

### *Protocol Deviation #1: A Scary Finger Cut in the Lab*

A few years ago while working in the lab, I attempted to grab a bottle of solution from a shelf. As I absentmindedly reached for the bottle, I felt a nasty pain and saw a tear in my latex glove with blood oozing from it. My gloved hand had brushed a broken glass pipette that was taped to and hanging from the shelf above.

Back then, I was very anxious about my productivity and whether the PI approved my work (and me). So, maybe not surprisingly, my first reaction was, “The PI is going to fire me! How clumsy can I be?” But then I really got scared as the research I do involves a host of blood born viruses. I looked at the pipette shard and noticed that it was caked with dried blood. Blood on that pipette might have entered my system. So I ran to the sink to clean my hands, following the biosafety protocol of a fifteen minute wash. At some point, a postdoc came along and asked me what happened.

I thought about making up a story because what is supposed to happen in a case like this is that I would go to Employee Health and get checked out and then report the incident. That report would trigger a lab inspection from the Office of Biosafety. But at that moment, as I stood over the sink feeling awful about this entire situation, the thought of bringing the Office of Biosafety down on the lab was the last thing I wanted to have happen.

As things turned out, all of my anxieties were unfounded. I did tell the PI what happened and, to my enormous relief, he was extremely concerned about my safety and just as upset about the obvious safety violation. He insisted the incident be reported to the Office of Biosafety. He then used that report to educate lab employees about the importance of protocol compliance.

In the months that followed, I discussed the incident with some of my peers. Interestingly, some of them immediately resonated with my fears about bringing an inspection down on the lab. I was fortunate to have a PI who invited the inspection without hesitation and made sure the rest of the lab workers learned something from it. But perhaps not all PIs would react the same way. I’m also concerned that had I not spoken up (and I was sorely tempted not to) about the protocol violation—*imagine, a pipette shard with dried and probably infected blood being taped to and hanging from a shelf!*—those kinds of lapses would continue.

Why do these temptations to keep silent exist, resulting in unsafe environments remaining unsafe? Why did a number of my colleagues share my anxiety over reporting this (with a couple even saying they wouldn’t have reported it)? Please comment.

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### *Protocol Deviation #2: I Should Have Spoken Up*

Some years ago when I was an undergraduate, I worked in a mouse lab. The euthanasia protocol was to place the mouse in a carbon dioxide chamber for five minutes and then take blood and organ samples. But the technician I worked with told me when I started that the mice usually died before the five minutes were up. His method was to remove the mouse after about three minutes and poke it to see if it would respond. When it didn’t, he’d start extracting blood. Unfortunately, the fifth or so mouse we did woke up when we inserted the needle and

started screaming. The tech immediately broke its neck and no one other than me knew about it. And that was the last time we euthanized a mouse for only three minutes.

However, at our next lab meeting, the PI scolded us for a recent and very disturbing occurrence. A few days before the meeting, one of the graduate students had found a mouse alive in the refrigerator where the mouse carcasses were stored. The PI told us that this was a huge problem requiring a number of experiments to be redone; that an investigation should be conducted; and that the individual who was responsible for this should either come forward or be identified.

I always wondered if my lab tech was the guilty party. But at least five other persons in the lab could have done it too. In any event, an investigation was never conducted. I was never asked if I knew anything. And I never came forward to say what I knew. My feelings at the time were that if the tech lost his job, he would be broke and I knew he already had financial difficulties. I also thought he had learned his lesson.

But even now, years later, I still feel guilty over not having said anything. I often wonder what I would have done if I was directly asked about what I knew. Was I right to protect the technician? In fact, and as I learned later, had certain people in research administration or leadership found out about any of this, my PI could have been in serious trouble for not reporting the incident.

Please comment.

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### *Expert Opinion*

After they are discovered and their harm-causing if not disastrous impact becomes abundantly apparent, protocol deviations often seem unfathomable. Thus, in Protocol Deviation #1, the deviation beggars belief: Someone has taped a glass shard containing encrusted, possibly virally infected, blood to a laboratory shelf.

Yet, sociologists tell us that system operators, such as laboratory personnel, usually have reasons that, at least to them, justify their deviant behaviors.<sup>1</sup> A good example is protocol deviation #2, where the more experienced lab technician has found that three rather than five minutes are sufficient to euthanize a mouse. Why waste an additional 2 minutes? The rule is inefficient. Why follow it?

