

Review

Narrative Review of Legal Aspects in the Integration of Simulation-Based Education into Medical and Healthcare Curricula

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Abstract: The quality of healthcare varies significantly from one country to another. This variation can be attributed to several factors, including the level of healthcare professionals' professionalism, which is closely linked to the quality of their education. Medical and healthcare education is unique in its need for students to learn and practice various clinical skills, algorithms, and behaviours for clinical situations. However, it is challenging to ensure these educational experiences do not compromise the quality of healthcare and patient safety. A simulation-based educational (SBE) approach offers a solution to these challenges. However, despite the widespread adoption of the SBE approach in medical and healthcare education curricula; its recognition for its high value among students, educators, and healthcare professionals; and evidence showing its positive impact on reducing risks to both patients and healthcare professionals, there is still an absence of a standardized approach and guidelines for integrating simulations, which includes determining when, how, and to what extent they should be implemented. Currently, there is no regulation on the need for SBE integration in medical and healthcare curricula. However, the framework of this article, based on the results of the analysis of the legal framework, which includes a set of laws, regulations, principles, and standards set by various government, administrations, and authoritative institutions, will determine the fundamental aspects of the integration of the SBE approach that justify and argue the need to (1) incorporate simulation-based education across all levels of medical and healthcare education programs and (2) adhere to certain standards when integrating the SBE approach into medical and healthcare programs. This is an area that needs to be developed with the involvement of legal, health, and education experts.

Keywords: simulation-based medical education; healthcare legal frameworks; medical training standardization; patient safety regulations; simulation-based education legal analysis; healthcare education policy; simulation-based education implementation; medical skill enhancement; legal document analysis; healthcare training challenges



Citation: Slavinska, Andreta, Karina Palkova, Evita Grigoroviča, Edgars Edelmars, and Aigars Pētersons. 2024. Narrative Review of Legal Aspects in the Integration of Simulation-Based Education into Medical and Healthcare Curricula. *Laws* 13: 15. <https://doi.org/10.3390/laws13020015>

Academic Editor: Patricia Easteal

Received: 29 November 2023

Revised: 3 March 2024

Accepted: 8 March 2024

Published: 14 March 2024



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1. Introduction

1.1. Quality and Safety of Healthcare in the Context of Healthcare

The principle of quality in healthcare, a cornerstone of health policy, is currently receiving paramount attention from policymakers at national, European, and international echelons. This heightened focus is reflective of its critical importance in shaping health outcomes and policy directions (Busse et al. 2019). The quality of healthcare is an extremely broad issue that can be analysed at different levels and from different points of views. According to the definition of the WHO, the concept of “quality of healthcare” can be viewed from various perspectives—effectiveness, safety, patient-centeredness, timeliness, efficiency,

equity, and integration (World Health Organization 2018). Therefore, it is important to emphasize that, in the context of this article, the focus will be on one dimension of quality in healthcare, namely safety.

The concept of safety in the context of healthcare is primarily associated with patient safety. According to the definition of the WHO, patient safety is the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. But within the broader health system context, patient safety is a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies, and environments in healthcare that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely, and reduce the impact of harm when it does occur (World Health Organization 2023a).

1.2. The Substantiating Aspects of the Significance in the Context of Safe and High-Quality Healthcare

Over two decades ago, the seminal study *To Err Is Human: Building a Safer Health System*, published in 1999 by the Institute of Medicine (IOM), emerged as a cornerstone in the domain of healthcare safety literature. Many articles discussing error prevention strategies cite this report, particularly the statistic that 44,000 to 98,000 people die every year as a result of medical error (Haba et al. 1989). In addition, the World Health Organization's reports highlighted this problem, stating that adverse events due to unsafe care rank among the top 10 causes of death and disability globally. Approximately one in every 10 patients suffers harm while receiving hospital care. A significant proportion of these adverse events, nearly 50%, are preventable. Harm in primary and outpatient healthcare settings affects four out of every 10 patients. At the same time, the reports stated that contributory factors to unsafe healthcare include human error, inadequate communication, resource limitations, systemic and procedural issues, and patient-related factors (World Health Organization 2023a). However, the Organisation for Economic Co-operation and Development (OECD) further highlights the global impact of unsafe care, equating its mortality toll to that of HIV/AIDS, with over three million deaths annually. The OECD underscores patient safety as a critical and ongoing challenge for health systems worldwide, emphasizing the preventability of many adverse events through adherence to safety protocols and clinical guidelines (OECD 2023).

Despite the importance of patient safety, statistics show that in order to prevent harm in healthcare, further significant improvements are needed in the field, not only in the development of processes and infrastructure improvements but also in improving the competence of healthcare professionals.

1.3. Healthcare Professionals—The Cornerstone of a Quality Healthcare System

Healthcare professionals play a central and critical role in enhancing access to and delivering quality healthcare for the population. The WHO states that health systems can only function with health workers and improving health service coverage and realizing the right to the enjoyment of the highest attainable standard of health is dependent on their availability, accessibility, acceptability, and quality (World Health Organization 2023b). Regardless of the availability of healthcare workers, another important aspect is the professionalism of the workforce, i.e., the knowledge, skills, and competencies possessed by the employees to perform their daily duties. Furthermore, the performance of the healthcare workforce is directly linked to the quality of health services (Kreutzberg et al. 2019). A well-performing health workforce is one that works in ways that are responsive, fair, and efficient in order to achieve the best health outcomes possible, given available resources and circumstances (i.e., there are sufficient staff, fairly distributed, and they are competent, responsive, and productive) (World Health Organization 2007). Quality in health services requires competent—that is, well-educated, trained, and skilled—health professionals (Kreutzberg et al. 2019). Thus, the education of healthcare professionals is one of the basic foundations for creating and developing safe healthcare in the health system.

1.4. High-Quality Medical and Healthcare Education—The Basis for the Professionalism of Healthcare Professionals

There is no doubt that quality and patient safety in healthcare are interrelated aspects, and healthcare professionals play an important role in ensuring both. However, it is crucial to acknowledge that the professionalism exhibited by healthcare professionals can be pivotal in this regard. Therefore, it is self-evident that the professionalism of any healthcare professional is grounded in high-quality education.

The quality aspects of medical and healthcare education are closely tied to the legal framework. In this context, it is crucial to emphasize the significance of EU DIRECTIVE 2005/36/EC and the Bologna Process, which provides guidance to EU countries.

1. DIRECTIVE 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications establishes conditions regarding the initiation, duration, and scope of educational programs, as well as the acquisition of certain knowledge and skills ([European Union 2005](#)). For instance, Directive 2005/36/EU, Article 24 of this directive mandates a minimum of six years of study or 5500 h of theoretical and practical training for basic medical training, while Article 31 specifies that the training of nurses responsible for general care should comprise at least three years of study or 4600 h of theoretical and clinical training, with stipulated proportions for theoretical and clinical components. Similar conditions apply to the education programs of other areas.
2. The Bologna process ([European Commission n.d.a](#)) envisages the implementation of the European Qualifications Framework (EQF) ([European Union n.d.](#)) and the European Credit Transfer and Accumulation System (ECTS) ([European Commission n.d.b](#)) in order to provide comparable, compatible, and coherent systems of higher education ([Crosier and Parveva 2013](#)), thus ensuring the mobility of both healthcare students and professionals.

Both of the above-mentioned initiatives outline the necessary requirements for attaining a specific level of education. These requirements include compliance with the duration and scope of educational programs, include the acquisition of certain knowledge and skills, and include the amount of credit points. The fulfilment of these criteria serves as a confirmation of the achievement of specific study results. However, it should be noted that the notion of study outcomes is not an abstract concept. It encompasses precisely defined knowledge, skills, and competencies. Therefore, all components included in the study outcomes must be important, avoiding a selective approach to acquisition and assessment of study results.

In medical and healthcare education, the challenge lies in acquiring and assessing skills. It is crucial to organize teaching, learning, and skills assessment processes in a manner that proactively prevents situations negatively impacting the quality of healthcare, patient rights, and patient safety in clinical practice.

