"But the guidelines say…"

Evaluating and Appraising Clinical Practice Guidelines

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Objectives

1. To define clinical practice guidelines and understand their role in practice
2. To understand and interpret the quality of evidence in "evidence-based" guidelines
3. To develop an approach to evaluating and appraising clinical practice guidelines
4. To gain familiarity with recently published cardiology-related clinical practice guidelines

What is a Guideline?

- A guideline is "any document that aims to streamline particular processes according to a set routine"
- "By definition, a guideline is **never mandatory**"
- Guidelines are ubiquitous!

www.wikipedia.org

Clinical Practice Guidelines

Definition:

- Clinical practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"

CMAJ 2001;165(2):157-63

Clinical Practice Guidelines

- Summary of recommendations
  - Screening, diagnosis, treatment, etc.
- Based on best available published evidence
- Reflect best practice with/without evidence
- Usually published and/or endorsed by a reputable organization
  - Guidelines from different organizations may conflict

Benefits of Clinical Practice Guidelines

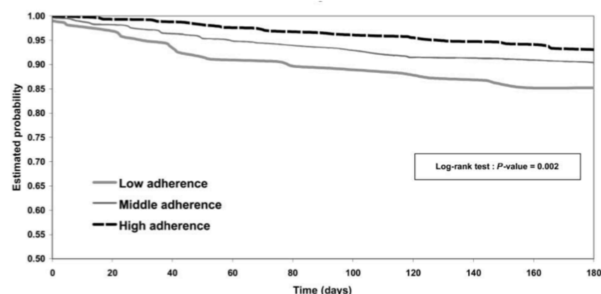
- Improve health outcomes
- Improve decision quality
- Influence public policy
- Support quality improvement initiatives
- Highlight gaps in evidence
- Optimize cost-effective care
- Empower patients

Adapted with permission from Dr. Sean Gorman

BMJ 1999;318:527-30

Improve Health Outcomes

MAHLER Survey – Cardiovascular Hospitalization



Adapted with permission from Dr. Sean Gorman *Eur Heart J* 2005;26:1653-9

Quality Improvement Initiatives

Get With the Guidelines Program

www.theheart.org

Advantages of Clinical Practice Guidelines

- Brief summary of evidence
- Convenient and readily usable
- Incorporate high-quality evidence
- Reflect best practice in absence of evidence
- Developed by experts
- Endorsed by reputable organizations

But still, they're only guidelines…

Clinical Practice Guidelines

"Guidelines are imperfect. Let me say that again: guidelines *are* imperfect."

theheart.org

Dr. Clyde Yancy, MD
August 2, 2011

www.theheart.org

Risks of Clinical Practice Guidelines

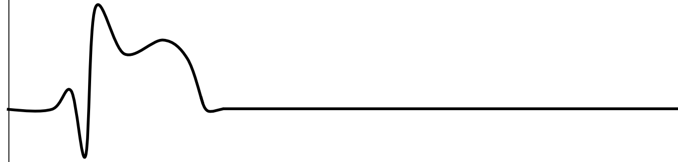
- Promote suboptimal practices
- Ignore patient preferences
- Adversely affect policy
- Misinform
- Waste resources
- Discourage future research

Adapted with permission from Dr. Sean Gorman *BMJ* 1999;318:527-30

Disadvantages of Clinical Practice Guidelines

- Unnecessary duplication
- Non-systematic approach to development
- Conflict of interest
- Ambiguity between grading systems
- Lack of tool to easily appraise guidelines
- Incorporate consensus statements
- Do not provide decision-making process
- Cumbersome or complex
- Lack of patient-centered approach

“Evidence-Based” Guidelines



“Evidence-Based” Guidelines

- Evidence-based medicine is defined as “the integration of the best research evidence with clinical expertise and patients’ values”
- Are all guidelines “evidence-based”?

