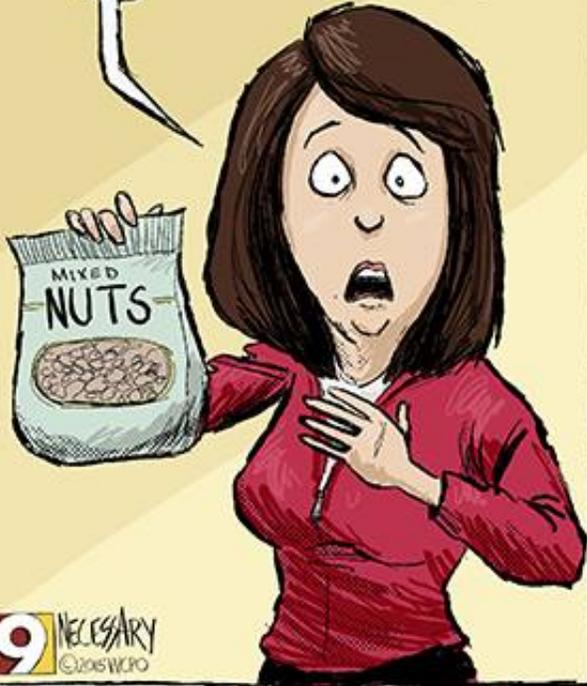


PEANUTS.

PLAIN NUTS.

MY SON IS DEATHLY ALLERGIC.
I CAN'T HAVE SOME OTHER
CHILD BRINGING THESE
TO SCHOOL AND RISKING
MY SON'S HEALTH.

I DON'T CARE IF MY KID
GETS YOUR KID SICK.
AIN'T NOBODY VACCINATING
MY CHILD.



9 NECESSARY
©2018 WCPO

A Global Perspective on Mandatory Infant & Child Immunization: Rationales, Issues and Knowledge Gaps

Kevin Necessary · @knecessary.

Editorial cartoonist & comics journalist at @WCPO

Noni MacDonald MD, FRCPC

Dalhousie University, IWK Health Centre, Halifax , Nova Scotia

Dec 5, 2018

Conflicts of Interest

No relationship with commercial interests

Professor, Dalhousie University & IWK Health Centre, Halifax NS

Adviser (occasional consultant) to WHO EURO, SEARO, WHO HQ & member of SAGE

Consultant CPS Imm/ID cmt; CPHA CANVax

Grants & contracts: CIHR, CIRN, NSHRF, WHO, PHAC

Major Contributions to this Overview

- **Shawn Harmon** – Lawyer, Dalhousie University and Univ Edinburgh
- **Eve Dube** , Medical anthropologist INSPQ
- **Audrey Steenbeek**, Professor of nursing Dalhousie University
- **Natasha Crowcroft**, Chief of Applied Immunization Research and Evaluation at Public Health Ontario; Professor Dalla Lama School Public health University of Toronto
- **Doug Opel**, Associate Professor of Pediatrics; Adjunct Assistant Professor of Bioethics and Humanities, University of Washington
- **David Faour**, Lawyer and now a medical student Dalhousie University
- **Julie Leask** Social scientist, Associate Professor in Sydney Nursing School and visiting Senior Research Fellow at the National Centre for Immunisation Research
- **Rob Butler**- Senior Social Scientist: Vaccine Demand, at UNICEF; previously at WHO EURO

MacDonald NE, Harmon S, Dube E, Steenbeek A, Crowcroft N. Opel D, Faour D, Leask J, Butler R. Vaccine 2018; 36; 5811-5818

