical analysis, was there a statistically significant change? If so, what was the effect size? What are the p values? Or was there a clinically significant effect?

Did the results address my PICOT question?

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Step 6: Disseminate the outcomes

If you found evidence to change practice and made a practice change, it is time to share the results of your study with your colleagues and perhaps the world.

Organization:

- Research to Practice Council
- Facility clinical practice councils
- Leadership meetings
- IU Health Research Conference
- The Synergist

Locally:

- Research conferences
- Professional organization local chapter presentations

National or international:

- National professional organization annual meeting
- Publish in a peer-reviewed publication

Institutional Review Board (IRB)

Institutional Review Boards (IRB) are branches of the federal government that oversee all research studies conducted with human subjects. The IRB grants permission to conduct a study if all criteria are met. One criterion is that all co-authors become certified in the protection of human subjects during research (https://www.citiprogram.org/).

Evidence-based practice projects that conclude with a search of existing evidence do not require IRB approval. Performance improvement projects that arise from your evidence search to further address your clinical question may or may not require IRB approval. Most original research study studies require approval at one of the three existing levels of IRB approval.

The IRB approval process can be overwhelming. The following links will provide access to the standard operating procedures. Start with your study design and decide what IRB category to apply for. The application process and forms are located on the IRB website: http://researchadmin.iu.edu/fo.html

Exempt studies:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.

2. Research involving the use of educational tests, (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (i) information obtained is recorded in such a manner that the participants can be identified, directly or through identifiers linked to the participants; and (ii) the participants' responses, if they became known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. All research involving survey or interview procedures is exempt when the respondents are elected or appointed public officials or candidates for public office. Confidentiality must be maintained when required by federal statute.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

4. Research and demonstration projects that are funded by a federal agency and determined to be exempt by the agency head and which are designed to study, evaluate, or otherwise examine.

Indiana University IRB Standard Operating Procedures, 2013

Expedited studies:

1. In general, research may be considered for expedited review if it involves no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate consent procedures. Expedited review may also be used when minor changes have been made to a previously approved research project during the period (of one year or less) for which approval is authorized.

2. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or during the performance of routine physical or psychological examinations or tests. Please keep in mind that research does not count as having "minimal risk" simply because it involves minimal physical risk or is non-invasive. There are many kinds of risk including financial risk, employment risk, criminal/civil liability, stigmatization, insurability and embarrassment. It is important to consider all of these when assessing risk.

3. Researchers engaged in human subjects research that qualifies for expedited (Level 2) review must still complete a full application form and prepare an informed consent statement. Researchers must engage in practices that minimize risk, maximize benefit and ensure privacy.

Expedited Research Checklist

Full board studies:

Seek assistance from your mentor and/or IRB representative

Indiana University IRB Standard Operating Procedures, 2013

IRB Requirements

Required CITI Training

1. All personnel associated with the study, including the co-investigators and affiliated researchers, must complete the Collaborative Institutional Training Initiative (CITI) training modules. There are nine biomedical and one sociological module required. CITI training modules are to be renewed every three years. CITI training is intended to teach the researcher about *Human Subject Protection* principles.

Conflict of interest (COI)

2. All personnel associated with the study or project must have a conflict of interest (COI) statement on file with the IRB. This is a requirement for each study in which the researcher participates.

Letter of participation

3. A letter of participation is required from each member of the research team. The letter is to be sent from the individuals e-mail address to the primary investigator indicating their willingness to participate professionally in the study. The letter must be signed and dated.

Primary investigator (PI)

4. Each study must have a PI who is willing to take responsibility for the study design, implementation and outcomes. The PI may not be a student working toward an advanced degree. Generally the PI is either an MD or a PhD-prepared individual; however those with an advanced degree and a letter of recommendation from a higher body may serve as the PI. Determination of eligibility is on an individual basis.

Pilot Study

Another consideration is to conduct a pilot project before beginning an original research study. Pilot projects provide an opportunity to:

- Determine feasibility of the study (availability of subjects, whether there is enough time and money to conduct the study)
- Determine if the sampling technique is effective or whether the sample is representative of the population (use a small sample of the same group or population intended for the larger study)
- Develop or refine data collection tools (use validated tools found in the literature if at all possible). ***Remember that you MUST have written permission from the author of the tool to use it for your study.*** Keep the written permission in your files.
- Examine reliability and validity of research instruments
- Develop or refine a research treatment
- Identify weakness with the design of the study
- Give researchers experience with the study subjects, setting, methodology and tools
- Assist in refining the plans for data collection and analysis
- Provide researchers with an opportunity to implement data analysis techniques

Pilot studies are a great way to get your feet wet. Remember that you cannot use data from the pilot study in your larger study. Before starting the larger study, Institutional Review Board (IRB) approval must be obtained. Any data collected prior to approval is **not** admissible in the larger study. IRB approval is not required for a pilot study; however the study may be mentioned in future publications when discussing the larger study.