Sackett DL et al. Evidence-based medicine: how to practice and teach EBM (2nd ed) 2000

“Evidence-Based” Guidelines

- Evidence-based guidelines are defined as “those that incorporate a **systematic search** for evidence, **explicitly evaluate** the quality of that evidence, and the espouse recommendations based on the **best available evidence**, even when evidence is not high quality”
- Most guidelines are “evidence-based”
- Guidelines ≠ evidence-based ≠ quality

McAlister et al. *PLoS Med* 2007;4(8):e250. doi:10.1371/journal.pmed.0040250

“Evidence-Based” Guidelines

How evidence-based are evidence-based guidelines?

- Cross-sectional analysis of CV risk guidelines
- Dyslipidemia, HTN, DM
- Canada, USA and Europe
- 338 recommendations in 9 guidelines
- 231 (68%) cite RCT evidence
- 105 (31%) based on high-quality RCT evidence

McAlister et al. *PLoS Med* 2007;4(8):e250. doi:10.1371/journal.pmed.0040250

“Evidence-Based” Guidelines

Consensus Recommendations:

- Based on expert opinion
- Class “C” recommendations
- Should they even be included in “evidence-based” guidelines?
- Consensus Statements

How to Use Clinical Practice Guidelines

Step 1

Start with a clinical question

Clinical Question

- PICO format
  - P = patient
  - I = intervention
  - C = comparator
  - O = outcome

Step 2

Locate applicable guidelines

Locating Guidelines

PubMed

Citations:

- Heart failure guidelines = 3,658
- Dyslipidemia guidelines = 2,790
- Atrial fibrillation guidelines = 1,238
- Acute coronary syndrome guidelines = 922

Locating Guidelines

- Organizations:
  - Canadian Cardiovascular Society (CCS)
  - Canadian Hypertension Education Program (CHEP)
  - American College of Cardiology/American Heart Association (ACC/AHA)
  - European Society of Cardiology (ESC)
- Regional Guidelines:
  - Toward Optimized Practice (TOP) - Alberta
  - Guidelines and Protocols Advisory Committee (GPAC) – BC

Locating Guidelines

- Databases:
  - PubMed
  - Canadian Medical Association (CMA) Infobase
  - National Guideline Clearinghouse – USA
  - NIH National Heart Lung and Blood Institute (NHLBI) – USA
  - NHS National Institute for Health and Clinical Excellence (NICE) – UK

Step 3

Are the recommendations practical and clinically relevant?

Practicality and Relevance

Recommendations should have:

1. What to do (summary of evidence)
2. How to do it (application in practice)

Practicality and Relevance

Recommendations should ideally:

- Reflect clinical questions
- Be specific to a defined clinical scenario
- Weigh benefits versus risk
- Reflect value judgments
- Incorporate cost considerations

JAMA 1995;274(20):1630-2

Practicality

- *Ideally* recommendations should give unambiguous advice about a specific problem
- Potential benefits should clearly outweigh the potential harms
- Present both expected relative and absolute changes in outcomes

JAMA 1995;274(20):1630-2

Relevance

- Recommendations should state a specific target population (but not be *too* specific)
- *Ideally* national guidelines should take precedence over international guidelines
- Should include a comprehensive, reproducible, recent literature review

JAMA 1995;274(20):1630-2

Step 4

How strong are the recommendations?

Recommendation Strength

- Based on:
  - Quality of evidence
  - Magnitude of effect
  - Consistency across studies
  - Value of outcomes
- Provide context
- Multiple grading systems exist

JAMA 1995;274(20):1630-2

Grading Systems

- Class
  - Strength of recommendation
  - Size of treatment effect
- Level
  - Evidence to support recommendation
  - Estimate of certainty of treatment effect

Grading System Example

SIZE OF TREATMENT EFFECT →

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *Risk ≥ Benefit* *No additional studies needed* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**
LEVEL A Multiple (3-5) population risk strata evaluated* General consistency of direction and magnitude of effect	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited (2-3) population risk strata evaluated*	■ Recommendation that procedure or treatment is useful/effective ■ Limited evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Limited evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited (1-2) population risk strata evaluated*	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard-of-care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard-of-care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard-of-care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard-of-care
Suggested phrases for writing recommendations†	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

Grading System Example

Class	Description
I	This treatment is beneficial, useful and good
IIa	Conflicting evidence but overall favouring treatment
IIb	Conflicting evidence but overall "less well established"
III	This treatment is not useful or harmful

Grading System Example

Level	Description
A	Multiple RCTs or meta-analyses
B	Single RCT or large, nonrandomized study
C	Consensus of opinion or small, retrospective studies

Grading System Example

- In other words…

I	A	Do this. We have lots of evidence.
I	B	Do this. We only have one study though.
IIa	B	Maybe do this. We only have one study.
IIb	C	Maybe don't do this. We think it may not work.
III	A	Don't do this. We have lots of evidence.
I	C	Do this. We think it's good.

