



## Evaluation of Oral Examination of Medical Undergraduates in Pharmacology – A Conceptual Study

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### Authors' contributions

This work was carried out in collaboration between both authors. Author SIM designed the study, wrote the protocol, and wrote the first draft of the manuscript. Author YSP managed the literature searches and analyses of the study. Both authors read and approved the final manuscript.

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### ABSTRACT

**Aims:** Oral examination has held an important place in medicine for centuries. Apart from some advantages, oral examinations are prone to many errors contributing towards threats to validity like Construct Under-representation and Construct Irrelevant Variance. Reliability, validity, feasibility and acceptability have to be considered when evaluating efficacy of any assessment protocol. Present conceptual study analyses the problems focusing on validity issues and other relevant challenges in present oral examination conducted for second year Bachelor of Medicine and Bachelor of Surgery (MBBS) undergraduates in pharmacology in Jawaharlal Nehru Medical College, Belgaum.

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**Study Design:** Experimental, Randomised, Controlled study with Cross over design.

**Methodology:** To overcome these problems a solution has been proposed in the form of Structured Oral Examination (SOE). Details of the process involved in actually conducting SOE and how it contributes towards validity is elaborated. Conceptual framework used in the present study consists of five sources of evidence for construct validity comprising content, response process, internal structure, relationship to other variables and consequences. Research Question: Efficacy (in terms of reliability, validity, feasibility, acceptability and test scores) of SOE differs when compared to that of conventional oral examination. Second phase MBBS students will be randomly divided into two groups. In cross over design, each group will be exposed to both types of interventions: Conventional oral examination and SOE in the formative assessment. Attitude/feedback tests will be conducted for both groups and educators. Apart from the routine conventional oral examination, SOE which contain different stations with standardized scoring scales will be administered. In SOE each student has to face all the stations and answer all the questions.

**Results and Conclusion:** SOE may replace the conventional oral examinations in pharmacology. Practicability of the present conceptual study has to be confirmed.

*Keywords: Conventional; examination; oral; pharmacology; structured; undergraduates; validity.*

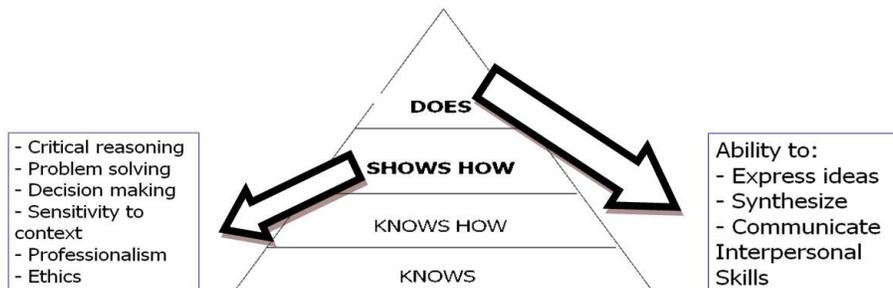
## 1. INTRODUCTION

Assessment motivates individuals to learn and practice the subject and helps to determine whether teaching and learning methods have achieved the learning objectives or outcomes [1]. Many types of assessments can be used in health professions education like: Written tests, Performance tests, Observational assessment and Miscellaneous tests (Oral exams, Portfolio etc) [2,3,4]. Present study is focused on oral examinations.

Oral exams have been used as a method of assessment for centuries [5,6]. Viva-voce examination is a general encounter between a candidate and one or more examiners [6,7]. Traditionally it is used for its flexibility [6], fidelity and potential for testing higher order cognitive skills [6] (Fig. 1). Oral exams have many benefits like: probing into candidates understanding of signs, symptoms and clinical reasoning with regards to a case, exploring topics and exposing to interactions [5,8,9,10].

Unfortunately oral exams are prone to many errors [7] like halo effects (a judgement of one attribute influences judgements of others), central tendency (judgements cluster in the middle), errors of logic (mistakes), a general tendency towards leniency and errors of contrast (judgements of a candidate are influenced by impressions of preceding candidates). These factors make oral examinations less reliable [7]. Scores of oral exams are related to irrelevant attributes of candidates such as appearance or confidence, poor agreement between examiners, generate marks unrelated to competence and moreover difficult to establish the validity [12]. Oral exams show poor reliability across cases and even a poor correlation between morning and afternoon sessions [13,14]. Even largely abandoned in USA, oral exams are still widely used in undergraduate and postgraduate exams in the UK [6] as well as in India.