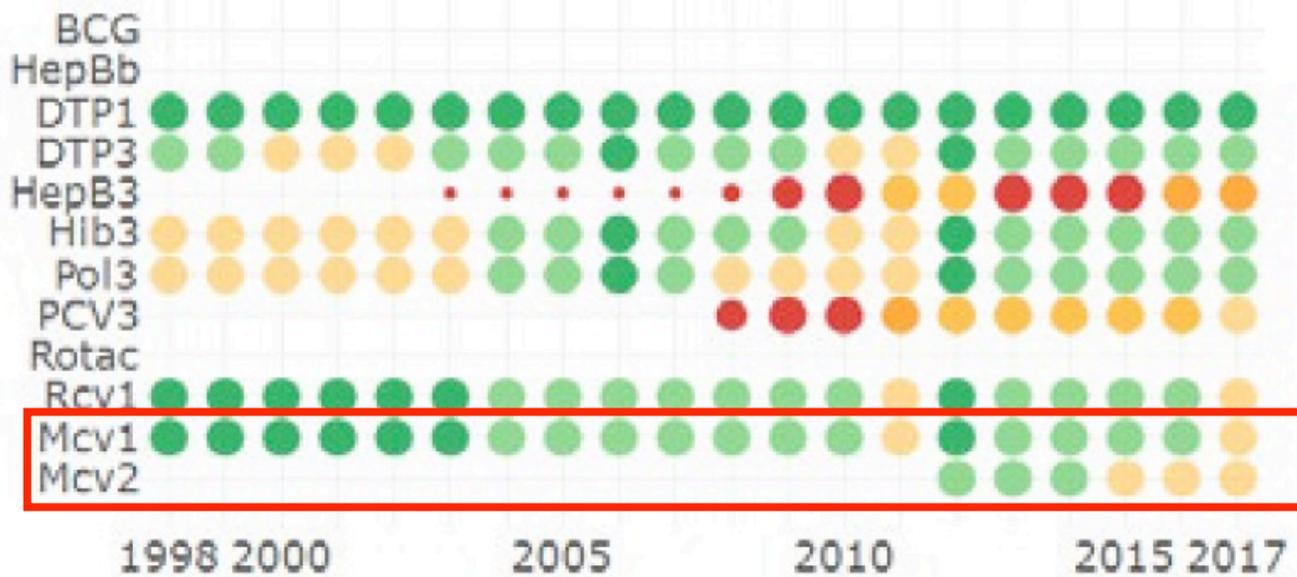
Session Objectives

1. Describe the complexity of mandatory immunization
2. Identify factors that need to be considered if/when mandatory immunization is being contemplated
3. Assess variable outcomes of mandatory immunization in different countries

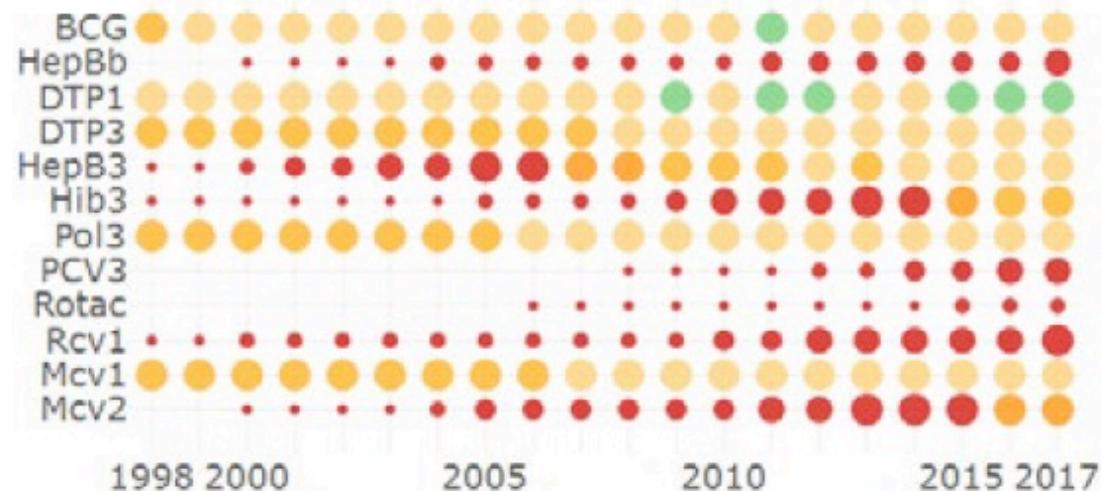
Vaccine Coverage: WHO

http://www.who.int/immunization/sage/meetings/2018/october/5_CoverageScoreCards.pdf?ua=1

