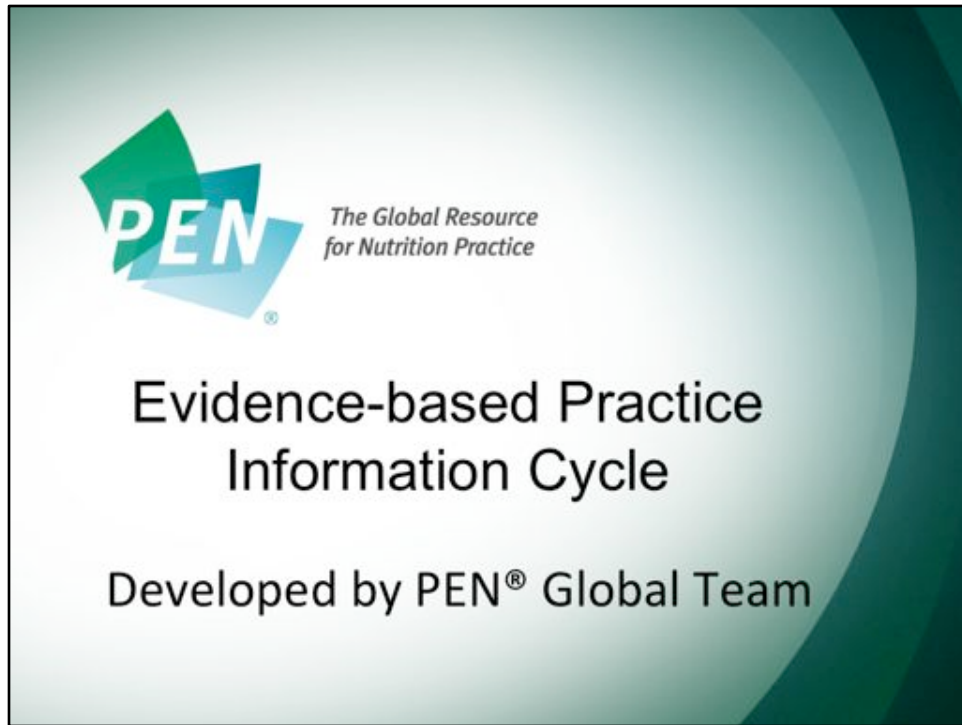




Practice-based Evidence in Nutrition (PEN®) www.pennutrition.com is the global resource for nutrition practice.



Welcome to the PEN® Evidence-based Practice Information Cycle Orientation tutorial developed by PEN® Global Team.

PEN® Orientation Tutorials



Five PEN® orientation tutorials have been developed:

Module 1: An Introduction to the Power of PEN®

Module 2: Searching PEN® Using the Table of Contents

Module 3: More Search Strategies

Module 4: More Great PEN® Features

Module 5: Navigating Through Practice-based Evidence Toolkits (PETs)

If you are not very familiar with the structure of PEN® we recommend that you complete the 5 orientation tutorial modules before continuing with this training module.

PEN® Orientation Tutorials can be accessed at this link:

http://www.pennutrition.com/module_library.aspx

Evidence-Based Practice Information Cycle



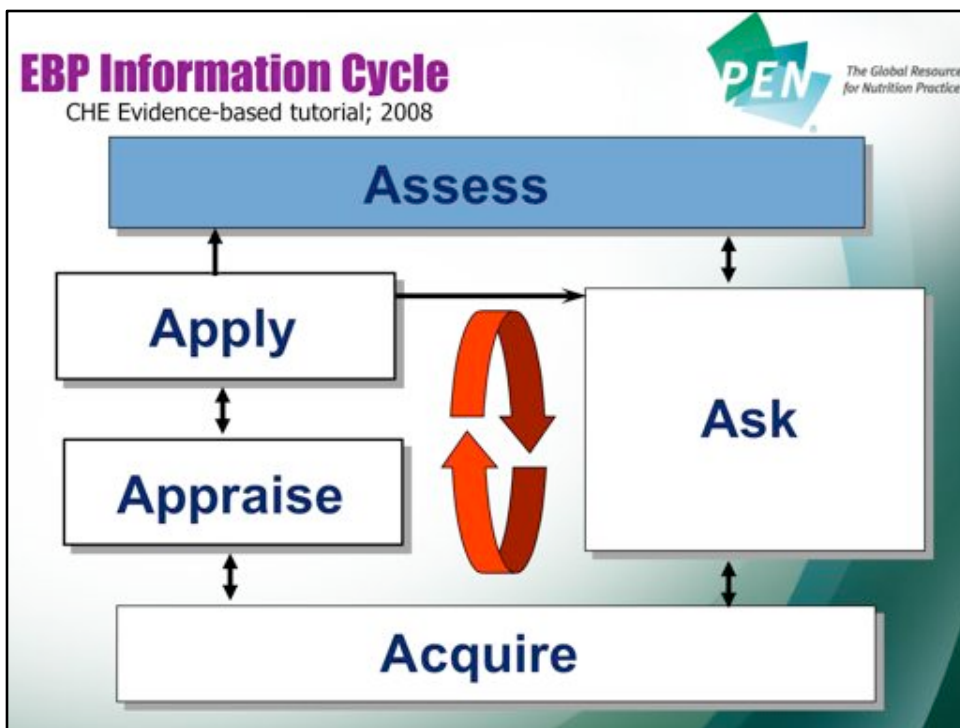
1. Assess the situation and define the “problem”
 2. Ask a specific question
 3. Acquire the best evidence
 4. Appraise
 - consider study design and hierarchy of evidence
 - assess the quality of the studies and applicability
 - make recommendations
 5. Apply to guidelines, resources or PEN® key practice point
- Then the cycle repeats.....
1. Assess impact on practice (evaluation, /quality improvement studies)

The framework we use for creating PEN® content is the Evidence-based Practice Information Cycle. It utilizes the 5 “A’s”

- Assess
- Ask
- Acquire (note this says acquire the BEST evidence, NOT all the evidence (an important distinction))
- Appraise
- Apply

...and then the cycle repeats...

We’re going to walk through each of the steps in some detail with you.



Assess is the starting point for Evidence-based Dietetic Practice

Evidence-based practice starts with a spirit of curiosity within a supportive dietetic culture.

Dietitians and health care practitioners can start by regularly asking questions about why they do what they do.

Assess



Detect and prioritize issues

- ◆ Define problem - What is the central concern?
- ◆ What decisions can be made? By whom?
- ◆ What is uncertain?
- ◆ What might be done differently?
- ◆ What are clients hearing / asking about?



Developing what is sometimes called a Clinical Inquiry Approach calls for practitioners to adopt a mindset of informed skepticism.

Detect issues and prioritize issues – What is the central concern? Harm, prognosis , therapy, rehabilitation

- What decisions are made by whom?

- What is uncertain? urgent, fixable, frequent, doable, interesting

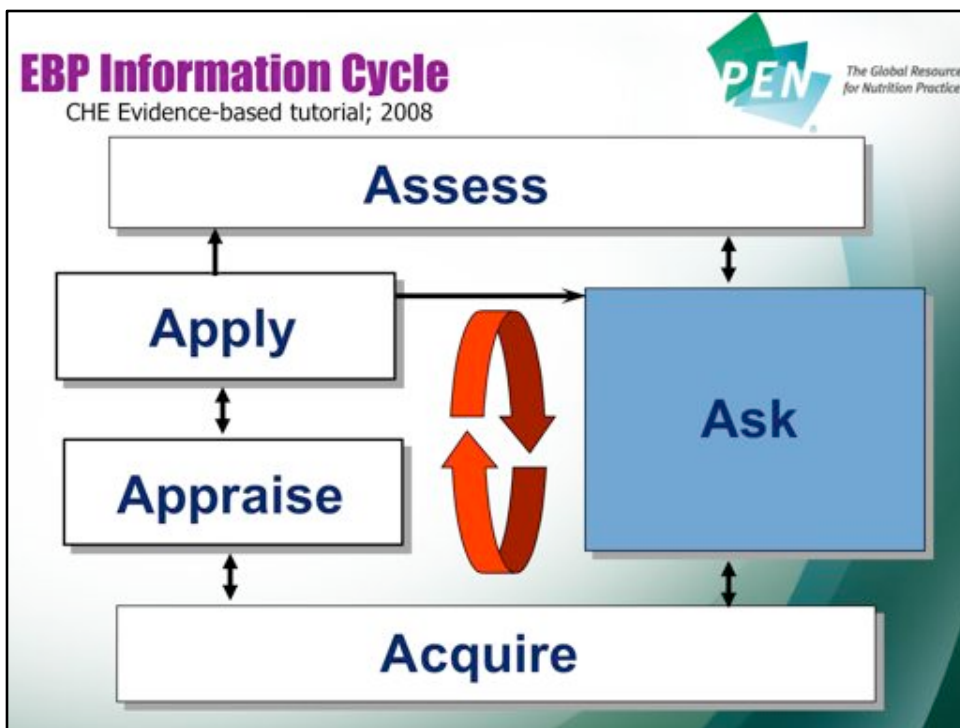
The evidence-based dietitian asks important and relevant questions.

What might be done differently? What choices would matter?

The focus here is finding and evaluating evidence that is: directly relevant to care, addresses knowledge gaps, is volatile.

Being driven by these questions, the informed skeptic goes to the literature and is able to find evidence to answer the questions.

The skills of finding the evidence replace the expectation that the individual clinician can be “all knowing”. Expertise now lies in part on being able to find the evidence. We begin by creating a searchable question...



The next step in integrating evidence into practice is to convert information needs from practice into focused, structured, searchable questions.

