Title:
Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students

Authors:
Simon RJ Maxwell *Medical Director* [1]
Jamie J Coleman *Chair Assessment Board* [2]
Lynne Bollington, *Lead Consultant* [3]
Celia Taylor *Lead Statistician* [4]
David J Webb *Co-Chair Executive Board* [5]

Affiliations:
[1] Clinical Pharmacology Unit, University of Edinburgh, Medical Education Centre, Western General Hospital, Edinburgh EH3 2XU
[2] School of Medicine, Institute of Clinical Sciences, College of Medical and Dental Sciences (CMDS), Medical School Building, University of Birmingham, Edgbaston, Birmingham B15 2TT
[3] British Pharmacological Society, 16 Angel Gate, City Road, London EC1V 2PT
[4] Department of Health Sciences, University of Warwick Medical School, Coventry, CV4 7AL
[5] Clinical Pharmacology Unit, University of Edinburgh, Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh EH16 4TJ

Keywords
prescribing, medicine, doctor, pharmacist, undergraduate, assessment, medication safety, error

Word count
4,400 words

Author for correspondence:
Professor Simon Maxwell
Clinical Pharmacology Unit, University of Edinburgh,
Medical Education Centre, Western General Hospital, Edinburgh EH3 2XU, UK
s.maxwell@ed.ac.uk

Accompanying documents:
Standard Exclusive Licence Form (ELF) – this will be provided
Declaration of Competing Interests Form (DCI) – a statement is included in the manauscript

Originality and agreement statement:
All of the authors above declare that this work has not been, and will not be published, in whole or in part in any other journal and agree to the contents of the manuscript in its submitted form (see cover letter).

What is already known about this subject

- Newly-graduated doctors prescribe medicines frequently and write a large proportion of prescriptions in UK hospitals but recent studies suggest that around one in ten of their prescriptions may contain errors
- The ability to prescribe safely and effectively is one of the competencies identified as a key outcome of undergraduate medical education by the General Medical Council (the UK medical regulator)
- There has been significant variation in the assessments used by medical schools to ensure that medical students have attained the necessary competence prior to graduation
- Prescribing is a complex skill to assess because of the number of prescribing scenarios that might be tested, the variety of documentation used and the challenge of marking large numbers of prescriptions in a standardised way

What this study adds

- The Prescribing Safety Assessment (PSA) has been developed as a 2-hour online assessment of competence in relation to prescribing and supervising the use of medicines in a modern healthcare setting
- The PSA delivers a standard national prescribing assessment involving around two hundred assessment events at academic centres around the UK (and overseas) each year and enables large numbers of prescriptions (around 60,000) to be instantaneously assessed against a standardised marking scheme
- There was significant variation in the performance of cohorts of students from different medical schools
- The vast majority of UK final-year medical students were able to meet the pre-specified standard of competence as defined by the PSA pass mark

Summary

Aim(s). Newly graduated doctors write a large proportion of prescriptions in UK hospitals but recent studies have shown that they frequently make prescribing errors. The Prescribing Safety Assessment (PSA) has been developed as an assessment of competence in relation to prescribing and supervising the use of medicines. This report describes the delivery of the PSA to all UK final-year medical students in 2016 (PSA2016).

Methods. The PSA is a 2-hour online assessment comprising eight sections which cover various aspects of prescribing defined within the outcomes of undergraduate education identified by the UK General Medical Council. Students sat one of four PSA 'papers' which had been standard-set using a modified Angoff process.

Results. A total of 7,343 final-year medical students in all 31 UK medical schools sat the PSA. The overall pass rate was 95% with the pass rates for the individual papers ranging from 93 to 97%. The PSA was re-sat by 261 students who had failed and 80% of those candidates passed. The internal consistency (Cronbach's alpha) of the four papers ranged from 0.74 to 0.77 (standard error of measurement 4.13 to 4.24%). There was a statistically significant variation in performance between medical school cohorts ($F=32.6$, $p<0.001$) and a strongly positive correlation in performance for individual schools between PSA2015 and PSA2016 ($r=0.79$, 95% CI 0.61 to 0.90; $p<0.01$).

Conclusions. PSA2016 demonstrated the feasibility of delivering a standardised national prescribing assessment online. The vast majority of UK final-year medical students were able to meet a pre-specified standard of prescribing competence.

248 words (maximum 250)

Introduction

Prescribing medicines is a core activity for the UK National Health Service (NHS), both in hospitals and primary care. Around 1 billion prescriptions are written annually in primary care in England, equating to an average of 20 for every member of the population [1]. Prescribing is a challenging task for any healthcare professional. Prescribers have to select the correct medicine, dosage, route, and frequency of administration, sometimes in the face of diagnostic uncertainty, taking into account potential individual variability in pharmacokinetics and response as a consequence of co-morbidity, genetics, and interacting drugs [2]. Given that individual patients have different ideas and expectations, and the outcome of any prescription is uncertain, the prescriber also needs to be able to counsel the patient and plan an appropriate strategy for monitoring and follow-up for evidence of benefit and/or harms.

With these complexities, it is perhaps not surprising that poor prescribing is common. Recent studies found an error rate of 7–10% amongst prescriptions written by doctors in their first year of clinical practice while senior doctors, both in hospital and general practice, have a prescribing error rate of around 5% [3–5]. Several factors continuously add to the demands made on all prescribers including increased age and frailty of NHS patients, the growing complexity of treatment regimens, and an increasingly pressurised healthcare system.

In these circumstances it is important that undergraduate medical education provides the training to ensure that new graduates meet minimum standards of prescribing competency. However, recent studies show that medical students and recent graduates often feel underprepared for and anxious about prescribing [6–9], a concern echoed by their supervisors [10,11] and the regulatory bodies [12]. Reliable evidence about prescribing competence is hard to find because relevant assessments have varied significantly between medical schools and none have been widely applied or validated [13].

In response to these concerns, the British Pharmacological Society (BPS) and Medical Schools Council Assessment (MSCA) developed the Prescribing Safety Assessment (PSA) as a summative assessment of

knowledge, judgement and skills related to prescribing and supervising the use of medicines in a modern healthcare system [14]. The PSA is intended to enable final-year medical students at the end of their undergraduate training to demonstrate that they have achieved the necessary competence to prescribe, and supervise the use of, medicines at the standard expected of a Foundation (first- and second-year) doctor in the NHS. The PSA is based on the competencies identified by the UK General Medical Council in *Outcomes for Graduates* (2015) (originally published in *Tomorrow's Doctors* (2009)) [15]. It is delivered online and is intended to assess, as far as possible within the confines of a virtual environment, complex skills including powers of deduction and problem solving that are relevant to the work of Foundation doctors.

This report describes the process and outcomes of the PSA in 2016 (PSA2016) including the development of the assessment papers, the delivery of the PSA, the performance of the candidates and medical schools, and the basic psychometric properties of the assessment.

Methods

Candidates

Final-year medical students from all 31 UK medical schools were offered the opportunity to take the assessment. The PSA was originally piloted in 2012 and 2013, before being fully implemented in all schools in 2014 (PSA2014). Prior to 2016, a majority of medical schools hosted the PSA as a low-stakes formative assessment. For the first time in 2016, the postgraduate training committee representing the four UK countries stipulated that all new doctors entering postgraduate (Foundation) training, either from UK medical schools or overseas, would be required to take the PSA (those who failed would be expected to participate in enhanced supervision and remediation, and would be required to pass the PSA before the end of their first year of training). A further 828 students from seven international medical schools also participated in PSA2016 but they are not considered in this report.

PSA structure

The PSA comprises eight sections, each containing a specific item style reflecting different aspects of the process of prescribing, reviewing and advising about medicines: prescribing (PWS), prescription review (REV), planning management (MAN), providing information about medicines (COM), calculation skills (CAL), adverse drug reactions (ADR), drug monitoring (TDM) and data interpretation (DAT) (Figure 1). The different sections are intended to reflect not only the process of prescribing but also the related skills when supervising patients prescribed medicines by others. The question items are based on 60 patient scenarios that offer a total of 200 marks and candidates have two hours to complete the assessment. The scenarios relate to one of seven clinical settings: General Internal Medicine (MED), General Surgery (SURG), Elderly Care (ELD), Paediatrics (PED), Psychiatry (PSY), Obstetrics & Gynaecology (O&G), and General Practice (GP).

