REACHING CONCORDANCE IN COMMUNITY PHARMACY REGULATORY AUDITS

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INTRODUCTION
Pharmacy practice is evolving to incorporate a patient-centred approach to the scientific background. Pharmacy audits reaching concordance between the practicing pharmacist and the auditor to the benefit of the patient are envisaged.

AIMS
- To develop and implement a tool for community pharmacy regulatory audits (CPRAs)
- To evaluate case studies from CPRAs to recommend improvements to patient safety

METHOD

- Retrospective analysis of 512 CPRA reports (January 2012-September 2016)
- Interviews with 12 community pharmacists (October and November 2016)
- Development and validation of CPRA tool
- Implementation of tool in 85 community pharmacies (January-November 2017)
- Documentation: Completing the CPRA tool
- Observation: 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 Dispensing 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 in CPRAs to reach concordance on how to address deficiencies related to patient safety, through an approach involving interactive educational discussions. Reaching concordance to regulation in CPRAs, as distinct from punitive enforcement, may improve pharmacist motivation and patient care outcomes.