With the volume of scientific literature today, the busy clinician doesn't have time to search through hundreds of articles to find an answer. The goal in asking clinical questions is to be able to find good quality, relevant research efficiently that will lead to sound evidence-based answers to resolve clinical problems and improve patient outcomes. One key to efficiency is asking a focused question.

Ask – frame the kinds of information you have identified in Step 1 or the ASSESS stage into searchable questions. Taking time to develop a “good” question will help you define what to look for and where to look.

Ask




Types of Questions:

Background

- General knowledge, conditions, regulations etc
- Background document template

Foreground

- Specialized knowledge
- About choices / decision making
- PEN PICO question

There are two types of questions – *background* questions and *foreground* questions. **Background** questions are often of a general nature and relate to a condition for clinical topics or are about basic facts, descriptive stats or regulatory issues etc for non-clinical issues. Questions that pertain to a description of a disease, its etiology, prevalence, incidence, course etc. would be background questions. These are often questions asked by new learners. Answers can usually be found in various resources and textbooks, online sources such as the Merck Manual and MedlinePlus Encyclopedia and even narrative reviews and some original research studies depending on the topic. The PEN® Background documents, not surprisingly, house most of our Background questions. We did this deliberately to make it easier to find information... you don't have to wade through background to get to foreground questions... or vice versa

This training module and the “PEN® Asking the Question” module focus on developing Foreground questions

Foreground questions generally relate to more specialized knowledge which address issues of care, or decision making. Foreground questions usually ask about treatment, prevention, prognosis or diagnosis. These are questions more often asked by experts to address clinical or policy problems. We will be focusing on asking and finding answers to to *foreground* questions.

Background Information Sources



- eMedicine (Medscape)
- Mayo Clinic
- Merck Manual Online
- Medline Plus Health Topics (NLM and NIH)
- NIDDK
- disease-related association websites

Here are some credible online sources to answer background questions.

- eMedicine (Medscape) <http://emedicine.medscape.com/>
- Mayo Clinic <http://www.mayoclinic.com/>
- Merck Manual Online
<http://http://www.merckmanuals.com/professional/index.html>
- Medline Plus Health Topics (NLM and NIH)
<http://www.nlm.nih.gov/medlineplus/healthtopics.html>
- NIDDK <http://www2.niddk.nih.gov/>

The PEN® Writer's Guide (<http://www.pennutrition.com/WriterGuide.aspx>) contains a more complete list and you all likely have your favourites.

Any favourites you don't see here you can submit them to us via "Contact Us" in PEN® and we could certainly add them to the list in the PEN® Writer's Guide.

PICO Questions

- **Population** – how would you define your population e.g. demographics, medical condition?
- **Intervention or Exposure of interest** – what are the intervention or prognostic factors?
- **Comparison** – is there an alternative or standard practice to compare to? What comparison is relevant? What is the control?
- **Outcome** – what do you hope to accomplish, improve or effect? What outcome is important to you and your patients/clients?

Use the PICO or PECO format to formulate a searchable question...

Prevention / Etiology





- Are _____ (P)
- who have _____ (E)
- compared with those without / low _____ (C)
- at _____ risk for _____ (O)

Treatment / Intervention

- In _____ (P)
- how does _____ (I)
- compared with _____ (C)
- affect _____ (O)

Your question might have slightly different wording depending on whether your question relates to prevention or etiology of disease versus a treatment or intervention type question. Different types of questions are best answered by different types of studies and we'll talk more about that in a moment.

Ask



Types of inquiry in nutrition

- Etiology
- Treatment / Intervention / Prevention
 - Efficacy
 - Harm

Most inquiries about nutrition evidence are regarding the etiology or the causes of diseases or about optimizing health via nutrition. Examples of etiology questions could include: does vitamin A deficiency cause night blindness?, is serum cholesterol associated with heart disease?

In nutrition, the majority of studies are observational, in which the investigators looked for associations between food or nutrient intakes and the occurrence of a disease, to describe the potential etiology of the disease. These studies usually describe the direction and strength of association of a particular exposure with a particular outcome. Examples of observational studies include cohort, cross-sectional, and case control studies.

In comparison, some studies include an intervention, to test a particular treatment or prevention strategy for effectiveness and the potential to cause harm. The best of these intervention studies are randomized, referred to as randomized controlled trials, and they provide the most reliable form of evidence.

When we move to the appraisal section, you'll note that different types of studies (along with things like how consistent are the results from study to study) to determine what letter grade we give the evidence.

Choosing the best study design to address your question

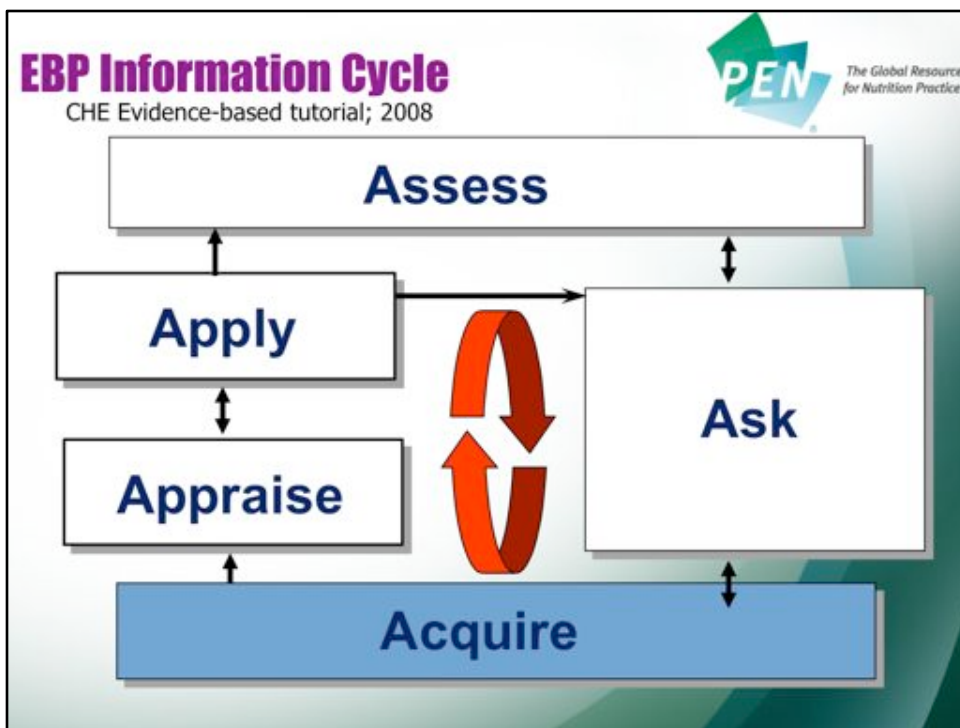


* Ideal study design; Adapted from NHMRC 2000b and The Endorsement Process for Evidence-based Clinical Practice Guidelines Dietitians Association of Australia 2006

Question Type	Example	Study Types	Appraisal Issues
Intervention	What are the outcomes of an intervention?	systematic review; RCT's*; cohort; case control	randomization; follow-up; blinding
Frequency	How common is a particular condition or disease?	systematic review; cohort; cross-sectional study*	sample frame; case ascertainment; adequate response and follow-up
Diagnostic test performance	How accurate is a sign, symptom or diagnostic test in predicting the true diagnostic category of a patient.	systematic review; cross-sectional study* (random or consecutive sample)	independent blind comparison with a gold standard; appropriate selection of patients
Etiology and risk factors	Are there known factors that increase the risk?	systematic review; cohort study*; case control study*	groups only differ in exposure; outcomes measurement; reasonable evidence for causation
Prognosis	Can the risk for the patient be predicted?	systematic review; cohort/survival study*	inception cohort; sufficient follow-up
Economics	What are the overall costs of using the procedure or service?		

This chart indicates the ideal study design for various question types. It also suggests what might be some of the appraisal issues.

If you would like more details and practice on developing PICO questions work through the “PEN® Asking the Question” training module. If you are OK with developing PICO questions the next phase in the evidence-based practice information cycle is the Acquire phase.



The goal in searching is ideally to find quality answers to your structured questions in a timely manner.

A number of sources are available that provide different types and levels or quality of evidence.

Remember earlier on, we said we are looking for **the BEST evidence**, usually not every shred of evidence on a particular topic.

To search efficiently, the first source that you search should be good pre-appraised or pre-filtered secondary sources that summarize the literature and give you a useful actionable plan based on the evidence. With these sources, the work of finding and critically appraising the literature has been done for you. Pre-filtered means that an individual or group of individuals with expertise in a particular area have reviewed and presented **the methodologically strongest data in the field**. We will spend a bit of time looking at credible examples of filtered literature in a moment.

Acquire



- ◆ What types of evidence exist?
- ◆ What levels of evidence exist?
- ◆ Where is evidence to be found?

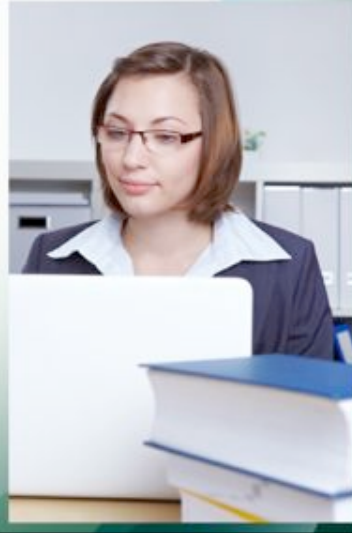
So we need to discover
What types of evidence exist?
How good is the evidence?
Where or how do I find the relevant evidence?

