

High-Fidelity Simulation and Health Sciences Student Learning: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION**Support** - Not applicable.**Review Stage at time of this submission** - Data analysis.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202670076**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 July 2026 and was last updated on 20 July 2026.**INTRODUCTION**

Review question / Objective What is the effectiveness of high-fidelity clinical simulation on the learning of health science students compared to other educational strategies?

Rationale The education of health sciences students requires teaching strategies that enable the development of clinical competencies in a safe environment before direct patient contact. However, increasing patient safety requirements, reduced opportunities for clinical placements, and the growing number of students have limited exposure to complex clinical situations during training. In this context, simulation-based education has become a widely adopted educational strategy that recreates realistic clinical scenarios in a controlled environment, allowing students to integrate theoretical knowledge, technical skills, clinical reasoning, communication, and teamwork through deliberate practice and structured debriefing.

High-fidelity simulation (HFS), characterized by the use of computerized manikins or standardized patients capable of reproducing realistic physiological responses and clinical scenarios, has been increasingly incorporated into nursing, medicine, and other health professions curricula to enhance learning and facilitate the transfer of clinical competencies to real-world practice. Evidence from randomized controlled trials suggests that HFS may improve multiple learning outcomes, including knowledge acquisition, clinical and psychomotor skills, clinical judgment, communication, leadership, self-efficacy, confidence, and learner satisfaction.

Nevertheless, the available evidence remains heterogeneous. While several studies have reported advantages of HFS over traditional teaching methods or lower-fidelity simulation, others have found comparable educational outcomes when lower-fidelity simulation is supported by well-designed instructional strategies and structured debriefing. In addition, substantial variability in study populations, interventions,

outcome measures, and assessment instruments, together with common methodological limitations in primary studies, makes it difficult to draw robust conclusions regarding the educational effectiveness of HFS.

Although previous systematic reviews have examined simulation-based education, the growing number of recent randomized controlled trials and the persistence of inconsistent findings warrant an updated evidence synthesis restricted to experimental studies. Therefore, the present systematic review and meta-analysis aims to synthesize and quantitatively summarize the available evidence on the effectiveness of high-fidelity simulation for improving learning outcomes among health sciences students compared with other educational strategies. The primary outcome will be clinical and psychomotor skills, while secondary outcomes will include other reported domains of learning. In addition, the methodological quality and risk of bias of the included studies will be assessed to determine the overall certainty and robustness of the available evidence.

Condition being studied Health professions education faces the ongoing challenge of ensuring that students acquire sufficient clinical competencies before engaging in direct patient care. However, increasingly stringent patient safety policies, reduced opportunities for clinical practice, growing student enrollment, and constraints within healthcare settings have limited students' exposure to complex clinical situations, particularly those that are infrequent but high-risk. These challenges have driven the adoption of educational strategies that provide safe, repeatable, and learner-centered experiences without compromising the quality of care or patient safety.

In response, simulation-based education has become one of the most important pedagogical approaches in health professions education. Clinical simulation enables students to integrate theoretical knowledge, technical skills, clinical reasoning, communication, leadership, and teamwork within realistic clinical scenarios in a controlled environment. By promoting experiential learning, deliberate practice, and structured debriefing, simulation facilitates the development of clinical competence and has become an integral component of healthcare education.

Within this context, high-fidelity simulation (HFS), defined as the use of advanced computerized manikins or standardized patients capable of reproducing dynamic physiological responses and

highly realistic clinical scenarios, represents one of the most significant technological and educational advances in health professions education. Its adoption has steadily increased across nursing, medicine, midwifery, perfusion, pharmacy, and other healthcare curricula based on the assumption that greater realism enhances the transfer of clinical competencies to real-world practice compared with traditional teaching methods or lower-fidelity simulation modalities.

