Guidelines

G. Michael Allan

Why they don't really apply to Family Medicine
Guidelines

**Presenter Disclosure:**

*G Michael Allan* has **no** potential for conflict of interest with this presentation

I have participated in guidelines
Objectives and Plan

• Review the strengths of guidelines
• Discuss the Limitations of Guidelines
• Issues in applying guidelines in practice
• Some examples were guidelines are not linked to best evidence

• The Goal: Worry less about taking care of guidelines (+ performance measures) and more about people
Guidelines: Answers for Uncertainty

• 3 “uncertainties” for every 2 patient encounters\textsuperscript{1}
• Searching (30-60 minutes\textsuperscript{2}) & appraising a paper
  – 30 patients = 45 questions
  – >60 hours/day

• In truth, Doctors\textsuperscript{3}
  – Spend 2 minutes getting answers to their questions
  – Search pubmed for <1% of their question
  – Do critical appraisals < 0.1% of their questions

Guidelines: What else they offer

• Help us keep up-to-date
• Alternatively: We need to read 7,287 articles per month relevant to primary care
  – That means: 21 hours of reading every day\(^1\)

• Guidelines also provide suggestions on issues lacking clear evidence.

Clear messages

Bottomless Pit
65 feet deep
How consistent are guidelines?

- There is disagreement between Task Forces\(^1\)
- Guidelines don’t seem to agree
- Example, in COPD, even the Diagnosis Debated.

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**TABLE 2–3 Staging Chronic Obstructive Pulmonary Disease for Disease Severity**

<table>
<thead>
<tr>
<th>Classification of disease severity</th>
<th>ATS(^3)</th>
<th>BTS(^7)</th>
<th>ERS(^9)</th>
<th>GOLD(^{10})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I (mild)</td>
<td>≥ 50</td>
<td>60–79</td>
<td>≥ 70</td>
<td>≥ 80</td>
</tr>
<tr>
<td>Stage II (moderate)</td>
<td>35–49</td>
<td>40–59</td>
<td>50–69</td>
<td>30–80</td>
</tr>
<tr>
<td>Stage III (severe)</td>
<td>&lt; 35</td>
<td>&lt; 40</td>
<td>&lt; 50</td>
<td>&lt; 30</td>
</tr>
</tbody>
</table>

*In all patients with a reduced FEV\(_1\)/FVC ratio, usually less than 70%, which is the mark of obstructive ventilatory impairment.

FEV\(_1\) = forced expiratory volume in 1 second; FVC = forced vital capacity; ATS = American Thoracic Society; BTS = British Thoracic Society; ERS = European Respiratory Society; GOLD = Global Initiative for Chronic Obstructive Lung Disease.

Why do “Evidence based” Guidelines Vary

• What is Evidence?

• Remember: expert opinion is still considered evidence.
“Evidence based” Guidelines

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Cardiology(^1)</th>
<th>Infectious Disease(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## “Evidence based” Guidelines

<table>
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<th>Cardiology$^1$</th>
<th>Infectious Disease$^2$</th>
</tr>
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<tbody>
<tr>
<td>Level 1</td>
<td>11%</td>
<td>14%</td>
</tr>
<tr>
<td>Level 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td></td>
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“Evidence based” Guidelines

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<tbody>
<tr>
<td>Level 1</td>
<td>11%</td>
<td>14%</td>
</tr>
<tr>
<td>Level 2</td>
<td>41%</td>
<td>31%</td>
</tr>
<tr>
<td>Level 3</td>
<td>48%</td>
<td>55%</td>
</tr>
</tbody>
</table>

Who is writing Canadian Primary Care Guidelines

• 190 primary care CPG with 2539 authors
  – 53% were specialists, 17% family doctors
  – 8% Non-clinicians, 5% nurses, 3% pharmacists
  – Rest: Other (NP, physio, unknown, etc)

• Specialists were more
  – > ¾ of the doctors & > ½ of everyone!
  – Higher in industry funded or national CPGs

• Family doctors=17% family medicine CPD teachers

So do Experts do a better job reviewing the evidence?

- “Our data suggest that experts, on average, write reviews of inferior quality;
  – that the greater the expertise the more likely the quality is to be poor;
  – and that the poor quality may be related to the strength of their prior opinions;
  – and the amount of time they spend preparing a review article.” (Oxman & Guyatt, 1993)
• The main authors of Canadian Primary Care Guidelines are specialists
• And they generally do a poorer job reviewing evidence without bias?
It can be confusing,…

• Editorial: “Treating to New Targets”: plea for a LDL cholesterol target of or below 2 in any patient with coronary heart disease”

• What TNT asked: With CVD and LDL <3.4 is 80 mg better than 10 mg (Atorvastatin).

