Checklist of Cognitive Contributions to Diagnostic Errors: a tool for clinician-educators.

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DECLARATION

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DISSERTATION ABSTRACT

Background: Experienced clinician educators readily identify trainees with diagnostic reasoning difficulties but often lack training to diagnose and remediate errors. Taxonomies of cognitive causes of diagnostic errors can inform remediation, but clinician educators need simple tools to identify, record, report and provide feedback on these errors. A checklist may help achieve these goals.

Objectives: To characterise the cognitive contributions to diagnostic errors (CCDEs), trainees make in patient encounters, with the view to develop training and remediation programmes for medical residents preparing for specialist examinations. Secondly, to determine examiners' perceptions of a checklist in order to document and provide feedback on CCDEs to unsuccessful candidates and trainees making diagnostic errors in examinations, on ward rounds and during bedside teaching activities.

Methods: Thirty examiners used a 17-item checklist to identify and record CCDEs made by medical residents failing patient encounters in a national specialist examination. A survey was used to explore examiners perceptions of the checklist to document and provide feedback on these errors.

Results: Ninety-eight of 264 patient encounters were failed (37%). Ninety-four completed checklists documented 691 CCDEs (median of 7 per encounter). Cardiac (28.7%) and neurology patients (18.1%) constituted approximately half of the failed encounters. By category: data synthesis was more problematic than data gathering, faulty knowledge or data interpretation (35.2% vs. 25.8% vs. 21.9% vs. 17.1%); χ^2=48.2, ($p<0.0001$ for all comparisons).

The 'top five' individual CCDEs were failure to elicit history and/or examination findings; poor knowledge of clinical features (illness scripts); case synthesis (putting the case together) and misinterpretation of clinical findings. History and physical examination-related errors accounted for 60% of the 'top 5' CCDEs, Examination-related errors were more common than history-related errors ($p<0.0001$). The survey of the checklist was completed by all (30) examiners. Seventy-three percent finished the checklist in less than five minutes, describing it as comprehensive and easy to use. The majority (96.7%) thought the checklist could be a better way of providing structured feedback to unsuccessful candidates. Most examiners (93.3%) considered it a useful way of guiding bedside

teaching for residents preparing for specialist examinations, and 76.7% thought it could improve feedback on CCDEs to unsuccessful candidates and guide remediation and training.

Conclusion: A 17-item checklist identified three priority CCDEs which require focussed remediation and training in South African medical residency programmes: improving clinical skills, developing adequate illness scripts and 'putting a case together'. This does not require extensive pedagogic expertise but rather use of a simple tool to provide customised feedback, remediation and faculty support. We showed that the simple checklist used in this study helped clinician-educators/examiners without pedagogic expertise to diagnose and record CCDEs contributing to poor performance in high stakes examinations. Examiners endorsed the use of the checklist and its potential to improve feedback and training addressing CCDEs made by trainees at the bedside.

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Contributions of Authors

Jonathan Naude - drafted research protocol; completed data capture; data interpretation and writing of first draft of the manuscript.

Vanessa Burch – conception and design of the checklist of Cognitive Contributions to Diagnostic Errors, data interpretation and critical review of the manuscript.

All the authors approved the publication of this manuscript.

ABBREVIATIONS

CCDE - Cognitive Contributions to Diagnostic Errors

CMSA - Colleges of Medicine of South Africa

CP - College of Physicians

FCP - Fellowship of the College of Physicians of South Africa

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CHAPTER 1: JOURNAL READY MANUSCRIPT AS ACCEPTED BY AFRICAN JOURNAL OF HEALTH PROFESSIONS EDUCATION

INTRODUCTION

Up to 5-15% of clinical encounters lead to diagnostic errors, i.e. delayed, incorrect or missed diagnoses. [1] The mortality, morbidity and cost of these errors are considerable,[2–5] and despite 40 years of technological advances they remain largely unchanged. [6] Strategies to address this major cause of patient harm must identify health care professionals at increased risk of making errors, characterise the errors they make and provide targeted, evidence-based intervention. [1]

Taxonomies of the 'root' causes of diagnostic errors have been developed with a view to error reduction and remediation. [1,7,8] Graber and colleagues identified three types of diagnostic errors (no-fault, system and cognitive) and reported that cognitive and system factors contributed to diagnostic errors. [1] They clustered the 'root' cognitive contributions to diagnostic errors (CCDE) in four categories: faulty knowledge, data gathering errors, data synthesis difficulties and failed verification of the data used to make the diagnosis. Schiff and colleagues categorised errors according to the phase of the patient consultation process: access /presentation to health care, patient-practitioner encounter (history and physical examination), ordering and interpreting tests, making a diagnosis (assessment) and further consultation or referral and follow up.[7] Retrospective studies using this taxonomy have found that practitioner-patient encounters (history and physical examination), ordering and interpreting of tests and making a diagnosis (assessment) contributed most to errors. [3,8–10]

Most of these studies were conducted in mixed populations of health care professionals [1,3,9,10] and did not focus on residents who are known to be at increased risk of making medical errors. [11] Two studies of residents showed that both cognitive and system factors contributed to diagnostic errors.[12,13] These studies of malpractice claims or self-reported data are, however, more than 10 years old and did not focus on characterising CCDEs. Furthermore, their retrospective design limits the accuracy of the data due to hindsight and outcomes biases, incomplete patient records, variable reviewer reliability and uncertainty about the final diagnoses made. [4,7,14] Prospective studies characterising CCDEs residents make in patient consultations are needed to better align current training needs and remediation efforts.

A central part of the diagnostic process is data gathering, i.e. performing a history and physical examination of the patient. While a thoroughly conducted history and physical examination can make an assessment in at least 60% of cases, [6,15,16] errors related to history and physical examination contribute to diagnostic errors in up to 61% of cases. [1,3,8–10] As summarised by Feddock,[17] the variable clinical competence of trainees[18,19] may be ascribed to many factors, including: progressive decline in bedside teaching, limited direct observation during real patient encounters, and limited feedback about clinical skills and performance in the workplace. Knowledge of the clinical skills deficits contributing to diagnostic errors residents make in authentic clinical contexts is required to address this matter.

Remediation of CCDEs requires a structured approach: multiple assessments to confirm the problem; an educational diagnosis (characterization of the causes); feedback with a targeted remediation plan, and reassessment. [20–23] While experienced clinician educators can readily identify trainees 'in trouble' they often lack pedagogic expertise to make an educational diagnosis and plan remediation. [24] This situation is aggravated by a paucity of evidence to guide remediation in medical education, [20] and few practical tools to help clinician-educators address diagnostic errors in clinical settings.[20,21]

Tools to help clinician educators characterise CCDEs residents make in practice are limited. Audétat and colleagues published a taxonomy of six common cognitive contributions to diagnostic errors,[21] and a guide to diagnose and manage these problems in clinical training settings.[22,23] One of the ongoing challenges, however, especially for clinician-educators with limited pedagogic expertise, is a reluctance to provide feedback when there is a lack of documentation of errors and limited knowledge of what to specifically document(the educational diagnosis).[25] Simple tools to characterise, document and report on CCDES observed in trainee-led patient consultations are needed.

Using checklists to reduce or remediate diagnostic errors is gaining traction in the literature. Differential diagnosis checklists successfully prompt consideration of additional diagnostic possibilities, [26,27] and limited data suggest that they can improve diagnostic accuracy in emergency departments. [27] To date, checklists have not been used to characterise and properly document CCDEs observed during patient consultations. This may help clinician-educators provide better feedback on, and remediation of these errors observed during high stakes examinations and at the bedside where trainees simultaneously require clinical supervision and teaching.

