Winnipeg Regional Health Authority | Office régional de la santé de Winnipeg
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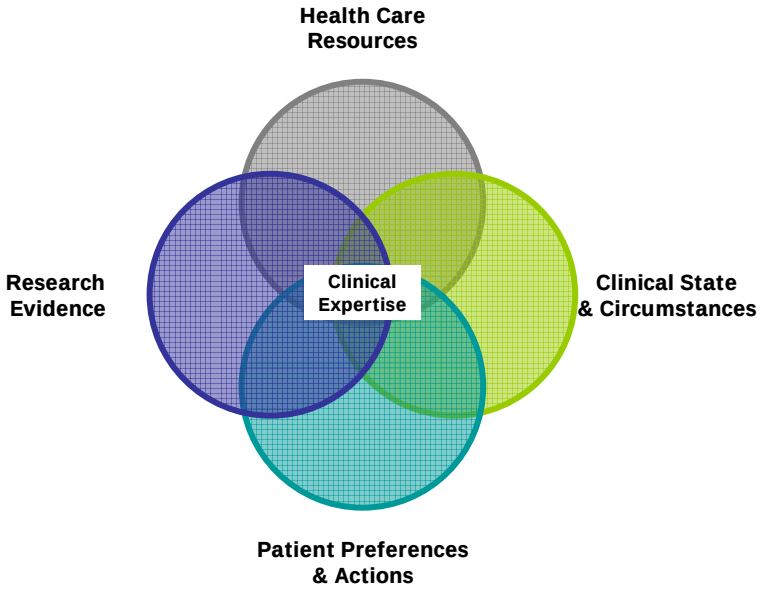
EVIDENCE-INFORMED PRACTICE
Resource Package

TABLE OF CONTENTS:

This package provides the framework for practitioners to apply best practices to clinical situations, increasingly be known as evidence-informed practice (EIP). It begins with introducing the concepts in evidence-informed practice and the steps from asking clinical questions, searching for and critiquing literature, grading literature and making recommendations, and finally planning and implementing practice change. An Algorithm for the entire process is found in Appendix A. Throughout this package there are levels, which correspond to the workshops that are offered to facilitate discussion and learning.

Level 1: INTRODUCTION TO EVIDENCE-INFORMED PRACTICE (EIP)

Evidence-Informed Practice Model



Evidence-informed practice is an approach to practice that is continuing to evolve as understanding and expertise increases. It is generally agreed that clinical practices should be based on "evidence". The nature of the evidence however is the most debatable. Not all areas of clinical practice are well studied. There are also other areas of evidence that must be incorporated. In this model, research evidence has an equal footing with health care resources, clinical state & circumstances and patient preferences. It is clinical expertise that

ties them all together to inform practice decisions. This clinical expertise takes the form of knowledge of each of the domains in the model, but also in the skills required to pull them into the equation when decisions about practice in individual situations or in more global recommendations are being deliberated.

The process that should be used to make decisions on best practices must involve a systematic approach to the literature and other sources of evidence. Be specific about the population, patient or clinical problem. This package outlines an approach that involves focusing the clinical questions, reviewing individual pieces of evidence using tools to guide assessment of quality of a study, and then evaluating the evidence *across* studies and other sources of evidence using the GRADE approach. There are many terms in this learning package that may not be familiar to you. Appendix F contains a glossary that gives definitions and explanations of how these terms apply to evidence-based practice.
The steps in the evidence-based practice process are outlined in the algorithm in Appendix A. They start with defining the clinical questions, gathering and then evaluating the evidence, grading the evidence across studies, assessing overall quality of the evidence and determine the influence of critical outcomes as well as impact of resources, clinical experience and patient preferences. The last two steps involve making the recommendation for practice and the last crucial step of developing an implementation plan. These steps are outlined in this package. This diagram also depicts the relationships between the research evidence, clinical expertise, which is considered the lowest level of evidence, but important particularly to practitioners, resources, and patient's preference. Where they intersect is best practice for that situation. This package provides the steps to finding that middle ground.
The Canadian Institutes of Health Research have published Knowledge Translation Learning Modules which are available free of charge to download.

Step 1: Forming Clinical Questions

Clinical questions arise from case studies, review of the patients in your practice, or from policies, procedures, practice guidelines or learning packages that are being developed or reviewed. Any one of these situations may raise a number of specific clinical questions. Each question should be addressed separately in order to assist you in determining what the best practice should be. Be specific about the population, the interventions that are relevant and appropriate comparisons or alternatives, and all relevant outcomes of the intervention.
Using the letters PICO may help you to remember the parts of the questions:

P = population
I = intervention
C = comparison
O = outcomes

When it is difficult to focus the question review articles are useful in helping to define the situation for you and may lead you in the right direction. They may also provide useful references to research studies.

Another approach to helping formulate questions is to frame them in a way that incorporates these components:
Among……Does…..Impact….? This provides you with the population, the intervention / comparisons, and the outcomes or effects.

Step 2: Gathering Evidence

There is a hierarchy of evidence that will help you in your search. Appendix B shows a picture of a proposed hierarchy of evidence. It is important not to view the hierarchy as a way to value but rather a ladder of increasing filtering and processing. The highest levels include resources where evidence is the most rigorously processed and filtered in reliable ways, with the most specific being the decision support systems. Systematic reviews and meta-analyses can also be very useful, as they have done some of the review of the evidence for you, and can point you to the original sources. Middle levels include well-designed and well-conducted randomized controlled trials performed on a population similar to your target population. Randomized controlled trials provide less biased estimates of potentially harmful effects than other study designs because randomization is the best way to ensure that groups are balanced with respect to both known and unknown determinants of outcome. Other types of clinical trials can provide a high level of evidence as well after careful examination, so they should not be eliminated. These include observational studies with case-control or cohort designs. As you go up the ladder there is more filtering and more evaluation of the evidence by the organization or group that has published it.

The lowest levels of evidence come from case reports, reasoning from principles of pathophysiology and expert opinion based on clinical experience. These sources of evidence guide much of our practice, and cannot be ignored when making practice recommendations, especially for questions where there are few or no randomized trials. It is also our clinical expertise which is necessary in pulling in the other realms of EIP, the clinical setting, resources and patient preference.

It is important not to assign the quality of the evidence based on an abstract or study design, but to look at it systematically first. As you go through the process you may find that evidence that starts out looking like high quality, comes out with a lower rating, and evidence which is not a randomized controlled trial, may indeed be high quality evidence. Reserve your value judgments.

Incorporate the aspects of your question to focus your literature search questions. The more exhaustive your search, the more confidence you have in your recommendations. You can either do the search yourself, or enlist the help of a librarian to teach you how, or conduct the search for you. They will provide you first with all abstracts and then collect the articles that you indicate that you require. To evaluate evidence it is helpful to limit your search to clinical trials, meta-analyses, and systematic reviews.

Published practice guidelines can be a useful source as well to help focus the questions and locate relevant references. It is important to read practice guidelines critically as well, to ensure that they are evidence-based and not just experience based. They should indicate the strength of their recommendations either at the end of the recommendation statements or in the reference list. When there is a lack of research related to the question lower levels of evidence such as review articles and expert opinion may be used.

Utilize library resources to collect all relevant literature. The Neil John McLean Health Sciences Librarian can be contacted at 789-3344 to set up an appointment if you need help or want a one-on-one tutorial.

Resources for Level 1:
Evidence-Based Journals (access through University of Manitoba Libraries website), provide excellent commentaries that define terms and explain concepts in evidence-based and evidence-informed practice. They also provide numerous examples of well formed questions that can serve as templates and examples to incorporate into practice situations. The University of Manitoba Neil John McLean Health Sciences Library provides services in literature search as well as session to teach groups and individuals how to do effective searches. Many of the textbooks listed in the reference list are useful to help understand EIP and learn various approaches to asking "answerable" questions. For each level there are resources found through the Winnipeg Regional Health Authority Research and Evaluation team. Their Intranet site is accessed through the link at http://home.wrha.mb.ca/research/index.php .

Level 2: CRITICAL APPRAISAL OF THE LITERATURE

Step 3: Evaluate the evidence

All research has flaws. Some are trivial enough that the results still stand. Others are serious enough to decrease the quality of the results, but they can still be used to guide practice in the context of other research. Some are so critical that the research provides no useful information at all. The trick in evaluating research is not in finding the flaws but in determining the extent to which they affect the credibility of the results.
Different types of research require different types of questions in order to evaluate them effectively. A full set of User's Guides are available on the website of the Centre for Health Evidence. These have a highly medical focus however and many of the questions may not be appropriate for nursing research. There are also worksheets available in the appendix of this package for some types of literature. When evaluating a clinical practice guideline, the most comprehensive instrument is the AGREE Appraisal Instrument. It can be downloaded from the website at www.agreecollaboration.org .
The following are some common questions that should guide you in evaluating the quality of individual treatment studies.

Study Question

- Is the problem clearly and concisely stated?
- Is the research question one that can be answered with research evidence?
- Does the report include definitions of terms needed for a clear understanding? Are they valid definitions?
- Is the problem likely to be relevant to people other than those involved in the study?

