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BMJ Open

Using prescribing very short answer questions to identify sources of medication errors

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Manuscripts

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3 **Using prescribing very short answer questions to identify sources**
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6 **of medication errors**
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3 **Objective:** To assess the utility and ability of the novel prescribing Very Short Answer (VSA)
4 question format to identify the sources of undergraduate prescribing errors when compared to
5 the conventional Single Best Answer (SBA) question format.
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9 **Design:** A prospective study involving analysis of data generated from a pilot two-part
10 prescribing assessment.
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14 **Setting:** Two UK medical schools.
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17 **Participants:** 364 final year medical students took part. Participation was voluntary. There
18 were no other inclusion or exclusion criteria.
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22 **Outcomes:** (1) time taken to mark and verify VSA questions (acceptability), (2) differences
23 between VSA and SBA scores, (3) performance in VSA and SBA format across different
24 subject areas and (4) types of prescribing error made in the VSA format
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28 **Results:** 18,200 prescribing VSA questions were marked and verified in 91 minutes. The
29 median percentage score for the VSA test was significantly lower than the SBA test (28% vs
30 64%, $p < 0.0001$). Significantly more prescribing errors were detected in the VSA format than
31 the SBA format across all domains, notably in prescribing insulin (96.4% vs 50.3%, $p < 0.0001$),
32 fluids (95.6% vs 55%, $p < 0.0001$) and analgesia (85.7% vs 51%, $p < 0.0001$). Of the incorrect
33 VSA responses, 33.1% were due to the medication prescribed, 6.0% due to the dose, 1.4%
34 due to the route and 4.8% due to the frequency.
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41 **Conclusions:** Prescribing VSA questions represent an efficient tool for providing detailed
42 insight into the sources of significant prescribing errors, which are not identified by SBA
43 questions. This makes the prescribing VSA a valuable formative assessment tool to enhance
44 students' skills in safe prescribing, and to potentially reduce prescribing errors.
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Strengths and limitations of this study

- There were a large number of participating medical students across two UK medical schools; this generated a data set of 18,200 prescriptions from the very short answer (VSA) paper to analyse and increases the generalizability of the findings.
- We assessed medical students' ability to generate an authentic prescription and identified the sources of prescribing errors on a large scale.
- The participants may be self-selecting to some degree; those that volunteered to participate may be more motivated or high achievers.
- Ideally, we would examine the longer-term impact of the use of VSA questions and examine effects on clinical practice at qualification, or attainment in the Prescribing Skills Assessment.

BACKGROUND

Prescribing drugs forms a large part of the workload of doctors, and newly graduated doctors prescribe a significant proportion of those medications prescribed in hospital settings. It is a high stakes task, with prescribing having significant implications for both hospitals and clinicians in terms of clinical risk and cost. Prescribing is a complex task for any doctor (1), with prescribers having to select the correct drug, dose, frequency and route, whilst also taking into account interacting drugs and pre-existing co-morbidities. Studies suggest an error rate of approximately 7-10% amongst prescriptions written by clinicians in their first year after graduation, while more senior doctors have an error rate of around 5% (2-4).

Poor prescribing is not without consequence; medication errors are a common cause of harm to patients, with prescribing errors being the medication error most likely to cause moderate or severe harm to patients (5-8). It has been estimated that 237 million medication errors occur per annum in England, with approximately 66 million of these being potentially clinically significant. These errors may have significant health and economic consequences with one study estimating that the burden of avoidable drug errors may cost the National Health Service approximately £1.6 billion per year and may contribute to 22,303 deaths (5). Developing interventions to reduce clinically important errors is therefore crucial to improve patient safety and to reduce the financial burden on the National Health Service. Furthermore, the World Health Organization has cited reducing harm from medication as one of its priorities since 2017 (9).

With such high stakes, it is crucial that undergraduate medical education prepares graduates to prescribe competently in a challenging work environment. However, many graduates report that they lack confidence in their prescribing abilities (10-15), with only 29% of UK students feeling assured in their ability to achieve the GMC's prescribing competencies upon graduating medical school (10). The same study also found that the majority of students did

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3 not feel their prescribing knowledge and skills were thoroughly examined prior to graduation
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5 (10). This concern has been shared by both junior clinicians' supervisors (16-19) and
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7 regulatory bodies (20).
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11 At present, prescribing skills are mostly assessed using the written Single Best Answer (SBA)
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13 examinations, the Objective Structured Clinical Examination (OSCE) or in Workplace-Based
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15 Assessments (WBAs) (21-22). However, there are limitations to these assessment methods.
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17 Whilst the SBA may allow broad sampling of the curriculum, it does not fully test the act of
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19 writing a prescription. Instead it tests the ability to select a correct prescription out of a choice
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21 of five options. The SBA also gives no insight into the sources of errors amongst students
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23 (23). The OSCE, conversely, can assess prescribing skills, but the scope of prescribing skills
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25 that can be tested is severely limited by the number of stations in the examination. WPBAs,
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27 likewise, can assess prescribing skills, however with the advent of electronic prescribing,
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29 undergraduates' ability to achieve this competency has since been restricted. The Prescribing
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31 Safety Assessment, a national exam taken by medical students in the UK (24-26), whilst going
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33 some way to address the issues described above, is an exam that is largely sat in the last few
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35 months of the undergraduate medical course. It is therefore not able to identify gaps in
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37 prescribing knowledge early enough, nor does it provide early and longitudinal feedback, for
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39 medical schools to be able to address deficiencies in prescribing knowledge and adjust the
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41 course content to strengthen skills in these areas. There is therefore a need to develop a
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43 means of formative assessment that facilitates learning by assessing students' ability to
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45 prescribe across a broad sample of the undergraduate curriculum.
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51 We have developed an online tool which allows thorough and authentic assessment of
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53 prescribing skills and medication management, in the form of the prescribing Very Short
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55 Answer (VSA) question format. The aim of the prescribing VSA is to improve the validity of
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57 assessment of prescribing skills, and by extension the learning behaviour of prescribing
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59 amongst undergraduates, to enable safer and more confident prescribing on graduation (27).
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3 Furthermore, by identifying the types of error students' make and areas of weaknesses in
4 prescribing, the medical school curriculum can be adapted and improved. Identifying these
5 deficiencies and remedying them is essential for both patient safety and a health economics
6 perspective.
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13 The prescribing VSA question format is based on similar principles to the Very Short Answer
14 (VSA) question, which has previously been shown to have high reliability, discrimination and
15 validity (28). The prescribing VSA format poses a clinical scenario and a lead-in question. The
16 key difference in the prescribing VSA question is that the student must input free text answers
17 for each of the medication name, dose, route and frequency answer fields.
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26 The newly developed online software allows for wide sampling of the undergraduate
27 curriculum for large numbers of students, using realistic clinical scenarios. The aim of this
28 study is to evaluate the acceptability, reliability and discrimination of prescribing VSA
29 questions in prescribing skills assessment when compared to the traditional SBA question
30 format, and to assess the types of error undergraduates commonly make when prescribing.
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39 **METHODS**

40 41 42 **Participants and assessment**

43 This prospective study was approved by the Medical Education Ethics Committee at Imperial
44 College London. Ethical approval was granted to invite all final year medical students at two
45 medical schools (Imperial College London and University of Edinburgh) to sit the formative
46 prescribing assessment. There were no other inclusion or exclusion criteria. The assessment
47 was conducted on iPad tablets or fixed terminal computers using the newly developed online
48 prescribing examination software (PRACTIQUE; Fry-IT Ltd, London, UK), and was held under
49 examination conditions.
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3 The students sat a formative examination in two parts. The first included 50 prescribing
4 scenarios in the prescribing VSA format for which student had to generate a full prescription,
5 including the medication name, dose, route and frequency. The second part included the same
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7 50 scenarios, in which the students selected the correct answer from five options, in the
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9 traditional SBA format. Students were allowed to assess the British National Formulary online
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11 throughout both parts of the assessment.
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18 Each question consisted of a clinical scenario (which included the presentation, examination
19 findings and investigation results, as necessary) and a lead-in question. The clinical scenarios
20 were constructed such that they could be used in both the prescribing VSA and SBA format
21 without any change to their content. The question topics were mapped to the final year
22 undergraduate curriculum to ensure a broad sampling of the syllabus. The length of the VSA
23 prescribing examination was 125 minutes, and the length of the SBA examination was 50
24 minutes.
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35 **Marking**

36 The answers to the prescribing VSA questions were captured by the examination software
37 (PRACTIQUE) and sent to a server via an encrypted connection. All identical responses were
38 grouped in blocks by the examination software, and then machine-marked using an automated
39 matching algorithm to match each students' answer against a set of preapproved acceptable
40 answers for each question. A Levenshtein distance of 0.0 was set for the automated marking,
41 and students had to have entered the correct medication name, dose, route and frequency to
42 score 1 mark. All match failures were highlighted by the software, and these responses
43 reviewed by two clinicians simultaneously. Marks for responses deemed correct by the
44 examiners could be awarded manually. Any responses marked manually as correct by the
45 examiners, would be applied to all identical answers. The examination software also permitted
46 answers marked manually as correct to be added to the correct answer database for that
47 question. The time taken by the two examiners to review the responses was recorded to
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3 assess acceptability. Responses to the SBAs were entirely machine-marked using the
4 examination software (PRACTIQUE).
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9 **Analysis**

10 Statistical analyses were performed using PRISM Version 8.0.0 (Graphpad Software, Inc.,
11 San Diego, CA, USA). Mann-Whitney test was used to compare the differences between VSA
12 and SBA scores. Spearman's correlation coefficient was used to assess the correlation
13 between the scores of the two formats. Cronbach's alpha was used to assess the reliability of
14 the assessments. The difference between proportion of correct and incorrect answers
15 between the VSA and SBA question formats was examined using Fisher's exact test.
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26 **RESULTS**

27 A total of 364 final year medical students sat the formative prescribing assessment.
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33 **Prescribing VSA utility**

34 The total time spent by examiners to review the non-matching answers for 50 Prescribing VSA
35 questions for all 364 students (18,200 prescriptions) was 91 minutes. This is an average of 1
36 minutes and 49 seconds per question. The median percentage score for the prescribing VSA
37 test (28%, interquartile range 20%-34%) was significantly lower than that of the SBA test (64%,
38 interquartile range 54%-70%) ($p < 0.0001$). There was a significant but modest correlation
39 between VSA and SBA scores ($r = 0.66$, $p < 0.0001$). Cronbach's alpha was 0.76 for the VSA
40 test and 0.82 for SBA test.
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51 **Sources of error**

52 Of the incorrect responses in the prescribing VSA assessment, 33.1% of these were due to
53 incorrect medications being prescribed, 6.0% due to incorrect doses, 1.4% due to incorrect
54 routes, 4.8% due to incorrect frequencies and 6.1% due to a combination of these errors.
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Prescribing errors identified by the two formats

The scores on individual items were aggregated by prescribing area to allow comparison between the prescribing VSA and SBA question formats. There was a statistically significant difference between prescribing VSA and SBA student scores for all subject areas (Table 1). Students consistently were less successful at writing a correct prescription compared to selecting the correct prescription from five options. In particular, they performed most poorly in prescribing fluids, insulin, anticoagulation, steroids and analgesia.

