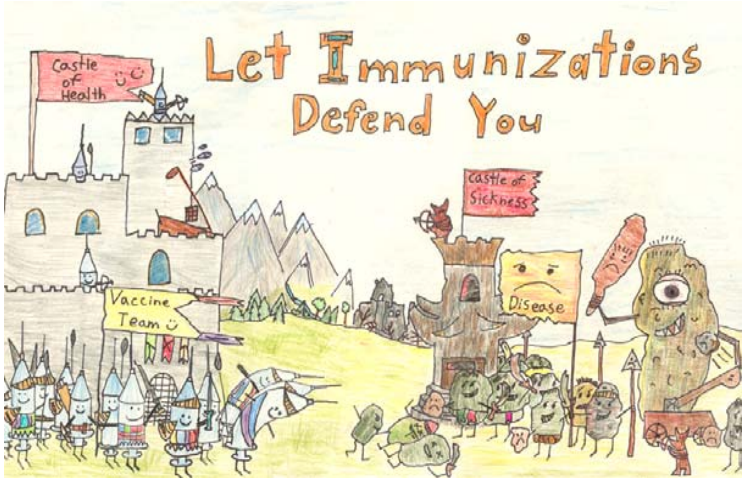


www.phac-aspc.gc.ca/cnic-ccni/2008/images/2008_01_t2.jpg

Risk Perception, Risk Management & Safety Assessment

What can Governments do to Increase Public Confidence in their Vaccine System?

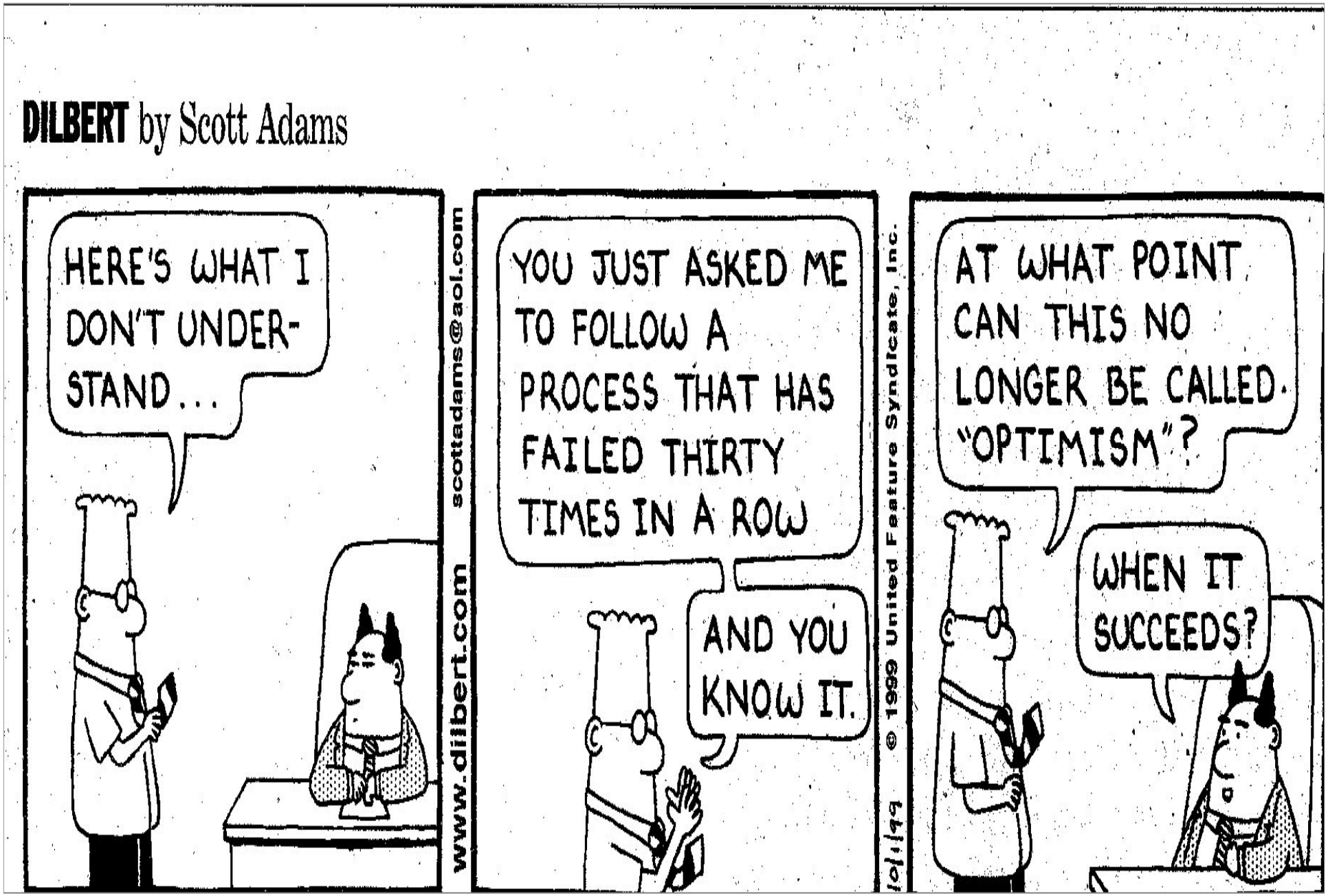
Noni MacDonald MD FRCPc FCAHS
Dalhousie University, Canadian Centre for Vaccinology
Halifax, Canada. Apr 28, 2011

Disclosures

I have no financial disclosures.