Context of the study

In South Africa, medical graduates complete six years of undergraduate training, three years of mandatory public service and four years of postgraduate training in preparation for the specialist licensing examinations of the Colleges of Medicine of South Africa (CMSA). The specialist examination of the College of Physicians, a member college of the CMSA, assesses theoretical knowledge of the basic sciences and medicine, interpretation of diagnostic tests and clinical competence. The latter comprises three real patient encounters followed by a bedside oral presentation and discussion with questioning conducted by two examiners. Examiners mark candidates' performance using a criterion-referenced scoring rubric and write a detailed description of the case presentation and ensuing discussion. The absence of a standard method of writing these notes and characterising (diagnosing) the CCDEs in failed patient encounters made it challenging for examiners to provide detailed feedback to, and plan remediation for, unsuccessful candidates.

Checklist of cognitive contributions to diagnostic errors

In 2015 these ongoing challenges prompted the College of Physicians to develop a checklist for characterising (diagnosing) and documenting CCDEs to provide feedback to and plan remediation for unsuccessful candidates. The checklist, based on the literature [1,7,8,21] included 17 CCDEs, grouped in four categories: knowledge gaps, data gathering errors, data interpretation errors and data synthesis difficulties. The checklist was reviewed and pilot tested by a panel of examiners prior to implementation in 2015.

Research questions

The newly implemented checklist provided an opportunity to use the specialist examination setting to prospectively address two research questions:

1. What are the priority CCDEs clinician-educators need to address in training and remediation programmes for medical residents preparing for specialist examinations?
2. What are examiners perceptions of the utility of the new checklist to characterise, document and provide feedback on CCDEs to unsuccessful candidates and trainees making diagnostic errors on ward rounds and during bedside teaching activities?

Study objectives

Based on the research questions, the objectives of this study were to:

1. Use a checklist to identify and record the key cognitive contributions to diagnostic error(s) (CCDEs) made by postgraduate trainees undertaking the fellowship examination of the College of Physicians of South Africa
2. Categorise the CCDEs using four categories: knowledge deficits, difficulty in gathering data, difficulty in interpreting significance of gathered data, and difficulty in synthesising the data to make a diagnosis.
3. Use a survey based on the Kirkpatrick framework of evaluation to determine the potential utility of the checklist to provide structured feedback to physician trainees failing the clinical component of the College of Physicians fellowship examinations.[28] The Kirkpatrick levels to be evaluated were: Level 1:Ease of use and participation (time taken, efficiency) - Items 1,4,5. Level 2: Comprehensive in identifying the errors; usefulness of the inventory - Items 6,8. Level 3: Perception to provide structured feedback; perceived potential benefit as a training tool for: post- and undergraduate training. Items 7,9,10,11. Level 4: Result in a change in organisational practice and a benefit to patients - Items 12,13,14,15.

METHODS

Research Setting

This study was conducted during the specialist examination of the College of Physicians held at three large South African teaching hospitals in October 2015.

Research design

This study used a prospective cross-sectional observational design.

Study population

The medical residents and clinician-educators involved in the examination were invited to participate in the study. All the invited participants agreed to join the study.

Study procedure

Before commencing the 3-day examination proceedings a 1-hour workshop, conducted by the chair of the Education Committee of the College of Physicians (VCB), an internationally recognised leader in the field of health professions education, was held to orientate examiners to the purpose, structure and use of the checklist. Each morning examiners were requested to complete a checklist for all failed patient encounters, i.e. use the tick boxes to record CCDEs and write a short description of each. Examiners completed a checklist immediately after assigning a final score to failing candidates. The decision to use failed cases was based on the presumption that most cognitive errors would occur in these cases, and that the greatest yield of data would be achieved by studying these cases. A secondary consideration was concern that examiners would find it burdensome to complete checklists for passing candidates since they would not require feedback.

Written consent was obtained from examiners prior to starting the proceedings on the first day, and written consent was obtained from candidates on the day of the examination prior to commencement of proceedings. Consent from examination candidates was obtained by staff administering the examination and not the researchers involved in the study. Also, the researchers were blinded to which candidates agreed to participate in the study.

On the final day of the proceedings, examiners completed an anonymous 15-item closed ended survey using a 5-point Likert response scale ranging from 'Totally disagree' to 'Totally agree.' The survey items explored examiners' perceptions of the utility of the checklist and were based on Kirkpatrick's four levels of programme evaluation.: [28] The completed surveys and anonymised checklists were collected by an administrator of the CMSA who removed all identifying data before handing the checklists and surveys over to the research team at the conclusion of the examination proceedings.

Diagnoses of patients included in the examination

The medical illness for which a patient was included in the examination was defined as the primary diagnosis. For example, a patient with mitral stenosis was coded as primary diagnosis: valvular heart disease; discipline: cardiology. Where patients had more than one diagnosis, the one accounting for most of the key clinical features (history and examination findings) was recorded as the primary diagnosis. In most of these cases the other problems were typically related to the primary diagnosis.

For example, a patient with rheumatoid arthritis and pulmonary fibrosis complicated by pulmonary hypertension was coded as: primary diagnosis: rheumatoid arthritis; discipline: rheumatology.

Data analysis

Checklist and survey data were collated using Microsoft Excel (Version 15.0.4823.1004 for PC, Microsoft, Redmond, Washington) spreadsheets and statistical analysis was performed using Stata (Version 15 for PC, Statacorp, Texas, United States of America). Likert scale responses of the survey were reported in three categories: agree, neutral and disagree. Variables were compared using the Kruskall-Wallis test (numerical), Chi-square goodness-of-fit test (categorical) and a Bonferroni correction was used for multiple comparisons. A p-value < 0.05 was considered significant except for multiple comparisons where a p-value < 0.01 was used.

Ethical approval

Institutional approval for this study was granted by the University of Cape Town, Human Research Ethics Committee (HREC 733/2015).

RESULTS

Patient encounters

A total of 88 candidates and 30 examiners from all eight medical schools in South Africa participated in the examination. A total of 98 of 264 patient encounters (37%) were failed. Four incomplete checklists were excluded and the remaining 94 (96%) were analysed.

Patient diagnoses

Forty-one unique diagnoses were present in 94 failed patient encounters. Table 1 shows that cardiac patients (28.7%) and neurology patients (18.1%) made up 46.8% of failed encounters; valvular heart disease was the commonest missed/incorrect diagnosis (18.1%). Failed encounters involving haematological and gastrointestinal illnesses were not reported.

Table 1. Primary missed diagnoses in 94 patient encounters, categorised by discipline

Cardiology (n = 27)
Valvular heart disease (17)
Atrial septal defect (2)
Atrial fibrillation (2)
Hypertrophic obstructive cardiomyopathy (2)
Dilated cardiomyopathy (1)
Hypertensive heart disease (1)
Ischaemic heart disease (1)
Constrictive pericarditis (1)

Neurology (n= 17)
Cerebrovascular accident (7)
Parkinson's disease (3)
Spinocerebellar ataxia (2)
Syringomyelia (1)
Myasthenia gravis (1)
Cerebellitis (1)
Neurofibromatosis (1)
Myeloradiculopathy (1)

Hepatology (n = 15)
Portal hypertension (4)
Chronic liver disease (4)
Hepatocellular carcinoma (2)
Viral hepatitis (2)
Cryptogenic cirrhosis (1)
Gaucher's disease (1)
Drug induced liver injury (1)

Endocrinology (n =12)
Acromegaly (4)
Hyperthyroidism (3)
Diabetes mellitus (2)
Cushing's syndrome (2)
Prader Willi syndrome (1)

Rheumatology (n =14)
Systemic lupus erythematosus (6)
Rheumatoid arthritis (3)
Scleroderma (2)
Systemic sclerosis (1)
Polymyositis (1)
Gout (1)

Pulmonology (n = 8)
Asthma (2)
Sarcoidosis (2)
Cystic fibrosis (1)
Kartagener's syndrome (1)
Post-tuberculosis bronchiectasis (1)
Idiopathic pulmonary fibrosis (1)

Nephrology (n = 1)
Autosomal dominant polycystic kidney disease (1)

Cognitive contributions to diagnostic errors

Examiners identified 691 CCDEs in 94 failed patient encounters; median (range) of 7(1-14) per encounter. Only three candidates failed a patient encounter on the basis of 1-2 CCDEs. They made multiple history and physical examination errors which they failed to recognise during the case discussion and limited time prevented further discussion of the investigation and management of the respective patients. Figure 1 shows that the discipline-specific CCDE rate was not significantly different (p=0.6). Nephrology was excluded because it included only one failed encounter.