Grouped by subject	VSA correct	VSA incorrect	SBA correct	SBA incorrect	p-value
Alcohol withdrawal	289	439	693	35	<0.0001
Analgesia	261	1559	928	892	<0.0001
Anticoagulation	292	1164	721	735	<0.0001
Antimicrobials	1168	2836	2625	1379	<0.0001
Emergencies	479	1341	1022	798	<0.0001
Fluids	80	1740	818	1002	<0.0001
Inhaled therapy	164	564	410	318	<0.0001
Insulin	26	702	362	366	<0.0001
Paediatrics	589	503	894	198	<0.0001
Steroids	98	994	620	472	<0.0001

Table 1: Student answers (correct and incorrect) to equivalent VSA and SBA questions in 10 prescribing areas.

DISCUSSION

Although prescribing skills are widely assessed through a variety of means in the undergraduate curriculum (21, 22), until now there has not been an accepted method of assessing students' ability to generate an authentic prescription on a large scale. Short answer

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3 questions have previously been acknowledged as a superior assessment format for testing
4 prescribing skills, but are labour intensive and time consuming to mark (29). The novel
5 prescribing VSA question format overcomes these limitations whilst still requiring knowledge,
6 judgement and skill in order to generate the correct answer. Furthermore, the rich data
7 generated regarding the sources of error undergraduates make can be used to inform and
8 improve prescribing skills teaching in the undergraduate curriculum. Additionally, personalised
9 feedback can be sent out to the students, including what they have written for each question
10 together with the correct answer. Our results suggest that the prescribing VSA question format
11 is an acceptable and reliable assessment method for prescribing skills, with a number of
12 advantages over using the traditional SBA.
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26 Compared to the SBA, the prescribing VSA has allowed for a much more authentic and valid
27 assessment process as students had to actually prescribe a medication rather than select the
28 correct response from five possibilities. There was a modest correlation between SBA and
29 VSA, which further suggests the assessment methods are measuring different constructs.
30 Many of the prescribing errors made by students in the VSA format are significant; yet when
31 answering the same question in an SBA format they are able to select the correct answer. The
32 corollary of this is that the SBA question format gives a falsely reassuring impression of
33 student's prescribing knowledge and skills.
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Furthermore, another significant advantage of the prescribing VSA questions compared to
SBA questions is the rich feedback it gains from student responses. SBAs only show the
examiner which questions student found more difficult, but does not provide any insight into
students' misunderstandings. The prescribing VSA, however, allows examiners to pinpoint the
specific areas of difficulty to the medication, dose, route or frequency of the prescription
written. This allows educators to tailor teaching to target problematic areas and common
prescribing mistakes.

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3 For example, the prescribing VSA test was able to identify that some students prescribed large
4 doses of rapid acting insulin for a hyperglycaemia scenario, which in clinical practice would be
5 a serious prescribing error. When prescribing fluids, students were frequently unable to select
6 the appropriate fluid or duration of administration. Students were consistently unable to
7 prescribe anticoagulation agents in a safe manner. Prescribing opiates, especially in a
8 palliative care context, was another question in which doses with a potential to cause serious
9 harm were often prescribed. It should be noted that the students were at the beginning of their
10 final year, and that their performance may improve as they approach graduation. However,
11 with the advent of electronic prescribing, it has become increasingly more difficult for students
12 to practice in the workplace, as the system only permits qualified doctors to prescribe. The
13 same questions in SBA format would not have yielded this important feedback. This rich
14 qualitative data can be utilised by medical schools to target interventions to improve
15 prescribing education for undergraduates.
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33 The prescribing VSA has also allowed 50 practical prescribing scenarios to be assessed in
34 one sitting, which cannot be achieved using the time and resource-intensive OSCE
35 examinations or opportunistic WBA methods.
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41 The use of the iPad application as a platform for the prescribing VSA assessment has shown
42 effective examination delivery. The machine-marking is labour-sparing as demonstrated by
43 the 91 minutes taken to mark a large number of prescriptions. This study may be limited by
44 the self-selecting nature of the sample; participation was not compulsory at either medical
45 school and it may be that those students who agreed to participate in the study are more
46 motivated or higher achievers. There are also inherent limitations in developing assessments,
47 no matter how authentic, which take place in a controlled environment albeit with a time
48 pressure. In real life clinical practice, prescribing is often performed in a hurry, whilst juggling
49 other clinical or workload priorities.
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CONCLUSIONS

Overall, VSA questions are an acceptable and reliable form of assessment of prescribing which provides detailed feedback, making it an excellent tool which supports students' learning of safe prescribing, as well as the thorough assessment of prescribing skills. The rich feedback that can be derived from analysis of the sources of error that students make, can be utilised to inform and improve the undergraduate curriculum. We hope that this intervention to improve junior clinician's prescribing has the potential to have a significant impact on patient safety.

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Availability of data and material: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics Approval: Ethics approval was granted by the Imperial College London Medical Education Ethics Committee.

Patient and Public Involvement: Patients/public were not involved in this study.

REFERENCES

1. British Pharmacological Society. Ten principles of good prescribing. Available at <https://www.bps.ac.uk/education-engagement/teaching-pharmacology/ten-principles-of-good-prescribing>.
2. Dornan T, Ashcroft D, Heathfield H, Lewis P, Miles J, Taylor D, et al. An in depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education: EQUIP study. Final report for the GMC, December 2009. Available at https://www.gmc-uk.org/-/media/documents/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf.
3. Ryan C, Ross, S, Davey P, Duncan EM, Francis J, Fielding S, et al. Prevalence and causes of prescribing errors: The Prescribing outcomes for trainee doctors engaged in clinical training (PROTECT) study. PLoS One 2014; 9(1): e079802
4. Avery T, Barber N, Ghaleb M, Franklin B, Armstrong S, Crowe S, et al. Investigating the prevalence and causes of prescribing errors in general practice: The PRACTiCe study (PRevalence And Causes of prescribing errors in general practiCe). Final report for the GMC, May 2012. Available at <https://www.gmc-uk.org/-/media/about/investigatingtheprevalenceandcausesofprescribingerrorsingeneralpracticethepracticestudyreoprtmay2012.pdf>.
5. Elliot R, Camacho E, Campbell F, et al. Prevalance and burden of medication errors in the NHS in England. Policy Research Unit in Economics Evaluation of Health & Care Interventions, February 2018. Available at <http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf>.
6. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA. 1995; 274(1): 35-43
7. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA. 1995; 274(1): 29-34.
8. Dean B, Schachter M, Vincent C, Barber N. Prescribing errors in hospital inpatients: their incidence and clinical significance. Qual Saf Health Care. 2002; 11(4): 340-4
9. Medication Without Harm – Global Patient Safety Challenge on Medication Safety. World Health Organization, 2017. Available at <http://apps.who.int/iris/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-eng.pdf>.
10. Heaton A, Webb DJ, Maxwell SRJ. Undergraduate preparation for prescribing: The views of 2413 UK medical students and recent graduates. Br J Clin Pharmacol.

- 2008; 66: 128-34
11. Monrouxe LV, Grundy L, Mann M, John Z, Panagoulas E, Bullock A, et al. How prepared are UK medical graduates for practice? A rapid review of the literature 2009-2014. *BMJ Open*. 2017; 7: e013656
 12. Monrouxe LV, Bullock A, Gormley G, Kaufhold K, Kelly N, Roberts CE et al. New graduate doctors' preparedness for practice: a multistakeholder, multicenter narrative study. *BMJ Open*. 2018; 8: e023146
 13. Tallentire VR, Smith SE, Wylde K, Cameron HS. Are medical graduates ready to face the challenges of foundation training? *Postgrad Med J*. 2011; 87: 590-5
 14. Miles S, Kellett J, Leinster SJ. Medical graduates' preparedness to practice: a comparison of undergraduate medical school training. *BMC Med Educ*. 2017; 17: 33
 15. Brinkman DJ, Tichelaar J, Graaf S, Otten RHJ, Richir MC, van Agtmael MA. Do final-year medical students have sufficient prescribing competencies? A systematic literature review. *Br J Clin Pharmacol* 2018; 84(4): 615-35
 16. Van Hamel C, Jenner LE. Prepared for practice? A national survey of UK foundation doctors and their supervisors. *Med Teach*. 2015; 37(2): 181-8
 17. Illing J, Morrow G, Kergon CR, Burford BC, Baldauf BK, Davies CL et al. Perceptions of UK medical graduates' preparedness for practice: a multi-centre qualitative study reflecting the importance of learning on the job. *BMC Med Educ*. 2013; 13: 34
 18. Kellett J, Papageorgiou A, Cavenagh P, Salter C, Miles S, Leinster SJ. The preparedness of newly qualified doctors- views of foundation doctors and supervisors. *Med Teach*. 2015; 37(10): 949-54
 19. Matheson C, Matheson D. How well prepared are medical students for their first year as doctors? The views of consultants and specialist registrars in two teaching hospitals. *Postgrad Med J*. 2009; 85(1009): 582-9
 20. Monrouxe LV, Bullock A, Cole J, Gormley G, Kaufhold K, Kelly N et al. How prepared are UK Medical Graduates for practice? Final report for the GMC, June 2014. Available at <https://www.gmc-uk.org/-/media/about/how-prepared-are-uk-medical-graduates-for-practice.pdf>.
 21. O'Shaughnessy L, Hag I, Maxwell S, Llewelyn M. Teaching of clinical pharmacology and therapeutics in UK medical schools: current status in 2009. *Br J Clin Pharmacol*. 2010; 70(1): 143-8
 22. Ross S, Loke YK. Do educational interventions improve prescribing by medical students and junior doctors? A systematic review. *Br J Clin Pharmacol*. 2009; 67(6): 662-70.
 23. Veloski JJ, Rabinowitz HK, Robeson MR, Young PR. Patients don't present with five choices: an alternative to multiple-choice tests in assessing physicians' competence.

