

Urgent Communication in Practice: How is it Done?

FDA Risk Communication Advisory Committee
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AnnaMaria DeSalva
Worldwide Director of Healthcare
Hill & Knowlton



Industry Plans Communication Across the Continuum of Risk



General and Special Controls

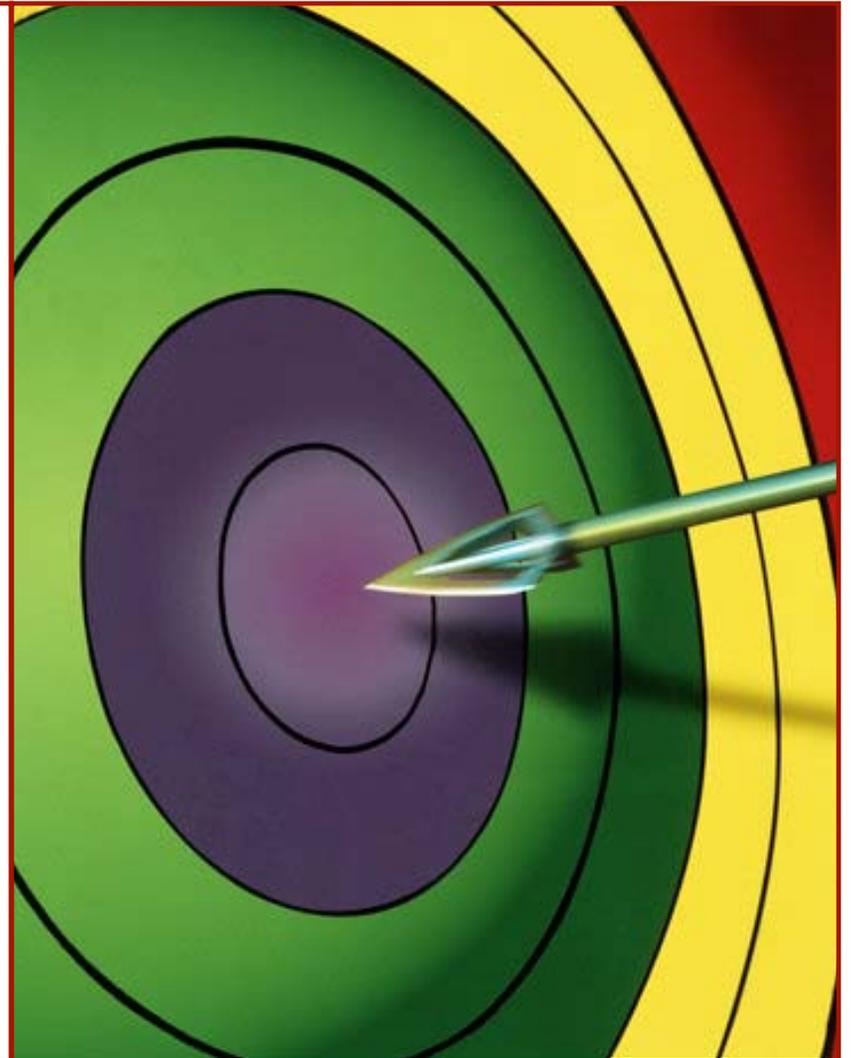


Industry's Communications Goals

- Minimize and manage risk for affected patient population
 - Define risk and support appropriate interpretation
 - Create a clear pathway for risk mitigation by both patients and HCPs
- Prevent undue fear, confusion, anxiety and skepticism
- Demonstrate credibility, commitment, trustworthiness
- Preserve ability to address medical need
- Preempt undue reputation damage

