The Evidence-based Healthcare

Overview and Development

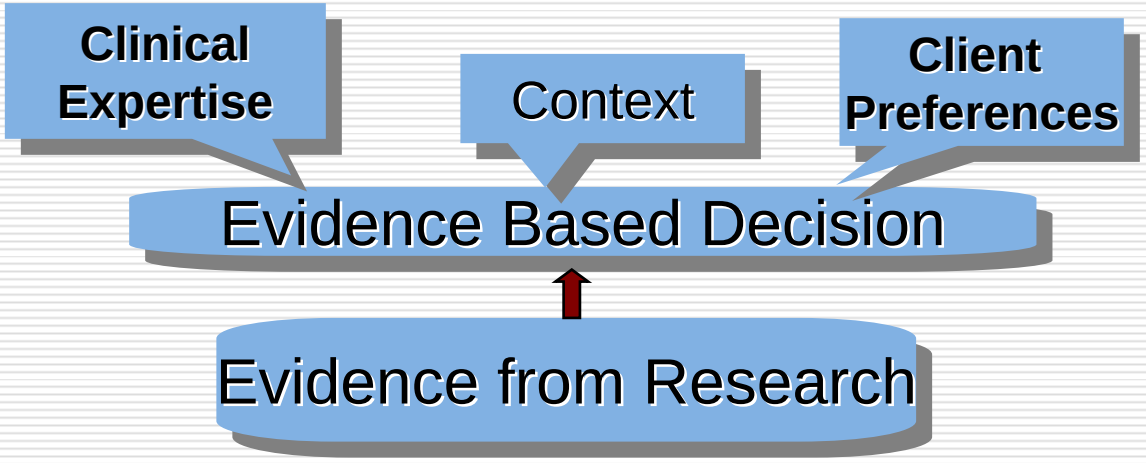
Yann-Fen Chao, RN, PhD

The spirit

- Evidence-based practice stems from A.L. Cochrane's work in relation to evidence-based medicine.
- Cochrane drew attention to the lack of information about the effects of health care, with particular reference to medicine.
- He argued that, as resources for health care are limited, they should be used effectively to provide care that has been shown, in valid evaluations, to result in desirable outcomes.
- He emphasised the importance of randomised controlled trials in providing reliable information on the effectiveness of medical interventions.

The practice of EBHC

- Evidence-based practice involves
  - giving consideration to the best available evidence;
  - the context in which the care is delivered;
  - client preference; and
  - the professional judgment of the health professional.



The challenge

- Evidence-based practice focuses on the need for health professionals to base their interventions and activities on the most up-to-date evidence or knowledge available.
- The evidence-based approach acknowledges the difficulties faced by busy practitioners in keeping up to date with an ever-growing literature in health care and emphasises the importance of providing them with condensed information gathered through the systematic review of the international literature on a given topic.

Topics which health care professionals concern

- Feasibility
- Appropriateness
- Meaningfulness
- Effectiveness
- Economical value

The identification and appraisal of the evidence are the fundamental skills in EBHC

Evidence of feasibility

- Feasibility is the extent to which an activity is practical and practicable.
- Clinical feasibility is about whether or not an activity or intervention is physically, culturally or financially practical or possible within a given context.

Evidence of appropriateness

- Appropriateness is the extent to which an intervention or activity fits with or is apt in a situation.
- Clinical appropriateness is about how an activity or intervention relates to the context in which care is given.

Evidence of meaningfulness

- Meaningfulness is how intervention or activity is experienced by the patient.
- Meaningfulness relates to the personal experience, opinions, values, thoughts, beliefs, and interpretations of patients or clients.

Evidence of effectiveness

- Effectiveness is the extent to which an intervention, when used appropriately, achieves the intended effect.
- Clinical effectiveness is about the relationship between an intervention and clinical or health outcomes.

The fundamental work

- The spirit of evidence-based health care asks to base clinical and other health care decisions on the best available evidence.
- However, not every evidence bears equal scientific significance.
- Practitioners have to be able to verify and select the best available ones.

Three international organizations reviewing evidence to inform clinical decision making

- The Cochrane Collaboration;
- The Campbell Collaboration; and
- The Joanna Briggs Institute

The four major components

- Evidence Generation;
- Evidence Synthesis;
- Evidence/Knowledge Transfer;
- Evidence Utilisation.