- 1
2
3 Acad Med. 1999; 74(5): 539-46.
4
5 24. Maxwell SRJ, Cameron IT, Webb DJ. Prescribing safety: ensuring new graduates
6 are prepared. *Lancet*. 2015; 385(9968): 579-81.
7
8 25. Maxwell SRJ, Coleman JJ, Bollington L, Taylor C, Webb DJ. Prescribing Safety
9 Assessment 2016: Delivery of a national prescribing assessment to 7343 UK final-
10 year medical students. *Br J Clin Pharmacol*. 2017; 83(10): 2249-58.
11
12 26. Hardisty J, Davison K, Statham L, Fleming G, Bollington L, Maxwell S. Exploring the
13 utility of the Prescribing Safety Assessment in pharmacy education in England:
14 experiences of pre-registration trainees and undergraduate (MPharm) pharmacy
15 students. *Int J Pharm Pract*. 2018. doi: 10.1111/ijpp.12479
16
17 27. Wormald BW, Schoeman S, Somasunderam A, Penn M. Assessment drives
18 learning: An unavoidable truth? *Anat Sci Educ*. 2009; 2(5): 199-204.
19
20 28. Sam AH, Field SM, Collares CF, van der Vleuten CPM, Wass VJ, Melville C, et al.
21 Very-short-answer questions: reliability, discrimination and acceptability. *Med Educ*.
22 2018; 52(4): 447-55.
23
24 29. Mucklow J, Bollington L, Maxwell S. Assessing prescribing competence. *Br J Clin*
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Using prescribing very short answer questions to identify sources of medication errors: a prospective study in two UK medical schools

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3 27 **Objective:** To assess the utility and ability of the novel prescribing Very Short Answer (VSA)
4 28 question format to identify the sources of undergraduate prescribing errors when compared to
5 29 the conventional Single Best Answer (SBA) question format, and assess the acceptability of
6 30 machine marking prescribing VSAs.
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11 32 **Design:** A prospective study involving analysis of data generated from a pilot two-part
12 33 prescribing assessment.
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15 35 **Setting:** Two UK medical schools.
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19 37 **Participants:** 364 final year medical students took part. Participation was voluntary. There
20 38 were no other inclusion or exclusion criteria.
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23 40 **Outcomes:** (1) time taken to mark and verify VSA questions (acceptability), (2) differences
24 41 between VSA and SBA scores, (3) performance in VSA and SBA format across different
25 42 subject areas and (4) types of prescribing error made in the VSA format
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29 44 **Results:** 18,200 prescribing VSA questions were marked and verified in 91 minutes. The
30 45 median percentage score for the VSA test was significantly lower than the SBA test (28% vs
31 46 64%, $p < 0.0001$). Significantly more prescribing errors were detected in the VSA format than
32 47 the SBA format across all domains, notably in prescribing insulin (96.4% vs 50.3%, $p < 0.0001$),
33 48 fluids (95.6% vs 55%, $p < 0.0001$) and analgesia (85.7% vs 51%, $p < 0.0001$). Of the incorrect
34 49 VSA responses, 33.1% were due to the medication prescribed, 6.0% due to the dose, 1.4%
35 50 due to the route and 4.8% due to the frequency.
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42 52 **Conclusions:** Prescribing VSA questions represent an efficient tool for providing detailed
43 53 insight into the sources of significant prescribing errors, which are not identified by SBA
44 54 questions. This makes the prescribing VSA a valuable formative assessment tool to enhance
45 55 students' skills in safe prescribing, and to potentially reduce prescribing errors.
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3 64 **Strengths and limitations of this study**
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- 5 65 • There were a large number of participating medical students across two UK medical
6 66 schools.
7
8 67 • We successfully assessed medical students' ability to generate an authentic
9 68 prescription and identified the sources of prescribing errors on a large scale using an
10 69 automated marking system.
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12 70 • The participants may be self-selecting to some degree; those that volunteered to
13 71 participate may be more motivated or high achievers.
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15 72 • Further work is needed to examine the longer-term impact of the use of VSA questions
16 73 and its effects on clinical practice at qualification, or attainment in the Prescribing
17 74 Safety Assessment.
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76 **BACKGROUND**

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78 Prescribing drugs forms a large part of the workload of doctors, and newly graduated doctors
79 prescribe a significant proportion of those medications prescribed in hospital settings. It is a
80 high stakes task, with prescribing having significant implications for both hospitals and
81 clinicians in terms of clinical risk and cost. Prescribing is a complex task for any doctor (1),
82 with prescribers having to select the correct drug, dose, frequency and route, whilst also taking
83 into account interacting drugs and pre-existing co-morbidities. Studies suggest an error rate
84 of approximately 7-10% amongst prescriptions written by clinicians in their first year after
85 graduation, while more senior doctors have an error rate of around 5% (2-4).

86
87 Poor prescribing is not without consequence; medication errors are a common cause of harm
88 to patients, with prescribing errors being the medication error most likely to cause moderate
89 or severe harm to patients (5-8). It has been estimated that 237 million medication errors occur
90 per annum in England, with approximately 66 million of these being potentially clinically
91 significant. These errors may have significant health and economic consequences with one
92 study estimating that the burden of avoidable drug errors may cost the National Health Service
93 approximately £1.6 billion per year and may contribute to 22,303 deaths (5). Developing
94 interventions to reduce clinically important errors is therefore vital to improve patient safety
95 and to reduce the financial burden on the National Health Service. Furthermore, the World
96 Health Organization has cited reducing harm from medication as one of its priorities since
97 2017 (9).

98
99 With such high stakes, it is crucial that undergraduate medical education prepares graduates
100 to prescribe competently in a challenging work environment. However, many graduates report
101 that they lack confidence in their prescribing abilities (10-15), with only 29% of UK students
102 feeling assured in their ability to achieve the GMC's prescribing competencies upon
103 graduating medical school (10). The same study also found that the majority of students did

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3 104 not feel their prescribing knowledge and skills were thoroughly examined prior to graduation
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5 105 (10). This concern has been shared by both junior clinicians' supervisors (16-19) and
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7 106 regulatory bodies (20). Moreover, this appears to be a worldwide issue; medical students
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9 107 consistently appear to lack essential prescribing knowledge and skills (21, 22).

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14 109 At present, prescribing skills are mostly assessed using the written Single Best Answer (SBA)
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16 110 examinations, the Objective Structured Clinical Examination (OSCE) or in Workplace-Based
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18 111 Assessments (WBAs) (23-24). However, there are limitations to these assessment methods.
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20 112 Whilst the SBA may allow broad sampling of the curriculum, it does not fully test the act of
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22 113 writing a prescription. Instead it tests the ability to select a correct prescription out of a choice
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24 114 of five options. The SBA also gives no insight into the sources of errors amongst students
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26 115 (25). The OSCE, conversely, can assess prescribing skills, but the scope of prescribing skills
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28 116 that can be tested is severely limited by the number of stations in the examination. WPBAs,
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30 117 likewise, can assess prescribing skills, however with the advent of electronic prescribing,
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32 118 undergraduates' ability to achieve this competency has since been restricted. The Prescribing
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34 119 Safety Assessment, a national exam taken by medical students in the UK that is being adopted
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36 120 in Canada, Australia and New Zealand (26-28), whilst going some way to address the issues
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38 121 described above, is an exam that is largely sat in the last few months of the undergraduate
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40 122 medical course. It is therefore not able to identify gaps in prescribing knowledge early enough,
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42 123 nor does it provide early and longitudinal feedback, for medical schools to be able to address
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44 124 deficiencies in prescribing knowledge and adjust the course content to strengthen skills in
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46 125 these areas. There is therefore a need to develop a means of formative assessment that
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48 126 facilitates learning by assessing students' ability to prescribe across a broad sample of the
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50 127 undergraduate curriculum.

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56 129 We have developed an online tool which allows thorough and authentic assessment of
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58 130 prescribing skills and medication management, in the form of the prescribing Very Short
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60 131 Answer (VSA) question format. The aim of the prescribing VSA is to improve the validity of

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3 132 assessment of prescribing skills, and by extension the learning behaviour of prescribing
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5 133 amongst undergraduates, to enable safer and more confident prescribing on graduation (29).
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7 134 Additionally, by identifying the types of error students' make and areas of weaknesses in
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9 135 prescribing, the medical school curriculum can be adapted and improved. Identifying these
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11 136 deficiencies and remedying them is essential for both patient safety and a health economics
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14 137 perspective.

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18 139 The prescribing VSA question format is based on similar principles to the Very Short Answer
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20 140 (VSA) question, which has previously been shown to be a valid form of assessment with high
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22 141 reliability and discrimination when compared to SBAs (30). Short Answer Questions (SAQs)
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24 142 have been shown to promote greater long term information retention compared to SBAs (31),
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26 143 but their use on a large scale has been restricted as they are not amenable to machine
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28 144 marking. VSAs, in which students provide an answer of 1-4 words in response to an open
29
30 145 ended question, are able to be marked electronically using new information technology,
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32 146 provide a way of utilising the benefits of SAQs whilst remaining feasible to mark efficiently on
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34 147 a large scale. The prescribing VSA format poses a clinical scenario and a lead-in question.
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36 148 The key difference in the prescribing VSA question is that the student must input free text
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38 149 answers for each of the medication name, dose, route and frequency answer fields.
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43 151 The newly developed online software allows for wide sampling of the undergraduate
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45 152 curriculum for large numbers of students, using realistic clinical scenarios. The aim of this
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47 153 study is to evaluate the reliability and discrimination of prescribing VSA questions in
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49 154 prescribing skills assessment when compared to the traditional SBA question format, to
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51 155 assess the types of error undergraduates commonly make when prescribing, and to assess
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53 156 the acceptability of using machine marking for prescribing VSA questions on a large scale.
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160 **METHODS**

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162 **Participants and assessment**

163 This prospective study was approved by the Medical Education Ethics Committee at Imperial
164 College London. Ethical approval was granted to invite all final year medical students at two
165 medical schools (Imperial College London and University of Edinburgh) to sit the formative
166 prescribing assessment. There were no other inclusion or exclusion criteria. The assessment
167 was conducted on iPad tablets or fixed terminal computers using the newly developed online
168 prescribing examination software (PRACTIQUE; Fry-IT Ltd, London, UK), and was held under
169 examination conditions. All students had had previous exposure to the VSA question format,
170 through their use in formative assessments.

