INTRODUCTION

تعريف

- *Clinical practice guidelines* are recommendations for optimizing patient care that are developed by systematically reviewing the evidence and assessing the benefits and harms of health care interventions.

- 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.

* clinical practice guidelines :-

هيه عباره عن (recommendation) توصيات ، هاي التوصيات حتى احنا نعزز الـ (patient care) ، نعزز الفوائد و الاضرار الي بتكون ناتجة منه الـ (health care interventions)

← هاي الـ (interventions) ممكن شرط (Just include medications) ممكن انها تكون (other types of therapy) مثل

- radiation
- surgery
- physical therapy

← الـ (clinical practice guidelines) هيَ (care developed) عن طريق (groups) او (organizations) ، بمعنى آخر الي بدو يكتب هاي التوصيات لـ (health care interventions) من اجل (optimizing patient care) لازم يكونوا متخصصين مثل

- federal
- state government
- professional associations
- managed care organizations
- third party payers
- (quality assurance organizations)
- (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.
- 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.

← هدول الناس الـ (practitioner's) الي بدهم يكتبو الـ (recommendations)
او الـ (clinical practice guidelines) لازم يعتمدوا على
(rigorous evidence-based methodology)

← ولازم هاي الـ (guidelines) تكون بتعتمد على (evidence) قوي.
وايكون هذا الـ (evidence)

← مثلاً: ← في عنا (recommendations) لـ
(some health care intervention)

هاي الـ (intervention) لازم تكون الها مرجع ،وا لازم يكون هذا
المرجع هوه مرجع قوي بيعتمد على
(strength of evidence is very important for each guideline)

← ولازم الـ (clinical practice guideline) تكون
(accessible)
(fo patient or for any health care professional)

← يعني اي شخص [redacted] بده يشوف ايش هية الـ (clinical practice guideline)
(so, these guideline should be accessible)

← بعد كتابة هاي الـ (guideline) والـ (recommendations)
(shouldbe reviewed by representatives of the pharmacist)

- 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.

← عن طريق

(Developed of clinical practice guidelines)

(we can Developed clinical performance measures)

← يعني اذا اجو هدول الـ (groups) او هدول الـ (representatives) كتبوا الـ (guidelines) واعملو (reviegen) ، [redacted] لازم احنا نعمل (measures) الـ (Performance) تبع هذا الـ (guidelines) ، انو الناس الي طبقوا هاي الـ (guideline) كيف ممكن نعملهم (measuring) ، هاي بتسميها الـ

(clinical performance measures)

← انو هل همة استفادوا ؟

← انو هل الـ (harms or risk) قلت ؟

← انو هل هاي الـ (guidelines) او الـ (recommendation) كانت (cost effectivness) ؟

- 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.

← انو هل هاي (clinical practice guideline) انو هاي الـ (intervention)
اوهاي الـ (recommendation) راح يعود لي بـ (high quality) ؟
انو هاي الـ (strength evidence) راح يعود لي بـ (high quaity) ؟
انو هل الناس الي راح يطبقوه (as performance) راح يستفيدوا منه ؟

← بتالي لانو الـ (evidence over time) بتطلها تتطور في (new evidence)
بتظهر عنا ، عشان هيك حتى الـ (clinical practice)
(should be updated)

※ الـ (guideline) اوهاي الـ (recommendation)
(for optimizing patient care)
بيكتبوها ناس مختصين وابراجعوها ناس مختصين وابيعملولها (updated) ناس مختصين بالاعتماد على الـ (new evidence) الي ظهرت .

← الـ (groups) او المختصين الي بيكتبوا هاي الـ (guideline) همه بيختلفوا بـ:

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

Vary

Evidence-based medicine (EBM) and Clinical Practice Guidelines

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.

→ each guideline should be dependent on strong evidence (optimizing of the patient care) لحتى يعمل

(Evidence-based medicine (EBM)) ← هاي الي احنا بنسميها

(the best clinical care of patient) تحقق لحتى : (E B M) ← بتالي الـ

it should involves making individual patient care decisions based on the best currently evidence

← بتالي الـ (EBM) بأيش بيهتم ؟

Why Does EBM Matter?

