## How to Present Medical Evidence to Patients

James McCormack BSc (Pharm), PharmD Professor

Faculty of Pharmaceutical Sciences
University of British Columbia
Vancouver, BC, Canada

## MY BELIEF



All Health Care Providers should have their practice underpinned by the best available evidence

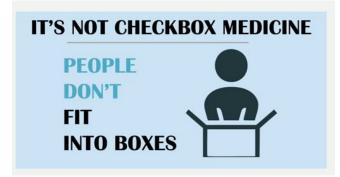
Evidence-Based Practice (EBP)



#### IT'S NOT ABOUT GUIDELINES

140/90 < 6.5% < 2.0

GUIDELINES RARELY CONSIDER PATIENT PREFERENCES



#### IT'S NOT SOMETHING "NEW"



DOING THE RIGHT THING IS NOT A NEW IDEA

#### IT'S NOT ABOUT SAVING MONEY



RATIONING
IS NOT THE
MOTIVE

#### IT'S NOT ABOUT RCTs



RCTs ARE USEFUL BUT THEY ONLY HELP

**INFORM DECISIONS** 

 $p<0.05 \neq GOOD p>0.05 \neq BAD$ 

# TO S NOT NECESSARILY ABOUT INFLUENCING OUTCOMES Heart attacks, strokes, renal failure, symptoms Quality of life, people on evidence-based treatments YEAR 1 YEAR 2 YEAR 3 YEAR 4