Consequently, a fundamental question arises: how to structure the teaching and learning process to train various clinical skills, clinical pathways, algorithms, and actions in clinical situations, without jeopardizing the quality of healthcare, patient rights, and patient safety? This balancing act is crucial to adequately prepare future professionals for a clinical environment.

Legal regulation plays a significant role in promoting the systemic development of specific areas. Legal regulation is an effective tool that ensures that all actions to promote the development of a specific case are coordinated. Moreover, legal regulation anticipates the implementation of clearly defined conditions and introduces control mechanisms for monitoring compliance with these conditions. For instance, legal regulation stipulates that medical and healthcare education programs must include both theoretical and practical components. The entire education system is designed to ensure the fulfilment and adherence to this condition; otherwise, the respective education programs may not receive accreditation. The aforementioned illustrates the crucial role of legal regulation, suggesting that incorporating appropriate norms could foster the integration of simulation-based

approaches in medical and healthcare education. This is particularly crucial in cases where the acquisition of specific clinical skills, clinical pathways, algorithms, and actions in clinical situations prevents risks to patient rights and safety while enhancing the quality of healthcare.

1.5. Simulation-Based Educational Approach—The Basis of Quality Medical and Healthcare Education

Decades of pedagogical research have unequivocally demonstrated that the actions of lecturers in the study process are undeniably the primary educational factor influencing student learning and achievement. It is self-evident that not all teaching practices are equal in their impact. Thus, it is crucial to identify and promote the most effective practices, namely those that facilitate students in attaining desired learning outcomes in the most efficient manner. The disparity in the impact of various teaching practices necessitates the identification and promotion of the most effective methodologies, those that enable students to achieve desired learning outcomes efficiently (Clermont et al. 2004).

Up until the 20th century, the traditional apprenticeship was the most common method used in healthcare education, but over the last 25 years simulation has been used as an adjunct to learn in real-life clinical settings. This trend is supported by the fact that several systematic reviews and meta-analyses showed a positive correlation between simulation-based training and improvements in technical skills, clinical decision-making, interprofessional teamwork, patient-related outcomes, and changes in organizational performance. Additionally, this positive correlation is stronger when compared to traditional learning methods and it remains consistent over time. As a result, there has been an exponential rise in the development, application, and general awareness of simulation use in the healthcare community over the last two decades (Maestre et al. 2024).

A simulation-based educational approach is a widely used pedagogical method in medical and healthcare education today, and professionals in the field point out that simulation education serves as a conduit between classroom learning and real-life clinical experience (Society for Simulation in Healthcare n.d.a). In addition, the imperative adoption of healthcare simulation in both undergraduate and postgraduate medical education is increasingly recognized, necessitating opportunities for students and residents to refine their skills in simulated environments before engaging with real patients. In summary, a new model of medical education is thus required that has patient safety at its core, avoids the flaws of a purely apprenticeship training model, and provides unlimited opportunities to practice and perfect skills in a risk-free environment (Ayaz and Ismail 2022). In addition, the World Health Organization advocates for the use of simulation methods in health professionals' education, tailored to contextually appropriate fidelity levels (World Health Organization 2013).

However, it should be noted that this method of simulation-based educational approach can achieve the most effective results only if quality requirements are developed and followed and quality criteria are defined for both the content of the simulation and its providers—simulation centres and simulation instructors.

1.6. Aim

The aim of the article is to substantiate the necessity of legal regulations that mandate the integration of a simulation-based education approach as an essential bridge between theory and practice in medical and healthcare education. Additionally, it aims to identify key aspects that must be strictly observed during the implementation of simulation-based education.

This article posits two fundamental propositions:

1. The simulation-based education approach should be recognized as an integral intermediary phase bridging theory and practice within medical and healthcare education curricula at all levels.

2. The implementation of simulation-based education must conform to universally acknowledged, evidence-based principles that harmoniously integrate theoretical and practical elements.

1.7. Methodology

To achieve these objectives, the study employed an interdisciplinary qualitative research methodology, encompassing analytical, descriptive, deductive, and synthetic research methods. This approach also involved the interpretation of legal norms within the theoretical framework, drawing upon a diverse array of theoretical materials, including policy planning documents, reports, legal framework documents, literature sources, and studies and standards in the field of simulation-based medical education.

The search methodology employed in this study utilizes the PRIMO search engine, a comprehensive tool designed to facilitate multifaceted searches across an array of sources and databases, including prominent platforms such as Scopus, Web of Science, and PubMed. PRIMO's advanced features enable customization of the search process, allowing researchers to define specific parameters, such as the time period and type of work, to refine their inquiries. This search strategy was meticulously executed with the aim of identifying significant and impactful legal documents and scholarly articles pertinent to the regulation of simulation-based medical education. The literature review covers the last five years. In our endeavour to present a thorough and wide-ranging overview of the various opinions and aspects related to this topic, we did not exclude any resources. This approach was adopted in response to the current dearth of comprehensive, objective overviews in the field of medical simulations, ensuring a more inclusive and diverse exploration of the subject matter.

2. Simulation-Based Education: Conceptual Framework and Standards

In this chapter, we intend to delineate the conceptual framework of simulation-based education and analyse the standards developed by pertinent associations within this domain.

2.1. The Core of Simulation-Based Education within Healthcare Curricula

The prioritization of patient safety is an imperative that must be steadfastly upheld throughout the medical and healthcare education continuum. Equally paramount is the assurance of learner safety during the educational process. This dual focus on safety necessitates the establishment of a secure learning environment, achievable through the integration of a simulation-based approach in medical and healthcare education. However, when integrating a simulation-based educational approach in medical and healthcare education, it is important to understand the conceptual framework of a simulation-based teaching and learning approach—the breadth of application of simulations and the specificity of pedagogical aspects, as well as the simulation aspects of the mutual interaction between technology and simulated environment.

2.1.1. Definitions

In order to establish simulation-based education as a recognized approach in health education, it is crucial to establish a shared conceptual understanding of what constitutes simulation-based education. The following definitions provide insights into the historical and contemporary use of simulations in medical and health education:

1. Simulation is a technique—not a technology—to replace or amplify real experiences with guided experiences that evoke or replicate substantial aspects of the real world in a fully interactive manner (Gaba 2004). The author of this definition is D.M. Gaba, whose substantial contributions to the progress of simulations fields are widely acknowledged (Center for Immersive and Simulation-Based Learning (CISL) n.d.).
2. Healthcare simulation—a technique that creates a situation or environment to allow persons to experience a representation of a real event for the purpose of practice,

learning, evaluation, testing, or to gain understanding of systems or human actions (Lioce 2020). This definition has been widely used for the past years.

2.1.2. Structure of Simulations in Medical and Healthcare Education

Simulations play a pivotal role in healthcare education, not only facilitating the acquisition of fundamental skills requisite for professional competency but also in the on-going development and enhancement of a broad spectrum of competencies across various domains of practice. The multifaceted applications of simulation-based learning activities encompass a comprehensive range of skills and practices (Palaganas et al. 2020):

Procedural Skills: Mastery of specific clinical procedures through repetitive practice in a risk-free environment.

Physical and Clinical Assessment Skills: Development of the ability to perform thorough physical examinations and clinical assessments.

Diagnostic Reasoning: Enhancement of critical thinking and diagnostic skills through exposure to a variety of clinical scenarios.

Psycho-social Skills and History-Taking: Improvement of interpersonal skills, empathetic communication, and effective history-taking techniques.

Clinical Management: Cultivation of the capacity to manage clinical cases effectively, from initial assessment to therapeutic intervention.

Team-Based Practices: Promotion of collaborative skills and teamwork in a clinical setting, emphasizing the importance of multidisciplinary approaches to patient care.

Communication Skills: Strengthening of communication abilities with patients, their families, and professional colleagues, crucial for comprehensive patient care.

Regulatory and Administrative Management: Familiarization with healthcare regulations, policies, and administrative tasks, essential for the efficient operation of healthcare facilities.

