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"Happy Trials to You"

## The 10 Essential Steps for Crisis Management

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Crises are common in clinical research. Leaving aside global catastrophes like the COVID-19 pandemic, there can be fires, floods, earthquakes, Internet security breaches, regulatory inspections and violations, scientific misconduct, study participant deaths, loss of key personnel, study cancellations, computer and other technology failures, financial shortfalls, litigation, supply-chain disruptions, etc. Positive events like an acquisition, a new product launch, or a surge in customer demand can also require the tools of crisis management.

Dealing with a crisis is a lot like management in normal times except the timeline is highly compressed and mistakes may be permanent. While the nature and scope of crises vary widely, the basic approach to managing them includes the following 10 steps:

- 1. Be prepared. Identify risks. Create and maintain contingency plans and emergency resources. Read a book about crisis management.
- Identify a leader, experts to handle specific roles, management decision-makers, and stakeholders who must be informed before the general public. Team members may need to give their full attention to the crisis, so others may have to take over their regular responsibilities. Everyone must be at the top of their game, even under the most trying circumstances.
- 3. Develop an aggressive but realistic crisis management plan, identifying strengths, weaknesses, opportunities, threats, risks, objectives, a course of action and who will be responsible for what.
- 4. Within the time available, consider your options carefully and then act decisively and courageously. Certain results are the priority, but it may be necessary to take some risks. Beware of half-measures that will look ineffectual or uncaring at that time or in hindsight. It might be time to spare no expense. Think Johnson & Johnson's management of the Tylenol poisoning crisis in 1982.
- 5. Communicate clearly, ethically and regularly with team members, management decision-makers, stakeholders, employees and the public. Communicate confidence without sugarcoating or downplaying bad news. Be honest and transparent; do not "spin" or conceal the facts. Be clear about the risks so nobody is caught by surprise. As quickly as possible, make an initial, brief announcement so people know the crisis has your full attention. As soon as practical, make a comprehensive announcement that sets a baseline for bad news so that future announcements will be good news in comparison. People will want to know that you are on top of the situation, will act decisively and place a high priority on protecting their not your interests. Provide periodic progress reports. Think Winston Churchill in World War II:

"We shall defend our island, whatever the cost may be, we shall fight on the beaches, we shall fight on the landing grounds, we shall fight in the fields and in the streets, we shall fight in the hills; we shall never surrender."

"In these sorrowful hours I think of the unhappy refugees who, in utter distress, flee along the roads. I express to them my compassion and my solicitude."

"We have become the sole champions now in arms to defend the world's cause. We shall do our best to be worthy of that high honor. We shall defend our island, and, with the British Empire around us, we shall fight on unconquerable until the curse of Hitler is lifted from the brows of men."

- 6. Create a secure "war room" that makes crisis-related documents easily available to the crisis management team, as required.
- 7. Monitor progress and efficiently deal with new developments.
- 8. Respect your privacy, confidentiality and other legal and ethical obligations, but a crisis is not the best time to be ultraconservative. Ask your attorneys, "how can we?" instead of "can we?" When someone's health or life is at stake, that is usually the highest priority.
- 9. Remember that a crisis is a high-visibility opportunity for inspirational leadership that can turn a disaster into a triumph. Prove you care about your employees, customers, study participants, etc. and that you will move heaven and earth to protect their interests. Use the crisis to forge your team under fire. Find ways to replace obsolete policies and practices.
- 10. Collect "lessons learned" and use them to update your contingency plans for the next crisis.

## Reference

"Chicago Tylenol murders," Wikipedia.

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