#### IT'S NOT ABOUT IGNORING BASIC SCIENCE





WE NEED TO UNDERSTAND HOW IT WORKS

#### IT'S NOT ABOUT ZERO COMPETING INTERESTS

RESEARCH COSTS MONEY SOMEBODY HAS TO

**PAY FOR IT** 



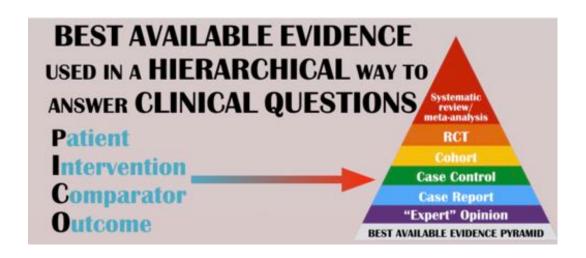
### WHAT IT IS



IT'S A WAY OF THINKING



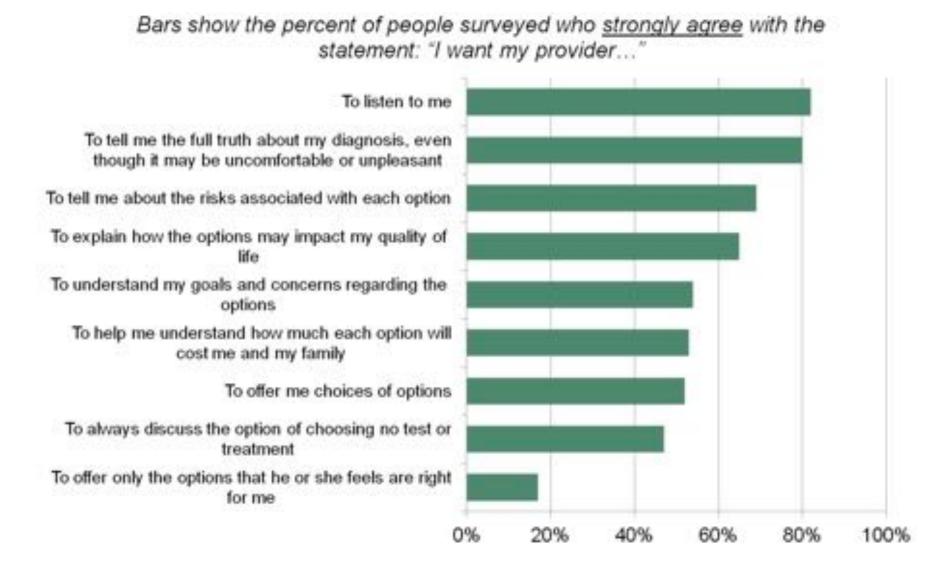
#### **EVIDENCE-BASED PRACTICE**







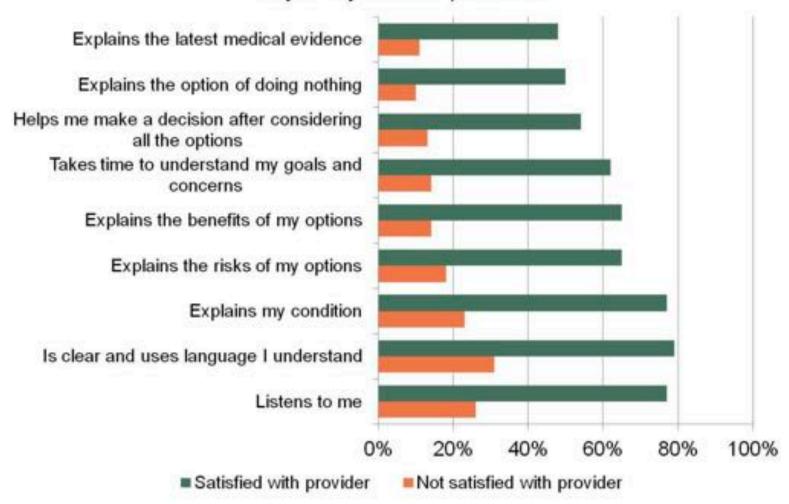
#### People want involvement in evidence and decisions



Communicating with patients on health care evidence. Discussion Paper, Institute of Medicine, Washington, DC 2012

#### Satisfaction is linked to shared decisions

People who are satisfied with their health care provider are more likely to say that their provider...



Communicating with patients on health care evidence. Discussion Paper, Institute of Medicine, Washington, DC 2012

"Most patients cannot recall a time when their care provider discussed scientific evidence as the basis for better care"

Communicating with patients on health care evidence. Discussion Paper, Institute of Medicine, Washington, DC 2012

## Many courts (UK, US, CA)

"The reasonable-patient standard ... requires physicians and other health care practitioners to disclose all relevant information about the risks, benefits, and alternatives of a proposed treatment that an **OBJECTIVE PATIENT** would find material in making an intelligent decision as to whether to agree to the proposed procedure"



# PATIENT REVOLUTION

Clinicians and patients working in partnership

KNOWING THE MAGNITUDE OF THE BENEFIT OF TREATMENT

KNOWING the POTENTIAL HARMS - SIDE EFFECTS, COST AND INCONVENIENCE

REALIZING HEALTH DECISIONS ARE YOUR DECISIONS

#### Why Most Clinical Research Is Not Useful

John P. A. Ioannidis 1,2\*

"The problem of non-useful research should not be seen as a blame game against a specific group (e.g., clinical researchers) but instead should be seen as an opportunity to improve."

"Much current public funding could move from preclinical research to useful clinical research" - pre-clinical funded by industry, blue-sky research by the public

"Instead of trying to make a prolific researcher of every physician, training physicians in understanding research methods and evidence-based medicine may also help improve the situation by instilling healthy skepticism and critical thinking skills."

#### Why Most Clinical Research Is Not Useful

John P. A. Ioannidis 1,2\*

"Overall, not only are most research findings false, but, furthermore, most of the true findings are not useful."

### Evidence Issues

Much of research is not going to be "right"

One study likely proves nothing - need reproducibility

"The evidence for nonreproducibility in basic and preclinical biomedical research is compelling" John Toannidis

Cohort trials don't prove causation

Research does go unpublished - but large studies do get reported



"Science can be used to inform clinical decisions, but cannot definitively inform value judgements, because the significance of potential benefits and harms of a therapy are in the eye of the beholder and will differ across individuals."

## Some clinical adages?

Ask - how do you feel about being involved in making decisions about your treatment?

It's OK if we say I don't know, let's look into it, it's your decision.

You and your patient's perception are not necessarily "right" and likely not the same

## Patients' Expectations of the Benefits and Harms of Treatments, Screening, and Tests A Systematic Review

Tammy C. Hoffmann, PhD; Chris Del Mar, MD, FRACGP

BENEFIT - 88% of study authors concluded that participants **overestimated benefits** 

HARM - 67% underestimated harm

## It's all about figuring out

The Chance

WITH NO

TREATMENT

VS

The Chance

WITH

TREATMENT

#### **Ballpark risk estimate**

Epidemiological data/cohort data - Framingham, QRISK, FRAX, CHA2DS2-VASc

#### **Ballpark benefit estimate**

RCT data

use the absolute benefit if people are similar to those in the studies or,

use the relative benefit and apply it to the baseline risk

## Key steps to communicating evidence

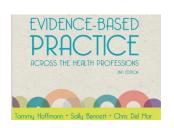
Understand the patient's (and family members') experiences and expectations.

