

Requiring Vaccines for Children: Are there Limits?

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10/90 Divide*

- Less than 10% of medical research funds are spent on the diseases that account for 90% of the global burden of disease.
- Selgelid charges that bioethics apparently suffers from a maldistribution of research resources analogous to the 10/90 divide.
 - Although infectious diseases should be recognized as a topic of primary importance for bioethics, it has received little attention. Three themes:
 - 1) Significant impact of infectious diseases on health historically (Black Death and small pox) and currently (SARS and AIDS) is unrivalled in medicine.
 - 2) Public Health versus Individual Autonomy
 - 3) Justice: Burden is most heavily shouldered by the poor (in developing countries).

* MJ Selgelid, Ethics and Infectious Disease Bioethics; 2005: 19(3): 272-89.

Universal Vaccinations and Exemptions

- State has the authority to require universal immunization for infectious conditions (parens patriae), but it is less clear how aggressively the state should use its power when the likelihood of infection is quite low.
- Three types of exemptions
 - Medical exemption: if vaccination would place the individual at risk (e.g., immunocompromised host)
 - Religious exemptions
 - Philosophical exemptions

Whether Failure to Vaccinate is Medical Neglect

- Failure to immunize children against certain diseases when a safe and effective vaccine exists is medically neglectful.
 - What is meant by safe and effective is not clear-cut.
- Medical neglect does not always merit legal intervention
 - What is the threshold for legal intervention is not clear-cut.
 - Treatment is of proven efficacy; has a high probability of success; and denial of treatment will most likely result in imminent death or serious morbidity.
 - Goldstein, Freud and Solnit use the criteria “least detrimental alternative” to justify state intervention
- Whether the neglect is due to religious beliefs (or other sincerely held beliefs) should not matter although both deserve greater respect than neglect due to laziness.

Balancing Public Health and Individual Freedom

- First, state has an obligation to ensure that all nonexempt children are fully immunized according to public health recommendations.
 - Requires improved access to such services.
- State intervention is justifiable in times of epidemics when non-immunization poses risks to many.

Requiring Childhood Vaccines: Case Studies

Case 1: Immunization Refusals

- Mr. T brings in his son Tommy for a pre-school physical exam. Tommy is 5 years old and will enter public school in September. Tommy recently moved from Ohio and has not received any immunizations. His parents base their refusal on religious grounds.
- FACTS: Most states respect religious refusals for immunizations unless there is an imminent public health threat.
- What do you do next?

Flanagan-Klygis, Sharp and Frader, Dismissing the Family who Refuses Vaccines.

Arch Ped Adol Med 2005; 159: 929-934.

- 1003 pediatricians from the American Academy of Pediatrics
 - 452 returned surveys (45%)
- 256 of 302 (85%) pediatricians reported encountering partial vaccine refusal during the preceding 12 months.
 - 162 of 302 (54%) reported encountering a parent who refused all vaccines.
- Reasons for refusals:
 - Safety concerns
 - Too many at one time
 - Philosophical or religious objections

Physician Response

- For parents refusing specific vaccines, 82 (28%) would ask the family to seek care elsewhere.
- For parents refusing all vaccines, 116 (39%) would refer the family
- Reasons:
 - Lack of shared goals
 - Lack of trust
 - Fear of litigation
- Some said the type of vaccine refusal was extremely important.
 - DTAP, HIB, MMR and IPV were more important than Pneumococcal, Hep B and Varicella-zoster vaccine.

Diekema & the Committee on Bioethics, Responding to Parental Refusals of Immunization of Children.

Pediatrics 2005; 115: 1428-1431.

- Cited other data: 7 of 10 pediatricians reported they had a parent refuse an immunization in the 12 months prior to the survey.
 - Usually MMR (fear of autism)
 - Also refused Varicella, then pneumococcal, Hep B
- 4% of pediatricians refused permission for an immunization for their own children younger than 11 years.
- Small percentage said they always (4.8%) or sometimes (18.1%) tell parents they will no longer serve as the child's physician.