171

172 The students sat a formative examination in two parts. The first included 50 prescribing
173 scenarios in the prescribing VSA format for which students had to generate a full prescription,
174 including the medication name, dose, route and frequency. They were required to enter the
175 medication name and dose in two separate free text fields, whereas the route and frequency
176 were selected from two separate dropdown menus. The second part included the same 50
177 scenarios, in which the students selected the correct answer from five options, in the traditional
178 SBA format. Students were allowed to access the British National Formulary online throughout
179 both parts of the assessment.

180

181 Each question consisted of a clinical scenario (which included the presentation, examination
182 findings and investigation results, as necessary) and a lead-in question. Example prescribing
183 VSA questions are available in the supplementary file. The clinical scenarios were constructed
184 such that they could be used in both the prescribing VSA and SBA format without any change
185 to their content. The question topics were mapped to the final year undergraduate curriculum
186 to ensure a broad sampling of the syllabus. The length of the VSA prescribing examination
187 was 125 minutes, and the length of the SBA examination was 50 minutes.

188 **Marking**

189 The answers to the prescribing VSA questions were captured by the examination software
190 (PRACTIQUE) and sent to a server via an encrypted connection. All identical responses were
191 grouped in blocks by the examination software, and then machine-marked using an automated
192 matching algorithm. This compares the student's answer against a set of preapproved
193 acceptable answers for each question, and uses a measure called Levenshtein distance (32)
194 to measure how closely a student's given answer matches those preapproved correct
195 answers. All student answers that were identical to the list of approved answers were
196 automatically marked as correct. This list of preapproved answers normally consisted of a
197 variety of correct drugs/doses/routes, as determined by a group of clinicians. Students had to
198 have entered the correct medication name, dose, route and frequency to score 1 mark. All
199 match failures were highlighted by the software, and these responses reviewed by two
200 clinicians simultaneously. Marks for responses deemed correct by the examiners could be
201 awarded manually. Any responses marked manually as correct by the examiners, would be
202 applied to all identical answers. The examination software also permitted answers marked
203 manually as correct to be added to the correct answer database for that question. The time
204 taken by the two examiners to review the responses was recorded to assess acceptability.
205 Responses to the SBAs were entirely machine-marked using the examination software
206 (PRACTIQUE).

207

208 **Analysis**

209 Statistical analyses were performed using PRISM Version 8.0.0 (Graphpad Software, Inc.,
210 San Diego, CA, USA). Mann-Whitney test was used to compare the differences between VSA
211 and SBA scores. Spearman's correlation coefficient was used to assess the correlation
212 between the scores of the two formats. Cronbach's alpha was used to assess the reliability of
213 the assessments. The difference between proportion of correct and incorrect answers
214 between the VSA and SBA question formats was examined using Fisher's exact test.

215

216 **RESULTS**

217 A total of 364 final year medical students sat the formative prescribing assessment.

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219 **Prescribing VSA utility**

220 The total time spent by examiners (acceptability) to review the non-matching answers for 50
221 prescribing VSA questions for all 364 students (18,200 prescriptions) was 91 minutes. This is
222 an average of 1 minutes and 49 seconds per question. The median percentage score for the
223 prescribing VSA test (28%, interquartile range 20%-34%) was significantly lower than that of
224 the SBA test (64%, interquartile range 54%-70%) ($p < 0.0001$). There was a significant but
225 modest correlation between VSA and SBA scores ($r = 0.66$, $p < 0.0001$). Reliability (Cronbach's
226 alpha) was 0.76 for the VSA test and 0.82 for SBA test.

227

228 **Sources of error**

229 Of the incorrect responses in the prescribing VSA assessment, 33.1% of these were due to
230 incorrect medications being prescribed, 6.0% due to incorrect doses, 1.4% due to incorrect
231 routes, 4.8% due to incorrect frequencies and 6.1% due to a combination of these errors.

232

233 **Prescribing errors identified by the two formats**

234 The scores on individual items were aggregated by prescribing area to allow comparison
235 between the prescribing VSA and SBA question formats. There was a statistically significant
236 difference between prescribing VSA and SBA student scores for all subject areas (Table 1).
237 Students consistently were less successful at writing a correct prescription compared to
238 selecting the correct prescription from five options. In particular, they performed most poorly
239 in prescribing fluids, insulin, anticoagulation, steroids and analgesia.

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Grouped by subject	VSA correct	VSA incorrect	SBA correct	SBA incorrect	p-value
Alcohol withdrawal	289	439	693	35	<0.0001
Analgesia	261	1559	928	892	<0.0001
Anticoagulation	292	1164	721	735	<0.0001
Antimicrobials	1168	2836	2625	1379	<0.0001
Emergencies	479	1341	1022	798	<0.0001
Fluids	80	1740	818	1002	<0.0001
Inhaled therapy	164	564	410	318	<0.0001
Insulin	26	702	362	366	<0.0001
Paediatrics	589	503	894	198	<0.0001
Steroids	98	994	620	472	<0.0001

Table 1: Student answers (correct and incorrect) to equivalent VSA and SBA questions in 10 prescribing areas.

DISCUSSION

Although prescribing skills are widely assessed through a variety of means in the undergraduate curriculum (23, 24), until now there has not been an accepted method of assessing students' ability to generate an authentic prescription on a large scale. Short answer questions have previously been acknowledged as a superior assessment format for testing prescribing skills, but are labour intensive and time consuming to mark (33). The novel prescribing VSA question format overcomes these limitations whilst still requiring knowledge, judgement and skill in order to generate the correct answer. Furthermore, the rich data generated regarding the sources of error undergraduates make can be used to inform and improve prescribing skills teaching in the undergraduate curriculum. Additionally, personalised feedback can be sent out to the students, including what they have written for each question

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3 259 together with the correct answer. Our results suggest that the prescribing VSA question format
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5 260 is an acceptable and reliable assessment method for prescribing skills, with a number of
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7 261 advantages over using the traditional SBA.
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11 263 Compared to the SBA, the prescribing VSA has allowed for a much more authentic and valid
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13 264 assessment process as students had to actually prescribe a medication rather than select the
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15 265 correct response from five possibilities. There was only a modest correlation between SBA
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17 266 and VSA, which suggests the assessment methods are measuring different constructs. Many
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19 267 of the prescribing errors made by students in the VSA format would have important clinical
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21 268 implications for patients; yet when answering the same question in an SBA format they are
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23 269 able to select the correct answer. The corollary of this is that the SBA question format gives a
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25 270 falsely reassuring impression of students' prescribing knowledge and skills.
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30 272 Another significant advantage of the prescribing VSA questions compared to SBA questions
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32 273 is the rich feedback it gains from student responses. SBAs only show the examiner which
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34 274 questions students found more difficult, but does not provide any insight into why it was more
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36 275 difficult. The prescribing VSA, however, allows examiners to pinpoint the specific areas of
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38 276 difficulty to the medication, dose, route or frequency of the prescription written. This allows
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40 277 educators to tailor teaching to target problematic areas and common prescribing mistakes.
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45 279 For example, the prescribing VSA test was able to identify that some students prescribed large
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47 280 doses of rapid acting insulin for a hyperglycaemia scenario, which in clinical practice would be
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49 281 a serious prescribing error. When prescribing fluids, students were frequently unable to select
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51 282 the appropriate fluid or duration of administration. Students were consistently unable to
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53 283 prescribe anticoagulation agents in a safe manner. Prescribing opiates, especially in a
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55 284 palliative care context, was another question in which doses with a potential to cause serious
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57 285 harm were often prescribed. The same questions in SBA format would not have yielded this
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59 286 important feedback. The students were at the beginning of their final year, so their

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3 287 performance may improve as they approach graduation. However, with the advent of
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5 288 electronic prescribing, it has become increasingly more difficult for students to practice in the
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7 289 workplace, as the system only permits qualified doctors to prescribe. This rich qualitative data
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9 290 can be utilised by medical schools to target interventions to improve prescribing education for
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11 291 undergraduates.
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15 293 The prescribing VSA has also allowed 50 practical prescribing scenarios to be assessed in
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17 294 one sitting, which cannot be achieved using the time and resource-intensive OSCE
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19 295 examinations or opportunistic WBA methods.
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24 297 The use of the iPad application as a platform for the prescribing VSA assessment has shown
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26 298 effective examination delivery. The machine-marking is labour-sparing as demonstrated by
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28 299 the 91 minutes taken to mark a large number of prescriptions. This study may be limited by
29
30 300 the self-selecting nature of the sample; participation was not compulsory at either medical
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32 301 school and it may be that those students who agreed to participate in the study are more
33
34 302 motivated or higher achievers. Whilst 18,200 prescriptions were generated across 364
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36 303 students, weaker students are likely to make the same error repeatedly across the paper; this
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38 304 may give an artificial impression of the number of errors made. Furthermore, it is possible that
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40 305 students from the same institution have a tendency to make the same category of error,
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42 306 perhaps related to curriculum or teaching. This limits the generalisability of the results and
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44 307 further work across a wider range of institutions is warranted. There are also inherent
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46 308 limitations in developing assessments, no matter how authentic, which take place in a
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48 309 controlled environment albeit with a time pressure. In real life clinical practice, prescribing is
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50 310 often performed in a hurry, whilst juggling other clinical or workload priorities.
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3 315 **CONCLUSIONS**
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5 316 Overall, VSA questions are an acceptable and reliable form of assessment of prescribing
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7 317 which provides detailed feedback, making it an excellent tool which supports students'
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9 318 learning of safe prescribing, as well as the thorough assessment of prescribing skills. The rich
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11 319 feedback that can be derived from analysis of the sources of error that students make, can be
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13 320 utilised to inform and improve the undergraduate curriculum. We hope that this intervention to
14
15 321 improve junior clinicians' prescribing has the potential to have a significant impact on patient
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17 322 safety.
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22 324 **Authors' Contributions:**
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24 325 AHS, CYF, RKW, EP, DK, ML, DO, CM and KM contributed to the conception and design of
25
26 326 the work, the analysis and the interpretation of the data, and the drafting and critical revision
27
28 327 of the paper. All authors approved the final manuscript for submission.
29
30

31 328

32
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34

35 330

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37 331 **Competing Interests:** The authors declare that they have no competing interests.
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39 332

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41 333 **Availability of data and material:** The datasets used and/or analysed during the current
42
43 334 study are available from the corresponding author on reasonable request.
44

45 335

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47 336 **Ethics Approval:**
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49 337 Ethics approval was granted by the Imperial College London Medical Education Ethics
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51 338 Committee (reference number MEEC1819-118).
52