Build partnerships.

Discuss the evidence, including a balanced discussion about uncertainties.

Present recommendations.

Check for understanding and agreement.



### Risky Relative Adjectives

HOW

low is low

moderate is moderate

high is high



## Evidence-based risk communication

"There is likely no single best method of communicating probabilities to patients but rather several good options with some better suited to certain risk scenarios."

### Recommended approaches

Need a time frame, main endpoints, ask what they know

GENERAL SUGGESTIONS - these are "relative" use percentages (5%) or natural frequencies (5 out of 100) - BOTH? use absolute terms add bar graphs or icon arrays use incremental risk format with icon arrays in the same array

#### avoid use of NNTs

if use relative risks add baseline risks

## Approaches differ depending on outcome

Every patient is an experiment - dose and effect

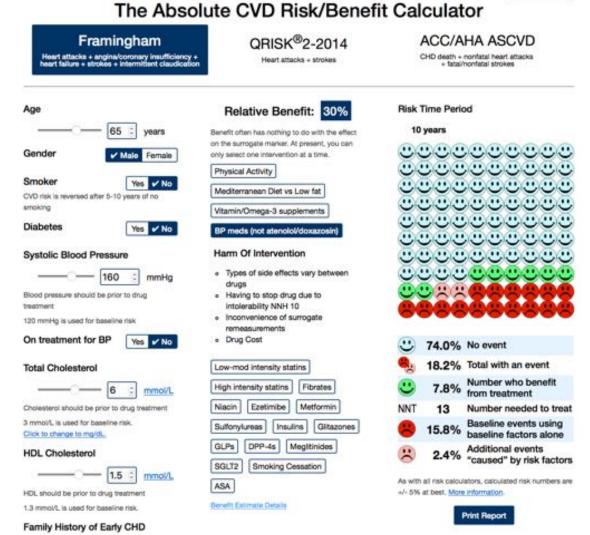
Prevention - one will never know if it worked

Symptoms - we can usually figure out if it is working - but it is tricky

Diagnosis - pre- and post-test probabilities

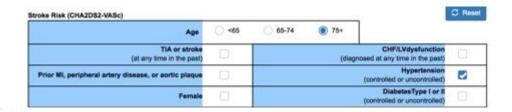
Expectations

## Prevention



Calculate ballpark 10-yr risk of CVD - BP, chol, diabetes
Make estimate of benefit based on the best available evidence Gives a list of adverse effects to discuss

cvdcalculator.com



http://www.sparctool.com

	PERCENT PER YEAR					
	annusi risk of stroke/embolism	annual risk of major bleeding (intracranial bleeding, bleeding requiring hospitalization, HgB decrease of > 20 g/L, or need for transfusion secondary to bleeding)				
NO THERAPY	4.3%	0.6%				
ASPIRIN	3.4%	1.1%				
WARFARIN	1.4%	2.2%				
DABIGATRAN 110	1.4%	1.8%				
DABIGATRAN 150	0.9%	2.2%				
RIVAROXABAN	1.4%	2.2%				
APIXABAN	1.1%	1.5%				

Calculate ballpark annual risk of stroke - based on risk factors- BP, chol, diabetes
Make estimate of benefit based on the best available evidence - all agents
Make estimate of a GI bleed



#### 10 year fracture risk %

Major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture)/Hip

RISK FACTORS		Z	ero			C	)ne			Т	wo	
BMI	35	30	25	20	35	30	25	20	35	30	25	20
Female											- 70	
50	2	3	3	3	4	4	5	5	6	6	7	8/1
60	5	6	6	7/2	7	9	10/1	10/4	11/1	13/2	14/2	16/6
70	8/1	9/2	10/2	11/4	11/2	13/3	15/4	17/7	16/4	18/6	21/7	25/12
80	14/4	16/5	19/7	21/11	20/8	23/10	27/13	31/20	28/14	33/18	38/22	43/32
Male	-	CONTRACTOR OF STREET	100000	n retirement or the	and experiences		and the resolution	and the second second	and the state of the state of	The state of the s		Control Sections
50	2	2	2	2	3	3	4	4	4	5	6	6
60	3	4	4	4	5	6	6	7/1	7	8	10/1	10/2
70	4	5/1	6/1	6/2	6	7	8/2	9/4	8	10	12/4	13/6
80	6/2	7/3	9/4	9/5	9/4	11/5	13/7	14/10	13/7	16/9	19/12	21/16

