

Evaluation of a quality system developed for pharmacy teaching laboratories

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Abstract

Background: The implementation of a quality system improves the educational quality of activities undertaken in a laboratory.

Aim: To evaluate the perception of undergraduate pharmacy students and laboratory demonstrators on the quality system implemented in the laboratories of the Department of Pharmacy at the University of Malta.

Method: A self-administered questionnaire was developed, psychometrically evaluated and distributed to second, third and fourth year undergraduate pharmacy students and laboratory demonstrators (N=110).

Results: Out of a total of 94 questionnaires collected, 91 participants agreed that the implemented quality system is important to carry out procedures correctly and safely in the laboratory and is a helpful educational tool for students to appreciate quality processes in pharmacy (n=84). Ninety two participants agreed that standard operating procedures are an essential aspect of a quality system and are important educational tools for laboratory work (n=73).

Conclusion: The implemented laboratory quality system is a valuable educational tool for pharmacy students.

Keywords: *educational tool, evaluation, laboratory, pharmacy students, standard operating procedures, quality system*

Introduction

Implementation of a quality system in a university-based laboratory gives significant value to the institution by introducing the concept of quality awareness among its students and laboratory demonstrators (Rodima *et al.*, 2005). A quality system facilitates the smooth running of a laboratory and improves the educational quality of the activities undertaken (Grochau *et al.*, 2010). Documentation, including standard operating procedures (SOPs), is an essential aspect of an implemented quality system (Sharp, 2000; Ferrero, 2007) and provides benefits for the institution in which it is implemented (Altman and Brown, 2004). SOPs should be followed to enable a task to be performed correctly and safely (Eastham, 2003; Hallin and Wichman, 2007; US-EPA, 2007) and help to achieve consistency in the activities being undertaken (Altman and Brown, 2004). They are also effective training tools for laboratory users (Hancock, 2002; Altman & Brown, 2004; Hayes, 2007; RPSGB, 2007). However, the development of a quality system consisting of detailed SOPs is time and labour consuming (Siloaho, 1999) since SOPs need to be regularly updated to ascertain relevance, and their effectiveness is dependent upon the individuals involved to actively follow and use them. SOPs may need to be adapted to different circumstances and staff members may also perceive SOPs to limit their professional judgement (Hayes, 2007) and academic freedom (Bode *et al.*, 1998).

Quality systems are being implemented in a number of different pharmacy settings including industrial (Geijo, 2000;

Pohl *et al.*, 2008), hospital (Francois *et al.*, 2003; Bedi *et al.*, 2006) and community pharmacy (Azzopardi, 2000; Eastham, 2003; RPSGB, 2007). This implies that pharmacy graduates will encounter the concept of quality systems during their working life. As summarised by Kaartinen-Koutaniemi and Katajavouri (2006), pharmacy education must provide students with the requirements of working life and must foster a good quality of learning to help develop expertise in the field of pharmacy. Thus, familiarisation of students with quality systems and SOPs during their academic training will help them to appreciate the importance and relevance of the use of quality systems. Since students are not generally familiar with quality systems and SOPs, they may not initially recognise their importance and may perceive them to be an imposed and unnecessary burden, creating restrictions whilst undertaking laboratory work. Vahdat (2009), emphasised that whenever students fail to see the relevance of a subject that they learn in their professional degree, their performance rate in that particular subject declines and they will start to consider it to be less important. Familiarisation with quality systems will therefore not only help students perform activities correctly and safely within the laboratory during their academic years at university, however will also help them to improve integration within their working environment (Hancock, 2002; Michalska-Cwiek, 2009). Implementation of a quality system may also increase research funding opportunities for the university by setting higher laboratory standards (Hancock, 2002) and enables lecturing on aspects of quality assurance to be undertaken in a more realistic manner, since the students would already have

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been exposed to such a system during their laboratory practical sessions (Rodima *et al.*, 2007; Zapata-Garcia *et al.*, 2007). Despite the advances in technology and the tendency to move away from the traditional learning approach, laboratory teaching is still considered to be an essential part of pharmacy professional education that requires implementation of 'hands on' teaching techniques (Vahdat, 2009), further justifying the relevance of the role of quality systems and SOPs in university pharmacy teaching laboratories. Students' perception of innovative aspects in teaching approaches is essential since if they do not acknowledge the importance of such an activity, benefit gained will be limited (Ingram *et al.*, 2007).