The detailed breakdown of marks allocated to each section is shown in Table 1. Additional rules of assessment construction are that each PSA 'paper' must have a minimum item coverage in the various clinical settings (MED – 8, SURG – 4, ELD – 8, PED – 4, PSY – 4, O&G – 4, GP – 8) and have minimum coverage of high risk drugs (at least two items on each of the following: opioid analgesics, anticoagulants, insulin, antimicrobials and intravenous infusion fluids). The PSA does not carry negative marks.

Figure 1 here. Structure of the Prescribing Safety Assessment (PSA).
Table 1 here. Allocation of question items and marks to each PSA section.

PSA question items and papers

PSA question items have been developed by a team of around one hundred trained authors (including clinical pharmacologists, other specialty and trainee doctors, general practitioners and pharmacists) who are mainly based in UK medical schools or NHS hospitals. Their question items undergo a strict 5-stage quality assurance process overseen by the PSA Assessment Board. Items that survived each stage of review, including a national peer-review meeting, were used to make four 60-item papers (A, B, C and D) conforming to the PSA blueprint [16]. The four papers included a total of 176 unique items with 32 classified as 'anchor' items which were used in three of the four papers. There were 78 items repeated from PSA2015. The four papers were then ratified by the Assessment Board (two-day meeting, November 2015), made available for standard-setting (two-day meeting, January 2016) and delivered to the candidates (February to June 2016).

Standard-setting

The pass marks for each paper were determined by the Standard-Setting Group comprising nine representatives from UK medical schools, who were selected for their knowledge of the appropriate minimum standard expected of Foundation year one doctors. The group used a modified Angoff method to derive the pass mark for each paper [17]. The meeting began with a discussion of, and agreement about, the attributes that would define the 'just passing' candidate. The group members then scored each item individually. To avoid 'paper bias', the order in which items were presented to group members was randomised. Those with outlying scores ('hawks' and 'doves'), were asked to justify their scores, to inform a discussion about the item, before all members were asked to reconfirm or adjust their scores. The final mean scores across all group members for each item were used to calculate the pass mark for the paper. The derived pass marks for the four papers ranged from 62.0% to 65.5%.

Candidate preparation

All candidates (final year medical students) were registered on the PSA online system and sent an e-mail requesting them to activate their accounts. After activation of their accounts they had access to general information about the PSA, 12 information videos and four 1-hour, 30-item, practice 'papers' with question-specific feedback. Candidates were encouraged to familiarise themselves with the different question types and the assessment environment and to practise finding information in the online version of the *British National Formulary* (BNF) [18].

Delivery of the PSA assessment events

The PSA online delivery system allows the PSA team to create unique events specific to a date, a time slot, a school, a location and a specific cohort of students thus ensuring that candidates get the correct paper within a secure time envelope. PSA assessment events were run on four dates (01.02.16, 14.03.16, 13.05.16, 01.06.16). The multiple dates enabled schools to schedule later events for cohorts who may have been absent on earlier days and to allow candidates who failed the opportunity to re-sit the PSA prior to graduation. Each PSA event was delivered live from a 'cloud-based' server to each event location under invigilated conditions. After logging into the PSA system on the day of the assessment candidates were given a unique event-specific password that allowed them to enter the 60-item assessment described above. Some examples of the assessment screens are shown in Figure 2.

All candidates had access to the online BNF throughout the assessment. Candidates identified by their medical schools as normally being entitled to an extra time allowance were given an additional 30 minutes (25%) to complete the assessments and other reasonable adjustments as required by individual students were made. Assessment centres were provided with administrative and technical support during the events by staff at the MSCA office and the technical team (Rave Technologies).

Figure 2 here. Example PSA question item screens: Prescribing (green), Prescription Review (blue), Planning Management (red), Calculation Skills (grey).

Post-assessment review

All prescriptions written by the candidates were scrutinised immediately after the assessment ('post-assessment review') to ensure that the answer matrix for the prescribing (PWS) items took into account any

creditworthy responses that had not been anticipated and included in the mark scheme. The PSA system automatically identifies all unrecognised drugs and unrecognised drug order sentences provided by candidates during an event. These were carefully reviewed by the PSA Assessment Board and appropriate scores allocated and added to the electronic marking scheme. Candidates' marks were automatically updated and the additions to the answer matrix are carried forward to subsequent uses of the item. The post-assessment review ensures that all candidates are marked in a fair and consistent way across event days. The performance of other item styles was also reviewed at this point for any unexpected answering behaviour. The final PSA results were released to medical schools within two weeks of each event and to the candidates shortly thereafter.

Feedback

After exiting the assessment on their computers, candidates were immediately presented with a standard feedback form designed to explore their views about the relevance and external validity of the assessment, their preparedness for taking it, the quality of the online delivery system and any other free text comments that they might wish to provide. The medical school PSA Leads were provided with a standard feedback form that allowed them to describe any administrative or process problems that they encountered.

Statistical analysis

Initial psychometric analysis was undertaken using classical test theory in both Excel and STATA v14. Data are presented as mean and standard deviation (SD) unless otherwise stated. For comparison between papers both raw and calibrated percentage scores are provided. Calibrated scores have been calculated using the pass mark for each paper, so that a raw score of 0% stays at 0%, a raw score equal to the pass mark becomes 50% and a raw score of 100% stays at 100%. Calibrated data were assumed to be sufficiently normally distributed to enable parametric statistical testing to be undertaken. One-way ANOVA was used to assess the significance of the variation between medical schools. Pearson rank correlation was used to measure the association between mean medical school performance in 2016 and 2015. Internal consistency of the papers was assessed using Cronbach's alpha [19]. Standard error of measurement (SEM) was calculated using Cronbach's alpha and the standard deviation of raw total scores for each paper [20].

268 The item-rest correlation for individual question items was calculated using Pearson's correlation between
269 candidates' scores on the item with their total score on all other items combined.
270

Results

Candidate performance

A total of 7,343 final-year students from 31 UK medical schools participated in PSA2016 and sat one of the four PSA 'papers' (A, B, C and D) in 200 PSA events held over four dates. Data from 254 students from one school that experienced considerable technical difficulties (where all candidates were allowed an additional 30 minutes in which to complete the assessment) were excluded from analysis. The following data summarises the performance of the remaining 7,089 candidates.

The mean raw scores (SD) for the four papers ranged from 80.0% (8.3%) on Paper A to 76.1% (8.8%) on Paper D with an overall pass rate of 95% (compared to 91% in PSA2015 and 94% in PSA2014) (Table 2). The range in pass rates for the individual papers was from 97.2% (Paper A) to 92.6% (Paper D). The pass rate amongst the 286 students re-sitting the PSA was 80% meaning that less than one percent of all UK students failed to pass the PSA by the end of the academic year.

Reasonable adjustment in the form of allocation of extra time was provided to 693 candidates (9.8%). The first-sitting pass rate amongst students with extra time was 94%, compared to 95% among students without extra time (chi-squared=2.31, p=0.128). The mean (SD) calibrated score amongst students with extra time was 70.5% (11.8%), compared with 71.5% (11.3%) for those without extra time (t=2.20, p<0.001).

When the individual sections of the PSA were considered separately, candidates appeared to do particularly well on the adverse drug reactions items (median section score on each paper 88%) and less well on the data interpretation items (median section score on each paper 67%) when compared to the overall paper (median scores 77 to 81%). A potential reason for the relatively poor performance on the latter section (which was also noted in PSA2015) is that data interpretation items are presented as the last section of the assessment and some candidates may be running out of time when these items are attempted (although questions can be attempted in any order).