Risk factors - Previous fracture "atraumatic", Parent hip fracture, Smoker, Rheumatoid arthritis, Glucocorticoids - now or more than 3 months, >3 drinks a day

https://therapeuticseducation.org/tools



## Misguided beliefs

Patients believe CVD "prevention" drugs produce a 70% absolute benefit over 5 years when at most only ~ 20-30% benefit is possible over a lifetime





Clin Med 2002;2:527-33



## Risk of future illness CVD risk/benefit



(most people don't benefit despite a lifetime of treatment)









Assume a person's lifetime risk of CVD is that of a male with two CVD risk factors - roughly 50% (NEJM 2012;366:321-9)

Assume that with multiple risk factor modification we can reduce that risk relatively by 60% (VERY optimistic)

Risk goes from 50% → 20%





70% DO NOT despite a LIFETIME of treatment

## Symptoms

## You primarily need to know IF it works

Safety, cost and convenience

Older medications first - safety

Head-to-head studies are uncommon

Doses in the CPS are "wrong"

N-of-1 studies

Let the patient tell you

## Symptom NNTs

PPIS, sildenafil - NNT ~2

NSAIDs, opioids - pain NNT ~3-5

Steroids - sore throat - NNT ~ 3, Bell's palsy - NNT ~10

Antibiotics - acute COPD exacerbation - NNT ~ 5

Topical antibiotics - bacterial conjunctivitis - NNT ~7

Antidepressants - severe depression - NNT ~10

Ipratropium - asthma attack - NNT ~11

Cholinesterase inhibitors - ADAS-Cog >4 - NNT ~10

Sleeping pills - improvement in sleep quality - NNT ~13

## But you need to know what goes on in the placebo group

	If person "responds", what is the % chance it was the medication			
Response in the placebo group	If Benefit 10% - NNT 10	If Benefit 20% - NNT 5		
0%	~100%	~100%		
20%	~33%	~50%		
40%	~20%	~33%		

## Diagnosis

## Likelihood Ratios

LRs are basically a ratio of the probability that a test result is correct to the probability that the test result is incorrect.

Pre-test probability (%)

- → apply a LR
- → post-test probability (%)



#### Rapid Antigen Group A Streptococcus Test to Diagnose Pharyngitis: A Systematic Review and Meta-Analysis

$$LR + = 10.8$$

$$LR - = 0.15$$

General practice clinic in Canada - people with a sore throat who have Strep ~10%

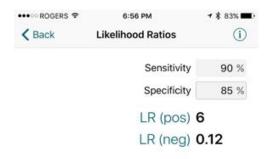
Prevalence	If positive Post test probability	If negative
1%	~10%	~0.2%
10%	~60%	~2%
40%	~90%	~10%

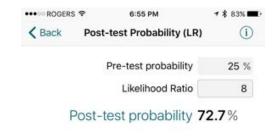
Table 4. Likelihood ratios and the impaction post test probabilities (modified by McGee 2002)8

Likelihood ratios		Approximate changes in pret-test probabilities		
Values between 0 and 1 decrease the probability of disease				
0.1	Strong evidence	Large	-45%	
0.2		Moderate	-30%	
0.3			-25%	
0.4			-20%	
0.5	Weak evidence	Slight	-15%	
Likelihood ratio = 1		None	0%	
Values greater than 1	increase the probability of disease			
2	Weak evidence	Slight	+15%	
3			+20%	
4			+25%	
5		Moderate	+30%	
6			+35%	
8			+40%	
10	Strong evidence	Large	+45%	

MedCalX - calculate likelihood ratios from sensitivity and specificity AND post-test probability calculator





