

# Routinely collected electronic health data and STI research: RECORD extension to the STROBE guidelines

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Electronic medical records (EMRs) are increasingly being used by health services including those that test for and treat sexually transmitted infections (STIs).<sup>1-3</sup> The implementation of EMRs opens up new opportunities for improving the quality, effectiveness and efficiency of sexual health services and brings with it the potential for enhanced research capacity.<sup>1-3</sup> Information from routinely collected health data can and should be leveraged for the evaluation of clinical services to improve STI and HIV care and to measure the impact of interventions aimed at curbing STI. This information has already been captured and, if appropriately harnessed, constitutes a rich repository of data that can be used for research.

Because information in EMRs has generally been gathered for patient management rather than to answer research questions, the use of such data for studies introduces potential limitations and biases. When examining treatment outcomes retrospectively for instance, observational studies will naturally fall short of rigorously conducted randomised trials. However, prospective trials can be prohibitively expensive and their results may not be generalisable to diverse real world settings and populations. In addition, observational research carries with it specific strengths and weaknesses. Transparency in reporting has been identified as key to the identification of possible bias in research. The guidelines for the Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) include a checklist of items recommended to ensure complete and transparent reporting.<sup>4</sup>

Observational research using EMR data carries with it specific strengths and weaknesses related to the data themselves. Growth in the use of routinely collected health data for research prompted an extension of the STROBE guidelines for routinely collected health data. This expansion in the use of routinely collected health data for research has led to the development of the guidelines for the REporting of studies Conducted using Observational Routinely collected Data (RECORD).<sup>5</sup> To inform the development of the RECORD guidelines, stakeholders including clinicians, researchers, journal editors, policy makers and pharmaceutical industry representatives were surveyed and invited to recommend essential items for reporting, and, as a further stage, to rank recommendations.<sup>6</sup> Through this process, a need for greater clarity in the reporting of the methodological aspects of studies using routinely collected health data was identified. Themes recommended for inclusion in the RECORD statement included: how subjects included in the study were selected; clear definitions for all exposures and outcomes; any filtering of participants based on data quality and availability; and discussion of the implications of using data that were not collected to answer the research question.

Sexual health services planning to adopt EMRs or which already have EMRs should consider how these are designed and used so as to optimise their application for evaluation and research. EMRs typically include unstructured, free text entries entered by healthcare providers during patient encounters. With technological advances it is likely that we will soon see the increased capability of computers to read unstructured text and turn these into data that can be meaningfully used for research. This will permit automated data mining of massive data sets, provided ethical approval is obtained.<sup>7</sup> For sexual health services, EMRs pave the way for automated clinical audits, which may be much faster, less labour-intensive, and less prone to error than traditional audits using paper records. In addition, there exists the ability to use EMR data as

part of large, powerful research studies, particularly when they are linked to other data sources such as population, socio-economic, health administrative or clinical registry data. However, the methods, accuracy and completeness of these linkages are important concerns<sup>8</sup> and require transparent reporting as described in the RECORD guidelines.

The inevitable expansion of the availability of EMR data will mean that we can expect an accumulation of vast amounts of routinely collected health data that can be used to improve the health of patients and populations.<sup>9</sup> The term 'Big Data' has been used to describe extremely large data sets that are analysed computationally to reveal otherwise hidden trends and patterns. The use of Big Data has been applied in fields as diverse as financial trading and national security and may prove useful for tracking the outbreak of infectious diseases in real time on a global scale.<sup>10</sup> Could Big Data help to improve the control of STI and HIV? In England, the genitourinary medicine clinic activity data set collects individual level information on patient demographics, STI services provided and diagnoses from STI clinics across the country. Between 2009 and 2013 electronic information from 25 million patient records and 205 STI clinics were submitted to this data set.<sup>11</sup> The Australian Collaboration for Chlamydia Enhanced Sentinel Surveillance, a national network of clinical sites which includes sexual health, family planning and general practice clinics, collates and automatically analyses routinely collected individual level data on patient demographics and STI testing from over 100 services across Australia.<sup>12</sup> Large-scale databases such as these, which draw electronic data from extensive networks of clinics, have the potential for revealing trends in the epidemiology of STI and HIV and, if engineered carefully, could be powerful tools for bettering clinical management and patient outcomes. However, the methods used to conduct research using these data, and the importance of transparent and complete reporting cannot be overemphasised. Transparency and completeness of reporting will ensure that the risk of bias and study strengths are available to all who may use the research to implement change.

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