

Validating tools for the monitoring of community pharmacy services

By Lilian M. Azzopardi, PhD, Sam Salek, PhD, Anthony Serracino Inglott, PharmD, Maurice Zarb Adami, BPharm, and Anton Buhagiar, PhD

AIM • To develop and validate tools with which to monitor the standards of professional services normally provided by community pharmacists and which measure the impact of their intervention on patient care.

DESIGN • Five tools based on a quantitative measurement system were established and their validity evaluated by psychometric testing.

SUBJECTS AND SETTING • A group of 10 community pharmacies from 184 pharmacies in Malta were selected by stratified random sampling.

OUTCOME MEASURES • Applicability and practicality of the tools to be used by the direct method of observation in community pharmacies, face and content validity, inter-rater reliability.

RESULTS • Raters said that they did not find difficulty documenting activities of any pharmacist using the tools. The level of agreement among the panel members examining the tools for face and content validity (review of measuring instrument to ensure that it measures what it is intended to measure) was high (Kendall coefficient of concordance <0.98 , $P<0.002$). The inter-rater correlation (0.70) and internal consistency ($\alpha>0.80$) were high for all five tools.

CONCLUSION • The five tools are user-friendly, valid and reliable, and can be used by community pharmacists to confirm the needs of their professional service and its impact on patient care.

In Europe, the largest proportion of pharmacists are employed on a full-time basis in community pharmacies. Validating practice in community pharmacy is essential for the profession of pharmacy to survive into the future.

The loss of the role of the pharmacist as compounder of medicines with the introduction of prepacked medicines was considered a threat towards the existence of the community pharmacist. When that role was phased out, the professional role as a drug expert, as an adviser on the use of medicines and as a diagnostician of minor illnesses was uncovered. Yet, the sustainability of the pharmacist solely in the traditional role was questioned and strategies to establish interventions by the pharmacist in a community setting were attempted.¹

The view that the traditional role of the community pharmacist is changing was the baseline for the setting up of the Nuffield Inquiry in the United Kingdom which set out to search an extended role for the community pharmacist. The report outlined the role of the pharmacist as an adviser on medicines, health matters and minor ailments. Audit procedures were adopted in the community to evaluate the advice given by the pharmacist in response to symptoms and during prescription monitoring activities.^{2,3} Work sampling techniques to monitor the interventions of the pharmacist in the community were another strategy adopted.^{4,5} In Britain, the Royal Pharmaceutical Society's "Pharmacy in a New Age" initiative, which was launched in 1995, initially aimed to develop strategies to demonstrate the value of community pharmacists, to identify functions that the pharmacist should do more of and to identify functions which should be given less importance.^{6,7} "Pharmacy in a New Age" achieved identification of strengths and weaknesses of community pharmacy and presented initiatives as to how the community pharmacist could survive. In these strategies no scientific measure of the contribution made by community pharmacists was attempted.

The assessment of professional services provided by community pharmacists based on a scientific dimension is today required

by patient organisations, health policy makers, insurance companies and many health care providers. Research in pharmacy practice has to deal with the pressure posed by society to establish a scientific method to prove the effectiveness and the impact of the community pharmacist on patient care towards achieving the desired outcomes. To this effect, a process of validation, as applied in the area of laboratory practice and measurement instrument development, was designed for adoption in the area of community pharmacy practice. The aims of this study were therefore (1) to develop a series of tools with which to monitor the standards of a range of professional services provided and to measure the impact of the intervention by the community pharmacist on patient care and (2) to establish the validity and reliability of these tools through standardised psychometric testing. It is hoped that the concept of validation of community pharmacy will be established as a scientific and pragmatic approach to confirm the effectiveness of a community pharmacist in a community setting.⁸

METHOD

Five tools were developed:

- Setting of the community pharmacy
- Equipment and professional services available in a community pharmacy
- Dispensing a prescription
- Responding to symptoms
- Communicating with the patient

The tools were designed to be used in community pharmacies through observation. For each tool, indicators of good standards were identified from various sources.

In the process of developing the tools "Setting of the community pharmacy" and "Equipment and professional services available in a community pharmacy", we consulted guidelines developed in the United Kingdom and in the United States.⁹⁻¹¹ The tool "Setting of the community pharmacy" was developed on the basis that the pharmacy setting may alter the quality of patient care and influence patient satisfaction. The tool evaluates the appearance and environment of the pharmacy and covers window dressing, pharmacy accessibility, toilet facilities and the dispensary. It also covers professional aspects, such as medicines storage and documentation systems, including patient medication records, dispensing protocols and formulary management.

The "Equipment and professional services" tool assesses the professional development of the pharmacists, specifications of equipment required at the

Dr Azzopardi is lecturer, Professor Serracino Inglott is professor and Mr Adami is senior lecturer in the department of pharmacy, and Professor Buhagiar is professor in the department of mathematics at the University of Malta. Dr Salek is senior lecturer in the centre for socioeconomic research at the Welsh School of Pharmacy, Cardiff. Correspondence to Dr Azzopardi at Department of Pharmacy, University of Malta, Msida, Malta (e-mail lilmaz@malta.net)

pharmacy (namely, dispensing equipment, refrigerator and Controlled Drugs cabinet), and containers and labels used during dispensing and diagnostic equipment, such as urinalysis test strips and blood pressure measuring equipment.