53 339

54
55 340 **Patient and Public Involvement:**
56

57 341 Patients/public were not involved in this study.
58
59
60

342 **REFERENCES**

- 343 1. British Pharmacological Society. Ten principles of good prescribing. Available at
344 [https://www.bps.ac.uk/education-engagement/teaching-pharmacology/ten-principles-](https://www.bps.ac.uk/education-engagement/teaching-pharmacology/ten-principles-of-good-prescribing)
345 [of-good-prescribing](https://www.bps.ac.uk/education-engagement/teaching-pharmacology/ten-principles-of-good-prescribing).
- 346 2. Dornan T, Ashcroft D, Heathfield H, Lewis P, Miles J, Taylor D, et al. An in depth
347 investigation into causes of prescribing errors by foundation trainees in relation to
348 their medical education: EQUIP study. Final report for the GMC, December 2009.
349 Available at [https://www.gmc-uk.org/-](https://www.gmc-uk.org/-/media/documents/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf)
350 [/media/documents/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pd](https://www.gmc-uk.org/-/media/documents/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf)
351 [f_28935150.pdf](https://www.gmc-uk.org/-/media/documents/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf).
- 352 3. Ryan C, Ross, S, Davey P, Duncan EM, Francis J, Fielding S, et al. Prevalence and
353 causes of prescribing errors: The Prescribing outcomes for trainee doctors engaged
354 in clinical training (PROTECT) study. PLoS One 2014; 9(1): e079802
- 355 4. Avery T, Barber N, Ghaleb M, Franklin B, Armstrong S, Crowe S, et al. Investigating
356 the prevalence and causes of prescribing errors in general practice: The PRACTiCe
357 study (PRevalence And Causes of prescribing errors in general practiCe). Final
358 report for the GMC, May 2012. Available at [https://www.gmc-uk.org/-](https://www.gmc-uk.org/-/media/about/investigatingtheprevalenceandcausesofprescribingerrorsingeneralpracticestudyreportmay2012.pdf)
359 [/media/about/investigatingtheprevalenceandcausesofprescribingerrorsingeneralpracti](https://www.gmc-uk.org/-/media/about/investigatingtheprevalenceandcausesofprescribingerrorsingeneralpracticestudyreportmay2012.pdf)
360 [cethepracticestudyreoprtmay2012.pdf](https://www.gmc-uk.org/-/media/about/investigatingtheprevalenceandcausesofprescribingerrorsingeneralpracticestudyreportmay2012.pdf).
- 361 5. Elliot R, Camacho E, Campbell F, et al. Prevalance and burden of medication errors
362 in the NHS in England. Policy Research Unit in Economics Evaluation of Health &
363 Care Interventions, February 2018. Available at [http://www.eepru.org.uk/wp-](http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf)
364 [content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf](http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf).
- 365 6. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems
366 analysis of adverse drug events. ADE Prevention Study Group. JAMA. 1995; 274(1):
367 35-43
- 368 7. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of
369 adverse drug events and potential adverse drug events. Implications for prevention.
370 ADE Prevention Study Group. JAMA. 1995; 274(1): 29-34.
- 371 8. Dean B, Schachter M, Vincent C, Barber N. Prescribing errors in hospital inpatients:
372 their incidence and clinical significance. Qual Saf Health Care. 2002; 11(4): 340-4
- 373 9. Medication Without Harm – Global Patient Safety Challenge on Medication Safety.
374 World Health Organization, 2017. Available at
375 [http://apps.who.int/iris/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-](http://apps.who.int/iris/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-eng.pdf)
376 [eng.pdf](http://apps.who.int/iris/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-eng.pdf).
- 377 10. Heaton A, Webb DJ, Maxwell SRJ. Undergraduate preparation for prescribing: The
378 views of 2413 UK medical students and recent graduates. Br J Clin Pharmacol.

- 1
2
3 379 2008; 66: 128-34
4
5 380 11. Monrouxe LV, Grundy L, Mann M, John Z, Panagoulas E, Bullock A, et al. How
6 381 prepared are UK medical graduates for practice? A rapid review of the literature
7 382 2009-2014. *BMJ Open*. 2017; 7: e013656
8
9 383 12. Monrouxe LV, Bullock A, Gormley G, Kaufhold K, Kelly N, Roberts CE et al. New
10 384 graduate doctors' preparedness for practice: a multistakeholder, multicenter narrative
11 385 study. *BMJ Open*. 2018; 8: e023146
12
13 386 13. Tallentire VR, Smith SE, Wylde K, Cameron HS. Are medical graduates ready to
14 387 face the challenges of foundation training? *Postgrad Med J*. 2011; 87: 590-5
15
16 388 14. Miles S, Kellett J, Leinster SJ. Medical graduates' preparedness to practice: a
17 389 comparison of undergraduate medical school training. *BMC Med Educ*. 2017; 17: 33
18
19 390 15. Brinkman DJ, Tichelaar J, Graaf S, Otten RHJ, Richir MC, van Agtmael MA. Do final-
20 391 year medical students have sufficient prescribing competencies? A systematic
21 392 literature review. *Br J Clin Pharmacol* 2018; 84(4): 615-35
22
23 393 16. Van Hamel C, Jenner LE. Prepared for practice? A national survey of UK foundation
24 394 doctors and their supervisors. *Med Teach*. 2015; 37(2): 181-8
25
26 395 17. Illing J, Morrow G, Kergon CR, Burford BC, Baldauf BK, Davies CL et al. Perceptions
27 396 of UK medical graduates' preparedness for practice: a multi-centre qualitative study
28 397 reflecting the importance of learning on the job. *BMC Med Educ*. 2013; 13: 34
29
30 398 18. Kellett J, Papageorgiou A, Cavenagh P, Salter C, Miles S, Leinster SJ. The
31 399 preparedness of newly qualified doctors- views of foundation doctors and
32 400 supervisors. *Med Teach*. 2015; 37(10): 949-54
33
34 401 19. Matheson C, Matheson D. How well prepared are medical students for their first year
35 402 as doctors? The views of consultants and specialist registrars in two teaching
36 403 hospitals. *Postgrad Med J*. 2009; 85(1009): 582-9
37
38 404 20. Monrouxe LV, Bullock A, Cole J, Gormley G, Kaufhold K, Kelly N et al. How prepared
39 405 are UK Medical Graduates for practice? Final report for the GMC, June 2014.
40 406 Available at [https://www.gmc-uk.org/-/media/about/how-prepared-are-uk-medical-](https://www.gmc-uk.org/-/media/about/how-prepared-are-uk-medical-graduates-for-practice.pdf)
41 407 [graduates-for-practice.pdf](https://www.gmc-uk.org/-/media/about/how-prepared-are-uk-medical-graduates-for-practice.pdf).
42
43 408 21. Brinkman DJ, Tichelaar J, Schutte T, Benemei S, Böttiger Y, Chamontin B et al.
44 409 Essential competencies in prescribing: a first European cross-sectional study among
45 410 895 final-year medical students. *Clin Pharmacol Ther*. 2017; 101(2): 281-9
46
47 411 22. Brinkman DJ, Tichelaar J, Graaf S, Otten RHJ, Richir MC, van Agtmael MA. Do final-
48 412 year medical students have sufficient prescribing competencies? A systematic
49 413 literature review. *Br J Clin Pharmacol*. 2018; 84(4): 615-35.
50
51 414 23. O'Shaughnessy L, Hag I, Maxwell S, Llewelyn M. Teaching of clinical pharmacology
52 415 and therapeutics in UK medical schools: current status in 2009. *Br J Clin Pharmacol*.

- 1
2
3 416 2010; 70(1): 143-8
4
5 417 24. Ross S, Loke YK. Do educational interventions improve prescribing by medical
6 418 students and junior doctors? A systematic review. *Br J Clin Pharmacol*. 2009; 67(6):
7 419 662-70.
8
9 420 25. Veloski JJ, Rabinowitz HK, Robeson MR, Young PR. Patients don't present with five
10 421 choices: an alternative to multiple-choice tests in assessing physicians' competence.
11 422 *Acad Med*. 1999; 74(5): 539-46.
12
13 423 26. Maxwell SRJ, Cameron IT, Webb DJ. Prescribing safety: ensuring new graduates
14 424 are prepared. *Lancet*. 2015; 385(9968): 579-81.
15
16 425 27. Maxwell SRJ, Coleman JJ, Bollington L, Taylor C, Webb DJ. Prescribing Safety
17 426 Assessment 2016: Delivery of a national prescribing assessment to 7343 UK final-
18 427 year medical students. *Br J Clin Pharmacol*. 2017; 83(10): 2249-58.
19
20 428 28. Hardisty J, Davison K, Statham L, Fleming G, Bollington L, Maxwell S. Exploring the
21 429 utility of the Prescribing Safety Assessment in pharmacy education in England:
22 430 experiences of pre-registration trainees and undergraduate (MPharm) pharmacy
23 431 students. *Int J Pharm Pract*. 2018. doi: 10.1111/ijpp.12479
24
25 432 29. Wormald BW, Schoeman S, Somasunderam A, Penn M. Assessment drives
26 433 learning: An unavoidable truth? *Anat Sci Educ*. 2009; 2(5): 199-204.
27
28 434 30. Sam AH, Field SM, Collares CF, van der Vleuten CPM, Wass VJ, Melville C, et al.
29 435 Very-short-answer questions: reliability, discrimination and acceptability. *Med Educ*.
30 436 2018; 52(4): 447-55.
31
32 437 31. Larsen DP, Butler AC, Roediger HL III. Test enhanced learning in medical education.
33 438 *Med Educ*. 2008; 42(10):959-66.
34
35 439 32. Levenshtein V. Binary codes capable of correcting deletions, insertions, and
36 440 reversals. *Soviet Physics Doklady*. 1966; 10(8): 707-10.
37
38 441 33. Mucklow J, Bollington L, Maxwell S. Assessing prescribing competence. *Br J Clin*
39 442 *Pharmacol*. 2012; 74(4): 632-9.
40
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Example prescribing scenario 1

A 16 year old girl presents to the GP unwell with a fever, headache and intolerance to light. She has no past medical history, other than developing a mild, non-specific rash after receiving amoxicillin for a sore throat as a child. Her temperature is 38.2°C, pulse rate 108 bpm, BP 103/76 mmHg, respiratory rate 22 breaths per minute and oxygen saturation 99% breathing air. She has a non-blanching, maculopapular rash on her trunk, neck stiffness and photophobia. She weighs 50 kg. An ambulance has been called.

Please prescribe the most appropriate immediate medication.

