The Pharmaceutical Analogy for Simulation: A Policy Perspective

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In this issue of *Simulation in Healthcare*, Dr. Matt Weinger provides a provocative conceptual piece that analyses simulation as if it were a drug. The principles of pharmacokinetics (what the body does to the drug) and pharmacodynamics (what the drug does to the body) are used as analogies to consider how to think about the impact that different kinds of simulation activities have on individual learners and learner populations. This thoughtful piece provides much food for thought. It is complemented by an editorial by Dr. David Cook that provides a cogent examination of the implications of this analogy for the practice of simulation and research concerning simulation techniques and their affects on learners. Dr. Weinger's inventive article and Dr. Cook's editorial are collectively a significant advance in our conceptualization of simulation as an intervention.

I like to expand a little bit on the thread of thought that they have initiated. Over the last few years, I have been speaking about issues at the level of public policy for which the comparison of the simulation endeavor to the pharmaceutical endeavor has been important. This analysis is quite complementary to the outstanding points raised by Drs. Weinger and Cook.

In general, at the policy level in the United States, the handling of drugs as interventions is quite different from the handling of simulation as interventions. First, there is a national organization [the Food and Drug Administration (FDA)] that is charged by law with regulating the approval of pharmaceuticals (and devices) for use in patient care. For the most part, no "drug" can be sold to patients in the United States unless it has been approved by the FDA as safe and effective (this neglects a small minority of situations where patients obtain non-FDA-approved drugs from other countries). Testing for safety and efficacy is the responsibility of the manufacturer, whose compiled data (from their own studies and those published by others) are presented for scrutiny by the agency.

There is of course no comparable regulation or regulatory agency for simulation as an intervention. Its relative safety has not been seriously challenged, although we all recognize that it is a powerful tool that can trigger unpleasant reactions, and possibly long-term side effects, in a handful of participants. The efficacy of simulation has been left to the marketplace of ideas, curricula, programs, and products to decide. Those of us who have been pioneers of simulation might consider ourselves lucky that we did not encounter regulatory barriers that might have stifled innovation in the development of simulation devices and techniques over the last 20 years.

However, the regulatory structure for "Big Pharma" (as it is often called) has created structural requirements and incentives for them to fund and conduct serious and costly research on the efficacy of the pharmaceutical interventions. Surely, drug makers would like nothing better than to forego such expensive studies. The only things that drive them to invest millions of dollars in studies, often lasting years, are that (i) they stand to make millions, or billions of dollars selling their (patented) molecules as drugs, and (ii) there is a regulatory gateway that they must prove efficacy before sales can begin. Neither incentive currently applies to simulation as an intervention.

I believe that the current status of research on the impact and efficacy of simulation as an intervention to improve patient care processes, patient quality and safety, and (ultimately) improved patient outcome is rather weak. If, along the lines of the approach of Weinger and of Cook, we use the pharmaceutical analogy, here is what we have typically done to date.

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Imagine there is a new drug to treat hypertension, which is expected to not only lower the blood pressure but also ultimately to thereby reduce the incidence of stroke, myocardial infarction, and renal failure in patients who take the drug. Table 1 describes how we would study this drug if we followed the research processes allowed to us for simulation to date.

No one in their right mind would run a drug trial similar to this. We have for the most part been forced to do one time (or at best intermittent repetitions) of training for small cadres of clinicians, most of whom are trainees. We less frequently target experienced personnel and teams. We often must use short sessions (people are busy), where we cannot assure a dose sufficient to change skill or behavior. We collect little process or outcome data either on the learning outcomes or even more rarely on clinical care and patient outcomes. We have exceedingly short time horizons that cannot capture cumulative effects of the intervention over time. We graft the intervention onto a system for which the confounds of production pressure and weak safety culture exacerbate the problems we hope that simulation will solve.

I submit that the studies we have done to date largely only "chip away" at the real questions we want to answer. The real question is whether a program that is:

- A comprehensive and integrated strategy.
- Of intensive, continuous, and repetitive simulation-based training.
- Carried out for all personnel (as individuals, teams, and work units).
- Over the entirety of their careers.
- Linked to programs of performance assessment.
- Evaluated over a long time horizon.
- For outcomes of individual knowledge, skills, and attitudes and for outcomes of patient care processes and patient outcome.

