



Guidance for Writing a Clinical Informatics Case Report

Matthew Sakumoto¹ Jeffrey A. Nielson²

¹Department of Medicine, Sutter Health, San Francisco, California, United States

²Department of Emergency Medicine, Kettering Health Network, University Hospitals Western Reserve Hospital, Northeast Ohio Medical University, Rootstown, Ohio, United States

Address for correspondence Matthew Sakumoto, MD, Department of Medicine, Sutter Health, 350 Rhode Island St, Ste 200, San Francisco, CA 94103, United States (e-mail: sakumoto@ucsf.edu).

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Introduction

Variation in human biology means that two seemingly similar patients may have different clinical presentations or therapeutic responses. Patient-centered case reports highlight these novel cases and help to broaden clinicians' knowledge of clinical manifestation of disease, diagnostic approach, or therapeutic alternatives. Similarly, in applied clinical informatics (CI), informatics professionals must grapple with the heterogeneity of health system structures and digital health tool configurations. Exposure to a breadth of different informatics program designs and implementations is crucial to this learning process. Sometimes known as organizational case reports, these nonclinical case reports provide educational exposure to multiple perspectives, different health system settings, and a variety of electronic health record (EHR) products. In the informatics literature, we call these CI case reports, and they offer insights into CI in a specific real-world context while illustrating fundamental CI principles. Examples of CI case reports are published in *NEJM Catalyst*, the *Journal of the American Medical Informatics Association (JAMIA)*, and *JAMIA Open*, *Applied Clinical Informatics (ACI)* and *ACI Open*, *Journal of Medical Internet Research (JMIR)*, and others.

CI case reports should be viewed as inspiration and education and not necessarily limited by a requirement for evidence generation. Organizational case reports are the springboard for ideas and future novel discovery from those on the frontlines. In this editorial, we want to facilitate a process where innovation and implementation at the local or regional level can have a wide impact on the broader community. We provide a brief outline of expectations for CI case reports, and our goal is to explain how authors can demonstrate CI significance, relevance, and impact

(**Table 1**) in their case reports. Additionally, we provide guidance to trainees and early career faculty on how to structure the planning phases of a local pilot project to facilitate dissemination of their findings in a manuscript or other scholarly presentation.

Expectations for Clinical Informatics Case Reports

While there are many examples of standardized reporting guidelines on the Enhancing the Quality and Transparency Of health Research (EQUATOR) Network,¹ there are few published recommendations specific to CI case reports. The "Methodological framework for organisational case studies" by Rodgers et al sets out broad requirements for rigorous and consistent reporting without constraining methodological freedom. This framework identifies four overall sections (describing the design, data collection, and data analysis and interpreting the results) and several reporting standards aimed at improving the consistency, rigor, and reporting of organizational case-report research.² In the following sections, we will expand on these sections with CI-specific guidance for design description, data collection, and data analysis frameworks.

Problem Statement and Study Design

Similar to clinical case reports, the introduction provides an appropriate background for the problem and its importance. A focused literature review also identifies prior descriptions of the issue and any previous solutions.

Problem statement/objectives: it clearly states that the problems being addressed at current state, why an informatics solution was needed, and the anticipated outcomes. The

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Table 1 Checklist for completion of elements of a clinical informatics case report

	Complete?
Problem statement and study design	
Statement of problem and importance?	
Explanation of why an informatics solution is needed?	
Study type delineated (proof of concept, implementation, or case series)?	
Context	
Contextual factors (patient population, software used, type of health system) sufficiently described to assess generalizability?	
Methods	
Core informatics concept(s) utilized?	
Uses an established design methodology or evaluation framework?	
Sufficient methodological detail to evaluate the validity and feasibility of the product or process described?	
Data collection and data evaluation	
Data type(s) feasible and consistent with the study type?	
Research question is aligned with the appropriate framework, data collection plan, and method of analysis?	
Results	
Results address the problem statement?	
Discussion/conclusion	
Findings are of broad interest?	
Includes limitations and lessons learned?	