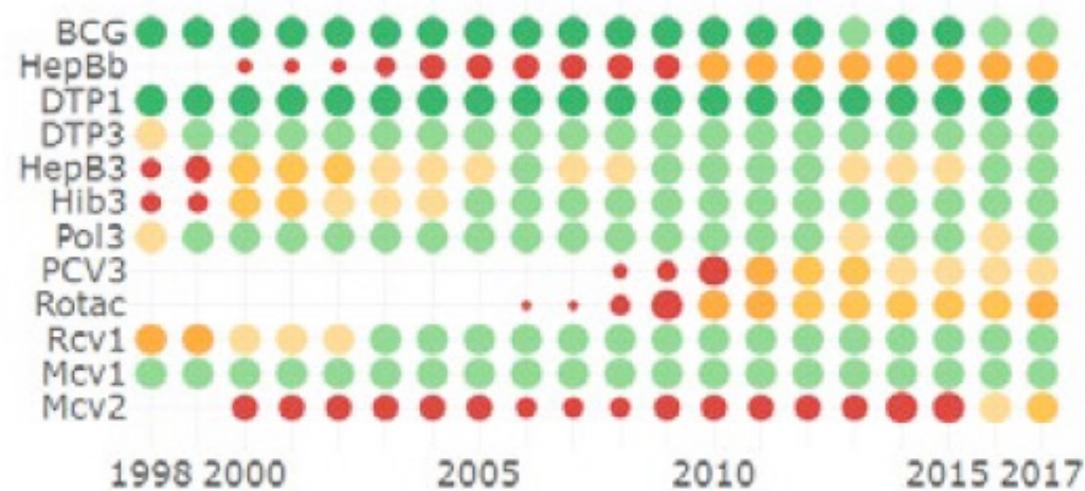
Canada



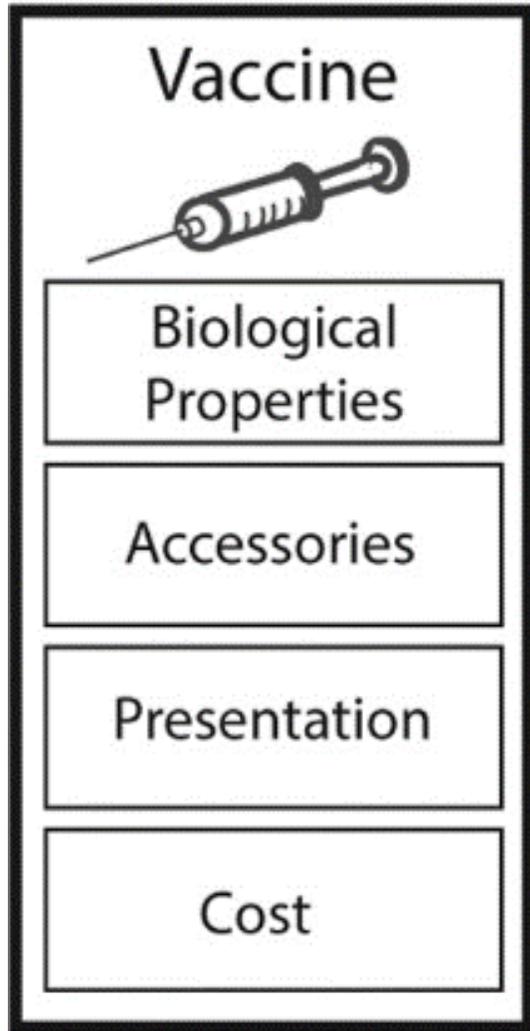
Global



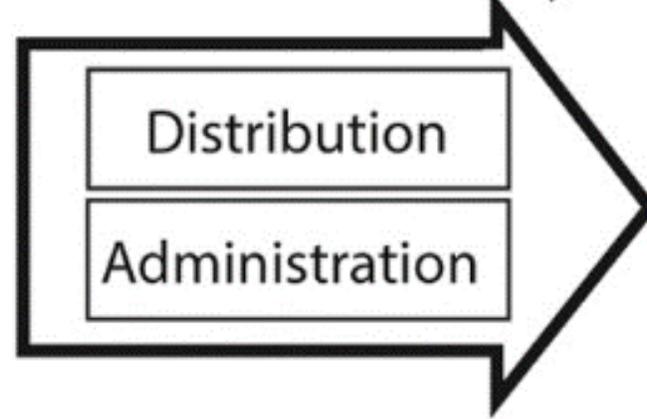