Major reimbursement – Dalhousie University

I will not be mentioning off label uses of vaccines.

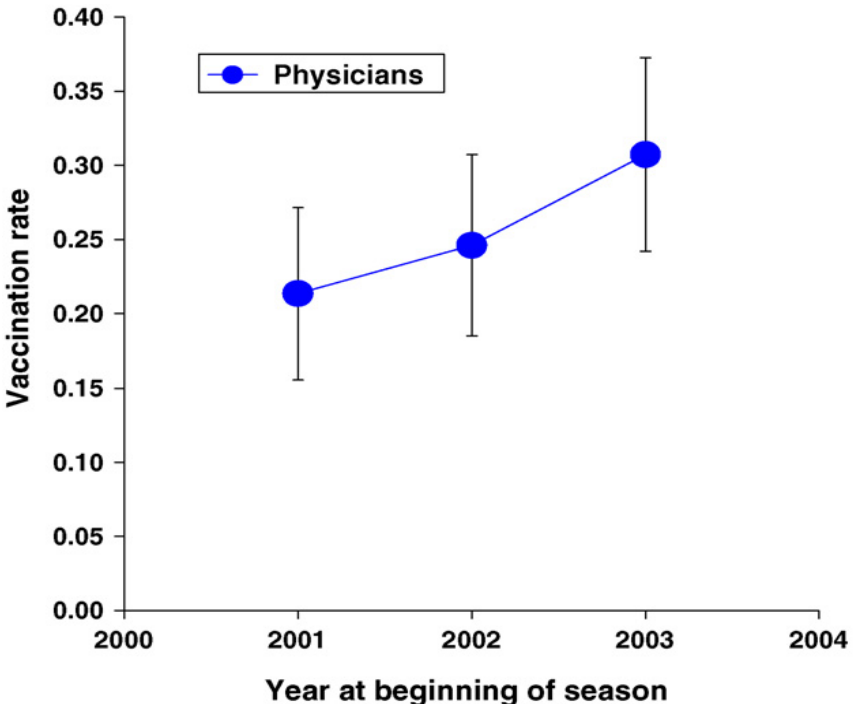

DILBERT by Scott Adams
HERE'S WHAT I DON'T UNDER-STAND...
www.dilbert.com scottadams@aol.com
YOU JUST ASKED ME TO FOLLOW A PROCESS THAT HAS FAILED THIRTY TIMES IN A ROW
AND YOU KNOW IT.
10/1/99 © 1999 United Feature Syndicate, Inc.
AT WHAT POINT CAN THIS NO LONGER BE CALLED "OPTIMISM"?
WHEN IT SUCCEEDS?

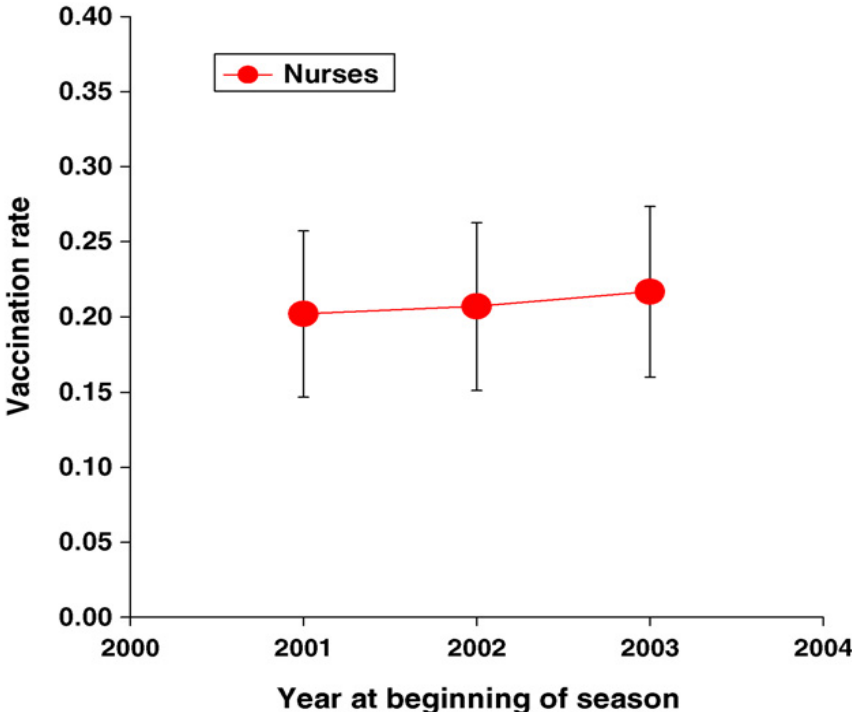
Annual Influenza Vaccination Rates in US Health Care Personnel: 2002-2008