Sampling

- Is the sample representative of the population to which investigators plan to generalize?
- Is the participant / refusal rate less than 20 percent?
- Were subjects randomized? Was randomization concealed?
- Did experimental and control groups begin the study with a similar prognosis?
- Are differences between experimental and comparison groups controlled?

Measurement & Follow-Up

- Did groups retain a similar prognosis after the study started?
- Were subjects, clinicians, outcome assessors aware of group allocation?
- Do the measurement methods/tools actually measure what they were intended to measure?
- How reliable and valid are the measurement tools used in the study?
- Were outcomes and exposures measured in the same way in each group?
- Were patients analyzed in the groups to which they were randomized? (intention-to treat)
- Was follow-up complete?

Validity

- Are the findings most likely caused by the variables being studied and not another cause that was not considered in the study?
- Have threats to validity been ruled out: history, experimental mortality, selection bias, maturation, testing effects, instrumentation error, statistical regression and selection-maturation interaction. (*see appendix F for definitions*)

Strength of the Results

- How large was the treatment effect?(risk reduction etc.)
- How precise was the estimate of the treatment effect? (How wide is the confidence interval)
- Are designated probability levels set at .05 or less? (*p-values*)
- Are claims of significant findings supported by the data? *(See Appendix C to do your own estimate based on the raw data that they provide in the report if they do not report their stats).*
- If more than one variable is manipulated in the study is adjustment made for the way the two or more variables influence each other?
- Has a power analysis been performed? Did they have the number of subjects that their power analysis indicated?
- Are statistically significant findings clinically significant?

Conclusions:

- Are conclusions warranted by data and/or the design of the study?
- Could the outcomes of the subjects be caused by something other than the study variables?

Applicability

- Were study subjects similar to my patients?
- Were all clinically important outcomes considered?
- Are the likely treatment benefits worth the potential harm and costs?

Resources for Level 2:

The Centre for Health Evidence is found at www.cche.net and the journal *JAMAevidence* (linked from the University library site in order to utilize their account), provide excellent resources for assisting in appraisal of the literature.

The "What is" series found at the website: http://www.whatisseries.co.uk/whatis/ provides straightforward explanations of terminology used in critical appraisals.

The Occupational Therapy Evidence-Based Practice Research Group at McMaster University provides downloadable critical appraisal forms and user guides on their website at: http://www.srs-mcmaster.ca/Default.aspx?tabid=630

Level 3: GRADING EVIDENCE AND MAKING PRACTICE RECOMMENDATIONS

There are several levels at which you may find yourself making recommendations. You may be making recommendation for wider application such as unit-based practices or guidelines. The following outlines the process for these types of recommendations using the GRADE Process which was introduced in 2000. It was developed by a consortium of individuals involved in organizations that grade evidence or make recommendations for practice. They are called the GRADE working group found at their website: www.gradeworkinggroup.org. They provide free software that you can download through their site to use for doing formal literature evaluations.

GRADE stands for "Grading of Recommendations Assessment Development and Evaluation. Some of the over 25 organizations that endorse the GRADE process and use it in their recommendations include:
Cochrane Collaboration
The Endocrine Society
The American College of Chest Physicians
Ontario Ministry of Health and Long Term Care
American Thoracic Society
British Medical Journal

Organize the Literature

Start by using the worksheet in the appendix to organize the literature that speaks to the same specific question. Once you have entered each study onto the worksheet you can make a first assessment of the strength of the evidence using the descriptions in the box below. Work through the questions that follow to either increase or decrease your assessment of the strength of the evidence in order to determine your final recommendation.

Step 4: Grade of Evidence for Each Outcome

Overall grade of the quality of the evidence:

High = Further research is very unlikely to change our confidence in the estimate of effect.
Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Very Low = Any estimate of effect is very uncertain.

Determine the quality of evidence ***for each main outcome*** after considering each of four elements: study design, study quality, consistency between studies and directness/applicability to your patient/s. Appendix C contains a worksheet that may be helpful in organizing your evaluation.

Design:

- Look at study design between randomized controlled trials and observational studies separately first.
- Look at your evaluation of all the studies that measured that outcome and consider whether there are serious limitations to the way the studies were conducted.

Quality:

- Compare the results from your analysis of the quality of each study.
- Determine if there are concerns about imprecise or sparse data.
    - Data are sparse if the results include just a few events or observations and they are uninformative
- Data are imprecise if the confidence intervals are sufficiently wide that an estimate is consistent with either important harms or important benefits.
- The threshold for considering data imprecise or sparse should be lower when there is only one study. A single study with a small sample size (or few events) yielding wide confidence intervals spanning both the potential for harm and benefit should be considered as imprecise or sparse data.
- If the Confidence Intervals for a study of a positive treatment effect include 1 or for a study of a harmful effect include 0, the data is imprecise.
- Quality of the data can also be downgraded if there is high risk of reporting bias (such as drug company sponsored study indicating their drug as better than another)
- Quality can be increased if there is a very strong association (a very low p-value, or a very high risk reduction rate), if there is evidence of a dose response gradient, or if there is still a statistically significant effect even if presence of all plausible confounders would have reduced the observed effect.

Consistency

- Are there consistent results between studies.
- Inconsistency exists when studies have opposing results for similar interventions.

Directness (Applicability)

- To what extent are the people, interventions, and outcome measures in the studies similar to those in your question? For example, there may be uncertainty about the directness if your patients are older, sicker, or have more comorbidity than those in the studies.

Start with a default rating based on the type of evidence:

Randomized trials = high
Observational studies = low
Any other evidence = very low

Decrease grade if:

- Serious (-1) or very serious (-2) limitation to study quality
- Important inconsistency (-1)
- Some (-1) or major (-2) uncertainty about directness
- Imprecise or sparse data (-1)
- High probability of reporting bias (-1)

Increase grade if:

- Strong evidence of association – significant relative risk of >2 (<0.5) based on consistent evidence from two or more observational studies with no plausible confounders (+1)
- Very strong evidence of association – significant relative risk of >5 (<0.2) based on direct evidence with no major threats to validity (+2)
- Evidence of a dose response gradient (+1)
- All plausible confounders would have reduced the effect (=1)

All of the considerations of design, quality, consistency and directness can lower the grade of the evidence. If all studies have very serious limitations the grade will drop by two levels. Fatally flawed studies may be excluded completely. In order to assign a grade you start with a default grade based on the type of evidence and move up or down based on evaluation criteria as outlined below. Other modifying factors can include any other concerns you may have with the studies.

Assess overall quality of evidence / select critical outcomes

Determine which outcomes are critical to making decisions:

- Critical
- Important but not critical
- Not important.

These are value judgments so you need to take into account the values of those who will be affected by the recommendations. When there is more than one outcome that is critical generally choose the lowest quality level of evidence among those outcomes. This is when you need to look at the balance between harm and good, if there is potential for harm from the intervention. Does the end justify the means, or is the cost too high?

Step 5: Make Recommendations About Specific Practices

Recommendations involve a trade-off between benefits and harms. You will need to place a value judgment on the weight to give each of outcomes, including adverse effects. First consider if the intervention does more harm than good in a specific setting to a specific group of patients. Then consider the costs involved, and if the benefits are worth the costs. This will unfortunately involve major value judgments. To categorize the trade-offs:

- Net benefits = the intervention clearly does more good than harm.
- Trade-offs = there are important trade-offs between the benefits and harms
- Uncertain trade-offs = it is not clear whether the intervention does more good than harm
- No net benefits = the intervention clearly does not do more good than harm.

When making recommendations consider the four main factors:

- The trade offs, taking into account the estimated size of the effect for the main outcomes, the confidence limits around those estimates, and the relative value place on each outcome
- The quality of the evidence
- Translation of the evidence into practice in a specific setting, taking into consideration important factors that could be expected to modify the size of the expected effects, such as proximity to a hospital or availability of necessary expertise
- Uncertainty about baseline risk for the population of interest.

If there is uncertainty about translating the evidence into practice in a specific setting, or uncertainty about baseline risk, this may lower the confidence in a recommendation

Categories for recommendations:

- "***Do it***" or "***don't do it***" indicating a judgment that most well informed people would make
- "***Probably do it***" or "***probably don't do it***" – indicating a judgment that a majority of well informed people would make but a substantial minority would not.

