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# **Accepted Manuscript**

Piloting the United Kingdom 'Prescribing Safety Assessment' with pharmacist prescribers in Scotland

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#### **TITLE PAGE**

# Piloting the United Kingdom 'Prescribing Safety Assessment' with Pharmacist Prescribers in Scotland

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# Piloting the United Kingdom 'Prescribing Safety Assessment' with Pharmacist Prescribers in Scotland

#### **Abstract**

### **Background**

Prescribing is a complex task requiring considerable knowledge and skills. The Prescribing Safety Assessment (PSA) was developed by the British Pharmacological Society and the United Kingdom (UK) Medical Schools Council. Between February and June 2014, over 7,000 final year medical students undertook the PSA, with an overall pass rate of 94%. Independent prescribing for suitably trained pharmacists was introduced in the UK in 2006. To date there has been little focus on any objective measures of the prescribing safety.

### **Objective**

To determine the PSA performance of a pilot group of pharmacist prescribers in Scotland relative to medical students and to test the feasibility and acceptability of running the PSA.

#### **Methods**

A group of 59 pharmacist prescribers took part in ten events. The PSA consisted of 30 questions to be completed over 60 minutes. All questions had been used in the 2014 assessments for final year medical students. The PSA was undertaken online under invigilated conditions, mirroring the medical student assessment. One month later, participants were invited to complete an online evaluation questionnaire.

# **Results**

The mean overall PSA scores (±SD) were 87.5%±8.7 (range 52-98) compared to a 88.5% for medical students. Based on an Angoff passmark of 76.0%, 53 pharmacists (89.8%) passed compared to an overall pass rate in PSA 2014 of 94%. Pharmacists performed equivalently to medical students in all assessment areas, with a slightly lower performance in the prescribing, drug monitoring and data interpretation questions offset by better performance in prescription review and adverse drug reactions. Feedback was positive in relation to appropriateness, relevance and level of difficulty of the PSA although several commented that they were practicing in very specific clinical areas.

#### Conclusion

These pilot events have benchmarked the PSA performance of pharmacist prescribers with final year medical students, and feedback confirmed feasibility and acceptability.

#### **Keywords**

Prescribing; pharmacists; safety; assessment; medical students; Scotland

#### Introduction

Prescribing is a complex and challenging task requiring considerable knowledge and skills, as evidenced by the ten principles of good prescribing defined by the British Pharmacological Society (BPS, Box 1).

Box 1. Ten principles of good prescribing, British Pharmacological Society.<sup>1</sup>

- 1. Be clear about the reasons for prescribing
- 2. Take into account the patient's medicines history before prescribing
- 3. Take into account other factors that might alter the benefits and risks of treatment
- 4. Take into account the patient's ideas, concerns and expectations
- 5. Select effective, safe and cost-effective medicines individualized for the patient
- 6. Adhere to national guidelines and local formularies where appropriate
- 7. Write unambiguous legal prescriptions using the correct documentation
- 8. Monitor the beneficial and adverse effects of medicines
- 9. Communicate and document prescribing decisions and the reasons for them
- 10. Prescribe within the limits of your knowledge, skills and competence.

The demands on prescribers have multiplied in recent years due to many factors including more complicated medicines regimens, combined with increasing prescribing prevalence. Scottish prescribing data from 2014 highlighted that 20.8% of patients with two clinical conditions were prescribed four to nine medicines, and 10.1% prescribed ten or more medicines; in patients with six or more comorbidities, these values increased to 47.7% and 41.7% respectively.<sup>2</sup> These data highlight even more the need for highly knowledgeable and skilled prescribers to ensure that all ten of the BPS principles are met.

