

## COMMENTARY

# Ethical issues and proposed solutions in conducting practical assessment of medical students involving patients

ANKIT CHANDRA

### Abstract

*Practical assessment involving patients plays a vital role in medical education, allowing students to demonstrate their clinical competencies. However, there are significant ethical concerns associated with these assessments that require careful consideration and resolution. The primary ethical concerns include violation of patient autonomy, lack of written informed consent, power dynamics, cultural differences, potential harm to patients, breach of privacy and confidentiality, discomfort to admitted patients, financial loss to patients, impact on other patients' care, and delays in workup/procedures. To address these concerns, measures such as respecting patient autonomy, obtaining written informed consent, ensuring patient safety, exploring alternative methods, providing reimbursement, resource planning, creating a supportive environment, developing cultural competency, putting in place a feedback system, prioritising patient care, and implementing ethical oversight and monitoring are recommended. The formulation of a guideline could be a crucial starting point, and it should be integrated into a broader ethical framework that encompasses education and training, ethical oversight, ongoing monitoring, and a culture that prioritises ethical conduct.*

**Keywords:** ethical consideration, examination, patient well-being, medical education

### Case study

Mrs T, a 29-year-old woman, had been recently diagnosed with systemic lupus erythematosus. While attending a follow-up visit in the outpatient department (general medicine) of a teaching hospital, she was selected to be a participant in the practical assessment conducted for final-year undergraduate

medical students. She was only informed that she needed to be admitted for further investigations related to her illness. She exhibited classic clinical symptoms related to her illness and was labelled as an interesting case, which led to her inclusion in the practical assessments of students over a period of four consecutive days. Over this period, Mrs T underwent daily evaluations, which included history-taking and physical examinations conducted by several medical students as part of their practical assessments. Mrs T stayed in a general ward (dormitory) due to financial constraints, as she could not afford a private room. Her husband, who worked as a contractual labourer, accompanied her during her stay. Unfortunately, her young children had to be left under the care of a neighbour.

By the third day, she started complaining of a constant cough, which was initially not given sufficient attention. On the fifth day, she was evaluated for the cough and diagnosed with hospital-acquired pneumonia. Her condition rapidly deteriorated, and on the seventh day, she developed severe breathlessness and hypotension due to myocarditis and was subsequently shifted to the intensive care unit (ICU). Inotropes were initiated to support her failing heart. Tragically, after three days of battling for her life, Mrs T succumbed to her condition and passed away.

What ethical principles were violated? Who is responsible for her death? How could this have been prevented?

### Introduction

Practical assessments serve as a vital component of medical education that helps train, equip, and assess future healthcare professionals. This allows students to develop clinical competencies and knowledge to provide quality patient care. In India, practical assessments are regularly conducted for various medical courses — Bachelor of Medicine, Bachelor of Surgery (MBBS), Doctor of Medicine (MD), Master of Surgery (MS), Doctorate of Medicine (DM), Magister Chirurgiae (MCH), Diplomate of National Board (DNB), and fellowships [1]. For the practical assessment (formative and summative) associated with these degrees, a specific process is followed, where selected patients are either admitted to the hospital or requested to be available at home for assessment (in community medicine). In practical assessments for the mentioned degrees, the process primarily involves history-taking and conducting a physical examination of the selected patient, followed by a viva voce session with the examiner. Alternatively, it may be

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To cite: Chandra A. Ethical issues and proposed solutions in conducting practical assessment of medical students involving patients. *Indian J Med Ethics*. 2024 Jul-Sep;9(3) NS: 217-222. DOI: 10.20529/IJME.2024.034

Published online first on June 1, 2024.

Manuscript Editor: Rakhi Ghoshal

Peer Reviewer: Priya Satalkar

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conducted in the Objective Structured Clinical Examination (OSCE) format. However, conducting practical assessments involving patients raises important ethical considerations that require careful attention and resolution [2,3].

