

## Adverse Drug Reactions: power, harm reduction, regulation and the ADRe profile

Patients should be checked systematically to ensure that they are not being harmed by their medication. Through case studies of prescriptions of antipsychotics to older adults in the UK, we have shown that if healthcare professionals systematically checked, harm could be prevented.

Healthcare professionals often place too much faith in the medication they prescribe. Prescribed medicines benefit between 4% and 25% of patients, but the harm caused by adverse drug reactions (ADRs) can outweigh these benefits. For example, 11% of hospitalised patients experience adverse effects from their medication, with 0.25% dying of ADRs. Up to 37% of patients with cognitive impairment may experience similar kinds of harm. Yet healthcare systems have failed to adopt standard procedures for checking for these harms, with many professionals finding it difficult to distinguish the negative effects of medication from other forms of illness. This, in turn, gives rise to more prescriptions, and more harm from medication.

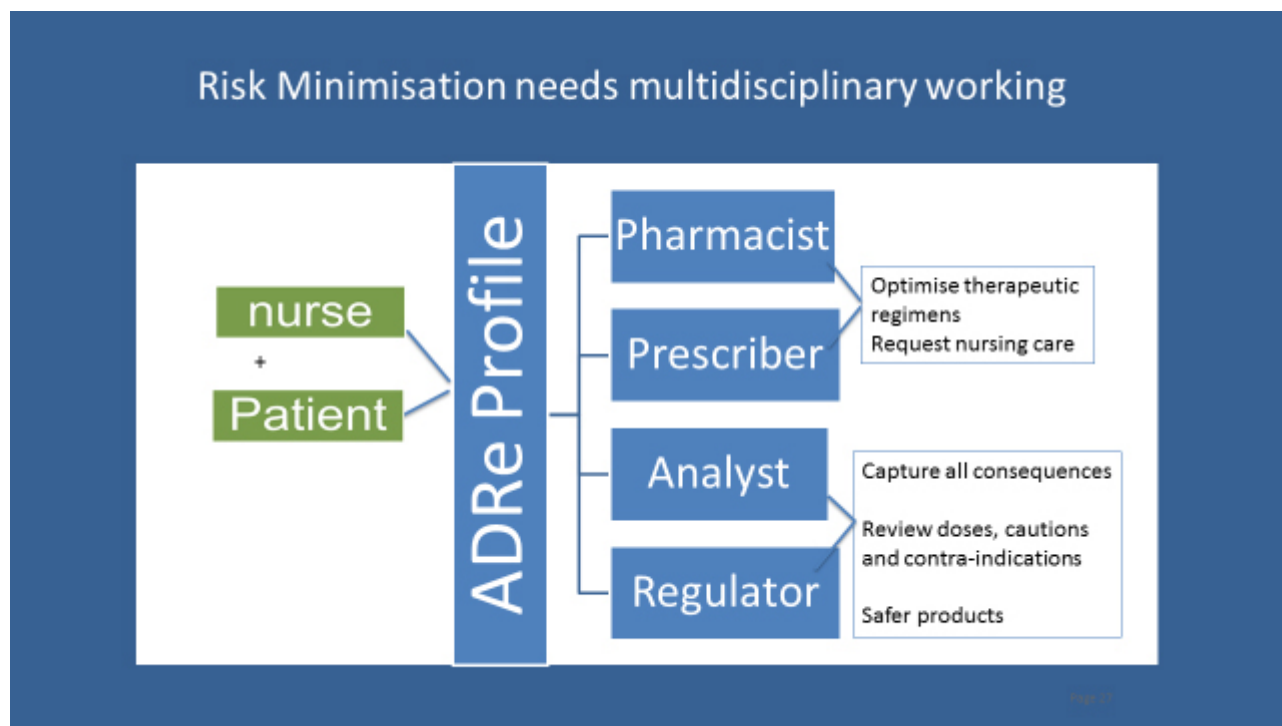


Fig. 1. ADRe records and reports patients' problems.