There is, however, a vast accumulation of evidence of widespread suboptimal prescribing leading to potential patient care and safety issues. In a systematic review of prescribing errors by junior doctors, Ross et al. found errors prevalent in 2–514 per 1000 items prescribed and 4–82% of patients or charts reviewed.<sup>3</sup> In a later systematic review of all prescribing errors in hospital inpatients, Lewis et al. reported 52 (8–227) errors per 100 admissions and 24 (6–212) errors per 1000 patient days.<sup>4</sup> A recent study of junior doctor prescribing in hospitals in Scotland identified an error rate of 36% (1700/4710) of patient prescription charts and 7.5% (3364/44726) of items prescribed.<sup>5</sup>

Given these statistics, assessing competence in prescribing is crucial within a framework of clinical governance and promoting patient safety. Given the widespread evidence of suboptimal prescribing, The Prescribing Safety Assessment (PSA) was developed by the BPS and the United Kingdom (UK) Medical Schools Council. The PSA assesses prescribing skills based on the competencies identified by the UK General Medical Council and outlined in 'Outcomes for Graduates', which sets out the knowledge, skills and behaviors that new UK medical graduates must be able to show. These prescribing competencies are: writing new prescriptions; reviewing existing prescriptions; calculating drug doses; identifying and avoiding both adverse drug reactions and medication errors; and amending prescribing to suit individual patient circumstances.

The PSA is designed to allow final year UK medical students to demonstrate that they have the necessary knowledge, skills and judgment (in relation to the safe and effective use of medicines) to begin their work as junior prescribers in National Health Services (NHS) hospitals in the UK. It is an open book assessment taken under time limited restrictions, with candidates having access to the British National Formulary (BNF). The PSA is delivered online from a 'cloud-based' server and comprises eight sections containing question styles that cover different aspects of the clinical activity undertaken by prescribers (Figure 1). Questions are set in any one of seven different clinical settings of medicine (med), surgery (surg), old people (eld), pediatrics (ped), psychiatry (psych), obstetrics and gynecology (O&G) and general practice (GP).

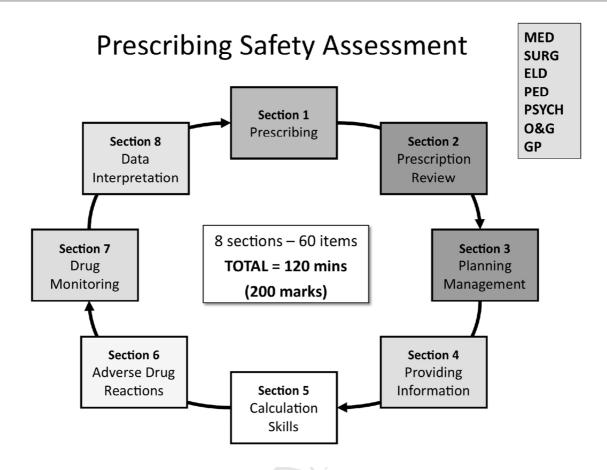


Figure 1. The standard structure of the Prescribing Safety Assessment.

The PSA has been piloted in UK medical schools over several years but was implemented widely for the first time in 2014 (PSA 2014). Between February and June 2014, over seven thousand final year medical students undertook the PSA, with an overall pass rate of 94%. This process has been repeated again in 2015 and now also includes medical schools in Ireland and Malta. As the PSA has been introduced relatively recently, no studies to date have provided evidence of impact on prescribing safety in practice and the prevalence and severity of prescribing errors. However, many medical students have commented that the experience of preparing with online practice papers and participation in the assessment had engendered an enhanced sense of confidence about their future prescribing of drugs.

Prescribing is no longer solely within the province of doctors hence there is a need to consider prescribing competence and safety of wider groups of health professionals. Key developments in prescribing policy and practice have been implemented in the UK with the introduction of prescribing rights for a range of healthcare professionals. For pharmacists, supplementary prescribing was introduced in 2003, and extended to independent prescribing in 2006.<sup>10</sup> Supplementary prescribing (SP) is defined as

'voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement'. While developing the CMP and obtaining agreement were found to be cumbersome, independent prescribing (IP) is a more autonomous model of prescribing, defined as 'prescribing by a practitioner responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about clinical management required, including prescribing'. There are no restrictions on the medical conditions managed or drugs prescribed by either supplementary or independent prescribers.

