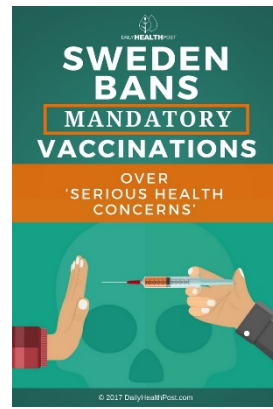




[www.march-against-monsanto.com/poland-calls-for-global-protest-against-mandatory-vaccination/](http://www.march-against-monsanto.com/poland-calls-for-global-protest-against-mandatory-vaccination/)



[dailyhealthpost.com/Sweden-bans-mandatory-vaccinations/](http://dailyhealthpost.com/Sweden-bans-mandatory-vaccinations/)



[simplyyourhealth.com/new-vaccination-rules/](http://simplyyourhealth.com/new-vaccination-rules/)



[mnbenchbar.com/2015/08/vaccines-and-the-law/](http://mnbenchbar.com/2015/08/vaccines-and-the-law/)

# Mandatory Immunization the good, the bad and the maybe.... Is there a future for mandatory ...

Noni MacDonald MD, FRCPC

Dalhousie University,

Canadian Centre for Vaccinology

Halifax , Nova Scotia, Canada

April 17, 2018

# Simple



Following a Recipe

- **Recipe essential**
- **Recipes-tested to assure replicability**
- **No particular expertise; knowing how to cook increases success**
- **Recipes produce standard products**
- **Certainty of same results every time**

# Complicated



A Rocket to the Moon

- **Formulae: critical and necessary**
- **Success with one rocket increases likelihood next will too**
- **Need ++ expertise in many specialized fields & coordination**
- **Rockets similar in critical ways**
- **High degree of certainty of outcome**

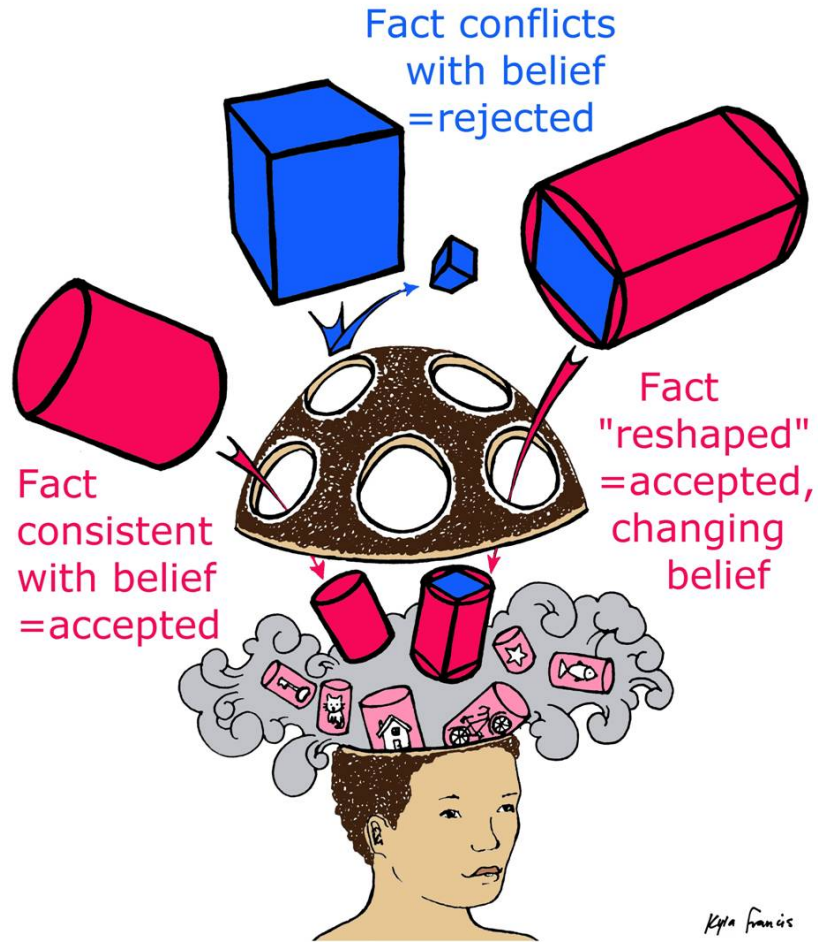
# Complex



Raising a Child

- **Formulae: only limited application**
- **Raising one child not mean success with next**
- **Expertise helpful but not sufficient; relationships are key**
- **Every child is unique**
- **Uncertainty of outcome remains**

# Risk Perception and Vaccine Decisions



Kyla Francis

Kahan D. *Sci* 2103; 342: 53-4  
Smith JC, Appleton M, MacDonald NE.  
*Adv Exp Med Biol* 2013; 764: 81-98.