"Dispensing a prescription" was developed following essential procedures of dispensing. It assesses the pharmacist-patient interaction, the handover of the prescription medicine to the patient, including the checking of expiry date and confirmation of the right choice of product, and the provision of advice and written information to the patient.

"Responding to symptoms" was developed to analyse the advice provided by the pharmacist when responding to 17 minor illnesses presented at the pharmacy. The symptoms considered were diarrhoea, constipation, nausea and vomiting, indigestion, cough and colds, sore throats and colds, headache, painful frequent and urgent urination, abdominal pain, musculoskeletal disorders, eye disorders, ear disorders, skin disorders, itching around the vulva, itching around the anus, foot disorders, and oral and dental disorders. The tool assesses the exploration phase of the presentation of the symptom, the decision by the pharmacist whether to refer or not to refer, and the recommended course of action suggested by the pharmacist. The tool was developed following established clinical data.¹²⁻¹⁶

"Communicating with the patient" assesses the pharmacist-patient relationship established during the interaction and the conveying of information to the patient. The tool was developed following the general principles outlined in communication and counselling processes.¹⁷⁻²¹

Each tool is a short, compact list of statements to which a score was preassigned. The statements are grouped under different sections and the total for each section adds up to 10 scores. There are 10 sections for each tool except for "The setting of the community pharmacy" which consisted of 20 sections. When using the tools, raters were asked to consider statements that were relevant to the procedure or setting being assessed. The total score for each tool was obtained by summing the scores obtained for each statement. The validation grade was then calculated by considering the total scores obtained for each tool.⁸

Psychometric evaluation Psychometric evaluation of the tools was carried out to assess applicability, practicality, validity and reliability. Face and content validity were aimed at examining whether the statements in the tools are specific. Reliability of the tools was evaluated to analyse the degree of stability of scoring between different raters.

Applicability and practicality Applicability and practicality were assessed when two raters visited, on separate occasions, one community pharmacy. The raters used the tools "Setting of the community pharmacy" and "Equipment and professional services available in a community pharmacy" once. Each rater used each of the other three tools 10 times in the community pharmacy each

time assessing a case that happens to be presented at the pharmacy during a three-hour observation session. After both raters performed the test, a discussion was held to examine how feasible it was to use the tools through observation in a community pharmacy and whether the tools were acceptable for use in the practical setting.

Validity To assess face and content validity of the tools, a panel of judges was formed. The panel was made up of three medical doctors, two community pharmacists, two consumers and a communications studies graduate. Six meetings were organised to review each tool separately and the average duration of each meeting was one hour. During the meetings the researcher chaired the ensuing discussion about the layout of the tools, set-up and scoring. The panel rated the five tools based on their relevance, completeness, comprehension, language clarity, emphasis and focus of content. The agreement among panel members was examined. The tools were amended according to the final deliberation of the panel by consensus.

Reliability The 184 community pharmacies in Malta in which the managing pharmacist agreed to take part in the research project were classified according to the five districts assigned by the Department of Public Health for demographic purposes. Two pharmacies were selected from each of the five districts using stratified random sampling. The researcher visited these 10 pharmacies and the study was explained to the managing pharmacist. They were informed that the researcher and other raters would visit the pharmacy on different occasions for the purpose of reliability testing and would not interfere with the dispensing process. Initially, seven managing pharmacists agreed to participate in this exercise. Subsequently, three further community pharmacies were randomly selected from the districts where pharmacies declined to participate in the study. Signed informed consent was then obtained from all 10 managing pharmacists.

To assess inter-rater reliability, the five tools were applied by two raters in the 10 randomly selected community pharmacies. The tools "Setting of the community pharmacy" and "Equipment and professional services available in a community pharmacy" were used by each rater once in each community pharmacy. The tools "Dispensing a prescription", "Responding to symptoms" and "Communicating with the patient" were performed by each rater 10 times in each community pharmacy to avoid scoring being affected by the prescription or the nature of the symptoms being presented. The second rater was given the tools before the start of the rating exercise and for each tool the rater was also provided with a definition sheet. In the definition sheet each statement of the tools was explained and criteria adopted to score the tools were specified. A training session was organised where the researcher discussed in detail with the rater the scoring procedure of each tool.

Statistics Factor analysis was carried out using the Biomedical Data Package software. Correlation tests were used to assess inter-rater reliability between the scores assigned by the two raters. Internal consistency measured using Cronbach's alpha. Friedman two-way analysis of variance and Kendall coefficient of concordance tests were carried out to establish the level of agreement among the panel members participating in the face and content validation.

RESULTS

Applicability and practicality The raters reported that the tools could be followed with ease. They stated that when collecting data in the pharmacies they did not find it difficult to follow the set-up of the tools and record actions of the pharmacist (Table 1).