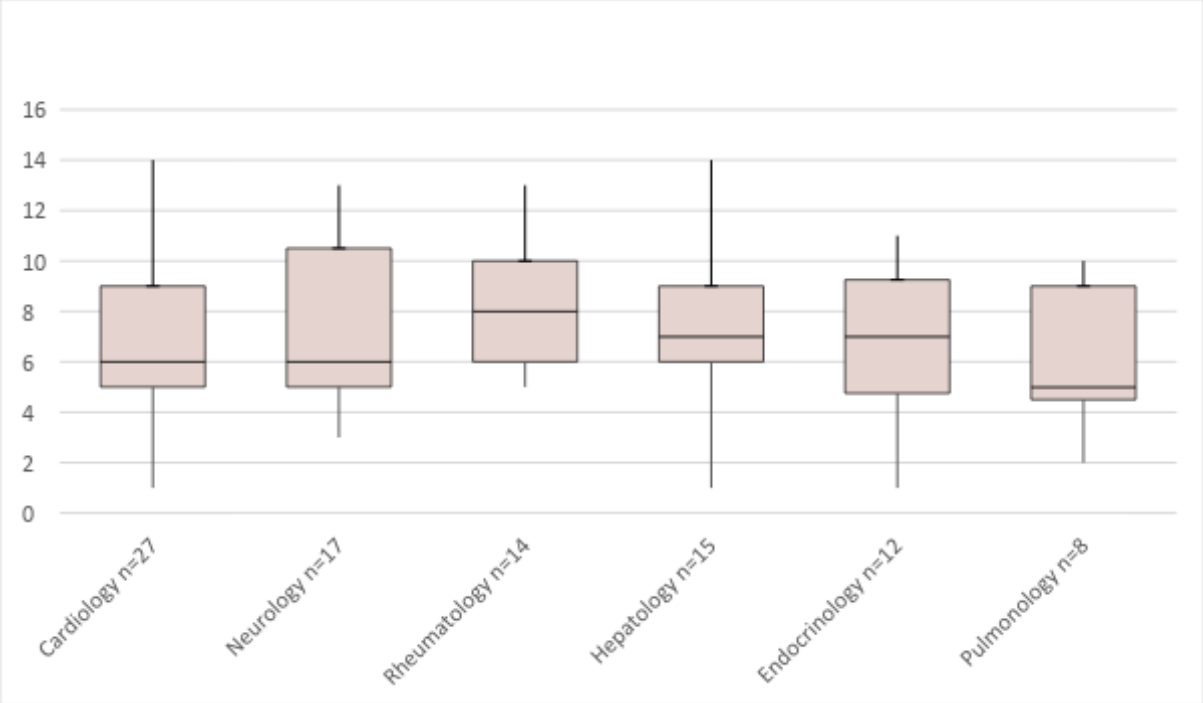

Figure 1. Errors (median, IQR, range) per patient encounter grouped by discipline

Table 2 shows that by category data synthesis was more problematic than data gathering, faulty knowledge or data interpretation (35.2% vs. 25.8% vs. 21.9% vs. 17.1%); χ^2=48.2, p<0.0001; for all comparisons).

Table 2. Cognitive contributions of diagnostic errors (n = 691) reported in 94 failed patient encounters, expressed as a proportion (total number of errors in parentheses)

Category of errors	Proportion	95% CI
Category 1: Knowledge gaps (n=151)		
Clinical features	0.48 (72)	0.40 to 0.56
Investigations	0.21 (31)	0.14 to 0.28
Basic science	0.17 (26)	0.12 to 0.24
Treatment	0.15 (22)	0.09 to 0.21
Category 2: Data gathering errors (n=178)		
Missed key findings of examination	0.39 (70)	0.32 to 0.47
Missed key findings of history	0.27 (48)	0.21 to 0.34
Reported physical signs not present	0.24 (43)	0.18 to 0.31
Incorrect history obtained	0.10 (17)	0.06 to 0.15
Category 3: Data interpretation errors (n=119)		
Inability to interpret physical signs	(0.56) 67	0.47 to 0.65
Inability to interpret history	(0.27) 32	0.19 to 0.36
Inability to interpret investigations	(0.17) 20	0.11 to 0.25
Category 4: Data synthesis errors (n=243)		
Unsatisfactory integration / synthesis	(0.21) 52	0.16 to 0.27
Unable to identify key features	(0.19) 45	0.14 to 0.24
Unable to make connections between data	(0.18) 43	0.13 to 0.23
Unable to prioritise patient problems	(0.16) 39	0.12 to 0.21
Early to focus on a diagnosis	(0.13) 32	0.09 to 0.18
Unable to generate alternate diagnosis	(0.13) 32	0.09 to 0.18

‘Top 5’ cognitive contributions to diagnostic errors

The ‘top 5’ CCDEs made up 44.7% of all CCDEs. Table 3 shows that errors to correctly gather (38.2%) and interpret (21.7%) the history and examination findings, which collectively made up 60% of the ‘top 5’, were more common than faulty knowledge of the clinical features of the case (23.2%) and failure to integrate and synthesise all the findings, i.e. ‘put the case together’ (16.8%).

Table 3. Top five cognitive errors (n=309) made during 94 failed patient encounters, expressed as a proportion (total number of errors in parentheses)

Cognitive errors	**Proportion**	**95% CI**
Knowledge gap of clinical features of presenting illness	0.23 (72)	0.19 to 0.29
Failure to elicit key physical examination findings	0.23 (70)	0.18 to 0.28
Failure to interpret physical examination findings	0.22 (67)	0.18 to 0.27
Unsatisfactory integration and synthesis of case	0.17 (52)	0.13 to 0.21
Failure to elicit key features of patient's history	0.16 (48)	0.12 to 0.20

Clinical features-related errors

Table 4 shows that 40% of 691 CCDEs were ascribed to failure to correctly elicit and/or interpret the clinical features of the case. Data gathering was more problematic than interpretation (χ^2=21.96, p<0.0001). Physical examination-related errors were more common than history-related errors (χ^2=24.28, p<0.0001).

Table 4. Clinical features-related errors (n=277) made during 94 failed patient encounters, expressed as a proportion (total number of errors in parentheses)

	History		**Physical examination**		**Total**
Clinical features-related errors	Proportion	95% CI	Proportion	95% CI	
Failure to elicit key clinical findings	0.17 (48)	0.13 to 0.22	0.25 (70)	0.20 to 0.31	118
Findings reported incorrect/not present	0.06 (17)	0.04 to 0.10	0.16 (43)	0.11 to 0.20	60
Misinterpretation of clinical findings	0.12 (32)	0.08 to 0.16	0.24 (67)	0.19 to 0.30	99
TOTAL	0.35 (97)	0.29 to 0.41	0.65 (180)	0.59 to 0.71	277

Examiners' perceptions of the checklist

All examiners completed the survey. Most (n=22, 73.3%) completed the checklists, including a written description of CCDEs, in less than five minutes; eight required up to 10 minutes and one examiner required more than 10 minutes.

Table 5 shows that the checklist was easy to use at the bedside, efficiently identified and recorded all the CCDEs previously observed and some not previously considered or identified. Most thought it would improve feedback and intended to use it. Examiners also thought the checklist could guide both undergraduate and postgraduate trainee teaching and feedback on CCDEs at the bedside. Some even thought that the checklist could improve patient care by improving diagnostic accuracy, more efficient use of investigations, reducing treatment errors and reducing length of hospital stay.

