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The Ethics of Simulation

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I. Bios

Dr. Smith started working with Standardized Patients in the 1990's. She helped develop a SP program for medical students and has been involved in simulation at all levels of medical education from high school students to senior health care providers. She understands the importance of ethical practice in teaching and assessment and is a champion for teaching ethics in medical education.

Dr. Lammers started working in clinical ethics in 1982. He helped develop the ethics program at Lehigh Valley Health Network. He is the co-editor of a standard work in medical ethics. His recent research has focused on ethics education for medical students and medical residents.

II. Case 1

Wednesday afternoon in the simulation center learners are practicing their lumbar puncture skills on a partial task trainer. They practice and are checked off on the skill and now feel confident to perform a lumbar puncture on a patient. A month after learning how to perform a lumbar puncture, a resident had his first opportunity on a "real" patient. The resident cleaned the site and prepared for the procedure and noticed it looked and felt different than what he remembered when he was learning. The resident was uncertain about what to do. What the learner did not know was that the task trainer he practiced with had been used many times, was old and worn but due to budget cuts and turnover in staff was not replaced.

III. Abstract

Simulation begins in response to three ethical imperatives: keep patients, learners and faculty safe; prevent errors; and facilitate engaged learning. This chapter reviews the central ethical issues involved in responding to those imperatives. Important is the safety, physical and

psychological, of all participants, the careful use of resources, well planned prebriefing and debriefing and full explanations of the purpose(s) of the planned simulations. If research is involved, a full consent of all participants is required. Many of the ethical issues that are found in healthcare in general are found as well in the practices of simulation.

IV. Introduction and Background

Simulation begins with an important moral claim: we must do the best we can to keep patients safe while training the next generation of clinicians and retraining current clinicians so that they are kept up-to-date. If we can introduce clinicians to patients when these clinicians have more “experience” with quasi-patients of a wide variety, we lessen the chances that vulnerable patients will be harmed. Ethics is not an add-on to simulation; an ethical claim drives the practices of simulation themselves.

Thus simulation is situated inside of healthcare, not alongside or outside of it. The practices of simulation in healthcare share many of the same ethical challenges and opportunities that are found in healthcare itself, and the ethics of simulation should be discussed within the context of the larger healthcare systems within which the practices of simulation are situated. Not only questions of informed consent, not only questions of research, but also issues of justice arise. These latter questions can be as broad as “Is this the wisest use of our limited resources?” or as focused as “Do our standardized patients have health insurance as part of their compensation?” (1).

By now it should be clear that ethical questions run throughout most of the topics in this book. There are questions specific to management, education, research, the use(s) of technology, and even the types of simulations.

This chapter will focus on some of the general issues in ethics in and of simulation. As

we proceed, we will point to questions that might be specific to a particular area of simulation. The effort here, however, is to introduce some general questions so that the simulation educator will be prepared for the specific questions that might arise. We hope to introduce a way of seeing what happens in simulation in light of the ethical imperatives that give rise to simulation in the first place. In this fashion the educator is prepared to raise and address new questions that might arise, in whatever area of simulation the educator finds her/himself involved.

Questions of ethics are as much a matter of discovery as responding to well-rehearsed norms. Questions need to be appropriate to the matter at hand, and the search for answers should respect the dignity of all the participants. As we shall see, these are challenging tasks. In what follows, we will rely on the Society for Simulation in Healthcare's definition of simulation. They state that the purposes of simulation in healthcare are "...education, assessment, research, and health system integration in facilitating patient safety" (2).

V. Significance

Ethics – in the literature

Why do we need to talk about ethics in simulation? It is not simply that simulation begins with the imperatives mentioned above. It is also the fact that simulation raises ethical questions of its own. Clinicians will always have a first patient. What is at stake for that first patient and for that clinician? Training is critical in the preparation of clinicians prior to that first "real" experience. That training is not simply technical. It is also a way to learn and practice collaboration through team training, interpersonal, interprofessional and decision making skills and not incidentally an opportunity for training in the ethics of the various healthcare professions.

Ziv, Wolpe, Small and Glick (3) discuss the conflicting needs to insure patient safety and

to learn with “real” patients. The questions of clinician competence and patient safety provide the context for the discussion of simulation. Because simulation is one method to train clinicians and to provide a level of competence prior to direct patient care the question is: Is it ethical not to use simulation in education and assessment?

As we shall see, these same questions frame the discussion of the various issues within the practices of simulation themselves. Keeping our attention on these questions keeps us from being distracted by other considerations that, while important, are not central to the matters at hand.