Research protocols—or rules, regulations, policies, standards of care and other required behaviors—generally exist to promote the safety of the involved parties, to insure that experimental results are valid and reliable, and to protect the integrity of research institutions. They are violated usually not for devious or maleficent reasons, but because 1) system operators are pressured to perform, 2) the rules strike them as counterintuitive, a drain on efficiency, or counter-productive, 3) system personnel don't know the rules or appreciate why they exist, or 4) they believe that the rules don't apply to them and that they have a better way.<sup>2-4</sup>

Ultimately, protocol deviations occur because they are allowed to occur. Given the above-listed reasons for protocol deviations, we suggest that there are proactive and reactive approaches that can reduce their incidence. The proactive response is to deliver more robust protocol instructions—to explain both what those instructions and why they exist. For

example, if the “what” (dispose of glass shards in this way, euthanize mice by a full five-minute exposure) were explained together with the “why” (dangerous exposure to a glass shard may shut down the lab, result in a biosafety investigation, and cost far more than the time and effort to dispose of the glass shard; attempts to euthanize mice by shorter exposure may result in some live mice, an animal use committee investigation, the loss of experimental results, and cost far more than the time and effort of engaging in the full five-minute euthanization procedure), system operators might be much more protocol compliant.

Nevertheless and regardless of the most robust proactive efforts, protocol deviations will occur, so it is essential to devise reactive approaches that also contribute to minimizing the future incidence of these deviations. Biosafety research indicates personnel often know about rules or protocol deviations (and their deviators) but—not surprisingly—opt not to call attention to them. The most prominent reason is that persons fear retaliation, either from the organization or from the individuals they identify as protocol violators.<sup>2</sup> Collegiality or, at least, not “rocking the boat” is an immensely important value in group work, so that the employee who calls a foul on co-workers seems to violate the *esprit de corps*. Thus, as in Protocol Deviation #2, there is the fear that an employee accused of violating protocols might experience a serious, perhaps career-ending penalty, not to mention the psychological trauma such an event would have on the rest of the staff. Furthermore, it is natural for the individual whose task performance is called into question to respond defensively, which sometimes takes the form of accusing the accuser(s) of incompetence, malevolence, deviousness, sabotage, or jealousy.<sup>3</sup>

Oftentimes, as in Protocol Deviation #1, the employee who considers calling attention to a protocol deviation realizes that his or her accusation will trigger some kind of official investigation, which can be very uncomfortable to the individual’s colleagues, not to mention his or her immediate supervisor. Interestingly, the dilemma contributor of Protocol Deviation #1 was so anxious in the lab that his or her first response to the injury was not righteous indignation over its actual, protocol-deviation cause, but that the injury was his or her fault. Yet, this is not a surprising response, especially from newly-hired beginners, who are often painfully aware of their lack of experience and acutely concerned about being accepted and respected by their peers.<sup>5</sup>

Consequently, if protocol deviations endure in professionals’ behaviors but only become matters of grave concern when disasters occur, it behooves organizations to evolve strategies that effectively identify and eliminate unacceptable protocol deviations before they allow mishaps to materialize. But this would mean that organizations are able to create work atmospheres that are keenly vigilant about the existence of protocol deviations and aware of the barriers to speaking up about them.

As was mentioned above, employees generally do not deviate from protocols because they are lazy, careless, or evil. Presumably, whoever hung the shard of glass from the lab shelf in Protocol Deviation #1 hardly intended to harm a colleague, while we see that the lab technician in Protocol Deviation #2 believes that the official protocol wastes time. The organizational lesson to take from these examples is that the oftentimes popular, knee-jerk response of penalizing rule violators is not a good idea.<sup>4</sup>

A better one is to evolve an organizational understanding of protocol deviations as *inevitable*. Humans in work situations frequently seek easier ways of accomplishing tasks; they

also like to experiment with different ways of doing things; and, as mentioned above, they might not know the rules or protocols, possibly because they weren't taught them in the first place.