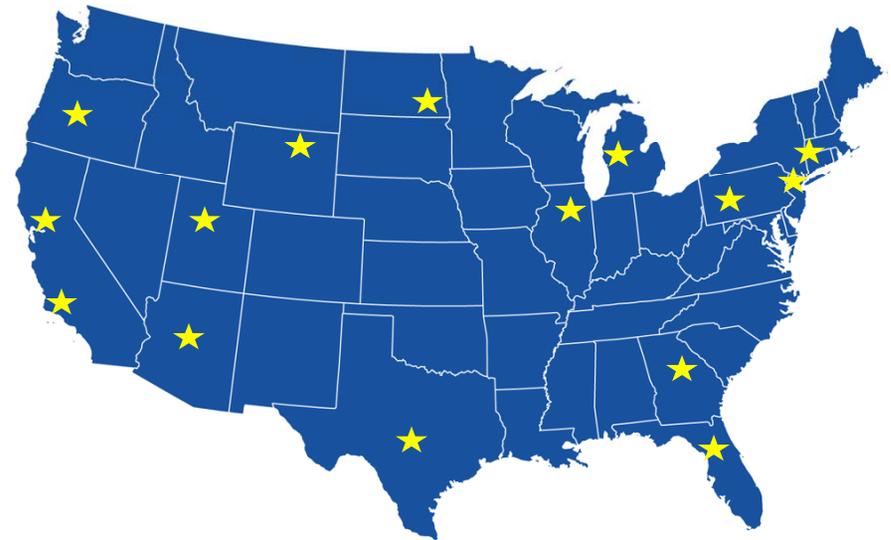
Critical Success Factors

- Early integration into risk evaluation process
- Prospective planning against major scenarios
- Rigor, appropriate speed, transparency, collaboration
 - To develop the correct strategy and maintain credibility
- Stakeholder engagement and understanding of fundamental issues
- Intelligent participation in the media coverage cycle
- Effective application of crisis and risk communication principles



Communications Planning in Practice— A Composite Case (Fictional) [1 of 3]

- A medical device used to treat a chronic condition may be causing material injury and disability in a subset of patients.
- Individual events have been reported in the U.S. but trending analyses over a 12-month period do not suggest a fundamental product safety issue
 - Root cause may be due to patient demographics or surgical implantation technique.
- At month 14, a prospective analysis indicates that within a year, events may reach statistical significance.



Communications Planning in Practice— A Composite Case (Fictional) [2 of 3]

- Based on the availability of some acceptable pharmacologic treatments for the same condition and out of an abundance of caution, the manufacturer decides to recall the device, removing it from the U.S. market.
- A comprehensive and highly visible announcement ensues.
- A root cause analysis will determine if the device should again be made available, with a different design or improved surgical technique training.



Communications Planning in Practice— A Composite Case (Fictional) [3 of 3]