Accepted VSA answers:

Benzylpenicillin 1.2g intramuscular once only

Benzylpenicillin sodium 1.2g intramuscular once only

Example prescribing scenario 2

A 22 year old man has acute breathlessness. He has a known history of asthma for which he takes regular beclomethasone and theophylline, and salbutamol as required. His temperature is 36.5°C, pulse rate 95 bpm, BP 110/68 mmHg, respiratory rate 30 breaths per minute and oxygen saturation 94% breathing air. He is unable to complete sentences in one breath, and has a loud wheeze bilaterally. His peak flow is 35% of predicted. He is initially treated with supplementary oxygen, salbutamol via oxygen-driven nebuliser and hydrocortisone 100 mg intravenously. A combination of salbutamol and ipratropium is then given, however his symptoms fail to improve significantly. The intensive care unit has been called to review the patient. He weighs 70 kg.

Please prescribe the most appropriate next medication.

Accepted VSA answers:

Magnesium sulphate 1.2 – 2g intravenous over 20 minutes

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5
Objectives	3	State specific objectives, including any pre-specified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	2,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	7
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	12
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	n/a
		(c) Explain how missing data were addressed	n/a
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	n/a

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	n/a
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(b) Report category boundaries when continuous variables were categorized	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	10,11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11,12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Using prescribing very short answer questions to identify sources of medication errors: a prospective study in two UK medical schools

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3 27 **Objective:** To assess the utility and ability of the novel prescribing Very Short Answer (VSA)
4 28 question format to identify the sources of undergraduate prescribing errors when compared to
5 29 the conventional Single Best Answer (SBA) question format, and assess the acceptability of
6 30 machine marking prescribing VSAs.
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10 31
11 32 **Design:** A prospective study involving analysis of data generated from a pilot two-part
12 33 prescribing assessment.
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15 35 **Setting:** Two UK medical schools.
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19 37 **Participants:** 364 final year medical students took part. Participation was voluntary. There
20 38 were no other inclusion or exclusion criteria.
21
22 39

23 40 **Outcomes:** (1) time taken to mark and verify VSA questions (acceptability), (2) differences
24 41 between VSA and SBA scores, (3) performance in VSA and SBA format across different
25 42 subject areas and (4) types of prescribing error made in the VSA format
26
27 43

28
29 44 **Results:** 18,200 prescribing VSA questions were marked and verified in 91 minutes. The
30 45 median percentage score for the VSA test was significantly lower than the SBA test (28% vs
31 46 64%, $p < 0.0001$). Significantly more prescribing errors were detected in the VSA format than
32 47 the SBA format across all domains, notably in prescribing insulin (96.4% vs 50.3%, $p < 0.0001$),
33 48 fluids (95.6% vs 55%, $p < 0.0001$) and analgesia (85.7% vs 51%, $p < 0.0001$). Of the incorrect
34 49 VSA responses, 33.1% were due to the medication prescribed, 6.0% due to the dose, 1.4%
35 50 due to the route and 4.8% due to the frequency.
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42 52 **Conclusions:** Prescribing VSA questions represent an efficient tool for providing detailed
43 53 insight into the sources of significant prescribing errors, which are not identified by SBA
44 54 questions. This makes the prescribing VSA a valuable formative assessment tool to enhance
45 55 students' skills in safe prescribing, and to potentially reduce prescribing errors.
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3 64 **Strengths and limitations of this study**
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- 5 65 • There were a large number of participating medical students across two UK medical
6 66 schools.
7
8 67 • We successfully assessed medical students' ability to generate an authentic
9 68 prescription and identified the sources of prescribing errors on a large scale using an
10 69 automated marking system.
11
12 70 • The participants may be self-selecting to some degree; those that volunteered to
13 71 participate may be more motivated or high achievers.
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15 72 • Further work is needed to examine the longer-term impact of the use of VSA questions
16 73 and its effects on clinical practice at qualification, or attainment in the Prescribing
17 74 Safety Assessment.
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76 **BACKGROUND**

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78 Prescribing drugs forms a large part of the workload of doctors, and newly graduated doctors
79 prescribe a significant proportion of those medications prescribed in hospital settings. It is a
80 high stakes task, with prescribing having significant implications for both hospitals and
81 clinicians in terms of clinical risk and cost. Prescribing is a complex task for any doctor (1),
82 with prescribers having to select the correct drug, dose, frequency and route, whilst also taking
83 into account interacting drugs and pre-existing co-morbidities. Studies suggest an error rate
84 of approximately 7-10% amongst prescriptions written by clinicians in their first year after
85 graduation, while more senior doctors have an error rate of around 5% (2-4).

86
87 Poor prescribing is not without consequence; medication errors are a common cause of harm
88 to patients, with prescribing errors being the medication error most likely to cause moderate
89 or severe harm to patients (5-8). It has been estimated that 237 million medication errors occur
90 per annum in England, with approximately 66 million of these being potentially clinically
91 significant. These errors may have significant health and economic consequences with one
92 study estimating that the burden of avoidable drug errors may cost the National Health Service
93 approximately £1.6 billion per year and may contribute to 22,303 deaths (5). Developing
94 interventions to reduce clinically important errors is therefore vital to improve patient safety
95 and to reduce the financial burden on the National Health Service. Furthermore, the World
96 Health Organization has cited reducing harm from medication as one of its priorities since
97 2017 (9).

98
99 With such high stakes, it is crucial that undergraduate medical education prepares graduates
100 to prescribe competently in a challenging work environment. However, many graduates report
101 that they lack confidence in their prescribing abilities (10-15), with only 29% of UK students
102 feeling assured in their ability to achieve the GMC's prescribing competencies upon
103 graduating medical school (10). The same study also found that the majority of students did

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3 104 not feel their prescribing knowledge and skills were thoroughly examined prior to graduation
4
5 105 (10). This concern has been shared by both junior clinicians' supervisors (16-19) and
6
7 106 regulatory bodies (20). Moreover, this appears to be a worldwide issue; medical students
8
9 107 consistently appear to lack essential prescribing knowledge and skills (21, 22).

10
11 108
12
13 109 At present, prescribing skills are mostly assessed using the written Single Best Answer (SBA)
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15 110 examinations, the Objective Structured Clinical Examination (OSCE) or in Workplace-Based
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17 111 Assessments (WBAs) (23-24). However, there are limitations to these assessment methods.
18
19 112 Whilst the SBA may allow broad sampling of the curriculum, it does not fully test the act of
20
21 113 writing a prescription. Instead it tests the ability to select a correct prescription out of a choice
22
23 114 of five options. The SBA also gives no insight into the sources of errors amongst students
24
25 115 (25). The OSCE, conversely, can assess prescribing skills, but the scope of prescribing skills
26
27 116 that can be tested is severely limited by the number of stations in the examination. WPBAs,
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29 117 likewise, can assess prescribing skills, however with the advent of electronic prescribing,
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31 118 undergraduates' ability to achieve this competency has since been restricted. The Prescribing
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33 119 Safety Assessment, a national exam taken by medical students in the UK that is being adopted
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35 120 in Canada, Australia and New Zealand (26-28), whilst going some way to address the issues
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37 121 described above, is an exam that is largely sat in the last few months of the undergraduate
38
39 122 medical course. It is therefore not able to identify gaps in prescribing knowledge early enough,
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41 123 nor does it provide early and longitudinal feedback, for medical schools to be able to address
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43 124 deficiencies in prescribing knowledge and adjust the course content to strengthen skills in
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45 125 these areas. There is therefore a need to develop a means of formative assessment that
46
47 126 facilitates learning by assessing students' ability to prescribe across a broad sample of the
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49 127 undergraduate curriculum.

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53 129 We have developed an online tool which allows thorough and authentic assessment of
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55 130 prescribing skills and medication management, in the form of the prescribing Very Short
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57 131 Answer (VSA) question format. The aim of the prescribing VSA is to improve the validity of

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3 132 assessment of prescribing skills, and by extension the learning behaviour of prescribing
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5 133 amongst undergraduates, to enable safer and more confident prescribing on graduation (29).
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7 134 Additionally, by identifying the types of error students' make and areas of weaknesses in
8
9 135 prescribing, the medical school curriculum can be adapted and improved. Identifying these
10
11 136 deficiencies and remedying them is essential for both patient safety and a health economics
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14 137 perspective.

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18 139 The prescribing VSA question format is based on similar principles to the Very Short Answer
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20 140 (VSA) question, which has previously been shown to be a valid form of assessment with high
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22 141 reliability and discrimination when compared to SBAs (30). Short Answer Questions (SAQs)
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24 142 have been shown to promote greater long term information retention compared to SBAs (31),
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26 143 but their use on a large scale has been restricted as they are not amenable to machine
27
28 144 marking. VSAs, in which students provide an answer of 1-4 words in response to an open
29
30 145 ended question, are able to be marked electronically using new information technology,
31
32 146 provide a way of utilising the benefits of SAQs whilst remaining feasible to mark efficiently on
33
34 147 a large scale. The prescribing VSA format poses a clinical scenario and a lead-in question.
35
36 148 The key difference in the prescribing VSA question is that the student must input free text
37
38 149 answers for each of the medication name, dose, route and frequency answer fields.
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43 151 The newly developed online software allows for wide sampling of the undergraduate
44
45 152 curriculum for large numbers of students, using realistic clinical scenarios. The aim of this
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47 153 study is to evaluate the reliability and discrimination of prescribing VSA questions in
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49 154 prescribing skills assessment when compared to the traditional SBA question format, to
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51 155 assess the types of error undergraduates commonly make when prescribing, and to assess
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53 156 the acceptability of using machine marking for prescribing VSA questions on a large scale.
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160 **METHODS**

161

162 **Participants and assessment**

163 This prospective study was approved by the Medical Education Ethics Committee at Imperial
164 College London. Ethical approval was granted to invite all final year medical students at two
165 medical schools (Imperial College London and University of Edinburgh) to sit the formative
166 prescribing assessment. There were no other inclusion or exclusion criteria. The assessment
167 was conducted on iPad tablets or fixed terminal computers using the newly developed online
168 prescribing examination software (PRACTIQUE; Fry-IT Ltd, London, UK), and was held under
169 examination conditions. All students had had previous exposure to the VSA question format,
170 through their use in formative assessments.

171

172 The students sat a formative examination in two parts. The first included 50 prescribing
173 scenarios in the prescribing VSA format for which students had to generate a full prescription,
174 including the medication name, dose, route and frequency. They were required to enter the
175 medication name and dose in two separate free text fields, whereas the route and frequency
176 were selected from two separate dropdown menus. The second part included the same 50
177 scenarios, in which the students selected the correct answer from five options, in the traditional
178 SBA format. Students were allowed to access the British National Formulary online throughout
179 both parts of the assessment.