The 32 anchor items were distributed such that eight items were used for each combination of three papers. The mean percentage scores achieved by candidates across the eight repeated items in each set of papers were ABC (74.7 to 76.7%), ABD (76.9 to 78.2%), ACD (76.3 to 77.1%) and BCD (81.5 to 82.1%) suggesting that there were only relatively small differences in performance of the cohorts attempting each paper.

Some items have been used in two or three of the assessment diets run over the last four years (2013 to 2016). For the 16 items used in 2013 and 2016 the total absolute improvement in mean item score was 11.7 percentage points. For the 40 items used in 2014 and 2016 the improvement was 1.1 percentage points and for the 78 items used in 2015 and 2016 it was 2.6 percentage points.

Table 2 here. Candidate performance in PSA2016.

Internal consistency

The mean Cronbach's alpha across the four papers was 0.75 (range 0.74 to 0.77) and the standard error of measurement was 4.19% (range 4.17 to 4.24%) (Table 2). The Cronbach's alpha was almost identical to the 0.76 achieved in PSA2015 and above the 0.70 achieved in PSA2014. Using classical test theory 52% of items showed good discrimination, with an item-rest correlation greater than 0.2 while 9% had an item-rest correlation less than 0.1.

Performance by medical school

The number of students taking the PSA at each school ranged from 47 to 430. Comparison of the performance of schools that took different papers was facilitated by calibrating the raw scores so that the pass mark was considered to be 50% for each. The mean calibrated scores across schools ranged from 63.2% to 78.2% (Figure 3). The result of a one-way ANOVA comparing mean student scores was $F_{29,7059}$ = 32.6, $p<0.001$, indicating statistically significant differences in performance between schools.

There was a strong positive correlation between the mean medical school scores recorded in PSA2015 and PSA2016 (Figure 4). The Pearson's correlation coefficient for 2015 to 2016 was 0.79 (95% CI 0.61 to 0.90; $p<0.01$). Mean scores improved between 2015 and 2016 at all but two schools. The variability across schools did reduce slightly, with standard deviations of mean scores (coefficients of variation) of 4.11% (0.061) in 2015 and 3.84% (0.054) in 2016.

Figure 3. Performance by medical school.
Figure 4. Mean calibrated score by medical school in 2015 and 2016.

Discussion

Although medical schools and NHS hospitals had previously developed local prescribing assessments, there has never been a widely accepted measure of prescribing performance in medical education. Our intention was to develop a reliable and valid national prescribing assessment that might serve to enable medical students (and their medical schools) to demonstrate that they had achieved a basic standard of prescribing competence by the time of graduation. In addition, we hoped that the PSA might increase the visibility of prescribing in the curriculum, promote better training experiences, and provide some feedback about the impact of varying education strategies. This might, in turn, raise and unify prescribing standards and ultimately contribute to enhanced quality and safety of patient care.

The PSA is the first national online prescribing assessment for final-year medical students. Since its original conception in 2010 it has become an annual part of the assessment cycle in all UK medical schools and is supported by a dedicated editorial team, a national panel of authors drawn from academia and the NHS, an Assessment Board responsible for a multi-stage quality assurance process, a Standard-Setting Sub-Group and a technical team responsible for maintaining and improving the online delivery system. The key points from this report of PSA2016 are that: (i) the overall performance of the candidates was good, (ii) there is some evidence that performance is improving, (iii) the reliability of the assessment is improving, and (iv) there is significant variation in the performance of students from different medical schools.

Candidate performance

The vast majority of final-year students were able to pass the PSA, meeting the standard of competence pre-defined by the Angoff-derived pass mark, and most of those who failed were able to pass the PSA after a period of revision and remediation. The pass rate of 95% represented an improvement on previous years (compared to 91% in PSA2015 and 94% in PSA2014), which might represent a progressive improvement in performance. However, there may be other relevant factors. It is possible that the 2016 papers were easier relative to pass mark even though the standard-setters followed the same process and definitions. The announcement by the Foundation Programme that all entrants would be expected to have taken the PSA

(and pass it by the end of their first year of training at the latest) undoubtedly raised the stakes for the students and might have increased the overall motivation of the candidates. This change would be particularly relevant for the majority of medical schools where taking the PSA was previously used as a formative assessment. There was also more support available for candidates than in previous years with four practice papers and 12 online videos describing the process and structure of the PSA. Some of the PSA2016 cohort also had experience of local 'mock' PSA events during their penultimate year of study in 2015. Anecdotal reports indicate that some medical schools had developed additional learning sessions focused on prescribing in an effort to prepare their students for the PSA. The better performance of candidates on items repeated over the years 2013 to 2016 and the slightly reduced variability in performance between medical schools also supports the belief that there is a genuine improvement in performance.

Although the performance of the candidates is generally good, and seems to be improving, we hope that further improvements might be achieved. Part of that process will involve identifying some of the common mistakes and misunderstandings demonstrated by candidates and providing detailed feedback to medical schools. This should support the improvement of teaching and learning of prescribing amongst future cohorts. A final point to make is that the Angoff standard-setting process used to define competence remains a subjective and imprecise prediction, even if carefully executed [21]. It is dependent on the interpretation of the definition of the 'just passing' candidate by each of the PSA standard-setters and how relevant the definition is to safe clinical practice and the risk of error. This uncertainty requires further exploration.

Reliability

The position of the PSA as a progressively high-stakes assessment of safe practice increases the focus on its reliability. The analysis of internal consistency showed that the mean Cronbach's alpha was 0.75, which was similar to PSA2015 (0.76) and higher than PSA2014 (0.70). Although this remains below the 0.8 that some have suggested to be the minimum acceptable reliability for a high stakes test [22], it compares well with

other multi-domain assessments limited to only two hours duration [23]. Indeed, others recommend acceptance of a lower alpha value (0.70) to ensure that the reliability of an assessment does not come at the expense of validity (i.e. high reliability would be achieved by assessing a narrow range of skills and areas of knowledge rather than sampling from the entire skill set required for safe prescribing) [24]. The Spearman-Brown formula predicts that the number of items in each section of the PSA would need to be increased by around 25% to achieve a reliability of 0.8, a change that might threaten the acceptability of the assessment. While we hope that the current reliability estimates will maintain support for the process, the PSA aims to identify and preserve the most discriminating question items, reject those that perform less well and provide constructive feedback to our item authors.

Medical school variation

There was a significant variation in the performance of final-year students studying in different medical schools and the performance in 2015 and 2016 was strongly correlated, implying that this is a real and consistent effect. There are a number of possible reasons for this variation. It might represent a genuine variation in the knowledge, skills and judgement that are the intended focus of the assessment. Previous reviews have suggested that there are variations in undergraduate training, visibility, emphasis and assessments in clinical pharmacology and prescribing [13]. These variations were one of the reasons why the Safe Prescribing Working Group previously recommended the need for the development of a clear description of relevant learning outcomes [15,25,26], and access to national eLearning support materials [27]. The variation may also represent more general differences in the aptitudes of the cohorts such as their ability to perform in high-stakes time-pressured assessments. A similar inter-school variation has been noted in other assessments such as subsequent performance in specific postgraduate examinations [28]. There may also be more subtle factors at play such as the timing of the assessments in relation to the local undergraduate curriculum, involvement of local teachers in the PSA process and the general enthusiasm and support for national assessments in general or the PSA in particular.

Important limitations

There are some important inherent limitations in developing and implementing the PSA as a national prescribing assessment. Foremost is the lack of a demonstrable association between performance in its controlled environment and prescribing competence in the real world of clinical practice. This question must be addressed but poses significant difficulties, primarily because of the lack of an easily applied measure of real life performance, the inherent variability of case mix in clinical practice and numerous other factors that influence individual practice (e.g. workload, supervision).

There are always potential technical risks in delivering live online assessments. Although major problems have been rare in our experience, network slowing can cause problems (e.g. slow page loading, slow item turnover, screen freezes) at peak times involving several thousand candidates. These problems severely affected one site involved in PSA2016 although online delivery from the 'cloud' means that candidate answers are not lost, even when connections fail.

