

How to be Smarter than the Guidelines

G. Michael Allan



**Shining
Evidence on
Guidelines &
Performance
Measures**



Faculty/Presenter Disclosure

- **Faculty/Presenter:** **G. Michael Allan**
- **Relationships with commercial interests:**
 - **Grants/Research Support:** Not applicable
 - **Speakers Bureau/Honoraria:** Not applicable
 - **Consulting Fees:** Not applicable
 - **Other:**
 - **Employed by University of Alberta, Alberta Health**
 - **Non-profit sources including Alberta College of Family Physicians, TOP, IHE, CADTH, etc.**

Faculty/Presenter Disclosure

- I have Chaired, Co-Chaired & Participated in guidelines on
 - Lipids
 - Diabetes
 - Cancer (Prostate)
 - Osteoporosis
 - Rheumatoid Arthritis



Objectives and Plan

- Review the strengths of guidelines
- Discuss the Limitations of Guidelines
- Issues in applying guidelines in practice
- Some examples where guidelines are not linked to best evidence
- The Goal: Worry less about taking care of guidelines (+ performance measures) and more about people

Don't think of yourself
as an UGLY PERSON
Think of yourself as a
BEAUTIFUL MONKEY

TOYOTA

Guidelines: Answers for Uncertainty

- 3 “uncertainties” for every 2 patient encounters¹
- Searching (30-60 minutes²) & appraising a paper
 - 30 patients = 45 questions
 - >60 hours/day
- In truth, Doctors³
 - Spend 2 minutes getting answers to their questions
 - Search pubmed for <1% of their question
 - Do critical appraisals < 0.1% of their questions

1. Ann Intern Med 1991; 114:576-81. J Fam Pract. 1992;35:265-9. 2. J Fam Pract. 1996; 43:140-4. Bull Med Libr Assoc 1994; 82: 140-146 3. BMJ 1999; 319: 358-61.

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 day¹
- Guidelines also provide suggestions on issues lacking clear evidence.

1. Alper et al. J Med Libr Assoc 2004;902(4):429-37.

Confusing Messages



Clinical practice guideline on diagnosis and treatment of hyponatraemia

Clinical Practice Guideline | G Spasovski and others | Diagnosis and treatment of hyponatraemia | 170:3 | G3

Michael Joannidis
Consultant Intensivist, Innsbruck University Hospital, Innsbruck, Austria.

high-quality guidelines in this field (1). The guidance documents scored low to moderate in the six domains of the AGREEII tool – scope and purpose, stakeholder involvement, clarity of presentation, clarity of presentation – and the different guidance history (2).

designed to provide information and assist in decision-making related to this topic. It was not intended to define a standard of care and should not be construed as one. It should not be interpreted as prescribing an exclusive course of management.

port clinical decision-making, dealing with hyponatraemia, internists, surgery, with hyponatraemia hospital setting. The guideline was developed for policymakers for informing the decision-making process.

This guideline was developed as a joint venture

Consultant nephrologist, Chair of ERBP, Ghent University Hospital, Belgium.

Sabine van der Veer
Implementation Specialist, Amsterdam Medical Centre, Amsterdam, The Netherlands.

line intended to cover and what the guideline developers considered. The scope was determined at a first meeting held in Barcelona in October 2010 with representatives of ESICM, ESE and ERBP present.

3. Purpose and scope of this guideline

3.1. Why was this guideline produced?

The purpose of this Clinical Practice Guideline is to provide guidance on the diagnosis and management of hyponatraemia in adult individuals with hypotonic hyponatraemia. It was designed to provide information and assist in decision-making related to this topic. It was not intended to define a standard of care and should not be construed as one. It should not be interpreted as prescribing an exclusive course of management.

This guideline was developed by three societies representing special interest in hyponatraemia: the European Society of Intensive Care Medicine (ESICM), the European Society of Endocrinology (ESE), and the European Renal Best Practice (ERBP).