180

181 Each question consisted of a clinical scenario (which included the presentation, examination
182 findings and investigation results, as necessary) and a lead-in question. Example prescribing
183 VSA questions are available in the supplementary file. The clinical scenarios were constructed
184 such that they could be used in both the prescribing VSA and SBA format without any change
185 to their content. The question topics were mapped to the final year undergraduate curriculum
186 to ensure a broad sampling of the syllabus. The length of the VSA prescribing examination
187 was 125 minutes, and the length of the SBA examination was 50 minutes.

188 **Marking**

189 The answers to the prescribing VSA questions were captured by the examination software
190 (PRACTIQUE) and sent to a server via an encrypted connection. All identical responses were
191 grouped in blocks by the examination software, and then machine-marked using an automated
192 matching algorithm. This compares the student's answer against a set of preapproved
193 acceptable answers for each question, and uses a measure called Levenshtein distance (32)
194 to measure how closely a student's given answer matches those preapproved correct
195 answers. All student answers that were identical to the list of approved answers were
196 automatically marked as correct. This list of preapproved answers normally consisted of a
197 variety of correct drugs/doses/routes, as determined by a group of clinicians. Students had to
198 have entered the correct medication name, dose, route and frequency to score 1 mark. All
199 match failures were highlighted by the software, and these responses reviewed by two
200 clinicians simultaneously. Marks for responses deemed correct by the examiners could be
201 awarded manually. Any responses marked manually as correct by the examiners, would be
202 applied to all identical answers. The examination software also permitted answers marked
203 manually as correct to be added to the correct answer database for that question. The time
204 taken by the two examiners to review the responses was recorded to assess acceptability.
205 Responses to the SBAs were entirely machine-marked using the examination software
206 (PRACTIQUE).

207

208 **Analysis**

209 Statistical analyses were performed using PRISM Version 8.0.0 (Graphpad Software, Inc.,
210 San Diego, CA, USA). Mann-Whitney test was used to compare the differences between VSA
211 and SBA scores. Spearman's correlation coefficient was used to assess the correlation
212 between the scores of the two formats. Cronbach's alpha was used to assess the reliability of
213 the assessments. The difference between proportion of correct and incorrect answers
214 between the VSA and SBA question formats was examined using Fisher's exact test.

215

216 **RESULTS**

217 A total of 364 final year medical students sat the formative prescribing assessment.

218

219 **Prescribing VSA utility**

220 The total time spent by examiners (acceptability) to review the non-matching answers for 50
221 prescribing VSA questions for all 364 students (18,200 prescriptions) was 91 minutes. This is
222 an average of 1 minutes and 49 seconds per question. The median percentage score for the
223 prescribing VSA test (28%, interquartile range 20%-34%) was significantly lower than that of
224 the SBA test (64%, interquartile range 54%-70%) ($p < 0.0001$). There was a significant but
225 modest correlation between VSA and SBA scores ($r = 0.66$, $p < 0.0001$). Reliability (Cronbach's
226 alpha) was 0.76 for the VSA test and 0.82 for SBA test.

227

228 **Sources of error**

229 Of the incorrect responses in the prescribing VSA assessment, 33.1% of these were due to
230 incorrect medications being prescribed, 6.0% due to incorrect doses, 1.4% due to incorrect
231 routes, 4.8% due to incorrect frequencies and 6.1% due to a combination of these errors.

232

233 **Prescribing errors identified by the two formats**

234 The scores on individual items were aggregated by prescribing area to allow comparison
235 between the prescribing VSA and SBA question formats. There was a statistically significant
236 difference between prescribing VSA and SBA student scores for all subject areas (Table 1).
237 Students consistently were less successful at writing a correct prescription compared to
238 selecting the correct prescription from five options. In particular, they performed most poorly
239 in prescribing fluids, insulin, anticoagulation, steroids and analgesia.

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242

Grouped by subject	VSA correct	VSA incorrect	SBA correct	SBA incorrect	p-value
Alcohol withdrawal	289	439	693	35	<0.0001
Analgesia	261	1559	928	892	<0.0001
Anticoagulation	292	1164	721	735	<0.0001
Antimicrobials	1168	2836	2625	1379	<0.0001
Emergencies	479	1341	1022	798	<0.0001
Fluids	80	1740	818	1002	<0.0001
Inhaled therapy	164	564	410	318	<0.0001
Insulin	26	702	362	366	<0.0001
Paediatrics	589	503	894	198	<0.0001
Steroids	98	994	620	472	<0.0001

Table 1: Student answers (correct and incorrect) to equivalent VSA and SBA questions in 10 prescribing areas.

DISCUSSION

Although prescribing skills are widely assessed through a variety of means in the undergraduate curriculum (23, 24), until now there has not been an accepted method of assessing students' ability to generate an authentic prescription on a large scale. Short answer questions have previously been acknowledged as a superior assessment format for testing prescribing skills, but are labour intensive and time consuming to mark (33). The novel prescribing VSA question format overcomes these limitations whilst still requiring knowledge, judgement and skill in order to generate the correct answer. Furthermore, the rich data generated regarding the sources of error undergraduates make can be used to inform and improve prescribing skills teaching in the undergraduate curriculum. Additionally, personalised feedback can be sent out to the students, including what they have written for each question

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3 259 together with the correct answer. Our results suggest that the prescribing VSA question format
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5 260 is an acceptable and reliable assessment method for prescribing skills, with a number of
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7 261 advantages over using the traditional SBA.
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11 263 Compared to the SBA, the prescribing VSA has allowed for a much more authentic and valid
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13 264 assessment process as students had to actually prescribe a medication rather than select the
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15 265 correct response from five possibilities. There was only a modest correlation between SBA
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17 266 and VSA, which suggests the assessment methods are measuring different constructs. Many
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19 267 of the prescribing errors made by students in the VSA format would have important clinical
20
21 268 implications for patients; yet when answering the same question in an SBA format they are
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23 269 able to select the correct answer. The corollary of this is that the SBA question format gives a
24
25 270 falsely reassuring impression of students' prescribing knowledge and skills.
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30 272 Another significant advantage of the prescribing VSA questions compared to SBA questions
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32 273 is the rich feedback it gains from student responses. SBAs only show the examiner which
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34 274 questions students found more difficult, but does not provide any insight into why it was more
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36 275 difficult. The prescribing VSA, however, allows examiners to pinpoint the specific areas of
37
38 276 difficulty to the medication, dose, route or frequency of the prescription written. This allows
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40 277 educators to tailor teaching to target problematic areas and common prescribing mistakes.
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44
45 279 For example, the prescribing VSA test was able to identify that some students prescribed large
46
47 280 doses of rapid acting insulin for a hyperglycaemia scenario, which in clinical practice would be
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49 281 a serious prescribing error. When prescribing fluids, students were frequently unable to select
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51 282 the appropriate fluid or duration of administration. Students were consistently unable to
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53 283 prescribe anticoagulation agents in a safe manner. Prescribing opiates, especially in a
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55 284 palliative care context, was another question in which doses with a potential to cause serious
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57 285 harm were often prescribed. The same questions in SBA format would not have yielded this
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59 286 important feedback. The students were at the beginning of their final year, so their

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3 287 performance may improve as they approach graduation. However, with the advent of
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5 288 electronic prescribing, it has become increasingly more difficult for students to practice in the
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7 289 workplace, as the system only permits qualified doctors to prescribe. This rich qualitative data
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9 290 can be utilised by medical schools to target interventions to improve prescribing education for
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11 291 undergraduates.

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16 293 The prescribing VSA has also allowed 50 practical prescribing scenarios to be assessed in
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18 294 one sitting, which cannot be achieved using the time and resource-intensive OSCE
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20 295 examinations or opportunistic WBA methods.

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24 297 The use of the iPad application as a platform for the prescribing VSA assessment has shown
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26 298 effective examination delivery. The machine-marking is labour-sparing as demonstrated by
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28 299 the 91 minutes taken to mark a large number of prescriptions. This study may be limited by
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30 300 the self-selecting nature of the sample; participation was not compulsory at either medical
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32 301 school and it may be that those students who agreed to participate in the study are more
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34 302 motivated or higher achievers. Whilst 18,200 prescriptions were generated across 364
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36 303 students, weaker students are likely to make the same error repeatedly across the paper; this
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38 304 may give an artificial impression of the number of errors made. Furthermore, it is possible that
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40 305 students from the same institution have a tendency to make the same category of error,
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42 306 perhaps related to curriculum or teaching. This limits the generalisability of the results and
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44 307 further work across a wider range of institutions is warranted. There are also inherent
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46 308 limitations in developing assessments, no matter how authentic, which take place in a
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48 309 controlled environment albeit with a time pressure. In real life clinical practice, prescribing is
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50 310 often performed in a hurry, whilst juggling other clinical or workload priorities.

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3 315 **CONCLUSIONS**
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5 316 Overall, VSA questions are an acceptable and reliable form of assessment of prescribing
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7 317 which provides detailed feedback, making it an excellent tool which supports students'
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9 318 learning of safe prescribing, as well as the thorough assessment of prescribing skills. The rich
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11 319 feedback that can be derived from analysis of the sources of error that students make, can be
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13 320 utilised to inform and improve the undergraduate curriculum. We hope that this intervention to
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15 321 improve junior clinicians' prescribing has the potential to have a significant impact on patient
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17 322 safety.
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22 324 **Authors' Contributions:**
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24 325 AHS, CYF, RKW, EP, DK, ML, DO, CM and KM contributed to the conception and design of
25
26 326 the work, the analysis and the interpretation of the data, and the drafting and critical revision
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28 327 of the paper. All authors approved the final manuscript for submission.
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36 331 **Competing Interests:** The authors declare that they have no competing interests.
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41 333 **Availability of data and material:** The datasets used and/or analysed during the current
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43 334 study are available from the corresponding author on reasonable request.
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47 336 **Ethics Approval:**
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49 337 Ethics approval was granted by the Imperial College London Medical Education Ethics
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51 338 Committee (reference number MEEC1819-118).
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55 340 **Patient and Public Involvement:**
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57 341 Patients/public were not involved in this study.
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342 **REFERENCES**

