

Explicit standards to evaluate the quality and safety of medication use in primary care: Expert consensus study

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Objective: A number of methods using explicit criteria to evaluate the quality and safety of medication use have been published. However, most instruments focus on a single disease or patient group. The aim of this study was to identify a set of prescribing criteria, which covers common aspects of medication use in primary care.

Method: A structured literature review of current evidence based guidance, epidemiological surveys on preventable drug related morbidity and previously developed sets of explicit medication use criteria (eg Beers, ACOVE, Start/Stop, MATs, PDRM) was conducted to identify standards of medication quality and safety. Based on this review, a questionnaire specifying 99 quality- and 288 safety criteria was designed. Quality criteria target prescribing practices, which current guidance recommends providing (the commission of a specific drug, drug group or dose or achievement of a therapeutic target). In contrast, safety standards target practices, which should be avoided or only applied with special caution and appropriate monitoring.

A modification of the RAND appropriateness method was used to evaluate consensus among a panel of experts on the relative clinical importance of the criteria: Panellists rated standards on two distinct 9 point scales ('appropriateness' and 'necessity'). The first round was conducted by post/email. Panellists subsequently met for a whole day where the first round ratings were fed back and discussed. Panellists then re-scored all standards (second round). Main outcome measures were the median ratings for all scales and the presence or absence of disagreement.

Results & Conclusion: The panel was composed of 4 general medical practitioners, 2 pharmacists working in general medical practices, 2 pharmacy academics and 2 pharmacists working in medicines governance. The results are currently analysed and will be available in time for the meeting.

We present a comprehensive set of explicit criteria to evaluate the quality and safety of medication use in primary care. The criteria set may be useful (1) as a screening tool to identify patients, who may benefit from a review of their medication, (2) as a clinical tool in the delivery of medication reviews and (3) as an intermediate outcome measure in the evaluation of medication review interventions (see second abstract).

Evaluating pharmaceutical care: A generic algorithm to operationalise 'adherence to standards' as an intermediate outcome measure

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Objective: Intermediate outcome measures offer a means of making transparent the processes used in complex healthcare interventions, such as pharmaceutical care. A number of instruments defining explicit quality standards of medication use have been developed, without evidence of widespread uptake of these measures for research purposes. A generic algorithm to quantify and categorise adherence of medication use to explicit standards is described and its application to detect change in the quality of prescribing is demonstrated.

Method: Validated best practice standards are translated into medication assessment criteria: Using these criteria, each patient is assessed in 3 consecutive steps: Step 1) assesses whether a standard applies to the patient, step 2) whether the standard is adhered to and step 3) whether exceptions to the implementation of standards are present. A standard is a recommendation concerning a compelling need for a treatment, the preferred choice, the dose, a measurable therapeutic target, such as blood pressure or a safety issue such as a contraindication to a drug group. Exceptions are scenarios, where adherence to a standard may be conflicting with co-existing medical conditions or co-prescribed treatments. Where it is known that standards apply to a particular case, **one** of the following answer categories will be fulfilled:

- a) **YES_{EXC}**: Standard is adhered to and patient has exceptions
- b) **NO_{EXC}**: Standard is NOT adhered to and patient has exceptions
- c) **YES** : Standard is adhered to and patient has NO exceptions
- d) **NO** : Standard is NOT adhered to and patient has NO exceptions
- e) **ID_S** : Information (eg current blood pressure level) is missing to
- f) verify adherence

For each criterion applied to a group of patients, the adherence rate to that criterion is calculated as the sum of a), b) and c) cases over all applicable cases. Improvements as a consequence of pharmaceutical care interventions result from addressing cases categorised as '**NO**' or '**ID_S**'. This is:

- Previously undocumented exceptions are identified (Change: **NO** → **NO_{EXC}**)
- The medication is changed (Change: **NO** → **YES/YES_{EXC}**)
- A necessary test/investigation is conducted, documented and consequent action taken (Change: **ID_S** → **YES/YES_{EXC}** or **NO_{EXC}**)

Such improvements are reflected by an increase in the adherence rate.

Result & Conclusion: The use of 'adherence to standards' as an intermediate outcome measure for pharmaceutical care interventions is relevant when standards are based on strong evidence linking treatment processes to clinical outcomes. The proposed algorithm is generic and may be used to operationalise any given set of explicit standards.