All three societies agreed that there was a need for guidance on diagnostic assessment and therapeutic management of hyponatraemia. A recent systematic review, which included three clinical practice guidelines and five consensus statements, confirmed the lack of

geons and other physicians dealing with hyponatraemia in both an outpatient and an in-hospital setting. The guideline was also developed for policymakers for informing standards of care and for supporting the decision-making process.

to the hyponatremic hyponatraemia, the guideline covers diagnosis and management of both acute and chronic hyponatremic hyponatraemia in case of reduced, normal and increased extracellular fluid volume. It does not cover the diagnosis or treatment of the underlying conditions that can be associated with hyponatremic hyponatraemia.

How does it happen?

CUA GUIDELINE

Prostate cancer screening: Canadian guidelines 2011

“However, the European Randomized Study of Screening for Prostate Cancer (ERSPC) showed that a DRE did not provide any additive information beyond PSA. **(Level 1 Evidence.)**” p236

Final Recommendation

“Initial screening should include DRE and PSA.” p239

How consistent are guidelines?

- There is disagreement between Task Forces¹
- Guidelines don't seem to agree
- Example, in COPD, even the Diagnosis Debated.

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

	<i>FEV₁ Predicted of Normal Value (%)</i>			
Classification of disease severity	ATS ³	BTS ⁷	ERS ⁹	GOLD ¹⁰
Stage I (mild)	≥ 50	60–79	≥ 70	≥ 80
Stage II (moderate)	35–49	40–59	50–69	30–80
Stage III (severe)	< 35	< 40	< 50	< 30

*In all patients with a reduced FEV₁/FVC ratio, usually less than 70%, which is the mark of obstructive ventilatory impairment.

FEV₁ = 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. 1995 - 2001

Why do “Evidence based” Guidelines Vary

- What is Evidence?
- Remember: expert opinion is still considered evidence.



Hierarchy of Evidence



“Evidence based” Guidelines

Level of Evidence	Cardiology ¹	Infectious Disease ²
Level 1		
Level 2		
Level 3		

1. JAMA. 2009;301(8):831-841. Arch Intern Med. 2011;171(1):18-22

“Evidence based” Guidelines

Level of Evidence	Cardiology ¹	Infectious Disease ²
Level 1	11%	14%
Level 2		
Level 3		

1. JAMA. 2009;301(8):831-841. Arch Intern Med. 2011;171(1):18-22

“Evidence based” Guidelines

Level of Evidence	Cardiology ¹	Infectious Disease ²
Level 1	11%	14%
Level 2	41%	31%
Level 3	48%	55%

Additionally: ~20% of recommendations are out-of-date at 3-6 yrs.

This is ~3x more common in lower levels of evidence.

1. JAMA. 2009;301(8):831-841.
- 2 Arch Intern Med. 2011;171(1):18-22
3. Garcia LM. CMAJ 2014. DOI:10.1503 /cmaj.140547. JAMA 2014;311:2092-100.

Depending on Experts



Who is writing 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
 - $> \frac{3}{4}$ of the doctors & $> \frac{1}{2}$ of everyone!

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; ” (Oxman & Guyatt, 1993)