A frequent concern expressed by the candidates is the timing of the assessment. Keystroke logs suggest that almost all candidates remain active throughout the two-hour duration of the assessment. While some candidates feedback that 'patient safety tasks should never be rushed' the reality of clinical practice is that time is often limited by workload pressures. Furthermore, the PSA is an open-book assessment during which all candidates have access to the BNF. The BNF cannot answer all questions but provides a valuable back up to support the candidates' knowledge. The time limit places a premium on being able to use the BNF efficiently but does not allow reliance on the reference source to override the requirement for basic knowledge and clinical judgement gained through clinical training.

The pass mark is relatively low for a high-stakes assessment. This reflects the fact that those items with the best discrimination tend to have a facility mid-way between guessing and maximum [29,30]. This highlights the tension between having an easier assessment composed of 'must-know' items with high facility and one that can more reliably differentiate candidates at the pass-fail cut score.

Future issues

A standardised tool for assessing prescribing competence might be deployed more widely than undergraduate medical education. Most doctors prescribe frequently throughout their careers and, like doctors in their first year of clinical practice, often make errors [3–5]. Since optimal prescribing practice changes frequently, an assessment of prescribing would also be highly relevant to postgraduate training and revalidation. Indeed, it might be argued that prescribing should feature prominently as an identifiable component of any broad assessment of competence to practise medicine. This will be an important consideration for the General Medical Council in its consultation about the structure of the new Medical Licensing Examination (MLA) [31]. Although identifying prescribing so clearly might run contrary to the current focus on integrated learning and assessment, we believe that it deserves such prominence. Few activities are undertaken so frequently by doctors, carry such immediate implications for patient health outcomes [32], have such clearly documented rates of error in modern healthcare [3–5], or carry such a clear training-practice deficit [12].

Prescribing rights have now been extended to other prescribing groups (e.g. nurse practitioners, pharmacists) [33]. In recognition of this broadened definition of a 'prescriber' a national prescribing competency framework has been developed that identifies the generic abilities that should be possessed by all prescribing professionals [34], many of which feature in the PSA. Some early pilot work has been started to explore the utility of the PSA amongst other professional groups [35].

A final consideration is whether the PSA will contribute to improved prescribing outcomes. It is well recognised that assessments influence learner and institutional priorities [36]. In this way the PSA is undoubtedly increasing the visibility of medicines safety as an outcome for graduates. As anticipated, evidence of 'teaching to the test' is emerging, so it is critical that the PSA remains firmly relevant to clinical practice. The candidate feedback suggests that the assessment is relevant to their training needs and that the chance to get feedback on their performance is welcomed. We believe that this initiative is beginning to deliver graduates who are better prepared to face the challenges of prescribing and supervising the use of

medicines in the NHS. However, that gain can only be part of a wider drive to improve patient outcomes, which will also include better supervision and team-working, point of care decision support, improved prescribing systems and avoiding unsustainable individual workloads [3,4,14].

Conclusion

The PSA is now a major national collaboration involving all UK medical schools. The annual scale of the PSA process (academic, administrative and technical) is now considerable: around 8,500 students from the UK and overseas, 17,000 candidate hours of assessment and over half a million patient safety-related questions posed and marked (including 70,000 prescriptions). The PSA is beginning to meet many of its initial objectives in providing a more reliable and consistent assessment of prescribing competence at graduation as well as stimulating increased visibility in this key part of undergraduate training. The future of the PSA must involve ongoing efforts to maximise its quality, reliability and external validity.

Acknowledgements

The authors wish to acknowledge the support of the following colleagues who made the delivery of PSA2016 possible:

- Staff at the many participating academic centres who efficiently coordinated and delivered the assessment events including the PSA academic leads, administrative and technical teams, and the event invigilators
- Staff at the Medical Schools Council and British Pharmacological Society
- Members of the PSA Assessment Board and its Standard-Setting Sub-Group
- Staff at Rave Technologies who provided technical support.

The authors would also like to thank all of the final-year medical students who worked hard to prepare for, took part in and provided feedback about the PSA.

The development and implementation of PSA has been funded by the Medical Schools Council and British Pharmacological Society. These lead organisations are grateful for additional grants awarded by Healthcare Education England and NHS Education Scotland to support this work.

CT is supported by the NIHR CLAHRC West Midlands initiative. This paper presents independent research and the views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

LB has been paid consultancy fees by the BPS for some of the editorial and other quality assurance work described in this paper.

SM has been paid consultancy fees by the BPS for contributions to other prescribing-related projects.

References

1. Prescribing and Medicines Team Health and Social Care Information Centre. Prescriptions dispensed in the community: England 2004–14. 7 July 2015. http://content.digital.nhs.uk/catalogue/PUB17644/pres-disp-com-eng-2004-14-rep.pdf

2. British Pharmacological Society. Ten principles of good prescribing. https://www.bps.ac.uk/BPSMemberPortal/media/BPSWebsite/Assets/BPSPrescribingStatement03Feb2010.pdf

3. Dornan T, Ashcroft D, Heathfield H, Lewis P, Miles J, Taylor D, Tully M, Wass V. 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 http://www.gmc-uk.org/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf

4. Ryan C, Ross S, Davey P, Duncan EM, Francis J, Fielding S, Johnston M, Ker J, Lee AJ, MacLeod MJ, Maxwell S, McKay GA, McLay JS, Webb DJ, Bond C. Prevalence and causes of prescribing errors: the PRescribing Outcomes for Trainee Doctors Engaged in Clinical Training (PROTECT) study. *PLoS ONE* 2014; 9(1). doi: 10.1371/journal.pone.0079802

5. Avery T, Barber N, Ghaleb M, Franklin B, Armstrong S, Crowe S, Dhillon S, Freyer A, Howard R, Pezzolesi C, Serumaga B, Swanwick G, Talabi O. 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 http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf

6. Heaton A, Webb DJ, Maxwell SR. Undergraduate preparation for prescribing: the views of 2413 UK medical students and recent graduates. *Br J Clin Pharmacol* 2008;**66**:128–34.

7. Monrouxe L, Bullock A, Gormley G, et al (2014) How Prepared are UK Medical Graduates for Practice? Final report from a programme of research commissioned by the General Medical Council available at: www.gmc-uk.org/about/research/23658.asp

8. Goldacre MJ, Lambert TW, Svirko E (2012) Foundation doctors' views on whether their medical school prepared them well for work: UK graduates of 2008 and 2009. *Postgrad Med J* 2014;**90**:63–8. Available at: http://pmj.bmj.com/content/ early/2012/12/07/postgradmedj-2012-131321.full

9. 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.

10. Skills for Health (2009) Junior Doctors in the NHS: Preparing medical students for employment and post-graduate training available at: http://medprof.bjmu.edu.cn/xsqy/56_ Tomorrows-Doctors-2009.pdf

11. Illing J, Morrow G, Kergon C, Burford B, Spencer J, Peile E, Davies C, Baldauf B, Allen M, Johnson N, Morrison J, Donaldson M, Whitelaw M, Field M. How prepared are medical graduates to begin practice? A comparison of three diverse UK medical schools. Final summary and conclusions for the GMC Education Committee, 15th December 2008. Available at http://www.gmc-uk.org/FINAL_How_prepared_are_medical_graduates_to_begin_practice_September_08.pdf_29697834.pdf

12. General Medical Council. The state of medical education and practice in the UK 2014. October 2014. http://www.gmc-uk.org/SOMEP_2014_FINAL.pdf_58751753.pdf

13. O'Shaughnessy L, Haq 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**:143–8.

14. Maxwell SRJ, Cameron IT, Webb DJ. Prescribing safety: ensuring that new graduates are prepared. *Lancet* 2015;**385**:579–581. Available at http://dx.doi.org/10.1016/S0140-6736(14)62339-4

15. General Medical Council. Outcomes for graduates (Tomorrow's Doctors), July 2015. http://www.gmc-uk.org/education/undergraduate/undergrad_outcomes.asp

16. Prescribing Safety Assessment Blueprint, 2016. https://prescribingsafetyassessment.ac.uk/aboutpsa

17. Angoff WH. Scales, norms, and equivalent scores, in: Thorndike RL (Ed.) Educational Measurement, 2nd edn, pp. 508–600. (American Council on Education, Washington DC, 1971.