Step 6: Apply Recommendations to Clinical Setting

The research evidence is not the only thing to consider when making recommendations. It is not always possible to do the "best" thing. The evidence may not be clear, and may provide little assistance in making recommendations. In addition to research evidence, the other three areas of evidence-based practice that one must consider (as per the model) include:

1. **Resource** allocation for any new intervention must be considered. For example: what sacrifices must be made if addition new funding is not available and funding must be reallocated from within the area. In some cases the resources may simply not exist.
2. **Patient Preferences** must be considered. In particular situations patients or families may not accept the recommendation(s). In some situations, you will be able to determine what groups or patients prefer. What works in one hospital or area may not work in another, if their patient population differs significantly. Surveys may provide some of this information. Past experience may provide additional insights. It is important to not make assumptions or paternalistic decisions before consulting with important stakeholders.
3. **Clinical Expertise** has an important role to play regardless of the strength of the evidence. When the evidence indicates the opposite of what local clinical experts believe to be true, something has to change. It may be that clinicians are holding fast to strong beliefs about specific practices that are not supported by research. These must be explored to determine the underlying beliefs in order to facilitate dialogue, plan and implement a more appropriate practice. Remember beliefs then attitudes then behaviours. In other cases, the research may unveil truths that no one has considered before. Patient population is also very important when applying research findings. If the local population is significantly different that the study populations, the findings will be difficult to apply. Other ways to gather the opinion of experts is through review of published reviews, talking to colleagues locally, phoning similar clinical areas across the country, utilizing Internet (reputable) discussion sites etc. These strategies can assist you to build a larger body of clinical expertise beyond a small group of local experts who may have very similar experiences. When a new practice is being considered it is always useful to discuss it with people who are already doing it to find out how they implemented it and what differences they see in the clinical area. It is important to involve the clinicians (general duty nurses etc) in this deliberation process so that when implementation plans are made, they are already invested in the process.

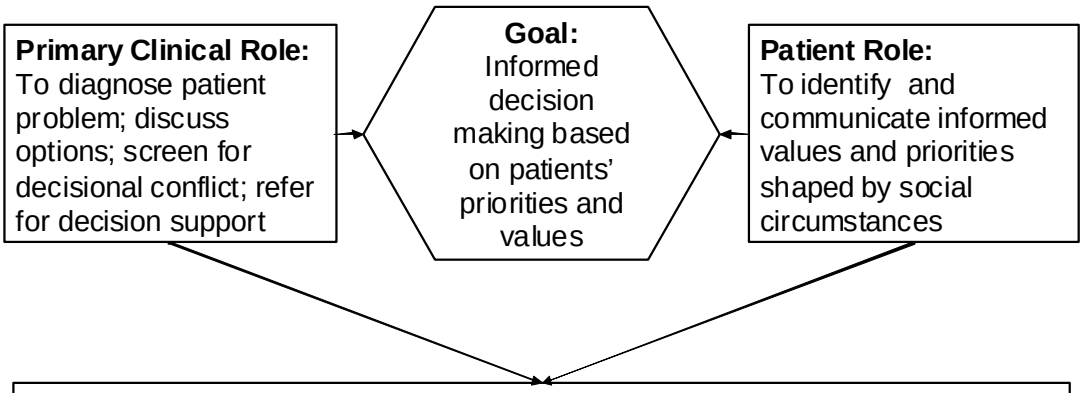
If the practice or innovation that you are recommending is not currently part of practice in your clinical setting, a practice change may be indicated. In order to assist you in assessing the value of pursuing this practice, use the scoring tool found in Appendix E.

Taking Existing Guidelines and Applying Them

There are many organizations and publications who make practice guidelines available. A literature review may help you find them. Internet searches can also be useful in finding them. If you are lucky enough to locate a practice guideline that relates directly to your clinical question, you will need to evaluate it carefully. A good resource to help you do this is from the AGREE collaboration. Their tools are available at www.agreecollaboration.org Tools can be downloaded directly from their site with instructions on how to use them. A clinical practice guideline should also be critically appraised to assess it's quality. Appendix C contains a worksheet to assist you in carrying out this critical appraisal.

Recommendations for Individual Patients: Decision Coaching

Health care practitioners have a long history of giving opinions and recommendations to patients and clients. This role is evolving into a non-paternalistic approach with a more supportive role which has been referred to as decision coaching. The decision coach assists. The following framework outlines the roles of individuals in situations where difficult decisions need to be made:



Decision Coach Role:(Ottawa Decision Support Framework)
Prepare the patient to participate in decisions by:

1. Assessing decisional needs (decisional conflict, knowledge, values clarity, support).
2. Providing decision support tailored to needs (evidence-based patient decision aids, coaching).
3. Monitoring and facilitating progress in resolving needs and decision quality.
4. Screen for implementation needs.

From: (Stacey et al. 2008)

Patient decision aids are tools that help people become involved in decision making by providing information about the options and outcomes and by clarifying personal values. They are designed to complement, rather than replace, counseling from a health practitioner. In these cases you are like a "decision coach", where your role is not to give advice or make a specific recommendation, but are there to provide the information necessary for them to make an informed decision. The decision aids available from the Ottawa Health Research Institute can be useful. If there is not a specific decision application to the situation, you can use the generic one to help guide you through the process. The website provides guidelines in how to develop evidence-based decision aids and houses an A to Z inventory of ones that have been developed using their criteria on a wide range of

very focused questions. When you can't find a tool for the question you have, they also have a general tool called the Ottawa Personal Decision Guide that assists the individual to walk through the decision. This process can be facilitated by the decision coach, but cannot be done for the individual as the integral parts of the decision rest with the individual and their family.

Resources for Level 3:

In addition to the resources already listed the GRADE working group website can also provide guidance in grading literature and making recommendations. It is found at www.gradeworkinggroup.org.

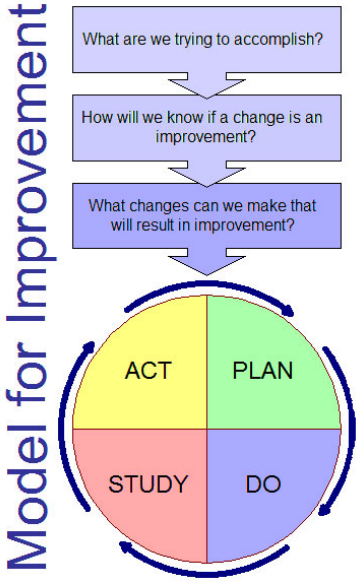
Decision aids and information about how to use them are found at the website of the Ottawa Health Research Institute at: http://decisionaid.ohri.ca. Find the Ottawa Personal Decision Guide and Family Decision Guides at this site.

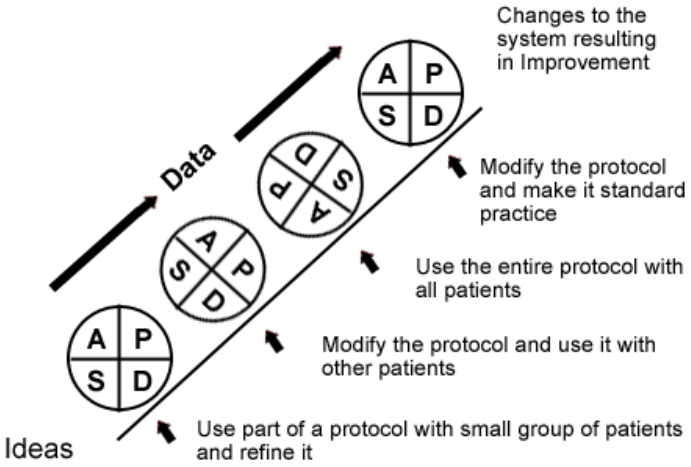
To learn more about how to be a Decision Coach try the Ottawa Decision Support Tutorial offered on their website.

Level 4: PLANNING AND IMPLEMENTING PRACTICE CHANGE

Introduction to Practice Change

Practice change cannot be successfully implemented by sending a memo. In order to obtain the best possible results from a practice change a very deliberate approach needs to be employed. The "Model for Improvement" was developed by the Institute for Health Care Improvement found at www.ihi.org . The model uses Plan-Do-Study-Act (PDSA) cycles, These cycles are designed to make change incrementally and test them along the way. The picture below depicts the model of how cycles "ramp up" towards practice change.





Reasons to Test Changes

- To increase your belief that the change will result in improvement.
- To decide which of several proposed changes will lead to the desired improvement.
- To evaluate how much improvement can be expected from the change.
- To decide whether the proposed change will work in the actual environment of interest.
- To decide which combinations of changes will have the desired effects on the important measures of quality.
- To evaluate costs, social impact, and side effects from a proposed change.
- To minimize resistance upon implementation.

Testing changes is an iterative process: the completion of each PDSA cycle leads directly into the start of the next cycle.
A team learns from the test — What worked and what didn't work? What should be kept, changed, or abandoned? — and uses the new knowledge to plan the next test. The team continues linking tests in this way, refining the change until it is ready for broader implementation.
Note: People are far more willing to test a change when they know that changes can and will be modified as needed. Linking small tests of change helps overcome an organization's natural resistance to change and ensure physician buy-in.

Tips for Successful Linked Tests of Change

1. Plan multiple cycles for a test of a change.
2. Think a couple of cycles ahead.
3. Scale down the size of the test (the number of patients or location).
4. Test with volunteers.
5. Do not try to get consensus, "buy-in," etc.
6. Be innovative to make the test feasible.
7. Collect useful data during each test.
8. Test over a wide range of conditions. Try a test quickly; ask, "What change can we test by next Tuesday?"