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

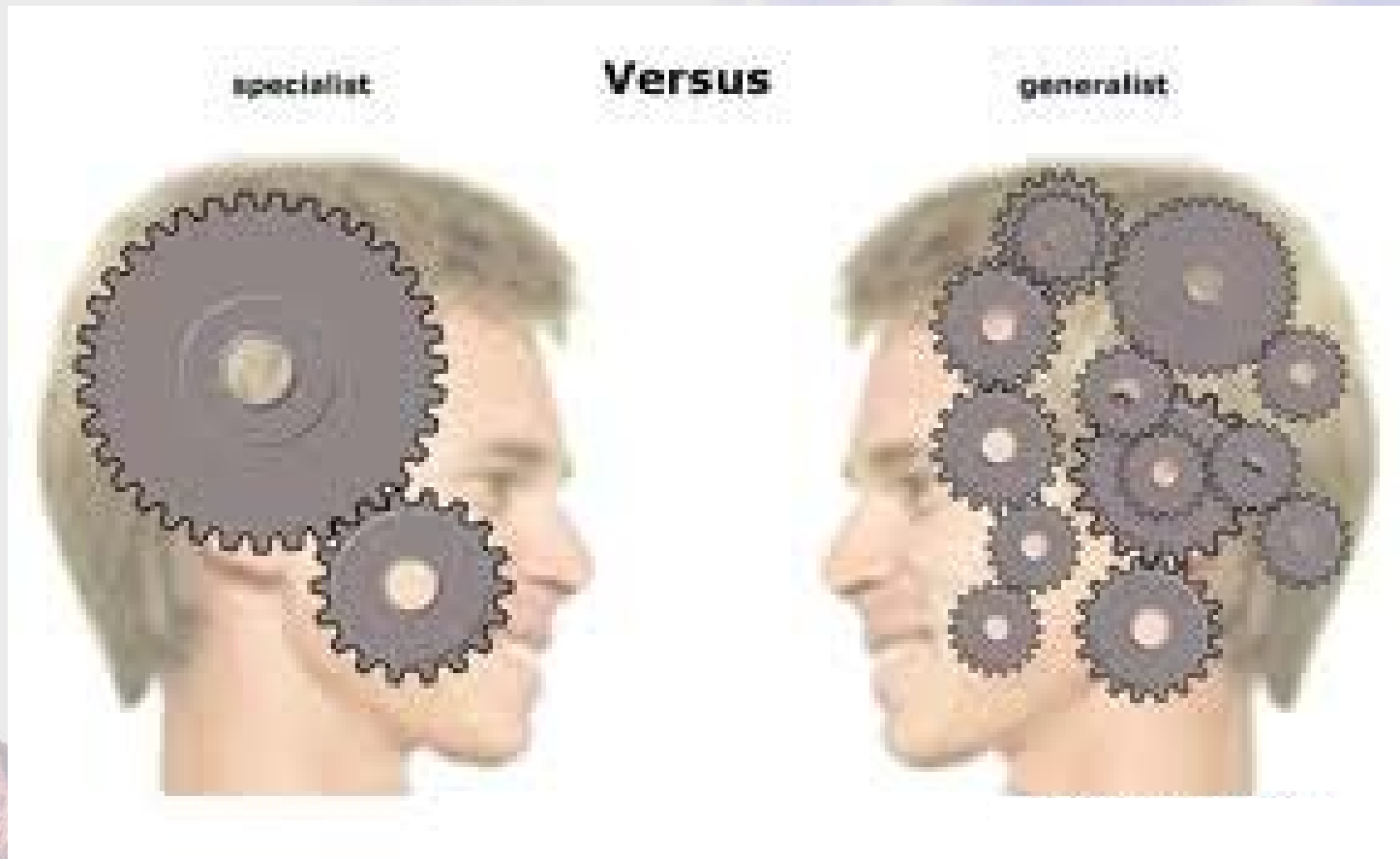
- Conflict of Interest: 14 CPG, 288 “authors”
- Of those that could report COI (211);
 - 65% reported COI
 - 35% reported no COI
 - 11% of them had a COI (reported within last 2 yrs)
- Canada: 69% of CPG don't include COI
 - COI: specialist 49%, FD 28%, Pharmacists 30%

Guidelines are too important to be left to clinical experts

- The main authors of Primary Care Guidelines are specialists
- And they generally do a poorer job reviewing evidence without bias?



Specialist vs Generalist



Applying Tertiary Research to a General Population

- Significant difference between primary care (most patients seen) & specialty care (most research)¹
- Tertiary care research often exaggerates benefit

1) Treatment of Depression²

- Tertiary care = 53% response or better
- Primary care = 39% response

2) Weight loss with Orlistat 1yr (120mg TID)³

- Tertiary care = 22% lost 5% weight
- Primary care = 13% lost 5% weight

1) Evid. Based Med 2008;13;132-3. 2) CMAJ 2008;178:296-305. Am J Psychiatry 2009; 166:599–607 3) JAMA 1999;281:235-42. J Int Med 2000;248:245-54

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.

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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.”

Target Shooting



How are “we” doing?

- Primary Care Clinicians are not hitting the guideline targets.
- DM in the US,
 - 93% DM pts did not hit all targets.
- CAD patients
 - 84% not at targets
- Cholesterol Targets in Canada,
 - 76% not at LDL targets

Do the RCT's hit Targets?