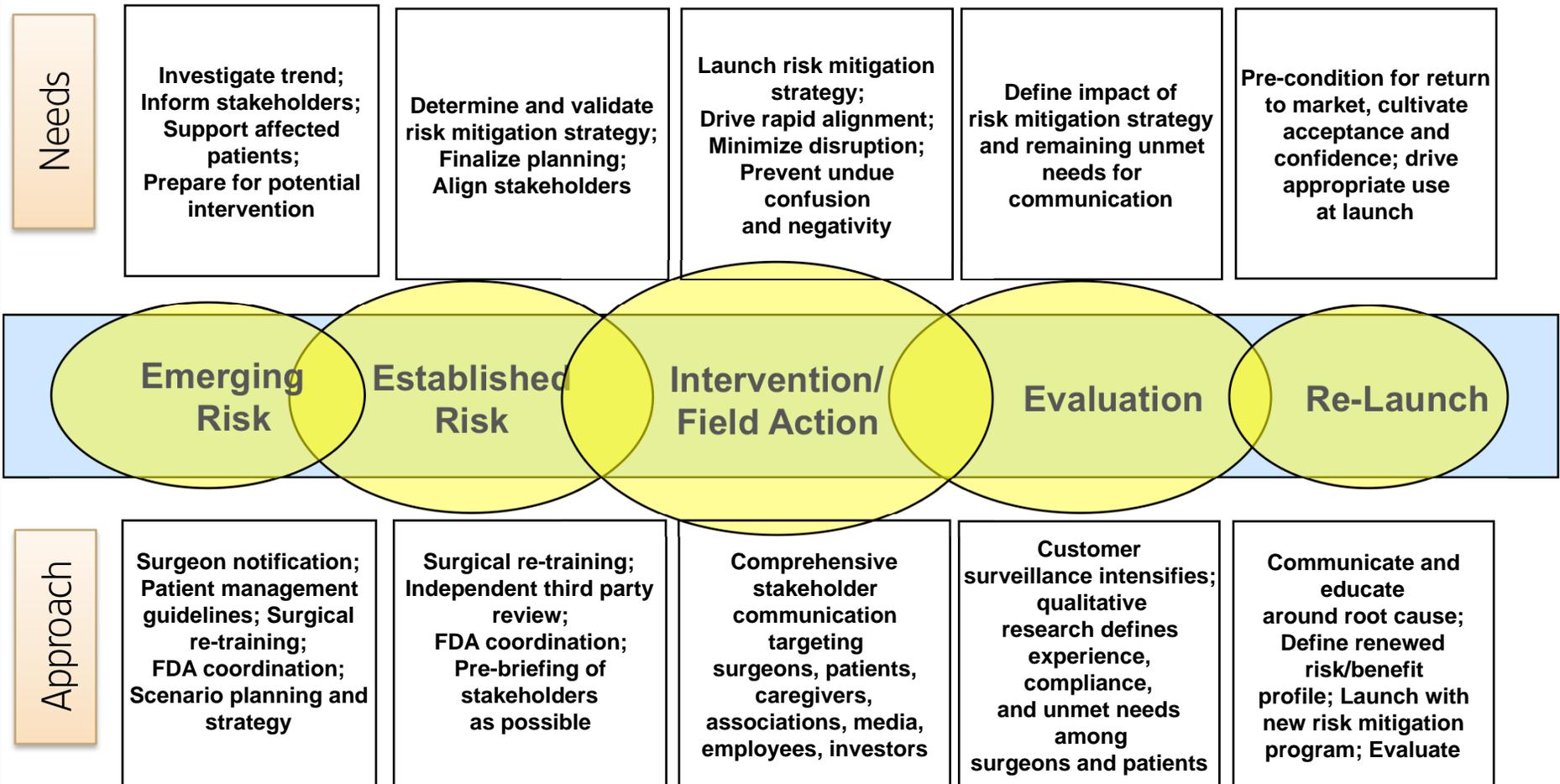
- Root cause analysis determines that a subset of patients who can be clearly identified are contraindicated for this device, based on certain physiological characteristics.
- With effective communication and education, the manufacturer hopes to re-introduce the device, because it addresses a significant unmet medical need.
- The manufacturer endeavors to advance knowledge and practice in risk management and communication, to improve clinical outcomes in affected patient population.



Special Communications Considerations

- This company is a market leader and well respected, but has experienced several recent product quality and corporate issues
- The media environment is intense and reflects keen interest in the subject of post-market medical device performance
- Surgeons like this device and many will be frustrated by a conservative course of action,. They also will be inconvenienced.
- The nature of the adverse event is understandably frightening to patients
- There are far greater risks associated with explantation of this device than maintaining the status quo
- This company is right minded, concerned principally with patient safety.