Starting Practice Change

Using the Plan-Do-Study-Act (PDSA) format recommended by the Institute for Healthcare Improvement, changes in clinical practice can be planned and evaluated continually to ensure that they are achieving the best possible patient outcomes. The Practice Change Project Worksheet found in Appendix

	WHAT	WHO
AIM	What is your practice recommendation? • Level of recommendation	Who takes ownership of current practice? • List all who would need to approve change (patient care managers, directors of different disciplines, executive etc)
PLAN	What needs to be in place? • Equipment • Supplies • Education • Space • Policies • Guidelines • Care maps	Who needs to be involved? (in both old and new practice) • Individuals • Groups • Different disciplines • Communication plan
DO	What is current practice? • Map out	Who should be involved to make this change happen? • Identify gaps
STUDY	What outcomes are you measuring? • Determine where the data will come from	Who evaluates the outcomes? • Determine who will collect the data
ACT	What did your outcome measures tell you to do? • Use this to revise or make your next recommendation	Who needs to know? • Communication plan

Resources for Level 4:

The Institute for Health Care Improvement found at www.ihi.org provides the best guidance for planning and implementing change. Other resources are found in the following appendices.

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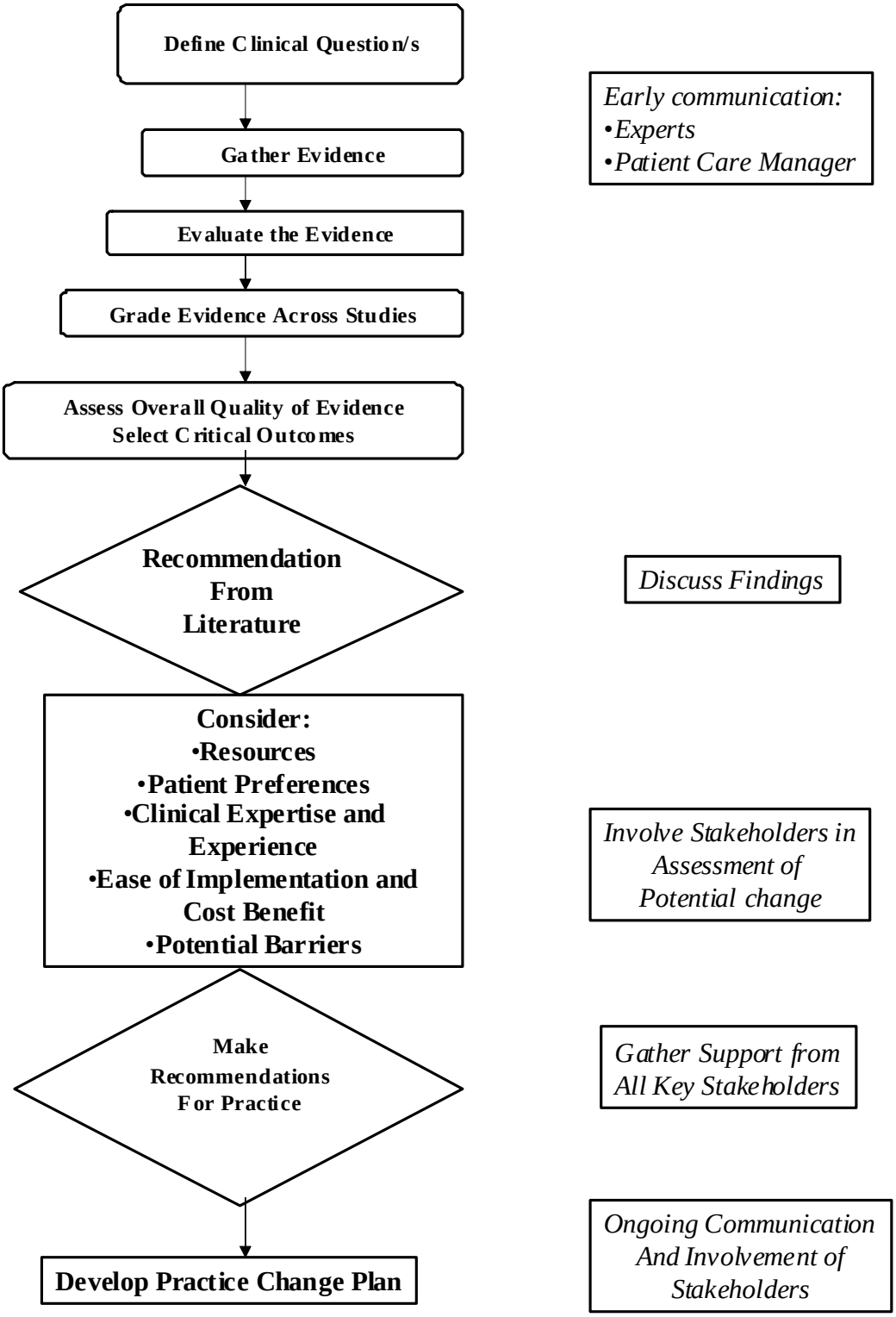
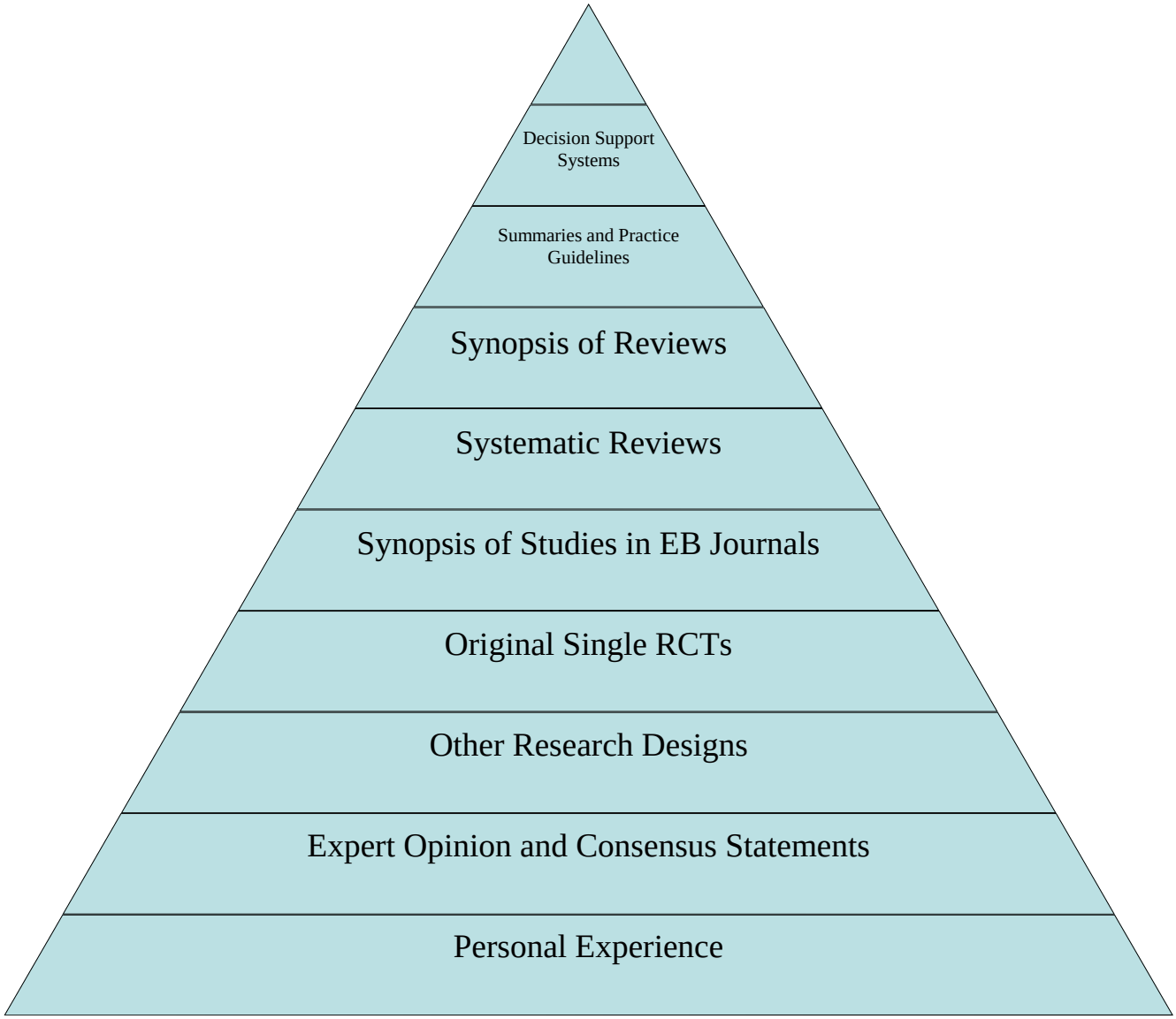
APPENDIX A
ALGORITHM FOR EVIDENCE-INFORMED PRACTICE