objectives should also reflect specific informatics fundamental knowledge or skills such as clinical decision support (CDS), data standards, interoperability, security and privacy practices, or health policy and regulatory frameworks. Other examples include improving care delivery and outcomes, development and deployment of enterprise health information systems, data governance and data analytics, and leadership and professionalism.³

Type of study: the introduction names the type of CI case report, including proof of concept, implementation report, or case series.⁴ A proof of concept case report examines an informatics solution or process independent of an implementation. These are often in the preliminary design or development phase, but there is room in the academic literature for advanced examples or interesting new concepts. An implementation case report examines how the deployment of an informatics solution is successful or fails in a health care system. As the most common type of CI case report, they explain the complex dynamics of matching the right informatics programs with health care system needs. A case series is a useful way to describe and compare a series of one of the aforementioned types. Usually, a case series involves only one program across several settings or an iterative implementation of the same program, such as successive quality improvement plan, do, study, act (PDSA) cycles.

Each study type is associated with different methodological frameworks and commonly used CI frameworks are

detailed in [Table 2](#). The methodological approach should align with the research question and study type.

Context

The context for the CI case report provides the equivalent of a hospital system's "past medical history" by describing the type of clinic or health system (e.g., rural, urban, multihospital), the target population (which could be patients or clinical end users), and the current and relevant past information systems (applicable EHR vendors, applications, and versions). Context is important because often these environmental factors have the greatest effect on the success of the applied solution.

Methods

The methods section is the main portion of the CI case report and is a design description or process description. Providing a detailed description allows for greater understanding, potential reproducibility, and allows the reader to evaluate the validity and feasibility of trying the intervention in their own system. The "Methods" section often has several subsections and headings that can vary based on the type of study and framework. We strongly suggest considering addressing all aspects of one of the frameworks from [Table 2](#) in the "Methods" and later in the "Discussion," citing the one you use at the beginning of the "Methods" section.

Table 2 Frameworks to describe and discuss clinical informatics case reports

Framework	Description
RE-AIM (1999–2019) ⁶	This model was designed to describe technology transfer/implementation in public health and behavioral health. Though mostly focused on describing proposed research interventions, it can be applied to operational goals and success factors. ⁷ It has been extended to HIT. ⁸ RE-AIM has five key dimensions with many specific sub-elements: reach, effectiveness, adoption, implementation, and maintenance. RE-AIM analyses do not need to include all sub-elements.
Availability, use, benefit (2005) ⁷	Sittig describes three phases of measuring and evaluating health information infrastructure. An analysis of any of these phases could be used as a basic approach to creating a case report's data collection and evaluation section.
The Systems Engineering Initiative for Patient Safety (SEIPS) 3.0 (2006–2020) ^{9–11}	The SEIPS "is a theoretical model rooted in human-centered systems engineering or 'human factors/ergonomics'. The model depicts three major components, the work system, processes and outcomes; key characteristics or factors of each; and how the components affect one another." ¹¹ The SEIPS model has been effective at evaluating EHR change processes. ¹¹ Fig. 4 in the SEIPS 3.0 paper could be used as a starting point for conceptualizing the discussion. ¹⁰
Consolidated framework for advancing implementation science (CFIR) ^{12,13}	The CFIR is a consolidation of nineteen published general healthcare implementation models, theories, and frameworks with a goal of aligning terminology and completeness of approach. It consists of five domains: "intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation." ¹³ The five domains include a total of thirty seven constructs with clear definitions providing a straightforward outline for describing a CI case report. This manuscript contains the best definitions for terminology, but these are often used inconsistently in the literature.
Sociotechnical model for studying HIT ¹⁴	This HIT-specific model defines the eight "dimensions" of a complex adaptive HIT system. These dimensions are straightforward, interdependent and interrelated concepts. With over 130 PubMed citations, this has been a popular analysis framework.
STatement on Reporting on Evaluation studies in Health Informatics ¹⁵ (STARE-HI) model	This health informatics-specific framework focuses on improving the quality of reporting on evaluation studies. The STARE-HI elements are organized around fourteen common manuscript headings to help authors and reviews apply appropriate judgements of validity and generalizability.
Additional resources	An extensive list of additional theories are listed on "Theories Used in IS Research Wiki" and include over 120 additional theories and frameworks. ¹⁶

Abbreviations: HIT, health information technology; RE-AIM, reach, effectiveness, adoption, implementation, maintenance.