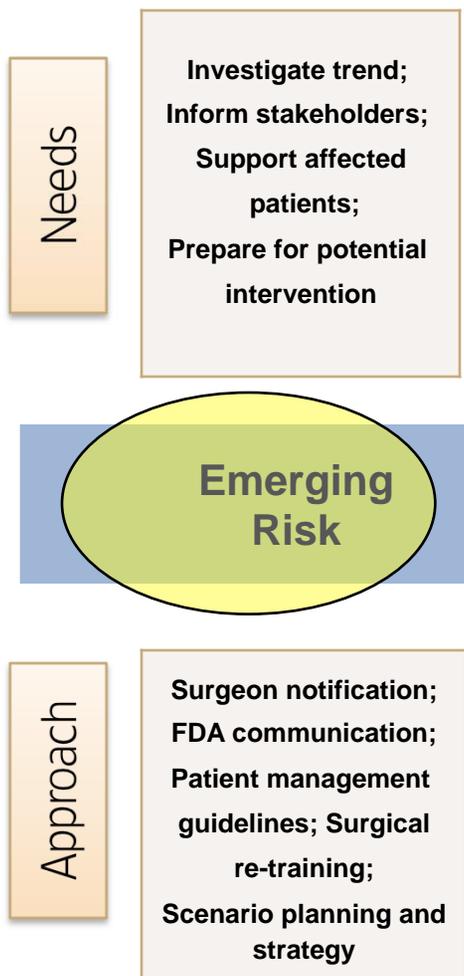
The Communications Planning Continuum



Urgency, speed, scope, needs of multiple audiences create a significant risk communication challenge in the acute phase

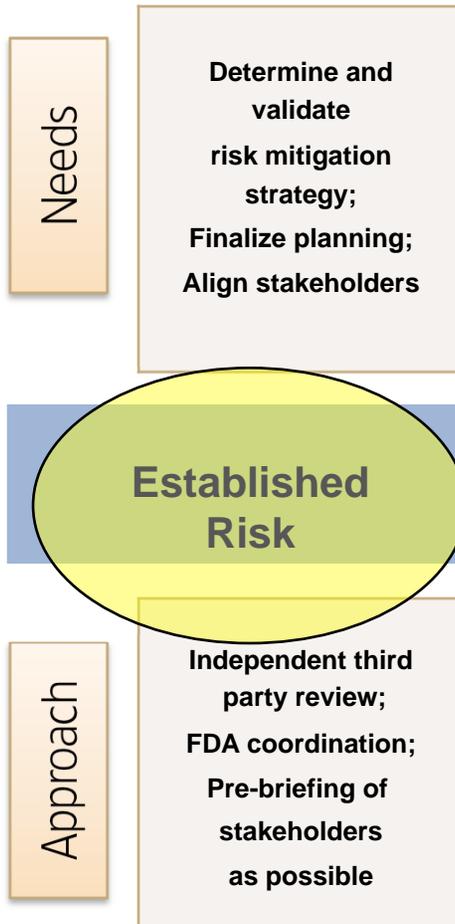


Emerging and Uncertain Risk



- FDA advised of investigation
- Letter to surgeons advises of adverse events, onset of investigation as well as patient monitoring and management considerations
- Medical affairs and communications teams map potential trajectory and initiate strategy and message formation
 - Mining existing knowledge and insights about needs of target audiences
 - Seizing opportunity to gain additional insights through stakeholder consultation and some qualitative research

Established Risk



- Investigation concludes
- Results point to several potential solutions
- Company reviews findings and potential risk mitigation strategies with expert external panel
- Decision to implement a recall/ withdrawal is finalized
- Communications plan is finalized almost simultaneously and systems are initiated
 - Materials, global communications networks, spokesperson preparation, call centers, select stakeholder engagement
- Comprehensive plan is reviewed with FDA

Intervention/Field Action

Needs

Launch risk mitigation strategy;
Drive rapid alignment;
Minimize disruption;
Prevent undue confusion and negativity

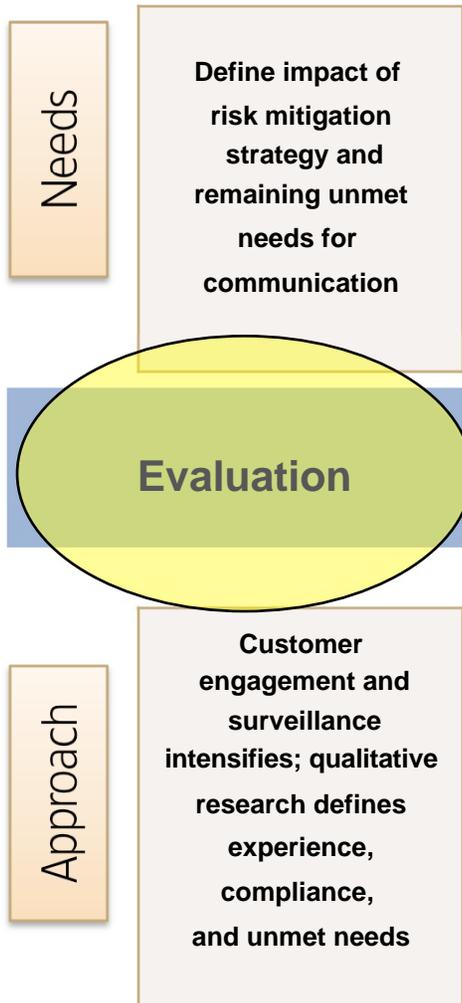
**Intervention/
Field Action**

Approach

Comprehensive stakeholder communication targeting surgeons, patients, caregivers, associations, media, employees, investors