CCS Antiplatelet Guidelines:

- Antiplatelet Therapy for Secondary Prevention in the First Year Following an Acute Coronary Syndrome:
  - In general, the adenosine diphosphate P2Y12 receptor antagonist added to ASA in the acute setting should be maintained for the duration of therapy **(Class I, Level C)**

Can J Cardiol 2011;27:208-21

Is the objective of the guideline consistent with your objectives?

- Each recommendation should include a desired outcome(s)
- The outcome should be specific enough for a clinician to assign value

JAMA 1995;274(20):1630-2

Are the recommendations applicable to your patients?

- Some degree of interpretation and flexibility required
- Allow for incorporation of patient-specific values and preferences

Remember, guidelines are imperfect and never mandatory…

JAMA 1995;274(20):1630-2

- Retrospective, observational review of 5 Canadian clinical practice guidelines
- 3 guidelines mentioned that patients' values or preferences should influence decisions
- No guideline recommended discussing benefits and harms of therapy with patients
- Identified a total of 99 words (0.1%) relevant to patients' values and preferences

McCormack JP, Loewen P. *Can Fam Physician* 2007;53:1326-7

Patient Values and Preferences

"It is important to remind healthcare professionals about the need to incorporate patient values and preferences into decision making"

published in the 2008 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. By doing so, they will remain current in this ever-changing field.

REFERENCES

1. McCormack JP, Loewen P. Adding "value" to clinical practice guidelines. *Can Fam Physician*. 2007;53:1326-1327.
2. Clinical Guidelines Task Force. *Guide for Guidelines: A Guide for Clinical Guideline Development*. Brussels, Belgium: International Diabetes Federation; 2003. Available at: http://www.idf.org/webdata/docs/Guide%20for%20Guidelines.pdf. Accessed September 1, 2008.
3. *United for Diabetes Campaign: Key Messages*. Brussels, Belgium: International Diabetes Federation; 2007. Available at:

2008 CDA Clinical Practice Guidelines *Can J Diabetes* 2008;32(suppl 1):S1-201

Step 7

How do you reconcile bias and conflict of interest?

Bias and Conflict of Interest

- Personal bias
  - Industry involvement
- Clinical and interpretation bias
  - Industry involvement
- Publication bias

Bias and Conflict of Interest

- Transparency
  - Disclosure of financial relationships
- Exclusion from voting on recommendations
- External stakeholders
  - Clinicians
  - Public

How to Appraise Clinical Practice Guidelines

AGREE II Instrument

- **A**ppraisal of **G**uidelines for **RE**search & **E**valuation (AGREE)
- Provides a standardized method to appraise the quality of the *development*, *presentation* and *applicability* of clinical practice guidelines
- Designed for clinicians, policy makers, educators, guideline developers

AGREE II

www.agreetrust.org

AGREE II Instrument

- Includes 23 items over 6 domains:
  - Scope and purpose
  - Stakeholder involvement
  - Rigour of development
  - Clarity of presentation
  - Applicability
  - Editorial independence

AGREE II Instrument

- Scoring system:
  - Each item is scored on a 7-point Likert scale

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

  - Points are assigned from 1 to 7
  - Each domain is given a score based on the sum of item responses
  - 100% is a perfect score

Scope and Purpose

- <u>Focus:</u> Overall aim of the guideline, the specific health questions and the target population
- <u>Example:</u> The overall objective(s) of the guideline is (are) specifically described
  - Health intent (i.e., prevention, screening, diagnosis, treatment)
  - Expected benefit or outcome
  - Target (e.g., patient population, society)