Risk perceptions are intuitive, automatic and often unconscious



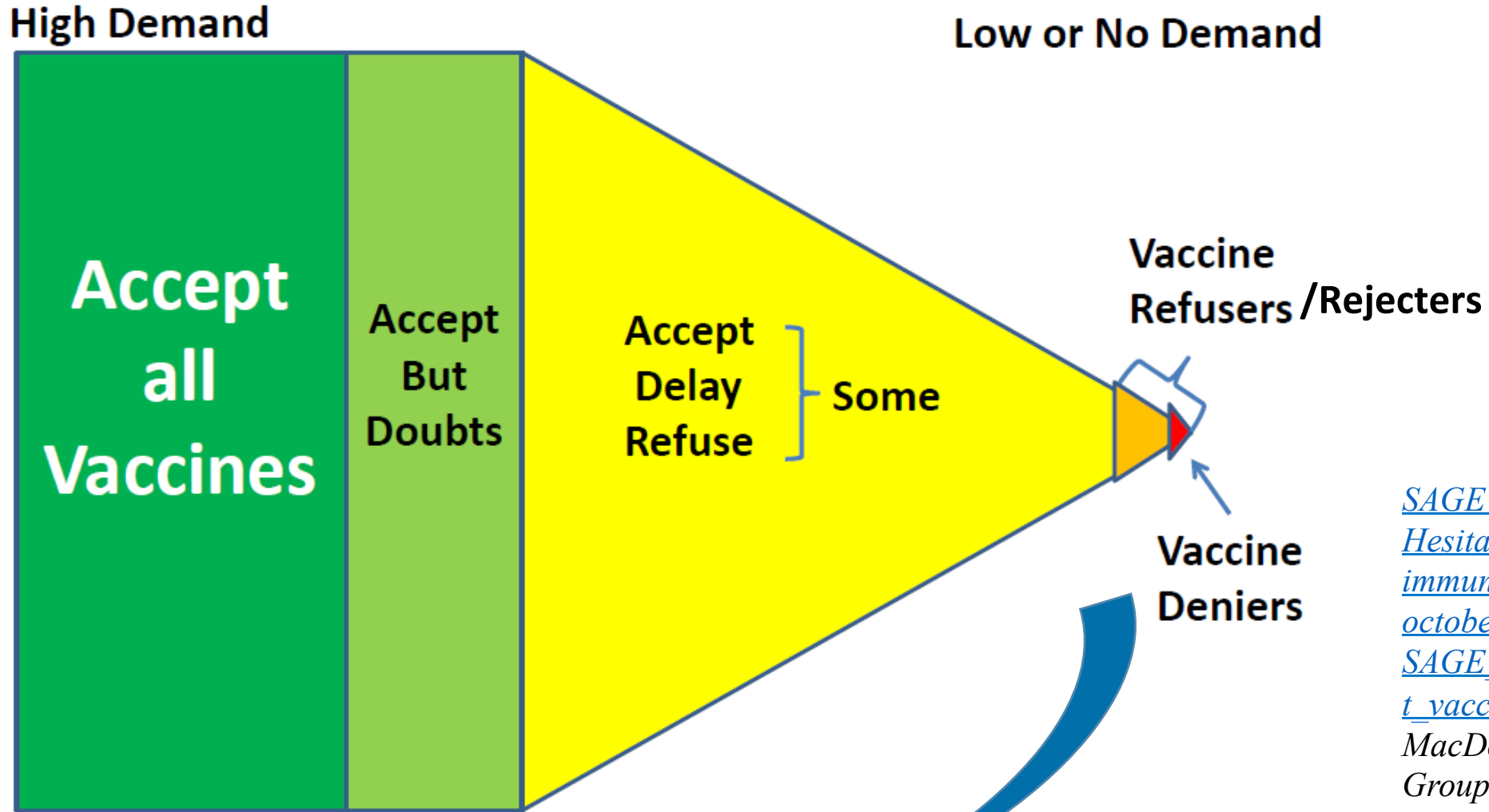
Emotions play a role in how people make decisions