• Proper: A plea for High Dose Statin in CVD patients regardless of cholesterol.

Another Reason Interpretation Varies

- Conflict of Interest: 14 CPG, 288 “authors”
- Of those that could report COI (211):
  - 65% reported COI
  - 35% reported no COI
    - 11% of them had a COI (reported within last 2 yrs)
- Canadian more COI than US (86% vs 58%)
- Our research finds 49% of specialists
  - 28% of Fam Doc, 30% of Pharmacists

BMJ 2011;343:d5621 doi: 10.1136/bmj.d5621
Applying Tertiary Research to a General Population

• Significant difference between primary care (most patients seen) & specialty care (most research)
  1) Treatment of Depression
     – Tertiary care = 53% response or better
     – Primary care = 39% response
  2) Weight loss with Orlistat 1yr (120mg TID)
     – Tertiary care = 22% lost 5% weight
     – Primary care = 13% lost 5% weight

How are “we” doing?

- Practicing physicians are not hitting the guideline targets.
- DM in the US,
  - 93% DM pts did not hit all targets.
- Cholesterol Targets in US,
  - 68% not at the 3 Cholesterol Targets

JAMA 2004; 291: 335-42. J Manag Care Pharm. 2006;12(9);745-51
Do the RCT’s hit Targets?

• **Small** RCT to hit targets in BP, Chol & sugar\(^1\)
  – 80 patients: only 1 hit all targets

• **Review:** CVD pts, highest dose of statins\(^2\)
  – <50% actual get an LDL < 2 mmol/L.

• **3 RCTs** of Diabetics with CHD
  – ~23% patients achieved all four targets (LDL <2.5, systolic BP <130, HbA1C <7, and not smoking)

• Outcomes regardless of hitting targets

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Is there time for Chronic Disease

Table 3. Effect of Disease Control Status on Time Requirements for 5 Chronic Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Total Cases</th>
<th>No. (%) of Cases</th>
<th>Number of Visits</th>
<th>Minutes per Visit</th>
<th>Hours Per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Uncontrolled</td>
<td>Controlled</td>
<td>Uncontrolled</td>
<td>Controlled</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>511</td>
<td>417 (81.6)</td>
<td>94 (18.4)</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Hypertension</td>
<td>472</td>
<td>312 (66)</td>
<td>160 (34)</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
<td>118</td>
<td>58 (49)</td>
<td>60 (51)</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Asthma</td>
<td>183</td>
<td>62 (33.6)</td>
<td>121 (66.3)</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes</td>
<td>145</td>
<td>91 (63)</td>
<td>54 (37)</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Total hours per year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total hours per work day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- For 10 conditions if not well controlled up to 10.6 hours/day.¹
  - Physicians also need 7.4 hrs/day for preventive services²

An Impossible Job?

- Specialists: Better target shooters
  - Example: Guideline targets for elderly\(^1\)
- In trials, no difference in outcomes
  - Same elderly study: outcomes same\(^1\)
  - Depression: Outcomes same\(^2\)
  - Diabetes: Outcomes Same\(^3\)
- In Populations: More family doctors = Better outcomes!\(^4\)

Many other studies done WITHIN countries, both industrial and developing, show that areas with better primary care have better health outcomes, including total mortality rates, heart disease mortality rates, and infant mortality, and earlier detection of cancers such as colorectal cancer, breast cancer, uterine/cervical cancer, and melanoma. The opposite is the case for higher specialist supply, which is associated with worse outcomes.

Thanks Barb Starfield.

Source: Starfield B. [www.pitt.edu/~super1/lecture/lec8841/index.htm](http://www.pitt.edu/~super1/lecture/lec8841/index.htm)
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Thanks Barb Starfield.
There is even a formula,…

• “An increase of 1 primary care physician per 10,000 persons was associated with a reduction of 3.5 deaths per 10,000.

• An increase of 1 specialty physician per 10,000 population was associated with approximately 1.5 additional deaths per 10,000.”

So Is there anything new?

- Women with breast cancer who have a family physician\textsuperscript{1}
  - Reduced risk of breast cancer mortality: 0.69 (0.63-0.75),
  - Reduced risk of overall morality 0.83 (0.79-0.87),

- What About here in Alberta
  - Readmission lowest if patients seen by their family physicians vs other physicians (adjusted HR 0.91, 0.85-0.98)\textsuperscript{2}

<table>
<thead>
<tr>
<th>Poor access to the following increases admission</th>
<th>Nephrology</th>
<th>Internist</th>
<th>Family Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Failure</td>
<td>7%</td>
<td>16%</td>
<td>44%</td>
</tr>
<tr>
<td>Malignant Hypertension</td>
<td>52%</td>
<td>137%</td>
<td>365%</td>
</tr>
</tbody>
</table>