Development and Refinement of Clinical Techniques: Continuous improvement and refinement of clinical skills, ensuring that healthcare professionals are equipped with up-to-date practices.

The simulation-based educational paradigm enables a systematic evaluation of theoretical knowledge, assessment of practical abilities, and prediction of performance quality and alignment with real-world work environments in a controlled setting as well as a secure and conducive learning environment, presenting invaluable opportunities for learning from errors without real-world consequences (Slavinska et al. 2021).

According to the contemporary definition, simulation also serves as a versatile tool for practice, learning, evaluation, testing, and the acquisition of a deeper understanding of complex systems or human behaviours. This broad spectrum of uses highlights simulation's integral role in preparing healthcare professionals.

2.1.3. Simulation-Based Education—The Pedagogical Approach

The adoption of simulation as a pedagogical strategy in healthcare education has its roots in diverse fields such as military training and aviation, where it has become an integral component of the training regimen. The genesis of rudimentary clinical simulation can be traced back to the use of anatomical models in the sixteenth century. However, the contemporary framework for medical simulation was established in the latter half of the twentieth century, influenced significantly by the medical education reform movement, the advent of the resuscitation movement, and the seminal report by the Institute of Medicine titled *To Err is Human* (Kshetrapal et al. 2023).

The methodological aspects of the simulation-based education approach are influenced by several pedagogical methods and approaches (Kshetrapal et al. 2023):

Social Cognitive Theory: Emphasizes the contextual nature of learning and professional development, underscoring the importance of real or simulated environments in the acquisition of knowledge and skills.

Adult Learning Theory: Recognizes the self-motivated and self-directed nature of adult learners, advocating for educational approaches that engage learners in the planning and evaluation of their learning experience.

Behavioural Learning Theory: Highlights the role of deliberate practice in enhancing performance, suggesting that repeated practice in a simulated setting can significantly improve clinical skills.

Constructivist Learning Theory: Focuses on how learners' perceptions, interpretations, and understandings influence their actions, advocating for simulation designs that allow learners to construct knowledge through experience.

Cognitive Load Theory: Acknowledges the limitations of working memory capacity and duration, advising that simulations should be designed to manage cognitive load effectively to optimize learning outcomes. However, it should be noted that it is essential to follow the implementation phases of this approach to achieve desired learning outcomes in the simulation:

Briefing Phase: This initial phase involves several key components, including setting the session's goals and objectives, establishing a fictional context, providing logistical details, and ensuring psychological safety. The establishment of psychological safety is critical, as it allows learners to fully engage and optimize their experience during the simulation (Hughes and Hughes 2023).

Simulation Phase: In this active phase, maintaining a high degree of validity and reliability is essential for accurately assessing participant behaviour and skills. Validity in the simulated environment is achieved by ensuring that the simulation features closely mirror real-world clinical settings. This fidelity or realism is necessary to engage participants effectively and elicit responses akin to those in actual clinical settings. Utilizing real clinical cases as the basis for simulated scenarios is recommended to ensure an accurate portrayal of real-world patient situations (Munroe et al. 2016). A systemic approach to scenario development should include intended outcomes, context, and specific goals/objectives (Harrington and Simon 2023).

Debriefing Phase: Post-simulation debriefing is a critical component of the simulation event, serving as the cornerstone of the learning experience. This phase involves a structured discussion following the active simulation, enabling participants to reflect on their actions and thought processes. The goal of this discussion is to enhance learning outcomes and improve future clinical performance (Abulebda et al. 2023).

Each of these phases is an essential element in the implementation of the method, and only the combination of these steps in a single process allows one to achieve the highest efficiency of teaching and learning.

Improperly executed simulations can lead to unaccomplished objectives, poor to no learning, and disengaged or even psychologically impacted participants (Ayaz and Ismail 2022).

The effective implementation of simulation-based education in healthcare requires a meticulous understanding of the intended learning objectives, encompassing both knowledge and skills development. Furthermore, strict adherence to established pedagogical principles during the design and delivery of simulation activities is essential for enhancing the learning experience.

2.1.4. Interaction of Simulation Technology and Simulated Environment

A sense of credibility and realism is crucial in the implementation of simulation-based educational programs, which requires considering various aspects related to the simulated environment and simulation technologies and their interaction.

In the context of simulations, the SimZone concept is currently a known and recognized approach to creating a simulated environment. The SimZone concept presents a nuanced framework for categorizing simulation activities into five distinct zones (0–4), each delineated by unique pedagogical principles and tailored technical solutions (Roussin et al. 2020). This framework facilitates a structured approach to simulation-based learning, enabling educators to design and implement simulations that are optimally aligned with specific educational objectives. Zone Classification:

Zone 0 Simulations: This foundational level incorporates autofeedback exercises designed for individual learners, frequently employing virtual technologies. These simulations are characterized by their focus on self-assessment and immediate feedback mechanisms, allowing learners to independently gauge their performance and identify areas for improvement.

Zone 1 Simulations: Aimed at the instruction of basic clinical skills, Zone 1 simulations provide a controlled environment in which learners can acquire essential procedural competencies. These simulations serve as the building blocks for more advanced clinical practice.

Zone 2 Simulations: Focused on situational instruction for managing acute care patient episodes, such as mock codes, Zone 2 simulations immerse learners in complex scenarios that require not only technical skills but also critical thinking and decision-making under pressure.

Zone 3 Simulations: This zone expands the scope of simulation to include exploratory learning experiences involving real-life teams. Simulations in Zone 3 are designed to address broader team and system issues, promoting collaborative problem-solving and interdisciplinary communication.

Zone 4 Simulations: At the apex of the SimZone framework, Zone 4 simulations are dedicated to high-level integration and the application of skills in multifaceted and unpredictable clinical environments. These simulations aim to synthesize all elements of clinical practice, preparing learners for the complexities of real-world healthcare delivery.

The SimZones framework serves as a versatile tool for competency-based assessment, enabling educators to systematically evaluate learner progress across a spectrum of skills and competencies. By conceptualizing learning in this structured manner, the framework supports both learners and facilitators in achieving clearly defined educational outcomes.

It is important for simulation implementers to orient themselves in the specifics of simulation technologies and simulation solutions. There is no single standardized typology of simulation technologies, but a commonly known categorization model provides for their classification ([Palaganas et al. 2020](#)):

Low-Fidelity Mannequins: These foundational educational tools serve as the initial step in simulation typology. Characterized by their static nature, low-fidelity mannequins may offer limited, if any, interactive feedback to the learner, focusing primarily on the physical aspect of procedures. They range from partial to full-body task trainers, including specialized models for airway management training. The primary utility of low-fidelity mannequins lies in their role in the development and assessment of basic technical skills, offering a tangible, albeit simplified, representation of human anatomy and procedural practice.

Mid-Fidelity Mannequins/Simulators: Occupying the middle ground in the simulation spectrum, mid-fidelity mannequins or simulators enhance the learning experience by providing more specific feedback to the learner. This category includes simulators capable of replicating physiological sounds, such as heartbeats and respiratory functions, without the accompanying physical movements of the chest. Mid-fidelity simulators are instrumental in bridging the gap between basic technical skill application and the interpretation of clinical signs, facilitating a deeper understanding of patient conditions through auditory cues.

High-Fidelity Simulators: At the apex of the simulation typology are high-fidelity simulators, renowned for their ability to offer highly realistic and interactive learning environments. These advanced models simulate human bodily functions with remarkable accuracy, including but not limited to, heart and lung sounds, chest movements, and palpable pulses. High-fidelity simulators are distinguished by their capacity to adapt to both the situation at hand and the inputs from the learner, enabling dynamic scenarios that require not only the application of technical skills but also critical clinical judgment and decision-making. Integrated into comprehensive patient scenarios, these simulators demand and facilitate a holistic skill set from learners, encompassing clinical expertise, problem-solving, and interpersonal communication skills, thereby preparing healthcare professionals for the multifaceted nature of patient care in real-world settings.