Ethical considerations are deeply ingrained in medical teaching and are included in all curricula [4]. Physicians are bound by regulations governing professional and ethical conduct, overseen by medical councils [5]. In the realm of medical research, stringent ethical reviews and approvals are mandatory for all protocols, and the respective institute's ethics committee is responsible for this [6]. Paradoxically, ethical aspects often receive inadequate attention when it comes to organising practical assessments for medical students. This article aims to delve into the ethical issues associated with practical assessments involving patients and sets out recommendations to ensure ethical conduct.

## **Ethical concerns**

### ***Violation of patient autonomy***

Although patient autonomy has been recognised as a basic right for decades, there is evidence suggesting that medical education often fails to uphold this principle [2,7–9]. Instances have been reported where patients are asked to return to the clinic or are admitted solely for teaching purposes, without being adequately informed about their participation in assessments [10]. Patients admitted solely for their own or routine care should not be subjected to repeated examinations by various students even when their clinical findings are of interest, because this would amount to infringing on their autonomy. Student involvement in their care can be valuable for educational purposes, but their well-being and medical needs should take precedence.

### ***Lack of written informed consent***

Prior to involvement in any practical assessment or educational programme, it is imperative to obtain valid and explicit informed consent. Regrettably, there have been documented instances in the past that highlight a lack of compliance in this regard [7,8]. This lack of transparency can lead to the occurrence of therapeutic misconception in medical education. This situation can exacerbate the problem by fostering false hope, particularly if the patient's condition is incurable and untreatable and they are admitted without being provided with the necessary information. This misconception can compromise their decision-making capacity and erode their trust in the healthcare system.

### ***Power dynamics***

The majority of patients seeking treatment in teaching (government) hospitals belong to vulnerable populations having low literacy and of low socio-economic status [11]. In such settings, medical teachers, driven by the need to ensure a smooth assessment process, may misuse their power to coerce vulnerable patients into participating in the students'

assessment process. Medical students frequently face immense pressure to excel in their practical assessments, which can result in them conducting unnecessary or overly thorough clinical examinations in pursuit of better grades. In such situations, patients may experience a heightened sense of vulnerability, because they depend on medical professionals for their well-being, and consequently, a loss of autonomy.

### ***Cultural difference***

Cultural difference between patients and students/staff can significantly impact the shared decision making, again leading to a perceived loss of autonomy on the part of the patients. This, in turn, affects the overall experience of patients in the hospital and may even give rise to conflicts [12].

### ***Potential harm to patients***

During the stay at the hospital, there is an increased probability of a person being exposed to diverse microbes, which can lead to hospital-acquired infections. This risk is particularly heightened for patients with compromised immune systems, such as pregnant women, children, or individuals on immunosuppressive medications [13]. Patients with comorbidities, despite being highly vulnerable, are often more likely to be selected as case studies for practical assessments because, from a student assessment perspective, they are more desirable candidates [14]. The practical assessment of undergraduate medical students is usually conducted over multiple days and in batches. Thus, there is a potential for prolonged hospital admission of a patient, with multiple examinations by different students. This repeated exposure to multiple individuals and intimate procedures can increase the risk of pathogen exposure and also make patients feel hassled by students, which can ultimately lead to reduced cooperation.

### ***Breach of privacy and confidentiality***

Studies have indicated that a substantial proportion of patients are unwilling to share their medical records with students or staff, and many patients feel uncomfortable when examined in the presence of a student [7].

### ***Restrictions on the admitted patient and associated discomfort***

Participating in the students' assessments causes disruptions to the patients' prior commitments and daily schedules. It separates them from their family and exposes them to an uncomfortable (stressful) environment [15]. The hospital stay of a patient can have an impact on the dependent individuals (children/elderly) and domestic animals/pets [16]. Patients can be uncomfortable as they may have to share toilet facilities and compromise on their food preferences as well as change their daily routine and activities.

