



## Drug informatics

Faculty of Pharmaceutical Sciences

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Evidence-Based Clinical Practice Guidelines

(Please return to Chapter 7,  
Reference 1 of the course outline)

# MIRACLE Academy

قال تعالى (يَرْفَعُ اللَّهُ الَّذِينَ آمَنُوا مِنْكُمْ وَالَّذِينَ أُوتُوا الْعِلْمَ دَرَجَاتٍ)

تفريغ المعلوماتية  
زميلتكم بتول حازم



لجان الرُفَعَات



- These interventions may include not only medications but other types of therapy, such as radiation, surgery, and physical therapy.

- Clinical practice guidelines are developed by a variety of groups and organizations including federal and state government, professional associations, managed care organizations, third-party payers, quality assurance organizations, and utilization review groups.

# Introduction

- Clinical practice guidelines should be developed using rigorous evidence-based methodology with the strength of evidence for each guideline explicitly stated. (rigorous) منهجية صارمة development منهجية صارمة Methodology

- Clinical practice guidelines should be feasible, measurable, and achievable.

- Clinical practice guidelines, from which quality performance measures will be developed, should be reviewed by representatives of the pharmacist they will impact.

should be feasible -- should be measurable  
and should be achievable --

They should be also reviewed by representatives of the pharmacist they will impact

## Clinical - Practice guidelines



Clinical practice guidelines  
Clinical performance measures  
Certain measures  
recommending  
incorporated  
Public reporting  
accountability  
Pay for performance  
Performance group  
measuring  
guidelines  
evidence  
strength  
and magnitude of benefit

# Introduction

Clinical performance measures may be developed from clinical practice guidelines and used in quality improvement initiatives. When these performance measures are incorporated into public reporting, accountability, or pay for performance programs, the strength of evidence and magnitude of benefit should be sufficient to justify the burden of implementation.

In the clinical setting, implementation of clinical practice guidelines should be prioritized to those that have the strongest supporting evidence, and the most impact on patient population morbidity and mortality.

Strength of evidence  
magnitude of benefit  
measurement  
recommendation  
Guideline  
المؤسسة القياسية

# Introduction

Research should be conducted on how to effectively implement clinical practice guidelines, and the impact of their use as quality measures.

Clinical practice guidelines, from which quality performance measures have been developed, should be updated as new evidence is available, and the producers of the performance measures should be notified of the work in progress.

Guidelines should be updated as new evidence is available, and the producers of the performance measures should be notified of the work in progress.

Producers of the performance measures should be notified of the work in progress.



كما قلنا ليس group أو Organization معينة تقوم بـ development له، الـ Guidelines هي عبارة عن هذا الكلام .. هذه الـ Organizations أو هذه الـ Groups .. كل ينظر إلى هذه الـ guidelines من point of view .. من وجهة نظر كل واحد منهم هذه الـ

Guideline سيكون لها differences :-

### Variations in :-

- 1 • The purpose of guidelines
- 2 • Methods used to develop guidelines
- 3 • Format of the document
- 4 • Strategy for implementation

Vary

Vary

Clinical Practice Guidelines

Evidence-based medicine

Another Concept وهو الـ

## Evidence-based medicine (EBM) and Clinical Practice Guidelines

Intervention أو Procedure  
→ Guideline

Certain Practice .. كيف سيكون الـ Practice .. هو عبارة عن فلسفة الـ Evidence based medicine

Evidence-based medicine (EBM) is a philosophy of practice and an (approach to decision making in the clinical care of patients) that involves making individual patient care decisions based on the best currently available evidence.

في عبارة عن approach .. الهدف منها .. أن تكون القرارات الـ Patient Care decisions .. evidence .. ما الـ evidence .. موجود لي .. ما القرار الذي .. Patient Care decision ..

