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A protocol to evaluate the effectiveness of competency-based simulation training modules on the educational outcomes among MBBS students - A mixed method study

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Abstract:

BACKGROUND: The growing recognition of the importance of simulation-based training has been a present focus of medical education curriculum planners. This study aims to design, develop, implement, and evaluate the educational outcomes of training modules for a list of essential skills that MBBS students in a tertiary care teaching hospital in South India need to learn as part of their competency-based MBBS curriculum.

MATERIALS AND METHODS: This sequential transformative mixed method study will be implemented in three phases: i) identification of essential skills for simulation-based training following the modified Delphi method, ii) development of skill training modules using ADDIE model of instructional design, implementation of the modules and collection of data on the educational outcomes and iii) a qualitative study involving in-depth interview and focus group discussion on understanding the potential for incorporating the modules into the present MBBS curriculum. Data on educational outcomes relevant to the study objectives will be collected using appropriate tools and analyzed using descriptive statistics and qualitative analytic methods.

RESULTS: Phase one will tabulate the list of five essential skills and phase two educational outcomes will contain descriptive statistics on knowledge and skill acquisition, perception of simulation-based teaching and learning, and higher-order thinking skills. Phase three qualitative analysis will highlight the enabling and barrier aspects for incorporating this approach of simulation-based skill training within the current MBBS curriculum.

CONCLUSIONS: The study outcomes will provide curriculum planners and educators insights into designing and implementing simulation-based skill training for undergraduate medical students. It will also help policymakers develop policies in medical education technologies to provide quality medical education and fulfill the objective of quality healthcare for all.

Keywords:

Academic success, competency-based education, clinical skills, medical education, simulation training

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Introduction

Competency-based medical education (CBME) has become a major twenty-first-century pedagogical approach to medical education in many countries.^[1-3]

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CBME has a history dating back half a century and is rooted in general educational approaches such as outcome-based education and mastery learning.^[2,3] International medical regulatory bodies in Canada, the United States, and other

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countries have embraced CBME.^[4] In India, the National Medical Commission (NMC) has implemented competency-based undergraduate medical education since 2019.^[5] Medical education is accountable for the graduates' professional level, ensuring they are skilled and competent in all key areas of their profession.^[6,7]

Acquiring basic procedural skills is one of the competencies required of a medical graduate to ensure patient safety.^[8,9] Traditionally, students have learned this art and science by observing their experienced counterparts at the bedside, followed by independent execution of skills on real human patients.^[10] However, in achieving these skills, patients' safety may be compromised as they may inadvertently be exposed to the hazards of medical errors. Simulation-based medical education (SBME) may address some of these concerns.^[11] "Simulation is a method, not a technology, to replace or amplify real experiences with guided experiences, often immersive in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion. 'Immersive' conveys that participants are immersed in a task or a setting as they are in the real world."^[11,12] Simulation is considered an integral method to educate and train procedural skills among medical professionals.^[12,13] There has been a rapid use of simulation in medical education over decades in the Western world.^[2,12]

CBME requires a robust multidimensional assessment system to measure and guide learners toward predetermined goals.^[13] Simulation has been proposed as one of the methods for assessing competency in health care.^[13,14] However, it is an unexplored new pedagogy in medical education in developing countries like India.

In addition, the growing recognition of the importance of simulation-based training has been a present focus of medical education curriculum planners. Though simulation-based training has been successfully institutionalized in other professions, its implementation in medical education curricula has lagged for various reasons, including cost, lack of rigorous proof of effectiveness, and lack of knowledge and training among teaching faculty.^[15] Addressing this substantial gap requires valid educational research to minimize disparities in teaching and training, ensuring effective replication of teaching practices. To achieve this goal, obtaining consensus from multiple clinical specialists on essential skills, course content, feasibility of implementation, and evaluating educational outcomes is essential.

This study aims to identify the essential procedural skills, design and develop training modules, and implement the training modules for third-year MBBS students in

a tertiary care teaching hospital in South India. The educational outcomes of this study in cognitive, affective, and psychomotor domains will be evaluated for their feasibility for incorporation into the present MBBS curriculum. Hence, the specific objectives of the study include:

1. To identify the five most essential skills for third-year MBBS students from the certifiable competencies listed in the Graduate Medical Regulations 2019.
2. To develop competency-based simulation training modules for the identified essential skills for the third-year MBBS students.
3. To implement the competency-based simulation training modules among the sixth-semester MBBS students following educational strategies.
4. To evaluate the educational outcomes of the competency-based simulation training modules.
5. To ascertain the student's perception of the training program imparted using the competency-based simulation training modules.
6. To assess the feasibility of incorporating the modules into the curriculum of the third-year MBBS program based on the educational outcomes.

Materials and Methods

Study design and setting

A sequential transformative mixed method^[16] approach will be used, which will be implemented in three phases. This method allows for merging inductive and deductive reasoning, maximizing the strength of each piece of information, and promoting a complete understanding of the application of simulation technology in medical education. The modified Delphi method^[17,18] will be conducted in the first phase, followed by a one-group pretest-posttest design and qualitative study involving interviews and focused group discussions (FGD).