Steps to conducting a pilot study

1. Develop your study question. Keep it simple. What exactly are you looking for?
2. Decide on the study design. Keep it simple.
3. Educate staff, etc. about the pilot study, give them all of the information about what you are doing and why, engage them in conversation about why you are doing this and what you hope to find. Enlist their help if applicable.
4. Support and monitor the progress of the study. Do not let it try to run by itself. Like a summer garden, if you do not water and weed then you will not get the results you hoped for.

5. Don't be surprised if your pilot study prompts you to change your study design, or even the question you are asking. One question often leads to several more.
6. Analyze your results. What did you learn or discover?
7. Make recommendations for any improvements or changes for the larger study after you have evaluated all aspects of the pilot study.

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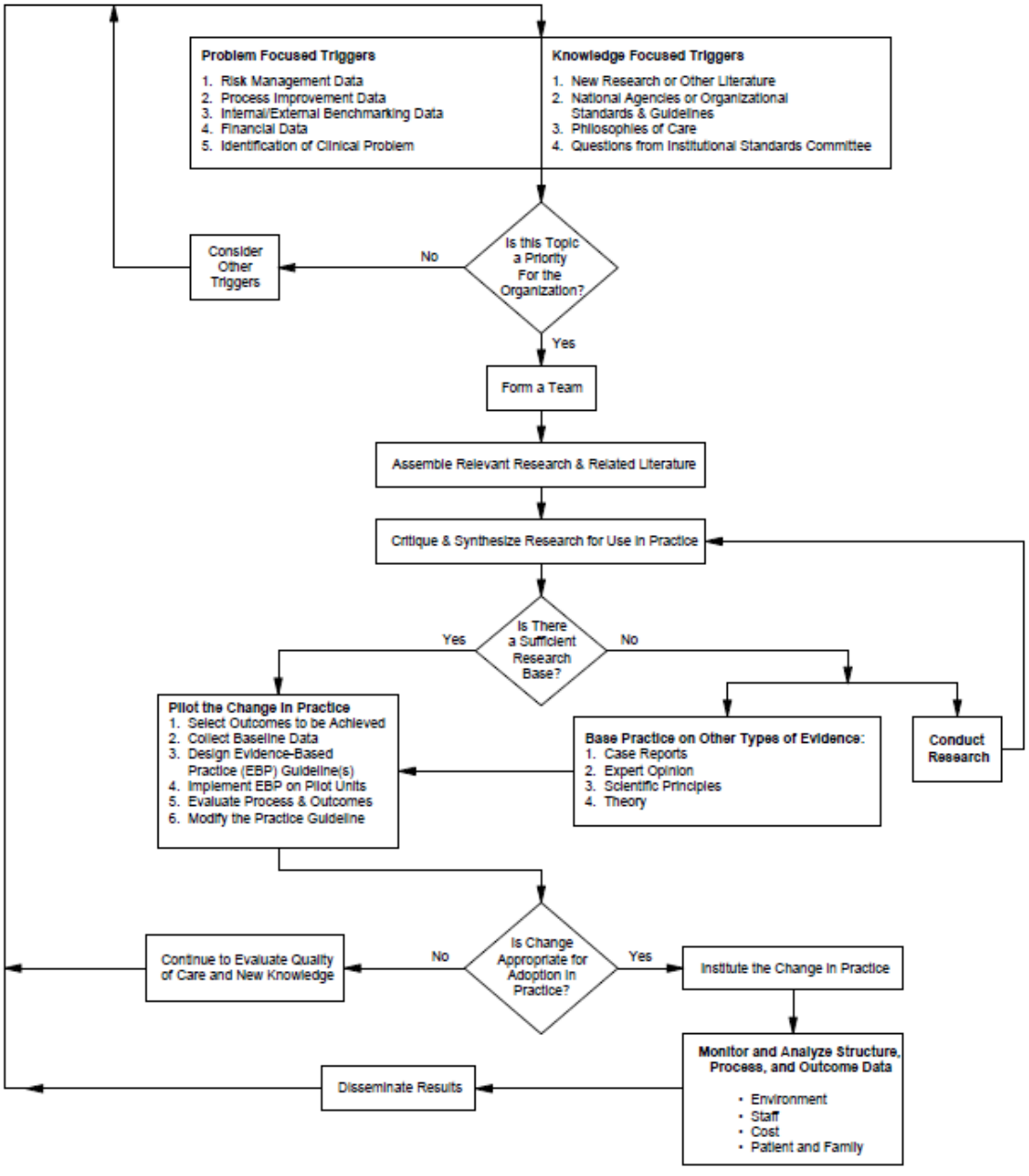
Tips:
Pilot study data is preliminary. Keep in mind that this data is a good start, however since the number of participants is smaller in the pilot study, the data is not conclusive. Avoid the temptation not to proceed with the larger study; the pilot is only a small representation of the larger pool of information.