اتخذته حق أعطي الرعاية للمريض



لماذا يُعد Evidence Based Medicine مهم جداً؟ ما أهمية؟  
① المقصود عندما يكون لدينا EBM أي سائر ثقة ال public ليس ال public حسب بل  
ثقة الطبيب Pharmacist ثقة الممرض مثلاً الخاليل الطبية مثلاً.. كورس جميعاً يكون لدي  
evidence ثقة لماذا اتباع هذه ال Procedure لماذا أعطي هذا ال medication لماذا أقوم بهذا ال test  
يكون لدي evidence لا أعطى test أو عمل هذا ال procedure أو أعطى هذا medication أو عمل هذا ال intervention...  
فهم أيضاً ال EBM لزيادة ال Confidence بال objectivity effectiveness reproducibility of the tests procedure medication

## Why Does Evidence Based Medicine Matter?

- ① Increases audience confidence in the value, objectivity, effectiveness and reproducibility of the tests or procedures or medication
  - ② Increases transparency. guideline
  3. Provides a balanced approach.
  4. Protects patients from ineffective or risky care.
  5. Increases cost-effectiveness and value.
- EBM هو مهم جداً أيضاً لزيادة ال transparency الثقافية والوضوح بال guideline  
مهم جداً أن لا نعرض المريض ل Certain intervention أو Certain procedure على سبيل المثال تكون ineffective (على المقاييس) .. (بكب فلون على المقاييس) أو risky أن تكون بها خطورة عليـ  
أيضاً نقمن زيادتها ال Cost-effectiveness ال value للمريض .. فلا نعطى medication عبثاً ولا نفل procedure لمريض معين بلا فائدة ولا نقوم بتحاليل على سبيل المثال لا داعي لها .

## To be trustworthy, guidelines should...

حق تكون هذه ال Guideline موثوقة .. يجب أن يكون لهم خصائص معينة وهي :-

1. Be based on a systematic review of the existing evidence.
  2. Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups.
  3. Consider important patient subgroups and patient preferences as appropriate.
  4. Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest.
- تلاحظ لي نوعاً معيناً أو تخصصاً قديماً معين عن نقوم بهذه ال Guideline  
ال سبب أنه في النهاية من سيترضى لهذه ال Patients interventions وال Guidelines .. ستطبق على ال Patients  
it should be a multidisciplinary representative of key affected groups  
فإن تكون أيضاً ال Patient former patient.. for example representative عن المرضى ال قديماً ال development ال Guidelines

يحدث عنهم لاحقاً "Conflicts of interest".



الهدف ان لا تقوم بعمل intervention جديد ولا تقوم بعمل مقارنة بينه وبين ال intervention القديم .. يجب ان يكون لدي Evidence ان ال Alternative التي وبقته ما ال effect على ال (Health - Outcome) فيجب ان يكون لدي Comparison بينه وبين ال intervention القديم

### To be trustworthy, guidelines should...

5. (Provide a clear explanation of the logical relationships between alternative care options and health outcomes) (and provide ratings of both the quality of evidence and the strength of recommendations)

ال evidence  
اعتبرها اعتمد عليه يجب ان تعرف ال quality ..  
ال strength of recommendation  
Is it Strong, weak?  
بناءً على ال Quality of evidence  
High quality, Moderate, Low-quality

6. Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

بما قلنا قبل قليل لو ظهر لدينا evidence جديد يجب ان يحدث Revision لهذه ال guidelines ويحدث تعديل عليهم بناءً على ال Evidence الجديد

developing evidence-based clinical practice guidelines  
بناءً على هذا الكلام ال Institute of Medicine عت 8 Standards  
وستحدث عنهم محلاً على هذا ...

### Institute of Medicine (IOM)

The IOM proposed 8 standards for developing evidence-based clinical practice guidelines.

1. Establishing transparency.
2. Managing conflict of interest.
3. Guideline development group composition.
4. Clinical practice guideline-systematic review intersection.
5. Establishing evidence foundations for and rating strength of recommendations.
6. Articulation (clear) of recommendations.
7. External review.
8. Updating.



# 1. Establishing Transparency

clinical practice guideline development process ... should be explicitly detailed funding manner ... Clear ...

★ The processes by which a clinical practice guideline (CPG) is developed and funded should be detailed explicitly (in a clear and detailed manner) and publicly accessible. Publicly accessible ...

\*\*\*

Important potential source of bias in the development of Clinical practice Guidelines ... Conflict of Interest ... Certain Circumstances ...

2. Conflict of Interest (COI) ...

• is one important potential source of bias in the development of CPGs. Guidelines

• A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

• A divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing.

COI ...

... financial ... Academic advancement ... Clinical revenue ... Community standing ...



