LETTERS

Letters to the Editor

Automated adverse drug reaction detection

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The recent article 'Pharmacovigilance and expedited drug approvals' by Matthew Linger and Jennifer Martin,[1] provided a timely summary of issues and pressures around our national adverse drug reaction reporting program, particularly in a changing Australian regulatory environment.

One factor not raised, but that I would like to highlight, is the potential for automated data analytic techniques to screen for significant (i.e. moderate, severe or fatal) adverse drug reactions. I am referring to events that would have gone otherwise undocumented to the Therapeutic Goods Administration (TGA) by usual reporting routes – manufacturers, clinicians or consumers.

In the tertiary hospital sector, there is interest in achieving this through tools such as International Statistical Classification of Diseases (ICD-10) coding (collected routinely through medical records departments), and Natural Language Processing. These are described as complementary adverse drug reaction reporting tools, which could work to greatly supplement current standard practice.

Tertiary hospitals manage patients with complex care needs. Hospital pharmacists frequently dispense medicines when there is limited global experience with use, but where local prescribers feel their benefit outweighs the risk. Access routes to these medicines can include clinical trials, patient familiarisation programs without Pharmaceutical Benefits Scheme listing, or importation.

Practical examples where these automated adverse drug reaction detection techniques may be useful include:

- severe immune adverse effects to cancer checkpoint inhibitors (nivolumab, ipilimumab and pembrolizumab)
- perioperative drug-induced anaphylaxis
- drug-induced angioedema.

I would be keen to hear the authors' comments on automated detection, particularly in the context of expedited approvals. The Austin Health pharmacovigilance team would look forward to further research funding and TGA collaboration in this area. When serious adverse drug reactions can be detected with greater precision early in the regulatory process, there is potential for the entire patient community to benefit, minimising medicine-related harm.

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REFERENCE

1. Linger M, Martin J. Pharmacovigilance and expedited drug approvals. Aust Prescr 2018;41:50-3. https://doi.org/10.18773/austprescr.2018.010

Jennifer Martin and Matthew Linger, the authors of the article, comment:

Thank you for raising the excellent point regarding the potential for automated data analytic techniques to screen for significant events. We agree this would be a helpful source of data collection for new drugs, those using the provisional approval process and those with added significant new concerns, such as medicines blocking major cell regulatory pathways like the checkpoint inhibitors. The changes around the electronic medical record will be a step in this regard. However there are issues with some of these automatic techniques in that they still require clinicians to consider that a patient symptom, presentation or disease might be drug related, or even dose related. Research has found that this link is quite commonly missed in clinical practice.[1]

Further, the systems around publicly and timely reporting of this collated data by the TGA still require systems updating to enable clinicians to become aware as soon as there is a signal that a drug might have unknown or unexpected toxicity. Support to get such upgrades before the provisional approval pathway is rolled out is encouraged.

REFERENCE

1. Skinner TR, Scott IA, Martin JH. Diagnostic errors in older patients: a systematic review of incidence and potential causes in seven prevalent diseases. Intern J Gen Med 2016;9:137-46. https://doi.org/10.2147/IJGM.S96741

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