

INTRODUCTION

Good Pharmacy Practice guidelines define standards for the community and hospital pharmacist for the benefit of patients.¹ The assessment of Good Pharmacy Practice (GPP) standards is used to measure compliance with established legislative criteria and ensure positive outcomes in patient management. The quality of pharmacy services and the achieved patient clinical outcomes are correlated to pharmacist competencies. Self-assessment is a fundamental method used for the enhancement of learning skills and the maintenance of a competent and independent professional while promoting motivation in health care professionals. The implementation of GPP standards in Malta and the evolution of pharmacy regulatory science led to an innovative patient-centred approach in regulatory audit.

METHOD

The methodology included:

1. the design and validation of the self-audit protocol consisting of a Pharmacist Competencies Self-Audit (PCSA) and a Regulatory Self-Audit (RSA)
2. the establishment of a risk-based assessment defining regulatory criteria in RSA as minor, major and critical and correspondingly classifying pharmacies in high (1 critical or above 5 major findings), medium (1-5 major) and low risk (only minor findings) categories (Table 1)
3. the performance of competencies and regulatory self-audits (PCSA and RSA) and regulatory audits in 61 community pharmacies
4. the measurement of compliance agreement between regulatory and self-audits and of risk categorisation with the Kappa test, mean percentage compliance with the Wilcoxon Signed Ranks test
5. the identification of correlations between pharmacist characteristics and self-audit results with the Chi square test.

RESULTS

1. The self-audit protocol consisted of a PCSA tool assessing pharmacist strengths, scientific interests, goals and opportunities for improvement, and a RSA checklist.
2. The risk analysis of the regulatory checklist identified 19 minor, 34 major and 23 critical criteria.
3. Pharmacists (N=61, 34 female, mean age 43, range 25-73) reported 'understanding patient needs' (57.4%) and 'patient-orientation' (49.2%) as the two highest strengths, 'personalised healthcare' (44.3%) as the major area of interest, 'service optimisation' (49.5%) as the main goal and 'continuous education' (63.9%) as an opportunity for improvement.
4. In the self-audits, pharmacies reported higher regulatory compliance (94.7% ± 4.65) and were classified in lower risk-categories (low-risk=27, medium-risk=18, high-risk pharmacies=16) than in regulatory audits (82.7% ± 8.14; low-risk=2, medium-risk=13, high-risk pharmacies=46). The difference on mean percentage compliance between regulatory and self-audits was statistically significant (p=0.000) (Table 2) while agreement on regulatory and self-audits risk categorisation was not achieved (Kappa= 0.050, p=0.395).
5. 'Understanding patient needs' and 'good communication skills' were reported as main strengths by 67.6% and 47% of the pharmacists with more than 6 years of experience (p=0.000). Pharmacists below-30 and over-60 years-old assigned a lower regulatory self-audit risk compared to intermediate age-categories (p-value=0.041).

AIMS

To establish a regulatory self-audit model in community pharmacy aiming at satisfying regulatory requirements while meeting patient needs.

The objectives of the study were:

- Evaluate agreement on regulatory self-audit and regulatory audit results.
- Analyse pharmacists' competencies and identify educational and professional needs.
- Establish a risk-based system for pharmacy audits for the achievement of patient-oriented standards.

Table 1: Risk categories according to regulatory findings²

Findings	Risk categories		
	High Risk	Medium Risk	Low Risk
<i>Critical</i>	≥1	-	-
<i>Major</i>	≥6	1-5	-
<i>Minor</i>	-	-	1-all

Table 2: Comparison of the regulatory self-audit and regulatory audit mean percentage compliance

	Mean	Standard deviation	Minimum	Maximum
<i>Regulatory self-audit Percentage compliance</i>	94.7	4.65	80.8	100
<i>Regulatory audit Percentage compliance</i>	82.7	8.14	51.9	100

Wilcoxon Signed Ranks test Z= -6.571, p=0.000

CONCLUSION

A self-audit showed highly significant differences from the established regulatory audit. A less policing approach in audits may lead to achieve concordance between regulation and pharmacy practice.

The assessment of GPP standards based on pharmacist competencies, on regulatory compliance and on a pharmacy-risk analysis is proposed to address pharmacy educational needs and optimise pharmacy practice towards meeting patient needs. The findings of the study propose the empowerment of pharmacists to perform a self-audit and the recognition of pharmacist competencies through a GPP certificate motivates pharmacists while promoting a patient-oriented pharmacy practice.

REFERENCES

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