EuroAsiaSPI² 2016 Proceedings

Proceedings

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A Preliminary Systematic Literature Review of the use of Formal Methods in Medical Software Systems[1]

Silvia Bonfanti, Department of Economics and Technology Management, Information Technology and Production, Università degli Studi di Bergamo, Italy, silvia.bonfanti@unibg.it
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Abstract

The use of formal methods is often recommended to guarantee the provision of necessary services and to assess the correctness of critical properties, such as safety, security and reliability, in medical and healthcare systems. Several research groups have proposed and applied formal methods related techniques to the design and development of medical software and systems. However, a systematic and inclusive survey with some form of analysis is still missing in this domain. For this reason, we have collected the relevant literature on the use of formal methods to the modeling, design, development, verification and validation of medical software systems. We apply the well-known systematic literature review technique and we run several queries in order to obtain information that can be useful for people working in this area. We present some research questions and the data answering these questions. We also discuss some limitations of the adopted approach and how to address these issues in order to have a comprehensive survey.

Keywords

Systematic Literature Review, Formal Methods, Medical Software, Medical Device, Validation, Verification, Certification

[1] The research reported in this paper has been partly supported by the Austrian Ministry for Transport, Innovation and Technology, the Federal Ministry of Science, Research and Economy, and the Province of Upper Austria in the frame of the COMET center SCCH.

1 Introduction

In modern medical devices, human safety depends upon the correct operation of software controlling the device: software malfunctioning can cause injuries to, or even the death of, patients. A crucial issue is how to guarantee that the medical software has all the qualities (e.g., safety, security, liveness, and utility) expected for critical components. One way to improve and assess software quality as suggested by the literature is to use formal methods or in general rigorous methods for the design, validation, and verification of medical software. Medical standards and certification procedures, that use formal approaches, have been proposed and taken into consideration during the development, but some research questions still remain open. With this paper, we try to give a preliminary overview of the research literature in this field. The goal is twofold: 1) to provide guidance to researchers starting to work on this topic 2) to assess the state of the art which is more useful for researchers already working on this subject.

We have applied a Systematic Literature Review (SLR) process (Kitchenham, et al., 2009) to the topic of rigorous methods for designing and validation of medical software and systems. The goals of this process are (1) to gather a sufficient number of relevant articles, (2) to perform a series of analyses, and (3) to publish the results of the findings to allow researchers to browse in the collected data. This activity follows a systematic process to avoid possible biases, inclusive in order to include as much information as possible, but at the same time capable of identifying only relevant papers. In section 2, we explain the activities we performed in order to reach this first goal, the data source we use, and the technologies and tools we adopted. After that, we perform several queries over the data we collected, in order to extract useful information. The queries are driven by a series of research questions (RQ1 to RQ5). In RQ1 and RQ2, we are interested in providing some evidence of the publication trends in this field, to objectively measure the interest in the scientific community during the last 30 years. In RQ3 we are interested in knowing which are the preferred journals and conferences in these topics. In RQ4 we try to give an insight on how the community is distributed, by looking on the number of papers among all the authors. We also perform a preliminary study regarding the impact of the research in this area. Assuming impact as a measure of the number of citations, we perform several queries about the significance of the articles. RQ5 identifies the publications that have had most impact in this research area. This information can be useful, for example, for PhD students who would like to know: which are the most cited papers they must be aware of?

To the best of our knowledge, there are no systematic reviews on the literature of formal methods in this field. In (Xinxin et al., 2009) the authors review the literature on the use of formal methods on medical terminologies, and not software itself.

Although we encountered several problems and limitations of our technique, we were able to collect a great number of papers (more than 200) to make our quantitative analysis meaningful. Overall, we have found out that the research area is still growing in terms of number of publications. The presence of papers in highly ranked journal witnesses that the scientific community is aware of the importance of the work done in this field. However, the contributions seem rather extemporary, since most of the papers have no impact (in terms of citations) and most authors have published only one paper in this field.

2 The SLR Process

We apply the SLR process to rigorous methods in medical software systems following the guidelines presented in (Kitchenham, et al., 2009) with some changes to fit our goal.