Healthcare Ethics

Anglo-American healthcare ethics is marked by attention to questions of patient autonomy and choice. Other perspectives often raise questions of justice first and in this chapter we have tried to be sensitive to these perspectives. In the American context, questions of autonomy can become important, especially when research is being done. Simulation, however, more directly raises questions of beneficence, doing good for the patient, and non-maleficence, preventing harm to the patient (4). These two concerns will be reiterated often during this chapter. One thing we would add is that it is also important to prevent harm, not only to the patient, but to all individuals involved with simulation, including staff, faculty and standardized patients.

Simulation (including Technology, Standardized Patients, Unannounced Standardized Patients)

Simulation in healthcare is delivered in many different ways; from low tech to high tech, from resource ‘lite’ to resource intense. Simulations can be delivered with high fidelity equipment, human simulators, standardized patients, and virtual reality. The methods can also

be combined to deliver hybrid simulations. Simulations also occur in various settings from large simulation centers, classrooms, the clinical environment, as well as the virtual environment. The ways simulation is delivered should be based on the goals and objectives of the program and the resources available.

What are the ethical considerations when developing a simulation activity? As we have stated, patient safety and clinical needs come first. After that, we believe the considerations include thinking of the resources, including the human resources (manpower) to conduct simulations. Those human resources include those needed for planning, execution, and review. Just because a simulation center or institution has high priced simulators, mannequins and equipment, this does not mean it is always the best or most effective way to provide learning and assessment. It is one way and there may be other more cost/time efficient methods to achieve the same goals.

Let's return to Case 1. It has become standard practice to train clinicians using mannequins and partial task trainers. We know that practice with simulation, deliberate practice with feedback and debriefing, improves performance. How close to reality are the experiences of practicing with mannequins and task trainers? Do learners have a false sense of confidence after they have simulated education? Can the mannequins and task trainers simulate the differences in the individual body composition of "real" patients? There is always the possibility that technical issues may arise when using high fidelity mannequins. These issues will have an impact on the realism which will impact the learning. The key element is to stay focused on the learning objectives.

Technology (High-, Low-, Mid-). When developing educational and assessment activities it is important to determine the learning objectives and outcomes and then determine whether

simulation is the appropriate method to achieve the outcome. For example, it is usually not appropriate to place a novice learner in a high-technology simulation with many tasks. A novice learner needs to learn one task at a time before applying that learning in a high-technology simulation (5).

There are different levels of fidelity from high cost, high technology computer controlled life-like mannequins to low fidelity inanimate mannequins and paper cases. High fidelity simulations have a high degree of realism but it has to be asked “Is this always necessary?

Resource questions persist at all levels. If a center has high fidelity mannequins do they have the resources to maintain the use of the mannequins, the human resources necessary to program and run the simulation as well as the supplies and replacement skins needed for ongoing simulations (5,6)?

Standardized Patients. “Standardized/Simulated Patients are individuals who are trained to portray a patient with a specific condition in a realistic, standardized and repeatable way (where portrayal/presentation varies based only on learner performance). Standardized patients can be used for teaching and assessment of learners including but not limited to history/consultation, physical examination and other clinical skills in simulated clinical environments. Standardized patients can also be used to give feedback and evaluate student performance” (7).

What are the ethical considerations when using SPs? There needs to be a thoughtful standard process in recruiting and hiring SPs. It is important to determine why an individual wants to work as a SP. Is it because they want to “fix” the system? Did they have a bad experience? Do the SPs have a history that might make them inappropriate for certain cases? It is the program’s responsibility to recruit appropriate individuals and assign them to appropriate

cases. A discussion of psychological harm to SPs and how to prevent this harm will be addressed later in this chapter.

Unannounced Standardized Patients. Standardized patients who are trained to portray a patient, family member, or healthcare provider and enter the clinical environment unannounced to assess the providers interaction with patients or the system are referred to in the literature as unannounced standardized patients (USPs), incognito standardized patients (ISPs), invisible patients, fake patients, secret shoppers and mystery shoppers (8-10). We will refer to all of these as USPs. We prefer using the term unannounced versus the potentially negative connotation associated with secret, or mystery, or fake.

Why USPs? One of the central questions surrounding simulation is: Does the training and assessment in a simulated setting transfer to “real” patient care? One way of assessing the transferability of skills is to employ USPs. Using unannounced standardized patients is the only choice for many to observe patient-clinician communication. There are ethical issues to consider when deciding to use USPs. Is using unannounced standardized patients deceptive? There are differing opinions.