ADRs are a drain on healthcare resources, causing 5-8% of unplanned hospital admissions, rising to 10% in older adults. This costs the UK's National Health Service up to £1.6bn each year. Even

this statistic may not represent the full problem: up to 60% of cases where patients are harmed by their medicines go unrecognised and unreported. The introduction of a comprehensive and systematic approach that bridges across healthcare professions would go a long way towards addressing these preventable problems.

Our solution is the Adverse Drug Reaction (ADRe) Profile. It asks nurses to systematically check patients for an itemised set of adverse or undesirable effects of their mental health medicines. It also asks them to take action in case of problems, and, crucially, to share that information with pharmacists or those prescribing medicines. It formalises and standardises the approach to monitoring patients prescribed mental health medicines (Fig. 1).

The profile asks nurses to check vital signs, and all the signs and symptoms associated with potential adverse side effects. Nurses then document observations, plus any changes ADRs (Fig. 2). ADRe also covers key areas of wellbeing affected by medicines, including diet, non-prescription medicines, service user's perspectives, and modifications to an individual's care plan. Nurses then pass this completed profile to pharmacists and prescribers, to inform reviews of individual patients' medication. The profile enables a deeper analysis of patients' problems, and enables medication to be changed to avoid harm to patients.

The image shows a printed form titled "ADRe - The Drug Reaction Profile for Medicines in Mental Health". The form is divided into several sections:
 

- 1 Vital Signs:** Includes fields for Heart rate, Irregular rhythm, BP lying/sitting, BP standing, Weight/BMI, Change since last recording (twice), Diets (fasting/intermittent), Change since last recording, Temperature (temporal/axillary/oral/rectal), Oxygen saturation, and SpO2.
- 2 Observations of Problems:** Includes fields for Head/tongue affecting drinking or ADs, Tongue tremor, Feet chaffing, Abnormal movements at rest, Posture abnormal, Gait abnormal on walking, Balance/co-ordination poor, often, ADs bleeding/bruising/haemorrhage, Feeling the cold, Cognitive decline (memory or concentration).
- 3 Reports of Potential Problems:** Includes fields for CNS: Any convulsions (not if epileptic), Behaviour problems, Self-harm, Physical violence to people or objects, Aggression (including verbal), Irritability, Agitation, anxiety, nervousness, Restlessness or pacing, Hyperactivity, Panic attacks, Confusion, Mood fluctuations - high or low mood, and Low energy, weakness, fatigue, apathy.

 The form has columns for "Problems" and "Actions / Notes". A clear plastic container with various pills and capsules is placed over the "Observations of Problems" section. The form also includes a footer with the date "© last updated 2009 / 2002 / 2007 / 2008 / 2014 / 2016 / 2018".

Fig. 2. The ADRe Profile

We found clear benefits to this approach in our case studies and randomised controlled trials. The ADRe Profile collects data on patient problems into a single document that prescribers can use to review medication. Use led to alleviation of patients' pain, falls, sedation, aggression and confusion, and reduced doses of antipsychotics and sedatives. Our findings indicate that the ADRe Profile works: it empowers nurses and carers through a transfer of useful, necessary, and practical knowledge.

Prescribers' lack of engagement with service users and reluctance to de-prescribe perpetuates the social distancing, 'othering', and control of service users. Health problems arising from prescribed medication can be stigmatising and disempowering: antidepressants can cause agitation, nervousness and anxiety, whilst antipsychotics can cause movement disorders and cognitive impairment. Relying on medication to address the problems caused by medication only compounds matters. It can lead to real harm, and places too much power in the hands of those prescribing. As our trials of the ADRe Profile have shown, regulation at the clinical level is insufficient. Healthcare systems need the comprehensive checking of adverse side effects from medicines that the ADRe Profile provides; this leads to improved care and understanding of the impact of ADRs.

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## **Publication**

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