FOCUSING AUDITS ON PATIENT SAFETY

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INTRODUCTION
Pharmacy practice is evolving to incorporate a patient-centred approach to the scientific background. Regulatory audits (RA) often take the form of a policing exercise. This method is not always conducive to produce optimal outcomes. In parallel with the pharmaceutical patient advice process, RAs could incorporate the concept in contrast to policing of advancing from compliance, adherence to concordance. Such an exercise may enhance patient safety while at the same time complying with the regulatory process.

METHOD

- Development and validation of RA tool
- Implementation of tool in 85 pharmacies (January-November 2017)
- Interviews with 12 pharmacists (October and November 2016)
- Retrospective analysis of 512 RA reports (January 2012-September 2016)
- Documentation Completing the RA tool
- Observation
- Case studies evaluation
- Interactive educational discussions to reach concordance on corrective and preventive actions (CAPAs)
- Identification of deficiencies related to patient safety

RESULTS
Seven case studies were evaluated relating to dispensing problems (n=4), inventory deficiencies (n=2) and inequity of treatment (n=1). The educational discussions led to reaching concordance with the pharmacists on 46 CAPAs to address the deficiencies identified (Table 1).

Table 1: Corrective and Preventive Actions for the case studies evaluated (N=46)

<table>
<thead>
<tr>
<th>Case study</th>
<th>Number of CAPAs</th>
<th>Examples of CAPAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Dispersing error of methotrexate 2.5mg instead of methyldopa 250mg</td>
<td>7</td>
<td>Cytotoxic drugs stored alphabetically in a labelled, separate cupboard; separators between ‘look-alike’ and ‘sound-alike’ medicines installed</td>
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<tr>
<td>2 Near-miss medication error</td>
<td>3</td>
<td>SOP for referral of patients to the pharmacist for ailments involving medicine dispensing developed and implemented; ‘near-miss’ medication error log developed and implemented as an error management system</td>
</tr>
<tr>
<td>3 Dispensing POM without a prescription</td>
<td>7</td>
<td>Patient contacted by pharmacist to confirm practice of effective contraception and to exclude pregnancy risk; Pregnancy Prevention Programme reviewed with patient; retinoid therapy acknowledgement forms made available in pharmacy</td>
</tr>
<tr>
<td>4 Filling of prescriptions by non-pharmacist staff</td>
<td>6</td>
<td>Training of non-pharmacist staff with regards to referral of patients to the pharmacist for ailments requiring medicine dispensing and training records made available</td>
</tr>
<tr>
<td>5 Expired vaccines</td>
<td>8</td>
<td>Point-of-sale system reviewed to identify whether any expired vaccines were dispensed; methods of alert implemented to identify short-dated medicines e.g. use of coloured labels</td>
</tr>
<tr>
<td>6 Inappropriate storage temperature: Refrigerator temperature below 2°C</td>
<td>11</td>
<td>Temperature monitoring SOP developed and implemented; medicines exposed to temperature excursions to be separated in container labelled ‘DO NOT DISPENSE’</td>
</tr>
<tr>
<td>7 Inequity of treatment between private and government-sponsored patients</td>
<td>4</td>
<td>Pharmacy technician employed; prioritisation of activities related to medical ailments irrespective of private and government-sponsored patients</td>
</tr>
</tbody>
</table>

CONCLUSION
The seven case studies of dispensing problems, inventory deficiencies and inequity of treatment exemplified a positive interaction between the pharmacists and the auditor. Follow-up audits confirmed that an approach that emphasises on reaching concordance with the pharmacist through identifying opportunities for improvement, rather than pointing non-conformances, improves pharmacist motivation, patient safety and patient care outcomes. Future studies may include the harmonisation of preventive actions across pharmacy services.

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