Region of the Americas



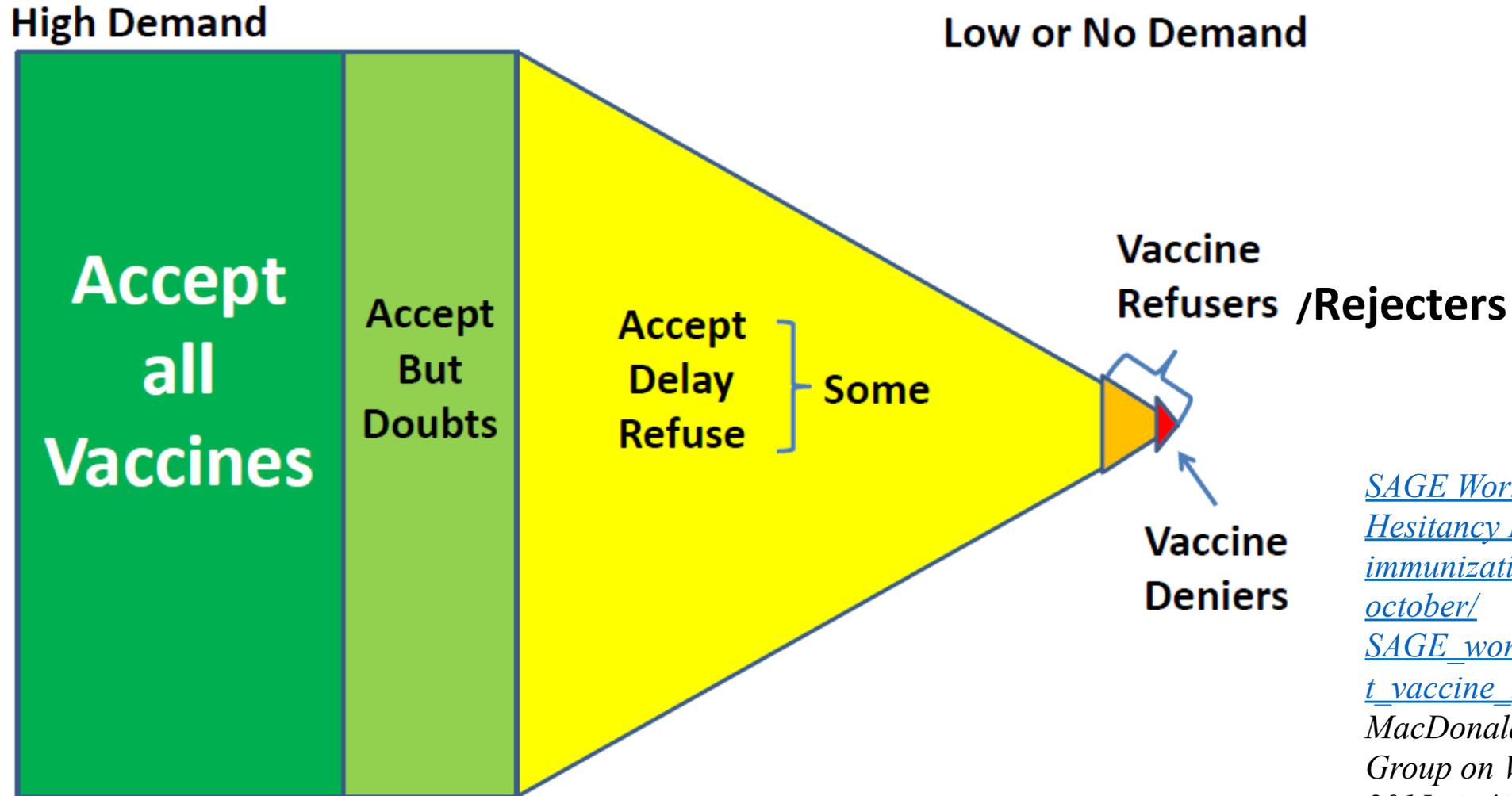
To Increase Vaccine Uptake: Must Address **Supply & Demand** (including hesitancy) Factors