Resource Documents (pages 25 - 43)

- Iowa Model for Evidence-based Practice
- Literature Search Strategy Worksheet
- IU Health Medical Library
- Levels of Evidence
- Pyramid of Rigor of Research Study Designs
- Choosing a Research Study Design
- Appraisal Prompts for Research Study Designs
- Table of Analysis of Research Studies
- Identifying a Research Study's Design
- Template Sample of SBAR Executive Summary of a Review of Evidence
- Evidence-based Practice Report Form
- Communication Tool

The Iowa Model of Evidence-Based Practice to Promote Quality Care



REQUESTS TO:
Marita Titler, PhD, RN
Office of Nursing Research
The University of Iowa Hospitals and Clinics
Iowa City, IA 52242-1009

Reference

Titler, M.G., Kleiber, C., Steelman, V., Rakel, B., Budreau, G., Everett, L.Q., Buckwalter, K.C., Tripp-Reimer, T., & Goode C. (2001).The Iowa Model of Evidence-Based Practice to Promote Quality Care. *Critical Care Nursing Clinics of North America, 13(4), 497-509.*

Preparing your Literature Search Strategy Worksheet

1. Write down your research question.

2. Separate out the various search concepts within your research question. List each concept.

   (Your question is likely to involve 2 - 4 different concepts)

Concept #1	*Concept #2*	*Concept #3*	*Concept #4*

3. If you do not get enough records …

   a. Below each concept, list 1-3 alternative words (synonyms) that you could try.

Synonyms for Concept #1	*Synonyms for Concept #2*	*Synonyms for Concept #3*	*Synonyms for Concept #4*

   b. List 1-3 alternative databases that you could try when searching for that concept.

4. Too many records?

   Narrow your search with one or more limiters.

   As a starting point, select two of the following possibilities that are relevant for your question, and circle both of them.

   English

   Research (only if using CINAHL)

   Human (only if using Medline)

   *Male or female (*if relevant for the research question)