Acquire – First Step



Searching for Evidence

Search Strategy Worksheet
in PEN® Writer's Guide
– Appendix 5



The first step in acquiring is searching the literature. You can use the “Search Strategy Worksheet” found in Appendix 5 of the PEN® Writer’s Guide (<http://www.pennutrition.com/WriterGuide.aspx>). A pdf of this worksheet can also be found on the PEN® website under the link to this training module: http://www.pennutrition.com/resources/PEN_resources/PEN%20Writer%20Training%20Modules/PENSearchStrategyWorksheet.pdf

PEN® Search Strategy Worksheet



- a. Define your topic (1 or 2 sentences in your own words, if possible, in the form of a well-built question – remember PICO)
- b. Identify main concepts (come up with 2 to 4 keywords that define your topic, the keywords should all be separate terms that represent your main ideas)
- c. Come up with as many synonyms for each main concept (first come up with the words you can think of, then use something like the MeSH dictionary to add to the list – **see PubMed module**)
- d. Combine your terms using Boolean terms AND and OR
- e. Identify any inclusion/exclusion criteria or limits (language, human vs animal, time period, types of study, etc...)
- f. Select databases that you want to search
- g. Record search strategies for each database and approximate number of results (# of articles / database)
- h. List other methods used to find information and record strategies used (reviewing references lists from key articles, searching the web for grey literature, other sources etc.)

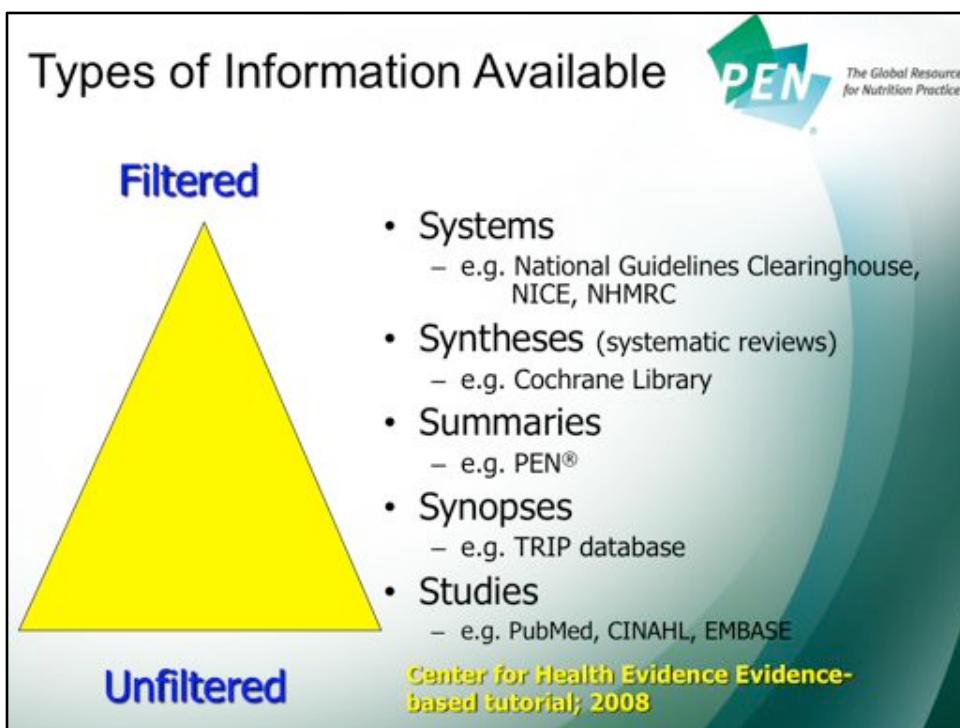
PEN® has created a Search Strategy Worksheet to help guide your search and document your strategy:

http://www.pennutrition.com/resources/PEN_resources/PEN%20Writer%20Training%20Modules/PENSearchStrategyWorksheet.pdf

Review the slide

Whether you are taking a filtered literature approach or looking for individual studies, you should also document your approach and the keywords you used.

Lets start by examining what we mean by filtered literature



In order to sort through the mountain of information in the literature, an accepted practice is to start with filtered literature. Classified as 5 ‘S’ s – Systems, Syntheses, Summaries, Synopses and Studies. The pyramid reflects the numbers usually found in these various types of literature and is not reflective of the quality of evidence.

Starting at the top with the likely smallest number we have:

Systems link evidence to practice and can be found in practice guidelines.

Syntheses summarize results of many studies; use a systematic process for pooling evidence from multiple studies to synthesize the information into a systematic review or meta-analyses e.g. Cochrane library.

Summaries are regularly updated summaries of best evidence about clinical interventions; topics generated by clinicians and presented as clinical questions e.g. PEN®

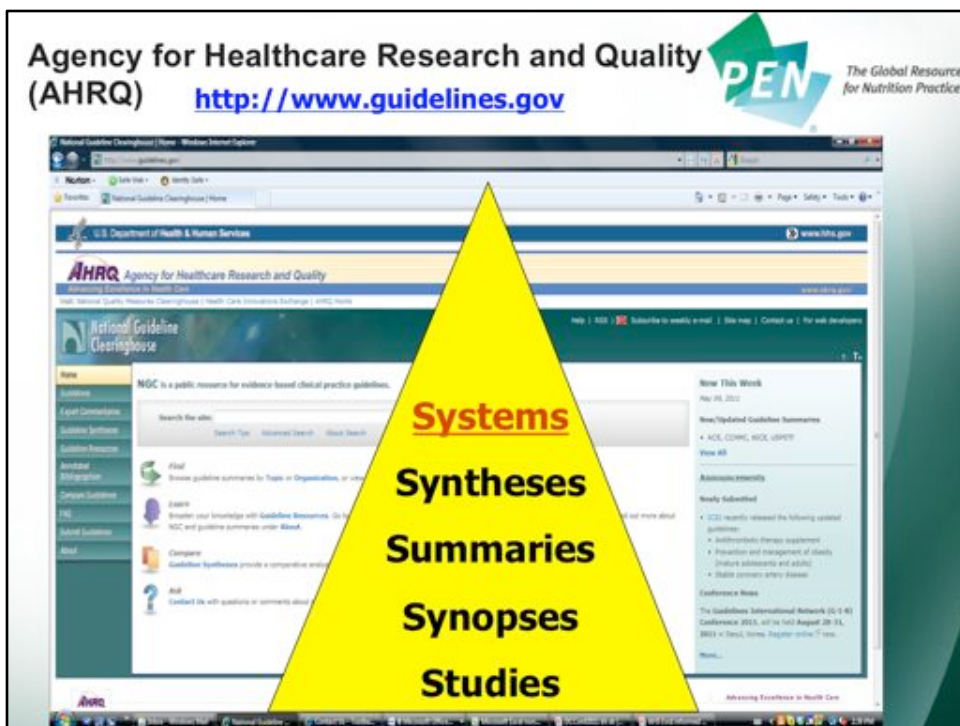
Synopses summarize high quality articles into brief synopses. We do not use Synopses to write evidence statements but to find studies to review.

If evidence can still not be found (for example the clinical issue involves a rare condition or needs to be updated), then a search in the ‘traditional literature’ for individual Studies is necessary.

There are many advantages to using pre-filtered evidence, not the least of which that someone has already reviewed the literature and chosen only methodologies from the strongest studies to answer the research question. Even with filtered sources we still look at what has been published on the topic since the filtered source of information e.g. if a systematic review was published 6 months ago and their literature search ended with a date a year prior to publication then we need to search the literature for the past 18 months to see what has been published since.

Evidence statements in PEN® are usually composed of CPGs, systematic reviews and original research studies – some or all depending on the topic.

Let’s look at accessing the sources of these 5 ‘S’ s in more detail.



The National Guideline Clearinghouse™ (NGC) (<http://www.guidelines.gov>) is a free comprehensive database of evidence-based clinical practice guidelines and related documents. NGC is an initiative of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.

We now ask our PEN® writers to scan guideline clearinghouses in all our partner countries... UK, AU, NZ and CDN
NICE, NHMRC, ESPEN etc.

Note: the quality of clinical guidelines need to be assessed just like is done for systematic reviews, meta-analyses and individual studies. CPG's are not necessarily better evidence than other sources of evidence. More on Clinical Practice Guidelines later.

World Wide Cancer Research Fund **PEN** The Global Resource for Nutrition Practice

<http://www.wcrf.org/>

World Cancer Research Fund International *Stopping cancer before it starts*

Home | Cancer research | Cancer statistics | Policy and advocacy | Conferences | WCRF global network

Get updates: Sign up to WCRF e-news | Share this: Like | Tweet | Facebook | YouTube | LinkedIn | Help our work: Donate

Continuous Update Project

Overview

The WCRF global network has established the Continuous Update Project, which benefits research institutions around the globe.

The aim is to update all 17 WCRF global network's systematic reviews in the original 2007 Report on a rolling basis by 2015. The Expert Panel will then recommend any changes should be made to the WCRF global network's Recommendations for Cancer Prevention.

Information as to whether any updates are confirmed or require changes will be communicated through our communications programmes in 2017.

