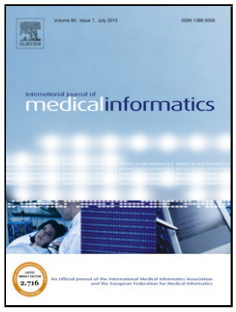

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Using formal methods for content validation of medical procedure documents

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HIGHLIGHTS

- Non-technical errors in standard operation procedures may compromise adherence
- A formal approach is proposed for content validation of medical procedure documents
- Ambiguities and other issues not detected by traditional approaches are discovered
- Proposed formal approach complements and facilitates further validation steps

ABSTRACT

Objective We propose the use of a formal approach to support content validation of a standard operating procedure (SOP) for a therapeutic intervention. Such an approach provides a useful tool to identify ambiguities, omissions and inconsistencies, and improves the applicability and efficacy of documents in the health settings.

Materials and Methods We apply and evaluate a methodology originally proposed for the verification of software specification documents to a specific SOP. The verification methodology uses the graph formalism to model the document. Semi-automatic analysis identifies possible problems in the model and in the original document. The verification is an iterative process that identifies possible faults in the original text that should be revised by its authors and/or specialists.

Results The proposed method was able to identify 23 possible issues in the original document (ambiguities, omissions, redundant information, and inaccuracies, among others). The formal verification process aided the specialists to consider a wider range of usage scenarios and to identify which instructions form the kernel of the proposed SOP and which ones represent additional or required knowledge that are mandatory for the correct application of the medical document.

Conclusion By using the proposed verification process, a simpler and yet more complete SOP could be produced. As consequence, during the validation process the experts received a more mature document and could focus on the technical aspects of the procedure itself.