## 2. Conflict of Interest (COI)

\* لدينا مجالين في Intellectual COI بناءً على هذا الكلام نسأول تجنب Intellectual COI عندما يكون لدى Academic Activities activity (Academic activity) .. تأملوا الـ Guideline تنص أكثر على

• Intellectual COI: (academic activities that create the potential for an attachment to a specific point of view) that could unduly affect an individual's judgment about a specific recommendation.

في البداية يحدث لدينا Research by academics usually

ذلك يُعطينا point of view معينة بناءً عليها نخرج لدينا guidelines .. فبناءً على Certain academic activities (Create potential for an attachment of a specific point of view) it effects point of view وهو الـ point of view تسبب في an individual's judgement about a specific recommendation تغيير محتوى الـ recommendation بطريقة معينة بناءً على الـ Academic activity

فنتيجة لها .. أن لا يكون لدينا Intellectual COI

لكن للأسف الناس لا تعادون تسمي في تطوير هذه الـ guidelines يقولون Experts وهو لا يكون لديهم usually COI أي إذا أنا يكون لديهم تضارب مصالح مع الـ guidelines التي تخاطب أن تدخل لها development .. والسبب 1 2 3

فلكم في النهاية Experts صحيح لديهم COI ، لكنهم في النهاية Experts يستطيعون ولديهم دقة معينة في الـ guidelines ولديهم information أكثر ، ولديهم insight أكثر على guideline relevant Content فحين لا نطيع الاستثناء عنهم في الـ Guidelines Development

### Experts with Conflicts

- 1 The most knowledgeable individuals regarding the subject matter addressed by a CPG are frequently conflicted.
- 2 These "experts" often possess unique insight into guideline relevant content domains.
- 3 They may be aware of relevant information about study design and conduct that is not easily identified.



نبذة على هذا الكلام، وكوننا لا نتطرح الاستفتاء عنهم في ال development Guidelines  
 كان لابد من وجود Certain Strategies لـ managing ال COI -  
 1. أول Strategies كانت عبارة عن Simple disclosure لأي Person يدخل في Managing أو developing ال  
 ال Guidelines (a person's financial interests)

## ● Strategies for Managing COI:

1. Simple disclosure (a person's financial interests).
2. Exclude from leadership roles.
3. Participation in certain restricted recommendations. they usually not allowed to participate
4. Formal or informal consultation.
5. Fully exclude <sup>or COI they are exclude</sup> conflicted members from panel participation.

لذا حق نقول ال Guideline ال development  
 كالتالي members (they are be considered for membership)  
 عليهم تواجبه تخرج (they should declare) يجب ان يحدروا declaration بايديهم و  
 مكل ال interests وال activities التي لديهم ليس لها effect ولن تسبب بينهم و  
 بين ال Guideline ال COI ... فقرة اول شغلة وهذا الكلام يكون (by written) disclosure  
 ال Guideline ال Group التي تحق الاحتمال  
 ال COI ليس لديهم CoI مع ال Guideline التي سيخلون فيها .  
 ★ يكون لدينا Disclosure، يكون مثل declaration يخرج كتابي خطية انه لا يوجد CoI، وموضح تمام بشكل  
 انه ليس لديه CoI مع ال Guideline التي سيخلون فيها .

## ● Managing conflict of interest:

- A. Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG.

★ <sup>افشاء/كشف</sup> Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), non-commercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the CPG.



20 1★ وكل ال COI لكل ال Group members المتواجدين بهذا ال group (They should be reported) ... their work  
 قبل حدوث اجتماع لمناقشة ال development guideline يجب على كل ال COI ان يوافق ال members او  
 ال report disclosure المحولة development group. it should be reported & discussed by the prospective development group.  
 النقطة الثانية :- بعض الناس لا يكون لديهم COI already لكن اذا ناس آخرين كان لديهم COI يجب ان

يشرح بالتفصيل كيف ال COI يمكن ان يؤثر على ال guideline الذي يقرر ال development ... فقه تنسيق  
 مثل اني يجب ان يكون حوضي بشكل تام ... فيجب تواجدها  
 شفافية بشكل عال جدا.

## ● Managing conflict of interest:

### B. Disclosure of COIs within GDG

1★ (All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work.)

2★ Each panel member should explain how their COI could influence the CPG development process or specific recommendations.

3★ Each panel member will update any COI at each meeting of the GDG.

4★ (COI conflicts will be reviewed and resolved by the GDG chair and staff.) The resolution may involve having the panel member recuse themselves from relevant discussion and/or voting.