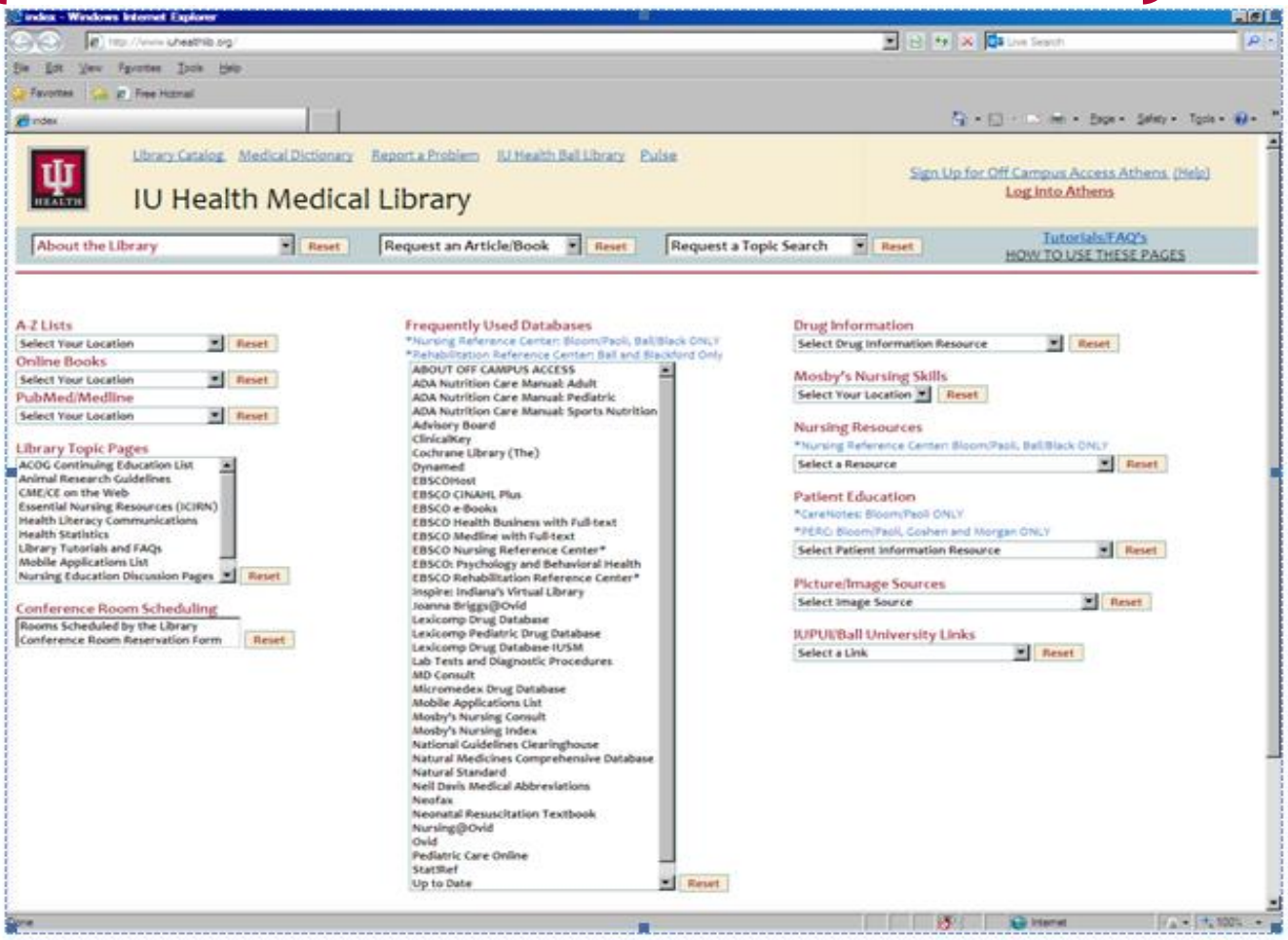
   A specific age group (if relevant for the research question*)*

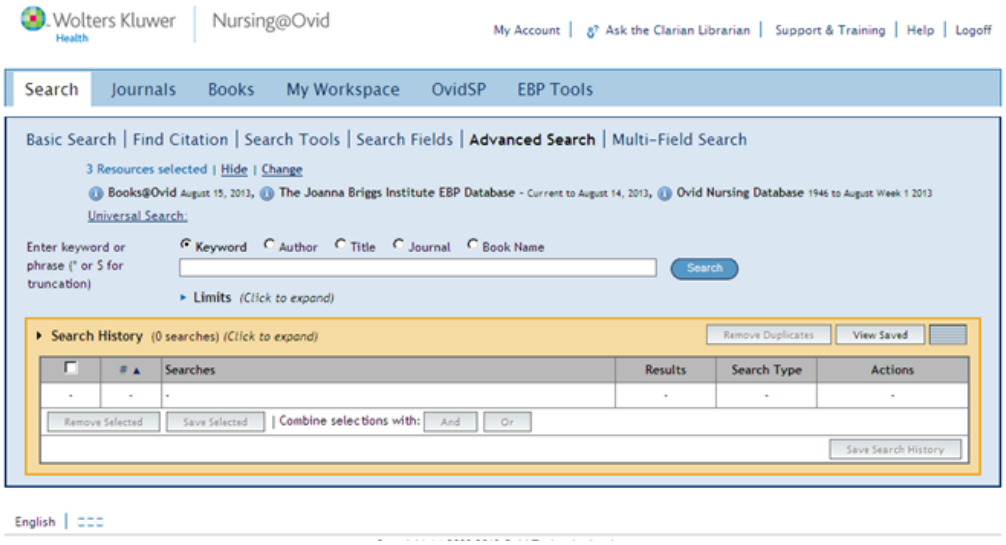
   Other limiters:

IU Health Medical Library

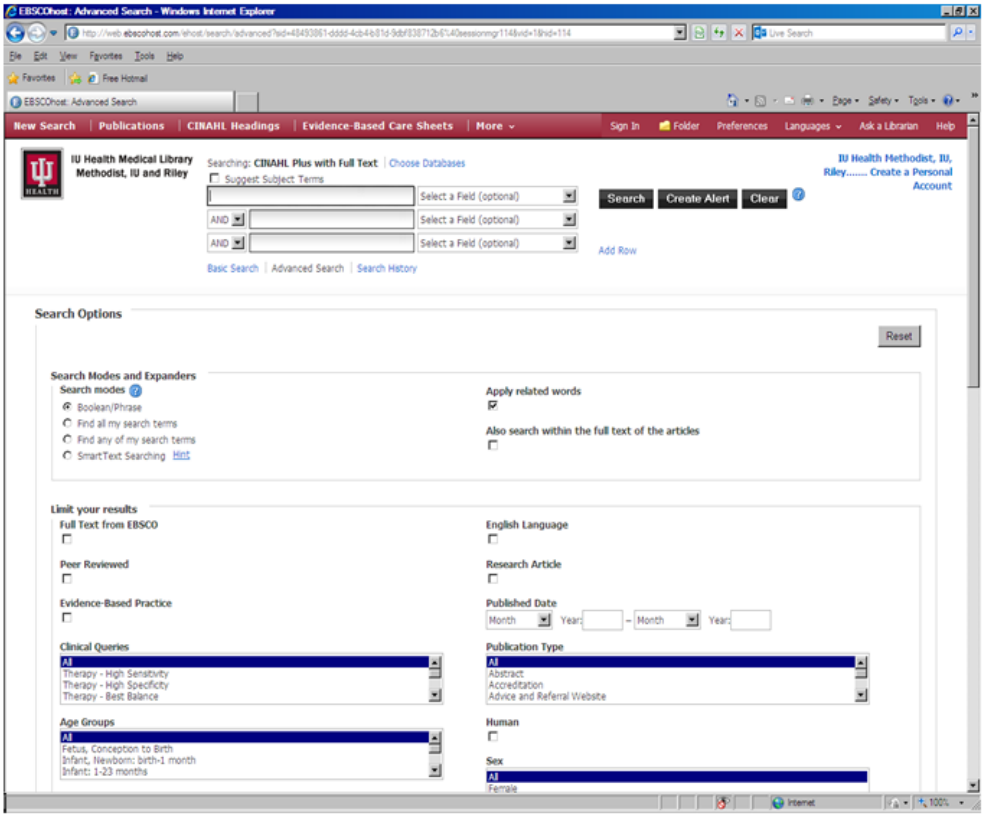
The IU Health Medical Library located at IU Health Methodist Hospital is an excellent resource for assistance with information searches. Electronically access the library at this link: http://www.iuhealthlib.org/

- **The IUH Medical Library is accessed from the Pulse page.**
- **It is listed under "Frequently Used Links" on the front page.**
- **The A-Z Lists in the database of the journal are titles owned by IU Health.**
- **Principle databases for EBP in nursing are EBSCO, CINAHL and Nursing@OVID.**
- **The Joanna Briggs database is a part of Nursing@OVID.**





Nursing @ OVID screen shot



EBSCO CINAHL screen shot

Tips:
Searching for the evidence can be overwhelming at first. Remember to narrow your search by key words, read the abstract, look for the PICOT features, and enlist the aid of the IU Health Medical Library (317.962.8021) or professional organization.

Different Levels of Evidence:

Level 1	**Evidence from a systematic review of all relevant randomizes controlled trials (RCT)**
Level 2	**Evidence-based clinical practice guidelines based on systematic reviews of RCTs**
Level 3	**Evidence obtained from a least one well designed RCT**
Level 4	**Evidence obtained from well designed controlled trials without randomization and from well designed case control and cohort studies**
Level 5	**Evidence from systematic reviews of descriptive studies and qualitative studies**
Level 6	**Evidence from a single descriptive or qualitative study**
Level 7	**Evidence from the opinion of authorities and or/reports of expert committees**

Melynk and Fineout-Overholt, 2010

Pyramid of Rigor of Research Study Designs

Rani Gereige, MD, MPH, FAAP, University of South Florida
health.usf.edu/NR/...AC48.../TypesofResearchStudiesAug1507.ppt

Choosing a Research Study Design

The following table provides the type of study design that may be most useful for your study:

If your question is about…	Consider this design…
Intervention or therapy	**Randomized controlled trial**
Diagnosis/screening **To assess effect of test on health outcomes**	• **Cohort study** where all subjects receive **both** the study test and gold standard reference test • Randomized control trial
Prognosis	• **Longitudinal cohort**
Etiology/risk factors	• **Randomized controlled trial** • Cohort for rare exposure with common outcome • Case control for rare outcome with common exposure

