

# Ethical and Legal Implications of Mandatory Vaccination for Health Care Personnel

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## Disclaimer

- This presentation is for general reference and educational purposes only, and does not constitute legal advice. Should you need guidance or assistance on a particular legal concern, you should seek the services of your local legal counsel.

## Outline

- Rationale for seasonal influenza vaccine mandates
- Ethical Arguments, Benefits & Burdens of Mandates
  - Traditional bioethics
  - Professional & population responsibilities
- Legal Rationale for Mandates
  - Traditional powers
  - “A Broader Freedom” & “Interdependency of Human Health”
- Mandate structure options
- Recent statutory & legal developments
- How is Pandemic Flu different?
  - Liability protection
  - Unknown risks make more difficult moral justification for mandate

## Public Health Rationale for Mandatory HCW Seasonal Influenza Vaccination

- Volunteer programs largely unsuccessful
  - 83%+ vaccination rate needed
- High morbidity, mortality & costs
  - 36,000 deaths/yr
  - 200,000 hospitalizations
  - \$3-5B in direct h.c. costs/yr
- Vulnerability of elderly, sick, immunocompromised populations to HCW infection
  - HCW show up to work sick or asymptomatic
- Precedents
  - Annual TB tests, Hep B & Rubella mandates, varicella, measles, mumps
  - LTC facilities
- Improve institutional safety
- Decrease HCW illness & absenteeism
- Improves health of vaccine manufacturing industry
- Pre-event vaccination preferred
  - Also helpful in pandemic preparation

## Bioethical Rationale

- Beneficence
- Nonmaleficence
- Autonomy
- Justice

## Professional Duties/Obligations

- Professional Duties as members of healing professions
- Core duties (Tilburt)
  - Trust
  - Benevolence
  - Effacement of self-interest
- Privilege of professional standing
- Duty of altruism
- Duty to care
- Duty to not infect others
- Collective Obligation?

## Burdens of Mandate

- Autonomy/Liberty/Trust/Respect
- Intrusiveness
- Coerciveness
- Potential illness of the vaccine recipient
- Cost (Justice)
- How is a HCW different from a hospital visitor?
- Right to conscientious objection

## Legal Rationale for Mandates

- State Police Powers
  - Great deference to public health decisions by states
- Jacobson v. Massachusetts (1905)
  - Police power support & recognition of social compact
  - Balance against protection of liberty interests (harm principle)
    - necessity, reasonable means, proportionality, and harm avoidance
- Universal Declaration of Human Rights
  - Limitations on individual rights to meet “[t]he just requirements of morality, public order and the general welfare” (Article 29)
- Commerce Clause
- National Security

## “A Broader Freedom”

- Gostin (2009), Jennings (2007)
  - Move away from individually-oriented “harm principle” approach
- “A Population-Based Health Law” – Parmet (2009)
  - Positive, as well as negative rights
  - Social contract
  - “Interdependency of human health both within populations and around the globe.” (Parmet @ 195)
  - Improve societal freedom

## Mandate Structures

- Poland et al.
  - Mandate with exceptions for :
    - Medical contraindication
    - Religious objection
    - Informed declination signed by HCW
- Statutory (Lindley et al. 2007)
- Regulatory (e.g., OSHA, Joint Commission)

## Recent Statutory/Legal Developments

- Passage of state laws
- Virginia Mason (9<sup>th</sup> Circuit)
- BJC
- Joint Commission
- Ferrari & Breusewitz (manufacturer liability)
- PREP Act – June 26, 2009 Declaration

## Mandates & H1N1

- Legal & constitutional protections for emergency use of vaccine, but mandate?
- With FDA approval, mandate for vaccine in face of epidemic would be justified
  - Still need to protect right to refuse
  - Mandate might not be necessary – people would want to receive the shot (see: Cipro, flu masks)
  - Trust in public policy
- May be constitutional concerns if drug is investigational, or given an emergency use authorization, as this may run up against fundamental liberty & due process concerns

## Differences Between Seasonal & H1N1

- Known risks & annual occurrence
- Known transmission pathways
- Known risks of vaccination
  - Risks minimal
- Established injury compensation
- High level of trust in vaccination & public health system

## CONCLUSION