18. Royal Pharmaceutical Society of Great Britain and British Medical Association. *British National Formulary*. https://www.evidence.nhs.uk/formulary/bnf/current

19. Tavakol M, Dennick R. Making sense of Cronbach's alpha. *International Journal of Medical Education* 2011;**2**:53–55.

20. Tighe J, McManus IC, Dewhurst NG, Chis L, Mucklow M. The standard error of measurement is a more appropriate measure of quality for postgraduate medical assessments than is reliability: an analysis of MRCP (UK) examinations. *BMC Medical Education* 2010;**10**:40. DOI: 10.1186/1472-6920-10-40

21. MacDougall M, Stone G. Fortune-tellers or content specialists: Challenging the standard setting paradigm in medical education programmes. *Journal of Contemporary Medical Education* 2015;**3**:133–142. 10.5455/jcme.20151019104847

22. Roberts C, Newble D, Jolly B, Reed M, Hampton K. Assuring the quality of high-stakes undergraduate assessments of clinical competence. *Medical Teacher* 2006;**28**:535–543.

23. van der Vleuten CP, Schuwirth LW. Assessing professional competence: from methods to programmes. *Medical education* 2005;**39**:309–317.

24. Streiner D, Norman G. Health Measurement Scales: a practical guide to their development and use. Third Edition. 2003, Oxford: Oxford University Press.

25. Lechler R, Paice E, Hays R, Petty-Saphon K, Aronson J, Bramble M, Hughes I, Rigby E, Anwar Q, Webb D, Maxwell S, Martin J, Maskrey N, Walker S. Outcomes of the Medical Schools Council Safe Prescribing Working Group. November 2007. Available at http://www.medschools.ac.uk/Publications/Pages/Safe-Prescribing-Working-Group-Outcomes.aspx.

26. Ross S, Maxwell S. Prescribing and the core curriculum for tomorrow's doctors: BPS curriculum in clinical pharmacology and prescribing for medical students. *Br J Clin Pharmacol* 2012;**74**:644–61.

27. British Pharmacological Society. Prescribe: eLearning in Clinical Pharmacology & Prescribing. http://www.e-lfh.org.uk/programmes/clinical-pharmacology-and-prescribing

28. McManus IC, Wakeford R. PLAB and UK graduates' performance on MRCP(UK) and MRCGP examinations: data linkage study. *BMJ* 2014;348 doi: http://dx.doi.org/10.1136/bmj.g2621

29. Lord FM. The relationship of the reliability of multiple-choice test to the distribution of item difficulties. *Psychometrika* 1952;**18**:181–194.

30. Sim SM, Rasiah RI. Relationship between item difficulty and discrimination indices in true/false-type multiple choice questions of a para-clinical multidisciplinary paper. *Ann Acad Med Singapore* 2006;**35**:67-71.

31. General Medical Council. Medical Licensing Assessment. http://www.gmc-uk.org/education/index.asp

32. Institute of Medicine. Preventing medication errors. Washington (D.C.): National Academy Press, 2007.

33. Department of Health. Improving Patients' Access to Medicines: A guide to implementing nurse and pharmacist independent prescribing within the NHS in England. 10 Apr 2006.

34. Royal Pharmaceutical Society. A competency framework for all prescribers. Available at http://www.rpharms.com/support-pdfs/prescribing-competency-framework.pdf

35. Reid F, Power A, Stewart D, Watson A, Zlotos L, Campbell D, McIntosh T, Maxwell S. Piloting the United Kingdom Prescribing Safety Assessment with pharmacist prescribers in Scotland. *Research in Social and Administrative Pharmacy* 2017; http://dx.doi.org/10.1016/j.sapharm.2016.12.009

36. Larsen DP, Butler AC, Roediger HL. Test-enhanced learning in medical education. *Med Educ.* 2008;**42**:959–66.

TABLES

Section	Description	Marks	Question items
1	Prescribing (PWS)	80	8 items of 10 marks each
2	Prescription Review (REV)	32	8 items of 4 marks each
3	Planning Management (MAN)	16	8 items of 2 marks each
4	Providing Information (COM)	12	6 items of 2 marks each
5	Calculation Skills (CAL)	16	8 items of 2 marks each
6	Adverse Drug Reactions (ADR)	16	8 items of 2 marks each
7	Drug Monitoring (TDM)	16	8 items of 2 marks each
8	Data Interpretation (DAT)	12	6 items of 2 marks each
	TOTAL MARKS	**200**	

Table 1. Allocation of question items and marks to each PSA section.

	Paper A	Paper B	Paper C	Paper D
Angoff pass mark (%)	62.0	65.5	63.0	63.0
Candidates	1,914*	1,869	1,746	1,560
Medical schools	20	16	16	17
Pass rate (%)	97.2	94.0	95.8	92.6
RAW SCORES (%)				
Mean (SD)	80.0 (8.3)	79.8 (8.5)	78.3 (8.2)	76.1 (8.8)
Median (IQR)	81.0 (75.0 to 86.0)	81.0 (75.0 to 86.0)	79.0 (73.5 to 84.5)	77.0 (71.0 to 82.5)
Range	36.5 to 97.5	38.0 to 97.5	32.0 to 98.5	34.0 to 95.5
CALIBRATED SCORES (%)				
Mean (SD)	73.8 (10.7)	70.9 (11.6)	70.8 (10.7)	68.0 (11.2)
Median (IQR)	75.0 (67.1 to 81.6)	72.5 (63.8 to 79.7)	71.6 (64.2 to 79.1)	68.9 (60.8 to 76.4)
Range	29.4 to 96.7	29.0 to 96.4	25.4 to 98.0	27.0 to 93.9
Cronbach's alpha	0.738	0.756	0.743	0.767
SEM (%)	4.24	4.17	4.13	4.23

Table 2. Candidate performance in PSA2016. * A further 254 candidates at one school sat Paper A but experienced significant technical difficulties and are not included in this analysis. Their pass rate (97.6%) was similar to the remainder of the candidates sitting Paper A.
SD: Standard deviation, IQR: Inter-quartile range; SEM: Standard error of measurement

Legends to figures

Figure 1. Standard structure of the Prescribing Safety Assessment.

Figure 2. Example PSA question item screens: Prescribing (green), Prescription Review (blue), Planning Management (red), Calculation Skills (grey).

Figure 3. Candidate performance by medical school.

Figure 4. Mean calibrated score by medical school in 2015 and 2016.