The aim of the study was to evaluate the perception of pharmacy students on a quality system which was developed and implemented in the teaching laboratories of the Department of Pharmacy at the University of Malta.

Setting

The study was undertaken in the four laboratories of the Department of Pharmacy at the University of Malta. The academic curriculum of second, third and fourth year undergraduate pharmacy students includes laboratory practical sessions related to medicinal chemistry, pharmaceuticals and pharmacy practice. A number of dissertation studies that are undertaken within the Department of Pharmacy also require laboratory work as part of their fieldwork investigations.

The implemented quality system

The developed quality system consists of three main groups of SOPs; high level SOPs, SOPs for point-of-care testing (POCT) devices and SOPs for pharmaceutical equipment and analytical instruments. The high level SOPs include 'Master SOP', which defines the entire quality system with respect to development, authorisation, distribution and review of SOPs, 'Good Laboratory Practice', 'Health and Safety in the Laboratory', 'Laboratory Logbooks' and 'Training'. A total of 42 SOPs for POCT devices, pharmaceutical equipment and analytical instruments were developed and implemented.

Each SOP was divided into nine sections; 'Scope', 'Objective', 'Definitions', 'Responsibility', 'Procedure', 'Precautions', 'References', 'Appendices' and 'Revision History'. For each SOP, the procedure section was also summarised into flow charts. The developed SOPs were reviewed by a Laboratory Officer and authorised by the Head of the Department of Pharmacy. A 'Distribution Points Form' was completed for each SOP to record the location of the authorised copies of each SOP. SOPs are reviewed every two years from their date of issue. Students were informed about the implemented quality system through notices that were uploaded on the website of the Department of Pharmacy, where all implemented SOPs were also uploaded (www.um.edu.mt/ms/pharmacy/coursework/lapsops).

Students were requested to read the SOPs prior to commencing with laboratory practical sessions or using a POCT device, pharmaceutical equipment or analytical instrument for their dissertation in order to familiarise themselves with the procedure. Students were then requested

to sign a 'Read and Understood Form' for each SOP after clarifying any points which may have not been well understood if required. A system of laboratory logbooks was also developed to complement the quality system, where each POCT medical device/pharmaceutical equipment was assigned a separate logbook to record use, calibration and maintenance procedures by the user.

Methods

Questionnaire development

A self-administered questionnaire consisting of 11 structured questions was developed. The first two questions concerned the collection of demographic data whilst the following four questions were 'Yes / No' close-ended questions. Another four questions were developed based on a 5-point Likert Scale rating, with 'Strongly Disagree' (1), 'Disagree' (2), 'Neither Agree nor Disagree' (3), 'Agree' (4) and 'Strongly Agree' (5) or 'Very Poor' (1), 'Poor' (2), 'Fair' (3), 'Good' (4) and 'Excellent' (5) to represent the scale. The questions addressed the following main topics: SOP awareness, availability, usefulness, presentation and comprehensiveness, use of logbooks, relevance and educational value of the quality system. The last question was left open-ended for participants to suggest improvements to the implemented quality system.

Psychometric evaluation

The questionnaire developed was tested for face and content validity by a panel consisting of five members; Head of the Department of Pharmacy, two Laboratory Officers and two undergraduate pharmacy students. The validation panel members were asked to read through the questionnaire and suggest any amendments to the investigator (CMT).

The validated questionnaire was tested for reliability using test-retest analysis where 15 students, selected by convenience sampling, were given the questionnaire and were asked to return it within a week. The same group of participants were given another copy of the same questionnaire to complete following a period of 15 days. A high Guttman Split Half Co-efficient of 0.860 was obtained, rendering the questionnaire reliable. The average time taken to complete the questionnaire was 4.5 minutes (range 3-7 min).

