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COMMENTARY

Systematic Collection of Patient-Reported Adverse Drug Reactions: A Path to Patient-Centred Pharmacovigilance

Ethan Basch

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1 Introduction

Over the past 15 years, evidence has mounted that patient self-reporting of symptomatic adverse drug reactions is both feasible and informative. Multiple recent reports have described programmes internationally in which patient self-reports provide data beyond reporting by health professionals [1–5]. Various models have been used and there are several essential lessons to be learned from these experiences, in addition to work using patient-reported data in related contexts such as clinical trials and routine clinical practice.

2 It is Essential to Systematically Collect Information from Patients Rather than Rely on Spontaneous Reporting

Many adverse event reporting systems rely on voluntary (spontaneous) reports by patients and/or clinicians. Although submitted information can be informative in some cases, the denominator of potential reporters is unknown, and many adverse reactions are missed due to lack of interest, willingness, availability, or awareness of stakeholders to report. As a result, the absolute number of reports collected via these systems is generally low and often does not reflect the experience of patients compared with systematic collection [6]. Patients are not engaged as partners in the data collection enterprise.

E. Basch (✉)
Cancer Outcomes Research Program,
University of North Carolina, 170 Manning Drive,
Chapel Hill, NC 27599, USA
e-mail: ebasch@med.unc.edu

Systematic elicitation of information from patients provides a known denominator and a more comprehensive picture within a population. This can be achieved in limited populations via registries, or through wide implementation using existing or envisioned infrastructure to engage patients. The paper by Leone et al. in this issue of *Drug Safety* [7] describes successful implementation of a regional programme through the mechanism of local pharmacies. Information is systematically elicited from patients who are engaged by their local pharmacists. This approach does more than use an existing infrastructure of local pharmacies for distribution of questionnaires–it creates a partnership between practitioners and patients in an endeavour to understand the experience of both the individual patient and the broader population.

This programme mirrors successful engagement approaches in other contexts, such as clinical trials where data managers form relationships with patients to encourage reporting, or routine practice settings where customized invitation letters are sent to patients from their doctor or nurse.

3 Backup Data Collection Systems Reduce Missing Data

A lesson learned from the collection of patient-reported information in prospective clinical trials and registries is that the frequency of missing patient reports is highly dependent on how this information is collected. In particular, data can be recovered from those who are initially unable or unwilling to self-report, through the use of backup data collection methods. These may include electronic reminders via mail, email or telephone, with a human call to those who continue not to report. This

approach requires a near-real-time monitoring system for who complies and who does not, in order to identify individuals for targeted backup data collection.

4 Linking Patient Reports to Other Patient-Specific Information is Valuable

Often, patient reports are collected via approaches not linked to electronic health records or other registries containing confirmed health and treatment information at the patient level. As a result, there is reliance on self-report for information about diagnosis, co-morbidities, allergies and other treatments. This is a substantial limitation when trying to understand the etiology of reactions, particularly rare reactions. An advantage of approaches that are tied to clinical practices or pharmacies, or are within national health systems, is the ability to link to such information for analysis of aggregated data.

5 Mixed Quantitative and Qualitative Analyses may Enhance Understanding of Adverse Drug Reactions

Semi-structured interviews with patients receiving particular treatments may provide information about common outcomes related to a treatment. Additionally, interviews with individuals who report an adverse drug reaction may provide additional insights about the quality and aetiology of that reaction. Instituting a mechanism that rapidly identifies individuals reporting reactions can allow for timely contacting and interviewing.

6 Involvement of Healthcare Providers with Patient Engagement and Data Collection at the Point of Care is Beneficial

Involving professionals such as pharmacists, nurses or physicians to enlist their patients to participate in data reporting plays several important roles. It activates patients and raises awareness of the importance of this activity. It builds upon the relationship of provider and patient, creating an active partnership in the pharmacovigilance enterprise. Moreover, reported information can be acted upon by a responsible individual, or can be reported to other local providers as appropriate. Finally, it provides a mechanism for a provider who knows the patient to report complementary clinical information or enable linkage to a medical record.

As we enter an era of increased attention to patient perspectives, preferences, engagement, activation and decision making [8], it is essential to include patients in processes for understanding the safety of drug products at every step of the drug product lifecycle—starting with early drug development through widespread community use.

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