Table 5. Examiners' perceptions of the Checklist of Cognitive Contributions to Diagnostic Errors

Survey item	Disagree n (%)	Neutral n (%)	Agree n (%)
1. I provide verbal feedback to unsuccessful examination candidates	9(30)		21(70)
2. The quality of feedback I provide is comprehensive and additional information would not be useful	17 (65.4)	5 (19.2)	4 (15.4)
3. The checklist provided an efficient means of identifying diagnostic errors	2 (6.7)		28 (93.3)
4. The checklist provided an efficient way of recording diagnostic errors	1 (3.3)	6 (20.0)	23 (76.7)
5. Based on your experience the checklist included all the common causes of diagnostic errors I have encountered in the past	4 (13.3)	6 (20.0)	20 (66.7)
6. Compared to your current practice, the checklist could be a better way of providing structured feedback to unsuccessful candidates	1 (3.3)		29 (96.7)
7. This checklist listed causes of diagnostic errors you have not considered or identified previously	7 (24.1)	10 (34.5)	12 (41.4)
8. This checklist could be a useful way of guiding bedside teaching and providing feedback for residents preparing for the examination	1 (3.4)	1 (3.4)	27 (93.1)
9. I plan to use this checklist to provide structured feedback to unsuccessful candidates at my training centre	1 (3.3)	6 (20)	23 (76.7)
10. I would consider using the checklist to guide bedside teaching and feedback for residents	1 (3.3)	3 (10)	26 (86.7)
11. I would consider using the checklist to guide bedside teaching and feedback for undergraduate medical students	2 (6.7)	6 (20)	22 (73.3)
12. The checklist can be easily utilized at the bedside	1 (3.3)	7 (23.3)	22 (73.3)
If the checklist were to be routinely used in clinical training it may contribute to improving patient care in terms of:			
13. Improved diagnostic accuracy	1 (3.3)	7 (23.3)	22 (73.3)
14. More efficient use of investigations	2 (6.7)	14 (46.7)	14 (46.7)
15. Reduction in treatment errors	3 (10)	14 (46.7)	13 (43.3)
16. Reduction in length of hospital stay	2 (6.7)	17 (56.7)	11 (36)z

DISCUSSION

This study explored the use of a novel 17-item checklist to characterise (make an educational diagnosis) and document CCDEs residents made during failed real patient encounters in a specialist examination in South Africa. It formed part of a project to educate clinician-educators/examiners about CCDEs and teach them to use a checklist to characterise and record CCDEs in order to provide standardised, structured feedback to unsuccessful examination candidates. The use of the checklist to guide feedback to undergraduate and postgraduate trainees about CCDEs observed at the bedside during ward rounds and teaching was also explored.

In this study, as elsewhere [1,3,8–10] CCDEs were multifactorial. Our median error rate per patient, which was slightly higher than retrospective studies, [1,3,4,9] may have been due to the prospective study design. Furthermore, unlike studies of mixed populations of doctors [1,3,9,10] or physicians only [8], we focused on residents where higher error rates were expected. [11,12]

History and physical examination-related errors accounted for 60% of the 'top 5' CCDEs identified in this study. Examination-related errors were more common. Other studies reporting the contribution of physical examination errors range from 14% to 42%, [1,3,8–10] with higher rates in studies including more residents. [3,9,10] This is consistent with work reporting differences in clinical competence between residents and physicians. [11,12] We observed similar CCDE rates in patient encounters across a broad spectrum of clinical disciplines. This is consistent with studies showing that trainees lack a broad range of physical examination skills. [19] The predominance of cardiology and neurology patients in this study is consistent with other work showing poorer physical examination competence in these disciplines. [19]

Faulty knowledge of clinical features contributed 23% to the 'top five' CCDEs. Figures in published studies vary from 10% [1] to 84%[5] suggesting that knowledge gaps may be underestimated in some retrospective studies. This examination-based study may have been better suited to identifying knowledge gaps at the bedside. Since candidates in this study had already passed the theory examinations, inadequate illness scripts (knowledge of the clinical features of the illness applied in a real patient setting) rather than theoretical knowledge gaps may have been the problem. [1] Further studies are needed to confirm this suggestion.

As observed elsewhere, we found data gathering more problematic than data interpretation. [3,8,9] This suggests that practical clinical skills rather than knowledge of the meaning of clinical findings is the key problem. This finding may also have been influenced by the study setting in which examiners do not pursue interpretation of missed clinical features, i.e. the examination aims to determine what candidates know rather than what they don't know. Studies in non-examination settings are needed to better understand our observation.

In this study we found that clinician-educators without pedagogic expertise could use a simple checklist to systematically characterise (make an educational diagnosis), document and report on CCDEs contributing to poor academic performance in a structured and standardised matter. In so doing, the checklist addresses two key issues which limit clinical supervisors' willingness to report on poor academic performance, i.e. lack of proper documentation of errors and uncertainty about what to record (making an educational diagnosis).[25] Since these basic tenets of feedback are adequately addressed by the checklist, it could serve as a useful tool for teaching and feedback at all levels of training, including the formative years of undergraduate education. The survey responses indicated that examiners also considered this a potential future use of the tool.

Limitations

In this study, patient consultation times were longer than in clinical practice. However, despite extra time candidates made many errors. While examination-induced anxiety may have contributed to this observation, it is known that more consultation time does not routinely improve diagnostic accuracy. [11] Although examiners were enthusiastic about the utility of the checklist to provide feedback on poor performance in high-stakes examinations and clinical teaching, the data were self-reported and reflected anticipated rather than actual behaviour. Future studies are needed to determine whether examiners adopt the checklist for feedback and remediation of CCDEs in unsuccessful candidates and those preparing for the examination. In addition, it would be useful to explore the utility of the checklist to provide feedback at an undergraduate level.

Strengths

Although this study only included one cycle of examination data, it represented candidates and examiners from all eight South African medical residency programmes. This prospective study of CCDEs focussing on residents obviated some of the limitations of retrospective studies previously described. [4,7,14] We could not find similar studies conducted in other international medical residency programmes. So, while more data are needed to confirm the findings of this study, it is an important step in the right direction.

CONCLUSION

This study has answered the two research questions it set out to address. First, we identified three priority CCDEs which require focussed training and remediation in residency training programmes in South Africa: inadequate clinical skills, limited quality of illness scripts (knowledge about the key features of an illness), and difficulty 'putting the case together'. This does not require extensive reading and studying, i.e. 'more of the same' but rather customised remediation and faculty support as discussed in the literature. [22,23] Second, we showed that the simple checklist used in this study helped clinician-educators/examiners without pedagogic expertise to diagnose and record CCDEs contributing to poor performance in high stakes examinations. Furthermore, clinician-educators/examiners were of the opinion that this tool may help them provide comprehensive, standardised feedback to unsuccessful examination candidates and trainees making diagnostic errors at the bedside during ward rounds and teaching. This study also suggests that clinical examinations may be a rich source of prospective data to better understand diagnostic errors trainees make and potential remediation strategies.