Those entering the IP training programme (which has superseded SP programme) must have at least two years' patient facing experience as a pharmacist, and provide evidence that there is a patient need for pharmacist prescribing in their place of employment. The course is accredited by the General Pharmaceutical Council (GPhC) and comprises two main components: a university component equivalent to 26 days of full-time education; and period of learning in practice (PLP), under the direction of a designated medical practitioner, of a minimum of 12 days. Both components must be passed prior to registration as a prescriber with GPhC. While assessment methods are varied and include written assessments, objective structured clinical examinations (OSCEs) and submission of a portfolio of evidence, there is no specific assessment of prescribing safety. Given that the use of the PSA within medical schools in the UK is increasing, and that IPs have the same prescribing rights as doctors, there is a need to benchmark their prescribing safety.

The aims of this research were to determine the PSA performance of a pilot group of pharmacist prescribers in Scotland relative to medical students and to test the feasibility and acceptability of running the PSA.

#### **Method**

PSA development

The PSA used for this pilot consisted of 30 questions to be completed over 60 minutes. All questions had been used in the 2014 round of assessments for final year medical students in 31 UK medical schools and standard set using a modified Angoff procedure (procedure for setting a criterion-referenced passing point), as per the medical student assessment. Questions were mapped to the eight areas of: prescribing; prescription review; planning management; providing information; calculation skills; adverse drug

reactions; drug monitoring; and data interpretation. Further detail of these areas is provided in Table 1.



<b>Question Area</b>	Reasoning and Judgement	Measurable Action
Prescribing	Deciding on the most appropriate prescription (drug,	Writing a safe, effective and legal prescription for
	dose, route and frequency) to write based on the clinical	medicines using the documentation provided to tackle
	circumstances and supplementary information	specific indications highlighted by the question
Prescription	Deciding which components of the current prescription	Identifying prescriptions (drugs, doses or routes) that
review	list are inappropriate, unsafe or ineffective for a patient	are inappropriate, unsafe or ineffective from amongst
	based on their clinical circumstances	the current list of prescribed medicines
Planning	Deciding which combination of therapies would be most	Selecting the most appropriate combination of treatment

Table 1 – Details of PSA question areas in terms of reasoning and judgement, and measurable action.<sup>7</sup>

management	appropriate to manage a particular clinical situation	strategies based on individual patient circumstances
Providing	Deciding what are the important bits of information that	Selecting the information that is most appropriate
information	should be provided to patients to allow them to choose	
	whether to take the medicine and to enhance its safety	
	and effectiveness	
Calculation skills	Making an accurate drug dosage calculation based on	Recording the answer accurately with appropriate units
	numerical information	of measurement
Adverse drug	Identifying likely adverse reactions of specific drugs,	Selecting likely adverse reactions of specific drugs,
reactions	drugs that are likely to be causing specific adverse drug	selecting drugs to discontinue as likely causes of specific
	reactions, potentially dangerous drug interactions and	reactions, avoiding potential drug-interactions and
	deciding on the best approach to managing a clinical	providing appropriate treatment for patients suffering an
	presentation that results from the adverse effects of a	adverse event
	drug	
Drug monitoring	Deciding on how to monitor the beneficial and harmful	Identifying the appropriate methods of assessing the
	effects of medicines.	success or failure of a therapeutic intervention.
Data	Deciding on the meaning of the results of investigations	Making an appropriate change to a prescription based on
interpretation	as they relate to decisions about on-going drug therapy	those data

The distribution of the diagnoses and settings of the clinical case scenarios are illustrated in Table 2.

Table 2 - Distribution of the cases included in the PSA, according to primary diagnostic

category and clinical setting

Diagnostic	Number	Clinical setting	Number
category	of		of
	questions		questions
Gastroenterology	2	Medicine	8
Cardiovascular	6	Surgery	2
Respiratory	3	Elderly care	2
Neurology	3	Paediatrics	4
Psychiatry	2	Psychiatry	2
Infection	3	Obstetrics &	4
		Gynaecology	
Endocrinology	3	General practice	8
Rheumatology	2	Total	30
Anaemia	1		
Contraception	1		
Pregnancy	1		
Dermatology	1		
Metabolic	1		
Overdose	1		
Total	30		

#### Recruitment

NHS Education for Scotland (NES) is an education and training body within Scotland with responsibility of developing and delivering education and training for the healthcare workforce. NES maintains an up-to-date database of all pharmacist prescribers and those in training in Scotland. An invitation email was sent out to all 744, with 102 noting interest in participating; they were invited to participate in ten PSA events planned in NES locations in Scotland (Glasgow (5 events), Edinburgh (3 events), Aberdeen (2 events)). Participants were registered on the PSA online system, which allowed access to PSA information and practice materials of three 1-hour test papers and a recorded presentation explaining the format of the assessment and how to use the online assessment. These processes mirrored those of the medical students.

