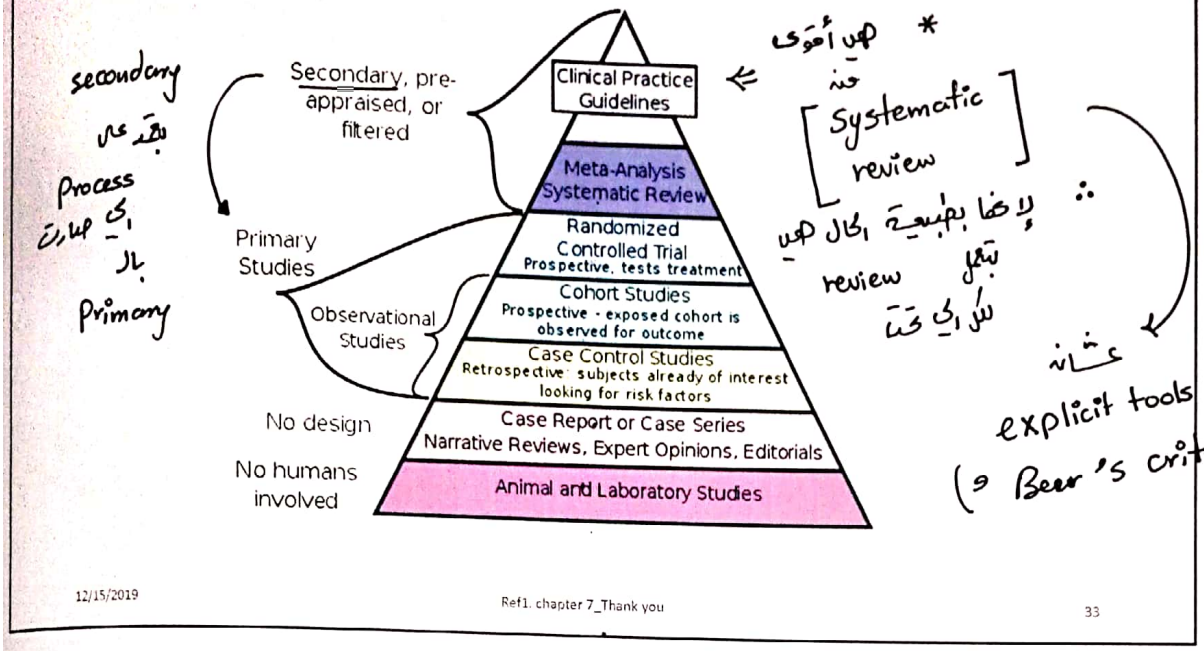


6. Articulation of Recommendations

1. Articulate recommendations in a standardized form, detailing precisely what the recommended action is, and under what circumstances it should be perfotmed.

2. Strong recommendations should be worded so that compliance can be evaluated.

* Ecological studies ⇒ (Primary studies)

إنها بتدرس على مستوى المجموع حتى على مستوى الأفراد ⇒ [مثلاً انتشار وباء على مستوى دولة ما بدروحوا يجمعوا معلومات كل شخص لاء بيوخذوا]

(Broad spectrum ⇒ حتى على مستوى عام حتى مستوى أفراد)

Levels of Evidence for Therapeutic Studies *

- **Level Type of evidence**

1A Systematic review (with homogeneity) of RCTs
1B Individual RCT (with narrow confidence intervals) → (عشان يكونه Precise)
1C All or none study
2A Systematic review (with homogeneity) of cohort studies → (RCT >> cohort)
2B Individual Cohort study (including low quality RCT, e.g. <80% follow-up)
2C "Outcomes" research; Ecological studies
3A Systematic review (with homogeneity) of case-control studies
3B Individual Case-control study
4 Case series (and poor quality cohort and case-control study
5 Expert opinion without explicit critical appraisal or based on physiology bench research or "first principles"

12/15/2019 Ref1 chapter (Ecological)

[*] ⇐ guildlines هيك أقوى إشي

[*] ⇐ حتى: نسبة تلوث بالجو ⇐ هاي ما بقدر أعملها هيك أخذ 15٪ من هواء ملوث وهيك تاني أخذ 10٪ من هواء ملوث لاء بدي على مستوى المجموع

(الدراسات إلي جمعت أعلاها على المستوى الفردي)

(هيك أضعفها إشي)