In the realm of contemporary healthcare education, the application of simulation encompasses a wide array of modalities, ranging from standardized patient simulations, task trainers, and high-fidelity manikins, to cutting-edge virtual and augmented reality solutions, comprehensive computer-based simulations, innovative hybrid models, interactive screen-based simulators, and the increasingly utilized telesimulation. This diversity in simulation technologies underscores the field's commitment to leveraging technological advancements to enhance educational outcomes.

2.2. Guidelines and Pillars for the Implementation of Simulation-Based Healthcare Education

The adoption of Healthcare Simulation Standards is a manifestation of a commitment to excellence and the implementation of rigorous, evidence-based practices in healthcare education, with the overarching aim of enhancing patient care (Watts et al. 2021). Nowadays, several international organizations have emerged as key players in the field of simulation:

International Nursing Association for Clinical Simulation and Learning (INACSL): This association is dedicated to the advancement of healthcare simulation science. The first edition of the Healthcare Simulation Standards of Best Practice, established in 2011, was designed to progress the science of simulation, disseminate best practices, and provide evidence-based guidelines for simulation practice (Watts et al. 2021).

Society for Simulation in Healthcare (SSH): As a global, multidisciplinary professional society, SSH is committed to advancing the application of simulation in healthcare education, research, and practice. Its primary objective is to enhance performance and reduce errors in patient care through simulation. Recognizing simulation as a paradigm shift in healthcare education, SSH endeavours to improve simulation technology, educational methods, practitioner assessment, and patient safety, contributing to superior patient care and outcomes (Society for Simulation in Healthcare n.d.b).

The Association for Simulated Practice in Healthcare (ASPiH): This not-for-profit membership association comprises individuals from healthcare, education, and patient safety backgrounds, including researchers, learning technologists, workforce development or education managers, administrators, healthcare staff, and students. ASPiH aims to establish an effective communication network for those involved in simulation and technology-enhanced learning; provide quality exemplars of best practice in simulated practice for healthcare education, training, assessment, and research; and support the expansion and adoption of simulated practice (Association for Simulated Practice in Healthcare n.d.).

Society in Europe for Simulation (SESAM): SESAM's mission is to promote and facilitate the use of simulation in healthcare for training and research purposes. Its vision is to enhance healthcare through simulation, aiming to enable safe and patient-centred care delivered by a competent and confident healthcare workforce within an effective healthcare system (SESAM n.d.a, n.d.b).

Upon analysing the core aspects of simulation-based education in healthcare, along with the related standards, frameworks, and guidance, it is evident that implementers of simulation-based education should base their activities on three fundamental pillars:

Pillar 1: In the realm of simulation-based education within healthcare, the establishment of an autonomous accredited organizational structure is paramount. This structure, which can manifest as an organization, institution, centre, department, or other similar entity within an educational or healthcare setting, is integral to the effective and efficient delivery of simulation-based education. The accreditation process for such a structure is rigorous, necessitating a comprehensive evaluation of various critical components.

Infrastructure is a foundational element: It includes not only the physical spaces, such as rooms and simulation environments, but also encompasses the extensive range of equipment necessary for conducting realistic and effective simulations. These environments and tools are pivotal in creating authentic scenarios that closely mimic real-life medical situations, thereby enhancing the educational value of the simulations (Society for Simulation in Healthcare 2021; SESAM 2019; Association for Simulated Practice in Healthcare 2016; Charnetski and Jarvill 2021).

Composition and expertise of the professional team: This team should comprise individuals with a diverse array of skills, encompassing management, education, healthcare, and technical expertise. The presence of such a multidisciplinary team ensures a holistic approach to simulation-based education, where each aspect, from strategic planning and educational design to clinical relevance and technical execution, is meticulously addressed (Society for Simulation in Healthcare 2021; SESAM 2019; Association for Simulated Practice in Healthcare 2016; Charnetski and Jarvill 2021).

Processes and quality management system: They form the backbone of the organizational structure. This system includes comprehensive policies and procedures that govern the operation of the simulation program. Confidentiality procedures are essential to maintain the integrity and privacy of the data and information involved. The aspect of physical and psychological safety is paramount, ensuring a safe and conducive learning environment for all participants. Conditions for video recording and data retention are also crucial, as they play a significant role in the post-simulation analysis and learning process. Finally, the prioritization of simulation resources ensures that the most critical educational needs are met efficiently and effectively (Society for Simulation in Healthcare 2021; SESAM 2019; Association for Simulated Practice in Healthcare 2016; Charnetski and Jarvill 2021).

Pillar 2: Certification of Healthcare Simulation Instructors encompasses a multifaceted framework, essential for ensuring the efficacy and integrity of simulation-based education in healthcare. This pillar is underpinned by several key aspects:

Professional Values and Capabilities: This aspect emphasizes the importance of leadership, the cultivation and maintenance of respectful relationships with faculty and simulation participants, and the demonstration of effective teamwork skills. It also underscores the recognition and adherence to ethical principles and the acceptance of personal responsibility in upholding these principles. A critical component of this aspect is the ability of professionals to discern the various roles of personnel involved in simulation and to evaluate the adequacy and suitability of resources, ensuring an optimal learning environment (SESAM 2019; Association for Simulated Practice in Healthcare 2016; Charnetski and Jarvill 2021).

Knowledge and Principles of Healthcare and Simulation: This aspect involves a comprehensive understanding of the factors influencing participant engagement during simulation activities. This includes an awareness of the learners' actual level of knowledge and skills, as well as the reliability level of the simulation itself. Professionals are expected to possess a deep understanding of how to effectively integrate simulations into education, research, and practice. This includes the ability to differentiate between the different phases of a simulation activity and the various methods of providing feedback. Additionally, professionals should be adept at recognizing the key elements of debriefing, differentiating between various simulation modalities and activity settings (such as in situ, centre-based, and mobile setups), and understanding the applications of simulation for individual, team, and system training. An understanding of the stressors that can impact individual and team performance, including cognitive, affective/emotional, and psychomotor factors, is also essential (SESAM 2019; Association for Simulated Practice in Healthcare 2016; Charnetski and Jarvill 2021).

Educational Principles Applied to Simulation: This competency involves the ability to apply and distinguish the principles of utilizing simulation as an educational tool. It encompasses a broad range of aspects, including learning taxonomies, assessment, and learning theories. Moreover, it involves the capability to plan and design simulation activities, facilitate simulations (which includes managing personnel and equipment, addressing issues that arise during the simulation, managing physical and psychological risks, identifying participant performance, and maintaining a psychologically-safe simulation environment), conducting participant assessments, participating in simulation team debriefings and feedback sessions, analysing simulation activity evaluations, and modifying future simulation activities based on these evaluations (SESAM 2019; Association for Simulated Practice in Healthcare 2016; Charnetski and Jarvill 2021).

Pillar 3: Licensing of Simulation-Based Educational Programs outlines a comprehensive framework for the development and implementation of simulation-based educational programs in healthcare. This framework is predicated on a series of guidelines that ensure the effectiveness, relevance, and educational integrity of these programs. The guidelines include the following ([Charnetski and Jarvill 2021](#); [Society for Simulation in Healthcare n.d.c](#); [SESAM n.d.c](#)):

Needs Assessment: The foundational step involves conducting a thorough needs assessment. This assessment should encompass an examination of the knowledge, skills, attitudes, and/or behaviours of individuals, alongside organizational initiatives, systems analysis, clinical practice guidelines, quality improvement programs, and/or patient safety goals. This comprehensive assessment ensures that the program is tailored to address specific educational and practical needs.

Measurable Objectives: The program should incorporate objectives that are not only measurable but also built upon the foundational knowledge of the learner. This ensures that the educational goals are clear, achievable, and quantifiable, facilitating the assessment of learning outcomes.

Alignment with Simulation Modality and Objectives: It is imperative that the program aligns with the chosen simulation modality, whether it be simulated clinical immersion, in situ simulation, computer-assisted simulation, virtual reality, procedural simulation, or hybrid simulation. This alignment ensures coherence between the educational objectives and the simulation methods employed.