There are many contradictory reports regarding the reliability of oral exams [15,16,17]. The key



**Fig. 1. Miller's assessment pyramid - what oral examinations can assess at higher levels [11]**

problem is being their potential for subjectivity [18]. Attempts to improve reliability of oral exams include increasing the number of oral assessments and number of examiners [19] as well as use of structured question grids [20]. Oral exams lack validity in terms of content sampling and its predictive validity of professional competence, which requires problem-solving skills, is questionable [21]. Reliability in oral exams can be affected by factors like anxiety of the candidate, inconsistency of the rater and various situational factors [7]. Involvement of 'leniency' by the pharmacology examiners to pass undeserving candidates has been reported [22]. It is difficult to establish in any formal way how valid an oral examination is [23]. There is a scarcity of published work on validity of the oral assessments used within medical education [24]. There is a need to improve the reliability and validity of the oral assessment [25].

There is a lack of a consistent teaching programme in medical colleges in India [26] and the confusion between conventional to contemporary still prevails. In the undergraduate medical education system in India, curricular guidelines of Medical Council of India (MCI), a regulating authority for medical colleges, lay emphasis on methods of assessment of knowledge and skills in pharmacology [27]. Although continuous formative assessment constitutes an integral part in the curriculum, the 'pass' and the 'fail' certificates are based to a great extent on students' performance in the final summative examination [27]. The final exam consists of written papers, viva-voce sessions and practical exercises. In viva-voce exam (40 marks), each student is assessed by four (two external and two internal) examiners [27]. Conventional oral exam is used for assessing the students for decades in the Department of pharmacology, Jawaharlal Nehru Medical College. There is a strong need to establish the reliability and validity for oral exams or in other words to propose a solution which is reliable and valid.

### 1.1 Goal

To assess the present system of oral examination (viva voce) in our institution and to propose a solution to improve validity of the same.

### 1.2 Objectives are to:

1. Highlight the present status of oral examination.

2. Identify threats to validity of the present used format of oral examination.
3. Propose a solution (changes) to improve the validity of oral examination.

## 2. MATERIALS AND METHODS

### 2.1 Research Question

Efficacy (in terms of reliability, validity, feasibility, acceptability and test scores) of SOE differs when compared to that of conventional oral examination.

Null hypothesis:  $H_0: \mu_{SOE} = \mu_{COE}$ , Alternative hypothesis:  $H_1: \mu_{SOE} \neq \mu_{COE}$  and Descriptive hypothesis:  $H_D: \mu_{SOE} > \text{or} < \mu_{COE}$ . ( $\mu$  = Efficacy, SOE = Structured oral examination, COE = Conventional oral examination).

Present oral exam in our institution has many threats to its validity. Threats may be classified into Construct Underrepresentation (CU) and Construct Irrelevant Variance (CIV) which are listed below.

### 2.2 CU (or Under Sampling)

*Lack of:* content specificity, assessment of clinical skills (limited or no scenarios), broad and systematic sampling of the content domain, real patients, fairness and comparison of test scores across examinees. Present oral exam tests only simple recall [21,28].

### 2.3 CIV (Systematic Error)

CIV (systematic error) is anything that systematically impacts scores aside from true differences between examinees or irrelevant to the competency being assessed. Some of the factors (have been mentioned earlier in other studies also) are: examinees' characteristics such as politeness, demeanour/appearance and attractiveness (e.g.: dress code), physical abnormalities/peculiarities or oddness, anxiety/stress level, emotional status [29], confidence [12], language and fluency. Other virtues like communication style [18], direct versus indirect eye-contact and moderate versus slower response rate can also influence. Facial expression can encourage or discourage an examinee's responses. Few examiners, can contribute to stringency and bias effects [17,30,31]. Language difficulty ex.: English language being different than the mother tongue.

