

Risk Communications- With a Focus on Smallpox Vaccine Adverse Events

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Objectives

- Describe Smallpox Risk Communication Environment
- Share Some Risk Communication Principles and Strategies
- Provide Information about CDC Smallpox Immunization Communication Resources and Activities



The Risk Communications Environment, I

- There are three relevant “risks” that must be recognized (and communicated about):
 - Risks associated with terrible vaccine adverse reactions
 - The risk of a smallpox attack
 - The risks associated with not being prepared for a smallpox attack



The Risk Communications Environment, II

- The smallpox vaccination program is grounded in much uncertainty:
 - Likelihood of an attack involving smallpox
 - Frequency of adverse events
 - The best ways to treat adverse events
 - Liability (and injury compensation)
 - Hospital and healthcare facility participation
 - Public reaction and actions



The Risk Communications Environment, III

- The scope of the smallpox vaccination program was— and still is— a difficult decision. It could change if:
 - The threat of an attack goes up or down
 - If the assessment of the frequency and severity of vaccine adverse effects goes up or down
 - If the availability of licensed vaccine goes up or down



The Risk Communications Environment, IV

- The first serious adverse reaction (claimed or real) will generate much local and national media attention and public interest.
 - How we respond (what we do and what we say) will have a significant impact on perceptions of the vaccination program.
 - State and local adverse event clinical and program personnel may be called upon to be spokespersons or help prepare spokespersons.
 - Hotline staff will also play a key role in responding to the interest and concerns raised.
 - The more messages, materials, and resources that are prepared and ready – before a confirmed adverse event – the better.



Possible Scenarios

- Large number of mild-moderate reactions, not severe but producing concern.
- Life-threatening reaction (in a vaccinee or a contact)
- Death (of a vaccinee or a contact)
- Unexpected contraindications/reactions
- Failure to properly respond to an adverse reaction (e.g., not diagnosed in a timely manner, not treated properly, etc.)
- Unexpected contact transmission (e.g., in the workplace)
- Allegations that smallpox vaccination caused health problems not known to be related to the vaccine.



Stakeholders and Concerns, I

- **Recent vaccinees** - *What happened? Why did it happen? How can you prevent it from happening again? What is being done to redress the damage? Should I be afraid? What should I watch out for? Am I doing everything I need to do to be safe? Is my family safe? Who is to blame? What did they do wrong? Will they be punished?*



Stakeholders and Concerns, II

- **Unions** - *How will the vaccinee and her/his family be compensated? Who will care for him/her? How? Will they be getting the best possible care? What is known about this that you're not telling us? Should this program be stopped? Why did this happen? Who screwed up? What's being done to investigate this and prevent it from happening again? We're going to recommend to our members that they not participate in this program.*



Stakeholders and Concerns, III

- **Program implementers** - *Are we going to continue the program? My oath/obligation as a health care/public health professional is to protect, not to harm. I am concerned about ethical considerations. Are the screening tools faulty? What systems will be put in place now? What are the lessons learned? I don't want to be a part of this program anymore.*



Stakeholders and Concerns, IV

- **Elected officials, policy makers** - *Why should we continue the vaccination program? Who is reviewing the situation? What are they doing to investigate? What improvements are needed? What is the impact on my state/district/constituency? Will my state be expected to provide compensation? Where will compensation funds come from? What are the next steps?*



Some Important Smallpox Immunization Risk Communication Principles and Strategies

- Embrace the “Risk” = Hazard + Outrage formula
- Do “anticipatory” guidance
- Express wishes and feelings
- Tolerate uncertainty; help others tolerate it too.
- Practice dilemma-sharing
- Recognize the risk communication “seesaw”
- Bend over backwards to avoid charges of cover-up

(Sandman 2003; www.psandman.com)



Embrace the Formula

“Risk” = Hazard + Outrage

- **Hazard** = actual likelihood and seriousness of a risk
- **Outrage** = cultural perceptions regarding a risk; includes levels of concern and interest.
- There is a relatively low correlation between the two (i.e., between how many people are actually harmed by a risk and the number people who get upset— or how badly upset they get);
- **Outrage has a far greater impact on risk perception than does hazard** (e.g., when people are upset, they will think the risk is great, even if it isn't).



Factors that Influence “Outrage” Include. . .

- Voluntary vs. mandatory
- Familiar vs. unknown
- Not dreaded vs. dreaded
- Knowable vs. unknowable
- Trustworthy sources vs. untrustworthy
 - empathy and caring, competence and expertise, honesty and openness, dedication and commitment
- Responsive process vs. unresponsive



“Risk = Hazard + Outrage” Applied to Smallpox Vaccine

- Smallpox vaccination “outrage” will almost certainly focus on side effects and terrible vaccine reactions;
- Smallpox attack outrage may also focus on vaccine availability (or lack thereof);
- Communications need to recognize both: “If the threat of an attack weren’t so awful, we would never have recommended vaccination. If rare side effects of the vaccine weren’t so awful, we would recommend even more people get vaccinated.”



Do “Anticipatory Guidance”

- Tell people in advance what to expect— including how they are likely to react (give them a chance to “rehearse”).
 - Normal reactions
 - Serious and life-threatening vaccine adverse reactions
 - The prospect of serious or even fatal outcomes from vaccinia virus shedding
 - The risks of facing a smallpox attack without having a trained cadre of vaccinated responders



“Anticipatory Guidance” for Possible Deaths

- “People may die as a result of this program. Some may die because of screening errors or other errors; some may die despite our doing everything right. Every death will be a tragedy. In the face of vaccination deaths, some people, maybe even some of us in the program, will be tempted to conclude that it was a mistake to launch the vaccination program at all. After all, these will be actual deaths ... compared to a merely *possible* smallpox attack. So it is important for me to say now that we are going into this with our eyes open, knowing that some deaths are likely and believing that protecting ourselves from a possible smallpox attack is important enough to bear that risk.”