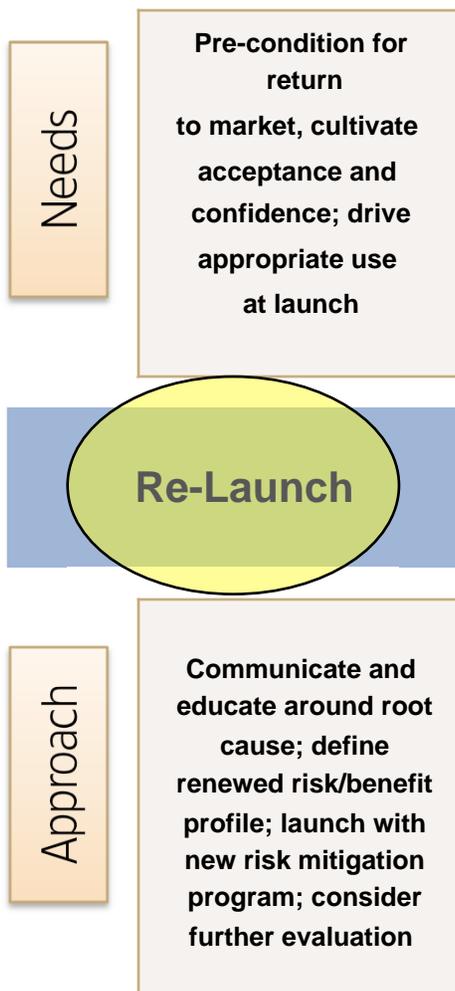
- Company announces field action
- Announcement strategy is highly coordinated with Agency to preempt confusion or mixed message
 - FDA mobilizes its own appropriate risk communication vehicles
- Day 1 communications:
 - Surgeon letter with patient communication guidelines (overnight)
 - Post-market press release (evening before)
 - 8 am investor call, followed by media briefing
 - Third party letters/ email alerts
 - Launch of consumer hotline
 - Individual briefings of key stakeholders,
 - Further targeted media outreach
 - Special employee announcement
 - Field force preparation and training
- Customer-facing surveillance systems expand and intensify

Evaluation



- Networks of clinical, sales and marketing teams reach out to touch just about every customer
- External expert advisory teams are expanded and convened with greater frequency
- Market research is fielded to evaluate systems, process, impact and unmet needs of surgeons and patients
- Gap analysis helps improve knowledge, current and future practice

Re-Launch



- Findings of root cause analysis are thoroughly communicated to regulators, customers and patients
- Data is analyzed to define relative risk/benefit in new target population
- Through stakeholder engagement, Company explores rationale and support for re-introduction
 - Demonstrating need and risk tolerance
- Company develops and launches new surveillance and risk management program
 - Intensifies monitoring; establishes registry
 - Creates risk communication demonstration project to advance knowledge and practice
 - Provides support to physicians and patients in treatment decision making, effective communication of risks and benefits, ongoing clinical management

A Few Reflections on This Case

- Effective communication strategy begins far ‘upstream’ as emerging risks are identified
- It’s important to build the knowledge, systems, networks of expertise before you need them in an urgent situation
- Effective crisis and risk communication is essential at the time of an urgent risk event, but often the work that immediately follows is central to an improved or desired outcome
 - A time when the most thoughtful work can be done
- Stakeholder engagement, coordination and participation in formative and implementation phases is central to success
- When all strategy flows from a primary concern for the patient, decisions and implementation take rapid shape

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