Table 1. A Drug Study Carried Out Similar to Current Simulation Studies

Aspect of Study	Characteristics Analogous to Simulation Studies
Number of patients	Handfuls (20–300) in clusters at only a relatively few sites around the country
Patient selection criteria	Variable; typically only young adults with new diagnosis of HTN; older adults and those with chronic HTN often excluded; and those treated as young adults do not continue to receive treatment as they age
Dose of drug	Variable; often lower than the expected effective dose to reduce cost of treatment and to increase willingness to use the drug
Frequency of administration	Variable; only a few doses of drug, scattered over time; different dosing schedules at each site; and some periods of intensive dosing followed by long periods with no dosing
Duration of administration	Variable; often only one or a few doses total; complete period of drug therapy rarely more than a few years
Duration of trials and follow-up	Typically hours-days; occasionally weeks or months
Effect data collected	Many data on immediate reactions to drug; little data on long-term reactions or patient outcome
Control of confounding variables	None; confounds such as diet, stress, and use of street drugs not measured and controlled, however, thought to often exacerbate HTN and its sequelae

HTN indicates hypertension.

can make a difference in important elements of patient care. Conducting such studies will require thousands (perhaps tens of thousands) of "patients" (or learners), in dozens of institutions, with outcomes followed for years.

This is no different than some large and long drug studies. Who pays for these costly trials? In most cases, as indicated at the beginning of this editorial, the drug manufacturer pays for the trials. How can they bear such a large expense? In the for-profit environment, these companies can do so because (i) they own a patent for the molecule, (ii) thus, they stand to make a great deal of money if the trials are successful, and they can sell the drug to millions of patients—often for each of them to take daily for the rest of their lives, and (iii) they do not have any choice but to do the trials if they hope to reap these benefits. The high profits generated from a few drugs can more than pay for the high cost of drug development. Most drug companies are very large, with deep pockets that can sustain these kinds of efforts, and they are used to this cycle of many trials with only a few "blockbuster" products that generate huge revenues.

Unfortunately, the same cannot be said for the entities involved in testing simulation interventions. Surely, the simulation manufacturers are neither large nor possessing of deep pockets. Even if simulation is proven to be "safe and effective," the scale of potential sales pales in comparison with that for drugs (or for iPods for that matter). Nearly, a trillion dollars a year flows through the healthcare system, but simulation companies, medical and nursing schools, and hospitals operate on very thin margins that—in the absence of regulation otherwise—do not prioritize the training or assessment of personnel. Although in the long run, they all might benefit from pooling resources to conduct large, long, and well-controlled studies of simulation, this has not yet happened because of bureaucratic, political, and economic realities.

For some drug and disease trials, especially for cancer therapy, there are good models of studies conducted by federally funded cooperative groups. Could federal funding support the kinds of long-term studies needed to properly define simulation policy? Perhaps. Simulation as an intervention is categorically different than drugs as interventions. In a drug trial, individual human beings are the targets of treatment. Each individual receives the intervention (or not if they are a control). The outcome of their response to the drug is more readily measured (although some outcomes do require a long time horizon to assess). For simulation as an intervention, the target of the treatment is different from the target of the ultimate outcome. Moreover, because patient care usually involves many different personnel, the target for treatment is really the system of care, not the particular individuals. Moreover, when it comes to optimal patient care processes, training is only one component of many that determines a process' utility. Other elements such as culture and the system or device design play as large a role as does training. All this means that the simulation "drug" has a much more complicated mode of action and connection to outcome than do

many pharmaceuticals administered to individual patients for their particular diseases.

In addition, the politics of simulation interventions is totally different than that of interventions targeting diseases. Cancer is a disease afflicting >40% of Americans; all of us fear it. There has been a "war on cancer" for decades. There are lobbyists of many stripes—from Big Pharma and from disease-specific groups—arrayed to support this war. In contrast, I believe that the populace does not fully understand or fear the risks and problems of medical errors and suboptimal care for which the simulation community believes that that simulation techniques can be key contributors to improvement. Historically, people have been more interested in cost of care and access to care than in the quality or safety of care. The people do not, in my opinion, understand how radically different are our mechanisms for training and assessing our workforce of clinicians compared with the processes we use in other high-risk endeavors in our society. There is only beginning to be a lobby and a thrust to build the will to support long-term simulation research like there is for cancer. The advocacy efforts of the Society for Simulation in Healthcare and of Advanced Initiatives in Medical Simulation are getting traction. Bills have been introduced in Congress—HR855 and S616—were drafted with input from Advanced Initiatives in Medical Simulation and Society for Simulation in Healthcare, but they are still "small potatoes" (calling for ~$50 million per year on a variety of programs) even if they are eventually passed and the necessary appropriations subsequently made.

Thus, as both Weinger and Cook point out, it is instructive to consider the pharmacology of simulation, because it can help us design better pedagogy and evaluate its short-term effects more precisely. We should do this work because it makes our teaching, learning, and performance assessment more scientific and more likely to have the impact we desire. At the level of health policy, we have a long way to go to put the evidence base for simulation on an equal footing with that we expect—indeed require—for pharmaceutical interventions that we all take for granted. We must find a way to let the public know the truth about the pitfalls of our current healthcare system's haphazard methods of ensuring competence (let alone excellence) of their healthcare professionals. In addition, when we are successful in making policy makers realize the need for complex trials with long time horizons, we should not shirk from our duty of conducting them carefully and accumulating the needed evidence for all to use.