## 2.4 Proposed Solution: Structured Oral Examination

SOE offers significant benefits in combating CU and CIV. In SOE, each examinee is exposed to the tasks, under same conditions, in the same amount of time and with scoring as objective as possible [32]. Various characteristics of SOE as well as newer modifications will be incorporated into the present study.

### 2.4.1 Conceptual framework

Health science programmes have an ethical responsibility to ensure that reliable and valid assessment tools are utilised [33]. All assessments in medical education require evidence of validity (usually assessment scores) to be interpreted meaningfully. Construct validity is the whole of validity but has multiple facets. Conceptual framework (model) used in the present study consists of sources (five) of evidence for construct validity adapted from SM Downing [34]. Five sources viz., Content, Response process, Internal structure, Relationship to other variables and Consequences – are noted by the Standards for educational and Psychological Testing as fruitful areas to seek validity evidence. Reliability, validity, feasibility and acceptability have to be considered when evaluating the efficacy of any assessment protocol [34].

### 2.4.2 Content

Blue print for the SOE is designed in the subject of pharmacology. Blueprint can be divided into content knowledge and skills which have to be assessed. *Content knowledge* may be divided into *Domains* like General pharmacology, Drugs acting on: Autonomous nervous system, Peripheral nervous system, Cardiovascular system, Central nervous system, Endocrines, Respiratory system, Kidney, Blood and its formation, Gastrointestinal system, Antimicrobial drugs, Autacoids, Antineoplastic drugs and Miscellaneous drugs (14 stations) and *Sub-domains*(for each domain) like Classification of drugs, Mechanism of action, Pharmacological actions, Pharmacokinetics, Preparations and doses, Adverse effects, Interactions, Precautions and contraindications, Therapeutic uses and management of patients (Table 1).

### 2.4.3 Skills

Blueprint of skills like Decision making/judgement (e.g.: A female aged 23 years has come to your

clinic complaining of severe diarrhoea. What drugs you/examinee will prescribe to the patient if the following drugs are available viz., Inj. Ciprofloxacin, Tab Tetracycline, Ringer lactate, Normal saline, Oral rehydration solution/ORS, Tab Paracetamol, Inj. Furosemide, Tab Cetrizine OR comment and rewrite on a given irrational prescription for a disease/patient); Patient management (e.g.: A 45 year old farmer has been admitted to the emergency department in unconscious state. Initial history taken from patient's wife revealed that he has consumed organo-phosphorous compounds (insecticides) to commit suicide as he has excess loan/debt. How do you manage the patient?); Diagnostic interpretations (e.g.: Prescribe for a female patient aged 50 years with severe pain in left side of the chest radiating to left arm); Communication and interpersonal skills (e.g.: a station with a simulated patient or real patient can be used) and Professionalism (e.g: prescribing cheaper medicine for a poor patient or providing physicians samples) (5 stations) has been shown in (Table 2).

Standardization of all the questions will be done. Questions will be designed so that knowledge of facts, understanding of basic concepts in pharmacology, identifying the problems like prescribing to patients with various underlying diseases, integrating relevant data(lab results etc), critical thinking/making proper decisions (e.g.: prescribing for different age groups like paediatrics, geriatrics as well as for pregnant, lactating women etc), motivation to prescribe the drugs rationally (ethics), communicating effectively, resourcefulness (can guide others with regards to clinical pharmacology) will be elicited. Difficulty of questions will be taken into consideration i.e., not too hard or too easy. Item difficulty index  $P = \frac{H + L}{N} \times 100$ , wherein H= number of students answering the item correctly in the high achieving group (higher  $1/3^{rd}$ ), L= number of students answering the item correctly in the low achieving group (lower  $1/3^{rd}$ ), N = Total number of students in the two groups [35,36]. Additional probes that explore the examiner's ability to deepen or broaden the challenges can be included. Test questions may be linked to a patient case, clinical chart or other clinical materials, specimens and x-rays. Trigger materials like Real patients, Simulated patients encounter (SPE), Laboratory results etc, can be used. These can increase the fidelity of the assessment [37].