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APPENDICES AND SUPPORTING MATERIALS

Appendix A - Checklist of Cognitive Contributions to Diagnostic Errors

KNOWLEDGE GAPS	DATA GATHERING DIFFICULTIES
€ Basic sciences	€ Failed to identify key data during interview
€ Clinical features of illness	€ Obtained incorrect data during interview
€ Investigations	€ Failed to identify key signs on examination
€ Treatment	€ Found clinical signs that were not present
€ Other, please explain below	€ Other, please explain below
DATA INTERPRETATION/MEANING/SIGNIFICANCE	DIFFICULTY IN MAKING A DIAGNOSIS
€ History findings	€ Unable to identify key features to make a Dx
€ Physical examination findings	€ Unable to prioritize patient's key problems
€ Investigations	€ Early focus on a Dx, unable to change mind
€ Other, please explain below	€ Unable to generate alternative diagnoses
	€ Unable to make connections between data
	€ Unsatisfactory integration and synthesis
	€ Other, please explain below

COMMENTS

Other reasons for failing the case that are not listed above

Appendix B - Survey of the utility of the Cognitive Contributions to Diagnostic Errors

1. How much time did you require to complete the checklist for a candidate?	< 5 minutes	5-10 minutes	>10 minutes		
Kindly tick a single box for each of the statements below:					
2. I provide verbal feedback to unsuccessful candidates	Yes	No			
3. The quality of feedback I provide is comprehensive and additional information would not be useful	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
4. The checklist provided an efficient means of identifying diagnostic errors	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
5. The checklist provided an efficient way of recording diagnostic errors	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
6. Based on your experience the inventory included all the common causes of diagnostic errors I have encountered in the past	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
7. Compared to your current practice, the checklist could be a better way of providing structured feedback to unsuccessful candidates	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
8. The checklist listed causes of diagnostic errors you have not considered or identified previously	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
9. This checklist could be a useful way of guiding bedside teaching and providing feedback for junior registrar preparing residents for the examination	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
10. I plan to use this checklist to provide structured feedback to unsuccessful candidates at my training centre	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
11. I would consider using the checklist to guide bedside teaching and feedback for undergraduate medical students	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly agree

If this checklist were to be routinely used in clinical training, it may contribute to improving patient care in terms of:

	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly agree
12. Improved diagnostic accuracy					
13. More efficient use of investigations					
14. Reducing treatment errors					
15. Reducing length of hospital stay					

Appendix C - Consent form for examiner feedback

Consent form to evaluate the Cognitive Contributions to Diagnostic Errors (CCDE) tool

Research Title

Development and evaluation of an Inventory of Bedside Diagnostic Errors designed to facilitate the training of specialist physicians in South Africa

Purpose of the study

Dissertation for Masters degree in Medicine (MMed)

Investigator

Dr Jonathan Naude, Registrar in Internal Medicine, University of Cape Town

Supervisor

Professor Vanessa Burch, Chair of Clinical Medicine, University of Cape Town

Study objectives

1. Identify and quantify the key reasons for bedside diagnostic error(s) made by postgraduate trainees undertaking the fellowship examination of the College of Physicians of South Africa
2. Provide data on diagnostic errors with reference to:
   2.1. Establish whether diagnostic inaccuracy is predominantly due to: knowledge deficits, difficulty in gathering data, difficulty in interpreting significance of gathered data or difficulty in making a diagnosis.
   2.2. Ascertain if specific clinical domains i.e. specific disciplines of internal medicine e.g. cardiology, pulmonology are more prone to specific errors.
   2.3. Determine whether there is a relationship between rate of error and case format i.e. short or long Case
3. Validate the use of a revised Cognitive Contributions to Diagnostic Errors (CCDE**)** form to provide structured feedback to physician trainees in South Africa sitting the clinical component of the College of Physicians examinations.
4. Explore the future use of this inventory
   4.1. by examiners of this College of Physicians to provide feedback to junior trainees preparing to write the examination
   4.2. by trainers of undergraduate medical students

Study Procedure

With your assistance we will be evaluating the ICDE (attached) which will be used in the categorisation of diagnostic errors to provide robust feedback to physician trainees, it will be completed by the examiner at the FCP clinical examination in the event of a candidate failing a case. After the form has been completed an anonymised copy will be kept for study purposes the original document will be used to provide feedback to trainees, at the discretion of the examiners.

On the final day of the examination examiners will be asked to complete a survey providing feedback on the form using the Kirkpatrick framework of evaluation. The survey will focus on ease of use; comprehensiveness; perceived usefulness as a tool for feedback and enhancing clinical training at the bedside. A follow-up survey will be done in May 2016. Completion of the feedback form will prove exceptionally useful in refining the inventory.

Cost for Participation

Your involvement in the research shall bear no cost nor will you receive payment for participation in the project.

Queries

Any questions or queries pertaining to the research project or future utilisation of the CCDE can be forwarded to Dr Jonathan Naude on 084 516 3198 or drnaude@gmail.com where I will be more than glad to assist.

Agreement

I have read the above information and have had any queries I might have answered appropriately. I understand that my confidentiality and anonymity as an examiner will be maintained. I hereby give my voluntary consent to take part in the project and for the information generated to be used in future research studies.

Name of Examiner…… Signature
…….

Years of Experience as an FCP examiner……..… Years of experience as a clinical teacher…….

Signature of Researcher……..……..
Date……

Appendix D - Copy of candidate consent form as drafted by the College of Medicine of South Africa

College of Physicians of South Africa

Review of FCP examiners' reports to determine current specialist training needs in South Africa

Project leader

This project is being conducted by Professor Vanessa Burch, Chair of Clinical Medicine, at the University of Cape Town.

Purpose of the project

The clinical training of medical registrars is a priority in South Africa. Examiners' reports contain important information about current training needs. These reports will be reviewed to plan the most appropriate training model for South African physicians.

Queries

Professor Vanessa Burch can be contacted at any time to answer queries regarding this project. Her contact details are 021 4066836 or 0837034662 or vanessa.burch@uct.ac.za. The Chair of the Human Ethics Research Committee at the University of Cape Town has approved this study. HREC 733/2015

Agreement

I have read the above information and I give consent that the FCP examiners' reports for this examination may be used to identify specialist training needs in South Africa. I understand that the examination results will not be recorded and all information will remain confidential and anonymous.

Name of candidate……..…… Signature of candidate ……

Date …..…….…….

Appendix E - Ethics approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

05 October 2015

HREC REF: 733/2015

Prof V Burch
Medicine Department
J47, Old Main Building

Dear Prof Burch

PROJECT TITLE: EVALUATION OF AN INVENTORY OF CLINICAL DIAGNOSTIC ERRORS DESIGNED TO FACILITATE THE TRAINING OF SPECIALIST PHYSICIANS IN SOUTH AFRICA (MMed candidate -Dr J Naude)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th October 2016.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that MMed student, Dr Jonathan Naude will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH

Appendix F - African Journal of Health Professions Education acceptance for publication

Ref.: AJHPE1059
Checklist of Cognitive Contributions to Diagnostic Errors: a tool for clinician-educators.
African Journal of Health Professions Education

Dear Dr Naude,

We are pleased to tell you that your work has now been accepted for publication in African Journal of Health Professions Education.

Thank you for submitting your work to the journal.

Best wishes

Marietjie van Rooyen, MMed(FamMed) MBChB(Pret)
Associate Editor
African Journal of Health Professions Education

Appendix G - African Journal of Health Professions Education reviewer comments

Reviewer's Responses to Questions
Relevance to HPE audience – Broad interest to all health professionals

Reviewer #1: Although this study was focused on a postgraduate examination in Internal Medicine, it has broad application and relevance to virtually all clinical disciplines. It should be a very useful point of departure for similar studies in other disciplines as well as for designing tools to evaluate CCDEs and provide helpful feedback to students and their mentors. It most certainly has relevance to an HPE audience and broad interest to health professionals involved in student teaching. In addition, it should inform educational policy in the HPE environment with the aim of making assessment more scientifically rigorous and defensible. It seems to be easy to use and a practical way of guiding bedside training as well. At the end of the day, patients should benefit.

Scientific rigour – Appropriate design, methods, instruments and data analysis procedures; explicit ethical review board approval; accurate, appropriate and complete results

Reviewer #1: Excellent study, well planned and executed with good description of data. It may be useful to provide a more in-depth narrative description of the specific comments made by examiners as these may be of interest in terms of a) seeing whether those who completed the checklist interpreted findings in a similar fashion, b) to understand how to use the checklist better and provide more specific feedback to the candidates.

It is not clear whether this degree of detail was recorded in the study. If not, this would be very interesting to pursue in future studies of a similar nature.

It was not clear who signed consent to take part - the examiners, the candidates or both - this should be explicitly stated.