النقطة الثالثة :- عند الاجتماع ونسحب لم يكن لديه COI واصبح لديه COI يجب قبل حدوث الاجتماع القادم عليه ان يقرر update ال status له.  
 النقطة الرابعة :- \*\* يجب ارسال resolving عن طريق ال Chair & Staff - فهذا ال resolution قد يكون فيه صلاحيات  
 الذين لديهم COI يخرجوا من ال discussion او قد لا يصح لهم ان يترشحوا (تصويت) على سبيل المثال، فبهذا الشكل فانهم يقومون بعمل Rescuing بحمايتهم من الترشح للمسئولية القانونية  
 للمسألة

## ● Managing conflict of interest:

### C. Divestment

★ Members of the GDG should divest (deprive someone of (power, rights, or possessions)) themselves of financial investments they or their family members have, and not participate in marketing activities or advisory boards of entities whose interests could be affected by CPG recommendations.

الdivestment المقصود بها ان ال members الداخليين ال development guidelines ال they should divest  
 ال financial investments ال investment ال family members  
 ال divest themselves  
 ال marketing activity or advisory boards ال recommendations  
 ال CPG ال (it may be affected by) ال recommendations  
 ال Managing Conflict of interest (COI)  
 ال they should not participate in marketing activity or advisory boards ال recommendations



Exclusions .. نحاول أن لا يكون لدينا members بال group التي لديها CoI ...  
Certain Circumstances كما قلنا يتواجد أشخاص Experts يجب تجنبهم / تفادي النظم ... (group)  
Sometimes Certain members يكون لديهم CoI ...  
relevant clinical specialists  
Certain measure ... group ...  
effect لهم داخل group ...  
members الذين يكون لديهم CoI ...  
they should not represent a majority of the GDG.

### Managing conflict of interest:

#### D. Exclusions

- ★ Whenever possible GDG members should not have COI.
- ★ In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
- ★ Members with COIs should not represent a majority of the GDG.
- ★ The chair or co-chairs should not be a person(s) with COI.
- ★ Funders should have no role in CPG development.

بعد ذلك من ال Strategies التي عليها Institute of Medicine ...  
Composition of Guideline development Group GDG ...  
multidisciplinary and balanced group include ...  
CoI ...

Composition of Guideline development Group GDG ...  
multidisciplinary and balanced group include ...  
CoI ...  
Patient/Consumer organization representative ...  
Adopt strategies to increase effective participation ...  
Patient/Consumer organization representative ...

## 3. Composition of Guideline Development Group (GDG)

1. The GDG should be multidisciplinary and balanced, (including methodological experts, clinicians, and populations expected to be affected.)
2. Include (at least at the time of clinical question formulation and draft CPG review) a current or former patient and a patient advocate or patient/consumer organization representative.
3. Adopt strategies to increase effective participation of patient and consumer representatives.



We should use systematic reviews that meet standards set by the institute of medicine's committee

Clinical Practice Guideline

حق نرج

Systematic methods to collect secondary data

Certain type of literature review

systematic review

Standards

لنا

## 4. Intersection of Clinical Practice Guideline and Systematic Review

Subject Articles data systematic review assessing and systematic review

1. Use systematic reviews (is a type of literature review that uses systematic methods to collect secondary data) that meet standards set by the institute of medicine's committee (e.g IOM Committee) on Standards for Systematic Reviews.

2. The GDG and systematic review team should interact.

Standards systematic review institute of medicine's committee Standards systematic review use of systematic review

## Standards for Systematic Reviews

1. Standards of initiation systematic review Standards for systematic review

RIGOROUS recommendations for:

1. Initiating a systematic review.
2. Finding and assessing individual studies.
3. Synthesizing body of evidence – Reporting.

guideline recommendation evidence assessing finding recommendation body of evidence synthesizing



For each recommendation provide:

6. A rating of the strength of the recommendation.

- values
- opinion
- theory
- clinical experience

in deriving the recommendation

recommendation  
ation  $\Pi = \sum_{i=1}^n \sigma_i$

explanation ۱۱ = ۱۱۱۱۱

١٥٥) evidence التي أخرجه والذي بناءً عليه أخرجت ال recommendation Level of evidence يا ال evidence  
 فيه هل يجب أن تكون مرفقة بال Recommendation ؟ لا - High Confidence ؟ Low, Moderate, very Low Confidence

دeterminants of Evidence Quality GRADE

1. Randomized controlled trials (RCTs) start high. <sup>recommenda-tion 1</sup>

- Observational studies start low.