**Table 1. Blue print of content [sub domains of a domain (endocrines ex: drugs used in diabetes mellitus)]**

SI. no.	Classification	Mechanism of action	Pharmacological actions (of insulin etc)	Pharmacokinetics	Preparations and doses	Adverse effects	Interactions	Precautions and contraindications	Uses and management of patients
Item 1	X								
Item 2									X
Item 3			X						
Item 4					X				
Item 5						X			
Item 6								X	
Item 7		X							
Item 8							X		
Item 9				X					

#### **2.4.4 Logistic decisions like**

Number (multiple) of stations required for oral exam, Time or duration of each station, Number of questions/cases per station, Number of examiners per station etc will be decided. Number of tests or stations has a large impact on reliability/generalizability by increasing the sampling across content and raters, decreasing CU and allowing CIV to cancel out across tests/examiners [31,38,39]. If feasible, video recording of examination process can be done which can become a part of the quality assurance exercise [24].

Nineteen stations will be designed and the main content, concepts or application involved in each question will be defined and written in each station test key. Exam can be conducted in two sessions with ten and nine stations respectively.

#### **2.5 Response Process: Preparation of the Examinee**

All examinees will be oriented to all the details involved in the process of exam like the objectives, setting, duration, number of examiners and the overall procedure in advance. Students will be informed about the type of questions and criteria for passing. Opportunities to practice will be provided by conducting SOE in the sessional exams (formative assessments).

##### **2.5.1 Scoring**

'Checklist' and 'rating scales' will be used to encourage focus on the critical components of the exam. Behaviourally anchored scoring or 'rubrics' will be used to standardize the ratings. 'Global rating' will be included to tap unique judgment and experience of expert examiners.

##### **2.5.2 Selection and training of the examiners**

Examiners will be chosen depending (inclusion criteria) on the appropriate knowledge and skills in the subject matter (pharmacology). Examiners will be trained/calibrated to the rating scale (more objective than the subjective scoring). Inconsistent examiners and extremely severe or lenient raters (exclusion criteria) will not be included. Single examiner will be scoring each station. Total ten examiners will be required and each will engage two stations. After initial studies number of total examiners can be reduced.

#### **2.6 Internal Structure: Standard Setting**

Cut scores for pass or fail will be set by using Angoff method, so that the cut scores are defensible and fair [40]. Standards will be set at individual station level by using a panel of carefully selected six examiners/judges. Each judge indicates the probability [successful accomplishment of exam by a borderline (who is on the cusp of failure) examinee] for ten items (check list) in a SOE station. Final cut score for the station will be calculated by using the total of ten items. Example: If raw score (A) of six judges = 5.4, 5.0, 5.2, 5.4, 5.2 and 5.5, Average =  $31.7/6 = 5.28$ . Angoff cut score =  $A/\text{total number of items in exam/station} \times 100 = 5.28/10 \times 100 = 52.8\%$ . *Quality assurance* will be done for obtaining reliability indicators such as rater consistency, inter-rater reliability and estimates of generalizability. Reviewing the blueprint for content validity, ensuring that examiners' adherence to implementation guidelines for questions, scoring etc will be mentioned.

#### **2.7 Relationship to Other Variables**

Whether SOE and other assessments like COE and written exams measure a particular content or skill in a similar (convergence) or in a dissimilar (divergence) way.

#### **2.8 Consequences**

Consequences (defensible and fair) of the cut-score standards set for the oral exams will be assessed. Chances for false negative and false positive results will be evaluated.

As with Structured Interview, standardization of questioning i.e. uniformity of procedure in administration & scoring can help to increase reliability and validity [41,42,43]. The McMaster University Admissions Multiple Mini-Interview (MMI) is a creative example of structured oral examination [44]. Similar to MMI, OSCE like short, structured interaction stations (or situational questions) can be used to assess non-cognitive qualities (as mentioned under blueprint of skills). After receiving a question or scenario, candidates will prepare (ability to think logically through a topic) for 2 min and then he/she will communicate his/her ideas effectively with an examiner/assessor (8 min). Interactions between students and faculty or standardized patients or real patients can be scored. Examiner can also observe the interaction and evaluate

(using a standard scale) the candidate's performance using a standard scale [45] while he/she moves to next station. Reliability of MMI has been reported to be 0.65 [44].