A corporate or lab policy that seeks first to *understand* why a protocol was violated is the best, initial response.<sup>6</sup> Upon learning what the protocol violator's rationale was and what variables were present that influenced his or her protocol deviation, an organization can then take action—which can be anything from agreeing that the violator's deviation is an improvement on the extant protocol (and so should replace it) to dismissing the protocol violator for reckless and egregious behavior. Because protocol violations are profoundly contextual and can run the gamut from benign to outrageous, we cannot elaborate on what form and gravity penalties, if any, should take. We do point out, however, that protocol deviations that have become normalized or “routinized,” i.e., that are going to replace the research methodology that was originally articulated, must be reported to an IRB in case of human subjects research or an animal use committee in case of animal research as an amendment to the original protocol.

Before a protocol deviation becomes normalized, however, labs should inculcate an expectation among their personnel that anyone spotting another's protocol deviation should speak to the (deviating) individual or to a supervisor, so as to consider whether or not its degree of deviance is acceptable or not.<sup>7-9</sup> Unfortunately, however, such “consideration” will depend on the judgment, experience, and discernment of the individuals involved, which might be inadequate to the task. Thus, in Protocol Deviation #2, the lab technician believed that decreasing the euthanasia process from 5 to 3 minutes was entirely reasonable, until that proved wrong. This underlines a profoundly upsetting aspect of protocol (or any kind of rule or standard) deviation: As noted above, protocols are usually in place for good reasons that might nevertheless be unknown to system operators. Very possibly, stipulating that the original euthanasia protocol in the second example was to last five minutes was based precisely on the experience of an animal's having survived a euthanasia attempt lasting less. Had the researchers in the second example known that, one would think that neither would have considered lessening the time of the euthanasia process. But if a system operator has not received proactive instructions, detailing both the above-mentioned “what” and the “why” of their existence, and has never experienced or had personal knowledge of “the edge of the hazard envelope,” his or her evaluation of “acceptable risk” may well be faulty, as the second example illustrates. Furthermore, a PI who comes upon knowledge of the protocol deviation in example #2 should very much consider one consequence of failing to report it: *Should the protocol deviation ever be discovered by others, the lab could easily be subject to an investigation over accusations of animal torture.*

Even the smallest, apparently most benign protocol deviation might merit some form of systematic review.<sup>2</sup> But in order for that to happen, system operators will need to feel comfortable in speaking up. They will need to feel confident that no retaliation will result and that their action will be supported by leadership—indeed, that leadership expects such “speaking up” rather than maintaining silence.<sup>7-9</sup>

An important skill that all lab personnel should develop is learning communication techniques around “speaking up behaviors.” Because it is often unpleasant to conduct such conversations, we have included a short list of items in Table 1 that might get such

conversations off to a good start. As they proceed, however, it is extremely important to maintain the distinction between the deviant behavior from the (presumably nondeviant) individual. As a minister once put it, “I love the sinner, but I hate the sin.” The lab (or corporation) that maintains that distinction will go far in creating a climate where employees might find protocol deviations a provocative learning opportunity rather than acts performed clandestinely to save time or toil.

Leaders must model the kinds of behaviors that enable speaking up. Again, these include a prima facie, nonpenalizing/nonretaliatory response to protocol violations, understanding that protocol violations are inevitable, constructing learning opportunities around them, and disseminating an organizational expectation that everyone in the lab will be vigilant about and take corrective action towards problematic behaviors.<sup>2</sup> Reducing protocol violations will make for better science and improved working conditions. While the risk management process involved in protocol deviations is hardly simple and never-ending, the end results surely argue for its importance.

Table 1: Helpful things to say in conducting difficult conversations around protocol deviations:

- “I’m sure you don’t realize this but...”
- “You are very important to this organization.”
- “I could be wrong here.”
- “Can I explain what I’m seeing and get your point of view?”
- “Right now, the way you do X would be considered risky or a departure from the standard of care” (focus on safety, not competence)
- “I value our friendship/relationship, and I want us to be honest with one another.”
- “My understanding is X, is that yours?”
- “What do you think can be done about this?”
- “I don’t mean to make you uncomfortable but when I bring up a concern, I see you tense up. Sometimes you cut me off or jump in with a disagreement. I think you stop listening and begin defending. You may not realize how you’re coming across, but that’s how it appears to me and others. Do you realize you’re doing that?”<sup>7-9</sup>

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