There was objection by physicians when the Department of Health and Human Services wanted to use mystery shoppers to study the access to primary care (11). The Emergency Nurses Association and the American Academy of Emergency Medicine (2007) (12) released a statement that they believe that using mystery shoppers in the Emergency Department is “not only dangerous and detrimental to quality care, but unnecessary since other more effective, less intrusive methods exist.” Less intrusive methods include customer satisfaction surveys and direct observations. Unannounced standardized patients are a way of testing two things, first, whether certain classes of persons have access to the system and second, what kind of care

persons who do obtain access receive. Those two matters do not have to be addressed in the same fashion, however. Research on access to care, as long as confidentiality is maintained, is relatively non-invasive and the most reliable results come when persons are not informed that research is being done (11). The second practice, using USPs to determine the quality of care that patients receive, needs not only the protections of confidentiality but the consent of the clinicians who are being observed. Siminoff et al. (2011) (10) argue that using USPs is the only technique to observe how the clinician interacts with the patient in the “real” environment and that this cannot be replicated with other methods. Observing clinicians with “real” patients is valuable, but provides no standardization since each “real” patient comes with their individual history and problems. Pott (2008) (8) refers to the invisible patient to assess learners in the clinical environment without the learner knowing the patient is actually a standardized patient. He states that this type of assessment is worth the effort and resources.

Successful unannounced standardized patient programs rely on flexibility and planning. Patient care always takes precedence and there are times when the unannounced activity needs to be postponed or rescheduled so as to not interfere with direct patient care. Planning an unannounced simulation involves discussions with stakeholders who may be involved including; triage, registration, and medical records. It is important to decide if a “dummy” medical record needs to be developed and how it will be implemented during the session and deleted after (10).

It is a challenge to notify providers in such a way as to not bias the results of the simulation. Consent is always an issue, however. At the end of a simulation in the Simulation Center or in another venue learners can be told that within the next “n” months they will be visited by an unannounced standardized patient in the clinical setting.

Will providing an unannounced standardized patient program in the clinical setting

improve practice habits? We believe that if there is effective feedback and debriefing after the session that practice habits will be improved. Miller (1990) (13) created a four level framework to assess clinical skills, competence and performance. The pyramid begins with the knowledge base (knows), moving to knowing how to perform a skill (competence), followed by performing the skill in simulation (shows how) and ultimately doing the skill in practice (action). This method provides a way for clinicians to demonstrate the top of Miller's pyramid, the action or performing the skill in the clinical setting and we can then measure if what is performed and shown in simulation transfers to the "real setting" (13).

Simulation Center versus In Situ

Simulation-based activities can be conducted in simulation centers or in the clinical environment (in situ). In situ simulation brings the simulation learning and training to the clinical environment in which the learners work versus taking the learners out of their work environment and taking them to a simulation center. In situ simulation is conducted in actual patient care areas using resources and actual members of the healthcare team (14).

The reason for selecting location for the simulation activity should be based on the objective of the activity. Simulation centers provide training to students, new trainees and healthcare providers where in situ simulation activities include practicing clinicians usually from different disciplines and professions. A systematic review by Rosen, Hunt, Provonost, Federowicz, and Weaver (2012) (15) found that in situ activities included multiple units, departments and clinicians from different professions. Programs are using in situ simulation to identify latent safety threats and results are showing that conducting in situ simulation with the purpose of identifying safety threats improves the safety climate in high risk clinical settings (14,16).

There are advantages and disadvantages with in-situ simulation. Patterson, Blike and Nadkarni (2008) (17) in “Advances in Patient Safety: New Directions and Alternative Approaches”, describe the challenges and benefits of in situ simulation.

Benefits. In situ simulation provides the opportunity to learn in context, for situated learning and for training where you work. Benefits of in situ simulation include identifying systems issues within a particular context as well as knowledge gaps.

Systems integration is another potential benefit. Simulation-based activities can be used to test new facilities, equipment and processes (2, 17, 18).

Challenges. There are as many challenges as benefits to conducting in situ simulation. Being aware of the challenges and planning for them will provide the opportunity to conduct in situ simulation and reap the benefits of this type of training (19).

Miller, Crandall, Washington and McLaughlin (2012) (20) studied in situ trauma simulations and observed an improvement in teamwork and communication during the simulation but it was not sustained. In situ training requires resources including faculty time. Training needs to be ongoing.

Patterson et al., (2008) (17) identify four areas of challenges in conducting in situ simulations (“technical issues, logistics, cultural obstacles, and medical-legal concerns”). As should be clear by now we would add the use of resources. Technical issues include transportation, set-up, and storage of simulators. If you use supplies on the unit, what is the cost and how do they get replaced?

Logistics. In situ simulation-based activities need to be made available to all shifts, including nights and weekends. Patients need to be kept safe 24/7. Questions to ask include: When are staff available? When is the equipment and space available? One of the greatest

challenges is finding time that is not too disruptive to patient care (17, 20, 21).