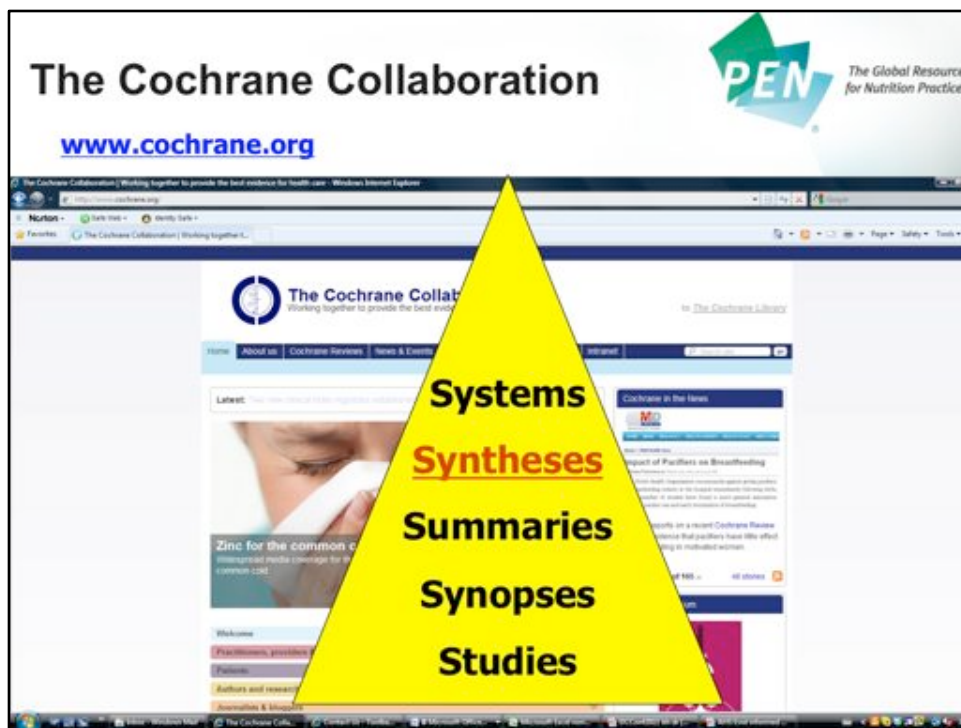
The CUP database, as requested, will be available for general access after 2015.

Diet and Cancer Report

For more details on the Continuous Update Project visit the [Diet and Cancer Report](#) website.

Systems
Syntheses
Summaries
Synopses
Studies

Here you see the World Wide Cancer Research Fund International (<http://www.wcrf.org/>) and a link to their Continuous Update Project or CUPS... Ongoing work, adding to their systematic reviews... explicit with their search criteria and their grading system



Cochrane systematic reviews (<http://www.cochrane.org/cochrane-reviews>) are another example of syntheses, based on the best available information about healthcare interventions, usually limited to randomized controlled trials but case control and observation studies are reviewed as well, especially in public health topic reviews. They explore the evidence for and against the effectiveness and appropriateness of treatments (medications, surgery, education, etc) in specific circumstances. There are over 2200 reviews. Summaries / abstracts are available free - the complete reviews are published in The Cochrane Library which is available by subscription though some countries (notably the UK and Australia), and some workplaces, provide free access for certain sectors of their populations.

Systematic Reviews



- ◆ Search strategies are explicit and comprehensive → reproducible
- ◆ Method used to interpret and assess the evidence is described → rigorous
- ◆ Single study results are combined if possible → meta-analysis (a statistical synthesis of the data)
- ◆ Includes consideration of harms, benefits and costs, where applicable.

A systematic review is a rigorous systematic approach to review of primary studies on a topic.

The search strategies are explicit and comprehensive - the databases searched, the dates included in the search and the selection criteria for studies are explicitly described (did the authors consider only RCTs? Study duration?). This means that anyone else conducting the review, would be able to replicate the review. Cochrane reviews include a detailed methods section that allows the reader to assess whether the review was done in such a way as to justify its conclusions – the type of clinical studies to be incorporated into a review is carefully considered, using predefined criteria; often only RCTs are used. Risk of bias is fully explored.

If the data collected in a review are of sufficient quality and similar enough, they are summarized statistically in a meta-analysis, which generally provides a better overall estimate of a clinical effect than the results from individual studies.

Systematic reviews also include a consideration of the harms or adverse effects associated with the treatment (or whether benefits outweigh harms) and occasionally the costs of treatment where this can be determined.

What distinguishes systematic reviews from traditional, narrative-type reviews?

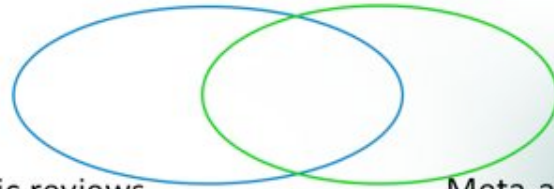
Systematic Reviews and Meta-Analyses



- ▶ **Systematic Review:** A systematic summary of studies: applies strategies to limit bias in the gathering, critical appraisal, and synthesis of all relevant studies on a topic
- ▶ **Meta-analysis:** a statistical synthesis of the data of several studies with predetermined quality

Read the definitions of systematic reviews and meta-analysis.

Systematic reviews and meta-analyses



Systematic reviews may or may not have a meta-analysis as a component. It depends on the characteristics of the studies identified

Meta-analyses may or may not be based on a systematic review

There is generally a lot of overlap between systematic reviews and meta analyses. If conducting a PubMed search one should include both study types as Limits for searching.

These should not be confused with narrative reviews....

Narrative reviews \neq systematic

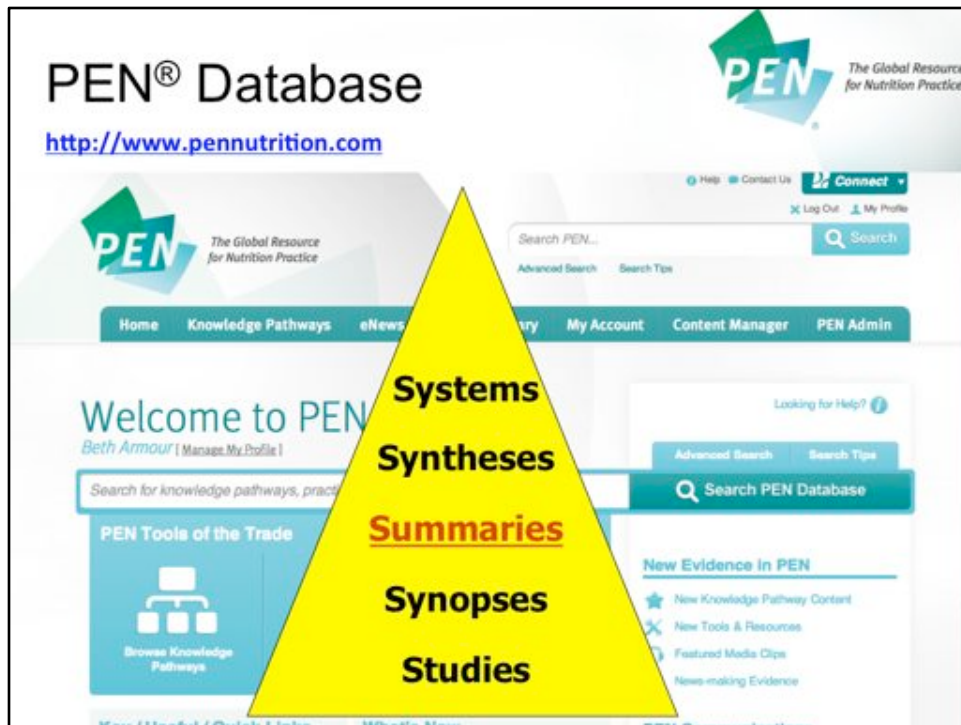


Narrative reviews:

- ◆ are a narrative summary of the evidence
- ◆ may be written by experts in the field
- ◆ are more susceptible to bias
- ◆ are not an exhaustive or structured review and may not systematically evaluate the quality of included studies
- ◆ may include mistaken scientific beliefs (of individual researchers or entire fields of study) leading to selectively citing studies; a systematic review can help clear up those beliefs

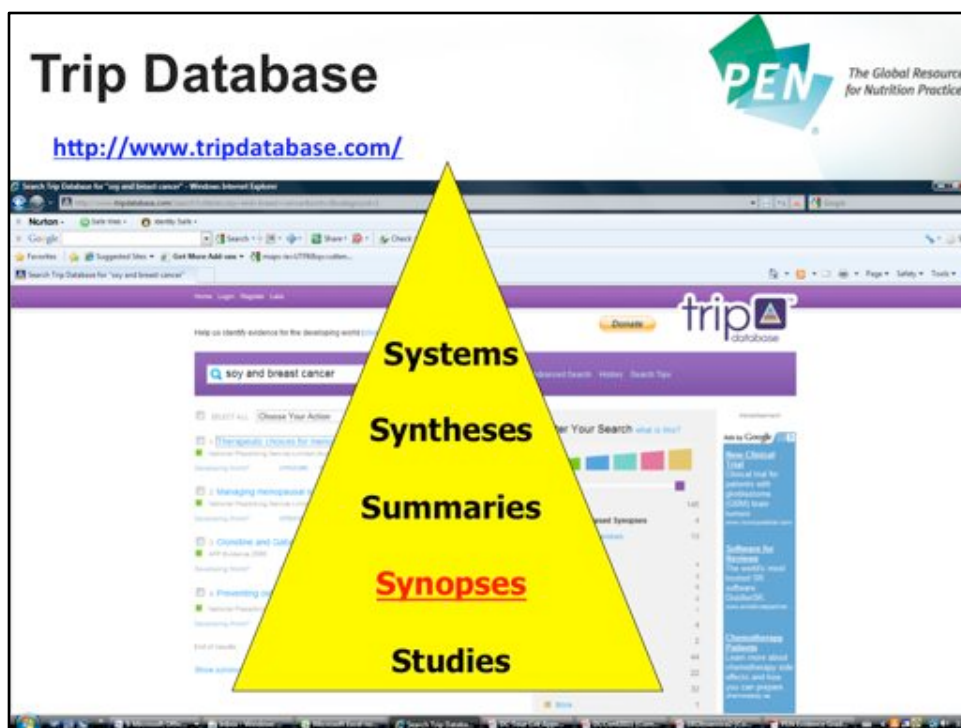
Narrative reviews are definitely not the same as systematic reviews