Figures

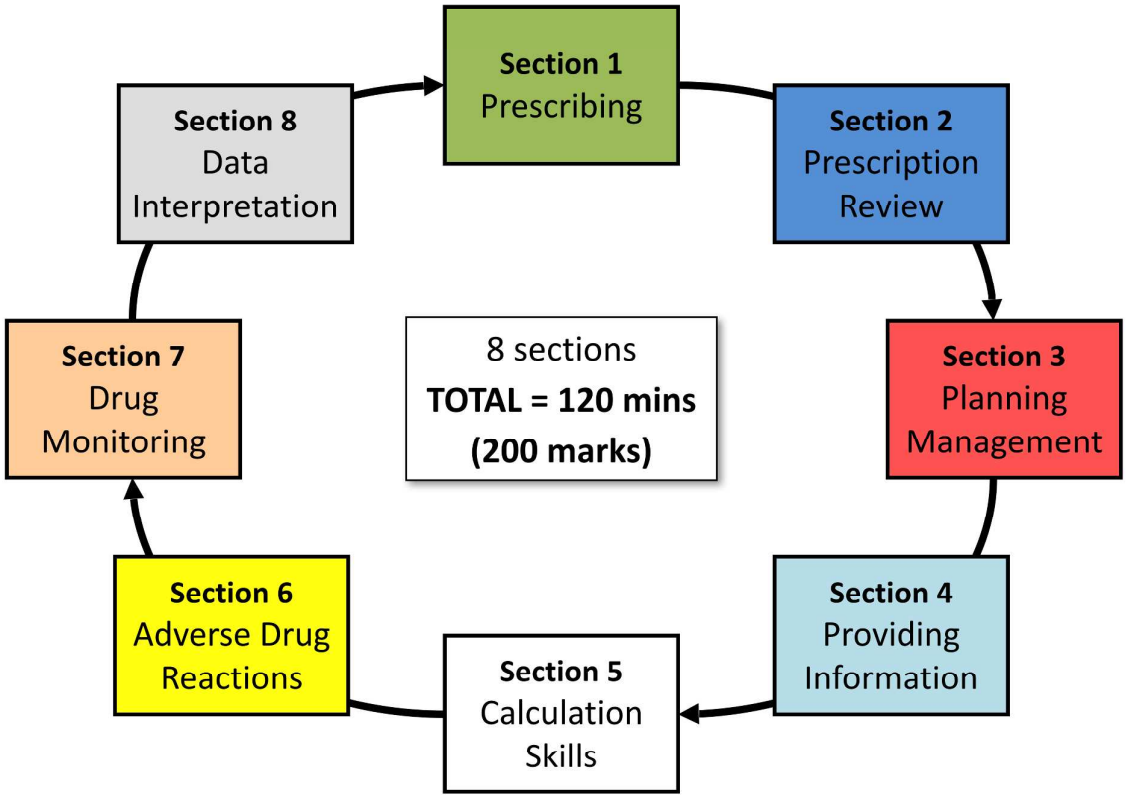

Figure 1. Standard structure of the Prescribing Safety Assessment.

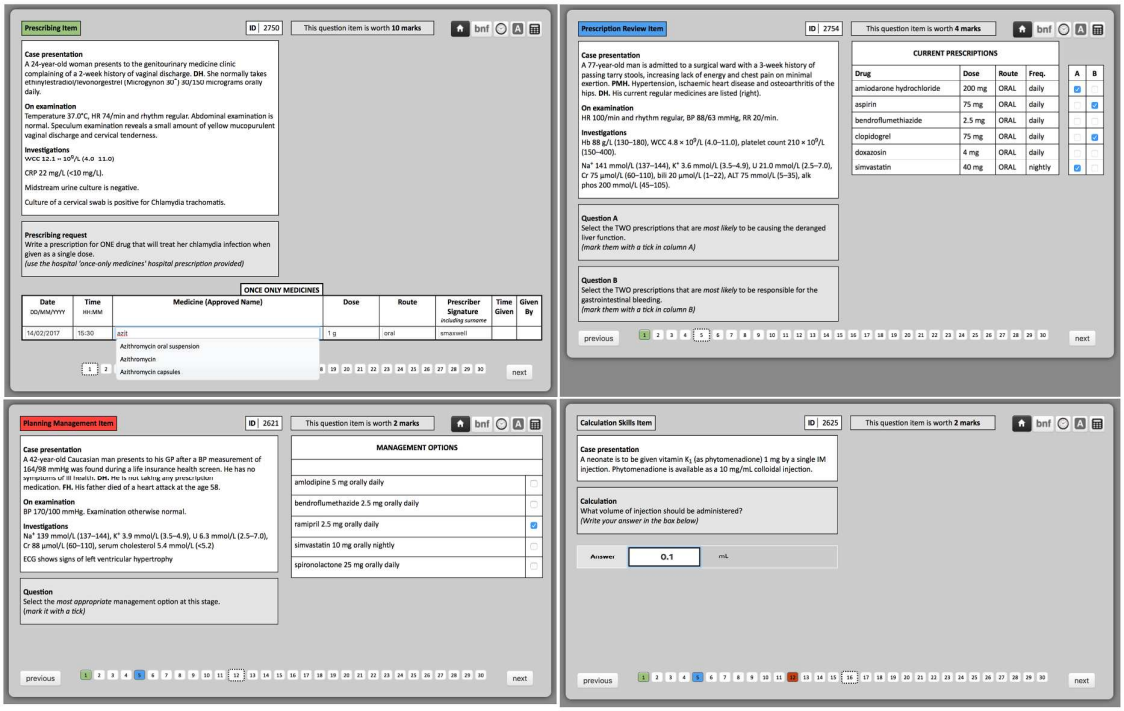

Figure 2. Example PSA question item screens: Prescribing (green), Prescription Review (blue), Planning Management (red), Calculation Skills (grey).

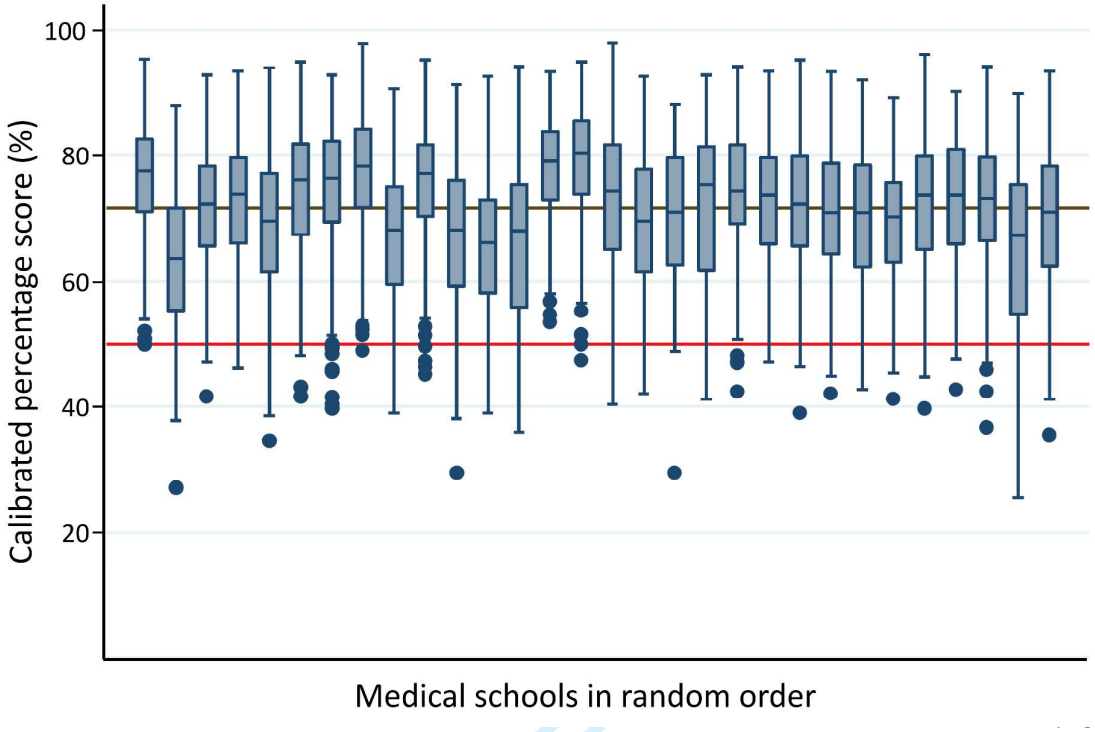

Figure 3. Candidate performance by medical school. The red horizontal line indicates the pass mark following calibration and the green horizontal line the median score across medical schools.