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Appraisal Prompts for Different Research Study Designs

	Study design				
	Systematic review	**RCT**	**Cohort**	**Case control**	**Case series**
Subject selection	• Focused research question • Specified inclusion/exclusion criteria • Comprehensive search strategy documented	• Specified inclusion/exclusion criteria • Adequate method of randomization • Groups similar at baseline	• Specified inclusion/exclusion criteria • Patient groups comparable except for exposure	• Specified inclusion/exclusion criteria • Explicit definition of cases • Controls of randomly selected from the source population • Comparable groups with respect to confounders	• Specified inclusion/exclusion criteria • Explicit description of study subjects
Blinding	• Reviewers blind to author, institution & affiliations	• Patients/ investigation/ assessors • Concealment of allocation	• Outcomes assessed blindly with respect to exposure	• Outcomes assessed blindly with respect to disease status	• Not applicable
Follow-up	Not applicable	• Sufficient duration • Proportion lost to follow-up	• Sufficient duration • Proportion lost to follow-up	• Sufficient duration	• Sufficient duration
Assessment of outcome/exposure/ intervention	• Validity of included trials appraised • Homogeneity between studies assessed • Summary of main results presented • Strengths and limitations of included studies discussed	• Assessed objectively and independently • Intention-to-treat analysis	• Assessed objectively and independently • All selected included in analysis	• Assessed objectively and independently • All selected included in analysis • Assessed same way for cases and controls	• Assessed objectively and independently • All selected included in analysis

Evidence-Based Answers to Clinical Questions for Busy Clinicians Workbook

Table of Analysis of Key Research Studies

PICO: ***In parents of high risk infants and children, is confidence and competency higher when they are trained by an instructor as compared to other methods?***

Tracy Swift, Lisa Demott, Terre Holland for Jul 21, 2015 NREBP

Source	Variables Studied	Sample	Key Findings	Level of Evidence	Should we discontinue use of (name of intervention) based on this study?
Example Only: Boelig et al., 2011	Inpatient falls and MCD	3,562 patients with MCD who fell during hospitalization	Less than 0.5% of falls were related to MCD and were no more injurious than other falls.	Level C – comparative correlational design	No. We should not discontinue MCD to prevent falls.
Duffield, C., et al (2011). Applied Nursing Research	Nurse staffing, nurse workload, working environment, skill mix, patient outcomes, patient discharge	Design: Combined longitudinal retrospective and concurrent cross-sectional methods. (Australia public hospital system) **Longitudinal design**: Data from Payroll for 286 units in 80 hospitals (workforce data). **Cross-sectional design**: Data from 80 med-surg units	Units with higher numbers of RN/CNS staffing had significant decrease rates ($p \leq .01$) in decubiti, GI bleeding, physiological/metabolic derangement, pulmonary failure, sepsis, and shock. There was also a decrease in medication errors, mostly correction of med delays without consequences. Lower RNs units staffed showed tasks most not	Level I -Mixed longitudinal/cross-sectional design In-depth literature review international with particular focus on UK, Canada, USA, including Magnet Hospitals	Our PICO questions are: Are quality and safety outcomes impacted by nurse staffing? **Yes** Is patient satisfaction impacted by nurse staffing? **Yes** **Article Supports Change in Practice for Nursing Practice? Yes**

		in 19 hospitals	done: comforting/talking to patients, skin care and back rubs, oral hygiene, education to patients/families, documentation. Most delayed tasks: call light response, medications, dressing changes, mobilization/turning patients, and giving pain medications.		
Shuldham, C., et al (2009). International Journal of Nursing Studies	Nurse staffing characteristics, clinical areas, patient outcomes, nurse hours worked by permanent and temporary staff	Two hospitals (Specialty: cardio/respiratory) (National Health Trust in England) n= 23,192 adult pt's n= 2315 pediatric pt's	Increased staffing: <Falls, < GI Bleeds, < Sepsis, and < DVT's. >Pressure Ulcers, > Shock	Level III - Is a non-controlled study based on existing on retrospective data. Numbers of patients and ties into the larger organization of the National Health Trust of England was confusing and not clear. The population n= was not clear because of this, though the authors cited a limitation of this	Are quality and safety outcomes impacted by nurse staffing? **Yes** Is patient satisfaction impacted by nurse staffing? **Yes** **Article Supports Change in Practice for Nursing Practice? No**

				study is small population studied. It would be hard to generalize across multi-specialty units and populations. Further studies would be indicated.	
Garrett, C. (2008). AORN, Inc.	Nurse staffing patterns, medical errors, nurse burnout, patient outcomes	Is not a study, but a literature review discussion.	The literature review indicates that inadequate staffing leads to adverse patient outcomes and increased nurse burnout.	Recommendation is for hospital administrators to increase staffing and decrease errors which also lead to cost savings. *Also cites an AHRQ report to support adverse patient events increased costs	Are quality and safety outcomes impacted by nurse staffing? **Yes** Is patient satisfaction impacted by nurse staffing? **Yes** **Article Supports Change in Practice for Nursing Practice? Yes**