Questionnaire distribution

The questionnaire was distributed to all second, third and fourth year undergraduate pharmacy students (n=106) and laboratory demonstrators (n=4), with a total (N) of 110 participants. This student cohort was selected to participate since all students in these year groups would have undertaken laboratory practical sessions as part of the academic curriculum. The questionnaire was distributed personally by the investigator and collected during the final laboratory practical session, allowing students and laboratory demonstrators two weeks to complete the questionnaire. Questionnaire distribution was undertaken seven months post-implementation of the high level SOPs and two months post-implementation of all the SOPs for POCT devices/pharmaceutical equipment/analytical instruments.

Once the completed questionnaires were collected, the data was analysed using SPSS® version 17 and descriptive statistics were undertaken.

Results

Out of a total of 110 questionnaires distributed, 94 completed questionnaires were returned (average response rate = 85.5%). Thirty five participants were second year students, 20 were third year students, 35 were fourth year students and 4 were laboratory demonstrators. Seventy-one of the respondents were female and 23 were male. The age distribution of the students was predominantly in the 19 to 22 year age group whilst that of the laboratory demonstrators ranged from 30 to 44, with a mean and median age of 21.5 and 21 years respectively for the group respondents (range 19-44 years).

Quality system awareness

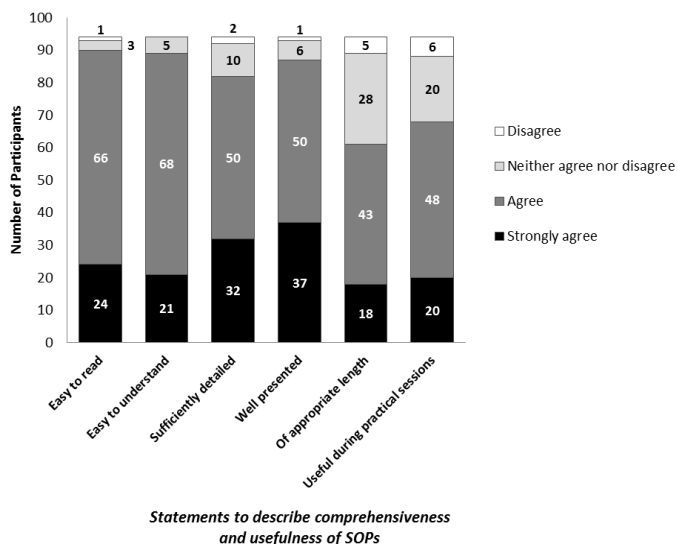
All 94 participants were aware of the implemented quality system in the laboratories and 91 participants (96.8%) regularly filled in the appropriate laboratory logbooks during laboratory practical sessions. Eighty eight of the participants (93.6%) agreed that availability of the SOPs on the website is the best way to access the SOPs.

Usefulness of the SOPs

The majority (n=92, 97.9%) of the participants agreed that SOPs are an important aspect of a quality system in a laboratory and 73 participants (77.6%) also agreed that the SOPs are important educational tools during laboratory practical sessions. Eighty two participants (87.2%) agreed that the SOPs improve the quality of laboratory practical sessions.

Sixty four participants (68.1%) perceived the SOPs as useful. Figure 1 represents results related to the presentation, comprehensiveness and usefulness of the SOPs. As shown in this figure, 90 participants (95.7%) agreed that the SOPs are easy to read and 89 participants (94.7%) agreed that the SOPs are easy to understand.

Figure 1: Presentation, comprehensiveness and usefulness of the SOPs (n=94)