Health Care Evidence

- The evidence will be generated to establish the feasibility, appropriateness, meaningfulness or effectiveness of a particular intervention, activity or phenomenon
- How this evidence is derived will have implications for how it can be utilised to change practice. The level of evidence is dependent on research methodology.
- Issues of sensitivity and specificity in literature review

The value of research findings

- **Validity (internal validity)**
  - The degree to which the results of a study are likely to be true and free of bias for the people recruited in that study. It refers to the integrity of the study design.
  - Bias is the deviation of results from the truth or processes leading to such deviation
- **Generalizability (external validity, applicability)**
  - The extent to which the effects observed in a study truly reflect what can be expected in a target population beyond the sample recruited in that study.
  - It refers to the applicability of results to people who did not participate in the study.

Sources of Bias

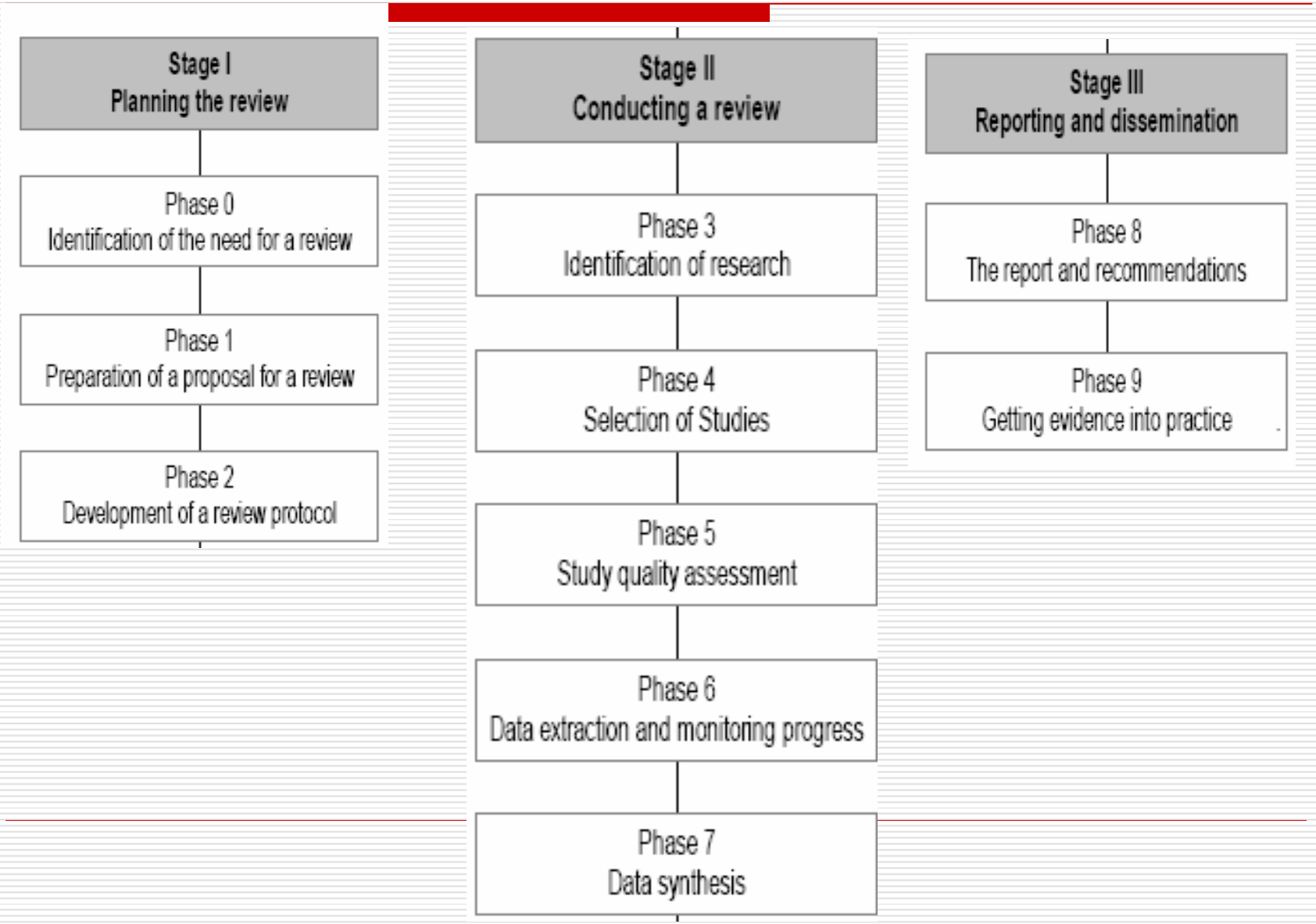
- Selection Bias
  - avoided by concealed randomisation
- Performance Bias
  - avoided by blinding the allocation to patients, practitioners, those who measure outcomes and those who carry out the data analysis
- Attrition Bias
  - differences in terms of losses of subjects between groups losses to follow-up should be reported, but is difficult to assess