الآن حق أقول هذا الـ evidence (إلى طالع عبي) √

Is Strong or Not?

### 5 factors that Can lower quality

1. Bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

### Factors increase confidence in quality

1. Large effect
2. Dose response

جودة  
quality  
دليل  
evidence

صَدَقَ عَلَيْهِمُ لَاحِقًا

5. Publication bias

فاداكات ال evidence الة اخرجت ع طريق RCTs <sup>according</sup> Evidence HIGH الة ادا كانت تقدر على  
Observational studies فال Evidence LOW الة usually ال Observational studies لا تحتوي على :-



# Grading of the strength of the recommendation

- ★ If you understand GRADE you understand how to use evidence to inform practice.

**GRADE**

هذه الـ institute أو groups أو Organizations التي من الممكن أن تقوم بعمل Grading أو تدخل بالـ GRADE لهذه الـ Guidelines أو الـ Recommendations.

Adopted by more than 90 organizations





1. GRADE (Grades of recommendation, assessment, development and evaluation) background.

2 Steps : USE GRADE !!

1. Two steps:

- Step 1 →
- Confidence in estimates (quality of evidence).
  - (Strength of recommendation.)
3. Evidence profiles.

4. An exercise in applying GRADE. Strength of recommendations

#### 4. An exercise in applying GRADE.

سأزيد مثلاً Evidence لا quality في كيف سأحسن evidence في .. فمثلاً يوجه لدينا  
كيف من الدراسات على .. يعني مثلاً لو كان لدينا Studies < They are Conflicted  
لدينا evidence سيكون weak أو low بناءً عليه أو Strength of recommendation سيكون ضعيف .. ما أنا بأتحدث على  
قراءات أو على articles أو مثلاً publications تقب جميعها في نفس الكلام دون وجود قراءات أو نتائج متضاربة  
في ذلك أقوم بالـ applying GRADE بمعنى كيف أزيد الـ Strength of recommendation أو أزيد أو أحسن الـ Quality of evidence

## Proliferation of systems

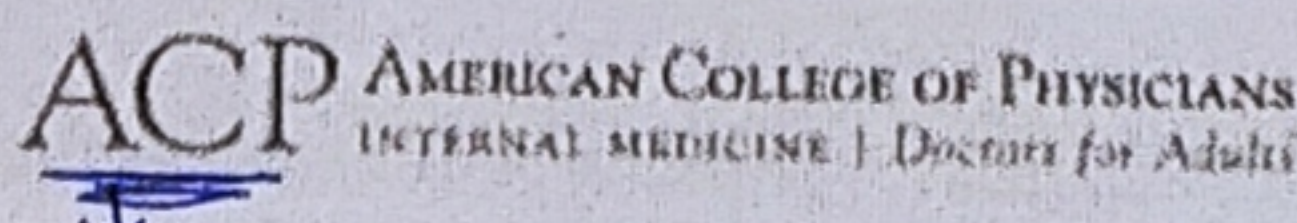
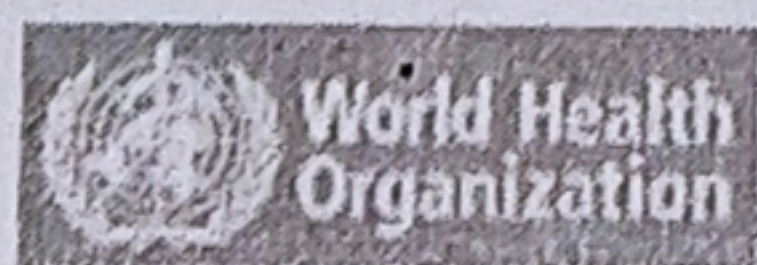
### Common international grading

\* فالـ grading هو الـ GRADE الذي هو الـ recommendations تحت عدة طرق international فليس كل أحد يستطيع  
 JE GRADE .. فليس Certain international groups .. لدينا أكثر من 100 Organizations  
 يجتمعون وللاّن لهم تقريباً ٤ اجتماع من ٦٠ سنة .. خلال الـ ١٦ سنة ٤٠ اجتماع أي ٤٠٠٠٠٠  
 • GRADE (Grades of recommendation, assessment, development and evaluation). اختصار  
 إلى