Vaccine Delivery



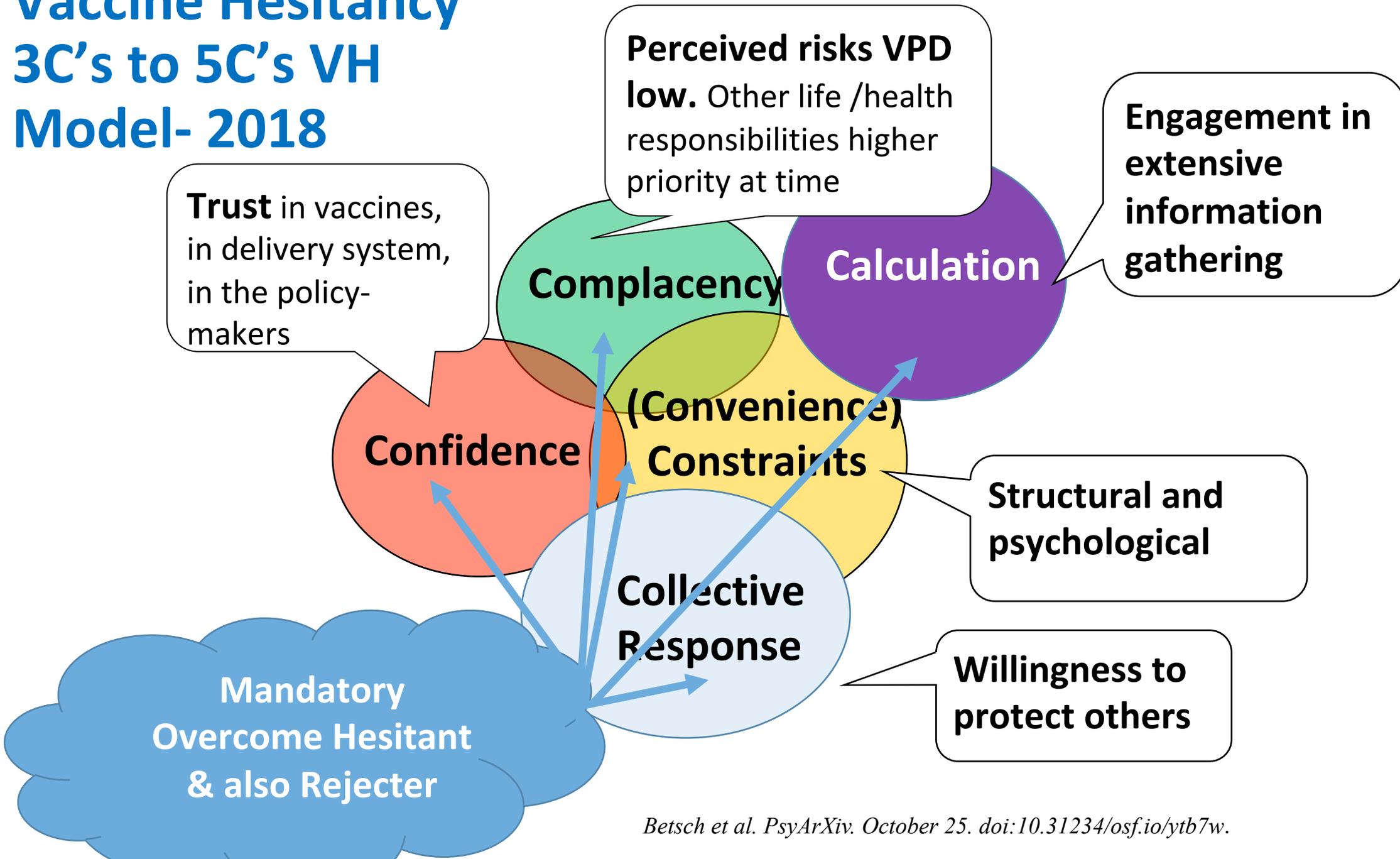
Vaccine Acceptance Spectrum: No supply side issues



[SAGE Working Group on Vaccine Hesitancy Final Report www.who.int/immunization/sage/meetings/2014/october/](http://www.who.int/immunization/sage/meetings/2014/october/)
[SAGE working group revised report vaccine hesitancy.pdf?ua=1](https://www.who.int/immunization/sage/meetings/2014/october/SAGE_working_group_revised_report_vaccine_hesitancy.pdf?ua=1)
MacDonald NE and SAGE Working Group on Vaccine Safety. *Vaccine* 2015; 33(34):4161-4

**Is mandatory immunization of
infants & children the way forward
to improve vaccine uptake ?**

Vaccine Hesitancy 3C's to 5C's VH Model- 2018



Situations Where Calls for Mandatory Immunization

3 situations often invoke calls:

1. Failure of less coercive methods to ↑ vax uptake
2. ↑ VPD outbreaks

Public Health and/or public and/or / gov't: demanding disease control → legal option = mandatory laws- looks appealing

- Even some countries with high uptake rates and no VPD outbreaks have considered this as Mandatory Imm gains traction globally

3. As part of global elimination VPD effort e.g. polio.....mandatory immunization a compelling component of polio endgame

Attwell & Smith Vaccine 2018; 36(44):6506-6508

Majumber et al JAMA Pediatr 2015;169(5):494-5

Caccitore et al Health Aff (Millwood) 2016; 35(2):334-40

Cochi et al J Infect Dis 2014;210 (Suppl1):S1-4

“Mandatory Immunization”: what does that mean?