Recent randomized controlled trials suggest that HFS may improve multiple learning outcomes, including theoretical knowledge, clinical judgment, clinical performance, technical skills, leadership, communication, self-efficacy, confidence, and learner satisfaction. For example, Ayed et al. demonstrated significant improvements in clinical judgment among pediatric nursing students following high-fidelity simulation compared with conventional teaching. Similarly, Hodrob et al. reported significant improvements in advanced airway management performance, learner satisfaction, and self-confidence after participation in an HFS-based training program. Other randomized trials have reported benefits in cardiac auscultation, clinical leadership, cardiovascular procedural performance, neonatal resuscitation skill retention, and the management of high-acuity clinical scenarios.

Despite these promising findings, the available evidence remains inconsistent. While numerous randomized controlled trials have demonstrated the superiority of HFS over traditional educational approaches, recent studies indicate that educational outcomes may be comparable to those achieved with medium-fidelity simulation when the latter incorporates sound instructional design, clearly defined learning objectives, and structured debriefing. These findings suggest that the effectiveness of simulation depends not only on simulator fidelity but also on educational factors such as scenario design, learner engagement, facilitation, and reflective debriefing.

Furthermore, recent evidence indicates that HFS simultaneously promotes the development of both technical and non-technical competencies, including leadership, communication, situational awareness, teamwork, and decision-making under pressure, all of which are essential for patient safety and effective clinical practice. Nevertheless, the substantially higher costs associated with implementing, maintaining, and operating high-fidelity simulation raise important questions regarding whether its educational benefits justify

the additional investment compared with lower-fidelity simulation modalities.

Despite the widespread adoption of HFS and the increasing number of randomized controlled trials published over the past decade, the available evidence remains fragmented because of considerable heterogeneity in study populations, healthcare disciplines, simulation scenarios, interventions, comparators, outcome measures, and assessment instruments. Moreover, many primary studies present methodological limitations, including small sample sizes, cluster randomization, lack of assessor blinding, participant attrition, and the use of non-standardized assessment tools, all of which may compromise internal validity and limit comparability across studies.

Although previous systematic reviews have evaluated simulation-based education, the rapid growth of experimental evidence and the persistence of inconsistent findings warrant an updated systematic review restricted to randomized controlled trials. In addition to estimating the pooled effects of HFS across different learning domains, such.

METHODS

Search strategy The search strategy was developed based on the components of the PICO framework and was adapted to the specific characteristics of each database. Controlled vocabulary (Medical Subject Headings [MeSH]) and free-text terms were combined using the Boolean operators AND and OR. The complete search strategies for each database were as follows:

PUBMED

((("Simulation Training"[Mesh] OR "Patient Simulation"[Mesh] OR "Computer Simulation"[Mesh] OR "High-Fidelity Simulation"[tiab] OR "High Fidelity Simulation"[tiab] OR "high-fidelity patient simulation"[tiab] OR "simulation-based education"[tiab] OR "simulation-based learning"[tiab] OR "clinical simulation"[tiab] OR "patient simulation"[tiab])

AND

("Students, Health Occupations"[Mesh] OR "Education"[Mesh] OR "Education, Professional"[Mesh] OR "Students, Medical"[Mesh] OR "Students, Nursing"[Mesh] OR "Students, Dental"[Mesh] OR "Students, Pharmacy"[Mesh] OR student*[tiab] OR undergraduate*[tiab] OR postgraduate*[tiab] OR resident*[tiab] OR trainee*[tiab] OR "health sciences student*[tiab] OR "health profession* student*[tiab] OR "medical

student*[tiab] OR "nursing student*[tiab] OR "pharmacy student*[tiab] OR "dental student*[tiab])

AND

("Learning"[Mesh] OR "Education Outcome"[Mesh] OR "Clinical Competence"[Mesh] OR "Educational Measurement"[Mesh] OR learning[tiab] OR knowledge[tiab] OR competence[tiab] OR competency[tiab] OR competencies[tiab] OR skill*[tiab] OR performance[tiab] OR confidence[tiab] OR self-efficacy[tiab] OR outcome*[tiab]))