### **Financial loss to patients**

The requirement for the patient and their caregivers/family members to be present in the hospital/home can disrupt their work. This leads to indirect costs in the form of lost wages, exhaustion of paid leave, or loss of productive time. This is in addition to the direct expenses associated with travel, food, accommodation, and other incidental costs related to hospital admission [17].

### **Delay in workup/treatment procedure of participating patients**

When patients are admitted for participation in the practical assessments of students, there is a potential for delays in their workup or treatment procedures, as their involvement in the assessment may take precedence. For instance, an admitted patient requiring inguinal hernia repair may have his/her elective surgery postponed, as his/her participation is required for conducting the students' assessments.

### **Affecting the care of other patients**

The practical assessment involving admission of patients increases the workload on hospital staff, is a strain on the hospital's resources, and can potentially impact the care of other patients. Accommodating admissions for practical assessments may also mean denying admission to patients in need, early hospital discharge of existing patients, or delay in the workup of other patients [18].

## **Mitigating ethical concerns**

### **Respect patient autonomy**

Patients have the inherent right to make informed decisions regarding their healthcare or participation in educational activities [19]. They have the autonomy to refuse to participate at any point of time, regardless of whether they seek care in a private or government health facility. Any refusal or non-cooperation should not impact the quality of patient care or priority provided to them.

### **Written informed consent**

When obtaining consent, it is essential to emphasise that the primary objective is to enhance the learning experience of medical students rather than provide direct therapeutic benefits to the patient. Standardised consent forms with a comprehensive patient information sheet can be provided beforehand [20]. The informed consent process should explicitly disclose the risks, benefits, role of the patient, and rights of the patient. Due to the complexity of the consent, a professionally trained or senior person can obtain the consent on behalf of the students and the institute [21]. However, providing written consent at one point does not imply that a patient is committed to participating on all days of the practical assessment. Consent should not be a blanket agreement.

### **Confidentiality and privacy**

Upholding patients' privacy and confidentiality is a fundamental principle of medical ethics. Patients can be pre-informed about the presence of and assessment by the students and should be made aware that their health information will be shared with and retained by students/staff/examiners [22].

### **Ensuring patient safety**

Infection control protocols need to be followed, which include proper hand hygiene, maintaining a clean and sterile environment, implementing appropriate isolation precautions, and ensuring the use of personal protective equipment (PPE). Each patient participating in the practical assessment should undergo a thorough risk assessment to identify highly susceptible individuals. An immunocompromised patient can be allotted an isolation room to minimise the risk of infection transmission. Precautionary measures such as offering day care admission and minimising the exposure by limiting the number of people can be employed.

### **Exploring alternative methods**

Alternative methods for conducting practical assessments, such as simulation models, virtual reality, or standardised patients (trained individuals to portray specific medical scenarios), can be explored [23]. This can involve the evaluation of the clinical skills of a student through real-time observation in outpatient settings by utilising clinical vignettes, artificial intelligence [24], or simulation-based or virtual platforms [25].

### **Honorarium or reimbursement to patients and families**

To recognise the time and cooperation of the patients/families, institutions can allocate special budgets to provide remuneration to them. This assistance can cover various expenses, including transportation, lodging, and compensation for any lost wages incurred by the patients or their caregivers [26]. To reduce the financial burden, free accommodation in best-available wards, free meals, and daily necessities should be provided during the hospital stay. However, it has to be kept in mind that this compensation can act as an inducement for patients with limited financial resources. Thus, it must be administered ethically by acknowledging and valuing participants' contributions.

### **Effective resource planning and allocation**

The hospital administration should take part in estimating the number of patients required for assessments and coordinating to allocate appropriate bed capacity, staffing, space, and resources to accommodate both practical assessments and routine patient care.

### ***Creating a supportive environment and developing cultural competency among students and staff***

It is essential to address power dynamics and cultural differences. Students and staff can be trained in communication skills and cultural sensitivity to ensure that they interact appropriately with patients [27]. Students often learn by observing how their teachers interact with patients. Therefore, it is imperative to provide comprehensive training for all staff members.