Levels of Evidence for Prognostic Studies *

(odds ratio حتى فوق relative risk.) ← إلها قوة وإلها دلالة

- **Level Type of evidence**

I High quality prospective cohort study with adequate power or systematic review of these studies

II Lesser quality prospective cohort, retrospective cohort study, untreated controls from an RCT, or systematic review of these studies

III Case-control study or systematic review of these studies

IV Case series

V Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"

12/15/2019 Ref1 chapter 7_Thank you 46

* هي مجموعة الدراسات إلي جابوط أعلاها RCT

لذلك حاج هيك observation studies

Observational studies ⇒ cohort >> case - control >> Cross-sectional

إلي أقوى منهم ≈ (Prospective studies)

[*] ⇐ كل هاي الدراسات هي [Traditional] تقليدية

* All or none study

حصة

↳ القوة بتعة هاي الدراسة عالية

مثال توضيحي :- جبت غاز وتسبب بوفاة الجميع أو تسبب بزرع الجميع

صورة عندي all or none

[ما في حل وسط انه نص تأثر ونص لا ء]

⇐ {العلاقة السببية بين المؤثر والنتيجة}

[ومابقدر أهملها] إذا ما في دراسة تدعم رأي الخبير ⇐ هي أضعف اشي بالدراسات ⇐ {*}(expert opinion)

∴ لكن إذا كان هاد الخبير عامل دراسة من الدراسات الي قبل RCT / Cohort ------.

⇐ هيك صارت [قوية]

↓ بتصير بدرجات أعلى بال levels

أو بتضل دليل علمي بدون دراسات بس ضعيف {*}

∴ هاي موجودة بالأشياء الي ماعليها دراسات

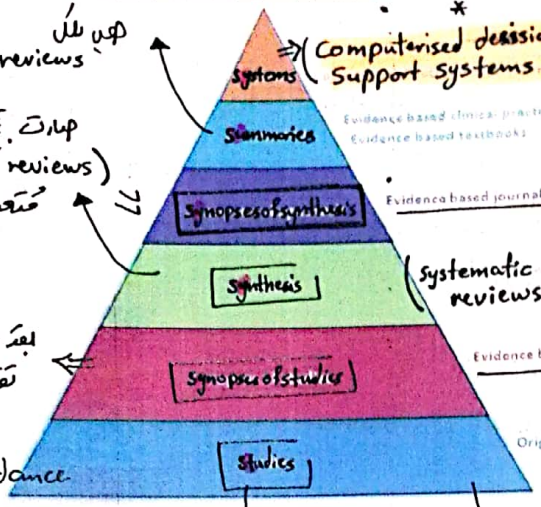
هاي الدراسات كلها ⇒

[In Theraputic guidelines]

* ما بقدر أجيب دراسة RCT لمرضى السرطان ⇐ ما بقدر أجيب شخص سليم وأعطيه سرطان (لا سمح الله) فصعب أجيبها عشان هيك عندي

* two levels groups → for theraputic guidelines
→ for prognostic studies.

Most Recent update of the Evidences, The 6S Hierarchy of Evidence Based Resources



Ref1. chapter 7_Thank you

Examples of summaries include

- *Clinical Evidence* (www.clinicalevidence.com),
- the Physicians' Information and Education Resource (http://pier.acponline.org),
- Dynamed (www.ebscohost.com/dynamed/default.php),
- UpToDate (www.uptodate.com).
- Another source of summary-level data are clinical practice guidelines (CPGs).
- National and international clinical guidelines organizations:

http://www.guideline.gov
http://www.openclinical.org/guidelines.html#comput
e-Guidelines
- Clinical guideline applications for handheld devices [OC]
- Canadian Diabetes Association e-guidelines (2003) (web-browsable)

Ref1. chapter 7_Thank you

{ (computer) زي كأنه طبيب ⇐ (في أمثلة متطورة أكثر انه ادخل بيانات المريض
لسه لسا مش كتير معتمدة وهو بيه يطلعلي العلاج)

مش موجود بالسلاية ومطلوبة ⇐ * **Computerised systems**
⇓
هي عبارة عن مصفوفات
لوغاريتمية
⇓
[بتحدد نوع الرعاية العلاجية]

مثال: ⇐ عندي مريض بالمشفى وصيدلي ⇒
⇓
هل الصيدلاني بـ (discharge point of patient)
⇐ معناها عايطلع المريض بالمشفى
هل مطلوب منه يتابع كل المرضى ولا في Priority ؟
⇓