Validity For each tool the panel members examined the statements according to six criteria described (ie, relevance, completeness, comprehension, language clarity, emphasis and focus). The agreement among panel members was high for each of the criteria. For each tool, the Kendall coefficient of concordance was <0.98 ($P < 0.001$). There were, however, suggestions for minor changes concerning the wording and rephrasing of few items, in particular with the tools "Communicating with the patient" and "Equipment and professional services available in a community pharmacy". Changes in the scores assigned to statements in the tools "Setting of the community pharmacy" (7), "Dispensing a prescription" (3), "Responding to symptoms" (4) and "Communicating with the patient" (4) were suggested. These minor changes agreed upon by the panel members were implemented before carrying out of psychometric tests.

Reliability Inter-rater correlation was high for all the five validation tools (Table 2). The correlation coefficient for the overall scores for each tool was high indicating consistency of scoring of the tools by the different raters. Internal consistency which was measured by Cronbach's alpha was also found to be high (Table 3).

DISCUSSION

From the applicability and practicality testing it was shown that the tools could be used in the practical setting. The time taken to use each tool was acceptable (<10 minutes). For the tools "Setting of the community pharmacy" and "Equipment and professional services available in a community pharmacy" the time taken to fill in the tools depended on how busy the pharmacist was since parts of the tools required questioning of the pharmacist. We estimate that the validation exercise using all the tools in one community pharmacy would take about two hours.

Validity is one of the key measurement properties that must be established for tools of this nature. This involves the use of standardised techniques with which to exam-

TABLE 1: APPLICABILITY AND PRACTICALITY OF THE TOOLS

Tool	Time for one (min)	Time for 10 (h)
Dispensing a prescription	3	2.75
Responding to symptoms	5	3.5
Communicating with the patient	3	2
Setting of the community pharmacy	8	N/A
Equipment and professional services available in a community pharmacy	5	N/A

Time for one = average time taken by the two raters to use one tool
 Time for 10 = average time taken by the two raters to assess procedure 10 times
 N/A = not applicable

TABLE 2: RELIABILITY OF TOOLS — INTER-RATER SCORE CORRELATIONS

Tool	Correlation
Dispensing a prescription	0.724
Responding to symptoms	0.850
Communicating with the patient	0.823
Setting of the community pharmacy	0.986
Equipment and professional services available in a community pharmacy	0.883

Correlation = Pearson co-efficient of correlation

TABLE 3: RELIABILITY SUMMARY TO DESCRIBE INTERNAL CONSISTENCY OF TOOLS

Tool	Co-efficient
Dispensing a prescription	0.840
Responding to symptoms	0.919
Communicating with the patient	0.903
Setting of the community pharmacy	0.993
Equipment and professional services available in a community pharmacy	0.938

Co-efficient = Cronbach's alpha

the evidence in order to respond to the fundamental question, "Does the instrument measure what it purports to measure?", in other words, are the tools providing a valid measure of community pharmacy services? Psychometrically, there are three different types of validity tests available, namely, content, criterion and construct validity. However, the choice of the method depends on the circumstances surrounding the measurement tool under scrutiny. To put things in the context of this study, the criterion and construct validity cannot be examined because of the lack of "gold standard" and related measures in the area. Thus content validity is the only method that could be applied in such circumstances. The level of agreement among the panel members is usually directly proportional to the degree of the validity. The agreement among panel members suggests that the five tools possess a highly favourable content validity and measure what they purport to measure.

The most commonly used indicator

of instrument reliability, the test-retest reliability method, was not adopted in this study because the tools are intended to be administered by different raters. The data collected by different raters could create a subjective component during the rating exercise. To this effect, it was considered important that the tools possess an acceptable degree of inter-rater reliability as part of their measurement properties. The inter-rater reliability of the tools was found to be high and this demonstrates that the five tools are reliable.

The instruments which assess the environment in which the pharmacist practises his profession and the equipment that is used present a smaller degree of subjective component than the other three tools. This is reflected in that the tools "Setting of the community pharmacy" and "Equipment and professional services available from a community pharmacy" showed a higher degree of inter-rater score correlation. To minimise difference in scoring between the raters as a result of symptoms or prescriptions presented, the tools "Dispensing a prescription", "Responding to symptoms" and "Communicating with the patient" were developed to be used 10 times in each

community pharmacy where the validation exercise is implemented. This eliminated, to a large extent, any bias and the tools exhibited good inter-observer score correlation.

This study has established the reliability and validity of the five tools. These measurement instruments can be confidently used by community pharmacists to confirm the impact of their service on patient care. We propose that the process of validation of community pharmacy should be endorsed by professional bodies as a process which demonstrates to patient organisations, insurance companies and health care providers that the services provided by the community pharmacist are valid.

ACKNOWLEDGEMENTS The authors would like to express their gratitude for the time and interest taken by the community pharmacists and raters who participated in this study. Dr Azzopardi is grateful for the support given by the International Pharmaceutical Federation Foundation for Education and Research, by the European Society of Clinical Pharmacy-German Foundation for Education and Research and by the University of Malta.