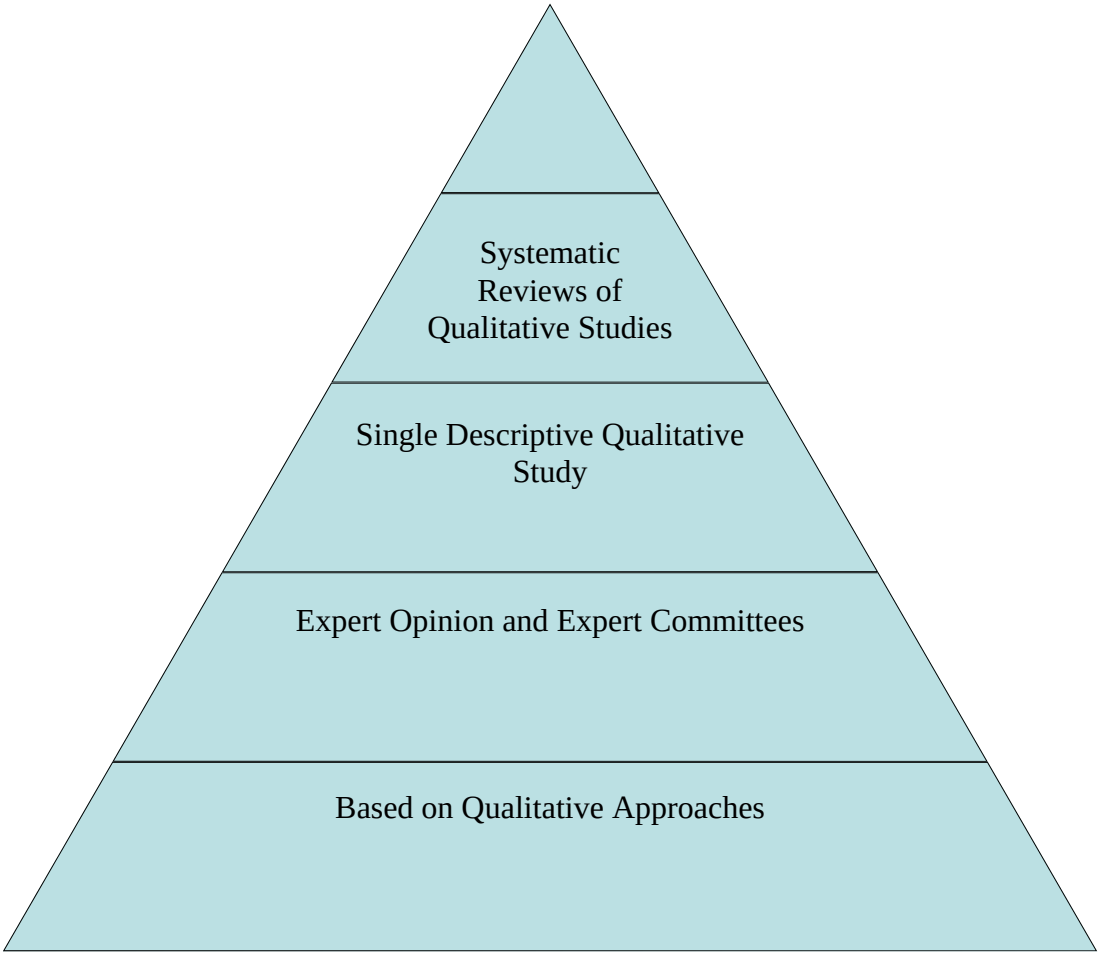


APPENDIX B

Hierarchy of Evidence



Hierarch of Qualitative Research Evidence



APPENDIX C

CRITICAL APPRAISAL WORKSHEETS

EIP Worksheet: *Health Care Interventions*
Citation:

Study Question:

Guide		Comments
I	**Are the results valid?**	
Yes/No/?	Were patients randomized?	
Yes/No/?	Was randomization concealed?	
Yes/No/?	Were patients analyzed in the groups to which they were randomized?	
Yes/No/?	Did the investigators demonstrate similarity in all known determinants of outcome or adjust for differences in the analysis?	
Yes/No/?	Were patients aware of group allocation?	
Yes/No/?	Were clinicians aware of group allocation?	
Yes/No/?	Were outcome assessors aware of group allocation?	
Yes/No/?	Was follow-up complete?	
II	**What are the results?**	
Yes/No/?	How large was the intervention effect?	
Yes/No/?	How precise was the estimate of the intervention effect?	
Yes/No/?	When authors do not report the Confidence Interval?	
III	**How can I apply the results to my patient care?**	
Yes/No/?	Were the study patients similar to the people in my clinical setting?	
Yes/No/?	Were all important outcomes considered?	
Yes/No/?	Are the likely intervention benefits worth the potential harms and costs?	

From DiCenso A, Guyatt G & Ciliska D (2005). Evidence-Based Nursing: A Guide to Clinical Practice. Elsevier Mosby: St. Louis MO, USA.

EIP Worksheet: *Qualitative Research*

Citation:

Study Question:

	Guide	Comments
I	**Are the results valid?**	
Yes No ?	Is the research question clear and adequately substantiated?	
Yes No ?	Is the design appropriate for the research question?	
Yes No ?	Was the sampling appropriate for the research question and design?	
Yes No ?	Were data collected and management systematically?	
Yes No ?	Were data analyzed appropriately?	
II	**What are the results?**	
Yes No ?	Is the description of results thorough?	
III	**How can I apply the results to my patient care?**	
Yes No ?	What meaning and relevance does the study have for my patient care?	
Yes No ?	Does the study help me understand the context of my patient care?	
Yes No ?	Does the study enhance my knowledge about my patient care?	
Additional Comments:		

From DiCenso A, Guyatt G & Ciliska D (2005). Evidence-Based Nursing: A Guide to Clinical Practice. Elsevier Mosby: St. Louis MO, USA.

EIP Worksheet: *Systematic Reviews*

Citation:

Study Question:

	Guide	Comments
I	**Are the results valid?**	
Yes No ?	Did the review explicitly address a sensible clinical question?	
Yes No ?	Was the search for relevant studies detailed and exhaustive?	
Yes No ?	Were the primary studies of high methodological quality?	
Yes No ?	Were assessments of studies reproducible?	
II	**What are the results?**	
Yes No ?	Were the results similar from study to study?	
Yes No ?	What were the overall results of the review?	
Yes No ?	How precise were the results?	
III	**How can I apply the results to my patient care?**	
Yes No ?	How can I best interpret the results to apply them to patient care?	
Yes No ?	Were all patient important outcomes considered?	
Yes No ?	Are the benefits worth the costs and potential risks?	
Additional Comments:		

From DiCenso A, Guyatt G & Ciliska D (2005). Evidence-Based Nursing: A Guide to Clinical Practice. Elsevier Mosby: St. Louis MO, USA.

EIP Worksheet: *Clinical Practice Guidelines*

Citation:

Study Question:

Guide		Comments
I	**Are the results valid?**	
Yes No ?	Were all relevant patient groups, management options and possible outcomes considered?	
Yes No ?	Was an explicit and sensible process used to identify, select and combine evidence?	
Yes No ?	Was there an appropriate specification of values or preferences associated with outcomes?	
Yes No ?	Is the guideline likely to account for important recent developments?	
Yes No ?	Has the Guideline been subjected to peer review and testing?	
II	**What are the results?**	
Yes No ?	Are practical, clinically important recommendations made?	
Yes No ?	Do the authors indicate the strength of their recommendations?	
III	**How can I apply the results to my patient care?**	
Yes No ?	Is the primary objective of the guideline consistent with my objective?	
Yes No ?	Was the duration of follow-up adequate?	
Yes No ?	Are the recommendations applicable to my patient care?	
Additional Comments:		

From DiCenso A, Guyatt G & Ciliska D (2005). Evidence-Based Nursing: A Guide to Clinical Practice. Elsevier Mosby: St. Louis MO, USA.

Critical Review Form – Quantitative Studies
©Law, M., Stewart, D., Pollock, N., Letts, L. Bosch, J., & Westmorland, M.
McMaster University
- Adapted Word Version Used with Permission –

The EB Group would like to thank Dr. Craig Scanlan, University of Medicine and Dentistry of NJ, for providing this Word version of the quantitative review form.

Instructions: Use tab or arrow keys to move between fields, mouse or spacebar to check/uncheck boxes.

