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## **Title: Health System Trials**

Pragmatic randomised trials aim to provide evidence to support decisions by stakeholders in healthcare systems (patients, clinicians, policy makers). The typical pragmatic trial recruits a group of participants who then provide data for the trial using purpose built data collection systems. Then at the end of the trial – all is disbanded. This approach is costly and frequently fails to recruit sufficiently large or representative samples.

Since the advent of electronic data, pragmatic trials are increasingly using routine health data collected from administrative, clinical and patient sources. A new group of trial designs have emerged which we describe as ‘Health System Trials’. These include Registry-based Randomised Controlled Trials (RRCTs), Electronic Health Record (EHR) Trials, Administrative Data (AD) Trials and Trials within Cohorts (TwiCs). These four designs purposefully utilise existing and/or newly created health system data structures for one or more trial activities: identifying potential trial participants, recruitment, randomisation, process and outcome data collection, etc. The process of informed consent is often spread out (staged) as occurs in routine healthcare especially with TwiCs designs.

By utilising populations within health systems and the data that derives from their healthcare encounters, these trials efficiently recruit large representative populations and obtain short and long term outcomes. These designs reduce the effort and cost of trials whilst improving the applicability of the trial results for decision makers in health systems.

We discuss the opportunities for these types of trial designs to be integrated within health systems, enabling the continuous generation of knowledge that is an essential feature of learning health systems.

CONSORT Reporting guidelines for Trials Using Cohorts and Routine Health Data are currently being developed. Drawing on development work for these guidelines we describe real world examples of ‘Health System Trials’ including examples of nascent vertical (disease focussed) and horizontal (e.g. practice based) learning health systems.

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