

# VALIDATION OF COMMUNITY PHARMACY

## confirming the effectiveness of a pharmacist in a community setting

*Validation of community pharmacy is a concept we coined to define the process carried out to demonstrate that the services provided by a community pharmacist are needed by the community.*

*One method to undertake such a process was developed. This method involves the use of a series of Validation Tools which are measurement tools with which to monitor the standards of the service provided by a community pharmacist. Five Validation Tools were developed and subsequently the validity and reliability of these tools were tested. The developed Validation Tools were found to be valid and reliable methods which can be confidently used by community pharmacists to confirm the impact of their services on patient care.*

### Keywords

community pharmacy, validation, psychometrics, reliability, validity

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### Community Pharmacy under scrutiny

Foundations of community pharmacy not exceedingly different to present time practice, date back to the early ninth century in the city of Baghdad.<sup>1</sup> Community pharmacy spread to the Western civilisation later on and today a large number of pharmacists across western Europe are employed in community pharmacies.<sup>2</sup> In the United Kingdom, the largest proportion of pharmacists are employed full time in the community.<sup>3</sup> Similarly, in Malta, 49% of Maltese active pharmacists are employed full time in the community. In addition other pharmacists work as locum pharmacists or part-time in a community pharmacy along with their full time job whether it is in hospital or as medical representatives.

Even though community pharmacy is an ancient profession and the majority of pharmacists practise in the community, much debate has centred around the professional role of the community pharmacist for the last thirty years. In the 1960s community pharmacy was attacked as being the cause of incomplete professionalization of the profession of pharmacy. The concept of having a business aspect in community pharmacy was considered to compromise the professionalism of the community pharmacist. In addition to this debate which is still going on today, perhaps, the need for the existence of the community pharmacist is being questioned. This is taking place in the light of declining economic growth and changes taking place in healthcare, in public expectations from community pharmacists, in attitudes of other health professionals and in the retail sector. The pharmacy profession is aware of the need to adapt to these changes. According to Professor Trevor Jones, ABPI director-general, "community pharmacy will only be able to survive if it demonstrably provides a service that is professional, unique, cost efficient and cost-effective".<sup>2</sup>

In 1995 the consultation 'Pharmacy in a New Age' was launched in the United Kingdom. This consultation aimed to develop strategies to demonstrate the value of community pharmacists, to identify functions that the pharmacist should indulge more in and to identify functions that should be given less importance.<sup>6,7</sup> As a result of this consultation the *Pharmacy Practice Research and Development Task Force* was set up in the UK to review pharmacy practice research.<sup>8</sup> During the launch of the report, 'A new age for pharmacy practice research: promoting evidence-based practice in pharmacy', Mr Ian Caldwell, president of the Royal Pharmaceutical Society at the time stated that every pharmacist assumes that society appreciates the services one is providing by

now pharmacy practice research should be directed to produce methods to examine this scientifically and produce evidence-based data.

Development of the concept of Validation of Community Pharmacy also started in 1995. Validation of community pharmacy aims to establish scientific, valid methods to confirm the effectiveness of the pharmacist in a community pharmacy. The concept of Validation of Community Pharmacy was considered by the *Pharmacy Practice Research and Development Task Force (UK)* as contributing to this new age of pharmacy practice research.<sup>8</sup>

## The Concept of Validation

Validation is derived from the Latin word *validus* meaning 'strong, powerful'.<sup>9</sup> The *Virtue's English Dictionary (1958)* defines *valid* as "sufficiently supported by actual fact, well grounded, just, good, not weak or defective, having sufficient legal strength or force". Subsequently the term to validate is defined as "to make valid, to ratify, to confirm, to substantiate".<sup>9</sup>

The word validation was introduced in the laboratory procedures jargon during the late 1960s to describe the process carried out to demonstrate that the instrument or the method under scrutiny is reliable for the intended application. The process of validation ensures confidence in the results obtained and minimizes consequences of error. Today, validation is an essential procedure in the area of chemical analysis.<sup>10</sup>

Validation is also used in social and behavioural science to examine the usefulness and accuracy of questionnaires and survey tools. Measurement tools involve the assignment of numerals, numbers or scores to properties or procedures. Variation in the scores could be either due to 'real difference' in the property being measured or else due to the influence of the measure itself or the setting in which measurement is taking place. Differences not due to 'real difference' are measurement errors. The validation of questionnaires and measurement tools reduces measurement errors prior to implementation by confirming that the instrument is measuring what it claims and/or what it is intended to measure.<sup>11</sup>

The concept of validation of community pharmacy involves these principles and may be defined as 'the process carried out to demonstrate that the services provided by a community pharmacist are needed by the community'.

## Development of Validation Tools

In order to develop validation tools for community pharmacy processes, baseline data was collected through a personal visit to all private community pharmacies in Malta. Data was collected on the services provided from 184 community pharmacies. Services identified include dispensing of prescribed medication, dispensing of over-the-counter medicines, responding to symptoms, giving advice when selling non pharmaceutical products and carrying out certain diagnostic tests such as pregnancy testing, urinalysis, blood pressure measurement, blood testing and weight monitoring.