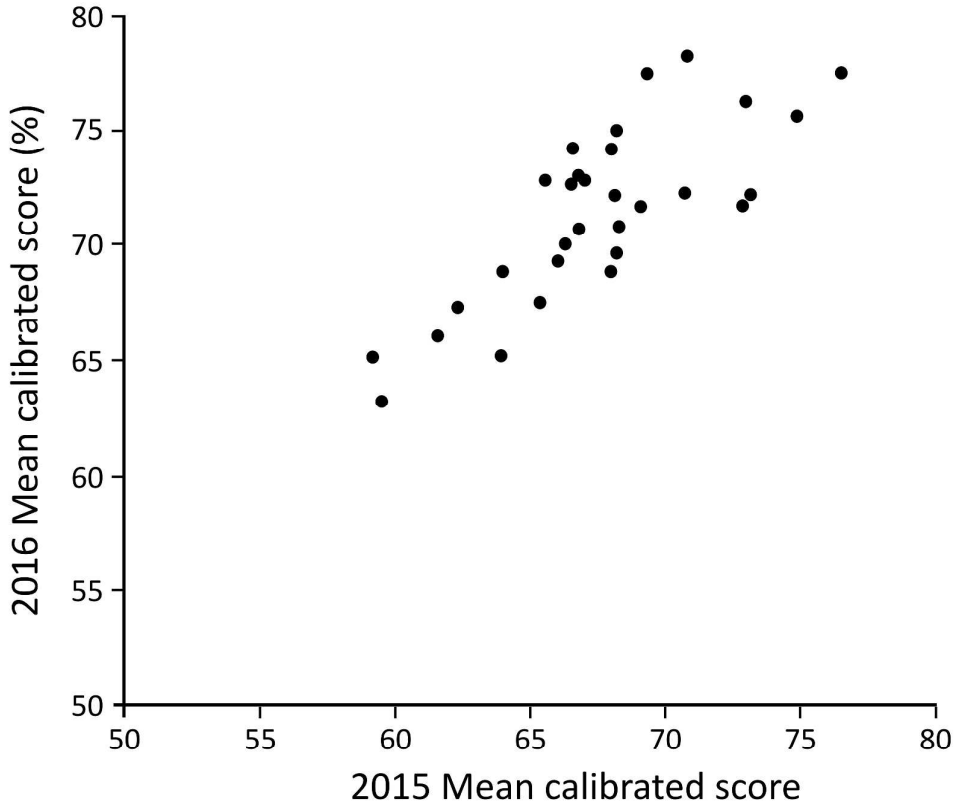

Figure 4. Mean calibrated score by medical school in 2015 and 2016.

Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students – Maxwell et al.

Table 1

Section	Description	Marks	Question items
1	Prescribing (PWS)	80	8 items of 10 marks each
2	Prescription Review (REV)	32	8 items of 4 marks each
3	Planning Management (MAN)	16	8 items of 2 marks each
4	Providing Information (COM)	12	6 items of 2 marks each
5	Calculation Skills (CAL)	16	8 items of 2 marks each
6	Adverse Drug Reactions (ADR)	16	8 items of 2 marks each
7	Drug Monitoring (TDM)	16	8 items of 2 marks each
8	Data Interpretation (DAT)	12	6 items of 2 marks each
	TOTAL MARKS	**200**	

Table 1. Allocation of question items and marks to each PSA section.

Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students – Maxwell et al.

Table 2

	Paper A	Paper B	Paper C	Paper D
Angoff pass mark (%)	62.0	65.5	63.0	63.0
Candidates	1,914*	1,869	1,746	1,560
Medical schools	20	16	16	17
Pass rate (%)	97.2	94.0	95.8	92.6
RAW SCORES (%)				
Mean (SD)	80.0 (8.3)	79.8 (8.5)	78.3 (8.2)	76.1 (8.8)
Median (IQR)	81.0 (75.0 to 86.0)	81.0 (75.0 to 86.0)	79.0 (73.5 to 84.5)	77.0 (71.0 to 82.5)
Range	36.5 to 97.5	38.0 to 97.5	32.0 to 98.5	34.0 to 95.5
CALIBRATED SCORES (%)				
Mean (SD)	73.8 (10.7)	70.9 (11.6)	70.8 (10.7)	68.0 (11.2)
Median (IQR)	75.0 (67.1 to 81.6)	72.5 (63.8 to 79.7)	71.6 (64.2 to 79.1)	68.9 (60.8 to 76.4)
Range	29.4 to 96.7	29.0 to 96.4	25.4 to 98.0	27.0 to 93.9
Cronbach's alpha	0.738	0.756	0.743	0.767
SEM (%)	4.24	4.17	4.13	4.23

Table 2. Candidate performance in PSA2016. * A further 254 candidates at one school sat Paper A but experienced significant technical difficulties and are not included in this analysis. Their pass rate (97.6%) was similar to the remainder of the candidates sitting Paper A.
SD: Standard deviation, IQR: Inter-quartile range; SEM: Standard error of measurement

Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students – Maxwell et al.

Figure 1

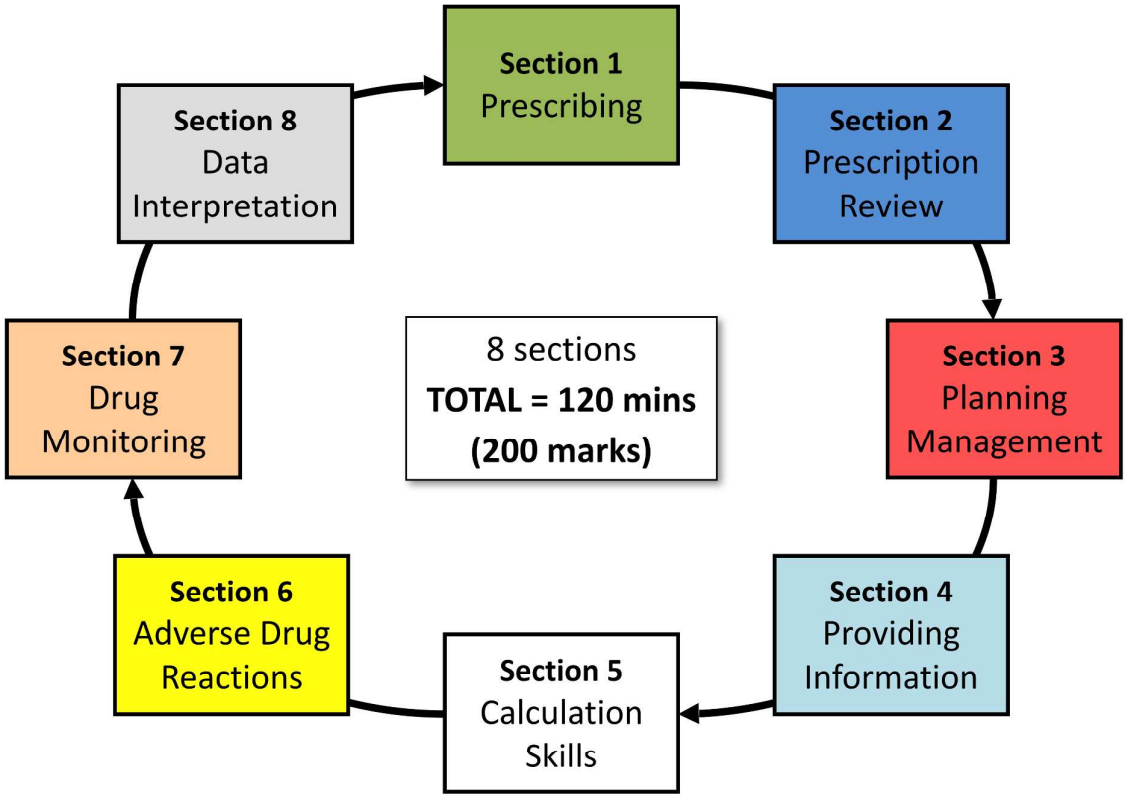

Figure 1. Standard structure of the Prescribing Safety Assessment.

Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students – Maxwell et al.