Read slide



PEN[®] itself is an example of a summary tool: <http://www.pennutrition.com>
It takes the best evidence and summarizes it into graded practice guidance.
Recall PEN[®] has:

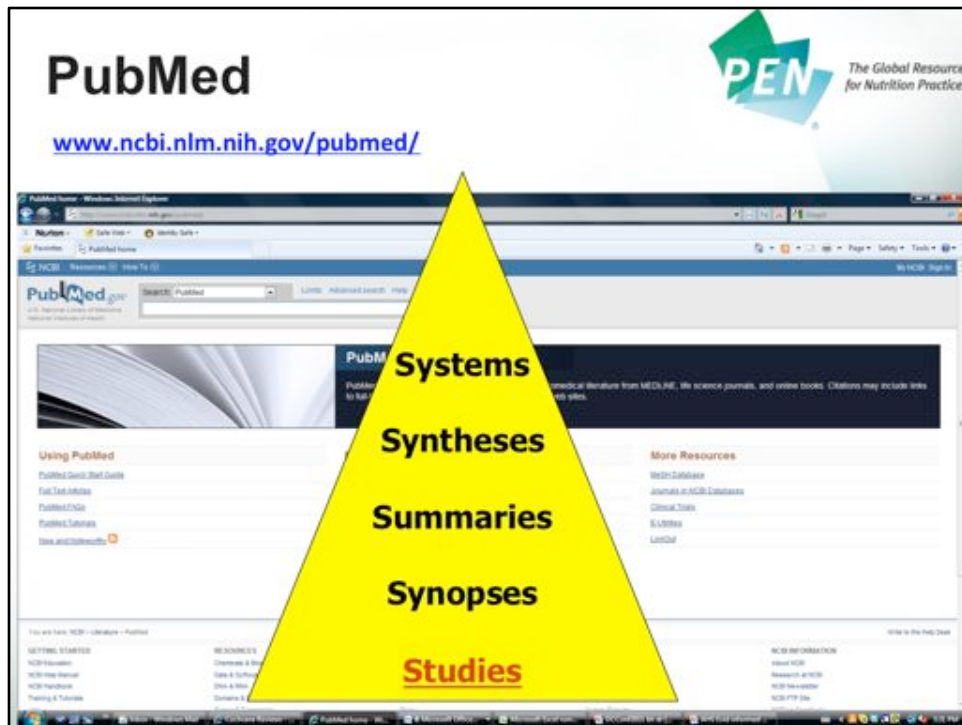
- Key practice points
- Evidence statements
- Practice guidance summaries
- Evidence summaries



Best Evidence and ACP Journal Club are examples of Synopses but both require a subscription.

The Trip Database - Taking Research into Practice (<http://www.tripdatabase.com/>) is a free tool that provides, among other things, synopses of the evidence in response to keywords. They also identify guidelines, clinical trials, systematic reviews plus a great deal more. The TRIP database helps to find the literature but you still need to analyze, critique and summarize the studies, guidelines and systematics reviews. The Trip database can not be cited as a reference for evidence.

It is medically focused though so not all your nutrition questions are likely to be addressed in the detail you might like to see or need.



Depending on the results of your search of pre-filtered literature you may find your answers without needing to do a traditional literature search or you may need to do a small search of the most recent literature. In some cases when there is no pre-filtered literature this may be the sole or primary type of searching. PubMed is a free tool for identifying studies and can also be used to access systematic reviews:

www.ncbi.nlm.nih.gov/pubmed/

Literature Searching Summary



- ◆ Find the terms for your PICO variables to search
- ◆ Prepare a list of your MeSH terms and text words
Look first for: Filtered literature (systematic reviews and clinical practice guidelines)
- ◆ After your search of the filtered literature, you likely will need to do some searching of primary studies (combine terms using Boolean connector “AND” or “OR”); use appropriate filters and don’t forget to check related citations
- ◆ In searching you may find other terms related to your topics that require you to do further searching
- ◆ Perhaps contact your local Librarian for a session on searching

If you have identified a systematic review that indicates the last search date of the review authors, you could filter your search of original research to only those studies published after that search date. Additionally, you may find additional studies that you missed in your original search by paying attention to the introduction and discussion of original research articles. Look to the article’s bibliography for the citations. Be systematic in your search strategies.

Remember defining your PICO question and searching are not always mutually exclusive. For example, in searching you may find in learning more about your topic that there are more appropriate search terms for locating the relevant literature and you may need to re-search.

If you would like more information on literature searching you can complete the “PEN® PubMed” training module.

Acquire – Second Step

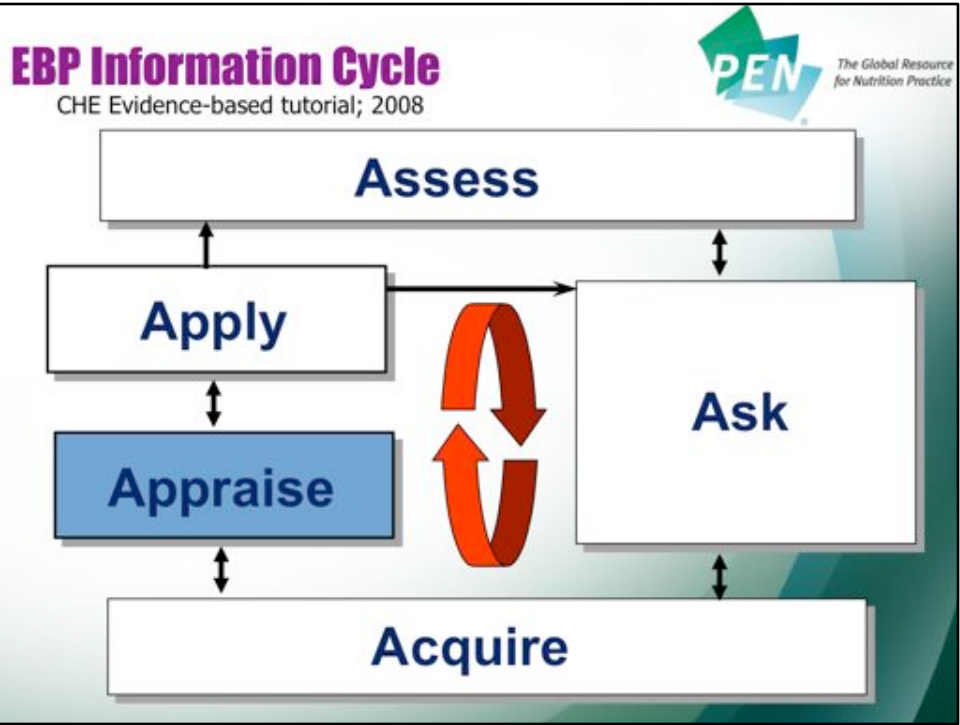


Sifting through the literature:

- ◆ **Exclude** some citations on the basis of relevancy: **Does it address your PICO question???**
- ◆ Delete those not relevant based on the title – usually there are several
- ◆ Delete those not relevant based on the abstract – a few more
- ◆ Those that still look valuable from the abstract, look at the paper. Discard more citations when you find the paper is not relevant

Once you have acquired the literature the second step is to sift through and see what is useful and what is not.

Read slide



Critically appraising the evidence



Hierarchy of Evidence: to help us understand that every study is not created equal and some are better quality evidence than others. Some types of studies are more appropriate depending on the question being asked.

In addition to the type or design of the study, the quality of the study (e.g. well designed, size, risk of bias...) is a key component in determining how it contributes to the graded evidence used in PEN®. **Slides 41 – 47** in this training module discuss the PEN® grading system and the PEN® Evidence Grading Checklist in some detail. Review the “Appraising the Literature” training module for more on assessing the quality of the study.

Depending on your quality assessment of the document then, generally the higher quality evidence in terms of design is from:

Higher quality: Systematic reviews – to be highest quality must be of RCTs, THEN RCTs THEN SRs of nonrandomized or cohort studies THEN Cohort studies THEN Case-control studies

Lower quality: Case series or Case reports - descriptions of a single or a series of cases of some illness

At the bottom are: Editorials, expert opinion – not actually evidence, but opinion

Animal research – studies conducted on animals cannot be applied directly to humans

In vitro - a biological process conducted in a laboratory container i.e. test tube or petri dish

Although there are some issues/questions where animal and in vitro studies are the most appropriate research design, the grade assigned to the resulting KPP would still be low.

As noted in PEN’s grading checklist; clinical impact, generalizability and applicability also are considered in assigning Grades A, B, C and D.

Note: (October 1, 2013) This is the current hierarchy of evidence but we are aware of continuing discussions taking place within groups such as Cochrane and GRADE on grading hierarchies. The PEN® team continues to monitor these discussions.