∴ عملية تحديد هاي ال [Priority] هي وظيفة Computerized systems in first level

بلشت في ناس عاملين umbralla reviews أو دراسات مختارة ⇐ لحتى يطوروا system

[مين أطور system] ⇒ بلشت عندي input values [variables]
معلومات المريض
- age
- gender
- عدد الأمراض
- عدد الأدوية
أنواع الأدوية

⇐ متعلقة (بشخص المريض ومعلوماته)

* بعد عملية جمع المعلومات
computer بعمل عملية Processing ⇐ هي شايع اشي اسمه regression
- pharmacist (Health care Provider.)
- It واحد بشتغل

regression ⇐ هي عملية إيجاد العلاقة بينه (input و output) والتنبؤ بها
لـ(بدرسها بالبداية طبيعة العلاقات المباشرة بحديث بتنبأ فيها)

* وفي عندي كمان (sensitivity analysis) ⇐ أناعلمت تنبؤ للعلاقة بينه (input و output) بدي أعرفه (هل تنبؤي صح ولالا)

Sensitivity analysis :-

True [Positive value] (+ve)

True [negative value] (-ve)

out put

أنا دخلت input المرضى

⇐ وبدي مثلاً ادرس احتمالية موت المريض او احتمالية وجود مشاكل بالعلاج او احتمالية رجوع المريض للمشفى مرة أخرى بسبب readmission

⇐ [المريض رجع للمشفى بسبب سوء الإدارة الصحية مثلاً] يعني =

out put = Death patient

or Drug related problems

or ----.

⇐ بس ادخل بيانات المريض بس بعمل click بوجيني مثلاً =

- % Death = 50%
- % Drug related problems = 70%
- % readmission = 95%

⇐ واحنا بنصير نحدد

بس للتذكير Primary studies بنجلها Precise By confidance interval

هاي الأرقام اجت منه

regrission → Sensitivity → True +ve / True -ve.

بنجلوا تنبؤ تجريبي ← طلعت نتيجة هادا التنبؤ

Death 20 شخص

من هدول 20 شخص مات؟ ⇐ هاي اسمها True positive

شخص ضل على قيد الحياة

True negative

* حتى أنا أكد Precise هاي الدراسة ⇐ بنجد عدد حالات True ⊕ و True ⊖

[≈ {*} computer ⇐ بتعامل مع الأمور
ك Digits مش كأسماء]

[*] رح نحكي عنها لقدام

⇒

مثل شركات التأمين → لازم يكون عندها software زي إلي حكيناعنه

منه input
↓
Process
↓
output

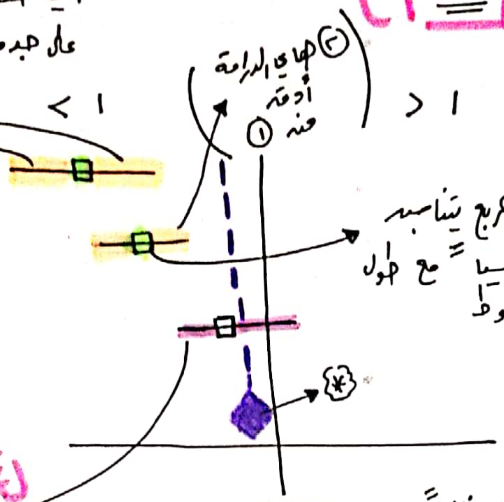
{:} = منها تحدد اذا رح تقبل المريض حتى يصير التأمين ولا لا و ع نسبة وجوده بالتأمين ⇐

ريفيو ⇒ Systematic review —جبوعوها→ [meta analysis]

19 جزء إضافي على العادة

Systematic review ⇓ بيوخذ الدراسات الي حققتها وبجمعها على جدول

meta analysis ⇓ [هي عملية إحصائية نتيجتها رسمة] ← {forest plot}



(Confidence interval) ← كل ما كانت الخطوط هاي أطول دقة الدراسة أقل

1)
2)
3)
4)

هاد المربع يتناسب عكسيا مع طول الخطوط → إذا زاد طول الخط ↑ CI ↓ precise ↓ المربع.

