Mandatory Immunization
the good, the bad and the maybe…..

Is there a future for mandatory ....

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**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

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**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

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**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

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Brenda Zimmerman  http://tyndaleblogs.ca/rethinkleadership/blogs/simple-complicated-and-complex/ 2018
Risk Perception and Vaccine Decisions

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

Kahan D. Sci 2103; 342: 53-4
Vaccine Acceptance Spectrum

SAGE Working Group on Vaccine Hesitancy Final Report 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

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

May need nudges (reminders) shoves & smacks -mandatory requirement: incentives & penalties

 Tailored programs: often focus on addressing confidence, complacency, convenience hesitancy concerns emphasize social norms build trust* in vaccines, in program in HCP

*WHO EURO
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?

commends 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

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: smallpox outbreak - **British troops had been variolated** – US not – **Washington then had all his soldiers variolated**

1798 – smallpox 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?

Perceived risks VPD low; vaccination not deemed a necessary preventive action. Other life /health responsibilities higher priority at time

Trust in vaccines, in delivery system, in the policy-makers who decide which vaccines are needed and when.

Physical access-availability, affordability, willingness to pay; geographical access, ability to understand (language, health literacy); appeal of immunization services

Confidence

Complacency

Convenience

Mandatory Overcome Hesitant & also Rejecters

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

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 for 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

Mandatory Immunization Laws & Ethics

For patients/parents/guardians

• Are refusers “responsible” for deaths of others?........

  Yes- “technical response”

• Refusal violates “clean hands principle” a moral principle that prohibits people from participating in collective imposition of unjust harm or risk of harm

• Conscientious objectors to vaccination should make an appropriate contribution to society in lieu of being vaccinated
  • i.e. putting others at risk so must contribute


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

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

**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.

**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 ...........


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

Grzybowski et al Pathogens & Global Health 2017; 111: 200-205
*Navin et al Vaccine 2018 online ahead print
Impact: Mandatory Immunization Laws

Systematic review – 2016

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


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)

- not difference imm uptake rates vs provinces not mandatory

US: adolescent HPV vaccine vs Tdap & meningoc


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

WHO EURO carrying out a survey re mandatory in 2018
What about $ Incentives?

Incentives:

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

Netherlands – FP RCT – no increase flu vax uptake, changed diabetes, other care  
\[ Kirschner et al \textit{Fam Pract} 2013;30:161-71 \]

US- RCT Peds-$ incentive, learning opportunities: subjective better : objective no↑
\[ Fu LY et al. \textit{Pediatrics} 2016; 137: e2 0154603 \]

Patient incentives:

UK - not much appetite - not enough evidence  
\[ Adams et al \textit{PLoS ONE} 2016; 11(6): e0156843 \]

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 govt’ >$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.*

www.thecommunityguide.org/sites/default/files/assets/Vaccination-Monetary-Sanctions_0.pdf [updated 16 April 2016]
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
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 ......