### ***Prioritisation of patient care***

The well-being of patients should be prioritised over the educational requirements. None of the necessary investigations or treatment procedures should be delayed or compromised.

### ***Feedback system from patients, students, and staff***

Feedback mechanisms and quality assurance programmes should be in place to identify and address any potential harm to patients or any other issues that may arise [21]. A daily debriefing session could prove valuable to not only have a sufficient number of patients for assessment, but also for the well-being of patients. Early intervention is possible if patients are encouraged to promptly communicate any discomfort or stress they might be feeling or any negative experiences they might have had with students/staff. Nurses, who have more extensive patient interaction, represent a valuable resource and can serve as strong advocates for patients.

### ***Expressing gratitude***

Expressing gratitude to patients for their participation through a vote of thanks serves as a powerful motivator and fosters a positive environment that encourages other patients to participate as well. This can be done by the team conducting the practical assessment (including the treating doctor and nurse), students, and administrative personnel.

### ***Ethical oversight and monitoring***

Practical assessments can be overseen by a team consisting of an ethics committee member, medical education unit, and hospital administration to ensure that ethical and educational standards are met.

### ***Standardised guidelines and training***

It is essential to establish standardised guidelines, which can be prepared at the institute level by the medical education department and the ethics committee or at the national level by the medical council involving ethicists and legal experts. Healthcare professionals and hospital staff should receive ethics training to understand the ethical principles and legal aspects involved in conducting practical assessments.

### ***Case study discussion***

In the light of the ethical issues and solutions discussed above, it is essential to analyse the case study of Mrs T in

terms of the ethical principles that were violated, who may bear responsibility for her unfortunate demise, and how this tragic outcome could have been averted.

Several ethical principles were violated in Mrs T's case:

1. Patient autonomy: Mrs T was wrongly informed about the purpose of her admission, and she was not given the option to participate or withdraw from the students' assessment. This breached her right to make decisions and her autonomy.
2. Lack of informed consent: Mrs T provided her consent for admission with the understanding that it was solely for the purpose of investigating her illness. She did not provide informed consent for participation in the students' assessment, which entailed multiple examinations by several medical students.
3. The treating physicians may have abused their position of authority by misleading her about the true purpose of admission. This situation also created a therapeutic misconception.
4. Non-maleficence: The failure to promptly address her complaints about a constant cough and her exposure to various people in an immune-compromised state resulted in hospital-acquired pneumonia, which led to further deterioration of her health. This demonstrated a failure to follow the dictum of "do no harm."
5. Beneficence: The hospital team did not act in the best interests of the patient. Rather than focusing on her clinical care and well-being, they primarily used her for educational purposes.
6. Privacy and confidentiality: Mrs T underwent examinations by multiple students, and these students subsequently shared their findings with the examiners. Her personal medical information was disclosed to a large number of individuals (staff, examiners, and students) without her explicit permission.
7. Mrs T, despite her low socio-economic status, was not provided with the necessary support or accommodation, such as a private room, which could have minimised her risk of exposure to infections. She was admitted for an extended period, and she was subjected to daily exposure to multiple students.
8. The sole breadwinner of the household, her husband, did not receive compensation for the wages he lost while accompanying her during her hospital stay.
9. Mrs T was compelled to leave her children in the care of neighbours without fully understanding

the real purpose of her admission. Her children would have also suffered due to their parents' prolonged absence and the ultimate loss of their mother for an undisclosed reason.

The teaching hospital bears significant responsibility for her tragic death due to its failure to ensure proper informed consent, inadequate supervision, and insufficient measures taken to ensure the patient's safety. Additionally, the hospital staff and the team that conducted the examination (including the examiners) share responsibility by not promptly addressing her deteriorating condition and repeatedly exposing her to various people.