Clinicians are concerned about taking time away from actual patient care and are concerned about what patients and families will think of this activity taking time from their care. They are concerned that this would be stressful for families. Cincinnati Children's Hospital Medical Center and the Children's Hospital of Philadelphia asked patients and families their perception of training in patient care areas. Responses included that the patients and families were glad that the clinicians were practicing and that the time waiting was not significant. If the simulation time is brief, the perception is that it is worth the wait (17). Patients and families need to be told the why and what of the simulation. The explanation helps with the perception being positive, ongoing training versus a negative perception that their trusted providers make mistakes (17). If patient safety is to continue to be a driving factor in simulation, in situ activities must always be considered, since those activities have seem to have a higher probability of revealing problems in the delivery of patient care in today's healthcare environment.

Recording Simulations

The most important question to be asked is: What is the purpose of the recording? How are the recordings used? Are they being recorded for both formative and summative assessments? Are they for debriefing and for the learners to review or are they for research? Students cannot opt out of being recorded for educational purposes. They can opt out for research purposes.

How long and in what setting are the recordings stored? Recordings need to be kept in a secure location. Students often worry that the recordings will show up on the internet. Anyone being recorded needs to know why they are being recorded, how the recordings will be used and

how they will be stored.

When SP encounters are recorded SPs should have the opportunity to view and reflect and be provided feedback on their performance. Recordings can also be used for training. All participants being recorded should sign a release or consent to be filmed. That release should include a date by which the recording will be destroyed. There is no standard best practice concerning the timeframe to destroy the recordings. Some programs keep the recordings indefinitely and other programs destroy immediately after viewing the recording. The decision should be based on the purpose of the recording. If a clinician is being recorded for remediation purposes, this recording may need to be kept longer for legal and ethical issues versus a recording of a clinician in a formative learning encounter. The temptation will be to hold on to these recordings for as long as possible. Simulation center directors should resist these temptations. Given the changing pace of health care, shorter rather than longer time frames should always be considered. Whatever time is chosen, steps should be put into place so that the promised destruction takes place as promised.

Simulation in Support of Ethics

Simulation is not a set of practices that serve only the technical aspects of healthcare. Simulations can be used in the service of education in professionalism and ethics themselves. The imaginations of the simulation providers and the ethics and professionalism educators and the availability of resources are the major constraints. For example, Vanlaere, Timmermann, Stevens, and Gastmans (2012) (22) designed a simulation exercise to foster empathy in nurses. Participants became elderly patients and were treated as such through such activities as bathing, feeding, being cared for, recreation, etc. The second day of the exercise involved a debriefing of the patient participants as well as the simulated care providers. The goal was to see whether such

exercises enhanced empathy in the providers who were patients for purposes of the exercise. Among the findings was the result that at least one experience during the simulation affected the learners in a profound way. How these findings become integrated into practice remains uncertain, for both the “providers” and the simulated patients.

Such an elaborate simulation exercise is only one example of how simulation can be at the service of professionalism and ethics. A standardized patient being given bad news, a standardized patient giving informed consent to an upcoming surgery, a standardized patient expressing his fears about his rapidly approaching death, all of these scenarios can be used to help students (medical, nursing, allied health), residents (medical, nursing, pharmacy, pastoral care), as well as practicing clinicians develop the skills necessary to become excellent clinicians. Again, the issue is not whether simulation and ethics and professionalism can be of service to one another; the issue is how a particular simulation exercise serves a particular goal in the education of future clinicians.

Psychological Safety

What is psychological safety?

Gaba (2013) (23) and Truog and Meyer (2013) (24) state clearly that anyone who has a role in simulation needs to consider the psychological effects of simulation on learners and be responsible to ourselves, the learners, as well as patients and families. It is also important not only to identify the needs of the learners, but also of the standardized patients, staff and faculty.

Calhoun, Boone, Miller, and Pian-Smith (2013) (25) describe a real case that illustrates the negative consequence of not speaking up. Members of a multidisciplinary team noticed that the physician ordered the wrong medication and no one spoke up resulting in severe hypotension and bradycardia. It is the norm that clinicians work within a hierarchy and too often do not

Speak up even when they question the appropriateness of an action taken by someone in a more powerful position. This is commonplace throughout the workforce and deadly in healthcare. More and more training, such as the AHRQ TeamSTEPPS[®] program is being developed around communication and speaking up. Clinicians need to be taught the skills and allowed time to practice the skills in a safe simulated setting.

The areas with the greatest concern for psychological safety include simulations around death and dying and speaking up or challenging authority. We offer a case around the first matter before our commentary on this important matter.