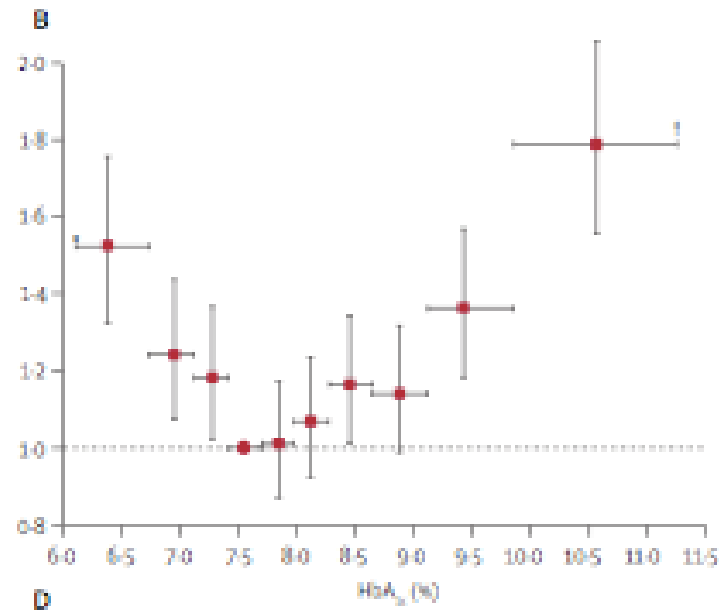
- Small RCT to hit targets in BP, Chol & sugar¹
 - 80 patients: only 1 hit all targets
- From 3 target based RCTs of Diabetics³
 - 77% did not hit targets for 4 outcomes.
- Review: CVD pts, highest dose of statins²
 - <50% actual get an LDL < 2 mmol/L.
- Outcomes improved in both, despite not hitting targets

1) N Engl J Med 2003;348:383-93. N Engl J Med 2008;358:580-91. 2) CMAJ 2008;178(5):576-84. 3) Can Fam Physician. 2014 Jun;60(6):541.

You can't be too rich or too low: Targets

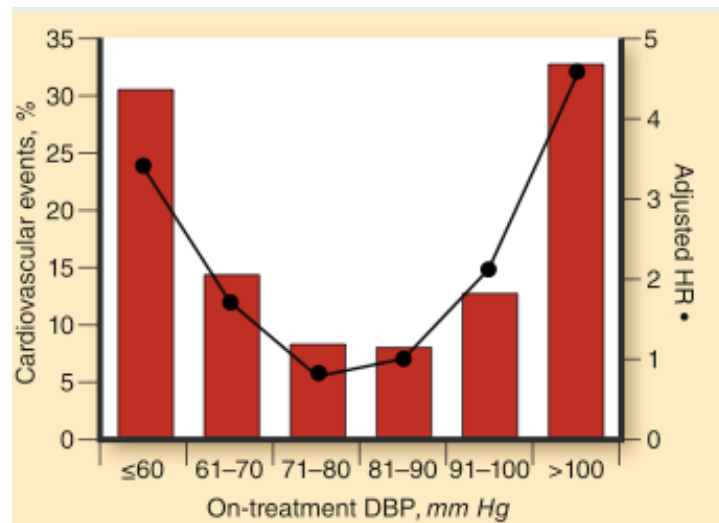
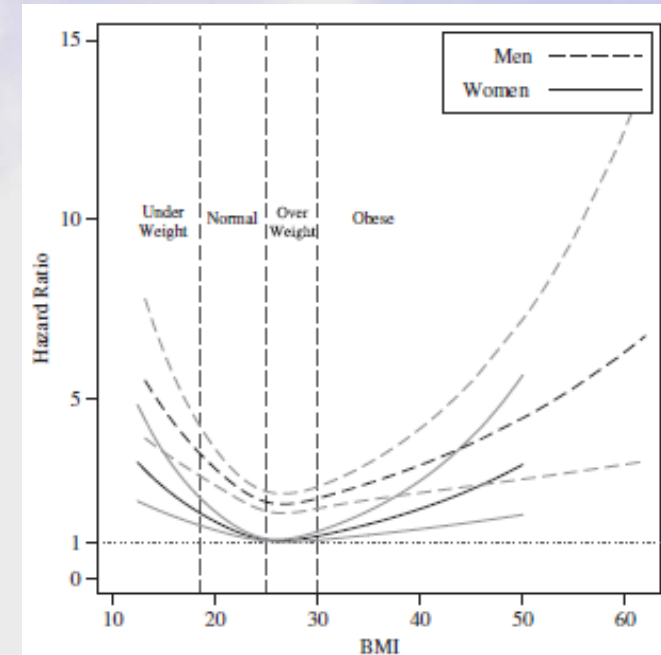
- Blood Glucose:
 - 2004: $A1c \leq 7\%$ (& $\leq 6\%$ “in whom it can be safely achieved”)
 - Now: $A1c \leq 7\%$ (& 7.1-8.5% for many)
- Lipids: LDL:
 - Old: $LDL \leq 2\text{mmol/L}$ in high risk or $\leq 3.5\text{mmol/L}$ in moderate.
 - New: No LDL target level.
- Blood pressure:
 - Old: 140/90 & 130 if Diabetic or renal disease
 - New: age ≥ 60 150/90, all others 140/90
- Rate Control:
 - Old: <80 Heart Rate, New <110 (<100)