CITATION	Provide the full citation for this article in APA format:
STUDY PURPOSE Was the purpose stated clearly? ☐ Yes ☐ No	Outline the purpose of the study. How does the study apply to your research question?
LITERATURE Was relevant background literature reviewed? ☐ Yes ☐ No	Describe the justification of the need for this study:
DESIGN ☐ Randomized (RCT) ☐ cohort ☐ single case design ☐ before and after ☐ case-control ☐ cross-sectional ☐ case study	Describe the study design. Was the design appropriate for the study question? (e.g., for knowledge level about this issue, outcomes, ethical issues, etc.): Specify any biases that may have been operating and the direction of their influence on the results:
SAMPLE N = Was the sample described in detail? ☐ Yes ☐ No Was sample size justified? ☐ Yes ☐ No ☐ N/A	Sampling (who; characteristics; how many; how was sampling done?) If more than one group, was there similarity between the groups?: Describe ethics procedures. Was informed consent obtained?:

<table>
<tr><td rowspan="2">OUTCOMES

Were the outcome measures reliable?
☐ Yes
☐ No
☐ Not addressed

Were the outcome measures valid?
☐ Yes
☐ No
☐ Not addressed</td><td colspan="2">Specify the frequency of outcome measurement (i.e., pre, post, follow-up):</td></tr>
<tr><td>Outcome areas:</td><td>List measures used.:</td></tr>
<tr><td>INTERVENTION

Intervention was described in detail?
☐ Yes
☐ No
☐ Not addressed

Contamination was avoided?
☐ Yes
☐ No
☐ Not addressed
☐ N/A

Cointervention was avoided?
☐ Yes
☐ No
☐ Not addressed
☐ N/A</td><td colspan="2">Provide a short description of the intervention (focus, who delivered it, how often, setting). Could the intervention be replicated in practice?</td></tr>
<tr><td>RESULTS

Results were reported in terms of statistical significance?
☐ Yes
☐ No
☐ N/A
☐ Not addressed

Were the analysis method(s) appropriate?
☐ Yes
☐ No
☐ Not addressed</td><td colspan="2">What were the results? Were they statistically significant (i.e., $p < 0.05$)? If not statistically significant, was study big enough to show an important difference if it should occur? If there were multiple outcomes, was that taken into account for the statistical analysis?</td></tr>
</table>

Clinical importance was reported? ☐ Yes ☐ No ☐ Not addressed	What was the clinical importance of the results? Were differences between groups clinically meaningful? (if applicable)
Drop-outs were reported? ☐ Yes ☐ No	Did any participants drop out from the study? Why? (Were reasons given and were drop-outs handled appropriately?)
CONCLUSIONS AND IMPLICATIONS Conclusions were appropriate given study methods and results ☐ Yes ☐ No	What did the study conclude? What are the implications of these results for practice? What were the main limitations or biases in the study?

Critical Review Form - Qualitative Studies (Version 2.0)

McMaster University

CITATION:

	Comments
STUDY PURPOSE: Was the purpose and/or research question stated clearly? ☐ yes ☐ no	Outline the purpose of the study and/or research question.
LITERATURE: Was relevant background literature reviewed? ☐ yes ☐ no	Describe the justification of the need for this study. Was it clear and compelling?
	How does the study apply to your practice and/or to your research question? Is it worth continuing this review?[1]
STUDY DESIGN: What was the design? ☐ phenomenology ☐ ethnography ☐ grounded theory ☐ participatory action research ☐ other – _____	Was the design appropriate for the study question? (i.e., rationale) Explain.

1 When doing critical reviews, there are strategic points in the process at which you may decide the research is not applicable to your practice and question. You may decide then that it is not worthwhile to continue with the review.

Was a theoretical perspective identified? ☐ yes ☐ no	Describe the theoretical or philosophical perspective for this study e.g., researcher's perspective.
Method(s) used: ☐ participant observation ☐ interviews ☐ document review ☐ focus groups ☐ other _ _____	Describe the method(s) used to answer the research question. Are the methods congruent with the philosophical underpinnings and purpose?
SAMPLING: Was the process of purposeful selection described? ☐ yes ☐ no	Describe sampling methods used. Was the sampling method appropriate to the study purpose or research question?
Was sampling done until redundancy in data was reached?[2] ☐ yes ☐ no ☐ not addressed	Are the participants described in adequate detail? How is the sample applicable to your practice or research question? Is it worth continuing?
Was informed consent obtained? ☐ yes ☐ no ☐ not addressed	
DATA COLLECTION: Descriptive Clarity Clear & complete description of site: ☐ yes ☐ no participants: ☐ yes ☐ no Role of researcher & relationship with participants: ☐ yes ☐ no Identification of assumptions and biases of researcher: ☐ yes ☐ no	Describe the context of the study. Was it sufficient for understanding of the "whole" picture? What was missing and how does that influence your understanding of the research?

2 Throughout the form, "no" means the authors explicitly state reasons for not doing it; "not addressed" should be ticked if there is no mention of the issue.

Procedural Rigour Procedural rigor was used in data collection strategies? ☐ yes ☐ no ☐ not addressed	Do the researchers provide adequate information about data collection procedures e.g., gaining access to the site, field notes, training data gatherers? Describe any flexibility in the design & data collection methods.
DATA ANALYSES: **Analytical Rigour** Data analyses were inductive? ☐ yes ☐ no ☐ not addressed Findings were consistent with & reflective of data? ☐ yes ☐ no	Describe method(s) of data analysis. Were the methods appropriate? What were the findings?
Auditability Decision trail developed? ☐ yes ☐ no ☐ not addressed Process of analyzing the data was described adequately? ☐ yes ☐ no ☐ not addressed	Describe the decisions of the researcher re: transformation of data to codes/themes. Outline the rationale given for development of themes.
Theoretical Connections Did a meaningful picture of the phenomenon under study emerge? ☐ yes ☐ no	How were concepts under study clarified & refined, and relationships made clear? Describe any conceptual frameworks that emerged.

OVERALL RIGOUR Was there evidence of the four components of trustworthiness? Credibility ☐ yes ☐ no Transferability ☐ yes ☐ no Dependability ☐ yes ☐ no Comfirmability ☐ yes ☐ no	For each of the components of trustworthiness, identify what the researcher used to ensure each. What meaning and relevance does this study have for your practice or research question?
CONCLUSIONS & IMPLICATIONS Conclusions were appropriate given the study findings? ☐ yes ☐ no The findings contributed to theory development & future OT practice/ research? ☐ yes ☐ no	What did the study conclude? What were the implications of the findings for occupational therapy (practice & research)? What were the main limitations in the study?

APPENDIX D: STATISTICS HELPERS

DETERMINING THE STRENGTH OF RESULTS

Estimating the Size of the Treatment Effect

This tool is useful for outcome measures that are discrete, such as cancer or no cancer. From the data in the report, enter the numbers in the appropriate box based on the actual numbers that they give for the treatment group and the control group. This is actually the proportion of subjects in each group who have a certain outcome.

	Outcome +	Outcome -
Treated (Y)	a	b
Control (X)	c	d

The risk of the outcome:
Y = a/(a+b)
X = c/(c+d)

These numbers are then used to determine the difference in outcome between the treated and control groups.

Relative Risk or Risk Ratio (RR), is the ratio of risk in the treated group (Y) to the risk in the control group (X): RR=Y/X

Relative Risk Reduction (RRR) is the percent reduction in risk in the treated group (Y) compared to the control group (X):
RRR = 1-RR = 1-Y/X x 100% or
RRR=[(X-Y)/X] x 100%

Absolute Risk Reduction (ARR) is the difference in risk between control group (X) and the treated group (Y):
ARR = X-Y

Number Needed to Treat (NNT) is the inverse of the ARR:
NNT = 1/ARR = 1/(X-Y)

Resources and calculators for these and other measures such as Confidence Intervals can be found at JAMA evidence journal website. Access the journal through the University of Manitoba library website.

APPENDIX E
GRADE WORKSHEET

This table is meant to provide a "birds-eye" view of the evidence. It can be utilized in any way that assists your deliberation. List studies under each outcome that they report. If there are few studies for each outcome, they can be listed separately. If there are too many to list separately, then they can be grouped by design. For each outcome measure indicate the level of importance of the outcome (low, medium, high or critical) This will help making the final recommendations. This table may work best as a spreadsheet.

Overall grade of the quality of the evidence:

High = Further research is very unlikely to change our confidence in the estimate of effect.
Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Very Low = Any estimate of effect is very uncertain.

# of studies	Design	Quality rating (range)	Consistency	Directness	Other	Summary of findings/ strength of results	Grade
Outcome Measure (importance):							
Outcome Measure (importance):							

Design:

- List type of study: RCT=Randomized controlled trials,
- CC=case control

Quality:

- Compare the scores that you gave each study.
- Evaluate the quality of the results to determine if there are concerns about imprecise or sparse data.
- Data are sparse if the results include just a few events or observations and they are uninformative
- Data are imprecise if the confidence intervals are sufficiently wide that an estimate is consistent with either important harms or important benefits.
- The threshold for considering data imprecise or sparse should be lower when there is only one study. A single study with a small sample size (or few events) yielding wide confidence intervals spanning both the potential for harm and benefit should be considered as imprecise or sparse data.
- Confidence intervals that are sufficiently wide that, irrespective of other outcomes, the estimate is consistent with conflicting recommendations should be considered as imprecise or sparse data.
- Quality of the data can also be downgraded if there is high risk of reporting bias
- Quality can be increased if there is a very strong association, if there is evidence of a dose response gradient, or if presence of all plausible confounders would have reduced the observed effect.

Consistency

- Are there consistent results between studies?
- Inconsistency exists when studies have opposing results for similar interventions.