Emotions play a role in how people interpret numerical information

2018

# Vaccine Acceptance Spectrum



[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](#)  
MacDonald NE and SAGE Working Group on Vaccine Safety. *Vaccine* 2015; 33(34):4161-4

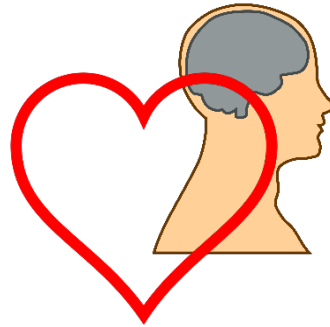
# Immunization Programs: Efforts to Increase Acceptance: Hearts, Minds, Nudges & Shoves

Tailored programs: often focus on

addressing  
confidence,  
complacency,  
convenience  
hesitancy concerns

**emphasize social norms**

**build trust\***  
in vaccines,  
in program  
in HCP



## Problem

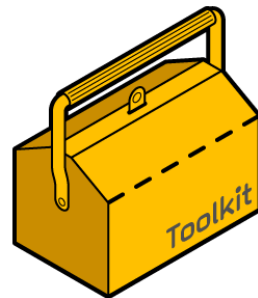
– hearts and minds campaign  
may not work  
or only work for some groups

## May need

**nudges (reminders)**

**shoves & smacks**

**-mandatory requirement:  
incentives & penalties**



\*WHO EURO

<http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/2017/vaccination-and-trust-2017>

Atwell & Smith Vaccine 2017 online

# “Mandatory”: what does that mean?

*“Structural public health intervention that reduces or eliminates individual choice about whether or not to engage with an intervention- e.g. immunization”*

## What is “the problem” mandatory trying to address?

concerns about

↑ vax hesitancy, anti vax voices

↓ vax acceptance

↓ community immunity

↑ VPD outbreaks

***Problem NOT all under-immunized are hesitant or refusers/rejecters***

BUT Public Health and public / gov’t: demanding disease control → legal option  
= mandatory laws

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

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

2018



# 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 –**Washington then had all his soldiers variolated**

1798 – small pox vaccine & Jenner  
- use spread across UK, Europe

**1806-** smallpox 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

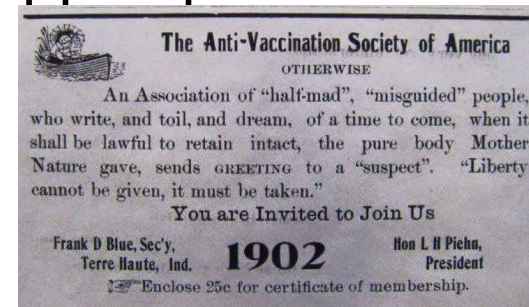
*Anti vaccine movement developed in UK and US*

