**The need to improve reporting of routinely collected dermatology data for patient benefit**

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The increasing availability of routinely-collected health data sources including electronic medical records, administrative data and registries, represents a major opportunity for efficient dermatology research. Understanding the epidemiology of skin diseases is critically important for a variety of reasons. Firstly, epidemiology can highlight the burden of diseases, including changes in patterns of skin diseases over time and place. These observations can provide aetiological clues to, for example, the rapidly increasing prevalence of eczema in developing countries.1 Routinely-collected health data can also help with both hypothesis generation and testing, and can provide signals and discoveries to inform translational research and trials. Randomised trials have provided excellent data about the efficacy of therapies in skin diseases, but are often challenged by logistics including time, cost and limited sample sizes, and their generalizability may be limited by strict inclusion criteria.2 Routine data may be a useful tool to bridge the gap between need and available resources and to provide key evidence about the real world effectiveness of therapies for skin diseases, including populations that might be excluded from clinical trials. For example, routine data could be used to undertake pharmacoepidemiology studies such as phase 4 post-marketing studies of biologics for risk and benefit or to identify adherence to biologic therapies. Data on rare but potentially serious adverse events typically only emerge from large databases of drug use in the population rather than trials. Indeed, the informatics revolution and the major opportunities from increasing access to healthcare databases have been highlighted in the recent BJD position statement as a major factor contributing to the growth of epidemiology of skin.3

Despite their vast potential, the use of routinely-collected health data for research also brings new challenges for researchers, editors, and those making decisions about healthcare policy. Routinely-collected health care data by definition are not captured to specifically answer an *a priori* research question. These data include a broad spectrum of resources captured for a wide variety of reasons, including clinical care of patients, administrative and billing purposes. Understanding the strengths, limitations and resulting biases associated with using individual data sources is challenging. The reporting of research undertaken using routine data is poor, with two recent systematic reviews identifying poor reporting of validation studies from routine health data; inadequate reporting compounds the challenge for readers of research and those using research to inform health policy decisions.4 Poor reporting of research is a major source of research waste, as it can reduce the usefulness of research findings, lead to unnecessary replication, and lead to conclusions that may not be valid.5

Reporting guidelines are useful to ensure transparency and to inform readers what was planned, what was done and what was found in the research. Reporting guideline initiatives, such as the CONSORT initiative, have led to an improvement in research reporting.6,7 The guidelines for Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) have been a welcome development to improve the reporting of observational studies such as case-control and cohort studies and provide a checklist of the minimum items that should be reported.8 STROBE has been implemented by the BJD since its publication in 2008.

The majority of research undertaken using routine data is observational in design, however there are specific features relating to the use of routine data for research that are not currently addressed by STROBE. These include the use of codes and algorithms to identify participants, exposures and outcomes, reporting of linkage characteristics, when linking more than one database and the characteristics of databases.

The REporting of studies Conducted using Observational Routinely collected health Data (RECORD) initiative is an international collaborative effort involving more than 100 stakeholders which has developed an extension to the STROBE guidelines to improve the reporting of research using routine health data. The RECORD guidelines were created using methods proposed by members of the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network.9 Briefly, following a wide recruitment of stakeholders representing researchers, editors, pharmaceutical industry and policy makers, a series of modified eDelphi surveys were undertaken to identify proposed themes stakeholders considered essential to reporting of research using routine data. Survey findings and input from all stakeholders using a message board informed the creation of the record checklist and explanatory document. The final RECORD checklist (Table 1) and explanatory document are available online at record-statement.org or in PLoS Medicine.11 The RECORD Steering group welcome comments and recommendations from any interested parties.

The RECORD statement focuses on observational studies, as an extension to STROBE. However, increasingly, routine data are being used for research that is not observational in nature, including pragmatic randomised controlled trials, where they have the potential for great efficiency and inclusiveness.12 In future, RECORD will be modified to encompass interventional studies and other research designs.

The RECORD Steering group are delighted that the *British Journal of Dermatology* has decided to endorse the RECORD statement and to implement its use for authors submitting relevant manuscripts. The RECORD Steering group look forward to working with the BJD to help implement the checklist. Endorsement of the checklist may not be sufficient to improve research reporting – the implementation of RECORD through rigorous evaluation and education of peer reviewers, authors, and editors are also essential. The RECORD Steering committee is currently planning prospective assessment of the impact of adopting RECORD and the quality and completeness of submitted reports using routine health data. Improving the quality of reporting of dermatology research using routinely collected health data and reducing research waste will ultimately help patients with skin disease.

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**References**

1 Odhiambo JA, Williams HC, Clayton TO *et al.* Global variations in prevalence of eczema symptoms in children from ISAAC Phase Three. *J Allergy Clin Immunol* 2009; **124**: 1251-8.e23.

2 Griffiths CE, Reich K, Lebwohl M *et al.* Comparison of ixekizumab with etanercept or placebo in moderate-to-severe psoriasis (UNCOVER-2 and UNCOVER-3): results from two phase 3 randomised trials. *Lancet* 2015; **386**: 541-51.

3 Anstey A. The British Journal of Dermatology: 125 years, 28 editors, enduring values. *Br J Dermatol* 2013; **169**: 238.

4 Langan S, Schmitt J, Coenraads P *et al.* The reporting of observational research studies in dermatology journals: a literature-based study. *Arch Dermatol* 2010; **146**: 534-41.

5 Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. *Lancet* 2009; **374**: 86-9.

6 Altman D, Schulz K, Moher D *et al.* The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001; **134**: 663-94.

7 Plint AC, Moher D, Morrison A *et al.* Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. *Med J Aust* 2006; **185**: 263-7.

8 von Elm E, Altman D, Egger M *et al.* The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet* 2007; **370**: 1453-7.

9 Moher D, Schulz KF, Simera I *et al.* Guidance for developers of health research reporting guidelines. *PLoS Med* 2010; **7**: e1000217.

10 Nicholls SG, Quach P, von Elm E *et al.* The REporting of Studies Conducted Using Observational Routinely-Collected Health Data (RECORD) Statement: Methods for Arriving at Consensus and Developing Reporting Guidelines. *PLoS One* 2015; **10**: e0125620.

11 Benchimol EI, Smeeth L, Guttmann A *et al.* The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Med* 2015; **12**: e1001885.

12 Gulliford MC, van Staa T, Dregan A *et al.* Electronic health records for intervention research: a cluster randomized trial to reduce antibiotic prescribing in primary care (eCRT study). *Ann Fam Med* 2014; **12**: 344-51.