1. Increases audience confidence in the value, objectivity, effectiveness of healthcare intervention and reproducibility of the tests or procedures .
2. Increases transparency. الصدقية
3. Provides a balanced approach. → انه لازم يعتمد على (approach) واضح
4. Protects patients from ineffective or risky care.
5. Increases cost-effectiveness and value. of the health care outcomes

لحتى تكون ←

TO BE TRUSTWORTHY, GUIDELINES SHOULD...

فيه الها شروط معينة ←

بتكون خلال secondary pathway of drug development ←

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.

TO BE TRUSTWORTHY, GUIDELINES SHOULD...

برضه لازم تكون هاي الـ (guidelines) :-

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 (1) and the strength of recommendations. (2)

يعتمد على ←

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

(8 standards) حطو ، (specific evidence-based clinical practice guidelines) حطو (IoM) اجو الـ ←
(development) لحتى نعمل

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

- 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.

← الشفافية الاساسية للـــ (healthcare intervention) لازم تكون فيها نوع من الشفافية و المصداقية

(in clear and detailed manner) ① ← في لازم تكون مذكوره

(accessible to publicly people) ② ← الشفافية لازم تكون

2. CONFLICT OF INTEREST (COI)

- is one important potential source of bias in the development of CPGs.
- 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) ← لازم يتقلل لحتى نعتبر انه هذا الـ (guideline) بيعملنا (optimizing patient health care)

← لانه ممكن الشخص الي بكتب هاي الـ ـــــ (guideline) يكون عندة (secondary professional obligation)

← انه هوه بده يقدم هاي الـ ـــ (health care intervention) نتيجة اسباب قد تكون هاي الاسباب ←
(تدعمة ماديا) financial
(تدعمة اكاديمياً) Academic Advancement
وابتدعمة بـ (community)

← بتالي هاي الاسباب صار عندنا (conflict of interest)

← يعني هذا الشخص الي كتب الـ (recommendation) هوه فعلياً ما كتبة من اجل انه يحسن من الـ (patient health care) هوه كتبه لانه عندة اسباب أخرى عندة ← (private interest) ←
(his or her professional obligations).

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.**

← انو بعض هدول الاشخاص اللي بدهم يكتبوا الـ (recommendation) يعملوا (attachment)، لانه عندهم همة (Intellectual) COI.

← يعملو (attachment) لي (specific point of view) & هاي الـ (recommendation)

← بتالي هاي الـ (point of view) ممكن تكون

financial
Academic
Community Standing

← هاي الـ (patient of view) ← بتأثر على رأي هذا الشخص اللي بدو يكتب الـ (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.

← الـ (experts) اللي بكونو عندهم (Conflict of interest) همه اكتر الاشخاص اللي عندهم (knowledge) بـ (subject) ، اللي عندهم اكتر معلومات عن هذا الـ (guideline) ، حتى همه بكون عندهم معلومات عن الـ (study design)

← هاي المعلومات مش اي حدا بيقدر يعرفها

← هدول الـ (experts) عندهم (unique insight into guideline relevant content domains)

← يعني همه بيعرفوا هذا الـ (guideline) بتفصيل ، بيقدرو يعملوا (conflicted of interest) بالاعتماد على مصالحهم الشخصية .

Strategies for Managing COI:

1. Simple disclosure (a person's financial interests).
2. Exclude from leadership roles.
3. Participation in certain restricted recommendations.
4. Formal or informal consultation.
5. Fully exclude conflicted members from panel participation.

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.

هذا الـ (conflict of interest) ممكن يكون سببة :
1

- Disclosure should **reflect all current and planned commercial** (including services from which a clinician derives a substantial proportion of income), **non-commercial**, 2 **intellectual, institutional, and patient/public activities** pertinent to the potential scope of the CPG.