Another point of interest would be to see whether candidates who failed multiple cases made the same CCDEs in different failed (or passed) attempts. I think it would also be interesting to look at those who passed and how many CCDEs they made, while still passing, and whether this is statistically significantly different from those who failed. This may be of use as there are many challenges with regards the validity and reproducibility of a high stakes exam with only three cases. Recognizing CCDEs in the whole cohort may identify areas of focus for the College to work on when addressing clinical training priorities and provide feedback to institutions.

Novel – Did you learn anything new?
(New knowledge, new application, new method)

Reviewer #1: Yes, I was not aware of the degree to which a taxonomy for CCDEs have been developed and its application as presented in a high stakes postgraduate examination was also new to me. I found this study of great interest and would like to apply this to my own teaching practice.

Quality of academic writing - Language, grammar, spelling

Reviewer #1: Excellent use of language, grammar and spelling. No major issues noted.

Reviewer #1: Very interesting and relevant study with great potential for further expansion. I hope this can be pursued further as the answers found actually raise a lot of other interesting questions.

One point of interest would be to see whether candidates who failed multiple cases made the same CCDEs in different failed (or passed) attempts. I think it would also be interesting to look at those who passed and how many CCDEs they made, while still passing, and whether this is statistically significantly different from those who failed. This may be of use as there are many challenges with regards the validity and reproducibility of a high stakes exam with only three cases. Recognizing CCDEs in the whole cohort may identify areas of focus for the College to work on when addressing clinical training priorities and provide feedback to institutions.

Reviewer 2: this study is methodological sound and rigorous with value to the whole HPE community.

Appendix H – African Journal of Health Professions Education instruction to authors

General article format/layout

Submitted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction prior to being sent for review, which will delay publication.

General:

- Manuscripts must be written in UK English (this includes spelling).
- The manuscript must be in Microsoft Word or RTF document format. Text must be 1.5 line spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes). Pages and lines should be numbered consecutively.
- Please make your article concise, even if it is below the word limit.
- Qualifications, ***full*** affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
- Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.
- Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
- Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

Preparation notes by article type

Research

Guideline word limit: 3 000 words (excluding abstract and bibliography)

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Where appropriate, sample size calculations should be included to demonstrate that the study is not underpowered. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

- May include up to 6 illustrations or tables.
- A max of 20 - 25 references

Tables

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Large tables will generally not be accepted for publication in their entirety. Please consider shortening and using the text to highlight specific important sections, or offer a large table as an addendum to the publication, but available in full on request from the author.
- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) consecutively as they are referred to in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ ‖ then ** †† ‡‡ etc.

Do not: Use [Enter] within a row to make 'new rows':

Rather:
Each row of data must have its own proper row:

Do not: use separate columns for *n* and %:

Rather:
Combine into one column, *n* (%):

Do not: have overlapping categories, e.g.:

Rather:
Use <> symbols or numbers that don't overlap:

References

NB: *Only complete, correctly formatted reference lists in Vancouver style will be accepted. If reference manager software is used, the reference list and citations in text are to be unformatted to plain text before submitting..*

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.
- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 **not** 1215-17.
- Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by CrossRef:
    - On the Crossref homepage, paste the article title into the 'Metadata search' box.
    - Look for the correct, matching article in the list of results.
    - Click Actions > Cite
    - Alongside 'url =' copy the URL between { }.
    - Provide as follows, e.g.: https://doi.org/10.7196/07294.937.98x

Department of Medicine, University of Cape Town

Protocol for submission of Masters in Medicine (MMed)

Date:	**22nd July 2015**
Candidate Name:	**Jonathan Naude**
Student No:	**NDXJON001**
Email address:	**drnaude@gmail.com**
Cell:	**0845163198**
Speed dial:	**76836**
Name of Supervisor:	**Professor Vanessa Burch**
Protocol Full Title:	**Development and evaluation of an Inventory of Clinical Diagnostic Errors designed to facilitate the training of specialist physicians in South Africa**
Short Title:	**Development of an Inventory of Clinical Diagnostic Errors to facilitate physician training in South Africa**

Background and Rationale

Diagnostic error, where the clinical hypothesis is discrepant from the actual diagnosis accounts for at least 15% of errors in clinical care and is often associated with secondary harm due to deviation from required management (Aalten et al. 2006). Diagnostic error is one of the top 10 causes of preventable death in the United States of America. Of 850,000 deaths recorded in the United States in 2002, approximately 72,000 were attributable to diagnostic error of which half would have survived to discharge had misdiagnosis not occurred (Burton et al. 2014).
Furthermore, physician misdiagnosis is the primary concern in 55% of outpatient respondents telephonically interviewed in 2002 (Burroughs et al. 2005).

Of greatest concern is that over a thirty year period improved diagnostic modalities have had little effect on the rate of diagnostic error which has remained static at approximately ten percent, (Kirch & Schafii 1996); (Podbregar et al. 2001). The authors highlighted that history and physical examination remain the cornerstone of making an accurate diagnosis.

Up to three quarters of diagnostic error can be attributed to a cognitive failure on the part of the clinician. The top causes of cognitive error include faulty knowledge, faulty information gathering, faulty information synthesis and faulty verification. Faulty information synthesis was noted as the most significant factor(Graber 2005). In a review of hospital adverse events, cognitive errors were associated with a three times greater risk of death over adverse events not relating to diagnosis (Zwaan et al. 2010). In a review of 141 articles pertaining to diagnostic error, it was concluded that reducing harm through diagnostic error required interventions which would improve the cognitive processes that underlie clinical reasoning(Graber et al. 2012).

A key mechanism for reducing diagnostic errors is the provision of good feedback in the workplace (Veloski et al. 2006). Unfortunately feedback is notoriously poor in medical training programmes, and few trainees receive feedback based on observed performance(Archer 2010). The need for improving feedback practises is clear but strategies to do so are lacking.

In 2008, Schiff described current health systems as structures in which there are minimal mechanisms for feedback, and physicians are unaware of their errors only becoming cognisant of prior errors through litigation or written complaint (Friedman et al. 2005). The failure to provide appropriate feedback leads to a situation where errors are perpetuated. The authors went on to postulate that implementation of systemic

feedback mechanisms would result in a reduction in diagnostic errors with immediate benefit to patients(Schiff 2008). The implementation of a multifaceted, well-structured feedback mechanism was shown in a Cochrane review to have a clear though modest benefit on improving professional practice (Jamtvedt et al. 2006); (Lau 2004).

In South Africa, there are no robust data regarding rates of diagnostic error or quantification of the extent of harm as a result of these errors. Furthermore, data regarding the prevalent causes and consequences of diagnostic errors are also not available. Given this current limitation it is impossible to define the training that needs to be put in place to address this problem

In order to address the issue of diagnostic errors and appropriate remediation it is essential to have a clear picture of the commonest causes of diagnostic errors. This matter has been explored in detail by Audétat and colleagues (Audétat et al. 2013), they have recently published a taxonomy of clinical reasoning errors to facilitate the task clinical teachers have of providing feedback and appropriate training for trainees struggling with this complex cognitive process. To date, the use of the taxonomy has not been reported in the literature.

This study aims to develop a process of robust feedback, regarding diagnostic errors in order to facilitate the training of specialist physicians in South Africa. This will be based on an inventory of common diagnostic errors derived from 1) the taxonomy proposed by Audétat and colleagues 2) literature of other authors in the field of diagnostic error. This project aimed at improving healthcare in the South African context, will form part of quality improvement project undertaken the College of Physicians of South Africa.

Purpose of the study

To determine the utility of an Inventory of Clinical Diagnostic Errors (ICDE) to identify common causes of clinical diagnostic errors made by postgraduate physician trainees undertaking national certification examinations in South Africa, in order to provide feedback and training targeted to address these errors. The inventory described in this study will form part of a quality improvement initiative undertaken by the College of Physicians of South Africa, and may find broader utility in health professions education in postgraduate and undergraduate teaching in South Africa.

