



Towards improving the reporting quality of clinical case reports in complementary medicine: Assessing and illustrating the need for guideline development



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Summary

Background: Case reports have had a varying level of recognition as a source of evidence throughout the history of medicine. In recent years, there has been a revival of interest in clinical case reports in both conventional and complementary medicine. There is a need to further improve the reporting quality of clinical case reports of different Complementary and Alternative Medicine (CAM) therapies.

Objectives: To provide an overview of the different objectives for clinical case reports, identify those that are most relevant for CAM, and to develop a conceptual framework for purpose orientated clinical case reporting guidelines for CAM therapies.

To practically illustrate the chosen approach by developing a clinical case reporting guideline for homeopathic cases.

Methods: The various objectives of clinical case reports were described by Prof. Milos Jenicek, and the potential relevance of these objectives for CAM were discussed and graded by a mixed panel of experts.

A conceptual framework for developing clinical case reporting guidelines for CAM treatments with specific objectives is proposed. The aim is to integrate both 'generic' and 'CAM therapy specific' quality items.

This framework has been practically applied to the development of a reporting guideline for clinical case reports in homoeopathy which will be reported in a second article.

Results: An overview is given of the clinical case reporting literature. The conceptual framework for the development of purpose orientated CAM clinical case reporting guidelines is presented. This framework is based on alignment with the recently published 'generic' CARE guideline for reporting of clinical case reports, whilst addressing the CAM specific elements at the same time.

Conclusions: The scope and importance of clinical case reporting guideline development in CAM is illustrated. A conceptual framework for developing CAM specific clinical case reporting

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guidelines was established. It has been implemented using homoeopathy as an illustration, and this will be reported in a separate article. Further improvements in clinical case reporting in CAM will greatly contribute to CAM research and education, as well as to improved patient care.
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Introduction

Case reports have had a variable level of recognition as a source of evidence throughout the history of medicine. Whilst case reports have remained consistently important as part of teaching medicine, the value attributed to case reports as a source of evidence has been greatly diminished since the predominant emergence of modern, evidence based medicine in the second half of the 20th century.¹ Within this framework several 'hierarchies' of evidence have been developed for assessing the quality of evidence, The US Preventive Services Task Force and the Oxford Centre for Evidence-Based Medicine schemes being prominent examples. In each of these, case reports feature low in, or at the bottom of, the hierarchy.

The hierarchical approach towards evidence has been criticised as being too one-sidedly focused only on the perspective of establishing causal attribution to a treatment within the context of assessing efficacy. Whilst from this perspective clinical case reports are justifiably graded as weak evidence, from another perspective such as for instance safety assessment, case reports are often the first 'signals' of potential adverse drug reactions and sometimes single cases can even contribute significantly to establishing a causal link. In particular in the CAM community, nonhierarchical systems have been propagated, using words and metaphors such as an 'evidence house',² 'evidence profile',³ 'evidence mosaic',⁴ or a 'circular' approach towards evidence.⁵

At the core of the above approaches is the notion that the hierarchy of evidence depends on the principal research objective, and as illustrated by the above example, the value of case reports is different in safety assessment as compared to efficacy assessment. Furthermore case reports can provide valuable insights in the development and cure of diseases in the course of time. The latter is also referred to as 'disease evolution' and this concept has been developed in various CAM systems such as for instance classical homeopathy⁶ and bioregulatory medicine.⁷ These research purposes can be categorised further using dimensions such as 'hypothesis confirmation' versus 'hypothesis generation', 'ideal world' versus 'real world' and 'absolute' versus 'relative' effects.⁸ Within such a framework, case reports are particularly appropriate/strong methods for hypothesis generation in the 'real world' setting of daily medicine.

The main pioneer who contributed to a re-appraisal of the millennia old art of case observation and case reporting in medicine is Prof. Milos Jenicek who published a book on the topic⁹ in the late 1990s. In other disciplines, such as the social sciences, further advances and contributions were made in the domain of case study research.¹⁰ It should also be noted that in the discipline of psychology, single case experimental designs were already developed in

the 1970s and received increasing attention in psychology,¹¹ conventional medicine, and also complementary medicine¹² in the 21st century. However, single case experimental designs are essentially clinical trials and the focus of this paper is on single clinical case reports as observational data.

In medicine, it was only in the 21st century that the interest in clinical case reports started to gain further momentum¹³ and this was accompanied by the launch of several journals dedicated to the publication of high quality clinical cases. The first of these journals, 'Grand Rounds', started publishing in 2001 and after this several other journals were launched, including 'Case Reports in Medicine' and 'The Journal of Medical Case Reports' as the most important general case journals, as well as a number of discipline specific cases journals (e.g. Elsevier recently launched a respiratory medicine cases journal). To facilitate easy exchange of information, most operate on an 'open access basis' and some journals (e.g. the BMC Cases Database associated with the Journal of Medical Case Reports) and disciplines, e.g. psychotherapy¹⁴ have set up associated online clinical case registries/archives.

A parallel development in Evidence Based Medicine has been the proliferation of reporting guidelines on different types of research studies, notably clinical trials (CONSORT statement) and Systematic Reviews (PRISMA statement). Apart from these 'high profile statements', there are currently a broad range of reporting guidelines available, focusing on a wide range of quantitative and qualitative research designs, as well as specific clinical domains. For an overview of reporting guidelines in general, visit the EQUATOR website (<http://www.equator-network.org/home/>). Surprisingly, despite this proliferation of reporting guidelines, until recently there was no published general reporting guideline on clinical case reports, and within specific clinical domains, there was only a guideline on reporting cases in clinical behavioural psychology.¹⁵ Also, the journal instructions to authors of case reports are limited.¹⁶ A positive development in this respect is therefore the publication of the CARE guideline for the publication of clinical case reports.¹⁷ The development of this guideline was inspired by the pioneering work of Prof. Jenicek, as well as the expert meeting referred to in this paper.

Building on the CARE guidelines, there is a need to further develop a scientific framework how to improve the reliability and value of clinical case reports in different CAM therapies for a variety of purposes. The aim of this paper is to provide an overview of the different objectives for clinical case reports and to identify those which seem most relevant and important to develop further in the context of that particular CAM modality. This approach has been implemented in the domain of homoeopathy, and will be reported in a separate article.

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