Study quality assessment

Studies may be biased due to

- inadequate randomisation,
- unsuitable comparison interventions,
- a lack of blind outcome assessment,
- inadequate follow-up times,
- inability to define and assess relevant outcomes,
- unreliable measurement techniques, and
- inappropriate statistical analyses.

Steps in conducting systematic literature review



Review vs. systemic review

- **Review**
  - An article that summarises a number of different primary studies and may draw conclusions about the effectiveness of a particular intervention.
  - A review may or may not be systematic.

- **Systematic review (systematic overview)**
  - A review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant primary research, and to extract and analyse data from the studies that are included in the review.
  - Statistical methods (meta-analysis) may or may not be used.

Evidence synthesis

- Meta-analysis
  - The use of various statistical methods to combine the results of multiple different studies to produce a stronger conclusion than can be derived from any one of the studies on its own.
- Meta synthesis
  - A process of combining the findings of individual qualitative studies (that is, cases) to create summary statements that authentically describe the meaning of these themes.

Evidence (Knowledge) Transfer

- Transferring knowledge to individual health professionals, health facilities and health systems by means of journals, other publications, electronic media, education and training and decision support systems.

- Strategies:
  - Developing understandable and actionable messages;
  - Accommodating the context of a target audience's information needs; and
  - Delivering messages in cost-effective ways (including information technology, print material, meetings, workshops and training programs)

The clinical application of research findings

to facilitate the treatment of patients

- with maximum chance of benefit,
- with minimum risk of harm, and
- at an acceptable cost.

Evidence level, quality, relevance and strength.

Critically Appraising
the Value of A Research

The most essential and fundamental job for clinical application

- The ‘level’ of evidence refers to the study design used to minimise bias:
  - the highest level involves a systematic review of randomised controlled clinical trials.
- ‘Quality’ refers to the methods used to minimise bias in the design and conduct of a study.
- ‘Relevance’ refers to the extent to which research findings can be applied in other settings.
- The ‘strength’ of evidence relates to the magnitude and reliability of the treatment effect seen in clinical studies:
  - strong effects are more likely to be real and more likely to be clinically important.

Study design hierarchy

- Level 1.
  - Experimental studies (e.g. RCT with concealed allocation)
- Level 2.
  - Quasi-experimental studies
- Level 3.
  - Controlled observational studies
  - 3a. Cohort studies, 3b. Case control studies
- Level 4.
  - Observational studies without control groups
- Level 5.
  - Expert opinion based on pathophysiology, bench research or consensus, etc.

Ranking the "Quality" of Evidence

- Grade I –
  - systematic review of all relevant RCTs
- Grade II –
  - at least one properly designed RCT
- Grade III-1 –
  - well designed pseudo-randomised controlled trials
- Grade III-2 –
  - cohort studies, case control studies, interrupted time series with a control group
- Grade III-3 –
  - comparative studies with historical control, two or more single-arm studies, or interrupted time series without control group
- Grade IV –
  - case series

(NH&MRC 2001)

Reading the Review Report Critically

- To judge the robustness of the results, particularly where there are missing data, uncertainty about study inclusion, or where there are large studies that dominate the data synthesis.
- Evaluating the meaning of the review's findings
  - Strengths and weaknesses of the evidence included in the review
  - Direction and magnitude of the effect observed in summarised studies
  - Applicability of the findings of the review
- Recommendations
  - Practical implications for clinicians or policymakers
  - Unanswered questions and implications for future research