Occupation	2004	2006	2008
HCP	46%	43%	49%
Non HCP White collar	31%	23%	28%

Caban-Martinez AJ et al. Prev Med 2010; 50: 210-212

Influenza vaccination in German health care personnel: after two rounds of a nationwide awareness campaign





Leitmeyer K et al Vaccine 2006;24:7003-8

Public Perspective of **Risk:** ***Personal*** not Sci/Pop^{n} Based

Renoir
The Frick Collection, New York

"What does it mean for me and my family- what should I do about it?"

Hesitation vaccine decisions attributed to:

1) Concerns vaccine safety
2) Perceptions risks vaccine high
3) Perception risk disease low

Even when believe vaccines imp for protection-may still have concerns about vaccine safety

Benin et al Pediatrics 2006;117:1532-41
Freed et al Pediatrics 2010;125:654-659

Knowledge and Attitudes Regarding Influenza Vaccination among Nurses

- Review of studies 2003-2010
- Factors influence ***vaccine status***

1) **knowledge** of influenza & vaccination
2) **believe** influenza =serious illness
   and vaccination = effective, safe
3) nurses' vaccination status and their promotion of vaccination to their patients.

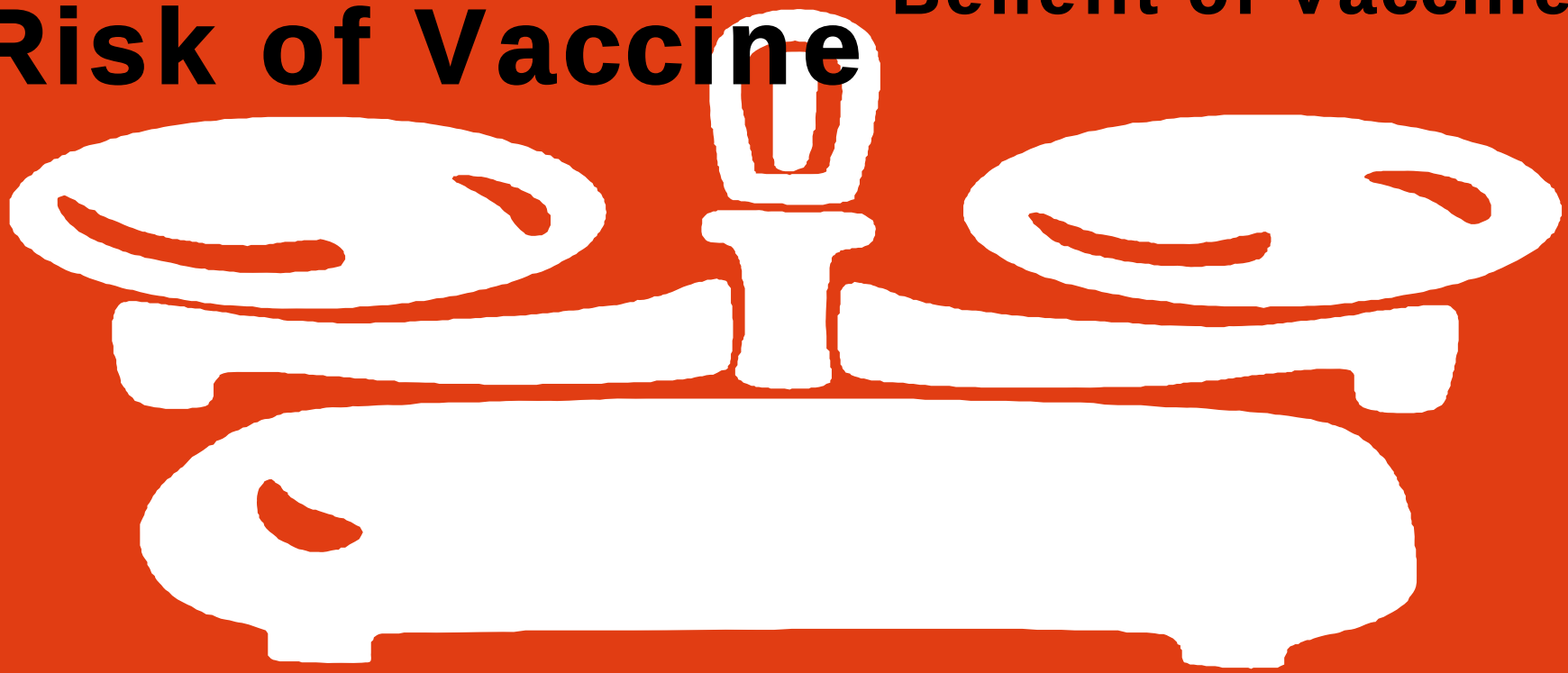
Zhang J., While AE, Norman IJ. Vaccine 2010, 28:7207-14

Perceptions

Risk of Disease

Benefit of Vaccine

Risk of Vaccine



Vaccination Hesitancy

Risk Perception Problem: Impact Cultural Factors

home.globalcrossing.net

"Hard wired" to deal with life threatening situations with reflexive reactions

Heuristics: cognitive shortcuts

-simplify complex decisions & judgments ..."automatic intuition"

Ball et al Pediatrics 1998 *Kimmel SR, Wolfe RM. J Fam Pract 2005*
Gardner, Dan. Risk: The Science and Politics of Fear 2008
Galdi S et al. Science 2008; 321:1100–2.