Scenario, Case, or Activity-Based: The educational program should be grounded in a scenario, case, or activity that includes a detailed description of the situation and backstory. This approach provides a realistic and structured starting point for the educational activity, enhancing the learning experience.

Identification of Critical Actions/Performance Measures: The scenario or case should clearly identify critical actions or performance measures. These are essential for evaluating the achievement of the scenario's objectives and for assessing the learners' performance.

Learner-Centred Approach: The implementation of simulation-based education programs should adopt a learner-centred approach. This involves considering the learners' differences in knowledge, competency, level of experience, cultural backgrounds, values, and responsibilities during the simulation design phase, ensuring that the program is inclusive and effective for a diverse learner population.

Pre-briefing Plan: A comprehensive pre-briefing plan should be developed. This plan should include preparation materials and briefing sessions to guide participants towards success in the simulation-based experience, setting clear expectations and providing necessary background information.

Debriefing or Feedback Sessions: Essential components of simulation-based education programs are debriefing or feedback sessions, accompanied by guided reflection exercises following the simulation-based experience. These sessions are crucial for consolidating learning and facilitating the reflection process.

Evaluation Plan: An evaluation plan should be established to assess both the learner and the simulation-based experience. This plan should inform participants about the assessment method, whether formative, summative, and/or high stakes, at the outset of the simulation.

Pilot Testing: Prior to full implementation, simulation-based education programs should undergo pilot testing. This phase is critical for identifying and rectifying any confusing, missing, or underdeveloped elements of the simulation based.

To ensure a cohesive and high-quality approach in implementing simulation-based education, the following requirements should be considered:

1. Accrediting institutions that conduct simulations.
2. Certifying simulation instructors.
3. Licensing simulation-based educational programs.

3. The Simulation-Based Education in Healthcare: A Legal Framework Perspective

Regulation is essential to define a clear framework within which healthcare professionals acquire and maintain the competence needed to provide health services that are of high quality, i.e., that are safe, effective, and patient-centred (Kreutzberg et al. 2019).

This section will examine aspects of the legal framework that justify and argue for the necessity to:

1. Incorporate simulation-based education across all levels of medical and healthcare education curricula.
2. Adhere to specific standards when integrating the SBE approach into medical and healthcare curricula.

The incorporation of simulation-based education into medical and healthcare curricula is imperative for two fundamental reasons: firstly, it upholds the right to receive healthcare that is both of high quality and intrinsically safe, and secondly, it guarantees the right to access quality education in the healthcare profession.

3.1. The Right of Safe and Quality Healthcare

The European Union (EU) has established a legal and policy framework that emphasizes the protection and improvement of human health, as well as the provision of high-quality healthcare. This framework is articulated through several key documents:

1. Treaty on the Functioning of the European Union (Article 6): This article grants the EU the authority to support, coordinate, or supplement the actions of Member States in various domains, including the crucial area of human health protection and improvement (European Union 2012a).
2. Charter of Fundamental Rights of the European Union (Article 35): This article asserts that every individual has the right to access preventive healthcare and to benefit from medical treatment under conditions established by national laws and practices. It also mandates the assurance of a high level of human health protection in the formulation and execution of all EU policies and activities (European Union 2012b).
3. Regulation (EU) 2021/522: Dated 24 March 2021, this regulation establishes the 'EU4Health Programme' for the period 2021–2027. It aims to enhance access to quality, patient-centred, outcome-based healthcare and related care services, with the goal of achieving universal health coverage. This regulation supersedes Regulation (EU) No 282/2014 (European Union 2021).
4. Directive 2011/24/EU: Issued on 9 March 2011, this directive concerns the application of patients' rights in cross-border healthcare. It outlines several critical provisions, including the responsibility of Member States to provide safe, high-quality, efficient, and adequately resourced healthcare to their citizens. It also emphasizes the need for continuous improvement in quality and safety standards in healthcare, in line with Council Conclusions and considering advances in international medical science, good medical practices, and new health technologies (European Union 2011).
5. Council Conclusions on Common Values and Principles in European Union Health Systems (2006/C 146/01): This document establishes the fundamental values of universality, access to good quality care, equity, and solidarity in EU health systems. It emphasizes the importance of continuous training for healthcare staff, adherence to national standards, and the provision of advice on best practices in quality. The document also highlights the need for innovation, good clinical governance, and the systematic monitoring of healthcare quality. Safety is underscored as a key principle in this agenda (European Union 2006).

These legal instruments and policy documents collectively underscore the EU's commitment to ensuring that all Member States provide healthcare that is not only accessible and equitable but also of high quality and safety. This commitment is integral to Europe's broader goals of social protection, cohesion, justice, and sustainable development.

The emphasis on high-quality healthcare is a prominent feature in the national legal frameworks of European Union (EU) Member States, as evidenced by the *Patients' Rights in the European Union Mapping Exercise* report (European Commission et al. 2016). This focus is reflected in various national legislations, each tailored to address the specific healthcare needs and rights of patients within their respective jurisdictions:

Austria: The right to safe, high-quality treatment in a timely manner is a fundamental part of the treatment contract, enforced through civil law.

Belgium: Patients are entitled to high-quality healthcare that meets their specific needs, respects human dignity and self-determination, and is free from discrimination.

Croatia: The Patients' Rights Protection Act ensures every patient's right to quality and continuous healthcare that aligns with professional standards and ethical principles.

Cyprus: The focus is on providing healthcare of good quality, marked by high technical standards and fostering positive relations between patients and providers.

Denmark: The Health Act prioritizes meeting patients' needs through accessible, high-quality treatment, comprehensive care, choice, information access, transparent services, and minimized waiting times.

Greece: Law 3418/2005 underscores the importance of quality, safety, and efficiency in healthcare, emphasizing physicians' responsibilities in these areas.

Latvia: The Patient's Rights Law acknowledges the right to safe, high-quality treatment, provided respectfully and by qualified professionals.

Lithuania: The Law on the Rights of Patients and Compensation for the Damage to their Health guarantees high-quality healthcare services.

Luxembourg: The patient rights law ensures the right to safe, quality treatment and equal access to healthcare services.

Netherlands: The Care Institutions Quality Act and the Individual Healthcare Professions Act, along with the Act on the Medical Treatment Contract, form the legal basis for ensuring high-quality healthcare.

Romania: The Patient's Rights Law mandates the provision of the highest attainable quality treatment, considering available resources.

Slovenia: The Patient Rights Act guarantees high-quality, safe healthcare.

Sweden: The Health and Medical Services Act requires the guarantee and continuous development of healthcare quality.

The legal regulation emphasizes that the priority is the protection and improvement of people's health. Many countries focus on the patient's right to receive safe, high-quality, and timely treatment that aligns with professional standards and ethical principles, highlighting the responsibilities of doctors in ensuring these rights.

3.2. The Legal Framework concerning the Quality of Education in the Fields of Medical and Healthcare Education

The European Union (EU) has established a legal and policy framework that emphasizes high-quality education. This framework is articulated through several key aspects:

1. The first international normative instrument regarding the right to education, the 1960 UNESCO Convention against Discrimination in Education (CADE), serves as a cornerstone in the realm of educational rights and standards. This convention, transcending mere anti-discrimination mandates, actively promotes equality of opportunity and access to free primary education, while also safeguarding the rights of minority groups. Article 4 of the CADE is particularly noteworthy, as it not only establishes legally binding clauses but also delineates the responsibilities and actions required of States Parties. Among these obligations is the requirement to ensure that the standards of education are equivalent in all public educational institutions of the same level, and that the conditions relating to the quality of the education provided are also equivalent (UNESCO Digital Library 2014).
2. In this context, it is essential to mention a document that all EU member states adhere to, namely the Standards and Guidelines for Quality Assurance in the European

Higher Education Area. The primary objective of this document is to contribute to the common understanding of quality assurance for learning and teaching across borders and among all stakeholders. In this document it is mentioned that quality, whilst not easy to define, is mainly a result of the interaction between teachers, students, and the institutional learning environment. Quality assurance should ensure a learning environment in which the content of programs, learning opportunities, and facilities are fit for purpose (ENQA 2015).