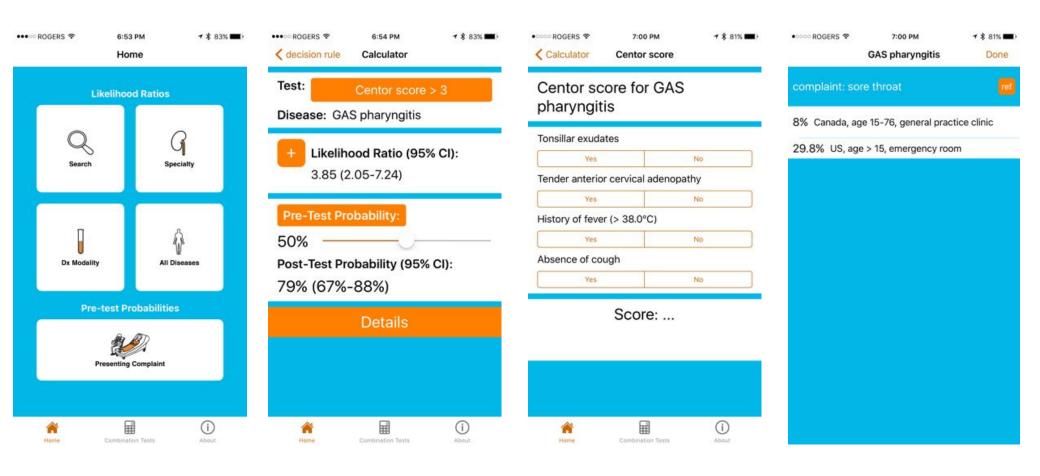


	9	8	7
	9		/
%	6	5	4
%	3	2	1
,	❷	*	0

8	9
5	6
2	3
	Ø
	5 2

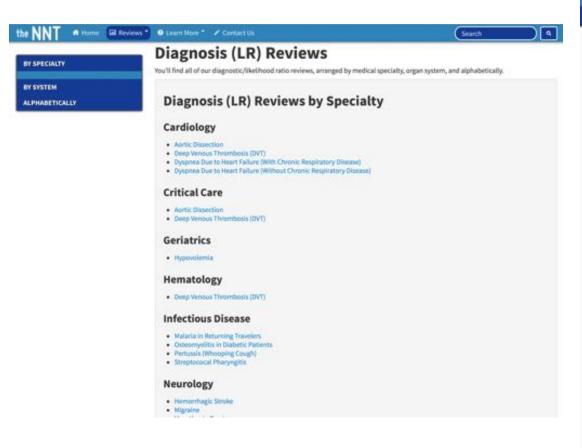
DxLogic - listing of LR and pre-test probabilities and a post-test calculator

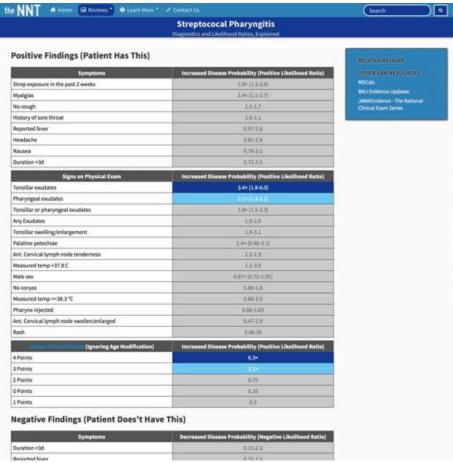




<u>Irdatabase.com</u> - home of DxLogic

http://www.thennt.com/home-lr/





http://getthediagnosis.org/

		Add An Entry Feedback	the age of 55 years and have no vomiting, family history of GI of	rly satiety, unexplained weight loss, progressive dysphagia, odynophagia, recurrent		
		Sensitivity and Specificity Calculator Sign Up	Helicobactor pylori: Sensitivity and Specificity  Introduction: From UpToDate (http://www.utdol.com/online/content/topic.do/?topicKey=acidpep/4732):  The AGG guidelines made the following conclusions:  Testing for H. pylori should be performed only if the clinician plans to offer treatment for positive results.  Testing is indicated in patients with active peptic ulcer disease, a past history of documented peptic ulcer or gastric MALT lymphoma.  The test-and-treat strategy for H. pylori (ie, test and treat if positive) is a proven management strategy for patients with uninvestigated dyspepsia who are			
Search:  Browse By Diagnosis Finding Category Random Entry Newest Entry	Go ntries	Explanation of ROC Curves				
Sanah.		About Us Explanation of Sensitivity and Specificity				

Rapid urease test

Sensitive Findings

Stool antigen test

The diagnosis disabase was created by Gari Kohlberg and Mark Hummer. Copyright 2008-2014. All Righis Reserved. Disclaimer: This site is for health prefessionals and does not dispense medical arises. The content on his site is provided without surrantee, expressed or implied, and without parameter of accuracy. For questions, estal high Byerkhedagoosis are or click here.

in patients with UGIB

In addition to diagnosis, biopsy culture allows for determination of antibiotic sensitivity