## Assessment

Approximately one month following registration, participants attended the event closest to their practice bases. Each completed a brief demographic questionnaire of current prescribing status, years registered as pharmacist and prescriber, and main practice setting. The PSA was undertaken online under invigilated conditions, with access to the online BNF, mirroring the medical student assessment.

#### Evaluation

One month following the PSA, participants were invited to complete an online evaluation questionnaire comprising ten Likert type items (strongly agree to strongly disagree) and ten items rating self-confidence in prescribing abilities (scale of 0, 'not confident' to 10, 'highly confident'). In addition, space was provided for free text comments on any aspect of the PSA. The items were developed by a member of the research team and reviewed by the others in terms of face and content validity. Data were analysed using descriptive statistics. Thematic content analysis was performed independently on the responses to free text comments by two members of the research team. Consensus was achieved without having to involve any others.

Figure 1 summarises the timeline of the key steps involved.

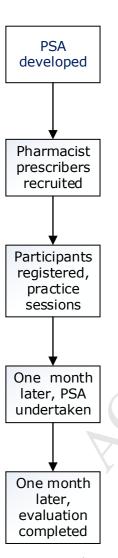


Figure 1 – the timeline of the PSA and evaluation

#### Results

#### **Participants**

Sixty-nine of the 102 (69.6%) interested were able to attend one of the ten events. Due to technical difficulties during one event, 10 were unable to complete the PSA hence data are provided for 59 participants. Of these, 42 (71.2%) were actively prescribing, 52 (88.2%) had been registered as pharmacists more than ten years, 31 (52.5%) had been registered prescribers for more than five years, and half (29, 49.2%) worked in primary care medical practices.

# Candidate performance

The mean scores ( $\pm$ SD) and range of performance for the PSA overall, and for each of the eight areas are illustrated in Table 3.

Table 3 – Participant PSA performance, N=59

Areas	Available marks	Mean scores <u>+</u> SD	Range	Mean PSA 2014, medical students
Prescription writing	40	36.6 <u>+</u> 4.9	19 - 40	37.1
Prescription review	16	15.0 <u>+</u> 1.4	11 - 16	14.3
Planning management	8	6.1 <u>+</u> 1.4	4 - 8	6.2
Providing information	6	5.4 <u>+</u> 1.0	2 - 6	5.6
Dose calculations	8	7.2 <u>+</u> 1.7	0* - 8	7.5
Adverse drug reactions	8	7.7 <u>+</u> 0.9	4 - 8	7.5
Drug monitoring	8	5.6 <u>+</u> 1.6	2 - 8	5.9
Data interpretation	6	3.7 <u>+</u> 1.7	0* - 6	4.5
Total	100	87.5 <u>+</u> 8.7	52 - 98	88.5

(\*note, the one participant scoring 0 in several areas misunderstood the instructions and answered only those questions related directly to the area of prescribing practice)

The mean score for the participants was  $87.5 \pm 8.7\%$  (range 52 - 98) compared to a mean score of 88.5% achieved by the final year medical students for the same assessment items in PSA 2014. The standard setting of the questions used for final year medical students suggested a pass mark for the assessment of 76.0%. Based on that cut off score, 53 participants (89.8%) passed compared to an overall pass rate in PSA 2014 of 94%. Analysis by section suggested that the participants performed equivalently to final year medical students in almost all areas, with a slightly lower performance in the

prescribing, drug monitoring and data interpretation items offset by better performance in prescription review and adverse drug reaction items.

# Candidate feedback

Responses to the evaluation items are given in Table 4, indicating favourable views on the appropriateness of the approach, the quality of the presentation and questions and the usability of the online interface.