Stakeholder Involvement

- <u>Focus:</u> The extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users
- <u>Example:</u> The views and preferences of the target population (patients, public) have been sought
  - Participation in guideline development group
  - Focus groups, surveys, literature review

Rigour of Development

- <u>Focus:</u> The process used to gather and synthesize the evidence, the methods to formulate the recommendations and to update them
- <u>Example:</u> Systematic methods were used to search for evidence
  - Databases, time periods and search terms
  - Full search strategy included as appendix

Clarity of Presentation

- <u>Focus:</u> The language, structure, and format of the guideline
- <u>Example:</u> The recommendations are specific and unambiguous
  - Statement of recommended action
  - Intent or purpose
  - Relevant population
  - Qualifying statements

Applicability

- Focus: The likely barriers and facilitators to implementation, strategies to improve uptake and resource implications of applying the guideline
- Example: The potential resource implications of applying the recommendations have been considered
  - Economic considerations
  - Health technology assessments, drug costs

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Editorial Independence

- Focus: The formulation of recommendations not being unduly biased with competing interests
- Example: Competing interests (CI) of guideline development group members have been recorded and addressed
  - Description of types of CI
  - Description of how CI influenced development

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AGREE II Instrument

Limitations:

- Only assesses *reporting* of development
- Inter-user variability
- Requires at least 2 assessors, preferably 4
- Difficult to translate score into practice
- Does not allow for scoring "not applicable"

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Recent Cardiology Guidelines

Heart Failure

Canadian Journal of Cardiology 27 (2011) 319–338

Society Guidelines

The 2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: Focus on Sleep Apnea, Renal Dysfunction, Mechanical Circulatory Support, and Palliative Care

Primary Panel Authors: Robert S. McKelvie, MD, PhD, FRCPC (Chair),[a] Gordon W. Moe, MD, FRCPC (Co-Chair),[b] Anson Cheung, MD, FRCSC,[c] Jeannine Costigan, RN, MScN, APN,[d] Anique Ducharme, MD, FRCPC,[e] Estrellita Estrella-Holder, RN, BN, MScA, CCN(C),[f] Justin A. Ezekowitz, MB, BCh, MSc, FRCPC,[g] John Floras, MD, DPhil, FRCPC, FACC, FESC,[h] Nadia Giannetti, MD, FRCPC,[i] Adam Grzeslo, MD, CCFP, FCFP,[a,j] Karen Harkness, RN, BScN, CCNC, PhD,[a] George A. Heckman, MD, MSc, FRCPC,[a,k] Jonathan G. Howlett, MD, FRCPC,[l] Simon Kouz, MD, FACC,[m] Kori Leblanc, BScPhm, ACPR PharmD,[n] Elizabeth Mann, MD, FRCPC,[o] Eileen O'Meara, MD, FRCPC,[p] Miroslav Rajda, MD, FRCPC,[q] Vivek Rao, MD, FRCSC,[n] Jessica Simon, MB, ChB, MRCP(UK), FRCPC,[l] Elizabeth Swiggum, MD, FRCPC,[r] and Shelley Zieroth, MD, FRCPC,[s] Secondary Panel Authors: J. Malcolm O. Arnold, MD, FRCPC,[t]

Can J Cardiol 2011;27:319-38

Atrial Fibrillation

Canadian Journal of Cardiology 27 (2011) 47–59

Society Guidelines

Canadian Cardiovascular Society Atrial Fibrillation Guidelines 2010: Rate and Rhythm Management

Anne M. Gillis, MD, FRCPC,[a] Atul Verma, MD, FRCPC,[b] Mario Talajic, MD, FRCPC,[c] Stanley Nattel, MD, FRCPC,[c] Paul Dorian, MD, FRCPC,[d] and the CCS Atrial Fibrillation Guidelines Committee[e]

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[c] *Montreal Heart Institute, Université de Montréal and McGill University, Montreal, Québec, Canada*

[d] *St Michael's Hospital and University of Toronto, Toronto, Ontario, Canada*

[e] *For a complete listing of committee members, see Gillis AM, Skanes AC. Canadian Cardiovascular Society Atrial Fibrillation Guidelines 2010: Implementing GRADE and Achieving Consensus. Can J Cardiol 2011;27:27-30.*