Study Objectives

4. Using the ICDE to identify key reasons for bedside diagnostic error(s) made by postgraduate trainees undertaking the fellowship examination of the College of Physicians of South Africa
5. Provide data on diagnostic errors with reference to:
    5.1. Establish whether diagnostic inaccuracy is predominantly due to: knowledge deficits, difficulty in gathering data, difficulty in interpreting significance of gathered data or difficulty in making a diagnosis.
    5.2. Ascertain if specific clinical domains i.e. specific disciplines of Internal Medicine e.g. cardiology, pulmonology are more prone to specific errors.
    5.3. Determine whether there is a relationship between case format i.e. short or Long Case
6. Use the Kirkpatrick framework to evaluate the utility of the Inventory of Clinical Diagnostic Errors (ICDE) form to provide structured feedback to physician trainees failing the clinical component of the College of Physicians fellowship examinations.
    6.1. Ease of use (time taken, efficiency)
    6.2. Comprehensive in identifying the errors
    6.3. Usefulness of the inventory
    6.4. Perception to provide structured feedback
    6.5. Perceived potential benefit as a training tool for:
        6.5.1. Postgraduate training
        6.5.2. Undergraduate training

Methodology

Study design

The cross-sectional observation study will be comprised of two components

1. A retrospective document review of ICDE forms completed as a pilot process in the May 2015 FCP exams.
2. A prospective study evaluating the use of the ICDE as part of a formal feedback process.

Characteristics of the study population

This study will evaluate the diagnostic errors made by post-graduate trainees who undertook / will undertake the clinical component of Part 2 of the examination of the College of Physicians of South Africa in May and October of 2015, respectively. This study will include performance data obtained from the records of approximately 140 clinical case events.

All examiners participating in the October 2015 College of Physicians of South Africa will be invited to participate in the prospective component of this study.

Instruments

Inventory of Clinical Diagnostic Error

The primary study instrument, an Inventory of Clinical Diagnostic Errors (Addendum A) is an eighteen-item tool which is sub-divided into four focus areas of diagnostic error, namely: knowledge gaps; data gathering difficulty; data interpretation difficulties and difficulty in knowledge synthesis i.e. difficulty in formulating a diagnosis. The initial instrument was formulated by a leading expert in the field of medical education, an FCP council member and supervisor of this study, and is based on current medical education literature regarding the nature and types of diagnostic errors made in clinical practice (Audétat et al. 2013) (Graber 2005)(Van Den Berge & Mamede 2013)(Singh et al. 2013). It was developed with a specific goal of improving the training of post graduate students by providing structured detailed feedback (Bowen 2006).

It was first administered as a pilot process at the May 2015 clinical examinations of the College of Physicians of South Africa.

Survey

A second study instrument, will constitute a feedback form (Addendum B) for the evaluation of the ICDE by the examiners. The survey consists of twelve Likert scale items which will look to ascertain the utility of the inventory as a feedback and clinical training instrument. The questions are based on a modification of the Kirkpatrick framework which was initially developed in 1999 where a tiered structure of evaluation focuses on specific items to ascertain the impact of an intervention in medical education(Harden 1999). The levels in the hierarchy are: the ease of use of the tool, did it bring about new learning or knowledge, did it result in a change in behaviour and finally whether there was a broader system impact.

The form will be completed in October 2015 by examiners who will use the ICDE document to record and report on the errors made by candidates during the examination. A follow-up survey will be completed four months later to assess whether it was utilized by the examiners at their respective training institutions and if this had an impact on their feedback and clinical teaching practice.

1. Retrospective Data

The study will review data that was anonymously collected at the FCP Clinical examination in May 2015. Examiners completed an ICDE prototype (Addendum A) for each candidate who failed one or more of the clinical cases during the examination. The completed forms were submitted to the exam facilitator and information linking the candidate and examiner to the forms were erased to allow for future anonymous analysis. The ICDE did not influence the current mechanism for feedback provided to unsuccessful candidates at the time of examination. It was administered as a pilot to test the use of the tool in May 2015 to collate all of the information with the intention of a developing a process of providing specific structured feedback to unsuccessful candidates.

2. Prospective Data

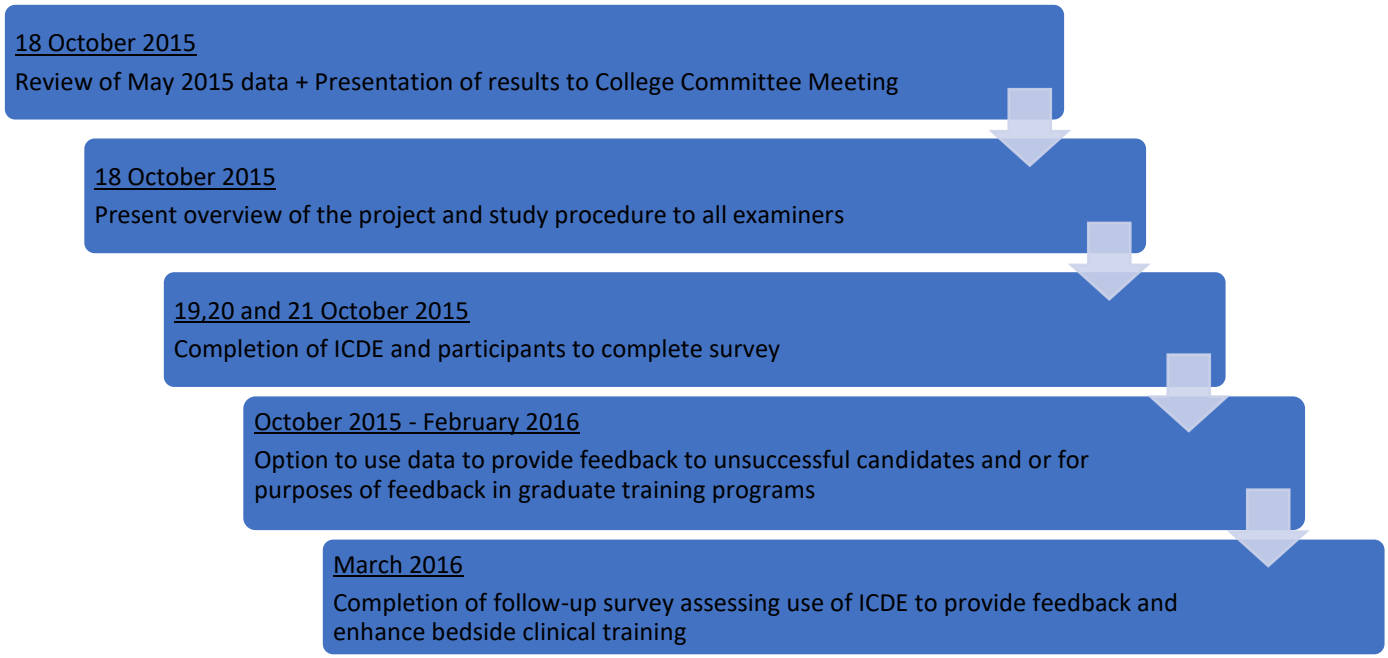
The ICDE would subsequently be revised and would be administered at the October 2015 sitting of the Oral and Clinical Examination. The ICDE feedback form will be completed by the examiners as a written survey. The descriptive data will be utilised by the investigator to be to further develop the ICDE. The examiners will be provided with a digital copy of the ICDE and encouraged to make use of it at their educational institutions. A follow-up survey of the examiners after a period of three months to assess whether they have made use of the ICDE outside of the exam setting and what the perceived utility of the form has been utilizing Kirkpatrick framework of evaluation (Bates 2004).

3. Survey of Examiners

Comments from examiners as captured by the feedback form will be collated and reviewed by the investigator, the comments will be subsequently grouped according to theme. A development evaluation

framework will be used in conjunction with collated feedback to make appropriate amendments to the ICDE. The new iteration of the ICDE will be administered at the October sitting of the clinical examination for the College of Physicians of South Africa.