Figure 1 shows the process applied. As a first step, we chose Scopus[2] to extract publications. Scopus is the largest database owned by Elsevier, it contains scientific journals, books and conference proceedings. There are more than 60 million records, over 21.500 peer-reviewed journals, over 360 trade

[2] http://www.scopus.com

publications, 7.2 million conference papers and 27 million patents. There are 5.000 articles-in-press from international publishers including Cambridge University Press, the Institute of Electrical and Electronics Engineers (IEEE), Nature Publishing Group, Springer, Wiley-Blackwell. It includes more than 113.000 books that will increase by 10.000 each year. The second step is the definition of search terms into the database. Scopus allows the user to perform different type of search, by title, by keywords, by authors or advanced search obtained by queries[3]. The research performed takes into account titles and keywords of the papers:

- TITLE(medical) AND (TITLE(software) OR TITLE(device*)) AND (TITLE(validation) OR TITLE(verification) OR TITLE(certification))
- TITLE(medical) AND (TITLE(software) OR TITLE(device*)) AND TITLE("formal methods")
- TITLE("formal method*") AND TITLE(medical)
- KEY(medical) AND (KEY(software) OR KEY(device*)) AND (KEY(validation) OR KEY(verification) OR KEY(certification)) AND KEY(formal)
- KEY(medical) AND (KEY(software) OR KEY(device*)) AND (KEY(validation) OR KEY(verification) OR KEY(certification)) AND KEY("formal method*")
- KEY(medical) AND (KEY(software) OR KEY(device*)) AND KEY("formal method*")
- KEY("formal method*") AND KEY(medical)

We obtained 238 papers[4]. We used Scopus functionality to merge the results of each search and then we downloaded the RIS[5] file containing all available papers information (e.g. title, authors and citations). After, we imported the RIS file into SciMAT[6] (Science Mapping Analysis Software Tool) (Cobo, et al., 2012). If users have more than one RIS file SciMAT allows deleting duplicate. SciMAT is open source tool and performs science mapping analysis. This tool is divided into three modules: 1. management of the knowledge base such as authors, keywords, references and citations; 2. carrying out the science mapping analysis; 3. visualization of generated results and maps. Before performing the analysis and depicting the results (see Section 3), we applied the following data pre-processing activities:

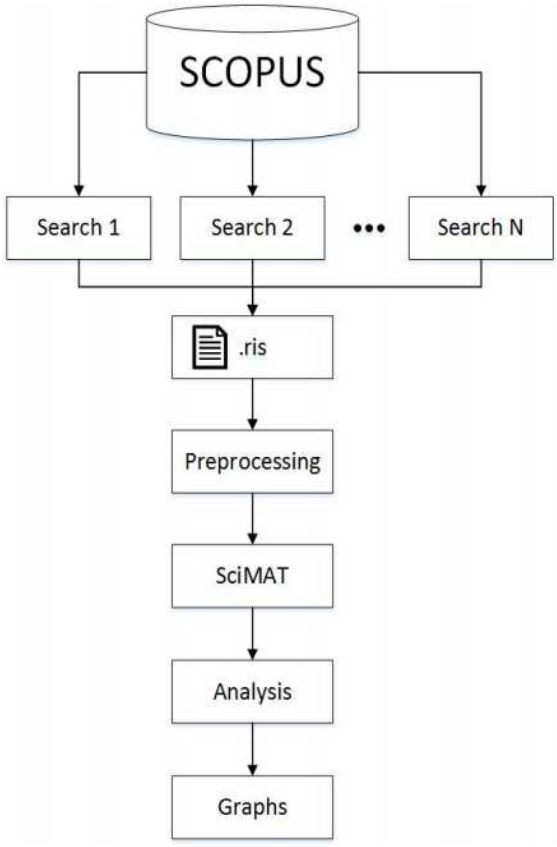

Figure 1:The applied SLR process

- We merged the authors written in a different way (i.e., with one or more names missing, extra dots or any other symbol between name and surname). SciMAT functionality finds similar authors by Levenshtein distance. The user set a number N that represents the number of deletions, insertions or substitutions required to transform a string into another one. In this set of authors, we set N equals to one and to two and we found some of duplicate authors.
- We merged the same keyword written in a different way (i.e., plurals, with symbols/spaces between words, with wrong letters inside words). SciMAT tool automatically finds and merges similar words by plurals. The search by Levenshtein distance is available to find similar words.

[3] Symbols in queries: use "quotation marks" to search for a phrase; the * symbol will replace multiple characters
[4] the list of publications is available at http://cs.unibg.it/bonfanti/EuroAsiaSPI2016SLR/ScopusResults.ris
[5] RIS is a file format developed by Research Information Systems, Incorporated to enable citation programs to exchange data
[6] http://sci2s.ugr.es/scimat/

3 Analysis and Results

In this section, we analyse the results by answering to a set of research questions (**RQ**).

