Preventing overdoses with over-the-counter medicines

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Engagement and education of the general public, together with regulatory reforms, are needed to prevent overdoses with non-prescription medicines

Two articles in this issue of the Journal show the ongoing challenge of preventing accidental and intentional overdoses with over-the-counter medicines. The two analyses used the same data source and similar methods, but identified contrasting outcomes of regulatory actions to reduce the risk of overdose.

Arbaeen and colleagues[1] evaluated the impact of a mandatory change in the labelling of over-the-counter cough and cold medicines, advising that these products should not be given to children under six years of age. Following the labelling change in 2012, which targeted both health professionals and parents, the annual number of calls to the NSW Poisons Information Centre (NSWPIC) about accidental overdoses with these products was about 50% lower than in 2010.[1]

Cairns and colleagues[2] examined the effect of a regulatory change that indirectly targeted medication users, the rescheduling of modified release paracetamol from a pharmacy only (Schedule 2) to a pharmacist only medicine (Schedule 3), meaning that it must be stored behind the counter and a pharmacist must be involved in all sales. The authors found no significant change in the number of intentional overdoses with modified paracetamol after the scheduling change in June 2020. It is also concerning that more than one-third of calls regarding intentional overdoses with modified release paracetamol involved children and adolescents, for whom it is unlikely to be indicated.[2]

These two studies, with their divergent findings, illustrate the importance for quality use of medicines strategies of engaging the general public and of regulatory actions taking health behaviours into account. Regulatory action unaccompanied by appropriate education can have unintended consequences, including inappropriate therapeutic shift.[3] Both studies found evidence of such shifts following regulatory changes. A therapeutic shift to herbal cough and cold remedies for young children after labelling changes for cough and cold medicines was presumably driven in part by the desire of parents to ease their children's symptoms. However, this therapeutic shift was problematic, as the number of calls to the NSWPIC about accidental overdoses with herbal products increased.[1] Following the rescheduling of modified release paracetamol, a therapeutic shift to immediate release paracetamol and ibuprofen was

suggested by increased numbers of calls about intentional overdoses with these products.[2] Although the therapeutic shifts were to medicines with lower risk profiles in cases of overdose, both examples indicate the need for public education about the safe storage and use of the alternatives.

The value of strategies directed at medication users was evident in the study by Arbaeen and colleagues.[1] The labelling change for packaging, bottles, and printed information directly informed parents of the updated advice regarding use. In contrast, the greatest effect of the rescheduling of modified release paracetamol would be through pharmacists minimising its provision to people who did not need it. Rescheduling, however, does not address the risk of intentional overdose by adolescents and young adults, which frequently depends on what is available at home rather than what is intentionally bought from the pharmacy.[4] To ensure safe storage of paracetamol at home, pharmacists would need to provide education at the time of sale, particularly regarding its potential misuse and risk to other household members. The consumer medicine information notes that the primary indication for modified release paracetamol is persistent pain, but also implies that it is suitable for treating acute pain.[5] It provides information about what to do in case of suspected overdose, but not advice about the value of keeping only limited quantities at home, particularly in households with people at risk of self-harm. The findings by Cairns and colleagues[2] highlight the need for independent comparative information to be available to medication users regarding the risks and benefits for users on different types of medicines, including their formulations.

To reduce the number of overdoses, Cairns and colleagues[2] call for further up-scheduling of modified release paracetamol. The study by Arbaeen and colleagues,[1] however, reminds us that this is unlikely to be sufficient alone, and that public engagement and education is also needed, as is guidance regarding appropriate therapeutic shifts. This is particularly important given that calls to NSWPIC for intentional overdoses with analgesics increased during the COVID-19 pandemic,[2] as did levels of mental distress among adolescents and young adults.[6,7]

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Quality use of medicines activities are being restructured in Australia, with many now transferred to the responsibility of the Australian Commission on Safety and Quality in Health Care.[8] The new model will require the Commission to play coordinating and advocacy roles to ensure that essential educational and behaviour change strategies in key problem areas are not overlooked, but implemented alongside regulatory reforms to avert unnecessary deaths, harms, and distress.

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8 Australian Commission for Safety and Quality in Health Care. Transition of quality use of medicines programs. 2023. https://www.safetyandquality.gov.au/our-work/transition-quality-use-medicines-programs (viewed Apr 2023). ■