In the second part of the project, ten community pharmacies were selected randomly, two from each of the five districts in which

Malta is subdivided for health purposes. Field observation studies were carried out in these pharmacies to quantify the division of time amongst specific services offered by the community pharmacist.

From the data collected five Validation Tools were developed namely: *Dispensing a Prescription*, *Responding to Symptoms*, *Communicating with the Patient*, *The Setting of the Community Pharmacy*, *Equipment & Professional Services available in a Community Pharmacy*.

The validation tool *Dispensing a Prescription* scores the procedure followed by the pharmacist during dispensing of a prescription. For example scores are assigned if the pharmacist checks the medication with the prescription to confirm that the right product was selected before dispensing. Another section of the tool assesses the information provided to the patient whether given in a printed manner, or as instructions written on the medicine packet or simply as verbal advice.

The tool *Responding to Symptoms* is the most extensive covering the intervention of the pharmacist when responding to symptoms presented at the pharmacy such as skin disorders, and eye disorders. This same tool is also used when a request for an over-the-counter preparation is made. The validation tool *Communicating with the Patient* assesses the pharmacist communicating role when interacting with the patient. The tool scores the pharmacist attending role by analysing verbal and non-verbal messages.

The two other validation tools aim to assess the environment in which the pharmacist practises his profession together with the equipment that is used. The tool entitled *The Setting of the Community Pharmacy* looks at different aspects of the pharmacy area such as the size and location of the dispensing area, the counselling area and the area for storing medicines. The image projected by the pharmacy promoting health aspects is assessed through analysing availability of informative leaflets to patients, display of health promotion posters, window dressing, cleanliness and neatness. The tool *Equipment and Professional Services available in a Community Pharmacy* aims to assess the equipment available in the pharmacy for example whether the refrigerator is checked to be at the required temperature, and the literature used as reference in the pharmacy.

## Psychometric Evaluation

Psychometric evaluation quantifies the precision of measurement of qualitative concepts. One aspect of psychometric evaluation is validity which assesses how well the tool measures what it sets out to measure. The assessment of face and content validity involves a review of the tool by a group of 'expert judges'. The expert panel of judges consisted of three medical doctors, two community pharmacists, two consumers, a communication studies graduate and the investigator. An initial meeting was organised for the expert judges to explain to the members the role and significance of the panel. This meeting took 1 hour. Subsequently each tool was submitted to each member one week prior to a meeting organised to review each tool. During the meeting the face and content validity of the tools were reviewed. Members discussed layout of the tools, set-up, scoring, and construction of phrases. The tools were amended according to the final deliberation of the panel of expert judges. For each tool the members of the panel met for a three hour session.

Another aspect of psychometrics is reliability which examines the reproducibility of the measuring instruments. The validation tools are intended to be administered by different raters. This creates a subjective component during the rating exercise. Thus, inter-observer reliability was analysed. The investigator used the tools in the ten community pharmacies selected for the field observation studies. The tools were used by another rater in the same Community Pharmacy. A training session for the rater was held prior to starting the scoring exercise. The length of the session varied depending on the tool but on average took 3 hours.

The investigator and the other rater went to the pharmacies on different occasions because having two observers in the pharmacy (sometimes in a very restricted area) was not practical. This, however, does not affect the reliability test because the tools are measuring the processes carried out by the pharmacist independent of the prescription dispensed or the symptom presented. Also for this reason the tools *Dispensing a Prescription*, *Responding to Symptoms* and *Communicating with the Patient* were performed ten times in the same pharmacy to avoid the scoring being affected by the prescription or the symptom.

The results were analysed using Biomedical Data Package software. The degree of association between the reported measurement for each tool was found to be above the accepted minimum level and so all the tools were found to be reliable.

## Conclusion

The Validation Tools are a series of valid, reliable and user-friendly methods with which to monitor the standards of the services provided by the community pharmacist. These tools could be confidently used by community pharmacists to confirm the impact of their service on patient care.

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## Glossary of terms

**Psychometrics** branch of survey research methodology which determines how good the survey, questionnaire or measurement instrument is

**Validity** how well the questionnaire measures what it is supposed to measure

**Face validity** casual review of questionnaire by individuals with no expertise in the field of study

**Content validity** formal review of questionnaire by individuals who are experts in some aspect of the subject being considered in the questionnaire

**Expert judges** a group of individuals with mixed expertise who reviewed the questionnaires for face and content validity

**Reliability** statistical measure of the reproducibility of the data produced from the questionnaire

**Inter-observer reliability** a measure of how well two or more evaluators agree in their assessment of a variable

**Training session** explanation of the use and method of scoring of the validation tools

Adapted from LITWIN, S. How to measure survey reliability and validity. USA: SAGE Publications Inc. 1995

As part of this research project, a Validation Pack has been produced and is available free of charge on request from the *Validation Research Project Unit, Pharmacy Department, Msida, Malta*

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