Table 4 – Responses to evaluation items, n (N=59) (\*some did not complete all items)

Items						
	Strongly disagree (=1)	Disagree (=2)	Neutral =(3)	Agree (=4)	Strongly agree (=5)	Median
The questions in the	0	3	7	43	6	4
assessment were clear and						
unambiguous				4.4	40	
*The questions were of a reasonable level of difficulty	0	2	1	41	13	4
The layout and presentation	0	0	2	27	30	5
of the questions was easy to						
follow					2	
The time provided for	3	9	3	29	15	4
answering the questions was						
sufficient				20		
*The online assessment was	0	1	1	28	27	4
The information about the	0	0	3	19	37	5
PSA (available prior to the event on psapilot.net) was helpful	U		31	19	37	3
*The assessment is a suitable	0	7	8	33	9	4
method to test pharmacist						
prescribers' knowledge		<u> </u>				
*The assessment is a suitable	0	3	5	43	6	4
test of prescribing skills						
expected of a pharmacist prescriber						
*The assessment is a suitable	0	5	10	34	8	4
method to test pharmacist	/ 0	5	10	J <del>-1</del>	U	7
prescribers' competence						
My prescribing course	3	25	14	17	0	3
prepared me for the content						
of the questions in this						
assessment						

Responses to the items on confidence are given in Table 5, demonstrating very high confidence in all aspects of prescribing.

Table 5 – Responses to confidence items, n (N=57, two did not complete this part of the questionnaire)

	24 15	2	9
25	15	2	0
25	15	2	0
			7
34	15	1	9
20	10	1	9
24	23	0	9
15	15	6	9
29	12	0	9
31	19	0	9
,			
20	25	0	9
23	14	4	9
	20 24 15 29 31	20 10 24 23 15 15 29 12 31 19 20 25	20 10 1 24 23 0 15 15 6 29 12 0 31 19 0 20 25 0

(0, 'not confident' to 10, 'highly confident')

Content analysis of textual responses identified positive comments that undertaking the PSA confirmed their competence and increased their confidence, and that it was suitable for all pharmacists and not just prescribers. Several commented that the PSA could be incorporated at the start of the prescribing course to give a baseline measure. A few noted that the PSA focused on information retrieval from the BNF rather than prescribing competence, which should include aspects of patient consultation skills. Several from primary care settings commented on the secondary care focus of the assessment questions and also that the assessment should be targeted to their specific areas of prescribing practice.

#### **Discussion**

This study has demonstrated that the overall performance and pass rate of the pharmacist prescribers in this pilot was remarkably similar to that of graduating medical students exposed to the same questions. The PSA was also found to be feasible and acceptable to pharmacist prescribers.

To our knowledge this is the first study which has used the PSA in a group of pharmacist prescribers. However, there are several limitations and hence the results should be interpreted with caution. The study sample size was limited and the participants a self-selected group hence there are potential issues of recruitment bias which impacts the generalisability of the findings to the population of pharmacist prescribers in Scotland and beyond. Indeed, the demographics of the participants shows this to be a relatively experienced group of pharmacist prescribers. One further limitation is that data from a group of individuals with no actual prescribing experience (final year medical students) were compared to registered, experienced pharmacist prescribers. It may be more appropriate to compare the outcomes to a group of equally experienced medical prescribers.

There is a vast accumulation of expertise around the utility of the PSA in all medical schools in the UK in 2014 and extended into Ireland and Malta in 2015. The PSA process of question development is robust with input from item authors, editors, peer reviewers, standard setters and psychometric support. 9 While it is accepted that performance in an online prescribing assessment may not relate to prescribing practice and that there are no data of improved patient outcomes and safer care, there is little doubt that implementing the PSA in final year medical students can facilitate raising and unifying prescribing standards. As noted previously, many medical students have commented that the experience of preparing for and undertaking the PSA has increased their confidence about their future prescribing. It therefore seems appropriate that pharmacist prescribers (and indeed all prescribers) are subjected to the same assessment as part of their training. This seems all the more relevant given that the National Prescribing Centre (now part of the National Institute for Health and Clinical Excellence) has produced a single competency framework for all prescribers. 13 Patient safety is an overarching theme of the competencies within a framework of the patient consultation, prescribing effectively and prescribing in context.