AAP Committee on Bioethics

- First response of most pediatricians
 - Attempt to educate
 - Document
- Consider 3 types of cases
 - Cases in which refusal risks harming the child sufficiently that the decision constitutes medical neglect and justifies DCFS involvement.
 - (Refusal of tetanus after sustaining a deep and contaminated puncture wound.)
 - Cases in which refusals puts other children at risk of harm sufficient to justify public health intervention
 - (Measles immunization requirements for school entry.)
 - All other cases...
 - (e.g., hepatitis B in newborns)

AAP Response to Parental Refusals

- Listen carefully and respectfully to parents' concerns recognizing that parents may not use the same decision criteria and may weigh evidence differently.
- Educate
 - Risks of encephalopathy from measles vaccine is 1 in 1 million
 - Risk of encephalopathy from measles disease is 1000X greater.
- Negotiate (some parents want to delay MMR until 3 years because of fear of autism)
- Continued refusal after adequate discussion should be respected unless the child is put at significant risk of harm (e.g., during an epidemic).
- In general, pediatricians should avoid terminating the relationship.
 - This allows for continued discussion
 - Child still needs and deserves access to medical care for other health problems.

Case 1: Resolution

- I accepted Tommy into my practice.
- I explained to the parents the limits of my willingness to respect treatment refusals.
 - Public health threats
 - If their decisions placed Tommy at serious risk of imminent harm.
- I continue to engage parents in discussions about immunizations.
 - Presently have begun the DTaP series because of plans for camping vacations.

Case 2: Immunization Refusals

- Mrs. V. brings in her daughter Violet who is 7 years old. Violet has been home-schooled and Mrs. V. has avoided all immunizations because she wanted her daughter to be part of the decision making process. Violet has agreed to at most two needles today.
- Questions
 - 1) Should you work with this family?
 - 2) Can you work with this family?
 - 3) What questions about Violet and the family do you want to ask?
 - 4) What immunization(s) do you recommend?

Case 2: Which Immunizations?

- AGE:
 - At age 7 years, HIB and PREVNAR are less necessary (risk highest in younger children).
 - Hepatitis B vaccine can surely wait until the child is a teenager.
- TRAVEL/foreign exposure
 - If the family lives in the US and does not plan to travel outside of the US, and does not have an international nanny, one can probably wait on the IPV.
 - Recent outbreak in an unimmunized community in Minnesota.
 - If one is not planning to go on a camping trip or walk barefoot in city parks, tetanus can be safely withheld.
 - And if necessary, can be given up to 72 hours post injury.
- Health of Family members
 - If a household member has severe COPD or asthma, thought should be given to influenza.

Case 2: Which Immunizations?

- Which immunizations would I choose for a healthy 7 year old child, given a history of unremarkable risks and exposures?
- (in order of importance)
 - MMR
 - DPT
 - Want to complete a series. Second dose can be as soon as one month; as long as years...(in contrast with Hepatitis A that must be completed in one year, for example).

Case 3: Immunization Delay

- Ms H brings in her twin children, Helen and Henry. They are both 2 months old. They were born at a birthing center and received no immunizations, but did receive vitamin K. When Ms H learns that you want to administer DTaP, Hib/HepB, IPV, and Prevnar, she becomes quite distressed. She asks you how many vaccines will her children need by age 2 years?
- Answer:
 - 20 +7;
 - DTaP 4; HIB 4; Prevnar 4; IPV 3; MMR 1; Varicella 1; Hep B 3; and possibly Hep A 2 and 2 doses of influenza (and we will be re-introducing RV vaccine [3 doses])
 - If you count DTaP as 3 different diseases, the answer is 11 disease (+3)
 - If you count the number of times each disease requires an immunization 30 (+7)

Case 3: Immunization Delay

- Ms H is willing to authorize the immunizations for her children, but asks if they can be delayed because of her fear that her children, particularly her son, might develop autism.
 - The media has described an association of autism and thimersol; and autism and MMR.
- What are the risks and benefits of delay?
- Which ones would you be more willing to delay?
- Answer: If I could only immunize for certain diseases in infants under one year, I would pick in this order
 - DTaP (for the diphtheria and pertussis);
 - HIB;
 - Prevnar

Case 4: School Entry

- Ms C is the principal of a private school in your area. She asks to have a meeting with you. The Montessori-type school admits children from age 1 year (“mommy and me” or more correctly “caregiver and child”) and into the nursery program at 2 years.
- The principal wants to know whether she should allow unimmunized children into the program.