يعني ≠

(*) ← هون CI قطعت odds ratio = 1 معناها مرات كانت البط > العقام ومرات العكس ⇓ معناها نتيجة هاي الدراسة statistically not signifiant

Odds ratio. ⇐ غالبا بيوخذوا هاد أو relative risk

(Odds ratio = 1) ⇒ معناها العقام = البط

[treatment = control]

اذا كانت ≮ 1 العقام > البط

> 1 البط > العقام

(*) ⇐ عنا دوا Ⓟ لعلاج Stroke وأقارنه بدوا Ⓒ لعلاج أدهنا Stroke

مش شرط دايما Control

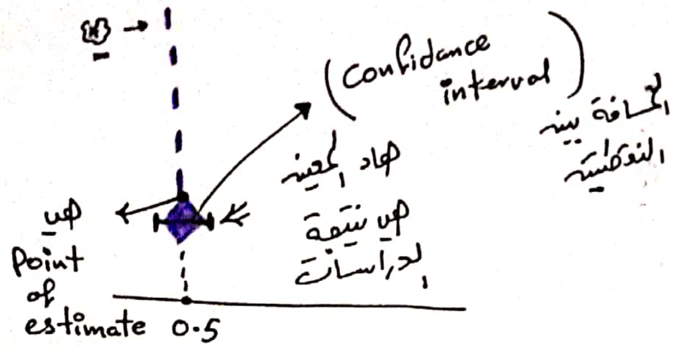
∴ لكل دراسة بطلع [Summary] ⇐ Point of estimate ← النتيجة في الدراسة

⇓

(*) اخنا عملنا نتيجة هاي الدراسة على شكل رسمة

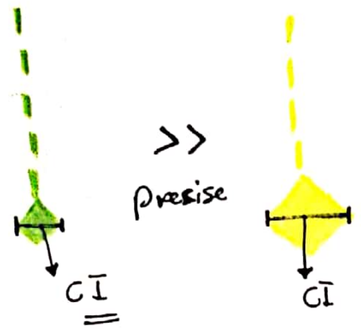
∴ Systematic review ⇐ مهمة كتير لأنها كتير جدا بحي دراسة في قوية جدا أقوى منه ١ عادي لكن أقوى منه ٣ مستحيل يكونه كلامه صحيح

(فهي زي نتيجة دراسات)



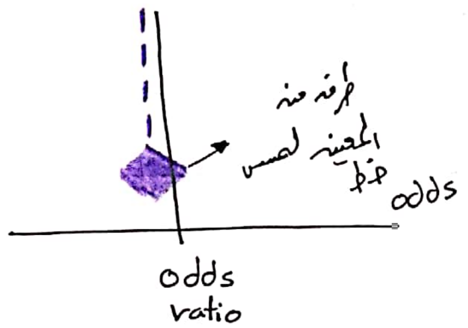
معناها odds ratio هون = 0.5

≠
* المقام ⇒ Denominator
* البسط ⇒ numerator



↓ CI

↑ Precise.



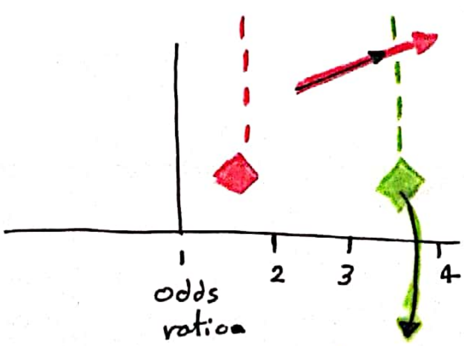
⇐ معناها systematic review هاي

⇒ (statistically not significant)

* ⇐ إذا كانت العينة كله قبل خط odds معناها
البسط < المقام

* ⇐ إذا كانت العينة كله بعد خط odds
المقام < البسط

⇒ مثال ⇙



* العينة اجت بين ١ و ٢ معناها odds بين ١ و ٢ يعني

quality of study = 1

(quality of study = 2)

SYNOPSES OF SYNTHESES

generally one-page, concise, user-friendly assessment, and summary of the evidence.

This type of article is generally published in evidence based abstraction journals such as *Evidence Based Nursing*, *International Journal of Evidence-Based Healthcare*, *Evidence-Based Mental Health*, and *ACP Journal Club*.