Disease Focused vs Patient

• Most of our patients excluded from most studies

• Good for the disease ≠ good for the patient\(^1\)

• Drug recommendations for patients with multiple conditions are presented but rarely rated in terms of priorities

Table 3. Treatment Regimen Based on Clinical Practice Guidelines for a Hypothetical 79-Year-Old Woman With Hypertension, Diabetes Mellitus, Osteoporosis, Osteoarthritis, and COPD

<table>
<thead>
<tr>
<th>Time</th>
<th>Medications†</th>
<th>Other</th>
</tr>
</thead>
</table>
| 7:00 AM  | Ipratropium metered dose inhaler 70 mg/wk of alendronate | Check feet  
Sit upright for 30 min on day when alendronate is taken  
Check blood sugar |
| 8:00 AM  | 500 mg of calcium and 200 IU of vitamin D  
12.5 mg of hydrochlorothiazide  
40 mg of lisinopril  
10 mg of glyburide  
81 mg of aspirin  
850 mg of metformin  
250 mg of naproxen  
20 mg of omeprazole | Eat breakfast  
2.4 g/d of sodium  
90 mmol/d of potassium  
Low intake of dietary saturated fat and cholesterol  
Adequate intake of magnesium and calcium  
Medical nutrition therapy for diabetes‡  
DASH‡ |
| 12:00 PM | Eat lunch  
2.4 g/d of sodium  
90 mmol/d of potassium  
Low intake of dietary saturated fat and cholesterol  
Adequate intake of magnesium and calcium  
Medical nutrition therapy for diabetes‡  
DASH‡ |
| 1:00 PM  | Ipratropium metered dose inhaler 500 mg of calcium and 200 IU of vitamin D | |
| 7:00 PM  | Ipratropium metered dose inhaler 850 mg of metformin  
500 mg of calcium and 200 IU of vitamin D  
40 mg of lovastatin  
250 mg of naproxen | Eat dinner  
2.4 g/d of sodium  
90 mmol/d of potassium  
Low intake of dietary saturated fat and cholesterol  
Adequate intake of magnesium and calcium  
Medical nutrition therapy for diabetes‡  
DASH‡ |
| 11:00 PM | Ipratropium metered dose inhaler  
As needed | Albuterol metered dose inhaler |

Abbreviations: ADA, American Diabetes Association; COPD, chronic obstructive pulmonary disease; DASH, Dietary Approaches to Stop Hypertension.

*Clinical practice guidelines used: (1) Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure VII,39 (2) ADA40-42; glycemic control is recommended; however, specific medicines are not described. (3) American College of Rheumatology33-35; recent evidence about the safety and appropriateness of cyclooxygenase inhibitors, particularly in individuals with comorbid cardiovascular disease, led us to omit them from the regimen.
Applying Guidelines to patients

• A study found that guidelines rarely included a discussion of patient-centered or shared informed decision making.
  – Of 5 large Canadian guidelines ≈ 0.1% content

# Quality of Life Comparison

<table>
<thead>
<tr>
<th>Outcome</th>
<th>QOL Utilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild Stroke</td>
<td>0.70</td>
</tr>
<tr>
<td>Angina</td>
<td>0.64</td>
</tr>
<tr>
<td>Diabetic Neuropathy</td>
<td>0.66</td>
</tr>
<tr>
<td>Comprehensive Diabetic Care</td>
<td>0.64</td>
</tr>
</tbody>
</table>
## Who really benefit from treatment?

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>HDL</th>
<th>LDL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Lipid</td>
<td>7.5</td>
<td>1.0</td>
<td>5.2</td>
</tr>
<tr>
<td>Mr Risky</td>
<td>4.9</td>
<td>1.0</td>
<td>2.6</td>
</tr>
</tbody>
</table>

- Who gets meds by guidelines?
- Who is higher risk?
Who really benefit from treatment?

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>HDL</th>
<th>LDL</th>
<th>Age</th>
<th>Smoke</th>
<th>BP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Lipid</td>
<td>7.5</td>
<td>1.0</td>
<td>5.2</td>
<td>35</td>
<td>No</td>
<td>120</td>
</tr>
<tr>
<td>Mr Risky</td>
<td>4.9</td>
<td>1.0</td>
<td>2.6</td>
<td>55</td>
<td>Yes</td>
<td>140</td>
</tr>
</tbody>
</table>

• Who gets meds by guidelines?
• Who is higher risk?
Who really benefit from treatment?