SCOPUS

((("Simulation Training"[Mesh] OR "Patient Simulation"[Mesh] OR "Computer Simulation"[Mesh] OR "High-Fidelity Simulation"[tiab] OR "High Fidelity Simulation"[tiab] OR "high-fidelity patient simulation"[tiab] OR "simulation-based education"[tiab] OR "simulation-based learning"[tiab] OR "clinical simulation"[tiab] OR "patient simulation"[tiab])

AND

("Students, Health Occupations"[Mesh] OR "Education"[Mesh] OR "Education, Professional"[Mesh] OR "Students, Medical"[Mesh] OR "Students, Nursing"[Mesh] OR "Students, Dental"[Mesh] OR "Students, Pharmacy"[Mesh] OR student*[tiab] OR undergraduate*[tiab] OR postgraduate*[tiab] OR resident*[tiab] OR trainee*[tiab] OR "health sciences student*[tiab] OR "health profession* student*[tiab] OR "medical student*[tiab] OR "nursing student*[tiab] OR "pharmacy student*[tiab] OR "dental student*[tiab])

AND

("Learning"[Mesh] OR "Education Outcome"[Mesh] OR "Clinical Competence"[Mesh] OR "Educational Measurement"[Mesh] OR learning[tiab] OR knowledge[tiab] OR competence[tiab] OR competency[tiab] OR competencies[tiab] OR skill*[tiab] OR performance[tiab] OR confidence[tiab] OR self-efficacy[tiab] OR outcome*[tiab]))

WOS

TS=((("high-fidelity simulation" OR "high fidelity simulation" OR "patient simulation" OR "clinical simulation" OR "simulation-based education" OR "simulation-based learning")

AND

(student* OR trainee* OR undergraduate* OR postgraduate* OR resident* OR "health sciences student*" OR "health professions student*" OR "medical student*" OR "nursing student*" OR "pharmacy student*" OR "dental student*")

AND

(learning OR knowledge OR competence OR competency OR competencies OR skill* OR

performance OR "clinical competence" OR confidence OR "self-efficacy" OR outcome").

Participant or population Health sciences students and trainees (undergraduate and postgraduate/residency level), with no restriction on age, sex, or country, enrolled in nursing, medicine, midwifery/obstetrics, pharmacy, or anesthesiology programs, who underwent high-fidelity clinical simulation training compared with lower-fidelity simulation or traditional teaching.

Intervention High-fidelity clinical simulation (HFS), operationally defined as the use of robotic/computerized manikins or standardized patients capable of reproducing realistic physiological responses (cardiopulmonary sounds, palpable pulse, vital-sign changes, chest movements, among others) in simulated clinical scenarios, with or without a subsequent debriefing session, delivered to health sciences students.

Comparator Compared to other educational strategies: Lower/medium-fidelity simulation, traditional teaching (lectures), or another active control group, depending on the study.

Study designs to be included Randomized Controlled Trials.

Eligibility criteria Population (P): health sciences students.

Intervention (I): high-fidelity simulation.

Comparator (C): different health professionals / other educational strategies (lower-fidelity simulation, traditional teaching).

Outcome (O): learning, competencies, educational performance.

Inclusion criteria:

Observation window: last 5 years.

Study type: randomized controlled trial (RCT).

No restriction on language or gender.

Human studies.

Information sources The sources of information were PubMed, Scopus, and Web of Science.

Main outcome(s) Database searches (PubMed, Scopus, Web of Science) identified 1344 records; after removing 486 duplicates, 858 were screened and 81 full texts assessed for eligibility. Twenty-eight studies met the eligibility criteria; after this review's methodological quality assessment (PEDro scale), 4 were further excluded (1 protocol without outcome data, 3 with PEDro<5), leaving 24 randomized controlled trials in the final analysis.

PEDro scores ranged from 5 to 9 out of 10 (mean 6.21, SD 1.22, median 6.0). By classification band, 9 studies (38%) were "fair" (4–5), 14 (58%) "good" (6–8), and 1 (4%) "excellent" (9–10). Overall risk of bias (RoB 2) was rated "some concerns" in 16 studies (67%), "high risk" in 6 (25%), and "low risk" in only 2 (8%); the domain most frequently rated "some concerns" was D5 (selection of the reported result).