Directness (Applicability)

- Refers to applicability, or the extent to which the people, interventions, and outcome measures are similar to those in your question. For example, there may be uncertainty about the directness if your patients are older, sicker, or have more comorbidity than those in the studies.

Other

- Imprecise or sparse data, a strong or very strong association, high risk of reporting bias, evidence of a dose-response gradient, effect of other possible causes of the treatment effect

Grade

Start with a default rating based on the type of evidence:
Randomized trials = high
Observational studies = low
Any other evidence = very low

Decrease grade if:

- Serious (-1) or very serious (-2) limitation to study quality
- Important inconsistency (-1)
- Some (-1) or major (-2) uncertainty about directness
- Imprecise or sparse data (-1)
- High probability of reporting bias (-1)

Increase grade if:

- Strong evidence of association – significant relative risk of >2 (<0.5) based on consistent evidence from two or more observational studies with no plausible confounders (+1)
- Very strong evidence of association – significant relative risk of >5 (<0.2) based on direct evidence with no major threats to validity (+2)
- Evidence of a dose response gradient (+1)
- All plausible confounders would have reduced the effect (+1)

From GRADE Working Group: www.gradeworkinggroup.org.

APPENDIX F
PRACTICE CHANGE SCORING ASSESSMENT TOOL

1. Factors Affecting Ease of Implementation	**Score (circle)**
a) How tangible (technological/material) or intangible (interpersonal/nonmaterial) is the innovation? 1= very intangible 5= very tangible	**1-2-3-4-5**
b) How much change in current nursing function(s) would this innovation require? 1 = extensive 5 = no change	**1-2-3-4-5**
c) To what extent does this innovation address a relevant nursing practice problem or need in your hospital? 1= there is little concern by anyone 5= there is concern by a great many	**1-2-3-4-5**
d) Would this kind of practice change be acceptable to you and others on your unit? 1= not acceptable at all 5= highly acceptable by all	**1-2-3-4-5**
e) To what extent is nursing in your hospital free to decide to carry out this innovation? 1= Requires hospital wide approval 5= Requires no other group's approval	**1-2-3-4-5**
f) To what extent would this innovation fall under the control of nursing in your hospital? 1= nursing would have no control 5= nursing would have clear control	**1-2-3-4-5**
g) To what extent does nursing staff have to be involved in implementing the innovation? 1= entire nursing staff must be involved 5= small group of nurses need to be involved	**1-2-3-4-5**
h) To what extent are the patients to whom the innovation is directed available on one unit or spread across many units? 1= many units with small numbers of patient 5= few units with large numbers of patients	**1-2-3-4-5**
i) To what extent would this innovation require changes in staffing patterns for nursing personnel? 1= substantial change required 5= no change required	**1-2-3-4-5**
j) To what extent can the innovation be divided into separate phases that can be implemented one step at a time? 1= complex and not divisible 5= easily divisible or not necessary	**1-2-3-4-5**
k) To what extent can the innovation be stopped if it does not prove desirable? 1= very difficult to stop 5= stopped without any difficulty	**1-2-3-4-5**
l) To what extent would a trial of this innovation disrupt or interfere with the way nurses currently function? 1= would be very disruptive 5= would not interfere or disrupt	**1-2-3-4-5**
m) What length of time would be required to carry out this innovation, considering the need for training, material staff? 1= along time 6 months 5= A short time; 2 weeks to 1 month	**1-2-3-4-5**
n) How difficult would it be to demonstrate that this innovation has had an effect on patient care? 1= very difficult 5= Easy	**1-2-3-4-5**
o) How difficult would it be to get appropriate staff (or others) involved in collecting evidence that the innovation is effective? 1= Very difficult 5= Easy	**1-2-3-4-5**
p) What length of time would be required to evaluate the benefits? 1= long time (several months) 5= short time	**1-2-3-4-5**
Ease of Implementation Subtotal *64-80 Very good* *48-64 Good* *Below 48 Questionable*	

2. Cost-Benefit Factors	
a) To what extent would the benefits derived from the innovation be visible? 1= intangible and not obvious 5= highly visible and obvious to all	**1-2-3-4-5**
b) To what extent would the benefits of the innovation affect the physical and emotional well being of the patients? 1= minimal improvement inpatient well being 5= major improvement in patient well being	**1-2-3-4-5**
c) To what extent would this innovation facilitate or interfere with the work of nurses in your hospital? 1= it will interfere with their work 5= it will facilitate their work	**1-2-3-4-5**
d) To what extent are the materials required by this innovation currently available in your hospital? 1= not at all available 5= readily available to nursing	**1-2-3-4-5**
e) To what extent would personnel require specialized training in order to implement the innovation? 1= extensive training 5= little or no special education	**1-2-3-4-5**
f) To what extent would the benefits support the time and energy involved in implementing the innovation? 1= take months to implement and benefits are obscure for a long time 5= takes a limited time and the benefits are readily felt	**1-2-3-4-5**
g) How costly would it be to start this innovation? 1= requires extra staff and costly materials/equipment 5= requires no additional staff, materials/equipment	**1-2-3-4-5**
h) How costly would it be to maintain the innovation once it was started? 1= requires ongoing budgeting 5= requires no additional staff, materials etc	**1-2-3-4-5**
i) To what extent would the monetary cost of nursing care (or costs of other aspect of hospital care) be altered by implementing this innovation? 1= increased costs per patient day 5= major savings per patient day	**1-2-3-4-5**
j) To what extent would the benefits of the innovation be proportional to all the difficulties inherent in implementing this innovation? 1= difficulties outweigh any benefits 5= benefits outweigh any difficulties	**1-2-3-4-5**
Cost-Benefit Subtotal *40 –50 Very Good* *30-40 Good* *Below 30 questionable*	

From " Using Research to Improve Nursing Practice: A Guide" (1983) CURN Project

APPENDIX G
PRACTICE CHANGE PROJECT WORKSHEET

Project Initiated by:	Project Lead:
Problem / Clinical Question:	
Background:	
Recommendation from Literature:	
Current Practice:	
Proposed New Practice:	
Goal (ie –↓ Length of stay, infection etc):	
How will you measure outcomes?	
Is this new practice supported by reputable sources? (ie. Centres for Disease Control, national organizations etc)	
Whose authority is required to implement this change?:	
Results of Practice Change Scoring Assessment Tool: Cost-benefit: ☐ Very Good ☐ Good ☐ Questionable	Ease of Implementation: ☐ Very Good ☐ Good ☐ Questionable
What do you think needs to be in place? (Equipment, Supplies, Education, Space Allocation, Policies, Guidelines, Care maps):	

What timeframe might be involved?

☐ Implement in one step

☐ Implement gradually:

☐ Implement in series of steps (outline)

What costs are predicted (if any)?

What barriers are anticipated?

What are the risks if this particular practice change does not occur?

What do you propose the next steps to be?

Communication Strategy:

List All Key Stakeholders: (Check boxes to indicate as communication has been done and support received)

Areas Involved:

Position/Name	**Support**		**Position/Name**	**Support**	
	Yes	No		Yes	No

Developed by D. Sawatzky-Dickson & Vivian Bicknell

APPENDIX H: GLOSSARY

This is a brief listing of terms used in this learning package as well as some terms that appear commonly in research studies.

Absolute Risk: The percentage or proportion of people who have a certain outcome. Usually used with a harmful exposure, such as the percentage of smokers who develop lung cancer.

Absolute Risk Reduction: The differences in the absolute risk in the exposed vs the unexposed group. This term is used with a beneficial exposure or intervention. For example: smokers who quit vs smokers who do not quit and the reduced rate of lung cancer. This tells us how much of the effect is a result of the intervention itself.

Allocation Concealment: The people making the decisions about enrolling a person in a research study is not aware of whether the next patient will be entered in the treatment group or the control group.

Alpha Level: The probability of erroneously concluding that there is a difference between two treatments when there is in fact no difference.

Baseline Risk: The risk of an adverse outcome in the control group of a study. Also called the Control Event Rate (CER)

Before-After Trial: Study of an intervention when there is a comparison before and after an intervention.

Bias: A systemic tendency or favouritism to produce an outcome that differs from the underlying truth and results in lopsided misleading results:

> **Channelling bias**: The tendency to prescribe treatment based on a patient's prognosis – this will bias the estimate of the treatment effect
>
> **Data completeness bias**: Using different methods of obtaining the data in the two groups.
>
> **Detection bias** / Surveillance bias: The tendency to look more carefully for an outcome in one of two groups being compared.
>
> **Incorporation bias**: Studying a diagnostic test that incorporates features of the target outcome.
>
> **Interviewer bias**: Greater probing by an interviewer in one of two groups being compared.
>
> **Publication bias**: Publication of a study depends on the direction of the study results and whether they are statistically significant. This occurs more commonly when studies that show no difference in an intervention are refused publication.
>
> **Recall bias**: Patients who experience an adverse outcome have a different likelihood of recalling an exposure than the patients who do not have an adverse outcome, independent of the true extent of the exposure.

Verification bias: results of a diagnostic test influence whether patients are assigned to a treatment group.