Clinical Practice Guidelines (CPG)



- ◆ CPGs should be considered in any evidence review.
- ◆ May or may not be a systematic review of your topic of interest, and may not include much on nutrition elements of care
- ◆ CPG recommendations are generally graded and if so may be considered equivalent to systematic reviews = top quality evidence

BUT

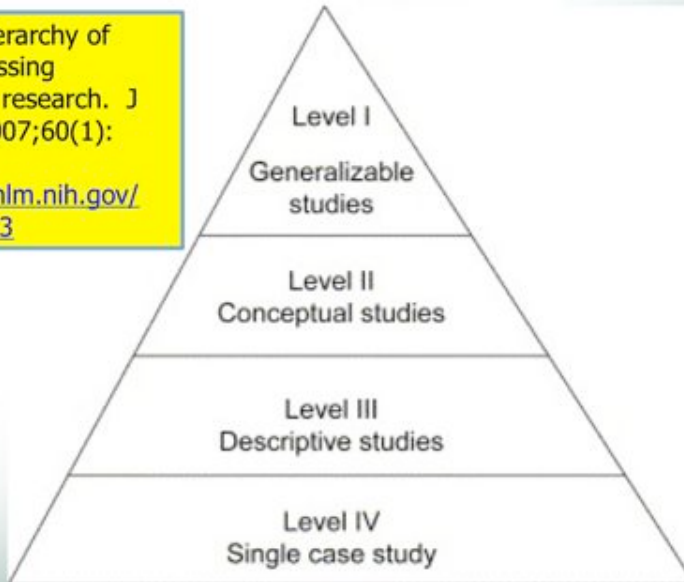
If they are consensus guidelines they are considered equivalent to expert opinion = lower quality evidence

Read slides... in the PEN® training module: “Appraising the Literature” we share some tools to evaluate CPGs...

Hierarchy of qualitative evidence



Daly J. et al. A hierarchy of evidence for assessing qualitative health research. *J Clin Epidemiol.* 2007;60(1): 43-9.
<http://www.ncbi.nlm.nih.gov/pubmed/17161753>



Here is a hierarchy for appraising qualitative evidence.

Qualitative studies use non-numerical information, and can provide valuable insight into how people experience states of health and illness or how things came about.


Generally qualitative studies are beyond the scope of this presentation. However, in case you are assessing qualitative evidence, here is a reference to a tool to assess their rigor. Abstract available at: <http://www.ncbi.nlm.nih.gov/pubmed/17161753>

Key points re: study designs



1. Observational studies only provide observations, and can always be confounded by related variables; so observational studies cannot be taken as proof of causation. We can use the terms “risk factor” and “association”
2. Usually a single study, even a well-designed one, does not provide sufficiently robust evidence to recommend changes to clinical practice.
3. If RCTs are well designed, and consistent results are seen in several RCTS, then, for the same PICO conditions, one could assume causation

Read slide. If study design is new to you and you would like more information, complete the “PEN Quick Review of Study Designs” training module



Data Extraction Table

Author year	Study design	Population	Intervention	Comparison	Outcome	Results	Appraisal - worth to practice

Consider setting up a Data Extraction Table.

This is a sample, you may find that you use more or less categories depending on your topic.

PEN[®] Writer's Guide



Appendix 2

Evidence Grading Checklist p 25

Appendix 6

***Selected User Guides to the Medical Literature
p 41***

PEN[®] Evidence Grading Checklist is in the PEN[®] Writer's Guide

http://www.pennutrition.com/resources/PEN_resources/PEN%20Writer%20Training%20Modules/PENEvidenceGradingChecklistOct2013.pdf

User guides are in PEN[®] Writers Guide (<http://www.pennutrition.com/WriterGuide.aspx>)

and PDF documents of both are linked just below the link to the "PEN[®] Evidence-based Process" training module in PEN[®] (<http://www.pennutrition.com/WriterGuide.aspx>)

Centre for Health Evidence
Users Guide – Therapeutic Intervention



Document appraisal topics from the User's Guide:

- ◆ Are the results valid – randomization, blinding, similar groups, similar prognosis throughout, was follow-up complete....
- ◆ What are the results – looks at treatment effect/ effect sizes, statistical significance...
- ◆ How to apply results to practice – study criteria, endpoints, NNT, worth the cost and risk

See PEN® Writer's Guide – Appendix 6 for actual form.

As an example, looking at the Center for Health Evidence - User Guide for Therapeutic Intervention - topics to consider in appraising your document....

Are the results valid – were the subjects randomized, were groups and staff involved blinded to which group they were in, were the groups similar before and throughout the intervention in terms of prognostic variables – those factors which might give an increased or decreased risk of adverse or positive outcomes, was follow-up complete – for ex: is 24 weeks long enough to see an effect?

What are the results – effect of intervention / treatment.

The confidence interval can be used to look at effect sizes, since, based on statistics, it estimates the extreme values that are likely to occur.

The p-value is used to determine if the results are statistically significant.

How can I apply the results to my practice – do your patients match the study inclusion criteria, are there any reasons why the results should not apply to your patient, what were the primary and secondary endpoints of the study, what is the number needed to treat (NNT) to prevent one adverse outcome or produce one positive outcome, is the clinical endpoint worth the increased cost and risk of harm?

See PEN® Writer's Guide – Appendix 6 for actual form:

<http://www.pennutrition.com/WriterGuide.aspx>

The PEN[®] Grading System



- ◆ Is based on the study designs and the number of studies
- ◆ Is based on the consistency of the evidence
- ◆ Considers clinical impact of findings
- ◆ Considers the applicability of the findings
- ◆ Considers the generalizability of the findings

Similar to other credible grading frameworks... the PEN[®] Grading system...read slide

PEN[®] GRADES VS NHMRC



Grade A	PEN	NHMRC
Description	Good	Excellent
Evidence Base	Systematic review of RCTs with low risk of bias; several smaller trials combined in a meta-analysis with consistent findings	1 or more level I studies with a low risk of bias or several level II studies with a low risk of bias
Consistency	Consistent results from all studies	All studies consistent
Clinical Impact	Clinically important	Very large
Generalizability	Results that are free of any sufficient doubts about generalizability, bias and flaws in research design	Population(s) studied in body of evidence are the same as the target population for the guideline
Applicability	Directly applicable to practice setting (considering access, cost issues etc.)	Directly applicable to Australian healthcare context

IN 2010 we compared the PEN[®] grading system with the NHMRC one, used in Australia, and found tremendous congruency. We actually tweaked the PEN[®] one to be closer in line with NHMRC

Giving Evidence a Grade



Grade (A):

The conclusion is supported by good evidence.

Grade (B):

The conclusion is supported by fair evidence.

Grade (C):

The conclusion is supported by limited evidence or expert opinion.

Grade (D):

A conclusion is either not possible or extremely limited because evidence is unavailable and/or of poor quality and/or is contradictory.

- A number of information sources were used in developing a grading system for PEN.
- Gray GE and Gray LK. Evidence-based medicine: Applications in dietetic practice. J Am Diet Assoc 2002; 102: 1263-1272. Abstract available from: <http://www.ncbi.nlm.nih.gov/pubmed/12792624>
- Grandage KK; Slawson DC; Shaughnessy AF. When less is more: a practical approach to searching for evidence-based answers. J Med Libr Assoc July 2002; 90(3): 298-2002. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12113514>
- Personal communication. R Hayward. Centre for Health Evidence. 2004.
- Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force of Preventive Health Care. CMAJ. 2003; 169(3): 207-208. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12900479>
- Upshur, REG. Are all evidence-based practices alike? Problems in the ranking of evidence. CMAJ; 2003; 169(7):672-673. Available from: <http://www.cmaj.ca/cgi/content/full/169/7/672>
- Schüremann HJ, Best D, Vist G, Oxmann AD On behalf of the GRADE Working Group. Letters, numbers, symbols and words: how to communicate grades of evidence and recommendations CMAJ. 2003; 169(7):677. Available from: <http://www.cmaj.ca/cgi/content/full/169/7/677>
- Ebell MH, Siwek J, Weiss BD, Woolf SH, Susman J, Ewigan B, Bowman M. SORT: A Patient Centered Approach to Grading the Literature. Am Fam Physician. 2004; 69(3):548-56. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/14971837>
- GRADE Working Group. Grading Quality of Evidence and Strength of Recommendations. BMJ. 2004; 328:1490. Available from: <http://bmi.bmjournals.com/cgi/content/full/328/7454/1490>

Grade (A):



The conclusion is supported by GOOD evidence.

Results are from studies of strong research design for answering the practice question, clear methodology and sufficient sample size.

Evidence examples:

Treatment / Intervention Studies

- good quality systematic review of RCTs (with or without a meta-analysis) with consistent findings and low risk of bias
- ≥ 2 high quality RCTs with low risk of bias

Etiology / Prognosis Studies

- systematic review of cohort studies (with homogeneity) or
- 2 or more independent well-done prospective cohort studies:
 - with consistent results in the absence of evidence to the contrary
 - with sufficiently large treatment/exposure effects

Also, studies are clinically important, generalizable and directly applicable to the practice setting

This slide and the next 3 slides provide examples of evidence and other factors to consider in grading the evidence (this information is drawn from the Evidence Grading Checklist in Appendix 2, p. 25 of the PEN Writer's Guide)

<http://www.pennutrition.com/WriterGuide.aspx>

Grade (B):



The conclusion is supported by FAIR evidence.

Results are from studies of strong research design with minor methodological concerns or inconsistencies, or from studies of weaker designs but with generally consistent results.

Evidence examples:

Treatment / Intervention Studies

- systematic review of RCTs with heterogeneity, but results support the conclusion
- a single RCT with low risk of bias
- ≥ 2 RCTs with a clinically significant conclusion and unclear risk of bias

Etiology / Prognosis Studies

- systematic review of cohort studies or case-control studies (with homogeneity) or ≥ 2 independent well-done prospective cohort studies with consistent findings

Also, there is minor doubt about the clinical significance of results and about generalizability. Results are generally applicable to the practice setting with few exceptions.

Grade (C):



The conclusion is supported by LIMITED evidence.

Results are from studies of weak design or there is uncertainty due to inconsistencies among results.

