

INTRODUCTION

The internationally agreed definition of primary health care is provided in point VI of the Declaration of Alma-Ata.¹ Although each country interprets the concept slightly differently, overall, *primary health care* describes the activity of health care providers who are the first point of health system contact for patients and who are based in a community, rather than in a hospital.²

The purpose of this paper is to critically appraise the methods used to research patient safety in primary health care studies and the metrics (measures) this research uses and produces. This document has been developed as part of a series of reviews proposed by the World Health Organisation (WHO) World Alliance for Patient Safety aiming at understanding the tools available for conducting research on patient safety in various settings.³

Companion papers review methods and measures used for patient research in acute hospital settings (focusing on higher income

countries),⁴ and in transitional and developing countries.⁵ In addition there are papers on the ontology,⁶ epistemology,⁷ and scope of patient safety research⁸ that set the context for these three reviews.

To date concern about the safety of patients in hospital settings has driven most research in the field. The seminal reports about patient safety in the US⁹ and the UK¹⁰ excluded primary care from their discussions. The UK report was specific about this exclusion and it was implicit in the US report. Hospitals were the focus of attention and have remained so to date.

A stronger emphasis on primary care patient safety research is important because the overwhelming majority of healthcare is delivered outside hospitals, in primary care settings.¹¹ Many safety incidents identified in hospitals originate elsewhere, often in primary care¹²⁻¹⁴ and most burden on health systems arises not from rare mistakes with drastic consequences, but from the more

mundane incidents that have effects that are magnified by frequent repetitions and exposure of a large number of people.¹⁵

Primary care may hold different threats to patient safety from hospital settings due to both the health care delivery environment and the type of health services provided. Primary care providers often have less control over care management and delivery than in the more continuously monitored hospital admissions, and more than one site is often required for an episode of care (having implications for patient and information transfer). Primary care sites are not necessarily designed for this purpose (for example: patients' homes, providers' cars, or on roads). As well, episodes of primary care may extend over very long time frames – sometimes years. There is an argument that incidents with immediate or close observable consequences should be defined within the *safety* paradigm but incidents with delayed effects should be regarded as primarily a *quality* issue.⁶ From a primary care

perspective this distinction based on time is problematic, but there remain challenges in identifying and measuring patient safety incidents that are associated with lengthy latency, and where incomplete records may mask complete understanding of contributing factors.

Further complicating patient safety research in primary care are the characteristics of patients who commonly present in primary care with undifferentiated problems, uncertain diagnoses and multiple co-morbidities.¹⁶ Appropriate and inappropriate delays in protecting their safety by making a correct diagnosis must be subjectively assessed. There are also substantial challenges in protecting patients' safety where the systems to support safe care may be poorly defined and idiosyncratic.

There is one notable exception to the overall dearth of patient safety research in primary care. Because of the need to test the safety of pharmaceutical products before they are released onto the market, and to

regulate their use after release, the pharmacovigilance literature has generated a great deal of knowledge about drug safety and much of this is primary care-based (see, for example¹⁷⁻²⁵). This paper reviews the methods and measures used for patient safety research conducted in, about, and for primary care patients and providers. We excluded papers concentrating on one particular primary care process or function (such as prescribing) and we focus instead on research aimed at investigating the full spectrum of patient safety issues in primary care.