You can't be too rich or too low: How many J-curves are enough?



A1C¹

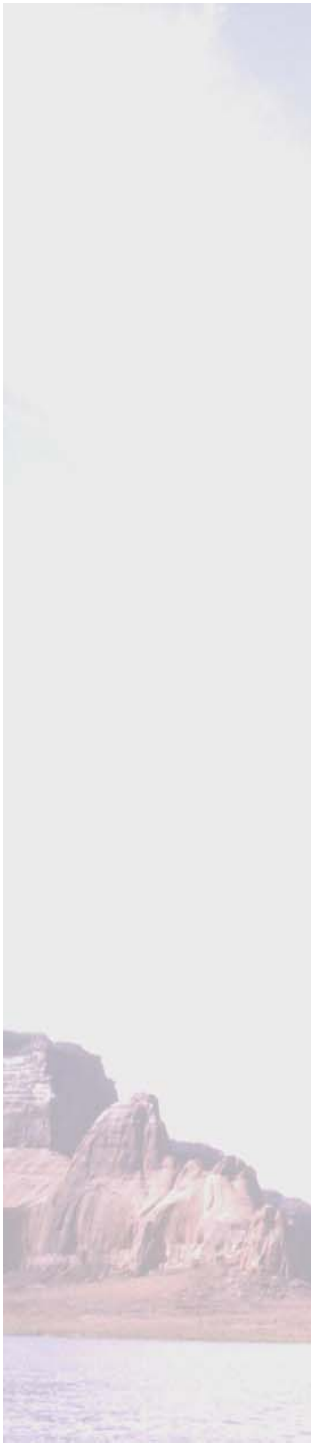
BMI³ over 65



Diastolic BP²

- 1) Lancet 2010; 375: 481–89
- 2) Curr Hypertens Rep (2010) 12:290–295
- 3) J Am Geriatr Soc 2010; 58:234–241.





Is there time for Chronic Disease

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

Disease	Total Cases	No. (%) of Cases		Number of Visits		Minutes per Visit	Hours Per Year
		Uncontrolled	Controlled	Uncontrolled	Controlled		
Hyperlipidemia	511	417 (81.6)	94 (18.4)	8	2	10	587
Hypertension	472	312 (66)	160 (34)	12	2	10	704
Depression	118	58 (49)	60 (51)	12	4	10	156
Asthma	183	62 (33.6)	121 (66.3)	4	2	10	82
Diabetes	145	91 (63)	54 (37)	4	2	10	79
Total hours per year							1,581
Total hours per work day							6.7

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

1) Ann Fam Med 2005;3:209-214. 2) Am J Public Health. 2003;93(4):635-41.