Identifying a Research Study's Design

<table>
<tr><td colspan="5">Are two or more groups of people being compared?</td></tr>
<tr><td colspan="4">Yes</td><td>No</td></tr>
<tr><td colspan="4">Comparative studies</td><td>Descriptive studies</td></tr>
<tr><td colspan="4">Are people randomly allocated to the groups?</td><td>Is there more than one person in the study?</td></tr>
<tr><td>Yes</td><td colspan="3">No</td><td>Yes</td><td>No</td></tr>
<tr><td rowspan="6">Randomized controlled trial (RCT)</td><td colspan="3">Non-randomized comparative studies</td><td rowspan="6">Case series</td><td rowspan="6">Case study</td></tr>
<tr><td colspan="3">Do the researches allocate people to the groups (but not randomly)?</td></tr>
<tr><td>Yes</td><td colspan="2">No</td></tr>
<tr><td rowspan="3">Controlled trial</td><td colspan="2">Are the people selected to be in the groups because they have had a particular treatment, test or exposure?</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td>Cohort study</td><td>Are the people selected because they have a particular disease (cases) or don't have that disease (controls)?
Yes
Case-control study</td></tr>
<tr><td colspan="6">←Highest quality evidence Lowest quality evidence→</td></tr>
</table>

Evidence-Based Answers to Clinical Questions for Busy Clinicians Workbook

Template Sample – SBAR Executive Summary of a Review of Evidence

Name: Edward Leung, PharmD with the Center for Medication Safety

Contact details: email = leunge@iuhealth.org phone = 317-962-0632

Situation	• Appendix A and B of the System Nursing Patient Care High Alert Medication (PCHAM) policy needs to be finalized by nursing.
	  ○ Appendix A includes a list of high alert medications and routes approved at IU Health and if mandatory independent double check (IDC) are required in Cerner.
	  ○ Appendix B includes the criteria IU Health uses to determine if a specific high alert medication qualifies or disqualifies for mandatory IDC.

Background	• Appendix A was revised in June 2015 to remove five medications from the mandatory IDC rule in patients less than 6 months of age.
	  ○ The high alert meds removed were Morphine, Methadone, Midazolam, Lorazepam, and Fentanyl injections in peds < 6 months of age.
	• In August 2015, a proposal was submitted to IDC chemotherapy medications only.
	• In January 2016, clinical nurses were uncomfortable with the proposal to remove all the mandated IDC except for chemotherapy medications.
	• In February 2016, a small task force convened to nominate criteria that IU Health will use to determine if a high alert medication requires IDC.
	• In March 2016, the IDC criteria were reviewed by 9 IU Health hospitals and the final version was submitted to the PCHAM policy as appendix B.
	 
	IDC criteria for Appendix B.pdf
	• Using the criteria in appendix B, IU Health removed 6 high alert medications that required IDC from appendix A and introduced a new high alert medication that will require IDC in the future.
	• In April 2016, Appendix A & B were submitted for final approval at MSAC. Appendix A was denied at MSAC. Rationale for denial:
	  ○ MSAC members felt the IDC safety strategy is not going to detect or prevent med errors when changing high alert medications' infusion rates.
	  ○ Members felt the IDC list is too long. IDC is effective when performed correctly and only if it is judiciously used. The list of high alert medications that must have IDC should be reduced.