Case 2

Friday morning in the simulation center an interdisciplinary team of clinicians comes together to participate in a patient safety simulation. One goal of the simulation was to assess how the team managed a trauma patient in shock. The case involved a critically ill patient that needed a number of immediate procedures for stabilization. The team provided IV fluids to the patient and moved on to the next procedure and assessment. No one monitored the patient's blood pressure to notice the patient was not responding to the fluids alone and needed blood products. A time-out was called at this point in the simulation. The patient would have died if nothing further was done to treat the septic shock.

It is important to acknowledge what effect an action or inaction will have on the patient, family and other clinicians. If the learners have the wrong diagnosis and the patient would die because of the wrong treatment this needs to be discussed and identified. Many people argue that the simulated patient should not die (26). The alternative view is that learners need to understand that every action and inaction affects the life and death of those they are treating and need to experience this in a simulated environment (27).

Psychological Harm to Learners

Simulations are stressful to students. Students experience physiological as well as psychological stress just thinking about having to perform a simulation, talk with a standardized patient, be videotaped and then receive feedback. Hulsman et al., (2010) (28) studied the physiological and psychological stress of medical students communicating with standardized patients and found an increase in heart rate, mean arterial pressure and cardiac output. Students in this study were presented two cases: history taking and delivering bad news. The students who delivered bad news first had a higher level of stress.

Simulation environments should be safe places to learn and make mistakes. Some stress is good, heightening the awareness of the situation and making an impact on the learner so if they experience a similar situation they can act effectively and efficiently. At the same time, it is imperative for learning that learners are not placed in situations where the level of stress is too high and impacts their cognitive abilities.

There is discussion within the simulation community about allowing death to be part of simulation (23, 24, 26). As with all aspects of simulation, the developers need to consider the level of the learner and the objective of the scenario. The simulation environment needs to be one that promotes trust and safety. It is appropriate to allow the mannequin to die in certain situations if the appropriate treatment was not provided. This provides the teachable moment and a learning opportunity for learners to realize the impact of their actions or inaction. The vital component in these scenarios is the prebrief and debrief. Prebriefing is important for new learners or providers with little experience with these types of cases. Debriefing is critical to highlight and reinforce the correct action as well as to discuss the emotional issues surrounding the case. If possible the schedule should allow enough time so that the case can be run a second

time using what was learned so learners can leave with a positive outcome.

Corvetto and Taekman (2013) (29) reviewed the literature to examine the issue of allowing the mannequin to die. Should mannequins only be allowed to die if that was the objective of the simulation? Or should the mannequin be allowed to die unexpectedly? The biggest concern about allowing the mannequin to die is the psychological safety of the student and their learning outcomes. Rogers, de Rooy and Bowe (2011) (27) found in their work with medical students that the death of a “patient” provided an opportunity for the students to reflect about death and how that might transfer to the real clinical setting.

Clinicians receive little training or experience in dealing with death, dying and end of life issues. Providing opportunities in a safe environment to experience these issues allows the students to practice difficult skills that they may not otherwise encounter during training. Leavy, Vanderhoff & Ravert (2011) (30) assessed student views on the benefits of participating in simulations when a patient dies and the effectiveness of the debriefing session in processing emotions. They state that students benefit in that they learn to process their anxieties and to develop coping skills.

Simulated death is an important and difficult teaching strategy for learners and faculty and “must be grounded in sound ethical principles that respect the teaching modality, promote a non-punitive culture around patient safety and interprofessional collaboration, and consider the well-being of learners” (26).

Case 3

Third year medical students are coming to the Simulation Center for an end of the year exam. One station is giving bad news to a young woman who has a recurrence of breast cancer. The standardized patient coordinator hired a number of women to portray this woman. One of

the SPs playing this role fell out of character during the session. Only later did the coordinator learn that the SP's sister, who was 38 years old with 2 small children, recently died from breast cancer.

Psychological Harm to SPs

Standardized patients are classified as another method or technique of simulation just like mannequins, and virtual reality. Standardized patients are human, however, and as humans have emotions and feelings and take on the character of the person they are portraying. This method of training and assessment provides learners an opportunity to practice communication skills on “real” people. Learners have an opportunity to practice how they would deliver bad news and review what worked and what was less than helpful for the patient and/or family. The learner has a chance to receive feedback on how the news was presented and should have an opportunity to watch a recording of their performance and reflect on how it felt and what they did well and how they might communicate differently next time.

Depending on the scenario, the SP may react with denial, tears, anger, or even yelling and may receive the news over and over allowing individual learners to present the same bad news. The SP needs to get back in character and take on the “burden” of this news for each new learner.