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

Time	Medications†	Other
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.³⁰ (2) ADA¹⁹⁻³²; glycemic control is recommended; however, specific medicines are not described. (3) American College of Rheumatology³³⁻³⁶; recent evidence about the safety and appropriateness of cyclooxygenase inhibitors, particularly in individuals with comorbid cardiovascular disease, led us to omit them from

Treatment for a Hypothetical 79-Year-Old Woman With Hypertension, Diabetes Mellitus, Osteoporosis, Osteoarthritis, and COPD

JAMA 2005;294:716-724.

Some things just don't make sense?



Quality of Life Comparison

Outcome	QOL Utilities
Mild Stroke	0.70
Angina	0.64
Diabetic Neuropathy	0.66

Comprehensive Diabetic Care	0.64
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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 \approx 0.1% content

Side Effects: What Patients think when we say it's Uncommon?

Description	EU Assigned Meaning
Very Common	>10%
Common	1-10%
Uncommon	0.1-1%
Rare	0.01 – 0.1%
Very Rare	<0.01%

Side Effects: What Patients think when we say it's Uncommon?

Description	EU Assigned Meaning	Patients Perceived Chance
Very Common	>10%	65%
Common	1-10%	45%
Uncommon	0.1-1%	18%
Rare	0.01 – 0.1%	8%
Very Rare	<0.01%	2%

- Patients over estimated risk by 5 to 200 times.

Administrators: Here to Help



Performance Measures Myths

- “Unintended” consequences are unpredictable
- False: Many (eg patient de-enrolment) predictable¹
- Exceptions will be over-used:
- False: 94% of exceptions are appropriate²
- More incentive = better performance
- False: Those with <10% pay from incentive³

1) *Ann Fam Med* 2009;7:121-127. 2) *Ann Intern Med.* 2010 Feb 16;152(4):225-31. 3) *J Gen Intern Med*

Misplaced priorities

AOM: TFP #42 (Mar 10, 2015 updated). Headache Treat (#95) or prevent TFP #51 & # 52. OA Knee: TFP #125 (March 30, 2015). Antidepressants: Cochrane. 2009;(3):CD007954. TFP #13. Constipation: TFP #45 (updated March 10, 2015). Statin: BMJ 2009;338:b2376. ACP J Club 2009; 151(4): 14 Br J Clin Pharm 2004; 57:640-51. Lancet 2004; 364: 685-96. Metformin: Lancet 1998; **352**: 854-65 ASA: JAMA. 2006;295:306-313. Mammo: Ann Intern Med. 2009;151:727-737. Cochrane. 2011;1:CD001877. FIT: Cochrane 1998 *CD001216*; Hewitson, Cochrane 2007: CD001216. PSA: N Eng J Med 2009;360(13):1320-8. Eur Urol. 2013;64(4):530-9. Lancet Oncol. 2010;11:725-32.

Misplaced priorities

				Cancer Screening
				Mammogram NNS 377- 2000 x 10 yrs
				FIT (FOB) NNS 1200 x 10 yrs
				PSA: NNS 441- 1410 x 10 yrs

AOM: TFP #42 (Mar 10, 2015 updated). Headache Treat (#95) or prevent TFP #51 & # 52. OA Knee: TFP #125 (March 30, 2015). Antidepressants: Cochrane. 2009;(3):CD007954. TFP #13. Constipation: TFP #45 (updated March 10, 2015). Statin: BMJ 2009;338:b2376. ACP J Club 2009; 151(4): 14 Br J Clin Pharm 2004; 57:640-51. Lancet 2004; 364: 685-96. Metformin: Lancet 1998; **352**: 854-65 ASA: JAMA. 2006;295:306-313. Mammo: Ann Intern Med. 2009;151:727-737. Cochrane. 2011;1:CD001877. FIT: Cochrane 1998 *CD001216*; Hewitson, Cochrane 2007: CD001216. PSA: N Eng J Med 2009;360(13):1320-8. Eur Urol. 2013;64(4):530-9. Lancet Oncol. 2010;11:725-32.