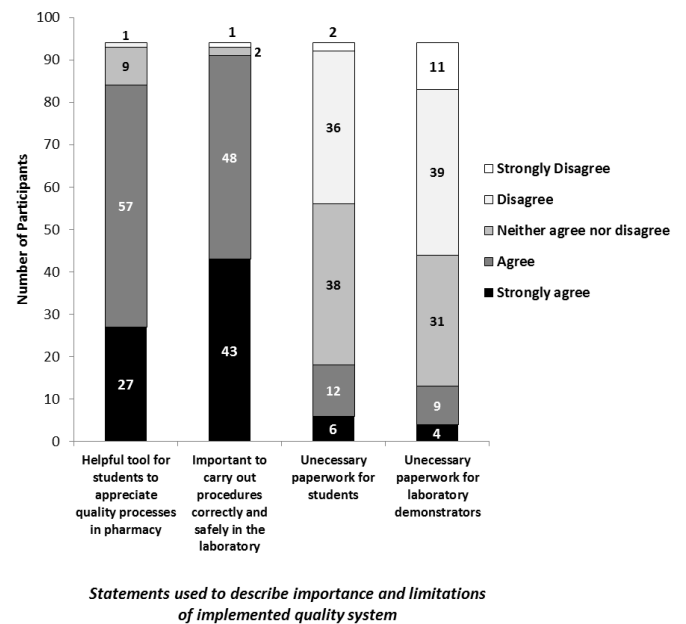
Use of laboratory logbooks

Eighty-one participants (86.2%) agreed that laboratory logbooks are an important element in a laboratory quality system and 90 participants (95.7%) also agreed that the implemented laboratory logbooks are important to keep track of the use, calibration and maintenance of equipment.

Use and relevance of the implemented quality system

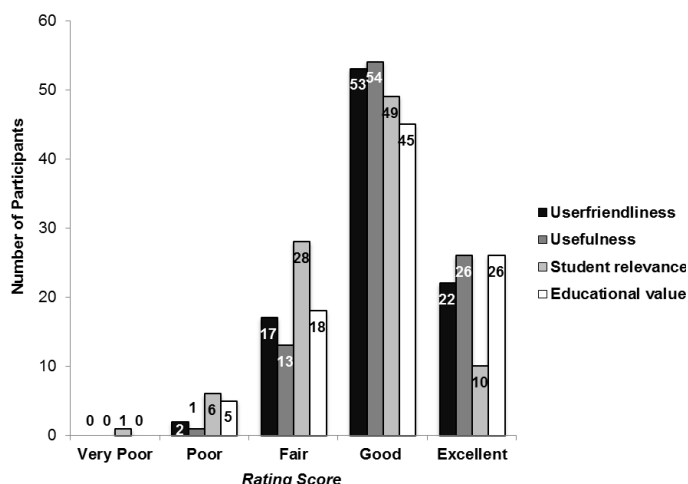
Figure 2 represents results related to the importance of the implemented quality system and a few limitations that may relate to its implementation. As shown in this figure, 91 participants (96.8%) agreed that the overall implemented quality system is important to carry out procedures correctly and safely in the laboratory. Figure 3 illustrates the results obtained with regards to the usefulness and relevance of the overall quality system. Fifty four participants (57.4%) rated the usefulness of the quality system as 'Good', with a further 26 students rating it as 'Excellent'. Fifty three participants (56.4%) rated the user friendliness of the quality system as 'Good', with a further 22 students rating it as 'Excellent'.

Figure 2: Importance and limitations of the implemented quality system (n=94)



Further recommendations

Eighteen undergraduate pharmacy students suggested that more diagrammatic representations should be included in the SOPs, particularly for complex procedures. Ten undergraduate pharmacy students and one laboratory demonstrator stated that some of the SOPs should be shorter in length to increase their readability. Another ten students suggested the incorporation of an introductory lecture or a course credit on quality systems to help them familiarise themselves with the system and seven students also suggested the presence of laboratory posters to act as reminders for students regarding SOP use and logbook entries.

Figure 3: Usefulness and relevance of the overall quality system (n=94)

Discussion

Undergraduate pharmacy students and laboratory demonstrators in this study have a positive overall perception of the implemented quality system in the laboratories of the Department of Pharmacy at the University of Malta.

All participants were aware of the implemented quality system, a feature that is considered to be important for its successful implementation (Bode *et al.*, 1998). Such a system will only be sustainable and successful if a positive attitude towards quality is put into practice (Bode *et al.*, 1998; Grochau *et al.*, 2010), where users are willing to accept and actively follow such a system (Mouillet, 1998). Islin and Thystrup (2000) stated that evaluation of a quality system by its users is an important tool to further develop and improve the system, encouraging them to provide constructive criticism and to increase their motivation. The aspect of user involvement will also take advantage of the individual skills and technical knowledge some of the participants may possess (De Nadai Fernandes *et al.*, 2006). In parallel with other quality system implementation studies carried out in Spain and Brazil (Abad *et al.*, 2005; Grochau *et al.*, 2010), the system was developed via a 'bottom-up' approach involving staff and students from all levels, rather than via a 'top-down' approach of managerial imposition.