Assessment	Baseline data: • The Center for Medication Safety performed a retrospective chart review on incident reports related to IDC between January 1st 2015 and December 31st 2015. • The results showed that IDC is performed incorrectly a majority of the time when high alert medications are administered. These findings are similar to the comments obtained from the August 2015 System Professional Practice Steering Committee.  Combined IDC Data Collection form.xls • Mandated IDC that is not understood by clinical nurses could create a false sense of security for IU Health system which was revealed in a round robin session in August 2015 at the Professional Practice Steering Group (PPSG).  PPS_IDC_Feedback_ 08.2015.pdf Points to Consider: • Med Safety is aware that medication variances occur when insulin infusion rate change, heparin infusion rate change, and opioid PCA setting change. In 2015, the number of high alert med errors reported as a result of infusion rate changes is approximately (TBD…) • Mandating IDC at the beginning of each new bag of high alert medication infusion and not mandating IDC when the infusion rate is changed renders the IDC process inconsistent and weakens the patient safety objective for using IDC. • Independently double checking every single infusion rate change for a specific high alert medication has been critiqued for the increase workload it will cause the nurses.
Recommendation	• IDC is effective if done correctly.[1,2,3,4,5] Pharmacy supports the use of IDC even with a lack of strong evidence supporting its efficacy. Med Safety is asking the Research to Practice Council and the PPC to review the list of medications in Appendix A and provide recommendations.  NURSING High Alert Med -Appendix A trac • Please suggest alternative solutions to make IDC a more robust safety strategy for detecting med errors with system high alert medications.

References	1. ISMP. Santa checks his list twice. Shouldn't we? *ISMP Medication Safety Alert!* 2009;14(25):1-2. 2. ISMP. The virtues of independent double checks—they really are worth your time! *ISMP MedicationSafety Alert!* 2003;8(5):1. 3. ISMP. Conducting an independent doublecheck. *ISMP Nurse Advise-ERR*. 2008;6(12):1. 4. Grasha T, Reilley S, Schell K, et al. Process and delayed verification errors in community pharmacy: implications for improving accuracy and patient safety. Technical Report Number 112101. Cognitive Systems Performance Lab. 2001. www.ismp.org. Accessed January 6th, 2015. 5. Campbell GM, Facchinetti JN. Using process control charts to monitor dispensing and checking errors. *Am J Health Syst Pharm.* 1998;55(6)492-7.

Evidence-Based Practice Report Form Advancing Research and Clinical Practice through Close Collaboration		
Step 1	**Ask a clinical question.** (Briefly summarize the inquiry or problem identified.)	(Specify the clinical question.) P: I: C: O: T:
Step 2	**Collect the best evidence.** (List pertinent references and indicate level of evidence, i.e. systematic review, randomized control trial, clinical practice guidelines, original research, qualitative studies, etc.)	

Step 3	**Critically appraise the evidence located.** (Summarize the findings for validity, reliability, relevance, and applicability.)
Step 4	**Integrate the evidence with one's clinical expertise, patient preferences, and values.** (Summarize the preferences/ values under consideration, and how your expertise impacts your understanding of the evidence located.)

Step 5	**Evaluate the practice change or decision.** -What change or decision was made? -What was the outcome or impact?

Melnyk, B. M. & Fineout-Overholt, E. (2005). *Evidence-Based Practice in Nursing and Healthcare: A guide to Best Practice*. Philadelphia, PA: Lippincott Williams and Wilkins.

Communication Template

(Could be used to communicate evidence or a clinical inquiry)

Structure format: Things to keep in mind

WHO The Recipients	**WHY** The Purpose	**HOW** The Process	**WHAT** The Result
Who do you serve? Why is IU Health in business?	What is your cause? What do you believe?	Specific actions taken to realize the WHY.	What do you do? The result of the WHY. Proof.

Communication is most effective when the recipient knows WHAT IS IN IT FOR ME (WIII-FM)!

Write a draft of your communication…

WHO	
WHY	
HOW	
WHAT	

References

Alper, B. S. *Practical Evidence – Based Internet Resources*, Family Practice Management, July/August 2003, Vol 10, No 7, pages 19-22

Evidenced – Based Answers to Clinical Questions for Busy Clinicians, (2009) The Centre for Clinical Effectiveness, Southern Health, Melbourne, Australia

Melynk, B., Fineout-Overholt, E., Implementing Evidence – Based Practice, Real Life Success Stories, Sigma Theta Tau International, 2011

Melynk, B., Fineout-Overholt, E., Evidence – Based Practice in Nursing and Healthcare, A Guide to Best Practice, 2nd edition. Lippincott Williams & Wilkins, 2010

Melynk, B., Fineout-Overholt, E., Evidence – Based Practice in Nursing & Healthcare, A Guide To Best Practice, Lippincott Williams & Wilkins, 2005

Joanna Briggs Institute, http://www.joannabriggs.edu.au/pdf/BPISEngSup2000pdf

Cochrane Collaboration, http://cochrane.org/reviews/revstruc.htm