Misplaced priorities

			CVD (primary prevention)	Cancer Screening
			Statin: NNT 77-55 over 5 years	Mammogram NNS 377- 2000 x 10 yrs
			Metformin in DM: NNT 29 over 5 years (MI only)	FIT (FOB) NNS 1200 x 10 yrs
			ASA: NNT 346-427 over 5 years.	PSA: NNS 441-1410 x 10 yrs

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Misplaced priorities

		Long-term/Prevent Symptoms	CVD (primary prevention)	Cancer Screening
		Antidepressants: Depression NNT 7-9 in 6 wks response	Statin: NNT 77-55 over 5 years	Mammogram NNS 377- 2000 x 10 yrs
		Constipation (chronic): PEG, NNT 2-3 for 6 months.	Metformin in DM: NNT 29 over 5 years (MI only)	FIT (FOB) NNS 1200 x 10 yrs
		Headache: TCA or Beta-blocker, NNT 4-8 x6 months reduce 50%	ASA: NNT 346-427 over 5 years.	PSA: NNS 441-1410 x 10 yrs

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Misplaced priorities

	Treating Symptoms	Long-term/Prevent Symptoms	CVD (primary prevention)	Cancer Screening
	AOM: Amoxil NNT 3-10 in 4-10 days Sx free	Antidepressants: Depression NNT 7-9 in 6 wks response	Statin: NNT 77-55 over 5 years	Mammogram NNS 377- 2000 x 10 yrs
	Headache: ASA - sumatriptan, NNT 5-9 pain free 2 hrs	Constipation (chronic): PEG, NNT 2-3 for 6 months.	Metformin in DM: NNT 29 over 5 years (MI only)	FIT (FOB) NNS 1200 x 10 yrs
	OA Knee: steroid shot, NNT 3-5 global improve x1 wks	Headache: TCA or Beta-blocker, NNT 4-8 x6 months reduce 50%	ASA: NNT 346-427 over 5 years.	PSA: NNS 441-1410 x 10 yrs

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	OA Knee: steroid shot, NNT 3-5 global improve x1 wks	Headache: TCA or Beta-blocker, NNT 4-8 x6 months reduce 50%	ASA: NNT 346-427 over 5 years.	PSA: NNS 441-1410 x 10 yrs
Patient Years	~1 benefit for every month	1 benefits for every 1-4 years	1 benefits every ~150-2000 yrs	1 benefits every ~10,000 years

AOM: TFP #42 (Mar 10, 2015 updated). Headache Treat (#95) or prevent TFP #51 & # 52. OA Knee: TFP #125 (March 30, 2015). Antidepressants: Cochrane. 2009;(3):CD007954. TFP #13. Constipation: TFP #45 (updated March 10, 2015). Statin: BMJ 2009;338:b2376. ACP J Club 2009; 151(4): 14 Br J Clin Pharm 2004; 57:640-51. Lancet 2004; 364: 685-96. Metformin: Lancet 1998; **352**: 854-65 ASA: JAMA. 2006;295:306-313. Mammo: Ann Intern Med. 2009;151:727-737. Cochrane. 2011;1:CD001877. FIT: Cochrane 1998 *CD001216*; Hewitson, Cochrane 2007: CD001216. PSA: N Eng J Med 2009;360(13):1320-8. Eur Urol. 2013;64(4):530-9. Lancet Oncol. 2010;11:725-32.

Sometimes, The answers are hard

SOUTH HAVEN

City unsure why the sewer smells

By KRISTIN HAY
H-P Correspondent

SOUTH HAVEN — The tests have been inconclusive in trying to locate the source of a mysterious odor that has been detected in several downtown South Haven businesses.

Bob Stickland, the director of the city's Board of Public Works, told the City Council in a work-

Stickland said he will discuss the strategy of putting a non-toxic smoke into the sewer to detect the path of the offensive gas emanating from basement drains.

"Somebody is putting something into the sewer that is creating the odor," Stickland said in an interview after the council meeting. "We are trying to find out what it is."

Heavy industries pre-treat waste

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

Be suspicious,...

vehicle description, the Scottlaw motorist was not found.

10:10 p.m.: Suspicious people were reportedly doing something with flashlights by the side of North 5th Street in Custer. A deputy checked and found the people were not suspicious, but merely Canadian. The out-of-towners were enjoying an evening stroll.

Questions?

