Title

*“The title should give a clear indication of the type of system evaluated, the study question and the study design. The use of the term “evaluation” (or “assessment” or “study”) preceded by a specification of the type of study in the title helps to detect evaluation studies (e.g. “Evaluation of the effect of a CPOE system on medication errors: a retrospective record analysis”). Please delete this text.*

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a Affiliation

b Affiliation

*The authorship should be in accordance with the ICMJE recommendations. The contribution of the authors should be indicated at the end of the paper. If there are too many authors, please indicate an author group (“on behalf of Software Research Group”). The members of the research group should be listed at the end of the paper in “Authors’ contribution”). Please delete this text.*

**Abstract.** Abstract goes here. The abstract should preferably be structured and must clearly describe the objective, setting, participants, measures, study design, major results, and conclusions. In case there are major limitations in the study, these should be mentioned as well. Lorem ipsum dolor sit amet, consetetur sadipscing elitr, sed diam nonumy eirmod tempor invidunt ut labore et dolore magna aliquyam erat, sed diam voluptua. At vero eos et accusam et justo duo dolores et ea rebum. Stet clita kasd gubergren, no sea takimata sanctus est Lorem ipsum dolor sit amet. Lorem ipsum dolor sit amet, consetetur sadipscing elitr, sed diam nonumy eirmod tempor invidunt ut labore et dolore magna aliquyam erat, sed diam voluptua. At vero eos et accusam et justo duo dolores et ea rebum. Stet clita kasd gubergren, no sea takimata sanctus est Lorem ipsum dolor sit amet. (**MAX 300 Words**)

**Keywords.** Keyword, keyword, keyword, keyword, keyword (4-8 Keywords. If applicable, please use MeSH\_Terms: <https://www.ncbi.nlm.nih.gov/mesh/> )

# Introduction

## Scientific Background

Please comply strictly with the instruction for the author and format specifications. ***We only accept camera ready word files (\*.doc / \*.docx).*** The article may not be longer than 8 pages. If the manuscript is longer than 6 pages a publication fee will be charged (7 pages = € 50, 8 pages = € 100).

If applicable, please use the reporting standards of the Equator Network (<http://www.equator-network.org/> ) for the structure of the contribution. **This template** follows the structure of STARE-HI - **STA**tement on **R**eporting of **E**valuation studies in **H**ealth **I**nformatics.” [1].if the paper is a case report or a paper about standardization or an engeneering paper, we recommend the template with the ISCIL scheme.

The structure and the following recommendations are copied from STARE-HI [1]: The scientific background is a description of what is already known about the (type of) system that is object of study. […] It does not necessarily refer to a complete system, but can be restricted to a certain functionality of a larger system, or the usage of a more general application in a specific domain or for a specific purpose, etc. The term covers both hardware and software systems, functionalities and algorithms, and the organizational and social environment where relevant.

## Rationale for this study

“Describes briefly the motivation for the study: what are the specific reasons to perform the study (scientific interest, justification for expenditure, insight into problems, addressing open research questions)? Is the study part of a larger research, development or implementation project? From which stakeholder viewpoint (if any) is the study performed? If possible, it should also be mentioned what influence the findings of the study may have.” [1]



**Figure 1.** Short caption.

## Objectives of the study

“The specific study questions and hypotheses must be described as concisely as possible. It should then be stated where appropriate whether any formal permission was obtained for example from institutional review boards (IRBs), ethics committees, staff committees, and the like.” [1]

# Study context

“Information on study context is important for the later assessment of generalisability5 of results. Clearly, giving all details on the context is not feasible—the authors of an evaluation paper have to decide to which extent information is needed to secure the validity and generalisability of the paper. “ [1]

## Organisational Settings

“This should describe the health organization(s) where the system is being evaluated, including its geographical location and preferably its name. It should indicate what kind of health care facility it is (primary, secondary, tertiary care, home care, etc.). In case the whole organization is not involved, it should be made clear which departments have been involved in the evaluation (e.g. a 12-bed intensive care unit of a 320-bed urban referral hospital.).” [1]

## System details and System in use

“The system description must permit the reader to understand how the system works (or is intended to work). The authors may refer to a technical description provided elsewhere, and this may reduce the technical description, but sufficient detail is still needed for the evaluation study report to be self-contained. Systems details should comprise the aim of the IT system (e.g. laboratory system, administrative system, nursing documentation system, CPOE system), type of system (home-grown, open source or commercial system), the type of information that is managed by the system (e.g. drug orders, nursing care plans), and the clinical or other tasks supported by the system (e.g. ordering processes, nursing documentation processes). The description should also include information on (1) how wide-spread the system is used in the facility in which the system is evaluated, for how long and for what purpose and (2) number and professions of the users of the system in that facility. Any additional information to detail relevant aspects of the context in which the study was conducted should be mentioned (e.g. customization of software, user training, additional attention to the study, system only implemented shortly before the evaluation).” [1]