- 343 1. British Pharmacological Society. Ten principles of good prescribing. Available at
344 [https://www.bps.ac.uk/education-engagement/teaching-pharmacology/ten-principles-
345 of-good-prescribing](https://www.bps.ac.uk/education-engagement/teaching-pharmacology/ten-principles-
345 of-good-prescribing).
- 346 2. Dornan T, Ashcroft D, Heathfield H, Lewis P, Miles J, Taylor D, et al. An in depth
347 investigation into causes of prescribing errors by foundation trainees in relation to
348 their medical education: EQUIP study. Final report for the GMC, December 2009.
349 Available at [https://www.gmc-uk.org/-
350 /media/documents/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pd
351 f_28935150.pdf](https://www.gmc-uk.org/-
350 /media/documents/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pd
351 f_28935150.pdf).
- 352 3. Ryan C, Ross, S, Davey P, Duncan EM, Francis J, Fielding S, et al. Prevalence and
353 causes of prescribing errors: The Prescribing outcomes for trainee doctors engaged
354 in clinical training (PROTECT) study. PLoS One 2014; 9(1): e079802
- 355 4. Avery T, Barber N, Ghaleb M, Franklin B, Armstrong S, Crowe S, et al. Investigating
356 the prevalence and causes of prescribing errors in general practice: The PRACTiCe
357 study (PRevalence And Causes of prescribing errors in general practiCe). Final
358 report for the GMC, May 2012. Available at [https://www.gmc-uk.org/-
359 /media/about/investigatingtheprevalenceandcausesofprescribingerrorsingeneralpracti
360 cethepracticestudyreoprtmay2012.pdf](https://www.gmc-uk.org/-
359 /media/about/investigatingtheprevalenceandcausesofprescribingerrorsingeneralpracti
360 cethepracticestudyreoprtmay2012.pdf).
- 361 5. Elliot R, Camacho E, Campbell F, et al. Prevalance and burden of medication errors
362 in the NHS in England. Policy Research Unit in Economics Evaluation of Health &
363 Care Interventions, February 2018. Available at [http://www.eepru.org.uk/wp-
364 content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf](http://www.eepru.org.uk/wp-
364 content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf).
- 365 6. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems
366 analysis of adverse drug events. ADE Prevention Study Group. JAMA. 1995; 274(1):
367 35-43
- 368 7. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of
369 adverse drug events and potential adverse drug events. Implications for prevention.
370 ADE Prevention Study Group. JAMA. 1995; 274(1): 29-34.
- 371 8. Dean B, Schachter M, Vincent C, Barber N. Prescribing errors in hospital inpatients:
372 their incidence and clinical significance. Qual Saf Health Care. 2002; 11(4): 340-4
- 373 9. Medication Without Harm – Global Patient Safety Challenge on Medication Safety.
374 World Health Organization, 2017. Available at
375 [http://apps.who.int/iris/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-
376 eng.pdf](http://apps.who.int/iris/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-
376 eng.pdf).
- 377 10. Heaton A, Webb DJ, Maxwell SRJ. Undergraduate preparation for prescribing: The
378 views of 2413 UK medical students and recent graduates. Br J Clin Pharmacol.

- 1
2
3 379 2008; 66: 128-34
4
5 380 11. Monrouxe LV, Grundy L, Mann M, John Z, Panagoulas E, Bullock A, et al. How
6 381 prepared are UK medical graduates for practice? A rapid review of the literature
7 382 2009-2014. *BMJ Open*. 2017; 7: e013656
8
9 383 12. Monrouxe LV, Bullock A, Gormley G, Kaufhold K, Kelly N, Roberts CE et al. New
10 384 graduate doctors' preparedness for practice: a multistakeholder, multicenter narrative
11 385 study. *BMJ Open*. 2018; 8: e023146
12
13 386 13. Tallentire VR, Smith SE, Wylde K, Cameron HS. Are medical graduates ready to
14 387 face the challenges of foundation training? *Postgrad Med J*. 2011; 87: 590-5
15
16 388 14. Miles S, Kellett J, Leinster SJ. Medical graduates' preparedness to practice: a
17 389 comparison of undergraduate medical school training. *BMC Med Educ*. 2017; 17: 33
18
19 390 15. Brinkman DJ, Tichelaar J, Graaf S, Otten RHJ, Richir MC, van Agtmael MA. Do final-
20 391 year medical students have sufficient prescribing competencies? A systematic
21 392 literature review. *Br J Clin Pharmacol* 2018; 84(4): 615-35
22
23 393 16. Van Hamel C, Jenner LE. Prepared for practice? A national survey of UK foundation
24 394 doctors and their supervisors. *Med Teach*. 2015; 37(2): 181-8
25
26 395 17. Illing J, Morrow G, Kergon CR, Burford BC, Baldauf BK, Davies CL et al. Perceptions
27 396 of UK medical graduates' preparedness for practice: a multi-centre qualitative study
28 397 reflecting the importance of learning on the job. *BMC Med Educ*. 2013; 13: 34
29
30 398 18. Kellett J, Papageorgiou A, Cavenagh P, Salter C, Miles S, Leinster SJ. The
31 399 preparedness of newly qualified doctors- views of foundation doctors and
32 400 supervisors. *Med Teach*. 2015; 37(10): 949-54
33
34 401 19. Matheson C, Matheson D. How well prepared are medical students for their first year
35 402 as doctors? The views of consultants and specialist registrars in two teaching
36 403 hospitals. *Postgrad Med J*. 2009; 85(1009): 582-9
37
38 404 20. Monrouxe LV, Bullock A, Cole J, Gormley G, Kaufhold K, Kelly N et al. How prepared
39 405 are UK Medical Graduates for practice? Final report for the GMC, June 2014.
40 406 Available at [https://www.gmc-uk.org/-/media/about/how-prepared-are-uk-medical-
41 407 graduates-for-practice.pdf](https://www.gmc-uk.org/-/media/about/how-prepared-are-uk-medical-graduates-for-practice.pdf).
42
43 408 21. Brinkman DJ, Tichelaar J, Schutte T, Benemei S, Böttiger Y, Chamontin B et al.
44 409 Essential competencies in prescribing: a first European cross-sectional study among
45 410 895 final-year medical students. *Clin Pharmacol Ther*. 2017; 101(2): 281-9
46
47 411 22. Brinkman DJ, Tichelaar J, Graaf S, Otten RHJ, Richir MC, van Agtmael MA. Do final-
48 412 year medical students have sufficient prescribing competencies? A systematic
49 413 literature review. *Br J Clin Pharmacol*. 2018; 84(4): 615-35.
50
51 414 23. O'Shaughnessy L, Hag I, Maxwell S, Llewelyn M. Teaching of clinical pharmacology
52 415 and therapeutics in UK medical schools: current status in 2009. *Br J Clin Pharmacol*.

- 1
2
3 416 2010; 70(1): 143-8
4
5 417 24. Ross S, Loke YK. Do educational interventions improve prescribing by medical
6 418 students and junior doctors? A systematic review. *Br J Clin Pharmacol*. 2009; 67(6):
7 419 662-70.
8
9 420 25. Veloski JJ, Rabinowitz HK, Robeson MR, Young PR. Patients don't present with five
10 421 choices: an alternative to multiple-choice tests in assessing physicians' competence.
11 422 *Acad Med*. 1999; 74(5): 539-46.
12
13 423 26. Maxwell SRJ, Cameron IT, Webb DJ. Prescribing safety: ensuring new graduates
14 424 are prepared. *Lancet*. 2015; 385(9968): 579-81.
15
16 425 27. Maxwell SRJ, Coleman JJ, Bollington L, Taylor C, Webb DJ. Prescribing Safety
17 426 Assessment 2016: Delivery of a national prescribing assessment to 7343 UK final-
18 427 year medical students. *Br J Clin Pharmacol*. 2017; 83(10): 2249-58.
19
20 428 28. Hardisty J, Davison K, Statham L, Fleming G, Bollington L, Maxwell S. Exploring the
21 429 utility of the Prescribing Safety Assessment in pharmacy education in England:
22 430 experiences of pre-registration trainees and undergraduate (MPharm) pharmacy
23 431 students. *Int J Pharm Pract*. 2018. doi: 10.1111/ijpp.12479
24
25 432 29. Wormald BW, Schoeman S, Somasunderam A, Penn M. Assessment drives
26 433 learning: An unavoidable truth? *Anat Sci Educ*. 2009; 2(5): 199-204.
27
28 434 30. Sam AH, Field SM, Collares CF, van der Vleuten CPM, Wass VJ, Melville C, et al.
29 435 Very-short-answer questions: reliability, discrimination and acceptability. *Med Educ*.
30 436 2018; 52(4): 447-55.
31
32 437 31. Larsen DP, Butler AC, Roediger HL III. Test enhanced learning in medical education.
33 438 *Med Educ*. 2008; 42(10):959-66.
34
35 439 32. Levenshtein V. Binary codes capable of correcting deletions, insertions, and
36 440 reversals. *Soviet Physics Doklady*. 1966; 10(8): 707-10.
37
38 441 33. Mucklow J, Bollington L, Maxwell S. Assessing prescribing competence. *Br J Clin*
39 442 *Pharmacol*. 2012; 74(4): 632-9.
40
41 443
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Example prescribing scenario 1

A 16 year old girl presents to the GP unwell with a fever, headache and intolerance to light. She has no past medical history, other than developing a mild, non-specific rash after receiving amoxicillin for a sore throat as a child. Her temperature is 38.2°C, pulse rate 108 bpm, BP 103/76 mmHg, respiratory rate 22 breaths per minute and oxygen saturation 99% breathing air. She has a non-blanching, maculopapular rash on her trunk, neck stiffness and photophobia. She weighs 50 kg. An ambulance has been called.

Please prescribe the most appropriate immediate medication.

Accepted VSA answers:

Benzylpenicillin 1.2g intramuscular once only

Benzylpenicillin sodium 1.2g intramuscular once only

Example prescribing scenario 2

A 22 year old man has acute breathlessness. He has a known history of asthma for which he takes regular beclomethasone and theophylline, and salbutamol as required. His temperature is 36.5°C, pulse rate 95 bpm, BP 110/68 mmHg, respiratory rate 30 breaths per minute and oxygen saturation 94% breathing air. He is unable to complete sentences in one breath, and has a loud wheeze bilaterally. His peak flow is 35% of predicted. He is initially treated with supplementary oxygen, salbutamol via oxygen-driven nebuliser and hydrocortisone 100 mg intravenously. A combination of salbutamol and ipratropium is then given, however his symptoms fail to improve significantly. The intensive care unit has been called to review the patient. He weighs 70 kg.

Please prescribe the most appropriate next medication.

Accepted VSA answers:

Magnesium sulphate 1.2 – 2g intravenous over 20 minutes

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5
Objectives	3	State specific objectives, including any pre-specified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	2,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	7
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	12
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	n/a
		(c) Explain how missing data were addressed	n/a
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	n/a

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	n/a
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(b) Report category boundaries when continuous variables were categorized	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	10,11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11,12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.