A key component of standardized patient work is the preparation and support when portraying a difficult or emotionally charged patient or family member. Getting into character and staying in character can be exhausting. The SP often takes on the characteristics of the individual they are portraying and they need time after the case to come out of character. It is important for someone to check in with SPs after all performances and it is most important when the SP is portraying someone receiving “bad” news, or is depressed, angry, etc. There may be SPs that are unaware that they are holding the emotions until they debrief about the experience

(31) (Please see chapter on Role Exit for more information).

What is an unexpected event when working with SPs? Refer back to Case 3, the case with the SP who became emotional during a case about breast cancer which triggered emotions about her sister who died from breast cancer. All unexpected events cannot be avoided but to minimize the occurrence SPs need to be screened for their case. When deciding which SPs should perform which cases it is key to ask about history, comfort level and confidence. Once an unexpected event occurs it is the team's responsibility to "deal" with the event and provide support to the SP. Simulation cases have the potential to trigger emotions in all of us and a plan and resources need to be in place to deal with the emotions. The emotions should be discussed during debriefing.

Taylor (2011) (1) discusses the moral commitment to avoid suffering and the aesthetic commitment to realistically portray it. Standardized patients are an important part of training because they portray suffering of another (real versus not real). When an SP portrays suffering they cannot avoid suffering at some level. One reason to use SPs is to protect actual patients from risk and suffering, yet we place SPs in a situation where they take on the suffering of another and the SP may suffer as a result of this portrayal. A mechanism needs to be in place to protect and address physical and psychological safety of all individuals involved in simulation.

Psychological Harm to Faculty

Faculty have an important role in simulation. They are not only content experts but also role models. Faculty need to feel safe in the learning/teaching environment.

Case 4

Wednesday morning the emergency medicine department sends an interdisciplinary team of students, residents and attendings to participate in Advanced Cardiovascular Life Support

(ACLS) training. Dr. S. has not been involved with ACLS workshops since 2009 and was not aware of the guideline changes.

The simulation team notices that one of the faculty members is using an older version of the ACLS algorithm. There are two issues with this case. First, the faculty member has not kept up-to-date with the current guidelines. Second, the resident has the potential problem of speaking up.

How can this be addressed without embarrassing the faculty, losing the credibility of that faculty member, and at the same time providing the most up-to-date information to everyone? Depending on when and who notices it should be noted that the algorithm has been updated and explain the updates. If possible, talking to the faculty member prior to the debriefing might provide a level of safety so they are prepared for the discussion. This having been said, this is an important issue to think through during the planning of an activity. In the “real” world, learners have to be willing to speak up if a faculty member’s failure might compromise the patient.

Given the goal of simulation is patient safety, a key part of the learning is the debriefing session. Debriefing is a skill that takes practice. It is also a skill that needs to be exercised during every simulation exercise. It is not something to be done only if there is time before the next task in a busy schedule.

To make the most of a debriefing session the environment needs to be one of safety in sharing what went well and what errors occurred. Further, confidentiality is maintained. If a faculty member made an error they need to have the skills to explain what they did and why. This illustrates to learners that everyone is human. This is a great opportunity for role modeling for taking ownership and displaying humility. This is especially important when the usual medical hierarchy comes into play and learners fear that their pointing out less than optimal

faculty performance will have negative consequences for the learners. Simulations and debriefings should not be yet another series of places where a professional identity is formed that prizes silence over patient safety. One cannot emphasize enough that at critical junctures, one has to remind oneself why one is doing the simulation in the first place and that is the patient.

Education versus Education + Research

Not surprisingly, educators who use simulation spend the majority of their time planning and executing simulations of various kinds so that learners can begin and advance in their care of patients. What are the ethical issues that arise when the educators begin to think of contributing to the literature through research?

There is a large literature in the ethics of research in medicine and anyone who wishes to do research should have a familiarity with it. Second, there are practices associated with research and these should be familiar. For example, has everyone on the research team been made aware of the responsibilities of researchers under the current IRB system in the United States? A wide variety of resources are available. The classic place to begin is with The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.⁽³²⁾ Beyond the national requirements, are members of the team aware of the requirements of the IRB at their institution? Even if the research turns out to be exempt from full IRB review, members of the team need to learn what the practices of the local IRB are (please see chapter on IRB for more information).

Besides these general considerations, there are some specific questions that need to be asked by researchers in simulation. In particular, the setting of simulation lends itself to the possibility that learners, who are lower in status in power, will be subtly coerced into participating in a research project that grows out of a legitimate learning exercise. Learners need

to be informed about what is expected of them and by continuing to participate, have given their consent to the learning exercise. Research participants need to give consent to the research component and, most importantly, need to be able to withdraw from the research. It may turn out that what this means in practice is that whatever data is collected around a particular participant will not be part of the data analyzed by the researcher. The possibility of non-participation as a research participant must be real. Even if the learner will be participating in whatever exercise is being investigated, they must always be able to insist that what they did does not “count” as part of the research.