3. The Treaty on the Functioning of the European Union, particularly in Article 6, endows the Union with the competence to support, coordinate, or supplement Member States' actions in several domains, including education and vocational training. Article 165 of the Treaty further specifies the Union's role in contributing to the development of quality education by encouraging cooperation between Member States and, if necessary, supporting and supplementing their actions. This is to be achieved while fully respecting the Member States' responsibility for the content and organization of their education systems, as well as their cultural and linguistic diversity (European Union 2012a).
4. The Union's significant strides in advancing quality education are exemplified by the implementation of the Bologna process. This process aims to establish a comparable, compatible, and coherent system of higher education across Europe, forming the European Higher Education Area (European Union 2015). The Bologna process, through its establishment of the European Qualifications Framework (EQF) and the European Credit Transfer and Accumulation System (ECTS), has been pivotal in standardizing quality assurance across European higher education institutions, thereby enhancing the quality and relevance of learning and teaching (European Commission n.d.a).
 - 4.1. The European Qualifications Framework (EQF) is a comprehensive, eight-level framework that is based on learning outcomes and functions as a translation tool among different national qualification frameworks. Its primary role is to enhance the transparency, comparability, and portability of qualifications across various countries and institutions, thereby facilitating a more unified educational landscape in Europe (European Union n.d.). The EQF defines a qualification as the formal outcome of an assessment and validation process obtained when a competent body determines that an individual has achieved learning outcomes to given standards. The EQF, and all National Qualification Frameworks (NQFs) that have been referenced to it, follow a learning outcomes approach. This means that both the content and the level of a qualification reflects what holders are expected to know, understand, and be able to do (learning outcomes). Qualifications usually take the form of certificates and diplomas awarded following education, training, learning, and (sometimes) work. The content and the level of qualifications that are part of a quality assured framework are trusted sources of information. They act as a form of currency that individuals can use for employment or further learning purposes. Thanks to the EQF, employers can more easily compare foreign qualifications to national ones and better understand the skill profiles of candidates (European Commission 2018). Thanks to the EQF, employers can more easily compare foreign qualifications to national ones and better understand the skill profiles of candidates (European Commission 2018).
 - 4.2. The European Credit Transfer and Accumulation System (ECTS) is a standardized system designed to compare the study the attainment and performance of students across the European Union and other collaborating European countries. Its primary objective is to foster transparency in learning, teaching, and assessment processes, thereby promoting high-quality education (European Commission 2015). ECTS facilitates the recognition and transfer of credits earned at one higher education institution towards a qualification pursued

at another institution, playing a crucial role in the Bologna Process, aimed at enhancing the international comparability of national education systems (European Commission n.d.b).

ECTS credits represent learning that is based on well-defined learning outcomes. Across Europe, the term “learning outcomes” is becoming increasingly integrated into the vocabulary of education and training policies. There are two main and interconnected definitions associated with this concept:

1. Learning outcomes encompass knowledge, know-how, information, values, attitudes, skills, and/or competences that an individual has acquired and/or can demonstrate upon completing a learning process, whether formal, non-formal, or informal.
2. Learning outcomes are statements that describe what a learner knows, understands, and is capable of doing upon completing a learning process. These statements are defined in terms of knowledge and skills, as well as responsibility and autonomy (European Centre for the Development of Vocational Training 2022).

Credits in ECTS are awarded to students who have completed the required learning activities and achieved the defined learning outcomes, as evidenced by appropriate assessment. This system also allows for the recognition of learning outcomes achieved in other formal, non-formal, or informal contexts through assessment and accreditation (European Commission 2015).

According to the provisions of the legal framework, the quality of education is a significant aspect. Enhancing the quality and relevance of learning and teaching is a core mission of the Bologna Process. Through the EQF, it is possible to ensure that the quality of education provided within the framework of the Bologna process is comparable, compatible, and coherent across the European region. EQF is based on the study outcomes approach, that both the content and the level of a qualification reflect what holders are expected to know, understand, and be able to do (learning outcomes). Conversely, ECTS stipulates that the proficiency level in knowledge, skills, and abilities is validated by the number of credit points acquired and the corresponding assessment.

3.3. Aspects Justifying the Need for Simulation-Based Education Stage

Directive 2005/36/EC of the European Parliament and of the Council outlines the framework for the recognition of professional qualifications within the EU, specifying the minimum training requirements for doctors and general care nurses, among other healthcare professions. For doctors, it mandates at least six years or 5500 h of combined theoretical and practical training, while general care nurses require three years or 4600 h, with specific allocations for theoretical and clinical training. However, despite the fact that the Directive sets certain requirements in the field of medicine and healthcare, and despite the need to adhere to EQI and ECTS principles, the quality of healthcare varies between countries.

This article emphasizes that the disparity in healthcare quality between countries is linked to the varying levels of education quality received by healthcare professionals.

The quality of education is influenced by several aspects, but a crucial role is played by the methods employed in the teaching and learning process and the organization of this process. In this context, several aspects warrant consideration and evaluation:

1. It is customary that the teaching and learning process is organized in two stages— theory and practice or work-based learning. However, the question becomes relevant of how to ensure that the acquisition and evaluation of knowledge and skills in such a model does not threaten the quality of healthcare, patient rights, and patient safety. This is particularly true of technical clinical skills such as anaesthesiology and reanimatology, surgery, gynecology, obstetrics, etc.
2. There are countries where a simulation-based educational approach is integrated into medical and healthcare education curricula in certain educational institutions, but

not all medical and healthcare educators have access to a simulated environment that integrates simulation technologies.

3. As a whole, there is no conceptualized comprehensive system, which means that the teaching and learning process should take place in three successive stages—theory, simulation-based learning and practice, and work-based learning. There are also no defined quality criteria that must be considered if a simulation-based educational approach is implemented in medical and healthcare education—neither in terms of content; in terms of procedural arrangements; nor in terms of rights, duties, and responsibilities.
4. Even if a simulation-based educational approach is provided in medical and healthcare curricula, given that there are no uniform standards observed, learning outcomes acquired during the simulation-based stage is not comparable according the EQF and ECTS.
5. While some medical and healthcare curricula have incorporated a simulation-based educational approach, the comprehensive and in general integration of the SBE component into the education of healthcare professionals necessitates the acknowledgment of the SBE concept within the legal framework.

However, there are also some challenges. One of them is the fact that simulation centres and simulation-based training programs can be costly to build and maintain and require substantial long-term investment from their affiliated organization. While simulation has been shown to improve patient outcomes, funding for training and education is finite, and understanding and justifying these costs can be challenging (Senvisky et al. 2023).

Simulation-based education is resource-intensive. Anticipating the mandatory phase of simulation-based education requires finding solutions to issues related to resource availability. The availability and redistribution of resources are closely linked to values. If the quality of healthcare is positioned as a value, certain investments, including those in medical and healthcare education, must be expected.

It is crucial to focus not on the lack of resources but on how to obtain them. Lobbying for public funding dedicated to educational initiatives can be a significant resource. A new practice for resource mobilization includes sponsorship and collaboration with private enterprises, especially from the sectors interested in the modernization of medical education, including the development of simulation-based education. Partnerships with educational institutions, research centres, and industry organizations are actively forming to consolidate resources and knowledge in the field of medical education.

4. Limitations

The narrative review on the integration of simulation-based education into medical and healthcare curricula encounters several limitations. The variability in legal systems across different jurisdictions poses a challenge in representing the global diversity in legal approaches to simulation-based education in healthcare education, limiting the generalizability of the findings. The focus on qualitative methodologies might overlook crucial quantitative data, limiting the review's comprehensiveness. The interdisciplinary nature of integrating legal, educational, and healthcare perspectives may lead to challenges in fully synthesizing these diverse fields, possibly resulting in gaps in understanding the complex relationship between legal considerations and educational practices in simulation-based education.