* ⇐ لو سألني الدكتور كيف بقدر أقيم الدراسة بـ:
  - Bias
  - CI

* ⇐ حيا لكل نوع دراسة في

guideline ⇐ كيف نعملها

لحابدي أعل ⇓ Critical appraisal to one study

RCT ⟶ guideline is consort ⇐ لهاي Professional tools

∴ بعطيني step ⇐ بنه الدراسة By step

و check list كانه بنه هاي الدراسة

two tools ⇐ في عادية
- Cast tool
- CPG tool

Risk/Benefit tradeoff

- aspirin after myocardial infarction
  - 25% reduction in relative risk
  - side effects minimal, cost minimal
  - benefit obviously much greater than risk/cost
- anticoagulants in low risk atrial fibrillation
  - anticoagulants reduce stroke vs ASA by 50%
  - but if risk only 1% per year, ARR (kept in reserve) 0.5%
  - increased bleeds by 1% per year

Strength of recommendations

Aspirin after MI – do it

Anticoagulants vs than ASA in low risk Afib
-- probably do it
-- probably don't do it

7. External Review

1. External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations, agencies, patients, and representatives of the public.
2. The authorship of external reviews should be kept confidential unless that protection has been waived.
3. The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers' comments.
4. A draft of the CPG prior to the final draft should be made available to the general public for comment.

8. Updating

1. The CPG publication date, date of systematic evidence review, and proposed date for future review should be documented in the CPG.
2. Literature should be monitored to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.
3. CPGs should be updated when new evidence suggests the need.

New American Cancer Society Process for Creating Trustworthy Cancer Screening Guidelines JAMA (12/14/2011)

Standards for Clinical Practice Guidelines: Institute of Medicine (IOM) Recommendations and American Cancer Society (ACS) Process

Standards	IOM Recommendations	New ACS Process for Cancer Screening Guideline Development
Transparency	The process and funding of guideline development should be completely specified	The article defines the new ACS process, and all ongoing an planned work in cancer screening guideline production, and revisions will be posted on the ACS website
Conflicts of interest	Conflicts of interest include commercial, institutional, professional, and intellectual conflicts, all of which must be openly declared. Members should divest conflicting financial relationships	ACS guideline developers will publicly disclare financial and intellectual conflicts, and all will be expert generalists to avoid the appearance of professional conflicts
Group composition	The guideline group should include multidisciplinary methodological experts, clinicians, and patient advocates	Guidelines will be developed by a 12 person panel of multidisciplinary experts in clinical screening, including a patient advocate
Systematic review of evidence	The guidelines should be based on systematic literature review that meets the standards set by the IOM	ACS will commission high-quality and independent systematic evidence reviews to serve as the basis for all guidelines
Grading strength of recommendations	For each recommendation, the text should explain the evidence and the reasoning, explain the balance of benefits and harms, an indicate the level of confidence in the recommendation	ACS will be explicit about harms, as well as benefits, and will develop a grading scheme to rate confidence in recommendations that will be consistent with methods used by other organizations
Articulation of recommendations	Recommendations should be clearly stated and actionable	ACS guidelines will be written for audiences of primary care clinicians, the general public, and policy makers
External review	The draft guidelines should be posted for public comment, and the final guidelines should be revised as appropriate before peer review	Before publication, all draft guidelines will be vetted by relevant experts, organizations and societies, and any differences will be explicitly discussed in the published guideline
Updating	Guidelines should be updated when new evidence should result in modifying the recommendations	ACS guidelines will be briefly updated as needed, and at a minimum at least annually online with relevant new studies, and rewritten every 5 years

Guideline Evaluation Tools

AGREE II Instrument Clinical practice guidelines

- The purpose of the AGREE II, is to provide a framework to:

1. assess the quality of guidelines
2. provide a methodological strategy for the development of guidelines
3. inform what information and how information ought to be reported in guidelines.

- The AGREE II replaces the original instrument as the preferred tool and can be used as part of an overall quality mandate aimed to improve health care.