The majority of the participants agreed that the implemented quality system is important to carry out procedures correctly and safely. This is in line with conclusions from a study conducted by Siloaho (1999), where a decrease in the number of errors resulted from the introduction of better implemented instructions and a more careful and responsible way of working. A good backbone in quality system regulations will help to strengthen a laboratory (Schmidt, 1999). It is therefore important to achieve a compromise to ensure that both flexibility and a good level of quality standard are achieved (Geijo, 2000).

A quality system is considered to be dynamic in nature, and therefore it must constantly be reviewed for further continuous development even following its implementation (Grochau *et al.*, 2010). This implies long term commitment from both students and laboratory demonstrators (Abad *et al.*,

2005; Zapata-Garcia *et al.*, 2007). In this setting, SOPs are reviewed every two years whilst logbooks are reviewed every six months. Students and laboratory demonstrators are required to input entries in logbooks whenever they use, calibrate or perform a maintenance procedure on a POCT device, pharmaceutical equipment or analytical instrument, and also to sign 'Read and Understood Form' for newly implemented SOPs or for newer versions of previously implemented SOPs.

The majority of participants agreed that the SOPs are an important aspect of a quality system in a laboratory and agreed that the SOPs are an important educational tool during laboratory practical sessions. This is in line with previous observations by Hancock (2002), who demonstrated that SOPs are excellent training tools for users within the laboratory setting.

The majority of the participants agreed that the laboratory logbooks are an important element of a quality system and are important to keep track of use, calibration and maintenance of equipment and activities being undertaken in the laboratories. Use of laboratory logbooks is referred to in a study by Penders and Hendriksen-Wissink (1999) that dealt with implementation of a quality system in a hospital laboratory setting. These authors stated that use, calibration and maintenance procedures of equipment should be appropriately documented in logbooks.

Most of the participants either disagreed or else took a neutral stand about whether the quality system should be considered as unnecessary paperwork for the students whilst the majority of participants disagreed that the quality system should be considered as unnecessary paperwork for the laboratory demonstrators. In a study conducted by Siloaho & Puhakainen (2000), some participating staff members felt that the quality system resulted in a large volume of paperwork and too many instructions, which outweighed the benefits. The tedious aspect of writing procedures was also reported in another study by Francois *et al.* (2003), wherein certain users were unmotivated by the large amount of documentation produced. These users did not appreciate the value of this work and were concerned that the increased amount of paperwork would be a burden on their workload.

Limitations

A limitation of this study is that the SOPs were implemented for a short period of time and both the undergraduate pharmacy students and the laboratory demonstrators were in the initial stages of familiarisation with their use. Re-evaluating the implemented quality system during future academic years will help to further determine the long-term usefulness of the implemented quality system.

Another limitation of this study is that the investigator could have further evaluated how the SOPs were being useful for the students during their time in the laboratories. Such an evaluation could include a comparison of the assessment marks obtained from laboratory practicals with assessment marks that were obtained during earlier years when no quality system was in place. This enables determination of whether the SOPs were actually improving students' knowledge and helping them to achieve higher grades. The number of

incidents that took place could also be included in this analysis to determine whether a significant lower amount of incidents were taking place due to the implementation of the SOPs, translating into better use of laboratory equipment and better competences in laboratory skills.

Since the concept of SOPs may not be considered as very interesting by students, further studies on the introduction of novel approaches to enhance their learning experience with regards to this subject are recommended.

Conclusion

Undergraduate pharmacy students had a positive overall perception of the implemented quality system, accepting its importance as an educational tool within the laboratory and helping them to carry out procedures correctly and safely. Further promotion and development of the system will increase student awareness and familiarisation and will continue to encourage them to actively make use of this system within the laboratory setting.

Conflict of Interest: The Author(s) declare(s) that they have no conflict of interest to disclose.

Funding: This research received no specific grant from any funding agency in public, commercial or non-profit sectors.

Acknowledgements

The authors acknowledge the assistance of Dr. Liberato Camilleri, Department of Statistics and Operations Research, Faculty of Science, University of Malta, with statistical analysis.

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