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



# With Mandatory Immunization Laws

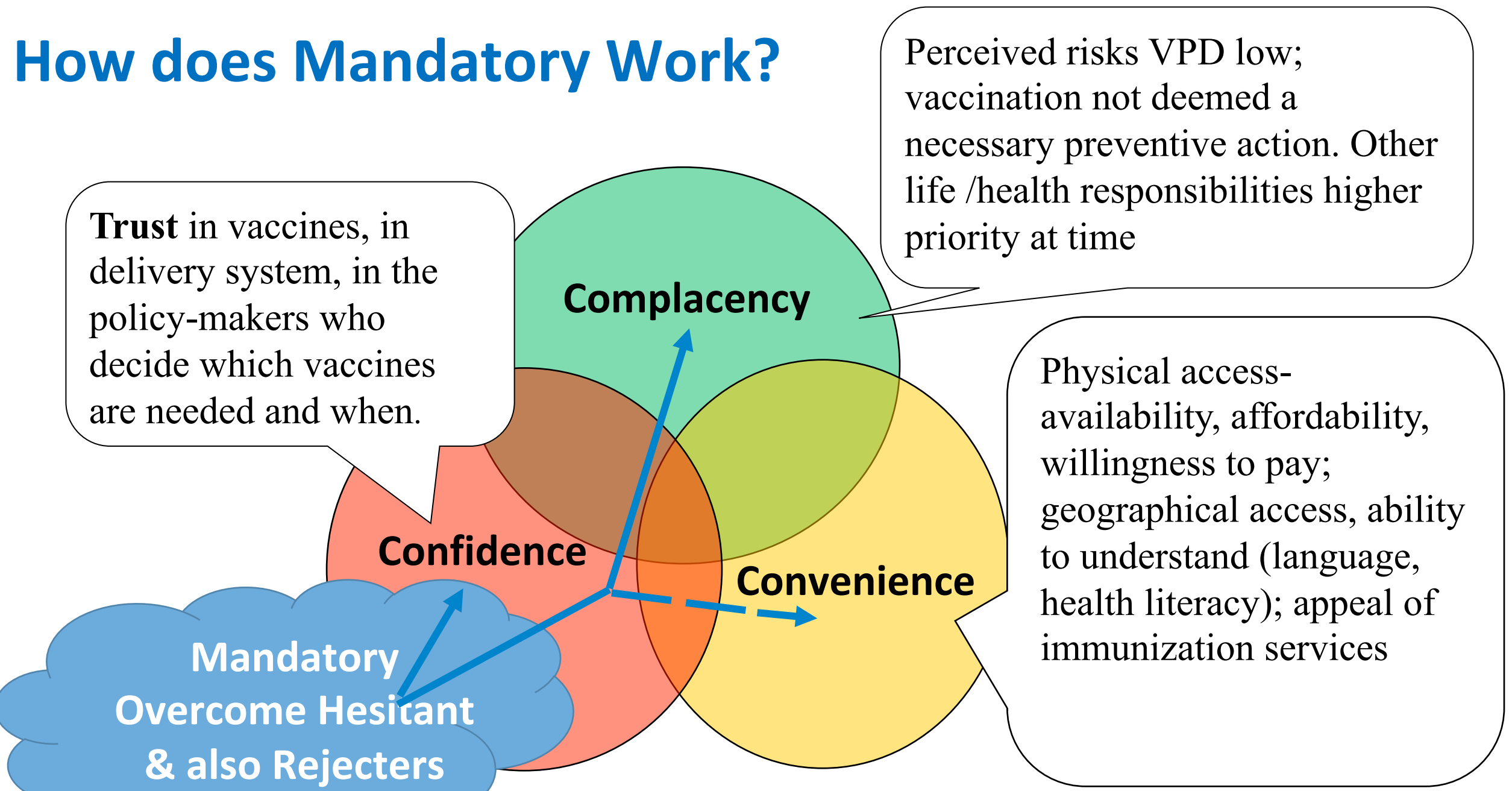
## Big Questions Arise

- Is mandatory vaccination a valid exercise of the state's powers to protect the common good?
- Is vaccine preventable disease eradication/control a sufficient ground for the exercise of these powers?
- What are the least restrictive means to achieve the objective of community immunity from vaccine preventable infectious diseases?

*Grzybowski et al Pathogens & Global Health 2017; 111 (4): 200-205*  
*Gostin Israel Journal of Health Policy Research 2018: 7:4*



# How does Mandatory Work?



# Mandatory immunization laws:

## Ethical Conflict

Autonomy vs medical coercion  
i.e. violates right to refuse

## Coercion:

*Use of physical or moral force to compel a person to do something or abstain from doing it, thereby depriving the person of free will*

what are other  
words for  
coercion?



compulsion, duress, force,  
constraint, pressure,  
intimidation, violence,  
enforcement, restraint



 Thesaurus.plus

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

# Mandatory Immunization Laws & Ethics

**For HCW:** mandatory immunization- flu and other vaccines

code of ethics- *put interests of patients above their own;*

*moral obligation tied to patient vulnerability;*

*first do no harm;*

*duty to set a good example disease prevention*

- - HCW may view this differently depending upon vaccine

**For Military:** mandatory immunization common

*“I understand that many laws, regulations, and military customs will govern my conduct and require me to do things under this agreement that a civilian does not have to do .....US*