5. Conclusions

The concept of quality of care, encompassing dimensions such as effectiveness, efficiency, patient safety, patient-centeredness, and equity, remains a pivotal component of health policy at national, European, and international levels. The enduring emphasis on these quality aspects is largely attributed to the escalating importance of patients' rights and patient safety. However, research underscores that, despite extensive efforts to bolster safety protocols and standards, patient harm during healthcare delivery persists as a significant issue.

The central element of the healthcare system is the professionalism of healthcare professionals, which is an essential aspect of ensuring high quality healthcare, including patient safety. The quality of healthcare is closely related to the quality of medical and healthcare education.

Medical and healthcare education has evolved considerably, notably through the increased adoption of simulation-based learning. This paradigm shift from traditional didactic methods to simulation-based education offers manifold benefits. This approach enables learners to acquire practical experience in patient care scenarios in a risk-free environment before transitioning to real clinical settings. This approach enhances skill acquisition, interdisciplinary training, decision-making, critical thinking, and emotional resilience, and it prepares learners for rare and complex cases.

Despite the logical rationale and demonstrated efficacy of simulation-based education in medical and healthcare curricula, current legal regulations do not mandate a distinct simulation-based stage between theoretical and practical or work-based learning.

From a legal perspective, the necessity of a simulation-based education approach can be viewed through two perspectives: the imperative to provide high-quality healthcare and the need to offer high-quality education.

Quality Healthcare Perspective: Legal frameworks establish patients' rights to high-quality and safe healthcare services. Therefore, the professionalism of healthcare professionals is critical. Future and current healthcare professionals must avoid actions that could compromise patient safety or health. There must be confidence in their ability to competently engage with patients in real clinical situations.

Quality Education Perspective: Educational frameworks should instil confidence in the knowledge, skills, and competence of learners, in line with the Bologna process principles. The European Credit Transfer and Accumulation System (ECTS) is central to this framework. Credits are awarded based on the completion of learning activities and achievement of defined learning outcomes. However, when prioritizing healthcare quality and patient safety, it becomes evident that certain learning outcomes are best learned and assessed in a simulated environment. Thus, while traditional clinical practice is essential, integrating simulation-based education is crucial for achieving educational and healthcare excellence.

Simulation-based education should be recognized as a distinct stage between theory and practice in medical and healthcare education curricula. The implementation of this stage should adhere to evidence-based principles that effectively integrate theory and practice. To ensure a cohesive approach, measures such as accrediting simulation institutions, certifying instructors, and licensing educational programs are necessary. Such an educational model is indispensable in preparing healthcare professionals for patient interactions in actual clinical situations. It promotes patient safety, ensures the safety of medical personnel, and elevates the overall quality of healthcare delivery.

Political planning documents in the field of healthcare and education confirm the continued relevance of these issues:

1. One of the United Nations' sustainable development goals is to ensure healthy lives and promote well-being for all at all ages. One of the sub-goals of this objective focuses on providing access to quality essential healthcare services for everyone ([United Nations 2022a](#)).
2. One of the United Nations' sustainable development goals is to ensure inclusive and equitable quality education and promote lifelong learning opportunities for all ([United Nations 2022b](#)).
3. According to Paragraph 16 of the European Pillar of Social Rights, everyone possesses the right to timely access to affordable, preventive, and curative healthcare services of good quality ([European Commission n.d.c](#)).
4. According to Paragraph 16 of the European Pillar of Social Rights, every individual has the right to quality, inclusive education, training, and lifelong learning ([European Commission n.d.c](#)).

By investing in the integration of simulation-based educational approaches into the medical and healthcare education curriculum, the quality of healthcare, as well as the safety of patients and healthcare personnel, are actually enhanced.

Author Contributions: Conceptualization, A.S., K.P., E.G., A.P.; methodology, K.P.; analysis, A.S., E.G.; investigation, A.S., K.P., E.G., A.P.; writing—original draft preparation, A.S.; writing—review and editing, A.S., E.G., E.E.; supervision, A.P. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

References

- Abulebda, Kamal, Marc Auerbach, and Faten Limaiem. 2023. *Debriefing Techniques Utilized in Medical Simulation*. Treasure Island: StatPearls Publishing.
- Association for Simulated Practice in Healthcare. 2016. *Simulation-Based Education in Helthcare: Standards Framework and Guidance*. Staffordshire: ASPiH.
- Association for Simulated Practice in Healthcare. n.d. About ASPiH. Available online: <https://aspih.org.uk/home/background/> (accessed on 19 October 2023).
- Ayaz, Omair, and Faisal Wasim Ismail. 2022. Healthcare Simulation: A Key to the Future of Medical Education—A Review. *AMEP* 13: 301–8. [CrossRef] [PubMed]
- Busse, Reinhard, Dimitra Panteli, and Wilm Quentin. 2019. An Introduction to Healthcare Quality: Defining and Explaining Its Role in Health Systems. In *Improving Healthcare Quality in Europe: Characteristics, EFFECTIVENESS and Implementation of Different Strategies [Internet]*. Brussels: European Observatory on Health Systems and Policies.
- Center for Immersive and Simulation-Based Learning (CISL). n.d. About Dr. David M. Gaba. Available online: <https://cisl.stanford.edu/about-cisl/about-dr-gaba.html> (accessed on 12 February 2024).
- Charnetski, Matthew, and Melissa Jarvill. 2021. Healthcare Simulation Standards of Best Practice™ Operations. *Clinical Simulation in Nursing* 58: 33–39. [CrossRef]
- Clermont, Gauthier, Martial Dembélé, Steve Bissonnette, and Mario Richard. 2004. Quality of Teaching and Quality of Education: A Review of Research Findings—UNESCO Digital Library. Available online: https://unesdoc.unesco.org/ark:/48223/pf0000146641_eng (accessed on 19 October 2023).
- Crosier, David, and Teodora Parveva. 2013. Fundamentals of educational planning. In *The Bologna Process: Its Impact in Europe and Beyond*. Paris: UNESCO, International Institute for Educational Planning, ISBN 978-92-803-1368-0.
- ENQA. 2015. *Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG)*. Brussels: European Association for Quality Assurance in Higher Education, ISBN 978-90-816867-2-3.
- European Centre for the Development of Vocational Training. 2022. *Defining, Writing and Applying Learning Outcomes: A European Handbook*, 2nd ed. Gare Luxembourg: Publications Office of the European Union.
- European Commission. 2015. Directorate General for Education and Culture. In *ECTS Users' Guide 2015*. Gare Luxembourg: Publications Office of the European Union.
- European Commission. 2018. Directorate General for Employment, Social Affairs and Inclusion. In *The European Qualifications Framework: Supporting Learning, Work and Cross Border Mobility: 10th Anniversary*. Gare Luxembourg: Publications Office of the European Union.
- European Commission, Directorate General for Health and Food Safety, Maastricht University, European Observatory on Health Systems and Policies, and KU Leuven. 2016. *Patients' Rights in the European Union: Mapping eXercise: Final Report*. Gare Luxembourg: Publications Office of the European Union.
- European Commission. n.d.a. The Bologna Process and the European Higher Education Area | European Education Area. Available online: <https://education.ec.europa.eu/education-levels/higher-education/inclusive-and-connected-higher-education/bologna-process> (accessed on 19 October 2023).
- European Commission. n.d.b. European Credit Transfer and Accumulation System (ECTS) | European Education Area. Available online: <https://education.ec.europa.eu/education-levels/higher-education/inclusive-and-connected-higher-education/european-credit-transfer-and-accumulation-system> (accessed on 19 October 2023).
- European Commission. n.d.c. The European Pillar of Social Rights in 20 Principles. Available online: <https://ec.europa.eu/social/main.jsp?catId=1606&langId=en> (accessed on 12 February 2024).
- European Union. 2005. Directive—2005/36—EN—EUR-Lex. Available online: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52006XG0622\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52006XG0622(01)) (accessed on 12 February 2024).