Evidence examples:

Treatment / Intervention Studies

- several RCTs with inconsistent results or high risk of bias
- non-randomized trial
- systematic review of observational studies (with homogeneity) or ≥ 2 well-done cohort studies with consistent findings

Etiology / Prognosis Studies

- systematic review of cohort studies or case-control studies (with heterogeneity) or several studies with some inconsistent results
- single cohort study or ≥ 2 case-control studies unconfirmed by other studies

Also, there is uncertainty about clinical impact and generalizability.

Results are generally applicable to the practice setting with some exceptions.

Grade (D):



A conclusion is not possible or extremely limited due to unavailable evidence and/or poor quality evidence and/or contradictory evidence.

Results are from a single study with major design flaws or from studies with such contradictory results that conclusions can't be drawn. Alternatively, evidence is lacking from either authoritative sources or research involving humans

Evidence examples:

- poorly designed or executed trial or intervention
- a single case report, case series, case-control or ecological study
- anecdotal reports
- small number of similar quality studies with contradictory results
- research in the *in vitro*, *ex vivo* or animal model

Also, clinical impact and generalizability are very limited. Results are not generally applicable to the practice setting.

PEN® Evidence Grading Checklist



Evidence Grading Checklist

The conclusion is supported by GOOD evidence. (A)

1. Evidence The results are from studies of strong research design for answering the practice question, clear methodology and sufficient sample size. Supporting studies might consist of: <u>Treatment / Intervention Studies</u> <ul style="list-style-type: none"> • good quality systematic review (SR) of randomized controlled trials (RCTs) with consistent findings and a low risk of bias^a • SR including several trials combined in a single well-done meta-analysis with consistent findings^a • two or more high quality randomized, controlled trials with a low risk of bias^a <u>Etiology / Prognosis Studies</u> <ul style="list-style-type: none"> • SR of cohort studies (with homogeneity) or two or more independent well-done prospective cohort studies with consistent results in the absence of evidence to the contrary, where treatment/exposure effects are sufficiently large and consistent Note: Evidence might also be in a position statement or practice guideline from a national body or organization reporting results of research studies based on the aforementioned types of research	√
2. Consistency ^a - results are consistent with minor exceptions at most	
3. Clinical impact ^a - results are clinically important	
4. Generalizability ^a - results are free of any sufficient doubts about generalizability	
5. Applicability ^a - results are directly applicable to practice setting	

Review the PEN® Evidence Grading Checklist – PEN® Writer’s Guide – Appendix 2

Review the PEN® Evidence Grading checklist – PEN® Writer’s Guide – Appendix 2 or linked directly below this training module on the PEN® database :
<http://www.pennutrition.com/WriterGuide.aspx>

When evidence is limited what do we do?



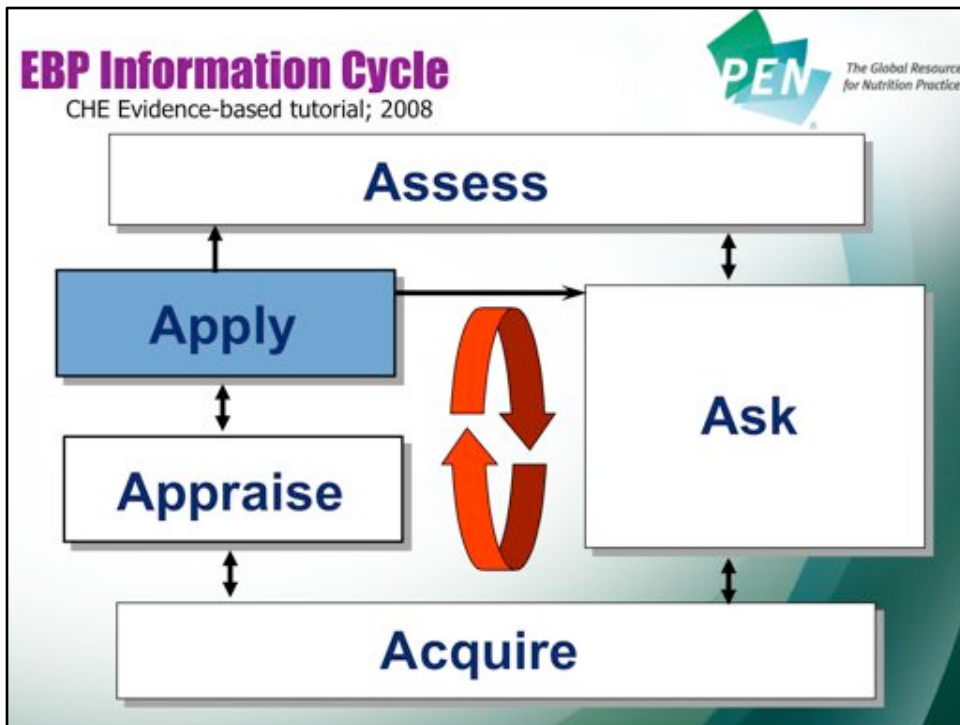
- Much that we do in nutrition and medicine is not yet based on solid evidence, but based on biochemistry and physiology, and sometimes limited or weaker evidence - *Grade C*

"What are we to do when the irresistible force of the need to offer clinical advice meets with the immovable object of flawed evidence? All we can do is our best: give the advice, but alert the advisees to the flaws in the evidence on which it is based."

Centre for Evidence Based Medicine, Oxford.

In other words, our job is to identify the level of evidence, whether it is high or low.

For more information on critically appraising the literature, we encourage you to view the "PEN® Appraising the Literature" training module which contains links to additional learning modules on appraisal as well as an additional guideline for appraising CPG's. It also walks you through an appraisal exercise.



Now the practical part – applying what you have found and developing the key practice point or practice recommendation. Applying the evidence you have found to answer your question is the basis of the PEN database and requires a number of steps that we are going to go through. This is the stage where the grade of evidence is assigned.

Evidence Statements



Summarize each document you are using for evidence into an evidence statement:

- Type of study
- Population studied and # of subjects
- Key inclusion / exclusion criteria
- Methods and interventions
- If diet included how was it assessed
- Key findings that pertain to the practice question
- Authors main conclusions and limitations noted separately from yours
- Any sources of bias

Keeping in mind these are suggested points of how you might summarize the article into an evidence statement. The PEN® user should be able to have a snapshot of the article, why it has been used to support the key practice point and how it influences the grade of evidence for the key practice point.

The evidence statement should not be a re-gurgitation of the paper's abstract. In fact, so as not to be biased by how the author's summarized the study as they did in their abstract you may find it helpful when writing your evidence statements to not re-read the abstract until you are done extracting from the full paper.

We want to be thorough but also concise. You will not always have to include inclusion/exclusion criteria in the evidence statement but should be evaluating these factors in your critical appraisal. Sometimes it can be concisely communicated in the description of the population. Likewise, the study methods do not need to be written in extreme detail but they should be evaluated in your critical appraisal for their limitations and appropriateness. Some aspects of methods and measures can be combined with the sentences describing the results. Additionally, you may find that there are results presented in the study that do not pertain to your practice question, these should not be included. Just include the findings that relate to your topic/question.

In addition to noting the study authors' main conclusions and admitted limitations, you should also note any limitations that you have identified in your critical appraisal of the study. To do this, re-insert the citation number to indicate that is the end of the information provided by the author and then make your statements regarding conclusions and limitations. See PEN® Writers Guide: <http://www.pennutrition.com/WriterGuide.aspx>

Evidence Statements (example)



A systematic review (including studies published up to 2007) examining the risk of malignancy in individuals with RA identified a total of 21 studies reporting overall malignancy (n=13), lymphoma (n=14), colorectal (n=10), lung (n=12) and breast cancer (n=9) (3). Meta-analysis showed that individuals with RA have a modestly increased risk of overall malignancy (standardized incidence ratio [SIR], 1.05; 95% CI, 1.01-1.09) compared to the general population. In particular, increased risk of lymphoma (SIR, 2.08; 95% CI, 1.80-2.39) (especially Hodgkin lymphoma) and lung cancer (SIR, 1.63; 95% CI, 1.43-1.87) were observed; however, rates of colorectal and breast cancer were lower than the general population (SIR, 0.77; 95%CI, 0.65-0.90 and SIR, 0.84; 95% CI, 0.79-0.90, respectively).

Read slide

Key Practice Points



When developing them take into consideration:

- study design / type of evidence
- population (if guidance targets a specific group, e.g. age, gender and/or a specific population is mentioned in the practice question it should be mentioned in the KPP)
- key conclusion/answer or practice guidance ± specify amounts if applicable e.g. x amount of a supplement daily
- limitations of the evidence may be included if critical, in this case they would also be included in the evidence statements
- point out any risks/benefits
- future research needed/suggested (either here or in the Comments section)

Writers are reminded to not let personal biases, if any, influence the wording or tone of the KPP.

Taking all of the evidence into consideration develop a key practice point or practice recommendation that also succinctly summarizes the evidence used.

Read slide.

When relevant, it is important to consider risk versus benefits of a health decision with the client instead of feeling pressure to make the decision in the KPP and saying there is not enough evidence to say one should..... There are many examples in nutrition where the evidence is mixed or grey or incomplete.

So a KPP conclusion may sometimes be: “discuss risks and benefits with the client” versus “there is not enough strong evidence to recommend.....”

Key Practice Points

(example)



Observational studies have demonstrated that compared to the general population, individuals with rheumatoid arthritis (RA) have a higher risk of many co-morbid conditions including cardiovascular disease, cancer, diabetes, pulmonary disorders, infections, osteoporosis, cataracts, gastrointestinal disease, psoriasis, renal disease and depression. A multidisciplinary team that includes a dietitian can be instrumental in assessing and managing co-morbid conditions and associated risk factors. In particular, maintaining a healthy weight and BMI is encouraged for all individuals with RA. Dietary modification to assist with weight reduction in individuals who are overweight or obese can reduce cardiovascular risk.