Among other questions that would-be researchers need to address is what exactly is being pursued by the research. Some simulation research depends upon self-report by the learner. This type of research is not nearly as valuable as simulation research where there is some attempt to validate through some type of assessment, exactly how far the learner has progressed given the simulation intervention or how the learner has been changed as a result of the intervention. The ultimate in research is to study the translation to patient outcomes over time (33).

Best Practices

What are simulation best practices? The best practices in simulation start and end with safety for any standardized patients, for the learner, and for the faculty and staff. Best practices in simulation education, assessment and research will be discussed. The best practices for learners have parallel best practices for the simulation team.

Education

Simulation, from low fidelity to high fidelity and many combinations in between, has become an expected method of educating healthcare providers. Simulation can be very costly, space, mannequins, equipment, as well as time and staff. Virtual reality simulations are being

developed and studied and can be used in conjunction with simulation. Simulation will always be necessary to allow learners to physically practice a skill on a mannequin, partial task trainer, or communicating with a standardized patient as they would in the “real” environment.

The question that needs to always be asked should be “Is this type of simulation the right method to achieve the desired outcome? There may be other more efficient strategies to achieve the learning or assessment outcomes. Is the simulation center and equipment being used because it is there and there needs to be a return on that investment, or is the simulation the best method to use for each the outcomes?”

The first step in developing simulation education is the planning. What are the learning objectives and what is the best way to achieve the objectives? A preliminary meeting with the simulation team to clarify objectives and scope the project is recommended. Questions that need to be answered include: What are the learning objectives? Who are the learners, what level and experience? What faculty will be involved? Do they have experience with simulation or will they need training? Does a scenario for the case exist or does one need to be developed? Is the complexity of the case appropriate for the level of the learner?

Anyone using the simulation center and/or simulation equipment should have an orientation. During the orientation the safe environment should be stressed. Learners also need to be told about the honor code and sign consent and release forms for recording prior to the simulation. The orientation can be “virtual” allowing learners to engage with the setting to alleviate concerns about the environment prior to arriving for the simulation.

Team training and interprofessional simulations. Teams work together and they should train together. The challenge is scheduling the different clinical specialties to attend.

Simulation team. The simulation team needs to continue to learn about simulation

techniques and modalities, adult learning, feedback, debriefing and communication to stay current with the field of simulation. The team should have opportunities to attend meetings and educational sessions locally and nationally.

Assessment (formative/summative)

Simulation is widely used in both formative and summative assessment. Formative assessments of clinical skills and communication provide opportunities for learners to practice skills and receive feedback. Allowing learners the opportunity for repetitive practice is a component of mastering a skill. The summative assessments have higher stakes; grades, licensure, or certification and may not provide feedback to the learner. It is important for anyone involved with simulation to know the purpose of the simulation. The resources and precision of the simulation need to be higher as the stakes of the session increase.

Prebriefing and debriefing. Prebriefing and debriefing are not add-ons or nice to have if there is time. Time needs to be scheduled for these activities.

Prebriefing. Prior to a simulation activity the participants should be briefed about the environment, equipment and objectives of the session. If the simulation is going to be recorded this is the time to explain how the recordings will be used and obtain consent.

Simulation team. To enhance efficiency and communication amongst the simulation team each day a huddle or prebrief of the day's activities should occur. This will allow all members of the team to be on the same page and identify where there may be need for assistance. It is a way to identify any issues prior to the simulations for the day.

Debriefing. An international study was conducted exploring debriefing practices in the OR (34). The authors identified that learners did not always believe there was a debrief at the end of the case and that the anesthesiologists reported most often that they give and or receive

debriefing. The simulation community can learn from the practices of the surgical community. Debriefing is key.

Often simulations are delayed or run long and for any number of reasons debriefing does not occur. Debriefing is a must. Debriefing is key for learning and many say that the debrief is the reason we have the simulation. Time needs to be scheduled for the debrief to be at least as long as the scenario. The key components for successful debriefs include safety and openness based on observable behaviors.

Simulation team. At the end of a simulation the simulation team should further debrief to identify what worked and what changes need to be made before the next simulation. The team's prebrief and debrief can be part of the team's performance/quality improvement.

Competency- Licensure/Certification. Simulation has become a method to assess competency. The American Heart Association has been using mannequins for certification of Basic Life Support (BLS) and Advanced Cardiovascular Life Support (ACLS).