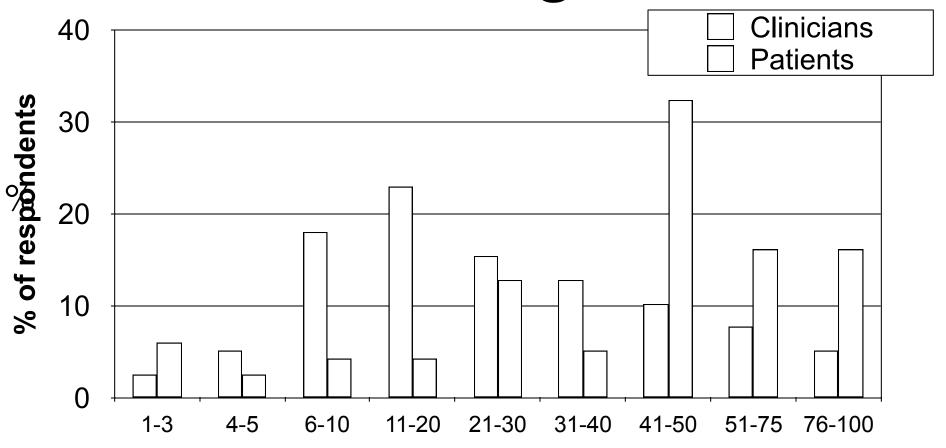
Study: Am J Gastroenterol. 2006 Apr;101(4):848-63. PMID 16494583

Study: Am J Gastroenterol. 2006 Apr;101(4):848-63. PMID 16494583 in patients with UGIB. Study: Am J Gastroenterol. 2006 Apr;101(4):848-63. PMID 16494583

Study: Am J Gastroenterol. 2006 Apr:101(4):848-63. PMID 16494583

Study: Am J Gastroenterol. 2006 Apr;101(4):848-63. PMID 16494583

#### What is "High Risk"



Chance of a heart attack in the next 5 years (%)

#### Beware of "qualitative quantification"

Qualitative descriptor	EU assigned frequency	Mean frequency estimated by participants (n=200)
Very common	>10%	65% (24-2)
Common	1-10%	45% (22.3)
Uncommon	0.1-1%	18% (13.3)
Rare	0.01-0.1%	8% (7.5)
Very rare	<0.01%	4% (6.7)

Values are mean (SD).

Lancet 2002;359:853-54

## Shameless self promotion



28TH ANNUAL

Best Science Medicine Course

Formerly The Drug Therapy Decision Making Course – 25 years

Friday, April 7, 2017 and Saturday, April 8, 2017
The Fairmont Waterfront – 900 Canada Place Way, Vancouver, BC

PREVIOUS YEARS' REGISTRANT TESTIMONIALS:

"This course definitely changed my practice"

"This is the most influential course I have ever attended"

"Nice to hear evidence instead of marketing messages"



April 7/8, 2017 - the Fairmount Waterfront <a href="http://bestsciencemedicine.com">http://bestsciencemedicine.com</a>

#### Schedule

#### FRIDAY, APRIL 7, 2017

07:00 Registration (Muffins & Coffee) Chairs - Mike Allan and James McCormack

#### "Laugh yourself into stitches" (Twelfth Night) THE START

08:00	Bless thee, bully doctor!	Robert Rangno
08:05	Shakespeare brings greetings from afar	Christopher Gaze
08:20	Much ado about nothing – and so much more	Mike Allan and James McCormack

#### "The game is afoot" (King Henry IV - Part 1) CVD

09:00	Urgent BP numbers – "ains well that ends well?"	Julian Marsden
09:20	Lowering BP numbers – is there "too much of a good thing?"	Mike Allan
09:40	Questions	
09:50	Bleeding in patients on antithrombotic therapy – "The short and the long of it"	Peter Loewen
10:10	Questions	
10:20	Refreshment Break	

#### "It was Greek to me" (Julius Caesar) COMMUNICATION

10:40	Speaking with patience – "Knock, knock! Who's there"	Tracy Monk
11:00	Communication of evidence – "what's in a name"	James McCormack
11:20	Questions	
11:30	"The Comedy of Errors" in medicine and how to prevent them	Kam Shojania
11:50	"Make short shrift" of 5 key pediatric studies	Tina Korownyk
12:00	Questions	
12:10	Lunch	

#### "Eaten me out of house and home" (King Henry IV - Part II) POTPOURRI

13:00	"The short and the long of it" – Two award winning resident presentations	Medical Residents
13:20	NSAIDs myths - "All that glitters is not gold"	Adrienne Lindblad
13:40	Preventing infections in hospital – "Out, damned spot! Out"	Victor Leung
14:00	Questions	
14:20	Refreshment Break	