Can J Cardiol 2011;27:47-59

Atrial Fibrillation

2011 ACCF/AHA/HRS Focused Update on the Management of Patients With Atrial Fibrillation (Update on Dabigatran): A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines

L. Samuel Wann, Anne B. Curtis, Kenneth A. Ellenbogen, N.A. Mark Estes, III, Michael D. Ezekowitz, Warren M. Jackman, Craig T. January, James E. Lowe, Richard L. Page, David J. Slotwiner, William G. Stevenson and Cynthia M. Tracy

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Circulation 2011;123(10):1144-50

Dyslipidemia

SPECIAL ARTICLE

2009 Canadian Cardiovascular Society/Canadian guidelines for the diagnosis and treatment of dyslipidemia and prevention of cardiovascular disease in the adult – 2009 recommendations

Jacques Genest MD[1], Ruth McPherson MD PhD[2], Jiri Frohlich MD[3], Todd Anderson MD[4], Norm Campbell MD[4], André Carpentier MD[5], Patrick Couture MD[6], Robert Dufour MD[7], George Fodor MD[2], Gordon A Francis MD[3], Steven Grover MD[1], Milan Gupta MD[8], Robert A Hegele MD[9], David C Lau MD[10], Lawrence Leiter MD[11], Gary F Lewis MD[12], Eva Lonn MD[13], GB John Mancini MD[14], Dominic Ng MD PhD[11], Glen J Pearson PharmD[15], Allan Sniderman MD[16], James A Stone MD PhD[10], Ehud Ur MD[14]

Can J Cardiol 2009;25(10):567-79

Dyslipidemia

European Heart Journal (2011) **32**, 1769–1818
doi:10.1093/eurheartj/ehr158

ESC/EAS GUIDELINES

ESC/EAS Guidelines for the management of dyslipidaemias

The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS)

Developed with the special contribution of: European Association for Cardiovascular Prevention & Rehabilitation†

Eur Heart J 2011;32:1769-1818

UA/NSTEMI

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PRACTICE GUIDELINE

This guideline contains hyperlinks to recommendations and supporting text that have been updated by the "2011 ACCF/AHA Focused Update on the Management of Patients With Unstable Angina/Non–ST-Elevation Myocardial Infarction" (J Am Coll Cardiol 2011;57:1920–59; doi:10.1016/j.jacc.2011.02.009). Updated sections are indicated in the Table of Contents and text.

2011 ACCF/AHA Focused Update Incorporated Into the ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non–ST-Elevation Myocardial Infarction

A Report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines

J Am Coll Cardiol 2011;57(19)1920-59

Antiplatelet Therapy

Canadian Journal of Cardiology 27 (2011) 208–221

Society Guidelines

The Use of Antiplatelet Therapy in the Outpatient Setting: Canadian Cardiovascular Society Guidelines Executive Summary

Alan D. Bell, MD, CCFP,[a] André Roussin, MD, FRCPC,[b] Raymond Cartier, MD,[c] Wee Shian Chan, MD, FRCPC,[d] James D. Douketis, MD, FRCPC,[e] Anil Gupta, MD, FRCPC,[f] Maria E. Kraw, MD, FRCPC,[g] Thomas F. Lindsay, MD, CM, FRCSC,[h] Michael P. Love, MB, ChB, MD, MRCP,[i] Neesh Pannu, MD, SM, FRCPC,[j] Rémi Rabasa-Lhoret, MD, PhD,[k] Ashfaq Shuaib, MD, FRCPC,[l] Philip Teal, MD, FRCPC,[m] Pierre Théroux, MD,[n] A. Graham Turpie, MD,[o] Robert C. Welsh, MD, FRCPC, FACC,[p] Jean-François Tanguay, MD, CSPQ, FRCPC, FACC, FAHA, FESC[q]

Can J Cardiol 2011;27:208-21

My Practical Approach

- Know the important (regional) guidelines
- Know the basic recommendations
- Always evaluate the strength of recommendation and quality of evidence
- Understand the evidence for key or controversial recommendations
- Build on your knowledge with new clinical trials
- Healthy skepticism is key!