“Anticipatory Guidance” for Unanticipated Events

- Anticipatory guidance must extend to unanticipated events as well— i.e., warn people to “expect the unexpected”
 - “It has been several decades since we stopped giving smallpox vaccinations in the United States. There is much that we never knew and much that has changed. We are going to learn things in the coming months that we will then wish we had known now.”



Express Wishes and Feelings

- Technical experts too often confine themselves to explaining facts, leaving the audience alone with its wishes and feelings.
- Expressing wishes and feelings shows that you are human.
- Helps stakeholders and publics cope with their own feelings.



Express Wishes and Feelings

- Wishes

- “We wish that smallpox could have remained a success story in public health history”
- “We wish we were certain, one way or the other, about the risk of a smallpox attack”
- “We wish we had a safer vaccine”
- “We wish we knew more about using smallpox vaccine in today’s population”
- “We wish we had more treatment options for serious vaccine reactions”



Express Wishes and Feelings

- Feelings
 - Sorrow for awful things that happen: “We are deeply saddened by the vaccine-related illness of our colleague.”
 - Guilt that they might have been prevented: “If only we’d known she had an immune disorder.”
 - Fear: that the vaccination program is unnecessarily putting people at risk; of not being prepared to respond to an attack.
 - Exhaustion, tension, frustration.
 - Even anger — it’s not the most attractive of feelings, but it is preferable to no feeling at all.



Tolerate Uncertainty

- Acknowledge the smallpox vaccination program is grounded in uncertainty.
 - Show that you can bear the uncertainty and expect others to do the same.
 - Predict that we will sometimes be wrong.
 - “It’s not being wrong that kills you— it’s being wrong after sounding sure.”
 - Don’t be over-optimistic when talking about uncertainties (e.g., the # of adverse events expected; outcome of a severe adverse reaction).



Practice Dilemma-Sharing

- Dilemma sharing is explicitly claiming that a decision is difficult, the right answer isn't obvious, and asking for help.
- Important to also practice in regard to decisions already made.
- It builds credibility— because it is usually the truth, and thus has the ring of truth.
- It disarms critics



Risk Communication "Seesaw"

- When people (e.g., the public) see merit on both sides of an issue, they will emphasize whichever side the communicator fails to emphasize. For example,
 - If you don't want people to be excessively fearful, don't be excessively reassuring.
 - If you take a particular risk very seriously, people will usually be less, rather than more, concerned.
 - If you emphasize the low probability of an AE, the ambivalent audience will emphasize its high magnitude. If you emphasize its high magnitude, they will emphasize its low probability. If you emphasize both, they will emphasize both.
 - If you don't want us to blame you for adverse events, blame yourself some.



Bend Over Backwards to Avoid Charges of Cover-Up

- Smallpox vaccine adverse reactions is the kind of issue that feeds cover-up conspiracy claims. Plan now to address such claims effectively.
 - Set up an independent accountability mechanism.
 - Don't just track the most serious adverse events; track everything that requires medical attention.
 - Empower local authorities to go public quickly.
 - Avoid withholding information even for good reasons.
 - Talk before you're sure. At the very least, don't use uncertainty as an excuse for withholding unpleasant news.
 - Be apologetic, not hyper-technical.



CDC Smallpox Immunization Communication Resources



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Currently Available Web Resources

- Main Website: www.cdc.gov/smallpox
- Smallpox Basics Index in Spanish:
<http://www.bt.cdc.gov/agent/smallpox/basics/espanol/index.asp>
- Smallpox Resource Kit for Health Professionals:
<http://www.bt.cdc.gov/agent/smallpox/reference/resource-kit.asp>



Available CDC Materials for the Public

- **Fact Sheets, including:**
 - Smallpox Overview
 - Vaccine Overview
 - Who Should NOT Receive the Smallpox Vaccine?
 - Reactions after Smallpox Vaccination
 - Information on Live Virus Vaccines and Vaccinia
- **Frequently Asked Questions & Answers**



Available CDC Materials for Public Health and Health Care Professionals Include. . .

- **In-Depth Resources:**
 - Smallpox Response Plan & Guidelines, including the Smallpox Vaccination Clinic Guide
 - Medical Management of Smallpox (Vaccinia) Vaccine Adverse Reactions
 - Smallpox: What Every Clinician Should Know Online Training (and CD-Rom)
- **Images (including smallpox disease and reactions to smallpox vaccination)**



CDC Clinician Resources continued. . .

- **Fact Sheets, including:**
 - Adverse Reactions Following Smallpox Vaccination
 - Smallpox Vaccine Information Statement
- **Training tools and materials**
 - Webcasts
 - Slide presentations (on the CDC website)
 - Smallpox vaccination and adverse events training module
- **Telephone information service (i.e., “hotline”)**



Pre-Vaccination Information Packet for Potential Vaccinees

- Cover letter
- Smallpox Vaccine Information Statement (VIS)
- VIS Supplements
- Pre-Event Screening Worksheet for Smallpox Vaccine
- VIG and Cidofovir Fact Sheets
- Patient Medical History and Consent Form
- Post-Vaccination and Follow-Up Information Sheet



Ongoing Activities

- Developing fact sheets on vaccine safety monitoring and adverse event reporting
- Developing crisis communication plans given several identified scenarios related to smallpox immunization program issues, including adverse events.
- Drafting messages, materials, and protocols for responding to vaccine-related crises.



Thank You for Listening!



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