Study participants and sampling

Non-probability convenient sampling method will be adopted as the researchers will involve all 160 third-year MBBS students for this educational research.

Phase 1

Identification of essential skills for simulation-based training

The National Medical Commission of India recommends a total of 54 certifiable skills for MBBS students, out of which 28 skills need to be performed independently on patients, 11 skills need to be observed directly on patients, and 15 skills demonstrated on patients.^[19] The modified Delphi method will be used to investigate educators' perspectives and reach a consensus on the essential procedural skills that can be considered for simulation-based training of MBBS students. Ten subject

experts from preclinical and clinical disciplines with a minimum of five years of teaching experience in the MBBS program will participate in the modified Delphi method. The experts will rank the skills listed in the NMC curriculum from “most important” to “least important” on a scale of 1 to 20. The weighted average method will be used to determine the top five preferred procedural skills.^[20]

Phase 2

Development of skill training modules

Simulation-based training modules will be developed using the ADDIE instructional design model^[21] for the five essential procedural skills identified through the modified Delphi method. ADDIE model is a five-step process for effective training and learning that includes Analyze, Design, Develop, Implement, and Evaluate. The developed modules will be validated for content validity by three clinical experts, and construct validity and reliability will be accomplished by a pilot test with 60 undergraduate medical students.

Training of instructors for skill training

A minimum of eight faculty volunteers will be trained to be instructors for the five skills. They will receive training in the principles of teaching and learning psychomotor skills, simulation pedagogy, and the use of assessment tools. Figure 1 shows the schematic representation of the study design.

Steps of implementation

After approval by the Institute Scientific and Ethics Committee, permission from the Dean Academic will be obtained to include the training sessions as part of the third-year timetable. The training sessions will be scheduled, and all 160 students will be grouped accordingly. Reading materials will be made available

online for the students to go through and learn the cognitive elements of the skills well before the start of the training session. On the day of the skill training, a pretest will be conducted to assess their preparedness for the training and their level of knowledge regarding the specific skill. Instructors will provide the training through hands-on skill practice following the principles of teaching psychomotor skills and simulation pedagogy. The data on the educational outcomes of each skill training session will be collected using validated checklists and observation schedules. For testing the “knows,” “knows how,” and “shows how” levels, Miller’s framework for competency assessment will be utilized.^[22]

Phase 3

The primary goal of the research at this point is to contextualize and support quantitative data to determine whether or not it is feasible to include the skill modules into the present MBBS curriculum. Focus group discussions and interviews will be used to gather meaningful iterative and inductive feedback from students and simulation instructors. This will give the researchers a thorough understanding of the potential for incorporating the modules into the present MBBS curriculum.

Data collection tools and technique

The following tools will be developed and standardized to collect data on the educational outcomes of skill training sessions:

1. Multiple choice questions for pre- and posttest.
2. Objective Structured Clinical Examination (OSCE) checklist for performance assessment.
3. A three-point Likert scale to measure students’ perception of simulation-based teaching and learning.
4. Scenario-based questions to assess higher-order thinking skills related to the procedures learned.

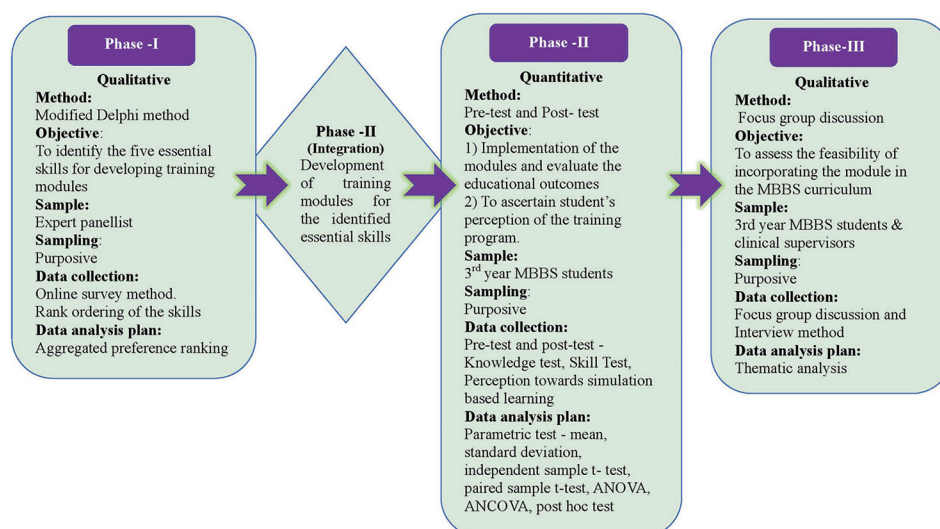


Figure 1: Schematic representation of the study design

5. A comprehensive tool for the direct observation of procedural skills for recording observable and measurable behaviors during the skill training.
6. A semi-structured interview schedule to collect information from trainers and information-rich respondents to assess the feasibility of incorporating the module into the current MBBS curriculum.
7. A digital learning management system to provide the students' access to reading materials, skill demonstration videos, steps of procedures, multiple choice questions for self-assessment and scenario-based questions.