Managing conflict of interest:

لازم يوضح كيف هاي الـ (COI) لكل (member) ممكن انها تأثر على (guideline Development process) ولازم يعملولها (update) بكل (meeting).

B. Disclosure of COIs within GDG

- **All COI of each GDG member** should be **reported and discussed** by the prospective development group prior to the onset of their work.
- **Each panel member should explain how their COI could influence the CPG development process** or specific recommendations.
- Each panel member **will update any COI at each meeting of the GDG.**
- **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.

* كل شخص ممثل بس لازم يعبر عن الـ (interest activities) الخاصة فيه الي ممكن انها تأثر على كتابة الـ (recommendation)، لازم ايضاً هذا الـ (conflict of interest) بعينة لازم يصيرلها (discussed) لازم يصيرلها (reported) لازم يصيرلها (reviewed) و(resolved) عن طريق الـ (chair and staff)

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.**

يعني انه الاشخاص الي بدهم يكتبوا هذه الـ(guideline) لازم يجردوا انفسهم ، يعني انتة لما
لما تكتب هاي الـ(guideline) لازم تجرد نفسك في انك راح تحصل على اي (financial benifit)
(guideline) ، يعني انته بدك تشارك بهاي الـ(guideline) (for you or for your family members)
و (financial investments) عندك عشان يكون مش (you shouldn't participate in marketing activities)

Managing conflict of interest:

(guideline) بد ه يكتب هاي الـ (members) اي ←

(shouldnot have COI)

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.

(should be perform without having any members who) ← (guideline) الـ وهاي ←
have COIs

3. COMPOSITION OF GUIDELINE DEVELOPMENT GROUP (GDG)

الناس اللي بدها تكتب (guideline) الـ should be

1. The GDG should be multidisciplinary and balanced, including methodological experts, clinicians, and populations expected to be affected.

الـ (groups) المسؤولة عن كتابة الـ (guideline) لازم يكون فيهم

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.

* بتالي الـ (guideline) لازم تحتوي على:

3. Adopt strategies to increase effective participation of patient and consumer representatives.

4. INTERSECTION OF CLINICAL PRACTICE GUIDELINE 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 FOR SYSTEMATIC REVIEWS

RIGOROUS recommendations for:

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

5. ESTABLISHING EVIDENCE FOUNDATIONS AND RATING STRENGTH OF RECOMMENDATIONS

كل (guideline) يجب ان يحتوي على ٦ ه

For each recommendation provide:

1. A summary of relevant available evidence, description of the quality, quantity, and consistency of the aggregate available evidence.
2. A clear description of potential benefits and harms.
3. An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
4. A description of any differences of opinion regarding the recommendation.
5. A rating of the level of confidence in the evidence.
6. A rating of the strength of the recommendation.

DETERMINANTS OF EVIDENCE QUALITY GRADE COLLABORATION

اذا كانت الـ (systematic reviews) (guideline) الي داخلة بهذا الـ تحتوي على :-

- ❖Randomized controlled trails (RCTs) start high. → high confidence في هوه
- ❖Observational studies start low. → Low confidence في هوه

5 factors that Can lower quality	Factors increase confidence in quality
1. Bias	1. Large effect
2. Inconsistency	2. Dose response
3. Indirectness	
4. Imprecision	
5. Publication bias	

← يعني اذا كان فيه (study) بتوضح علاقة الـ (dose) مع الـ (clinical intervention)

* هون في هاي الحاله بكون (strong) يعني (high confidence in quality)

← اذا انا عندي دراسة، درسنا ها على اعداد كبيرة من الـ (patient) وطلع انه الها (effective) واضح بـ هاي الـ (healthcare intervention) بكون الها (high confidence)

← لكن اذا بدها تحتوي على ← اخطاء
← معلومات غير دقيقة
← معلومات متناقضة مابين (different study in systematic reviews)

* في كل هاي الأشياء بدها تقلل الـ (confidence)