No standard WHO definition

Europe: 2010 Venice Study: proposed – *“a ‘mandatory’ vaccine: every child in country / state must receive by law without possibility for parent to accept or refuse it, independent of whether a legal or economical implication or sanction exists for the refusal”*

Adams et al 2016

“immunization requirements implemented at the individual level to control a vaccine preventable disease(s) at the population level ”

Adams J et al PLoS ONE 2016; 11(6): e0156843. doi:10.1371/journal.pone.0156843

Haverkate M et al Euro Surveill. 2012;17(22):1-6.

Grzybowski et al Pathogens & Global Health 2017; 111: 200-205

Lessons from History

Variolation: long before 1700's

- in Africa, India, and China

- introduced into Europe in 1700's

1766 –US unable to take Quebec : small pox outbreak - **British troops had been variolated** – US not – **Gen Washington then had all his soldiers variolated**

1798 – small pox vaccine & Jenner

- use spread across UK, Europe

1806- small pox vaccine required in 2 provinces in **Italy**

- law required university students in **France** to be vaccinated

1809 USA – state **Massachusetts**– all had to be vaccinated

1853 – UK: all newborns had to be vaccinated- required to register birth

Anti vaccine movement

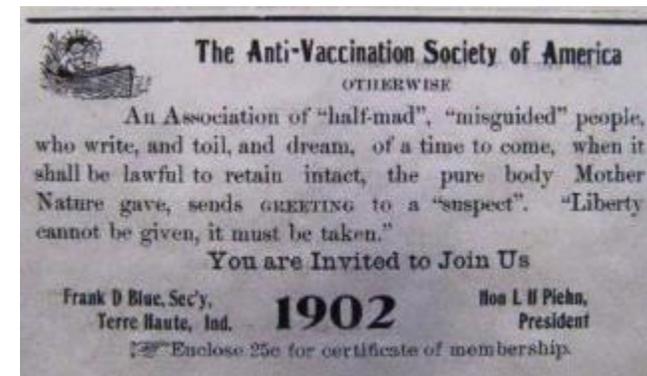
developed in UK and US

1885: e.g. riots in Leicester

government ordered Royal Commission

-lead to **UK Vaccination Act 1898**

- enabled parental conscientious objection and dropped penalties not vaccinate



Legal Frameworks: Mandatory Childhood Immunization

Foundation: varies

- Statutes, regulations, or less formal instruments
 - e.g., Presidential or Ministerial Decrees, or Departmental Policies
- long-term practice vs recent policy change

Scope:

- May apply mandate to:
 - entire country,
 - part of country (provinces) e.g. Ontario
 - or some identified populations.
- -May cover 1 , some or all recommended vaccines

Mandatory Immunization Laws: Vary Widely

Kenya 2010
check on
school entry
no penalty

Soft/
Flexible
Mandate

France before
changes in 2018

Ontario before
change 2016

Opt Out/
Education
Mandate

Ontario after
change 2016
Australia
before 2016

Australia,
California
After 2016

Hard/Strict
Mandate

Australia	2016	DPT, Hib, MMR, MenC, Pneumo, HBV	Media – Pertussis deaths	Medical Limited others	Loss of up to \$8350 /yr financial assis
France	2018	DPT, polio, Hib,HBV,MMR, Pneumo, MenC	Coexist mandatory & recommended; citizen juries, reports, gov't decision	Medical only	Exclusion daycare, school, holiday camps. Potential legal proceedings
Germany	2017	DPT, Hib, HBV, polio, MMR, MenC, Rota, VZV, Pneumo	Measles outbreaks	Vax exemp form	Fine up to €2500
Italy	2017	DTP, polio, MMR, VZV	Decline rates, ↑ VH	Medical only	Exclude daycare/ preschool Fines €100-200
California	2016	DTP,MMR HBV, Polio, VZV	Measles outbreak, many personal exemptions	Medical only	Exclusion daycare, school
Washington	2011	DTP, polio, HBV,MMR,VAV	High personal exemptions, pertussis outbreak ²⁰¹⁸	Religious personal beliefs after medical counselling	Exclude daycare, schools unless exemption obtained ¹⁵
<i>Attwell et al Vaccine 2018;36:7377-7384</i>					