The overall performance and pass rate of the participants was similar to that of the medical students who had been exposed to the same questions in PSA2014. Importantly, the cut-off pass mark score for the participants was set at exactly the same level as for

the final year medical students to permit comparison and benchmarking. The questions covered a spectrum of clinical settings and while many pharmacist prescribers are likely to be practicing within defined therapeutic areas, they are expected to be able to review the clinical appropriateness of their patients' entire medicines regimens. The performance is therefore encouraging and should provide confidence in the pharmacists' prescribing skills. While no inferential statistical analysis was conducted, the participants slightly better performance in prescription review and writing may reflect their medicines related training and clinical experience. Similarly, the lower scores in patient monitoring and data interpretation may reflect lesser training and experience in these areas, which may improve over time. However, it must be acknowledged that there were some instances of poorer performance in the PSA with six participants not achieving the pass mark; this merits further exploration. Overall performance also appeared to be in line with the participants' self-ratings of their confidence in prescribing, providing evidence of the validity of their self-ratings.

The PSA was also found to be feasible and acceptable with only a few participants disagreeing with statements on question clarity and ambiguity, time allowed and ease of use. Importantly, the majority agreed that the PSA was an appropriate test of prescribing knowledge, skills and competence. Interestingly, around half disagreed that their prescribing course prepared them adequately in terms of the content of the questions. However, the prescribing course does not focus greatly on therapeutics as all pharmacists are expected to possess in-depth knowledge, understanding and application. Rather, the course focuses more on processes of prescribing around consultation skills, shared decision making, team working and governance. It may be that incorporating the PSA as a compulsory element of the course would provide some evidence of ability in aspects of therapeutics.

While a number of studies on UK pharmacist prescribing have researched aspects such as the experiences of patients, the general public and other members of the healthcare team, generating very positive findings, <sup>14-19</sup> there has been little focus on any objective measures of prescribing safety. In one very small study in three hospitals in England, pharmacists prescribed 680 from 5274 items, noting an error rate of 0.3%. <sup>20</sup> While this is a positive outcome, there is a need for further research to confirm prescribing safety. Pharmacist prescribing is a key strategic area for development supported by the Scottish Government. In 2013, the Scottish Government published their Vision and Action plan, 'A Prescription for Excellence' which states that all pharmacists with a patient facing role should be NHS accredited clinical pharmacist independent prescribers managing caseloads of patients by 2023. <sup>21</sup> Implementing the PSA for all pharmacist prescribers will

increase confidence amongst patients and other members of the healthcare team in the skills of these prescribers. Research which provides evidence of the internal and external validity of the PSA as an actual measure of prescribing safety is therefore warranted.

There is merit in extending the PSA across a larger and more representative group of pharmacist prescribers and embedding it within the pharmacist independent prescribing course. While this study was based in Scotland, there are clear implications for all countries in which prescribing by pharmacists has been implemented and those in which pharmacist prescribing is part of the strategic direction of the profession and health service.

#### **Conclusion**

These pilot events have benchmarked the PSA performance of pharmacist prescribers with final year medical students and feedback confirmed feasibility and acceptability. The PSA may be a useful test of pharmacist prescribers' skills and safe prescribing and should be considered further as an element of the prescribing course.

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# Piloting the United Kingdom 'Prescribing Safety Assessment' with Pharmacist Prescribers in Scotland

# **Highlights**

This study reports the performance of a pilot group of 59 pharmacist prescribers in Scotland undertaking the Prescribing Safety Assessment (PSA) of the British Pharmacological Society and the United Kingdom Medical Schools Council. The PSA consisted of 30 questions to be completed over 60 minutes. The mean overall PSA scores (±SD) were 87.5%±8.7 (range 52-98) compared to a mean score of 88.5% for medical students in 2014. This pilot has benchmarked the PSA performance of pharmacist prescribers with final year medical students, and feedback confirmed feasibility and acceptability.