Heuristics & Risk Assessment 1

Compression

Over *estimate rare*, underestimate frequent

Insensitivity to sample size

Flu vaccine common "bad" side effects

Risk of influenza in un-immunized-"low"

Availability

Judge an event as frequent or likely to occur if can easily *imagine or recall* it

Not recall serious vaccine preventable dis eg measles

Have seen autism

Heuristics & Risk Assessment 2

Anchoring

Estimate by starting from a value know (anchor)

Judge probability future event by what occurred in past

HCP see serious AEFI

- ***estimate AEFI as"more common" than reality***

Overconfidence….. Knowing with Certainty

Place great faith in ***own judgments***

Experts-including HCP biased towards believing in what they do

Tend to be sure ***"bad won't happen to them"***

HCP- won't get flu & won't transmit it

Access to Vaccine Information

- Canada, US, UK – 1 in 2 people who use internet – use it to seek health information
- 2009 >70 % households in US, Can, UK internet access
- **Google**™ provides ***personalized*** search results based on user's ***previous browsing habits***
- Critics concerned-infringe users' privacy (2009)

- **Immunization problem** – if find anti vaccine sites in searches and use them – will appear on first pages next searches...

Influence Vaccine Critical Websites on Perceiving Vaccine Risk

Table 1. Changes in risk perception and intention as a function of search environment and focus of information search

		Search environment					
		Vaccine-critical		*Control*		*Both*	
Search focus	*Changes in ...*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Vaccinating is risky	risk of vaccinating	0.400	(1.476)	–0.444	(1.382)	–0.125	(1.238)
	risk of not vaccinating	–0.467	(1.008)	0.056	(0.791)	–0.094	(1.510)
	mean intention	–0.283	(0.811)	–0.014	(0.207)	–0.156	(0.689)
Not vaccinating is risky	risk of vaccinating	0.529	(1.637)	–0.500	(1.502)	–0.150	(1.001)
	risk of not vaccinating	–0.294	(1.060)	0.104	(0.928)	0.100	(1.057)
	mean intention	–0.059	(0.364)	0.172	(0.511)	–0.069	(0.663)
No specified direction	risk of vaccinating	0.525	(1.754)	–0.143	(1.287)	–0.167	(1.234)
	risk of not vaccinating	–0.325	(0.944)	–0.086	(0.658)	0.300	(1.264)
	mean intention	–0.231	(0.523)	0.107	(0.390)	–0.125	(0.424)

Accessing vaccine critical websites for 5 to 10 minutes

-↑ perception of risk of vaccination

-↓ perception of risk of omitting vaccination and changes intention to vaccinate.

Betsch et al J Health Psychology 2010 15:446-455

Heuristics & Risk Assessment3

Coincidence Dragon

Kirsty B, grade 5, Emma Doubs Integrated Arts and Technology School, Funkstown, MD. www.wcboe.k12.md.us/

- ***After this, therefore because of this***
- HBV vaccine: SIDS, MS
- MMR vaccine: Autism
- Thimerosal containing vaccines: Autism
- DTwP: Encephalopathy

Common Flaws in Reasoning: Anti vaccine websites

Cognitive determinants

- Desire to order and predictability in random data
- Difficulty in detecting and correcting biases in incomplete and unrepresentative data
- Interpret ambiguous and inconsistent data to fit theories and expectations

Motivational/social determinants

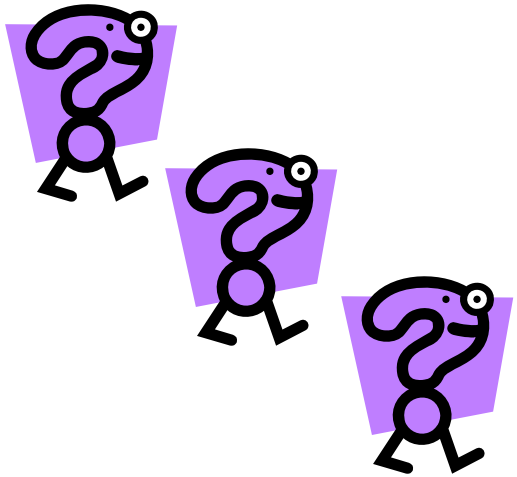
- Wishful thinking and self distortions of reality
- Pitfalls of 2nd hand information and miscommunication
- Exaggerated impressions of social support