Blinding / Masking: The participant of interest in unaware of whether patients have been assigned to the experimental or control group. Patients, clinicians, those monitoring outcomes, assessors of outcomes, data analysts and those writing the paper can all be blinded or masked.

Case Studies / Case Reports: Descriptions of individual patients. These do not provide any comparison groups and so there is no treatment and control group that share a similar prognosis.

Case Series: A study reporting on a consecutive collection of patients treated in a similar manner without a control group.

Case Control Study: a study designed to determine the association between an exposure and outcome in which patients are sampled by outcome (that is, some patients with the outcome of interest are selected and compared to a group of patient who have not had the outcome ie. SIDS), and the investigator examines the proportion of patients with the exposure in the two groups (ie. co-sleeping)

Chi-square Test: A statistical test that examines the distribution of categorical outcomes in two groups, the null hypothesis of which is that the underlying distributions are identical.

Comorbidity: Diseases that coexist in a study participant in addition to the index condition that is the subject of the study.

Cohort: A group of persons with a common characteristic or set of characteristics. Typically, the group is followed for a specified period of time to determine the incidence of a disorder or complications of an established disorder (prognosis).

Cohort Study: Prospective investigation of the factors that might cause a disorder in which a cohort of individuals who do not have evidence of an outcome of interest but who are exposed to the putative cause are compared with a concurrent cohort who are also free of the outcome but not exposed to the putative cause. Both cohorts are followed to compare the incidence of the outcome of interest.

Confidence Interval (CI): Quantifies the uncertainty of a statistic. It provides two numbers, and between the two it is probable that the true value lies for the whole population of patients from whom the study patients were selected. Usually expressed as the 95% confidence interval, which means that you are 95% certain that the true treatment effect lies between these two numbers. If the 95% CI for an odds ratio or relative risk includes 1, then there is no statistical difference. If the CI for a risk or harm, includes 0, there is no difference. The farther apart the two numbers, the less precise the estimate of the effect.

Confounder: A factor that distorts the true relationship of the study variable of interest by virtue of also being related to the outcome of interest. Confounders are often unequally distributed among the groups being compared.

Construct Validity: The degree to which an instrument measures the concept under investigation.

Contamination: When participants in a study receive the treatment that was meant for those in the other arm of the study.

Correlation Coefficient: The degree of relationship between two variables ranging from +1 (a perfect direct relationship) through 0 (no relationship) to –1 (a perfect inverse relationship).

Crossover Trial: When all patients in a study receive both the experimental and control treatments in sequence.

Dependent Variable: The target variable or outcome variable of interest.

Dose Response Gradient: The effect of an intervention increases as the quantity or duration of exposure increases. This applies to both positive and negative effects.

Effect Size: The difference in outcomes between the intervention and control groups divided by some measure of variability, usually the standard deviation.

Event Rate: Proportion of patients in a group in whom an event is observed. Control Event Rate (CER) and Experimental Event Rate (EER) refer to the rate in each of the groups in a study.

Face Validity: A measurement instrument appears to measure what it is intended to measure.

Follow-Up: The investigators are aware of the outcome in every patient who participated in the study.

Independent Variable: The variable that is believed to cause or influence the dependent variable. This is usually the variable that is manipulated in a study.

Intention-to-Treat: Analyzing patient outcomes based on which group they were randomized regardless of whether they actually received the planned intervention. This preserves the power of randomization, thus maintaining that important unknown factors that influence outcome are likely equally distributed in each comparison group.

Internal Validity: The findings can be shown to result only from the effect of the independent variable of interest and cannot be interpreted as reflecting the effects of extraneous variables.

Empirical Evidence: Evidence that is rooted in objective reality and that is gathered through the collection of data using one's senses; used as the basis for generating knowledge through the scientific approach.

External Validity: The degree to which the results of a study can be generalized to settings or samples other than the ones studied.

Flaws: "fatal" flaws are limitations to a research study that lead you to consider the results invalid. "Non fatal" flaws are limitations that are serious enough to decrease the level of the evidence but not enough to throw out the results entirely.

Mean: Mathematical average.

Median: The middle number where half the results are above and half are below.

Meta-analysis: A research method that takes the results of multiple studies in the same area and combine the findings into a pooled result. ie. if there are only 100 subjects in 3 different studies, the meta-analysis would calculate the statistics again using the results from all 300 subjects.

N of 1 RCT: An experiment in which there is only one participant, designed to determine the effect of an intervention or exposure on that individual.

Null Hypothesis: The starting hypothesis in a study that states that there is no relationship between the variables under study. Statistical tests are set up in order to try to reject this hypothesis.

Number Needed to Harm (NNH): The number of patients who would need to be treated over a specific period of time before one adverse side effect of the treatment will occur. It is the inverse of the absolute risk increase.

Number Needed to Treat (NNT): The number of patients who need to be treated over a specific period of time to prevent one bad outcome. It is the inverse of the absolute risk reduction (AAR).

Observational Studies: Studies in which patient or physician preference determine whether a patient receives treatment or control. Often the case when variables cannot be randomized such as smoking vs not, or breastfeeding vs bottle feeding.

Odds Ratio (OR): A ratio of the odds of an event in an exposed group to the odds of the same event in a group that is not exposed.

Outcomes: Changes in health status that may occur in following subjects or that may stem from exposure to a causal factor or to a therapeutic intervention.

Percentile: The line at which x% of subjects or responses were below. I.e. the 90^{th} percentile means that 90% of subjects scored below that number.

Power: The ability of a research design to detect existing relationships among variables.

Power Analysis: A procedure for estimating either the likelihood of falsely concluding that a relationship exists or that there really is a difference between two groups when there really isn't.

Practice Guidelines: Guidelines that are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical situations. They are a set of statements, directions or principles concerning the proper indications for performing a procedure or treatment or the proper management for specific clinical problems.

Predictive Value: Used for diagnostic tests. Positive predictive value is the proportion of people with a positive test who actually have the disease. Negative predictive value is the proportion of people with a negative test who are actually free of the disease.

Probability: The estimate of the likelihood of a condition existing or of subsequent events. Expressed as a p-value. When it is p=<.05 this means that the likelihood of the outcome being from chance alone, and not a result of the study intervention is less than 5 out of 100. If p=<.05, then the result is said to be statistically significant.

Randomized Controlled Trial: Experiment in which individuals are randomly allocated to receive or not receive an experimental preventative, therapeutic, or diagnostic procedure and then followed to determine the effect of the intervention.

Rate: Reflects some quantity per a certain unit percentage – a proportion of the whole.

Ratio: A fraction that divides two quantities.

Regression: A statistical procedure for predicting values of a dependent variable based on the values of one or more independent variables.

Relative Risk Reduction (RRR): Ratio of the proportion of baseline risk that is removed by the therapy. It is calculated by dividing the absolute risk reduction by the absolute risk in the control group.

Reliability: The degree of consistency or dependability with which an instrument measures the attribute it is designed to measure. This does not mean that it is giving the right answer, just consistently the same answer or result

Standard Deviation: How spread out the numbers are. The average distance from the mean.

Statistical Significance: The results obtained in an analysis of sample data are unlikely to have been caused by chance, at a preset level of probability.

Systematic Review: A critical assessment and evaluation of research that attempts to answer a focused clinical question using methods that are designed to reduce bias. If you find a good one that answers the exact question you are asking, you may not need this learning package.

Treatment Effect: There are different ways to express the results of a comparison. When a study measures discreet variables such as an outcome that you either have or don't have, then absolute risk reduction (ARR), relative risk reduction (RRR), odds ration (OR), and number needed to treat (NNT) are useful. When the variable is continuous and the study looks at decreasing or increasing something, then effect size is used to express the treatment effect.

Validity: A study is valid insofar as the results represent an unbiased estimate of the underlying truth. A measurement tool is valid to the extent that it measures what it is intended to measure. It refers to the accuracy of the tool or study.

Validity Threats:

> **History**: The occurrence of external events which happen at about the same time as the introduction of the independent variable that can affect the dependent variable.

Experimental Mortality: The loss of subjects or the number who drop out during the course of the study and do not complete the entire study. The research design may cause subjects in one group to drop out at a higher rate than those in another group.

Selection Bias: The groups are not equivalent. This is a particular risk when groups are not randomly assigned. This may also be a result of the bias from the differences between those who volunteer for a study and those who refuse. Even randomization can have problems, so it is important to look carefully at the way subjects were randomized and to ensure that the group allocation could not be influenced in any way and that it was truly random.

Maturation: Processes occurring within the subjects during the course of the study as a result of time rather than as a result of the treatment or independent variable. An example of this is subject who have a certain disease that tends to have peaks and troughs. When a treatment seems to cause improvement, the improvement may have occurred naturally anyway. Proper randomization of subjects can help to spread this effect evenly in the two groups.

Testing Effects: The effects of taking a pretest on the scores of a post-test. The mere act of collecting information from people changes them.

Instrumental Error: Changes in the measuring instruments between an initial point of data collection and a subsequent point.