The United States Medical Licensing Examination (USMLE) added computer-based case simulations in 1999 and in 2004 the Step 2 Clinical Skills was added (35). There are three Steps of the USMLE that certifies that an individual has the minimum knowledge and clinical skills for the practice of medicine. Step 2 Clinical Skills (CS) "uses standardized patients to test medical students and graduates on their ability to gather information from patients, perform physical examinations, and communicate their findings to patients and colleagues" (36).

Levine, Schwartz, Bryson and DeMaria (2012) (37), discuss the future of using simulation for licensure and certification. They state that the ethical benefits are significant. They believe that being trained and assessed using simulation prior to "real" patient encounters "reduces a patient's exposure to less-seasoned professionals".

VIII The How to - Novice to advanced beginner

Planning

Ensuring simulations are conducted fairly and ethically starts with planning and preparation. The goals and objectives of the simulation need to be identified to determine what the best methodology is to achieve the stated outcome and to acknowledge when simulation is not the best method to achieve the outcome. During the planning phase it is important to identify what resources are needed to ensure safe and effective simulations and develop a cost/benefit ratio.

Standardized Patients. Standardized patients are not necessarily interchangeable. An interview process needs to be defined when hiring SPs. Each role/character has unique characteristics and it is important to identify appropriate SPs for each case. A key question when interviewing is to determine the motivation of the applicant. A red flag might be if the applicant wants to “fix” the system.

It is important when scheduling SPs for emotionally charged cases not to schedule more than 3 or 4 sessions. Portraying an emotionally charged case can be draining on the person portraying the character.

Implementation

Preparation is key to a successful simulation experience. At the start of the simulation it is important to set expectations with the learners, have them sign consent forms and answer any questions. It is as important to provide time to debrief and be prepared for any unexpected responses during the simulation.

The simulation team should have a team huddle prior to the simulation to ensure everything is in place prior to the learners' arrival. The simulation team should also debrief about

the session and make notes about what worked and what changes should be addressed for future simulations.

A useful technique to capture what is working and what changes need to be addressed is by keeping a journal of events occurring during simulations.

IX. Been there, done that. Competent to expert

Experienced simulation educators who have been practicing in the field of simulation have had many opportunities, some successes, and some failures. All of the experiences need to be shared to help those starting out in the field and to continue to expand and refine the field of simulation. Curriculum development, debriefing, interprofessional simulation, teamwork and communication and scholarly activity are highlighted. Currently, what did not work is not shared. Here the simulation community loses an opportunity.

Curriculum development needs to take into account what resources will be necessary to accomplish the objectives and if it is the best method to achieve the objectives. The importance of matching resources (equipment, faculty, and staff) to learners and learning objectives cannot be understated. Matching resources comes with time and experience and needs to be outlined so everyone is working from the same framework. What is the policy and procedure for prioritizing resources? This should be a written policy.

Some say debriefing is the reason for the simulation. We learn who we are and what our frames are during debriefing. Experienced debriefers should be training, observing and providing feedback to faculty. It is through the debrief sessions that the best learning takes place and systems issues can be identified.

Interprofessional simulations, teamwork, and communication are vital components of patient safety. Healthcare is a team sport yet traditionally we have trained in silos. Simulation

is a methodology that encourages interprofessional training on teamwork and communication. The Interprofessional Education Collaborative Expert Panel (2011) (38) developed core competencies for interprofessional collaborative practice and devote one of the four domains to values/ethics for interprofessional practice. Communication and teamwork are factors in all that we do. Here again the simulation team is a team and can model good teamwork and communication skills.

Scholarly activity includes evidence-based research, writing articles and books for publication, and sharing ideas in less peer-reviewed venues, blogs, listservs, etc. Experienced simulation educators need to share what has worked, what has not worked, and what issues have been identified. Sharing can take place with colleagues at their own institution, at local, national and international meetings, as well as writing and publishing.

Simulation educators have a responsibility to society to study simulation education to determine the methods and techniques that help learners understand and retain concepts, to identify if the knowledge, behaviors, skills and attitudes learned and practiced in the simulated environment translate to practice at the bedside. Rigorous research will influence future educational design, ultimately leading to better patient outcomes, safety and public health (39, 40). At the end of the day it is the simulation educator's job to ask, answer and share – “does this make a difference?”

X. Summary

Simulation in healthcare provides a series of techniques to increase patient safety and provide better patient outcomes. It is our responsibility to everyone working in simulation, the learners and faculty, the patients and families and society to be aware of the ethical considerations from the planning, to the implementation, to the debriefing and to the sharing of

information. Doing this will always be a work in progress. Ongoing reflection and practice in simulation will ultimately transfer to thoughtful practice in the clinical situation.

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