Table 1. Comparison of original AGREE and AGREE II items

Original AGREE Item	AGREE II Item
Domain 1. Scope and Purpose	
1 The overall objective(s) of the guideline is (are) specifically described.	No change
2 The clinical question(s) covered by the guideline is (are) specifically described.	The health question(s) covered by the guideline is (are) specifically described.
3 The patients to whom the guideline is meant to apply are specifically described.	The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
Domain 2. Stakeholder Involvement	
4 The guideline development group includes individuals from all the relevant professional groups.	No change
5 The patients' views and preferences have been sought.	The views and preferences of the target population (patients, public, etc.) have been sought.
6 The target users of the guideline are clearly defined.	No change
7 The guideline has been piloted among end users.	Delete item. Incorporated into user guide description of item 19.
Domain 3. Rigour of Development	
8 Systematic methods were used to search for evidence.	No change in item. Renumber to 7
9 The criteria for selecting the evidence are clearly described.	No change in item. Renumber to 8
	NEW Item 9. The strengths and limitations of the body of evidence are clearly described.
10 The methods for formulating the recommendations are clearly described.	No change
11 The health benefits, side effects, and risks have been considered in formulating the recommendations.	No change

Original AGREE Item	AGREE II Item
12 There is an explicit link between the recommendations and the supporting evidence.	No change
13 The guideline has been externally reviewed by experts prior to its publication.	No change
14 A procedure for updating the guideline is provided.	No change
Domain 4. Clarity of Presentation	
15 The recommendations are specific and unambiguous.	No change
16 The different options for management of the condition are clearly presented.	The different options for management of the condition or health issue are clearly presented.
17 Key recommendations are easily identifiable.	No change
Domain 5. Applicability	
18 The guideline is supported with tools for application.	The guideline provides advice and/or tools on how the recommendations can be put into practice. AND Change in domain (from Clarity of Presentation) AND renumber to 19
19 The potential organizational barriers in applying the recommendations have been discussed.	The guideline describes facilitators and barriers to its application. AND change in order – renumber to 18
20 The potential cost implications of applying the recommendations have been considered.	The potential resource implications of applying the recommendations have been considered.
21 The guideline presents key review criteria for monitoring and/ or audit purposes.	The guideline presents monitoring and/ or auditing criteria.
Domain 6. Editorial Independence	
22 The guideline is editorially independent from the funding body.	The views of the funding body have not influenced the content of the guideline.
23 Conflicts of interest of guideline development members have been recorded.	Competing interests of guideline development group members have been recorded and addressed.

i) Rating Scale

All AGREE II items are rated on the following 7-point scale:

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Score of 1 (*Strongly Disagree*). A score of 1 should be given when there is no information that is relevant to the AGREE II item or if the concept is very poorly reported.

Score of 7 (*Strongly Agree*). A score of 7 should be given if the quality of reporting is exceptional and where the full criteria and considerations articulated in the User's Manual have been met.

Scores between 2 and 6. A score between 2 and 6 is assigned when the reporting of the AGREE II item does not meet the full criteria or considerations. A score is assigned depending on the completeness and quality of reporting. Scores increase as more criteria are met and considerations addressed. The "How to Rate" section for each item includes details about assessment criteria and considerations specific to the item.

Computerized guidelines

- Computerized guidelines encode evidence-based recommendations for and can automatically generate recommendations about what medical procedures to perform tailored for an individual patient.

- Computerized guidelines offer benefits over and above those offered by paper-based guidelines:

•They offer a readily accessible reference, providing selective access to guideline knowledge.
•They help reveal errors in the content of a guideline;
•They help improve the clarity of a guideline, e.g. in decision criteria and clinical recommendations;
•They help offer better descriptions of patient states;
•They can automatically propose timely, patient-specific decision support and reminders.

Sources of Clinical Practice Guidelines

- National and international clinical guidelines organizations:

http://www.guideline.gov
http://www.openclinical.org/guidelines.html#comput

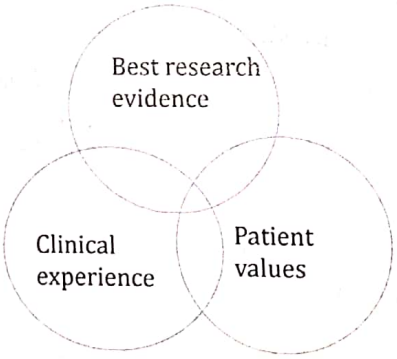
e-Guidelines

- Clinical guideline applications for handheld devices [OC]
- Canadian Diabetes Association e-guidelines (2003) (web-browsable)

Evidence-based practice involves

Integration of:

- **Best research evidence:** Clinically relevant research that has involved patients
- **Clinical expertise:** Using clinical skills and past experience
- **Patient values:** Unique preferences, concerns, expectations



To support clinical / therapeutic decisions.
With the aim to ensure optimal outcomes for the patients.