# Methods

“This section of a paper describes in sufficient detail the study design and the methods used in the study. STARE-HI contains items which have been dealt with in more detail in guidelines for medical studies; where appropriate we will refer to these.” [1]

## Study design

“This describes the overall study design and the motivation for choosing it. The description of study design comprises the type of study, for instance observational study (case study), quasi-experimental study (e.g. before–after, with or without control; interrupted time-series with or without on–off-design), or experimental study (RCT). […]” [1]

## Theoretical background of the study

“Where appropriate, state the theories – with sufficient references – on which the study is based, which guided the selection of the measurement instruments used and which form the basis for interpretation of the results (e.g. the user acceptance model that guided a quantitative survey or the organizational theories that guided a qualitative study).” [1]

## Participants

“Describe the methods of selection of participating users, patients, units, hospitals, etc., including – if applicable – inclusion and exclusion criteria for each type of participant in a study. In case of a controlled trial, it should be specified how participants were allocated to intervention and control groups (randomization or other approaches […])” [1]

## Study Flow

“Give sufficient details on date of beginning and end of the overall study and any study periods; give clear description and date of intervention (in experimental studies). In case of a study in which several methods have been used, specify when each method was used for which group. A flow diagram should be used to summarize the experimental study designs (like the RCT flowchart as required in CONSORT). For observational studies, use a diagram showing study activities over time. In each case, indicate time line and mark any important dates such as beginning of study, intervention, end of study, where appropriate compared to development milestones of the system (place/phase in life cycle).” [1]

## Outcome measures

“Cleary state outcome measures or other evaluation variables of interest that were used in the study. Define to a sufficient detail the key concepts in the study such as medication error or user satisfaction. In open qualitative studies, no pre-defined outcome measure can be defined; however, when certain aspects are more in the focus of the researcher than others, these can be stated here” [1]

## Methods for data acquisition and measurement

“This section should provide sufficient detail such that others are able to duplicate the study or to use some of the methods for other studies. All relevant aspects of applied methods (e.g. questionnaire, interview, observation, log file analysis, chart review) should be described. Examples of aspects are location and setting of data collection, number and type of interviews, type and duration of observations, whether data collection was retrospective or prospective, professional background of the interviewers, blinding of observer and/or participants and/or analysts, etc. It should also be identified which outcome measures are covered by each of the selected methods.

For every measurement or observation, information on their validation has to be given, with references to earlier work where necessary (e.g. was there a pre-test with assessment of inter-rater reliability? Was the questionnaire previously validated?). Newly designed measurement tools should be described in more detail, full disclosure of such tools should be given in the appendices or as supplementary material.” [1]

## Methods for data analysis

“This section describes the methods used for data analysis. The selection of those methods depends on data acquisition methods and study questions. When several methods are used, combine the description of data acquisition and data analysis for each method. For quantitative data, state the statistical techniques that have been used for analysis. For the analysis of qualitative data, indicate the analysis methods in detail. For all data analysis methods, indicate any software product used.

Triangulation may be used to combine data from various sources. When triangulation is used, it should be specified what kind of triangulation was applied (methods, measures, data, investigator or theory triangulation), and how the data were combined.

Throughout the description of the data acquisition and data analysis, the authors must show their awareness of specific and potential data analysis biases.” [1]

# Results

“The result section presents mainly the data obtained from applying the methods as described in Section 3. Depending on the type of study, the organization and naming of sections may be done in a different way. The interpretation and discussion of the results should be left to the discussion section.

Sections 4.2 and 4.4 are of special importance for but not limited to qualitative studies, as one of their objectives is to obtain new insight for example social and organizational aspects of Health Informatics applications. ” [1]

## Demographic and other study coverage data

“Give basic numbers on the size of the study, for example number of users observed/interviewed, documents or medical records analysed, distribution and return rate of questionnaires, number of observation days, pages of transcripts analysed, etc. When the study measures are related to persons, baseline demographic data and/or (clinical) characteristics of study participants (users, patients, and units) should be given, such as age groups, professions, usage patterns, patients’ diagnostic scores, etc. In particular in qualitative studies the characteristics and qualities of the participants may be of more importance than sheer numbers. Information on number and type of drop-outs should be added as well with identification of reasons. Where appropriate, baseline data must be given for relevant groups separately (e.g. for control and intervention groups in trials, or for different professions or age groups when that is relevant). ” [1]