- International group

Australian NMRC, SIGN, USPSTF, WHO, NICE, Oxford CEBM, CDC, CC

- ~ 40 meetings over last 16 years
- The system – over 100 organizations thus far



American College of physicians

و غیره...



grading assessment evidence .. evidence

High Moderate Low Very low Confidence with low confidence

Totally Confident ? ⇒ Strength of recommendation evidence

# What are we grading?

two components

Weak recommendation

Very Low

Moderate

totally confident

no

confidence

Low

High

totally Confident, High, Moderate  
Strong recommendation

strength of recommendation:

strong and weak

Is it Strong recommendation or Weak recommendation?

(no Confidence) لا ثقة

Weak recommendation ضعيف التوصية

Very low low

weak recommendation ضعيف التوصية



# Grading Recommendation Strength

هذه السلايد تتحدث عن Randomized Controlled trails & Observational Studies وما تأثيرهم .

TABLE 7-2. GRADE SYSTEM TO RATING CONFIDENCE IN EFFECT ESTIMATES<sup>28</sup>

| 1. Establish initial level of confidence |                                             | 2. Consider lowering or raising level of confidence                                                                                              |                                                                                 | 3. Final level of confidence rating                                 |
|------------------------------------------|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Study design                             | Initial confidence in an estimate of effect | Reasons for considering lowering or raising confidence                                                                                           |                                                                                 | Confidence in an estimate of effect across those considerations     |
|                                          |                                             | ↓ Lower if                                                                                                                                       | ↓ Higher if                                                                     |                                                                     |
| Randomized trials →                      | High confidence                             | Risk of bias<br>-1 Serious<br>-2 Very serious<br>Inconsistency<br>-1 Serious<br>-2 Very serious<br>Indirectness<br>-1 Serious<br>-2 Very serious | Large effect<br>+1 Large<br>+2 Very large<br>Dose response<br>+1 gradient found | High<br>⊕⊕⊕⊕<br>Moderate<br>⊕⊕⊕○<br>Low<br>⊕⊕○○<br>Very low<br>⊕○○○ |
| Observational studies →                  | Low confidence                              | Imprecision<br>-1 Serious<br>-2 Very serious<br>Publication bias<br>-1 Likely<br>-2 Very likely                                                  |                                                                                 |                                                                     |



## 2. Conflict of Interest (COI)

- **Intellectual COI:** academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation.

## Experts with Conflicts

The most knowledgeable individuals regarding the subject matter addressed by a CPG are frequently conflicted.



These “experts” often possess unique insight into guideline relevant content domains.



They may be aware of relevant information about study design and conduct that is not easily identified.

## Lecture 7

سؤال :- كيف يحدث Conflict بين Experts ؟

1. Development → Guideline - N  
 2. expert already → expert

Certain procedure or  
Certain pathway →

أند مثلا = procedure يعرف فيها أكثر على صيغ المثال

له علاء Clinician أو جراح يعرف بهذه المنة Procedure الحية وال  
 guideline الحية تتحدث أن هؤلاء (certain patients) علاء الأولاد أن

11. Expert in 11. procedure 11. 11. 11.

guideline أو دليل recommendation تعني 'ملاحظة' هي في  
الكتابة ... هي أفضل الممارسات هي صحيح تعني 'ملاحظة' هي

11 intervention المصححة المرفقة ... فهي من جهة تصحح للرفق (وصف  
جهة مرفقة) أن تقيس مصلحته على أن تقيس Outcome جديد أو

Financial already procedures already ..  
benefit recommendation procedure ..

ان شاء الله procedure اذا علمت ان المريض يستفيد من الفحص  
 expert او Clinician او already procedure اذا علمت ان المريض يستفيد من الفحص

Conflict of interest already  
procedure في كل الأحوال في هذه الـ procedure

Certain procedure  
Circumstances:  $\text{أَيُّهَا أَحْسَنُ لِمَنْ يَكُونُ عَلَيْهِ سَيِّئٌ}$   $\text{أَنْ يَقُولُوا}$   
Over another alternative

- Over another alternative intervention



بُسْرَتُمْ بِكُلِّ جَمِيلٍ تَنْتَظِرُونَهُ .