Ethical considerations

The institute's ethical review board has approved the study (JIP/IEC/2021/054 dated 15/12/2021). Informed consent will be obtained from all the participants. Risks involved in the study are similar to attending a live lecture for 15 minutes or a lecture podcast for 15 minutes on clinical topics from the MBBS course and giving feedback on teaching methods. The assessment of the modules taught will be strictly only for the research study. The marks obtained will not be considered for the evaluation of the academic performance of the participants. Data collected will be anonymous, and the confidentiality of the data will be maintained and only used for research and publication purposes. Dissemination of the findings will be through conferences and publications.

Data analysis plan

As part of the study's need analysis, the first step is to choose the five essential skills from the list of skills that have already been made. After tallying and analyzing the responses from the first and subsequent rounds, until the study panelists agree on the five most important skills, an anonymous internal report will be made. A statistical method called 'aggregated preference ranking' will be used to figure out the order of the skills.^[20]

Quantitative data analysis will be performed using IBM SPSS ver. 26.0 (IBM Corp., Armonk, NY, USA). Statistical significance will be set at a P value <0.05 .

Demographic variables such as age, gender, and graduation grades will be categorical variables presented in frequencies and percentages. The data on educational outcomes such as knowledge, skill level, and perception toward simulation-based skill learning after implementing the simulation skill module will be tabulated. The continuous variable of pretest and posttest scores of simulation skill module knowledge scores will be expressed as mean $\pm$ SD. The independent sample t test and analysis of variance (ANOVA) will be used to determine the mean significant differences in pretest and posttest scores. P value <0.05 will be considered statistically significant. Descriptive analysis will be used

to analyze the data on additional variables chosen to understand the educational outcomes of the study such as deliberate practices, chronometry, retention, and decay of knowledge and skill performance. The outcomes of the scenario-based questions will be analyzed to determine the degree of success. Descriptive analysis will be used to analyze the participants level of agreement with the statements provided in the perception tool.

The third stage of research involves investigating the adaptability and feasibility of implementing the skill module. Because it will take an inductive approach, data analysis will involve an open and reflexive engagement with existing literature and therefore will support the findings of the second stage of the research methodology. Our analysis at this stage will involve coding on different levels about the implementation, simulation environment, and possibility of simulation-based teaching. Interviews will be considered an important resource providing an objective reality. As this will allow the emergence of participants' views and descriptions of the skill module implementation rather than 'theory-testing strategy.' Thus, the approach will involve many of the processes described as ground theorizing.

Limitations

Apart from parameters such as students' beliefs about simulation-based learning, the Hawthorne effect, the control of case scenarios, the number of skills taught, the inadequacy of evidence to generalize educational outcomes with reference to one tertiary care teaching hospital, and student diversity, the other general limitations applicable to simulation-based educational training research apply to this study. The absence of a control group would limit the internal validity of this educational research.

Expected outcomes and implications

The study will provide us with valuable insights on the fidelity and reliability of the simulators used for the skill training. We will be able to decide how many times the simulation skill session has to be incorporated into the future timetable as a result of the researchers' evaluation of the retention of knowledge and skill. The results of a qualitative study will provide indications of the elements that support and constrict the acquisition of new skills. Additional interviews will show how students interpret the simulation-based skill training programs offered in their curricula. The study outcomes will also provide directions on the nature and strength of resources required for implementing simulation-based skill training for MBBS students studying in tertiary care teaching hospitals. The study results may influence module developers to develop training modules for additional skills listed by NMC. The study outcomes will indicate to policymakers and educators the effective implementation of simulation-based skill training as recommended by NMC.

Conclusion

Simulation-based skills training that adheres to educational principles is a promising method for improving clinical outcomes and patient safety. The results of this study will provide robust evidence of the educational outcomes of simulation-based training using competency-based training modules. Medical educators and curriculum planners can gain insights into simulation-based skills training for MBBS students. The findings of this study will allow educational researchers to identify existing gaps in simulation-based skill training and move forward with the study's recommendations for future research. This study will help administrators and leaders in medical education make decisions about mobilizing resources for skills training and inform future curricular designs.

Abbreviations

ADDIE = Analyze, Design, Develop, Implement, and Evaluate

ANOVA = Analysis of variance

CBME = Competency-based medical education

FGD = Focus group discussion

MBBS = Bachelor of Medicine and Bachelor of Surgery

NMC = National Medical Commission

OSCE = Objective Structured Clinical Examination

SBME = Simulation-based Medical Education

SPSS = Statistical Package for the Social Sciences.

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Conflicts of interest

There are no conflicts of interest.

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