Ontario Example

Medical and Non Medical Exemptions in Ontario 2002-2013

School year	Proportion of students, %			
	Medical exemptions	Prior immunity	Religious/ conscientious exemptions	Total exemptions
2002/03	0.51	0.07	1.05	1.63
2003/04	0.48	0.06	1.10	1.65
2004/05	0.38	0.09	1.15	1.62
2005/06	0.31	0.07	1.14	1.52
2006/07	0.29	0.07	1.32	1.68
2007/08	0.20	0.06	1.34	1.61
2008/09	0.21	0.08	1.41	1.70
2009/10	0.19	0.05	1.65	1.90
2010/11	0.17	0.05	1.42	1.64
2011/12	0.17	0.06	1.41	1.63
2012/13	0.16	0.06	1.54	1.75
	$p < 0.001$	$p < 0.05$	$p < 0.001$	$p < 0.001$

Wilson SE et al CMAJ Open 2015 ; 3: 317-323

2014 CMOH report: Vaccines the Best Medicine

http://www.health.gov.on.ca/en/common/ministry/publications/reports/cmoh_14_vaccines/docs/cmoh_14_vaccines.pdf

Struggling- many Toronto schools < 70% up to date

2016 New Requirements *Dyer O. BMJ 2015;351:h6821*

Unless they have a valid exemption, children who attend primary or secondary school must be immunized against req'd VPD:

Valid exemption:

med form

religious or conscientious beliefs:

requires Vax ed* + certificate from PH

complete form and get signed by

commissioner affidavits

copy all, submit originals to local PH unit

<https://www.ontario.ca/page/vaccines-children-school#section-3>

Mandatory Immunization & Ethics

*Community Immunity
protect community
& individuals*



*Not immunize
both potential
VPD victim & vector*

For patients/parents/guardians

Vaccine refusal puts others at risk

refusal violates “clean hands principle”

Refusal to accept based upon philosophy = *conscientious objectors*

“make appropriate contribution to society in lieu”

Gov't should use *“Least restrictive alternative”* to enhance achieving goal

Justice: equity in risk and benefit – Australia*

Vaccines Included – Vary as does Impact

Risk to Others vs Risk to Self

Tetanus

- no risk to others; 10% mortality rate
- no “outbreaks”

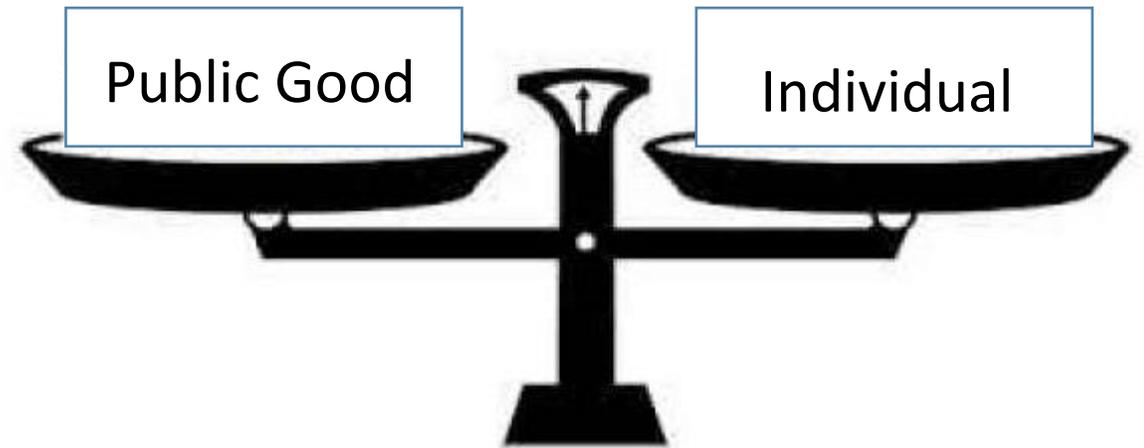
Measles

- +++ risk to others; 0.1% mortality rate
- +++ costs to mop up outbreaks; need 95% uptake to prevent outbreaks

Polio

- ++ risk to others; 1% develop paralysis if infected
- working on global elimination-++ costs

Does this change ethical



Mandatory & Serious AEFI, Vaccine Injury Compensation- *an ethical issue*

Vaccines not perfect

may have associated risks

- Hard Mandatory – no longer choice about accepting risk
- Some countries **to increase trust:**
 - compensation for serious AEFI causally related to immunization

Study in 2011 – 19 countries with compensation programs

- Germany first –
- Note **predominately HIC**
- PQ since 1985 but no mandatory



Looker and Kelly Bull WHO 2011;89(5):371-8

What is the impact of mandatory policy for parents of infants & children ?