Read slide. See Rheumatoid Arthritis KP for more examples:
[http://www.pennutrition.com/KnowledgePathway.aspx?
kpid=978&pqcatid=144&pqid=976](http://www.pennutrition.com/KnowledgePathway.aspx?kpid=978&pqcatid=144&pqid=976)

Comments Section



- ◆ A KPP may or may not have a comment section
- ◆ Relevant information that does not belong in an evidence statement (and therefore can't be included in the KPP) can be included as a comment
- ◆ Information provided should be referenced and reference is added to the KPP reference list
- ◆ Often where Partner Country Differences are noted

Not all key practice points have comment sections. However, going forward we would like to see writers make an effort to include the extra information they come across in their research for the comments section. The information in the comments sections has helped guide practice as it contains additional information that informs action but is not necessarily “gradeable”. Additionally, the information in the comments sections is important for the development of practice guidance summaries and toolkits.

Comments example



- ◆ Chromium comment – sources of chromium in foods, different valances of chromium – food versus chemical and industrial; length of trials and lack of clarity on safety
- ◆ If the key practice point refers to national healthy eating guidelines it might say: “Follow the national healthy eating guidelines for your country. [See Comments]” then in the Comments section it links to the document which contains healthy eating guidelines for each partner country

Read and then next slide for Example of country partner differences

PEN Partner Country Differences



Healthy Eating Guidelines:

- **Australia: The Australian Guide to Healthy Eating**
- **Canada: Eating Well with Canada's Food Guide**
- **New Zealand: Food and Nutrition Standards (by life stage)**
- **United Kingdom: The Eatwell Plate**
- **United States (include if relevant) : My Plate**

[International Healthy Eating Guidelines Collection](#)



This is an example of what the Comments section might look like if the KPP mentions: It is recommended to follow your country's national healthy eating guidelines. For some of the country specific links our PEN resource managers have created collections – like you see in this example and therefore only one link is necessary.

The [International Healthy Eating Guidelines Collection](#) is available from:

<http://www.pennutrition.com/KnowledgePathway.aspx?kpid=3127&trid=19351&trcatid=27>

These collections are clearly referred to the PEN Writer's Guide :

<http://www.pennutrition.com/WriterGuide.aspx>

PEN Partner Country Differences



PEN Writer's Guide - Appendix 7

Is a document containing country specific information:
on

- dietary /healthy eating / physical activity guidelines
- food safety
- food labelling
- dietary guidance for infants and young children
- disease association guidelines.....

Please let us know if there are other topics you think
we should add!

In the PEN® Writer's Guide (<http://www.pennutrition.com/WriterGuide.aspx>) we have a document which gets updated as needed to reflect our partner country differences. It includes healthy eating; dietary guidance for adults, children and infants....

Rationale



- ◆ explains the proposed mechanism of action
- ◆ reasoning behind the research hypothesis
- ◆ explanations for theories
- ◆ it should be referenced and references are added to the KPP reference list

Some KPPs may include a rationale for asking the question, if the reason for asking it isn't obvious. Read slide

Every effort should be made to include the rationale and proposed mechanisms of action in PEN. It is important to be clear what types of research/evidence/observation is informing the proposed mechanism of action. Is it in vitro? Human or animal ex vivo, in vivo? Observational or from randomized trials? Actual articles or a narrative or systematic review that has explored the mechanism may be cited for this. Try to avoid relying just on original research articles' introductions and discussions for this material when possible. See in PEN eNews- article: And Yet Another Thing About Bias... Citation Distortion. (August 2013 Vol 3 #3) <http://www.pennutrition.com/enews.aspx?id=14#172>

Rationale example



The adhesion of pathogenic bacteria to the uroepithelium is considered an important step in the initiation of a urinary tract infection (after which time the bacteria multiply and colonize the urinary tract) (17). *Ex vivo* and *in vitro* evidence suggests that ingestion of cranberry (*Vaccinium macrocarpon*) products by humans can decrease the adherence (sticking) of pathogenic bacteria like *E. coli* to the uroepithelial cells of the urinary tract and in a dose dependent manner (9-14).....

Here is an example of the Rationale associated with the PEN question: Can the ingestion of cranberry products (juice, tablets/capsules, dried cranberries, cranberry seeds) prevent urinary tract infections? This information can be found at the following link:

<http://www.pennutrition.com/KnowledgePathway.aspx?kpid=7285&pqcatid=144&pqid=8866&kppid=8867&book=Rationale#Rationale>

Related Tools and Resources



- ◆ tools and resources can exist as stand alone tools added to Background documents, Practice Guidance Summary (PGS) and Toolkits– writers to specify where to add
- ◆ not an exhaustive list but key tools on the topic for each partner country
- ◆ tool name, description, URL, key words, KP, developer/publisher, author, country of origin
- ◆ PEN Tool/Resource Approval Checklist

Read slide and of course, we have a PEN® Tool/Resource Approval Checklist
- linked under the link for this training module:
<http://www.pennutrition.com/WriterGuide.aspx>

Related Tools and Resources



Tools and resources recommended should be:

- new to PEN®
- consistent with PEN® evidence or is PEN® evidence missing to support the tool
- literacy level
- quality of content and print quality
- no sponsorship on tool or website
- applicable to an area, country or international

See: PEN® Tool/Resource Approval Checklist (PEN® Writer's Guide – Appendix 14)

PEN® Writers are asked to identify and recommend tools that:

- are not already in the PEN® system
- agree with the evidence, no conflicts
- do not have corporate sponsorship, or if they do, alert the PEN® Tool and Resource Managers
- are for professionals and those that are for clients

PEN® Tool and Resource Managers

- will look at literacy, white space, print quality etc.

PEN® Style Guide



PEN® Writer's Guide - Appendix 18

- ◆ PEN® Style Guide helps to provide consistency in PEN® content with so many different writers and writing styles
- ◆ Using the KP Template in the PEN® Process Dropbox folder will help to ensure you start out with the right format.
- ◆ Refer to the document: "Keeping the PEN® Editor Happy" in the PEN® Style Guide and the Dropbox folder

Appendix 18 of the PEN® Writer's Guide:
<http://www.pennutrition.com/WriterGuide.aspx>

Read slide.

PEN[®] Writer's Checklist



- ◆ Two sections – one for new content and one for updating content
- ◆ Check the PEN[®] Writer's Guide – Appendix 13 to see if you have or can check off everything including these which are sometimes missed:
 - ◆ evidence statements support the key practice points
 - ◆ references match the evidence statements and are in the PEN[®] format
 - ◆ you have signed the IP waiver and Declaration of Affiliations and Interest form – form in the PEN[®] Process Dropbox folder

PEN[®] Writer's Checklist is Appendix 13 in the PEN[®] Writer's Guide (<http://www.pennutrition.com/WriterGuide.aspx>) and can also be found linked under this training module on the PEN website:

http://www.pennutrition.com/resources/PEN_resources/PEN%20Writer%20Training%20Modules/PENEvidenceGradingChecklistOct2013.pdf

Intellectual Property



PEN writers assign ownership of the PEN pathway content to DC

“The Assignor represents and warrants that, in respect of the Works, the Assignor has not infringed, violated or misappropriated the rights of any other person..”

However, a special clause can be invoked for academic or student writers to permit publication of research or theses.

Conflict of Interest



Affiliations and Interests Checklist

In reviewing your activities (and those of your spouse and immediate family members) to determine whether they affect your impartiality or create a real, potential or apparent conflict of interest, among other things, consider the following:

- Investments in a business enterprise (Other than mutual funds or Registered Savings Plans)
- Retirement Savings Plans (that are not self-directed);
- Participation as investigator in clinical trials of relevance to the knowledge pathway;
- Previous, present and potential Contracts, Grants and/or Contributions;
- Pending negotiations regarding potential contracts;
- Honoraria and other sources of personal income;
- Gifts and hospitality of significant value;
- Travel sponsorship;
- Promotion of a product(s) of relevance to the knowledge pathway;
- Publications;
- Public statements;
- Lobbying activities;
- Membership in special interest groups;
- Expert testimonies in court;
- Any interest or activity, which may create a reasonable apprehension of bias.

Copyright



Dietitians of Canada holds the copyright on Knowledge Pathways in PEN®.

- We seek permission from other copyright holders to use tables, figures etc. within the pathways.
- Tools and resources may be owned by DC or the group that created them and holds the copyright (third party).

As mentioned previously, DC requires authors to assign IP ownership to DC allowing us to hold the copyright.

Plagiarism Guidelines



PEN® Writer's Guide – Appendix 11

“Writing for PEN® means following guidelines for professional ethics and integrity.”

- use of quotation marks
- paraphrasing
- self-plagiarism



PEN eNews article:

“The “P” word... and we don't mean PEN”

<http://www.pennutrition.com/enews.aspx?id=6#48>

While it doesn't happen often, from time-to-time we do find some examples of plagiarism in PEN®. We do recognize that plagiarism can sometimes be un-intentional. To make sure you are well aware of all that may be deemed plagiarism and how to avoid it see the guidelines we have developed - Appendix 11 of the PEN® Writer's Guide. To access the PEN eNews article: “The “P” word.... And we don't mean PEN” go to: <http://www.pennutrition.com/enews.aspx?id=6>

PEN® Training Modules



The following other PEN® Training Modules are available:

- Asking the Question
- Appraising the Literature
- PubMed Module
- Quick Review of Study Designs

The other PEN® Writer training modules can be accessed at:
<http://www.pennutrition.com/WriterGuide.aspx>

*Thank you for your
time in reviewing this
module.*

Come be social with PEN



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