Students' and educators' attitude/perception towards both the type of oral exams will be obtained. Respondents are required to indicate their agreement or otherwise with the modified Likert's-type scale item [46] (Table 3).

Present research project involves true experimental design and Randomised, Controlled study with Cross over design. *Project methods:* Second MBBS students will be randomly divided into two groups

viz., COE (active control group) and SOE group. Tests will be conducted as follows:

R1 ----- XCOE ----- O1, ----- XSOE  
----- O3,O5

R2 ----- XSOE ----- O2, ----- XCOE  
-----O4,O6

XCOE= Exposed to conventional oral examination

XSOE= Exposed to structural oral examination.

O means outcome, scores of Attitude/feedback test (by using Likert's-type questions/items).

O1 = Outcome of Group-1 after exposed to the intervention COE during first internal exams,

O2 = Outcome of Group-2 after exposed to the intervention SOE during first internal exams,

O3= Outcome of Group-1after exposed to the intervention SOE during second internal exams,

O4= Outcome of Group-2after exposed to the intervention COE during second internal exams,

O5 and O6 = Educators' feedback tests.

## 2.9 Sampling

Target population will be MBBS (second phase) students in medical colleges in India (generalisability). Almost all medical colleges in India follow the rules and syllabus defined by the MCI. Sample population will be undergraduate students of KLE University. Sample consists of

second year MBBS students. Present year, second phase MBBS students (126 students) will be learning pharmacology subject for 1 and 1/2 years. They have to appear for the oral exams in pharmacology subject as prescribed in the syllabus which is non-compensatory. Depending on the scores in first sessional written examination (consisting selected and constructed responses), students will be categorised into high and low scorers. These students are randomly assigned (by using computer software for randomisation) into two groups (n=63 in each group) viz., COE and SOE. Care is taken so that high and low scorers are equally distributed in the two groups. Sample size will be calculated with the help of a statistician. Smallest meaningful difference (range  $7 \pm 1.5$ ), effect size, power (80%), confidence interval (95%), correlation co-efficient (-1/+1) etc will be considered. Confounding variables like pre-intervention knowledge, differences between instructors, equal treatment of both groups, blindness of interventions and tests, drop-outs for follow-up studies etc will be considered.

Data will be collected and expressed as Mean  $\pm$  S.E.M. Scores of undergraduates in attitude tests (i.e., O1 Vs O2 and O3 Vs O4) will be compared using standard statistical tests like chi-square test (nonparametric) etc. Percentage of passing or mean scores can be compared between the two groups.  $P < 0.05$  will be considered as significant for all the tests. Cronbach's alpha will be calculated. In future test-retest reliability and validity can be established. Initially a pilot study can be undertaken to get the immediate feedback. Efficiency of SOE in terms of time, money, ethics, human resource etc will be evaluated. Cost-benefit ratio will be analysed.

## 2.10 Ethical Approval

Ethical clearance will be obtained from the Institutional Review Board (IRB) for Human Research. Voluntary consent of all the participants will be taken in the prescribed format.

## 3. RESULTS AND DISCUSSION

Initial comparison shows that SOE (45 points) is more valid than COE (16 points) (Table 4). This Comparison has been done by the authors depending on: the operational definitions (sources of evidence for construct validity) of the conceptual framework, literature review and the present oral examination pattern which is practiced routinely.

**Table 2. Blue print of the skills to be assessed**

Sl. no.	Decision making/ judgement	Patient management	Diagnostic interpretations	Communication and interpersonal skills	Professionalism
Item 1	X				
Item 2					X
Item 3			X		
Item 4				X	
Item 5		X			

**Table 3. Examples of Likert's type items/questions used for attitude test (Please tick one of the five alternatives on 5 point scale viz., strongly agree, agree, neither agree or disagree, disagree and strongly disagree)**

No.	Students' items/questions	Educators'/Examiners' items/questions
1	Orientated to the details of procedure of exam before start of the exam.	Training of examiners is adequate.
2	Oral exams holistically assess the knowledge of pharmacology*.	Oral exams produce more competent doctors.
3	Clinical applications of pharmacology are assessed*.	Scoring is more objective in nature.
4	Comfortable with the procedure of the exam	Adequate scoring scales are used.
5	Oral exams holistically assess the subject	Comfortable with the conductance of exams.