**In Jacobson et al Vaccine. 2007;25(16):3146-52*

Vaccine Concerns of Parents, Patients and HCP

Concerns vary

- with vaccine
- with and within populations
- background/experience
- where in cycle disease control

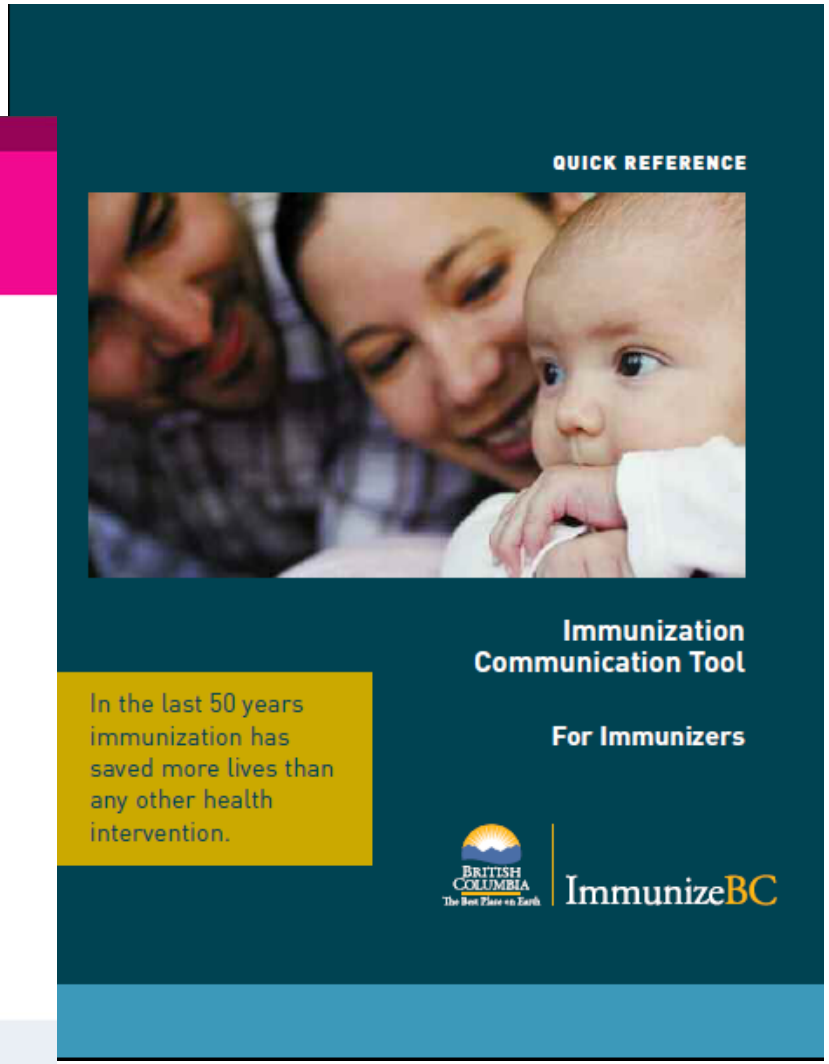


Some questions predictable but many are not…

What can Governments/IMM Programs do to better address concerns and influence beliefs about immunization?

Risk Management:Evidence-1

Targeted / Tailored



seetheperson.co.uk/.../expanded/hpv-website.jpg

http://www.bccdc.ca/NR/rdonlyres/DADA3304-7590-48AC-8D2C-65D54ADFC77E/0/CDC_IC_Tool.pdf

Risk Management: Evidence-2

Disease Data

Polio Tajikistan 2010

topnews.us/.../7-Tajikistan-Children.jpg

rates disease

country, within country

other countries

morbidity & mortality

with care/resources

"mitigation perception"

Timing

perception of risk

anchor and recall

MacDonald NE, Hebert PC. Polio outbreak in Tajikistan is cause for alarm. CMAJ 2010 182(10):1013.

Risk Management: Evidence-3

Vaccine Benefits

rates disease

country:

before and after

other countries

recurrence of dis

when rates lowered

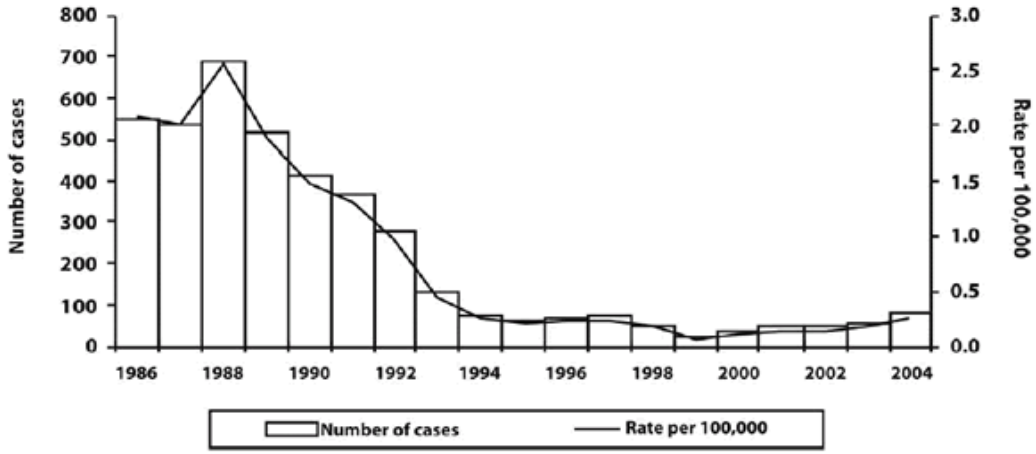
diseases: no herd imm

e.g tetanus

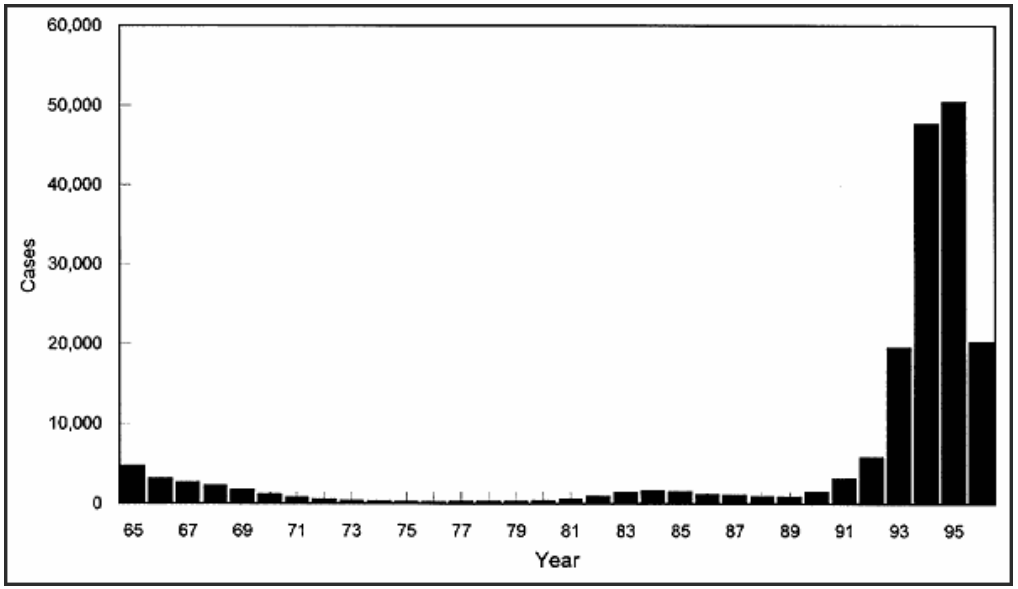
perception of benefit

anchor and recall

H influenzae b Canada 1986 -2004 (PHAC)



Diphtheria in the Former Soviet Union (CDC)



Safety Assessment:Evidence -1

Vaccine Risks

Adverse Events Following Immunization

real time data

doses given

AEFI- recognized

- signals

- new

rapid high quality causality assessment

http://yle.fi/ecepic/archive/00342/narkolepsia_lapset_342825b.jpg

feedback

HCP, parent/patient

perception of benefit

anchor and recall

"A REPORT RELEASED Feb 1 , 2010 SAYS THERE IS LIKELY A LINK BETWEEN THE SWINE FLU VACCINE USED IN FINLAND AND CASES OF NARCOLEPSY IN CHILDREN"

Safety Assessment:Evidence -2

Vaccine Risks
Purported AR

rates with and without vaccine

why these illnesses:

unknown etiology (MS, autism, SIDS, encephalitis etc)

causality assessment

feedback

	Incidence (per 100 000 person-years)
Acute infectious and postinfectious polyneuritis*	
Brazil[10]	
0–15 years	0.46
0–4 years	0·56
5–9 years	0.47
10–15 years	0·37
Finland†	
0–17 years	Female 1·68, male 0·18
18–44 years	Female 1·24, male 3·02
45–64 years	Female 3·95, male 7·15
≥65 years	Female 6.18, male 10·13
UK‡	
0–17 years	Female 0.79, male 0·70
18–44 years	Female 1·57, male 1·63
45–65 years	Female 2·07, male 2·50
>65 years	Female 2·52, male 4·57

Black et al .Lancet 2009 December 19; 374(9707): 2115–2122.

perception of benefit

anchor and recall

What can Governments do to Increase Confidence in their Vaccine System?