A proof of concept description includes the various solutions utilized, the anticipated end users, and could show user interface screenshots and workflow diagrams. Links to web site demonstrations may be included but should never replace attached content since web content is not durable and does not meet the needs of long-term knowledge sharing and archiving. The proof of concept description discusses proposed workflows and data management plans. An implementation case report includes specific details about the setting (size of practice and available resources), adoption plan, proposed success metrics (whether or not the end points have actually been met yet), and anticipated or actual barriers faced. In a case series, highlighting the foundational process, note the overall thematic similarities, and then highlight any key differences in outcomes across settings or iterations.

Data Collection and Data Evaluation

The design or process descriptions from the Methods section are analogous to the Subjective section of a clinical case report. Similarly, the Data Collection section of a CI case report is analogous to the Objective section of a clinical case report (which includes physical exam, laboratory, and imaging data to further explore observations presented in the clinical history). CI "vital signs" could include adoption rate, system usage, throughput times, or changes in billing or revenue. Since many CI projects have long timelines and lots of metadata, there are many opportunities for data collection.⁵

The primary objective(s) of the project are measured by key metrics that objectively (either quantitatively or qualitatively) measure success. We recommend choosing metrics that are

feasible for collection at outside sites (to improve potential generalizability). Studies often collect data on multiple secondary metrics, and it is worthwhile to list in an appendix; all the metrics examined for transparency. Consider also collecting data on potential indirect effects to operations. For example, a CDS tool may decrease infection rate, but increase hospital length of stay. Another important consideration is the development of proxy metrics. In small studies, estimated results are often necessary due to time or resource constraints on data collection. These proxy estimates translate into impact on cost or savings. Lastly, any tools used to extract, compile, or analyze data should be cited.

There are many methodologic approaches available, and a successful CI case report aligns the research question with the appropriate framework, data collection plan, and method of analysis. For example, a proof of concept design uses primarily qualitative end user feedback on usability and navigation. In contrast, an implementation case report may include usage rate or uptake at multiple time points.

Results

The results section can include both quantitative and qualitative data and should address the problem statement. Quantitative results are generally preferred, and often include utilization metrics (such as change in patient portal activation) or satisfaction surveys. Qualitative content, such as user observation or narrative responses, is also valuable data, and these qualitative observations may also serve as the basis for future survey design. The results of statistical tests may not reach statistical significance but should reflect and demonstrate the impact of the solution deployed. Additionally, negative or unexpected results are an important part of the biomedical literature and will be considered for publication.

Discussion/Conclusion

The discussion section differentiates a scholarly case report from a simple process description. It connects the specific case back to the literature and fundamental informatics concepts (such as interoperability, change in management, and CDS). The CI case report results should build on prior published data or cite the unavailability of existing data to highlight the novelty of the program described. Existing literature can include clinical guidelines, accrediting body recommendations, as well as any peer-reviewed scientific studies or meta-analyses, and regional legislation or policy. The discussion is an explanation of not only the value and limitations of the case described but also the potential reproducibility of the findings to other settings.

The conclusion includes specific lessons learned, takeaways, and advice for others. It reiterates why the particular issues highlighted in the CI case report are novel or noteworthy. However, be careful to avoid overstatements and make sure to give appropriate context or restrictions on the conclusions.

Final Thoughts

Given the descriptive nature of a CI case report, authors must choose the salient points worthy of emphasis while briefly addressing the others for sake of completeness. Maintaining a clear focus on the initial problem statement and objectives, aligning the conclusions can help produce a successful manuscript. In addition to choosing a framework to organize your approach to analysis, the overall manuscript may benefit from a checklist (→Table 1) to serve as a rubric for your work.

In summary, although the total length of a CI case report is often short, each section must be carefully considered for maximal impact. CI interventions simultaneously address multiple topics at the sociotechnical interface, making controlled generalizable large-scale studies difficult. The in-depth descriptions in a CI case report, coupled with connections to existing evidence base, yield insights into the fast-paced, complex ecosystem of health care innovation.

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Conflict of Interest

None declared.

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