*Consent not same – view military persons “body” – much lower requirements for consent than civilians.....e.g. anthrax vax problem in US*



[https://ec.europa.eu/  
programmes/horizon2020/en/  
h2020-section/ethics](https://ec.europa.eu/programmes/horizon2020/en/h2020-section/ethics)

Dubov A, Phung C. Vaccine 2015;33: 2530-35   Jamrozik E et al J Med Ethics 2016;42:762–768. Brennan J. J Med Ethics 2018;44:37–43. Clarke S et al Bioethics 2017;31(3):155-16  
Black L. American Medical Association Journal of Ethics 2018; 9(9): 698-702.



# Where are there Mandatory Immunization Laws?

In high, middle & low income countries

PAHO - e.g. US example

EURO –see Table for Europe

- NB France Jan 1, 2018 – shifted from only BCG, DTP IPV to also include all 11 ped vaccines

also many former USSR countries

e.g. Georgia

AFRO – e.g. Uganda: mandatory law – need to go to day care/ school but not clear how/if enforced

WPR e.g. Australia, Cambodia\*

EMR- e.g. Haij- menigo-SA & external pilgrims

SEARO- *none*

Table 1. Obligatory vaccinations in the EU ([http://venice.cineca.org/Report\\_II\\_WP3.pdf](http://venice.cineca.org/Report_II_WP3.pdf)) and the USA.

1	Belgium	Only Polio/OPV
2	Bulgaria	Adult/BCG/DTP/IPV/OPV/MMR/DT/Td
3	Czech Republic	Adult/BCG/DTP/IPV/OPV/MMR/DT/Td
4	France	BCG DT IPV
5	Hungary	BCG Hib DTaP IPV MMR HepB
6	Italy	DT/IPV/HepB
7	Latvia	BCG/DT/DTP/IPV/MMR//HepB/TBE/Adults/Td
8	Poland	BCG/HepB/DT/IPV/OPV/MMR/PCV (since 2017)
9	Slovakia	DTwP/IPV/HiB/HepB/MMR/BCG/Td
10	Slovenia	DTaP/IPV/Hib/HepB/MMR/BCG
11	USA – vaccination against:	(1) Diphtheria (2) Haemophilus influenzae type b. (3) Measels (4) Mumps (5) Pertussis (6) Poliomyelitis (7) Rubella (8) Tetanus (9) Hepatitis B (10) Varicella

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

El Bashir H et al *Lancet* 2007; **369**: 1343. Yang and Reiss *Vaccine* 2018

<https://www.sabin.org/programs/legislation/country-laws-and-regulations>

# Mandatory Laws – differ, vary widely

## .....examples

*Some countries allow exemptions:*

- *medical,*
- *Philosophical/moral*
- *religious*
- *personal*

*Others – only medical exemptions*

### **Nepal:**

4.Immunization shall be compulsory

(1) the ministry may, for the sake of prevention, control and alleviation

of prescribed diseases, stipulate some vaccine as compulsory to all.

(2) The concerned person shall be obliged to take such vaccine .....

### **Georgia:**

1. Every person on territory of Georgia is obliged to:

f) Receive the vaccination when there is an outbreak or wide spreading or possible epidemic of communicable disease, ***providing that there are no side effects.***

g) Receive the preventive vaccination when involved in the activity associated with the high risk of spreading the communicable disease.

<https://www.sabin.org/programs/legislation/country-laws-and-regulations>



# Penalties with Mandatory

- Administrative requirements
- Fines, financial penalties \$ €
- Conditions for social entrance or exclusion
- Attendance at day care
- Education: restrict access, require lectures\*
- Social assistance
- Freedom restriction
  - not attend theme parks

- Wide range of penalties
- Some NO penalty or not enforced e.g several Eastern European countries
- No RCT to see if /which penalties 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

a) 2001-2002 US National Immunization Survey not higher rates at 24 mo in childcare (required) versus not in childcare *Stanwyck et al Am J Prev Med 2004 ; 27: 161-3*

b) pertussis immunization rates in countries with (US, Australia) vs no mandates (UK, Canada, France etc ): no difference between the two groups. *Girard Public Health 2012; 126:117- 22*