Evidence: vaccine benefits, disease risks, vaccine safety

timely

tailored- to population

- use of new media

address hesitancy

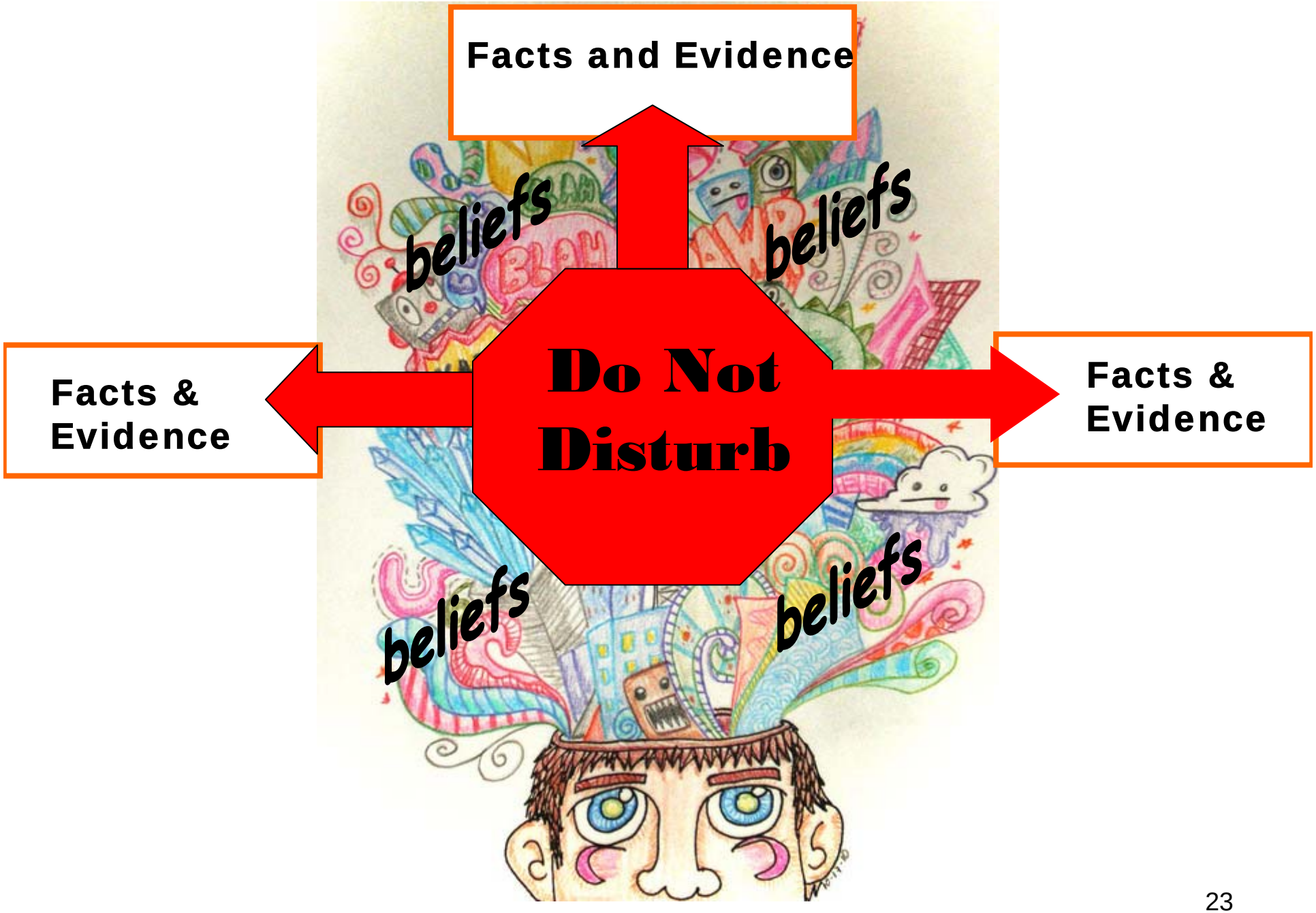
– old and new concerns

Problems using techniques relied on to date

New concerns keep arising-$$$ and time

Beliefs key- evidence may not be enough to change beliefs

Nyhan B, Reifler J. When Corrections Fail: The Persistence of Political. Misperceptions. Polit Behav (2010) 32:303–330



28.media.tumblr.com/tumblr_laztkiIDRK1qz7t

What can Governments do to Increase Confidence in their Vaccine System?

1. Knowledge Vaccine Safety System
2. Avoid Pitfalls of Academe
3. Address Pain Management in Immunization
4. Transparency and Credibility in Decision Making
5. Marketing Strategy – COMBI?

1. Vaccine Safety System Components

1. Pre-licensure review and approval
2. Good manufacturing procedures
3. Lot assessment before release
4. Post marketing surveillance AEFI –reporting
5. Causality assessment review: serious AEFI
6. Process for action if vaccine performance issue
7. Vaccine recommendations based upon epidemiology, vaccine effectiveness and efficacy (NITAG-e.g. Canada NACI, US ACIP)
8. International collaboration (WHO/GACVS)

MacDonald N & Pickering L
www.cps.ca/english/statements/ID/VaccineLiteracy.pdf

Cuba: Vaccine Perceptions

General public

-Aware robust vaccine safety system

-Importance vaccines individual and community health

www.londonmet.ac.uk/library/o51675_9.jpg

Public health: annual national polio vaccine campaign done with Cuban Federation of Women Committees for the Revolution each neighborhood