This tragic outcome could have been prevented if the precautions detailed below had been taken:

1. The patient was in an immune-compromised state, warranting special precautions such as isolation in a separate room to minimise infection risk from other patients. Strict infection control measures, including mask wearing and sanitation, should have been enforced. Her exposure to multiple students could have been reduced by limiting the number of examinations.
2. Instead of a hospital admission, and after obtaining her consent for participating in the students' evaluation, an option for day care admission could have been offered to her, along with compensation for her time.
3. Daily monitoring and timely response to her complaints could have facilitated early intervention and potentially saved her life.
4. To prevent such tragic incidents in the future, it is imperative to commit to ethical practices, provide comprehensive training to staff, and foster a culture that prioritises patient well-being and autonomy.

## Conclusion

While practical assessments play a crucial role in enhancing students' clinical skills, there is a potential risk of harm to patients. Striking a balance between ethical duties, educational responsibilities, and patient welfare becomes paramount. This necessitates a collective effort involving a spectrum of stakeholders within an educational institution, including patients, healthcare professionals, the hospital administration, the medical education unit, patient advocacy groups, ethicists, and legal experts. Implementation of the suggested solutions would depend on various factors such as available manpower, resources, and leadership. It's possible that a more nuanced understanding of their effectiveness may emerge after implementing a subset of these solutions. Future research efforts can delve into uncovering additional ethical challenges and devise effective strategies to address them.

Currently, there is a lack of guidelines or protocols to ensure that practical assessments for students are conducted in an ethical manner. A guideline can be a vital starting point and can be part of a broader ethical framework that includes education and training, ethical oversight, continuous monitoring, and a culture that values ethical behaviour. The educational institution must take responsibility for both the successful implementation of such guidelines/checklists and the sensitisation of staff and students to these important ethical issues.

**Conflict of Interest:** None to be declared.

**Funding:** No funding received.

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## COMMENTARY

# “Research paper mills”: A factory outlet for dubious research

SHUBHADA NAGARKAR

### Abstract

The primary objective of any research, regardless of its domain such as health, technology, psychology, or any other subject, is to enhance the overall well-being of individuals. Rigorous processes are involved in conducting research ethically and in communicating its outcomes to society. However, as publishing research has become a mandatory requirement for career advancement and appointments, academics are resorting to several unethical practices to get substandard work published quickly. Consequently, predatory publishing markets have emerged, which publish data that is falsified and fabricated, along with plagiarised textual matter. The emergence of “paper mills” is a further step in the corruption of research, where a group of persons or automated systems generate papers for publication. Anyone desirous of publishing a paper can purchase one, akin to

any desired fast-moving consumer product, with the added guarantee of publication in indexed journals. Therefore, paper mills and their unethical modus operandi are discussed in this paper in detail, with relevant examples. The article unfolds the consequences of publishing such fraudulent research papers and concludes with the challenges in combating paper mills.

**Keywords:** paper mills, dubious research papers, publication misconduct, machine generated papers

### Introduction

Honestly and ethically conducting research, and transparently communicating its results to society, are rigorous and demanding processes. To carry out any original research, a researcher is required to formulate and conduct a study, undertake an exhaustive literature search, and uphold the integrity of experimentation and data collection processes. These endeavours demand significant time and concerted efforts. Following meticulous editorial scrutiny, the outcomes of such research are published in the form of a “research paper”. Thus, quality is the soul of the research.

Over the last few decades, the publication of research has been made compulsory for the recruitment and promotion of researchers and teachers in higher educational institutions. This has led to the emergence of the predatory journal market and exacerbated the production of bogus research papers [1]. Furthermore, during annual appraisals, the practice of assigning marks to papers published in high-impact-factor journals has led to the emergence of over 20

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To cite: Nagarkar S. “Research paper mills”: A factory outlet for dubious research. *Indian J Med Ethics.* 2024 Jul-Sep; 9(3) NS: 222-227. DOI: 10.20529/IJME.2024.025

Published online first on April 26, 2024.

Manuscript Editor: Sandhya Srinivasan

Peer Reviewers: Two anonymous reviewers

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