Editorial

A Balancing Act: How to Mitigate Overregulation in Healthcare Playfully

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Dear readers of Simulation and Gaming, In order to meet the challenges in healthcare to date, we do need to innovate. This won't get more people in the healthcare domain, while the demand for care is rising, and costs for doing so burden our societies. In this rapidly evolving scenario, the imperative to innovate is all too often rather stifled by stringent regulations and governance structures. This balancing act really has two sides. While governance, rules, and frameworks aim to ensure patient safety and standardize care, they often inadvertently suppress creativity, hindering the development of novel solutions to contemporary health challenges. As your editors, we aim to take you on a journey to review some of the effects.

Overregulation and the Stifling Effect

Healthcare regulations are, of course, needed, as many are primarily designed to protect patients and ensure the level and quality of care. But when these regulations become overly complex or rigid, they can impede the creative processes essential for medical advancement. This was signaled by a recent report from the Innovation Ecosystem Program of the NHS, highlighting that regulatory hurdles and inadequate support are indeed significant barriers to health innovation. The report signals disjointed policies and a risk-averse culture, noting that in healthcare, staff often lack the capacity and support to test, adopt, and scale innovations (The Innovation Ecosystem Program, 2024). Clearly, such an environment discourages experimentation and hinders the

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implementation of new medical technologies, potentially depriving patients of improved care options and staff of a better workflow.

A problem to signal, especially as we are now stepping into the age of Artificial Intelligence (AI). AI in healthcare has been met with great regulatory caution and ambiguity, further stifling innovation. A study by Tranto et al. (2023) assessing the impact of regulations on AI in healthcare found that unclear regulations and overlapping directives, such as the Medical Devices Directive and the AI Act, create uncertainty and stall innovation.

It is currently expected from healthcare organizations and their workers in it to understand about 'what is under the hood of AI' -more than they can perhaps really do. Unrealistic or unfitting requirements may prevent the domain from actual use and benefit. This uncertainty can lead to a loss of competitiveness and may drive innovators to relocate to regions with more accommodating regulatory environments. So how do we move from here?

Challenges posed by stringent regulations hindering the development and/or use of solutions have underscored the need for a more balanced approach. An approach safeguarding patient welfare without hindering innovation too much. One critical lesson here is that we need clear, consistent, but also adaptable regulatory frameworks that evolve alongside – and not after- technological advancements. Along with that, it is important to emphasize the necessity of detailed data dictionaries, data-sharing agreements, data protocols, and databases. This not only prevents misuse or breaches but also offers a wealth of data, along with potential new insights. Hence, we must emphasize regulations that are both stringent and flexible, especially when large data sets are involved, as good data must lend itself to be re-used for the better and to advance the field.

How to Rebalance the Game?

To better support healthcare workers and encourage communal creativity, governance structures must be recalibrated. This is to strike a better balance between regulation and innovation, as we need innovation to stay on top of our healthcare game. To do that, we first must better streamline regulatory processes to be able to reduce complexity and ambiguity. Clear guidelines on the use of AI and the introduction of innovations that are regularly updated can help healthcare professionals navigate the regulatory landscape without feeling too constrained. Additionally, fostering a culture that encourages calculated risk-taking and experimentation within healthcare can lead to the development of innovative solutions and help build robust and executable guidelines

Balance requires shifting back and forth. As editors, it is also our mission to level the playing field between regulations and innovation, promoting research as a catalyst. We do feel that regulations are essential to ensure patient safety and standardize care, but also that overly stringent governance can suppress the creativity that is rather necessary for medical innovation. This realization opens up a new playing field in itself. Where lessons from current regulatory challenges are barriers, innovations may act as

facilitators, and the need for clear, adaptable frameworks that can evolve with technological advancements is the desired outcome. By integrating that outcome in patient-centered, playful design interventions, we will foster a culture that balances regulation with innovation so that healthcare systems can better support their workers and, ultimately, improve patient outcomes.

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