-**Little to no vaccine angst**

2. Pitfalls of Academe: a) Jargon

IOM 2001: review evidence MMR and autism

"*evidence favors rejection of a causal relationship at the population level between MMR vaccine and autistic spectrum disorder (ASD)….*"

" *the committee notes that its conclusion* **does not exclude** *the possibility that MMR vaccine could contribute to ASD in a small number of children….*"

1. Scientific method does not allow negative proof
2. Epi studies can never be large enough to offer definitive proof

Offit PA, Coffin SE. Vaccine 2003; 22: 1-6; MacDonald N, Picard A. CMAJ 2009; 180:697-8

Clear, Plain Language

A thorough review of the research involving people and animals provides no evidence that the measles–mumps–rubella vaccine causes autism. However, because the causes of autism are unknown, research on autism needs to continue.

MacDonald N, Picard A. CMAJ 2009; 180:697-8

2.Pitfalls of Academe: b)Research

1. ***Evidence based medicine and meta-analysis***

Jacobson et al. Why is evidence-based medicine so harsh on vaccines? An exploration of the method and its natural biases. Vaccine. 2007;20;25(16):3165-9.

Jacobson et al. Meta-analyses in vaccinology. Vaccine. 2007;25(16):3153-9.

2. Publication – assess quality of science and think of potential consequences.

3. Address Pain Management

Vaccine Pain

Concerns
patient, parent* , HCP
44% parents
measures to mitigate

perception of benefit
anchor and recall

**Kennedy et al*
Pediatrics 2011;127 suppl S92-99

Reducing the pain of childhood vaccination: an evidence based clinical guideline CMAJ 2010. DOI:10.1503/cmaj.092048

4. Transparency and Accountability in Vaccine Decision Making

Conspiracy theories

- hard to refute if all decisions made behind closed doors
- even when meetings open to public – may not be clear how decisions are determined

Transparency and clarity on COI

- history of drug safety issues ignored/denied

All about TRUST

5. Combi – Communication for Behavioural Impact*

1. Overall goal
2. Behavioral objective(s)
3. Situational market analysis vis a vis precise behavior goal-
4. Overall strategy to achieve stated behavioural result
5. The Combi action plan
6. Management & implementation of Combi
7. Monitoring implementation
8. Assessment of behavioural impact
9. Calendar/time/implementation plan
10. Budget

WHO – needs to be adapted for vaccination

http://www.k4health.org/sites/default/files/COMBI.pdf

Vaccines are NOT a 'Love In' for General Public

Vaccination: critical component in any public health program

Vaccination concerns and hesitancy undermine benefit potential of vaccines

Evidence – helpful but not enough

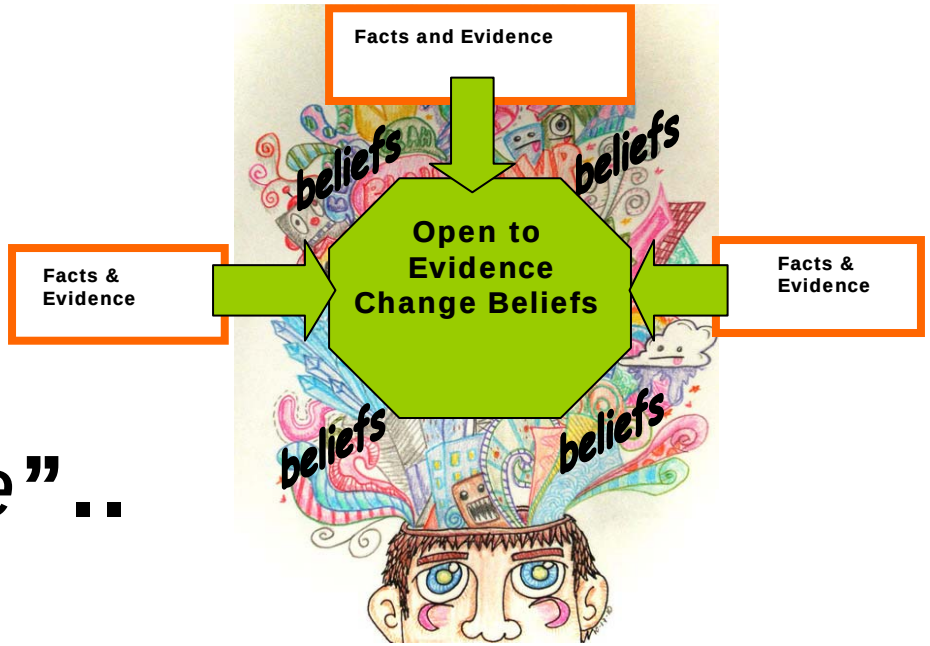
Beliefs are key

Make better use of evidence and develop a strategic "marketing" program (COMBI?)

shape beliefs

Goethe….

“Belief is not the beginning but the end of all knowledge”..



28.media.tumblr.com/tumblr_laztkiIDRK1qz7t

“We are so constituted that we believe the most incredible things; and, once they are engraved upon the memory, woe to him who would endeavor to erase them”