GRADING OF THE STRENGTH OF THE RECOMMENDATION

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

GRADE

ADOPTED BY MORE THAN 90 ORGANIZATIONS

← هاي الـ (organizations) اللي بيعملنا لـ (Grading)
اوال (confidence) (estimation to confidence level)

PROLIFERATION OF SYSTEMS
COMMON INTERNATIONAL GRADING

- **GRADE** (Grades of recommendation, assessment, development and evaluation).
- **International group** ← هو ه المسئول عنه (GRADE) هذا الـ *
  Australian NMRC, SIGN, USPSTF, WHO, NICE, Oxford CEBM, CDC, CC
- **~ 40 meetings over last 16 years**
- **The system – over 100 organizations thus far** مثل :-

هاي الـ (organization) اللي بتعمل عملية الـ (GRADE) للـ (evidence) او لي الـ (strength of recommendation)

THE COCHRANE COLLABORATION · World Health Organization · ACP American College of Physicians · UpToDate

WHAT ARE WE GRADING?

two components

no confidence — Very Low — Low — Moderate — High — totally confident

* strength of recommendation: strong and weak)

Very low confidence ←
Low confidence ←
Moderate confidence ←
High confidence ←
← حكينا انو بعض الـ (evidence) بكون الها

* strong
* weak
← ممكن يكون (strength of recommendation) * الـ

PLAN

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

2. Two steps:
   - Confidence in estimates (quality of evidence).
   - Strength of recommendation.
3. Evidence profiles.
4. An exercise in applying GRADE.

PROLIFERATION OF SYSTEMS
COMMON INTERNATIONAL GRADING

GRADING RECOMMENDATION STRENGTH

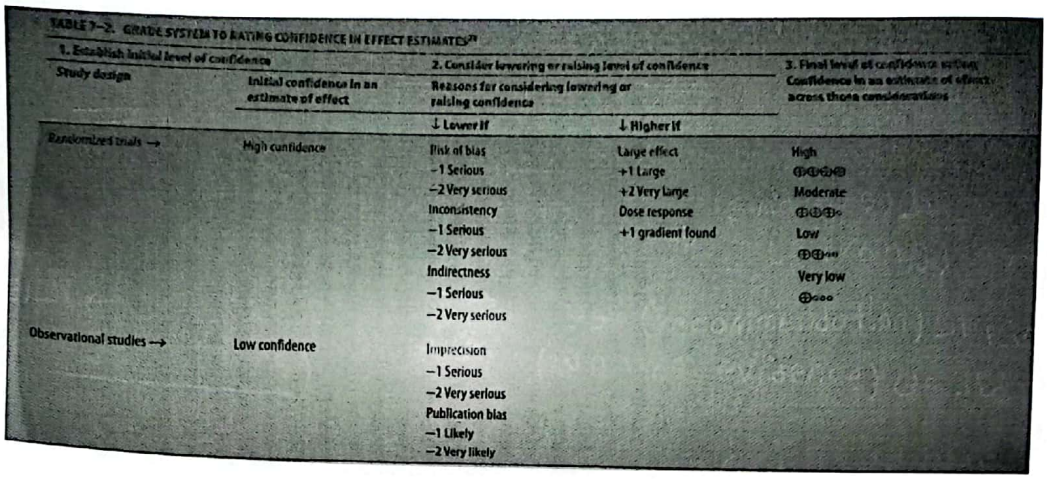

TABLE 7–2. GRADE SYSTEM TO RATING CONFIDENCE IN EFFECT ESTIMATES[a]

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

(Randomized trials) هذا الجدول بوضح انه الـ ←

عندها (High confidence)

(observational studies) والـ ←

عندها (Low confidence)

(bias) اذا دخل عنا الـ ← (confidence)؟ ← متى بقل الـ

(inconsistency) // // // //

(indirectness) // // // //

(imprecision) // // // //

(publication bias) // // // //

Large effect

Dose response ← اذا كان عنا ← (confidence)؟ ← ومتى بترتفع عنا الـ

هديل الزعبي