For the primary outcome — clinical/psychomotor skills, reported by 20 of 24 studies — two subgroups were analyzed by comparator type. Subgroup A (high-fidelity vs. lower-fidelity simulation, $k=7$) showed a positive but statistically non-significant pooled effect (SMD=0.56, 95% CI -0.16 to 1.28, $p=0.125$), with very high heterogeneity ($I^2=90.5\%$). Subgroup B (high-fidelity simulation vs. traditional teaching, $k=2$) had an insufficient number of studies for pooling and was reported narratively ($g=1.37$ and $g=4.89$). A sensitivity analysis showed that the significance of Subgroup A's pooled effect was driven by the study with the largest effect magnitude, and was lost after excluding the 3 studies with PEDro<5.

Secondary outcomes (theoretical knowledge, self-confidence, satisfaction, critical thinking, anxiety, teamwork, and retention) were reported heterogeneously across studies and could not be pooled ($k<3$ per outcome in all cases); these are presented descriptively.

Data management It was done through Ryan.

Quality assessment / Risk of bias analysis The methodological quality assessment was performed using PEDRO and the risk of bias was assessed using ROB2.

Strategy of data synthesis Quantitative synthesis (meta-analysis) will be performed for outcomes reported by a minimum of 3 independent studies ($k\geq 3$), using the standardized mean difference (SMD, Hedges' g with small-sample correction) as the effect measure, given the expected heterogeneity of instruments across studies. Pooled estimates will be calculated using a random-effects model (DerSimonian-Laird method), given the anticipated clinical and methodological heterogeneity among included trials.

Studies will be stratified into subgroups according to comparator type (e.g., high-fidelity simulation vs. lower-fidelity simulation; high-fidelity simulation vs. traditional teaching/no simulator practice), and pooled effects will be estimated separately for each subgroup rather than combined into a single overall estimate, to preserve interpretability given the differing nature of the comparators.

Statistical heterogeneity will be assessed using the I^2 statistic, τ^2 (between-study variance), and Cochran's Q test. A sensitivity analysis will be conducted by sequentially excluding studies with lower methodological quality (PEDro<5) and/or high influence on the pooled estimate, to assess the robustness of the results.

For outcomes reported by fewer than 3 independent studies, or for which pooling was not appropriate due to substantial clinical/methodological heterogeneity, results will be synthesized narratively/descriptively rather than quantitatively, following a structured summary approach consistent with PRISMA 2020 guidance for reviews without meta-analysis (SWiM).

All analyses will be conducted using R (metafor/meta packages) or equivalent validated statistical software. Risk of bias (RoB 2) and methodological quality (PEDro) will be considered in the interpretation and, where relevant, in the grading of the certainty of evidence.

Subgroup analysis Subgroup analysis was performed. The 20 studies reporting the primary outcome (clinical/psychomotor skills) were stratified into 2 subgroups by comparator type:

Subgroup A: high-fidelity simulation vs. lower/medium-fidelity simulation (k=7) — positive but non-significant pooled effect (SMD=0.56, 95% CI -0.16 to 1.28, p=0.125, I^2 =90.5%).

Subgroup B: high-fidelity simulation vs. traditional teaching (k=2) — insufficient studies for pooling; reported narratively (g=1.37 and g=4.89).

Sensitivity analysis A sensitivity analysis was performed on Subgroup A. The 3 studies with PEDro<5 were sequentially excluded, revealing that the significance of the pooled effect depended on the inclusion of Al-Mugheed et al. (2025), the study with the largest effect magnitude in the subgroup (g=2.98). After excluding the lower-quality studies, the confidence interval of the recalculated pooled effect came to include the null value.

Language restriction Not applicable.

Country(ies) involved Colombia.

Keywords High fidelity simulation, learning, competencies, education.

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