**Canada:** Ont/ NB (DTP, MMR); Manitoba (measles) *Walkinshaw CMAJ 2011; DOI:10.1503/cmaj.109-3992*  
– not difference imm uptake rates vs provinces not mandatory

**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

*WHO EURO carrying out a survey re mandatory in 2018*

# What about \$ Incentives?

## Incentives:

HCW: UK -GP imm \$ incentives ↑ imm uptake *Hull et al British Journal of General Practice. 2000;50:183-7*

Netherlands –FP RCT – no increase flu vax uptake, changed diabetes , other care

*Kirschner et al Fam Pract 2013;30:161-71*

US- RCT Peds-\$ incentive, learning opportunities: subjective better : objective no ↑

*Fu LY et al. Pediatrics 2016; 137: e2 0154603*

## Patient incentives:

UK - not much appetite - not enough evidence *Adams et al PLoS ONE 2016; 11(6): e0156843*

Australia - *Leask, Danchin J Peds and Child Health 2017 doi:10.1111/jpc.13472*

- Vax hes & rejecters – not easy to reach:
- Underimm more related to – access barriers including missed opportunities
- Media frame as antivax: pressure to ↑ penalties /incentive; no non med exempt.
- **no jab not pay-** (low income = \$15,000) Variable exclusion from services
- sl increase uptake (0.94%), but ↓ daycare access, save gov't >\$500 M
- “unintended consequences “ – esp poor not all who reject

# Reviews: US Community Preventive Services Task Force

## Recommended EB Strategies to Increase Uptake

### Enhancing Access to Vaccination Services

e.g. home visits, reducing client out of pocket costs, vaccination programs in schools and child care centres

### Increasing Community Demand for Vaccinations

e.g. incentives, reminder and recall, community based interventions implemented in combination, *vac required for day care, school, college*

### Provider- or System-Based Interventions

e.g. healthcare system based interventions implemented in combinations, imm information systems, provider assessment and feedback, provider reminders and standing orders

**BUT: *The Community Preventive Services Task Force finds insufficient evidence to determine the effectiveness of monetary sanction policies to increase vaccination rates among children in families receiving government assistance.***

# Mandatory, Serious AEFI, Vaccine Injury Compensation.....

Vaccines not perfect  
may have associated risks

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

As of 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*

# Mandatory, Serious AEFI, Vaccine Injury Compensation.....

AEFI Compensation – complex

- Legislative – no fault
- Regulations- no fault
- Practical – law suits

Decisions:

- Criteria based or case-by-case
- Standard of proof usually less than for court cases
- Benefits:
  - medical costs,
  - disability pensions
  - benefits for noneconomic loss and death.

*Most countries allow claimants to seek legal damages through the courts or a compensation scheme payout but not both.*

SEARO Region

one country with mandatory imm

- no compensation programs for serious AEFI

More UMIC developing such programs

– e.g. China

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

*Kim et al Clin Exp Vaccine Res 2017;6:146-155*

*Fei, Peng Med Law Rev 2017 Feb 1;25(1):99-114*



# Mandatory Immunization: Examples Gaps



## Need to Fill

1. No recent global survey number countries with and without mandatory
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
4. Not evidence how different subgroups assess/ value mandatory in HIC, MIC, LIC
5. Not evidence on if “ best “ strategy and in what circumstances fits into addressing issues of rejecters
6. Need evidence on role AEFI compensation plays if at all in acceptance of mandatory
7. Need evidence on differential impact of mandatory with respect to SEC and other variables
8. Need evidence on if, where and when i.e. circumstances - mandatory increases immunization acceptance

# Mandatory Immunization – complex area

- “Facts on the ground – social, political, and cultural – should determine the best way to achieve high compliance. Thus, while sovereign states have the power to vaccinate as part of the global eradication campaign, they should ***utilize compulsion only if*** it would be more effective than voluntary or less restrictive measures.”

*Gostin Israel Journal of Health Policy Research 2018: 7:4*

- “Nobody should be forced to any medical intervention; however, we all individually (and not the healthcare system) should face consequences of our choices. “

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

Even if country decides wants mandatory law,  
no one size fits all, impact varies with similar laws,  
beware unintended consequences .....



<https://www.demandgen.com>