Case 4: School Entry

- Can the school require immunizations for school entry?
 - YES
- Must the school respect religious or philosophical refusals?
 - This depends upon state laws.
- If the school does allow children who are unimmunized, do other parents have a right to know?
 - Does it matter if it is one child who is not immunized or if it is 25% of the children?
 - Issue of herd immunity
 - Issue of greater likelihood of spread with larger pockets of unimmunized children.

Case 4: School Entry

- What recommendations would you have for Ms C if she decides to allow unimmunized children to attend her school?
 - A clearly written policy would be ideal.
- Policy should address:
 - What will be done if a child comes down with any of these conditions? To whom will cases be reported?
 - Will there is a maximal number (or percentage) of unimmunized children who can attend?
 - What rights do parents (both refusers and non-refusers) have to know about the policies and about the percentage of unimmunized children who attend the school?
 - What happens if a child, or child's sibling develops an underlying condition like cancer and the treatment leaves him immunocompromised? Will the school defend the right to refuse or the right to community protection?

Case 5: Adolescent Vaccines

- CURRENTLY

- Tdap (or at least dT) [one dose booster]
- Menactra (previously for children entering college, now being recommended for children entering middle school) [one dose]
- Hep B (if not previously given) [series of 3; possible need for a booster in those immunized in infancy]
- Varicella (if not previously given and no immunity) [series of 2]
- (Influenza in teens with chronic health conditions or who live in households with “at risk” members) [yearly]

- IN THE NEAR FUTURE

- HPV vaccine for Sexually transmitted infections (STI) [series of 3]
- Herpes vaccine

Case 5: Adolescent Refusal

- Ms M comes in with her teenage son Mark. Mark is a nationally-ranked squash player and is being recruited to attend boarding school on the East Coast.
- The school requires that all entering students have received Menactra in the past 5 years and Tdap; and that they be tested twice for TB. He needs 2 vaccines and the first of 2 TB tests.
- Ms M consents but Mark says “no”.
 - What do you do?

Case 5: Adolescent Refusal

- Why is Mark saying no?
 - Fear of needles?
 - Use EMLA cream
 - Philosophical or religious belief?
 - Mark states he is a vegetarian and believes in meditation to achieve holistic well-being.
 - How strong are these convictions? Is he willing to forego Boarding School?
 - Are you willing to call the school and see if an exception can be made?
- Do you need Mark's consent to administer these vaccines?
- Do you need his active assent?
 - Or will you administer if he says "I'd rather not" but sticks out his arm and does not fight when the nurse comes in with the needles?
 - How is this different than holding a four year old child down?
 - How is it different if the vaccine were experimental?

Case 5: Resolution

- Mark and his parents went home with numerous references and website addresses.
 - I specifically recommended the AAP website and hand-outs.
 - I specifically discussed the Waksman scandal in the Lancet.
- Mark and his parents called for a nurse visit approximately 3 weeks later.
 - EMLA was ordered and applied prior to the appointment.
 - School form updated at that time.

Childhood Vaccinations:

Are there limits?

Childhood Vaccinations: Are More Better? Are there Limits?

- From a public health perspective, more seems better.
- From the perspective of the individual patient's medical well-being, more seems better although some individualization may be appropriate.
- From the perspective of the provider, uniform policies are needed (e.g., what population, what age, timing if the vaccine requires multiple doses).
 - Pros and Cons of vaccinating infants rather than teens may be based on severity of illness (HiB more likely in a young child) or based on convenience (Hep B series).

Childhood Vaccinations: Are there Limits?

- Limits based on
 - absolute risk;
 - risk: benefit to the child
 - risk: benefit to the community
- Parents can refuse provided it is not seriously neglectful of the child.
 - Balance between respect for parents to raise their children according to their own values and the well-being of the child
- Parents can refuse provided it does not pose serious risk to the community.
 - Balance between respect for family autonomy and community well-being.
- Sincere convictions (whether religious or philosophical) should have greater weight than objections due to inconvenience

Future Considerations regarding Childhood Vaccinations: Are there Limits?

- If the state is going to mandate these immunizations, do they have an obligation
 - To ensure safety (vaccine databases)?
 - Phase IV clinical trials...
 - Stricter reporting laws to VAERS
 - To provide the immunizations free-of-charge?
 - To provide compensation if an adverse event occurs (VAERS)?
 - To continue to track potential long-term risks of both individual vaccines and multiple vaccines.