Does mandatory immunization increase vaccine uptake ?

Penalties with Mandatory

Wide range of penalties

Fines, financial penalties \$ €

Conditions for social existence

Attendance at day care

Education: restrict access,
require parental lectures*

Social assistance

Freedom restriction

- not attend theme parks

*No RCT to see if /which penalties/
incentives make most difference*

**NO
VACCINES**



no vaccines vs school entry
child's needs

Impact: Mandatory Immunization Laws

Systematic review – 2016

Lee C, Robinson JL. J Infect 2016 72.6: 659-66

Included: 11 before-and-after studies; 10 comparison uptake in similar populations with and without mandates were included

US (18), France (1) and Canada (2)

Results: **“generally work”** – showed increase uptake in all but 2 of 21

US: adolescent HPV vaccine vs Tdap & meningo:

Moss et al Pediatrics. 2016;138(6): e20161414

- States with mandates 22-24 % higher Tdap & meningo; no difference HPV

US 2018 MMWR: Reported Exemption rates

– Non Medical , Any Exemption for Kindergarten

median: Medical exemptions 0.2 % ;

2016-2017 – 2.0 ; 2017-2018 – 2.2 i.e. increasing variation by state in exemption rates

Mellerson et al MMWR 2018;67: 1115-1122

Unintended Consequences

Australia : Incentives

no jab not pay

- some increase uptake (0.94%) overall
- but low income = \$15,000
 - Variable exclusion from services
 - ↓ daycare access,
 - -low SEC bearing brunt- family hardship

Raises further ethical issues :

Justice/ fairness

.....children being punished by removing their right to an education (DCC) due to parental decision re immunization.....yet low SEC parents least able to follow thru

California –

increase in dubious medical exemptions
gaming the system
issues around who is responsible to enforce

Mohanty et al Pediatrics. 2018; 142(5):e20181051

Serbia –

tightened penalties in 2014-2015
as measles outbreak

- ↑ anti vax messages in media,
- ↑ vax hesitancy

Disconnect risk perception and outrage

Mandatory Immunization: Examples Gaps Need to Fill



1. No recent global survey number countries with and without mandatory
GNN survey prelim, WHO EURO survey pending
2. No comprehensive research on mandatory in LIC and MIC
 - # countries
 - types of laws
 - penalties or incentives
 - implementation
 - impact /effect
 - Value added ?
3. No RCTs within HIC countries on most effective penalties/incentives
within different groups/contexts
4. No evidence how different subgroups assess/ value mandatory in HIC, MIC, LIC

Mandatory Immunization: Examples Gaps Need to Fill

5. Need evidence on whether mandatory is a “good/best” strategy to address vaccine rejecters and/or hesitant
6. Need evidence on whether the presence of AEFI compensation plays a role in acceptance of mandatory
7. Need evidence on differential impact of mandatory with respect to SEC and other variables beyond Australia data
8. Need evidence on if, where and when i.e. circumstances - mandatory increases or does not increase immunization acceptance
9. Need to know “costs” different mandatory strategies
10. Need to know best communication strategies when mandatory implemented

Questions to ask when considering Mandatory Immunization



1. Is there a problem with vaccine uptake rates?
Or is it another problem that is being addressed ?
1. Is it the right solution at this time in this context ?
2. What **components** need to be considered in a mandatory framework in this context ?
3. Do other strategies proven to increase uptake need to be part of this immunization program change ?
4. Will a shift to a mandatory program bring increased resources to the immunization program and where will these come from?
5. What might the public response be to such change esp if choice is restricted? Can this be effectively managed ?
6. Is there potential for harm to vulnerable populations i.e. unintended consequences ?

Components: Mandatory Immunization Program

Basis and method of implementing mandatory:

e.g. law, regulation, decree etc

Scope of application:

e.g. country wide, prov, district etc

Focus:

e.g. soft vs hard ; exemptions or not

Vaccines included and why:

e.g. age group, specific vaccines

Penalties and incentives

e.g. fines, financial incentives, restricted access , required education, freedom restrictions

Enforcement

e.g. by whom – PH, school, daycare , police etc

Assessment and Evaluation

e.g. impact , costs , public trust

Compensation for serious AEFI

e.g. criteria based, case based

Accountability

e.g. to whom, how often reviewed , updated etc

Ontario Application of Mandatory: if increases uptake, at what cost

Soft/
Flexible
Mandate



Hard/Strict
Mandate

Too Cold

Is this
Just Right??

Too Hot