\*= Items 2 and 3 are also used for educators/examiners. All items are used for both SOE and COE

Acceptability, comfortability etc., of both types of oral exams will be compared by analysing the data obtained by attitude tests of students and educators. Results may suggest that there is no significant difference in attitudes between the two methods of evaluation or there may be significant positive attitudes among the SOE or COE group. Importance of views or attitude of the students has been stressed and students are in the best position to assess the teaching and evaluation methods [47,48,49].

Accreditation Council for Graduate Medical Education (ACGME) lists oral examinations as a candidate method for the assessment of competencies such as decision making, analytic thinking, use of evidence from scientific studies and sensitivity to contextual issues such as age, gender and culture [6,50,51]. Blueprint of content and skills in the present study covers most of the competencies mentioned by ACGME. Questions should cover all stages of the decision-making process [24]. Approach to decision making should be coherent, rational, ethical and sensitive [52] which is included in skills section of the present study. As used in the present study, a detailed blue print can improve the reliability [26]. Higher order cognitive skills can be tested by an in-depth questioning which can be used to discriminate among the top students. In present study, test scores across examinees may be comparable because of equal difficulty or content.

Performance in oral exams can be affected by the anxiety level, attitude, perceptions, learning

environment etc [53]. Orienting the examinees to the details of process of SOE and prior exposure to the SOE will help to reduce the apprehension associated with newer evaluation method. In the present study, inclusion and exclusion criteria for selecting examiners and training has been given importance which can reduce threats to validity and improve the same. Oral exams can be improved by careful selection and training of examiners [54,55], otherwise oral exams may become haphazard and can generate marks unrelated to competence [6], as with the present COE.

When efficacy of SOE compared with that of COE, the results may suggest that SOE can be used as an adjunct or as a replacement for the COE in pharmacology. Threats (CU and CIV) to validity of COE can be overcome by the proposed solution i.e. SOE. SOE may show reliability and validity so that it can be regularly included for the oral exams. This will abide the ethical responsibility to conduct a valid assessment. Medical Schools will produce more skilled doctors and can have the accreditation of the school. Society will have better, competent doctors and improvement in health care can be achieved. Present study may be used as a reference for future research or scholarly activities in other disciplines also.

Limitations of present study may involve initial investments in terms of cost, human resources (training of multiple examiners, patient availability etc) and time.

**Table 4. Comparison of the two types of oral examinations in terms of sources of validity evidence**

Sl. no.	Operational definitions of conceptual framework (A to E) [34] or sources of validity evidence	Conventional oral examination	Structured oral examination
A	Content	Sources of validity	Sources of validity
1	Examination blue print		
a.	Examination of content/knowledge	+	+++
b.	Examination of skills	+	+++
c.	Triggering materials	+	+++
<b>B</b>	<b>Response process</b>		
1	Preparation of the examinee	+	+++
2	Selection & training of the examiners	+	+++
3	Scoring and interpretation	+	+++
4	Fidelity of format	++	+++
<b>C</b>	<b>INTERNAL structure</b>		
1	Standard setting	+	+++
2	Quality assurance	+	+++
3	Reliability/generalisability	+	+++
4	Lower case specificity	+	+++
<b>D</b>	<b>Relationship to other variables</b>		
1	Correlation with other assessment	+	+++
<b>E</b>	<b>Consequences</b>		
1	Reasonable Cut score (Pass-fail)	+	+++
2	On learners	+	+++
3	On University and Society	+	+++
	<b>Total</b>	16	45

#### 4. CONCLUSION

Present oral examination faces many threats to validity like CU and CIV. To overcome these problems a solution has been proposed in the form of SOE which will be an innovative effort for undergraduates in pharmacology. Conceptual framework used in the present study consists of five sources of evidence for construct validity viz., content, response process, internal structure, relationship to other variables and consequences. SOE may replace the conventional oral examinations in pharmacology. Practicability of the present conceptual study has to be confirmed. Similarly, SOE may be introduced to the undergraduates in other disciplines as well as postgraduates in pharmacology.

#### COMPETING INTERESTS

Authors have declared that no competing interests exist.

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