**Table 1.** Long caption. Long caption. Long caption. Long caption. Long caption. Long caption. Long caption. Long caption. Long caption

|  |  |  |
| --- | --- | --- |
| **Column1** | **Column2** | **Column3** |
| –10.2 | 10.2 | 10.2 |
| 5.36 | 6.32 | 6.32 |
| –5.7 | 5.7 | 0.326 |



## Unexpected events during the study

“Any event that may have influenced study design and/or results has to be described (e.g. deviations from timeline, system updates during the study, staff changes, educational interventions, system failure, high drop-out rate in one group and changes in management or organizational strategy during the study period). If possible, these events should be related to the timeline of the study. The authors should indicate to what extent these unexpected events might influence (bias) the study findings. ” [1]

## Study findings and outcome data

“This is the major section, presenting the results of the study. For each study question, outcome variable and evaluation criterion, sufficient data should be presented. Qualitative data may be presented as text. Quotations from participants should be used to illustrate major points. These quotes should be anonymous, but have an indication of the type of person being quoted (e.g. Nurse 3). Quantitative data can be presented in tables and figures. Typically, each table, figure, etc., should be referenced in the text. The most important or relevant results should be emphasised here, and special notion should be given to unexpected or striking results such as differences between groups. Absolute numbers should always be provided; not only relative numbers. ” [1]

## Unexpected observations

“Any unintended (positive or negative) side-effects of the system that were not in the focus of the study but that seem remarkable should be reported here. This could be, for example, the observation of bottlenecks in the clinical workflow after system implementation, severe organizational problems that seem related to the new system, or persistent unsolicited responses on a specific effect of a system during a qualitative study that focused on other aspects. Here the authors may report about the difference between the intended use as described in Section 2.2 (Study settings) and the observed actual use.

The difference with Section 4.2 is that unexpected events may influence the findings (and may have caused changes of the study protocol), while unexpected observations relate to issues that arose during the study that could lead to additional insights, further recommendations, potential explanations for the findings or future research topics. ” [1]

# Lessons learned (Discussion)

“The discussion should be a critical interpretation and assessment of the study results and the study itself in view of the study questions. We suggest authors should make the discussion structured with the following clear subheadings: ” [1]

## Answer to study questions

“Interpret the data and answer your study question(s). Whereas in Section 7 the results are presented in detail, in this part of the report the answers to the study questions are in focus. Make explicit reference to the specific study questions either by restating them or by other cross-reference mechanisms. ” [1]

## Strengths and weaknesses of the study

“This section contains a critical discussion of the methods used. Describe the strong and weak points of the study, for example concerning the study design, comparability of intervention and control group with respect to baseline data, study execution, confounders, internal and external validity of findings, completeness of acquired data, drop-out of participants, representativeness of the participants, low- or high-response rates, etc. Refer here also to the information presented in Section 4.2. Discuss any biases that could be present and that would influence the findings of the study or the interpretation of the data. ” [1]

## Results in relation to other studies

“Make clear what exactly is novel about your results. Describe to what extent the results are in agreement with findings of others and in this light provide information about the comparability with the study setting. When there is disagreement with findings of others, discuss possible reasons. ” [1]

## Meaning and generalizability of the study

“Describe the meaning of the study findings, both for the various stakeholders in the study, for other institutions and for Health Informatics in general. In this context, discuss the generalisability/applicability of the study for other organizations. Refer here also to the information given in Sections 2.1, 2.2 and 5.2. ” [1]

## Unanswered and new questions

“Discuss whether the study has shed new light on an issue and/or has raised new questions. Describe what research should/could be performed in the future to further improve our knowledge about the system and its effects. Refer here also to the information presented in Section 4.4. ” [1]

# Conclusion

“The conclusion summarizes the main findings, discusses the impact of the findings and how they relate back to the big picture described in the Section 1, gives recommendations by the authors and provides a short outlook for future research. ” [1]

Authors’ contribution

“An increasing number of journals require making the contributions of the authors to a paper explicit or at least to make clear that each author qualifies for authorship. It is recommendable to make that information part of the paper. “” [1]

If an author group was indicated in the head of the manuscript, the names of the scientists involved can be listed here.

Acknowledgements

“Acknowledge any financial or other support you got when conducting the study or writing the paper. ” [1]

Conflict of Interest

Please indicate if one of the authors have an conflict of interest according to the principles of the ICJME. (<http://icmje.org/conflicts-of-interest/> ) Otherwise indicate, “The authors state that they have no conflict of interests.”

References

1. Talmon J, Ammenwerth E, Brender J, de Keizer, N, Nykänen P, Rigby M.: STARE-HI - Statement on reporting of evaluation studies in Health Informatics. *Journal of Medical Informatics* **78** (2009):1-9. DOI: 10.3414/ME10-01-0072
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