Figure 2

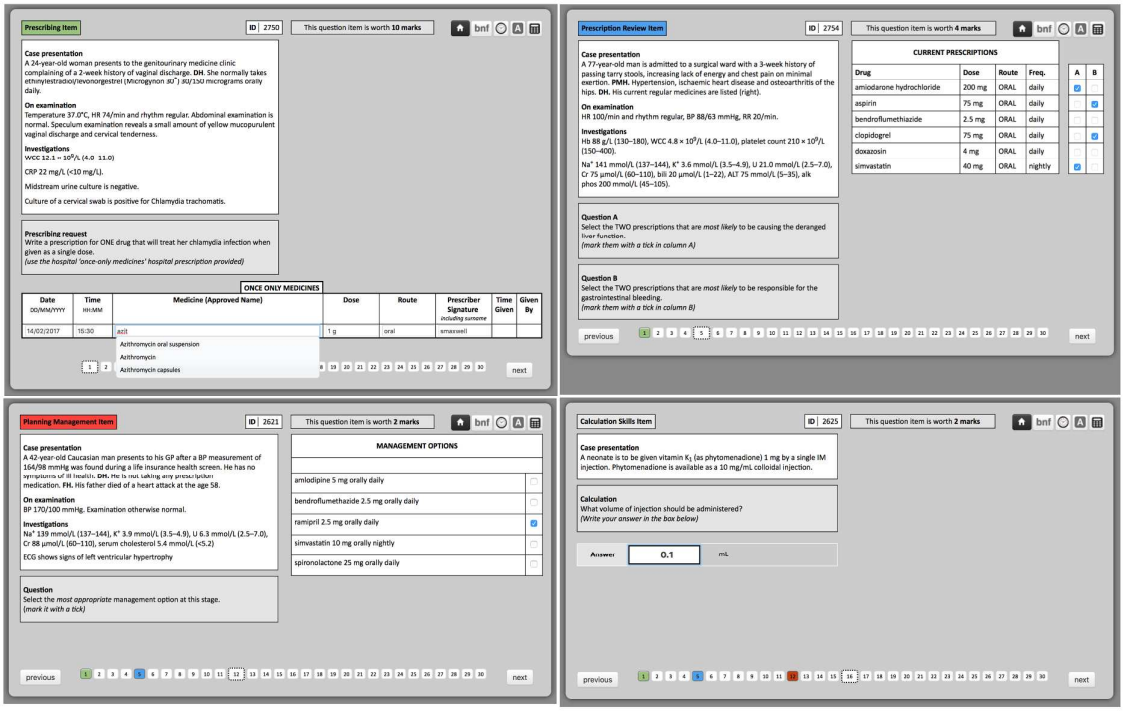

Figure 2. Example PSA question item screens: Prescribing (green), Prescription Review (blue), Planning Management (red), Calculation Skills (grey).

Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students – Maxwell et al.

Figure 3

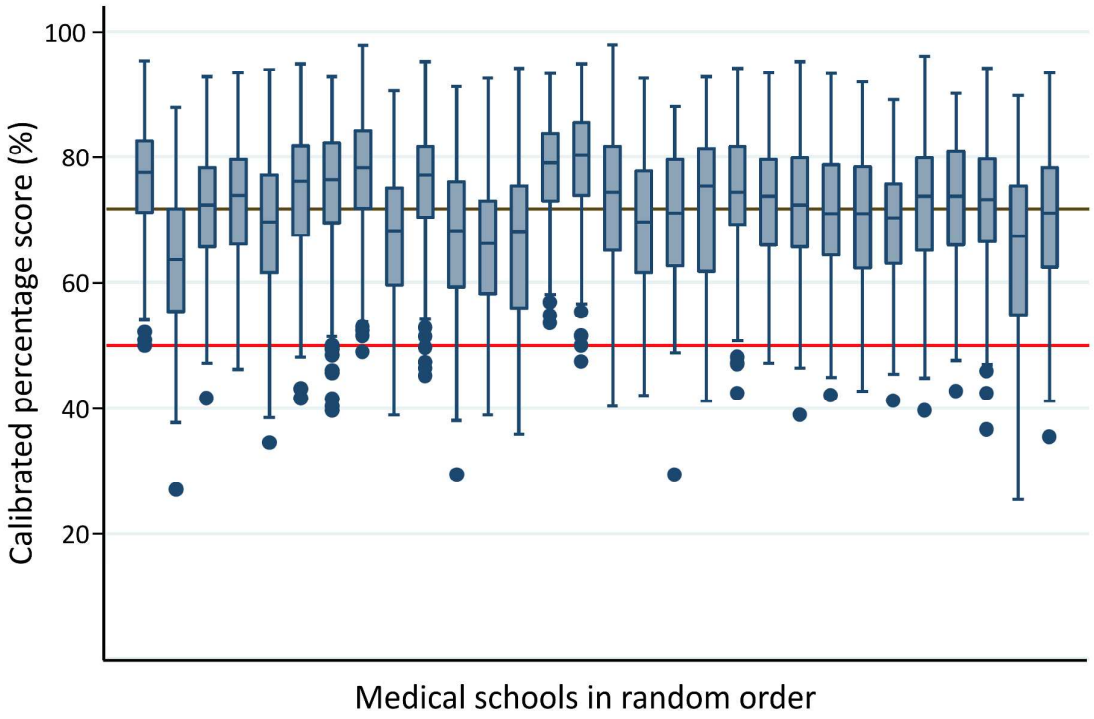

Figure 3. Candidate performance by medical school. The red horizontal line indicates the pass mark following calibration and the green horizontal line the median score across medical schools.

Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students – Maxwell et al.

Figure 4

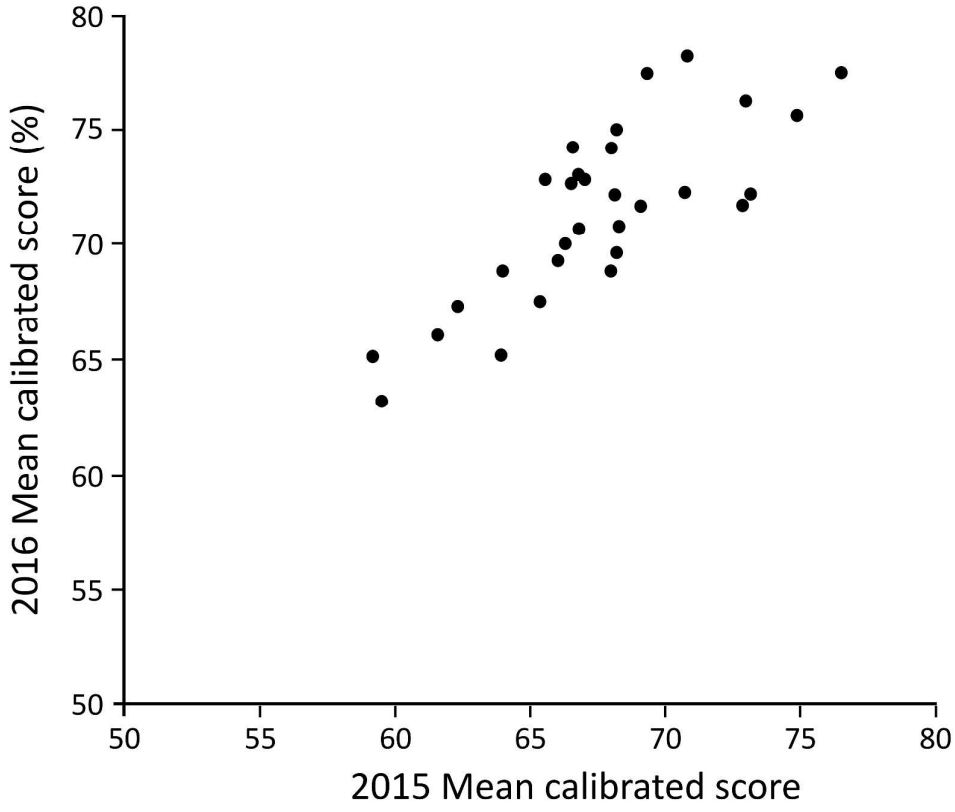

Figure 4. Mean calibrated score by medical school in 2015 and 2016.