Study Selection and appraisal

- Select only those studies that address the review question
  - Inclusion and exclusion criteria basis for selection of studies.
- Include only studies with good quality in evidence synthesis
  - Combining results of poor quality research may lead to biased or misleading estimates of effectiveness

The mission in study appraisal

- to understand
  - the rigor of the studies,
  - randomization, concealment of randomization, and blinding.
  - the extent to which the study design, conduct, and analysis minimize the potential of bias.
  - the reasons for differences among study results,
  - the applicability of the review to their clinical practice.

Data extraction

Data Extraction Form

Author _____ Record Number_____

Journal _____

Year _____

Reviewer _____

Method _____

_____

Setting _____

Participants _____

Number of Participants

Group A _____ Group B _____ Group C _____

Interventions

Intervention A _____

Intervention B _____

Intervention C _____

Outcome Measures

Data extraction form (cont)

Outcome Measures

Outcome _____

Description _____

_____

Blinded outcome measurement yes☐ no☐

Dichotomous Data

	Intervention 1	Intervention 2	Control or Placebo	
Outcome Measures	number/total	number/total	number/total	P Value

Continuous Data

	Intervention 1	Intervention 2	Control or Placebo	
Outcome Measures	Mean and SD (n)	Mean and SD (n)	Mean and SD (n)	P Value

Data synthesis

- to collate and summarise the results of included primary studies in a meaningful way.
- The key characteristics in data analysis are
  - the participants, interventions or outcome measures (clinical heterogeneity);
  - the study designs and quality (methodological heterogeneity)
  - the reported effects (heterogeneity in results).
- computation of an average effect where the results of each study are weighted according to some measure of the study's importance.

Steps in conducting meta-analysis

- Deciding whether to combine data and defining what to combine.
- Evaluating the statistical heterogeneity of the data.
- Estimating a common effect.
- Exploring and explaining heterogeneity
- Assessing the potential for bias.
- Presenting the results.

Pooling the study results

- Binary data
  - Odd and Odd ratio
  - Risk, relative risk
  - absolute and relative risk reduction
  - Number needed to treat(NNT)

- Continuous data
  - same scale: mean of means difference b/w t and c
  - Different scale: mean of standardized means difference
    - The standardized mean difference, the effect size, dividing the difference between the mean in the treatment group and the mean in the control group by the SD in the control group.

Development of Evidence-based Clinical Practice Guideline

實證為基之臨床作業指引的發展

Objectives

- 增進健康照顧之品質(improve the quality of health care),
- 減少不必要的、無效的、或有害的處置(to reduce the use of unnecessary, ineffective or harmful interventions),
- 促進病患治療之(to facilitate the treatment of patients)
  - 最大可能之利益(with maximum chance of benefit),
  - 最小的傷害風險(with minimum risk of harm), and
  - 可接受之花費(at an acceptable cost).

發展指引之重要原則

- 著重在成果Focus on outcomes.
- 以可得之最佳實證為基並敘述實證建議點之強處

  實證可以 層次品質相關性與強度分級
- 用來整合可得之實證的方法必須是最適用的
- 指引宜保留彈性以因地制宜
  - 實證之相關性包括不同之族群地域與臨床設備
  - 並考慮費用與限制
  - 提供依病患不同之價值觀與喜好之調整辦法
- 指引之實施與效應須作評估
- 指引須定期修訂

The six “steps to evidence-based practice”

- ***searching for the evidence;***
- ***appraising the evidence;***
- ***summarizing the evidence;***
- ***embedding the evidence;***
- ***utilizing the evidence; and***
- ***evaluating the impact of the evidence on outcomes***

Evidence translation (synthesize)

Evidence transfer

Evidence utilize

Evidence generalize

Grading of recommendations

Grade	Level of Evidence	Effectiveness
A	1	High quality experimental studies without heterogeneity and with precise results
B	2/3	Low quality experimental studies, high quality controlled observational studies
C	4	Low quality controlled observational studies, case series
D	5	Expert opinion