Timeline of Data Collection



Methods of data analysis

Descriptive statistics will be used to determine the prevalence of specific diagnostic errors, and relate these to the respective disciplines of Internal Medicine and the format of the examination items – short or long cases.

The data from the feedback form will be analysed using descriptive statistics using mean, median and standard error from mean.

Comments from examiners will be qualitatively analysed.

Ethical Considerations

The first part of the study will retrospectively evaluate anonymised data which was submitted by examiners, at the end of the May 2015 cycle of the FCP examinations. These data will be anonymised prior to analysis.

Neither the identity of the examiner(s) nor of the candidate will be recorded on the ICDE document that will be utilised in this part of the study.

In the second part of the study examiners will be invited to participate in this component of the study and written consent will be obtained prior to their participation in the study. Their identity will be withheld from the principal investigator by utilising an alpha-numeric study number which will be provided and held by an independent party. Feedback from the examiners regarding the utility of the Inventory of Clinical Diagnostic Errors will be obtained using an anonymous paper based survey, Addendum B.

Examiners will be free to withdraw from the study at any stage and this will not compromise the examination process.

Permission to conduct the study will be obtained from the Council of the College of Physicians of South Africa and the Examinations and Credentials Committee of the Colleges of Medicine of South Africa (CMSA).

The data is intended to improve physician training programmes in South Africa by identifying the most common causes of diagnostic errors made by trainees so that these can be specifically addressed during their post-graduate training. Ultimately this may contribute to reducing rates of physician diagnostic error and improved patient care.

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Addendum A - Inventory of Clinical Diagnostic Errors

KNOWLEDGE GAPS	DATA GATHERING DIFFICULTIES
€ Basic sciences	€ Failed to identify key data during interview
€ Clinical features of illness	€ Obtained incorrect data during interview
€ Investigations	€ Failed to identify key signs on examination
€ Treatment	€ Found clinical signs that were not present
€ Other, please explain below	€ Other, please explain below
DATA INTERPRETATION/MEANING/SIGNIFICANCE	DIFFICULY IN MAKING A DIAGNOSIS
€ History findings	€ Unable to identify key features to make a Dx
€ Physical examination findings	€ Unable to prioritize patient's key problems
€ Investigations	€ Early focus on a Dx, unable to change mind
€ Other, please explain below	€ Unable to generate alternative diagnoses
	€ Unable to make connections between data
	€ Unsatisfactory integration and synthesis
	€ Other, please explain below

COMMENTS

OTHER REASONS FOR FAILING THE CASE THAT ARE NOT LISTED ABOVE

Addendum B - Survey of the utility of the Inventory of Clinical Diagnostic Errors

1. How much time did you require to complete the checklist for a candidate?	< 5 minutes	5-10 minutes	>10 minutes		
Kindly tick a single box for each of the statements below:					
2. I provide verbal feedback to unsuccessful candidates	Yes	No			
3. The quality of feedback I provide is comprehensive and additional information would not be useful	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
4. The checklist provided an efficient means of identifying diagnostic errors	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
5. The checklist provided an efficient way of recording diagnostic errors	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
6. Based on your experience the inventory included all the common causes of diagnostic errors I have encountered in the past	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
7. Compared to your current practice, the checklist could be a better way of providing structured feedback to unsuccessful candidates	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
8. The checklist listed causes of diagnostic errors you have not considered or identified previously	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
9. This checklist could be a useful way of guiding bedside teaching and providing feedback for junior registrar preparing residents for the examination	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
10. I plan to use this checklist to provide structured feedback to unsuccessful candidates at my training centre	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly Agree
11. I would consider using the checklist to guide bedside teaching and feedback for undergraduate medical students	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly agree

If this checklist were to be routinely used in clinical training, it may contribute to improving patient care in terms of:

	Strongly disagree	Disagree	Neither agree Nor disagree	Agree	Strongly agree

12. Improved diagnostic accuracy					
13. More efficient use of investigations					
14. Reducing treatment errors					
15. Reducing length of hospital stay					

Addendum C - Consent Form for examiner feedback

Consent form to evaluate the Inventory of Clinical Diagnostic Errors (ICDE) tool

Research Title

Development and evaluation of an Inventory of Bedside Diagnostic Errors designed to facilitate the training of specialist physicians in South Africa

Purpose of the study

Dissertation for Masters degree in Medicine (MMed)**Investigator**

Dr Jonathan Naude, Registrar in Internal Medicine, University of Cape Town

Supervisor

Professor Vanessa Burch, Chair of Clinical Medicine, University of Cape Town

Study objectives

5. Identify and quantify the key reasons for bedside diagnostic error(s) made by postgraduate trainees undertaking the fellowship examination of the College of Physicians of South Africa
6. Provide data on diagnostic errors with reference to:
   6.1. Establish whether diagnostic inaccuracy is predominantly due to: knowledge deficits, difficulty in gathering data, difficulty in interpreting significance of gathered data or difficulty in making a diagnosis.
   6.2. Ascertain if specific clinical domains i.e. specific disciplines of internal medicine e.g. cardiology, pulmonology are more prone to specific errors.
   6.3. Determine whether there is a relationship between rate of error and case format i.e. short or long Case
7. Validate the use of a revised Inventory of Clinical Diagnostic Errors form to provide structured feedback to physician trainees in South Africa sitting the clinical component of the College of Physicians examinations.
8. Explore the future use of this inventory
   8.1. by examiners of this College of Physicians to provide feedback to junior trainees preparing to write the examination
   8.2. by trainers of undergraduate medical students

Study Procedure

With your assistance we will be evaluating the ICDE (attached) which will be used in the categorisation of diagnostic errors to provide robust feedback to physician trainees, it will be completed by the examiner at the FCP clinical examination in the event of a candidate failing a case. After the form has been completed an anonymised copy will be kept for study purposes the original document will be used to provide feedback to trainees, at the discretion of the examiners.

On the final day of the examination examines will be asked to complete a survey providing feedback on the form using the Kirkpatrick framework of evaluation. The survey will focus on ease of use; comprehensiveness; perceived usefulness as a tool for feedback and enhancing clinical training at the bedside. A follow-up survey will be done in May 2016. Completion of the feedback form will prove exceptionally useful in refining the inventory.

Cost for Participation

Your involvement in the research shall bear no cost nor will you receive payment for participation in the project.

Queries

Any questions or queries pertaining to the research project or future utilisation of the ICDE can be forwarded to Dr Jonathan Naude on 084 516 3198 or drnaude@gmail.com where I will be more than glad to assist.

Agreement

I have read the above information and have had any queries I might have answered appropriately. I understand that my confidentiality and anonymity as an examiner will be maintained. I hereby give my voluntary consent to take part in the project and for the information generated to be used in future research studies.

Name of Examiner…… Signature
…….

Years of Experience as an FCP examiner……..…. Years of experience as a clinical teacher…….

Signature of Researcher…….……..……..
Date……

Addendum D - Copy of candidate consent form as drafted by the College of Medicine of South Africa

College of Physicians of South Africa

Review of FCP examiners' reports to determine current specialist training needs in South Africa

Project leader

This project is being conducted by Professor Vanessa Burch, Chair of Clinical Medicine, at the University of Cape Town.

Purpose of the project

The clinical training of medical registrars is a priority in South Africa. Examiners' reports contain important information about current training needs. These reports will be reviewed to plan the most appropriate training model for South African physicians.

Queries

Professor Vanessa Burch can be contacted at any time to answer queries regarding this project. Her contact details are 021 4066836 or 0837034662 or vanessa.burch@uct.ac.za. The Chair of the Human Ethics Research Committee at the University of Cape Town has approved this study. HREC 733/2015

Agreement

I have read the above information and I give consent that the FCP examiners' reports for this examination may be used to identify specialist training needs in South Africa. I understand that the examination results will not be recorded and all information will remain confidential and anonymous.

Name of candidate……..…… Signature of candidate ……

Date …..…….…….