<table>
<thead>
<tr>
<th>Total</th>
<th>HDL</th>
<th>LDL</th>
<th>Age</th>
<th>Smoke</th>
<th>BP</th>
<th>10 yr Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Lipid</td>
<td>7.5</td>
<td>1.0</td>
<td>5.2</td>
<td>No</td>
<td>120</td>
<td>1.7%</td>
</tr>
<tr>
<td>Mr Risky</td>
<td>4.9</td>
<td>1.0</td>
<td>2.6</td>
<td>Yes</td>
<td>140</td>
<td>13.6%</td>
</tr>
</tbody>
</table>

- Mrs Risk: lowest risk but LDL > 5 so medication
- Mr Risky: Moderate risk, but LDL & ratio in target, so no med

Who really benefit from treatment?

<table>
<thead>
<tr>
<th>Risk* (x10 yrs)</th>
<th>Med</th>
<th>Treating (statin) 5 years</th>
<th>Risk</th>
<th>Benefit (~28%)</th>
<th>New risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Lipid</td>
<td>1.7%</td>
<td>Yes</td>
<td>0.6%</td>
<td>0.17%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Mr Risky</td>
<td>13.6%</td>
<td>No</td>
<td>6.2%</td>
<td>1.7%</td>
<td>4.5%</td>
</tr>
</tbody>
</table>

- Mrs Risk would treated with a drug due to her lipid levels while Mr Risk would not (although he would get 10 x the benefit).
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Guideline</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering CRP for CVD</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Regular home glucose test</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>ASA in DM</td>
<td>Yes</td>
<td>Maybe</td>
</tr>
<tr>
<td>Lubricant for PAP test</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>BMD testing after med</td>
<td>1-3 yrs</td>
<td>≥3yrs</td>
</tr>
<tr>
<td>Some Antidepressants better</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Glucose Targets</td>
<td>&lt;7</td>
<td>variable</td>
</tr>
</tbody>
</table>
Outcomes: Surrogate, Subjective, Objective

- Ask yourself: Can a patient feel the outcome?
- If No; it is a surrogate marker
## Surrogates: The Never-ending Story

<table>
<thead>
<tr>
<th>The Marker</th>
<th>The Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDL</td>
<td>Torcetrapib</td>
</tr>
<tr>
<td>LDL</td>
<td>Niacin</td>
</tr>
<tr>
<td>BP</td>
<td>Ezetimibe</td>
</tr>
<tr>
<td>A1C</td>
<td>Atenolol</td>
</tr>
<tr>
<td>CRP in CVD</td>
<td>Doxazosin</td>
</tr>
<tr>
<td></td>
<td>Aliskerin</td>
</tr>
<tr>
<td></td>
<td>Rosiglitazone</td>
</tr>
<tr>
<td></td>
<td>Almost any diabetes medications except Metformin</td>
</tr>
<tr>
<td></td>
<td>Vitamin E, Rosiglitazone, etc.</td>
</tr>
</tbody>
</table>

We have no real idea why,...

**This stuff works**
- Lithium for Bipolar
- Vitamin D for Falls
- Nitro patches for tendinopathy
- Nifedipine for renal stones
- Most drugs really

**This stuff doesn’t**
*(Other wrong theories)*
- Oral HRT for incontinence
- Anti-oxidants
- Cough Meds in kids
- Febrile seizure antipyretics
- Plus the non-drug theories
  - Analgesia in Abdo pain
  - Lubricant on a speculum
Performance measures

Measuring the right thing
Measuring with the right tool
Performance Measures Myths

- “Unintended” consequences are unpredictable
  - False: Many (e.g., patient de-enrolment) predictable\(^1\)

- Exceptions will be over-used:
  - False: 94% of exceptions are appropriate\(^2\)

- More incentive = better performance
  - False: Those with <10% pay from incentive\(^3\)

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The future

- **Guidelines** should
  1. Increase primary care involvement,
  2. Be transparent with conflict of interest,
  3. Interpretation of evidence and
  4. State they augment decision-making, not direct it

- **Performance measure**, if present, should
  1. Stop focusing on what can be measured (numbers) and more on,
  2. What should be measured
Reconciling Guidelines and Patient-Centered Care

• Strict guideline adherence is not needed
  – “These recommendations are systematically developed statements to assist practitioner & patient decisions about appropriate health care for specific clinical circumstances. They should be used as an adjunct to sound clinical decision making.” TOP
Performance Measures and Patient-Centered Care

• US Veterans Affairs

• “Only when those who promulgate measures are held personally responsible for their decisions should they hold physicians on the front line personally responsible for their implementation”
Quotes from my work CPG

• Two Diabetes Guideline participants: “Mike, we don’t know the evidence.”

• To Victor Montori on lipid CPG: “Victor, Victor, Victor. We write what we want and sprinkle in some references.”

• On how to base practice recommendations: “We have decided to base them (algorithms) more on familiar guidelines for now, with not as much emphasis on the newest evidence.”
Questions?