- European Union. 2006. Council Conclusions on Common Values and Principles in European Union Health Systems. *Official Journal of the European Union*. Available online: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52006XG0622\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52006XG0622(01)) (accessed on 29 November 2023).
- European Union. 2011. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the Application of Patients' Rights in Cross-Border Healthcare. *Official Journal of the European Union*. p. 57. Available online: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011L0024> (accessed on 29 November 2023).
- European Union. 2012a. Official Journal of the European Union Consolidated Version of the Treaty on the Functioning of the European Union, Article 4. Available online: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:en:PDF> (accessed on 19 October 2023).
- European Union. 2012b. Charter of Fundamental Rights of the European Union. *The Review of International Affairs* 63: 109–23.
- European Union. 2015. The Bologna Process: Setting up the European Higher Education Area | EUR-Lex. Available online: <https://eur-lex.europa.eu/EN/legal-content/summary/the-bologna-process-setting-up-the-european-higher-education-area.html> (accessed on 12 February 2024).
- European Union. 2021. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 Establishing a Programme for the Union's Action in the Field of Health ('EU4Health Programme') for the Period 2021–2027, and Repealing Regulation (EU) No 282/2014 (Text with EEA Relevance). *Official Journal of the European Union* 107: 1–3.
- European Union. n.d. The European Qualifications Framework (EQF) | Europass. Available online: <https://europa.eu/europass/en/europass-tools/european-qualifications-framework> (accessed on 19 October 2023).
- Gaba, David M. 2004. The Future Vision of Simulation in Health Care. *Quality and Safety in Health Care* 13: i2–i10. [CrossRef] [PubMed]
- Haba, S., M. B. Lascombe, R. J. Poljak, and A. Nisonoff. 1989. Structure of Idiotope Associated with Antiphenylarsonate Antibodies Expressing an Intrastrain Crossreactive Idiotype. *The Journal of Experimental Medicine* 170: 1075–90. [CrossRef] [PubMed]
- Harrington, Douglas W., and Leslie V. Simon. 2023. *Designing a Simulation Scenario*. Treasure Island: StatPearls Publishing.
- Hughes, Patrick G., and Kate E. Hughes. 2023. *Briefing Prior to Simulation Activity*. Treasure Island: StatPearls Publishing.
- Kreutzberg, A., C. Reichebner, C. B. Maier, F. Destrebecq, and D. Panteli. 2019. Regulating the Input: Health Professions. In *Improving Healthcare Quality in Europe: Characteristics, Effectiveness and Implementation of Different Strategies [Internet]*. Brussels: European Observatory on Health Systems and Policies.
- Kshetrapal, Anisha, Mary E. McBride, and Candace Mannarino. 2023. Taking the Pulse of the Current State of Simulation. *Critical Care Clinics* 39: 373–84. [CrossRef] [PubMed]
- Lioce, Lori, ed. 2020. *Healthcare Simulation Dictionary*, 2nd ed. Rockville: Agency for Healthcare Research and Quality.
- Maestre, Jose M., Elena Rojo, and Ignacio Del Moral. 2024. Future Directions for Simulation in Healthcare: A Critical Review. *Journal of Healthcare Quality Research* 39: 120–25. [CrossRef]
- Munroe, Belinda, Thomas Buckley, Kate Curtis, and Richard Morris. 2016. Designing and Implementing Full Immersion Simulation as a Research Tool. *Australasian Emergency Nursing Journal* 19: 90–105. [CrossRef]
- OECD. 2023. *Fast-Track on Digital Security in Health*. OECD Health Working Papers. Paris: OECD, vol. 164.
- Palaganas, Janice C., Beth Tamplet Ulrich, and Mary E. Beth Mancini, eds. 2020. *Mastering Simulation: A Handbook for Success*, 2nd ed. Sigma Theta Tau International. Indianapolis: Sigma Theta Tau International, ISBN 978-1-948057-33-2.
- Roussin, Christopher, Taylor Sawyer, and Peter Weinstock. 2020. Assessing Competency Using Simulation: The SimZones Approach. *BMJ STEL* 6: 262–67. [CrossRef] [PubMed]
- Senvisky, Jared M., Ryan T. McKenna, and Yasuharu Okuda. 2023. *Financing And Funding A Simulation Center*. Treasure Island: StatPearls Publishing.
- SESAM. 2019. SESAM Accreditation of Simulation Based Educational Institutions—Principles. Available online: https://www.sesam-web.org/media/documents/sesam-accreditation-of-simulation-based-educational-institutions-principles_2019.pdf (accessed on 19 October 2023).
- SESAM. n.d.a. About SESAM. Available online: <https://www.sesam-web.org/about-SESAM/> (accessed on 19 October 2023).
- SESAM. n.d.b. Strategy | SESAM. Available online: <https://www.sesam-web.org/strategy/> (accessed on 26 October 2023).
- SESAM. n.d.c. Accreditation | SESAM. Available online: <https://www.sesam-web.org/accreditation/> (accessed on 12 February 2024).
- Slavinska, Andreta, Evita Grigorovica, Karina Palkova, Nora Jansone-Ratinika, Matiss Silis, Oļegs Sabelņikovs, and Aigars Pētersons. 2021. Skills monitoring in healthcare studies—For patient safety and healthcare quality. *SIE* 1: 611–30. [CrossRef]
- Society for Simulation in Healthcare. 2021. Core Accreditation Standards. Available online: <https://www.ssih.org/Portals/48/2021%20SSH%20CORE%20ACCREDITATION%20STANDARDS.pdf> (accessed on 19 October 2023).
- Society for Simulation in Healthcare. n.d.a. About Simulation. Available online: <https://www.ssih.org/About-SSH/About-Simulation> (accessed on 19 October 2023).
- Society for Simulation in Healthcare. n.d.b. *The Purpose of the Society for Simulation in Healthcare Is to Serve a Global Community of Practice Enhancing the Quality of Healthcare*. Available online: <https://www.ssih.org/About-SSH> (accessed on 19 October 2023).
- Society for Simulation in Healthcare. n.d.c. *Teaching/Education Accreditation Standards*. Available online: [https://www.ssih.org/Portals/48/2021%20SSH%20TEACHING%20EDUCATION%20ACCREDITATION%20STANDARDS%20\(1\).pdf](https://www.ssih.org/Portals/48/2021%20SSH%20TEACHING%20EDUCATION%20ACCREDITATION%20STANDARDS%20(1).pdf) (accessed on 19 October 2023).
- UNESCO Digital Library. 2014. The Right to Education: Law and Policy Review Guidelines—UNESCO Digital Library. Available online: <https://unesdoc.unesco.org/ark:/48223/pf0000228491> (accessed on 12 February 2024).

- United Nations. 2022a. Goal 3 | Department of Economic and Social Affairs. Available online: <https://sdgs.un.org/goals/goal3> (accessed on 12 February 2024).
- United Nations. 2022b. Goal 4 | Department of Economic and Social Affairs. Available online: <https://sdgs.un.org/goals/goal4> (accessed on 12 February 2024).
- Watts, Penni I., Kelly Rossler, Fara Bowler, Carrie Miller, Matthew Charnetski, Sharon Decker, Margory A. Molloy, Lori Persico, Erin McMahon, Donna McDermott, and et al. 2021. Onward and Upward: Introducing the Healthcare Simulation Standards of Best Practice™. *Clinical Simulation in Nursing* 58: 1–4. [CrossRef]
- World Health Organization. 2007. *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action*. Geneva: World Health Organization, ISBN 978-92-4-159607-7.
- World Health Organization. 2013. Transforming and Scaling Up Health Professionals' Education and Training. Available online: <https://www.who.int/publications-detail-redirect/transforming-and-scaling-up-health-professionals%E2%80%99-education-and-training> (accessed on 19 October 2023).
- World Health Organization. 2018. Handbook for National Quality Policy and Strategy: A Practical Approach for Developing Policy and Strategy to Improve Quality of Care. Available online: <https://www.who.int/publications/i/item/9789241565561> (accessed on 19 October 2023).
- World Health Organization. 2023a. Patient Safety. Available online: <https://www.who.int/news-room/fact-sheets/detail/patient-safety> (accessed on 12 February 2024).
- World Health Organization. 2023b. Health Workforce. Available online: <https://www.who.int/teams/health-workforce/about> (accessed on 19 October 2023).

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