RQ1: Which is the trend of publications?

As a first question, we wanted to observe the trend of publications about formal methods applied in medical field. We analysed the number of publications from 1982 (the year of the oldest publication we found) until 2015 (we did not consider 2016 since this year is not finished yet). As shown in Figure 2, until 2006 the number of paper was equal or less than five, except for 2001 and 2003. From 2006, the number of papers has started to grow until 2011. In the last four years, the number of publications has decreased (less than 20 publications per year) except in 2014 in which the number of publications has reached the maximum value over all years. The behaviour in the recent years should be taken with caution, probably because the updating of publications is not finished yet.

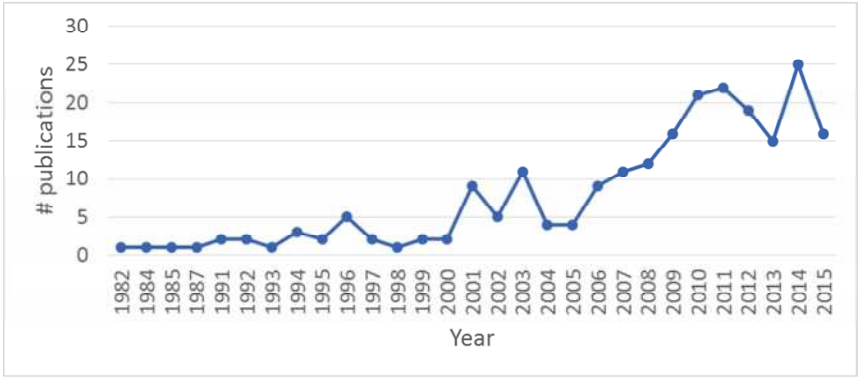

Figure 2: Publications per years

RQ2: Are there more publications in Journals or Conferences?

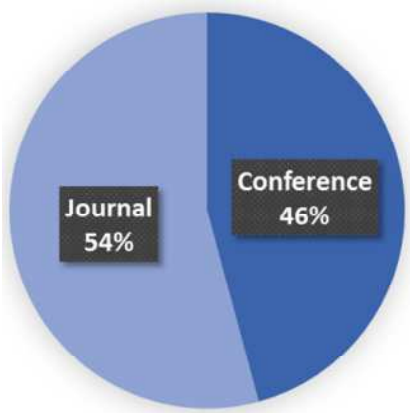

Figure 3: Journal or Conference

In Figure 3, the pie chart shows the percentage of publications in journals and in conferences. The number of publications is quite similar, but it is greater in journals (54%) compared to conferences (46%).

In Figure 4 the trend of the number of publications in journals and in conferences is depicted. For all years (except in 1984), the number of publications in journals is always greater than the number of publications in conferences and their behaviour is always the same (when the number of publications in journals grows, the number of publications in conferences grows as well).

In medical field, the number of journals is bigger than the number of conferences; this difference could be the motivation of the major number of publications in journals.

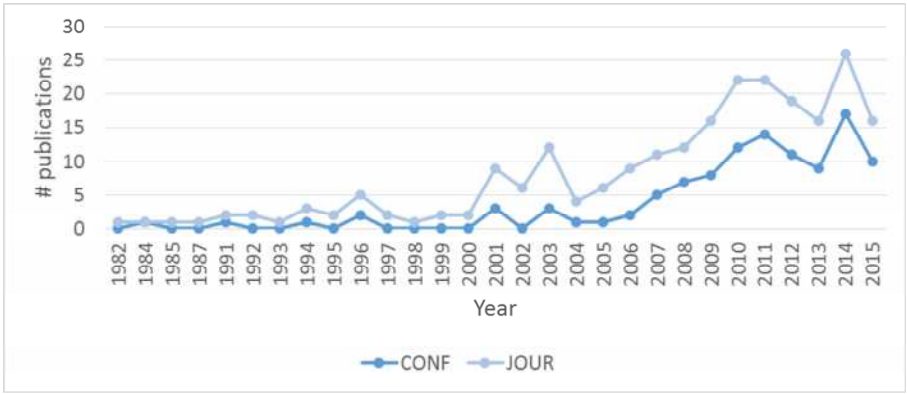

Figure 4: Publications in Journal/Conference per year

RQ3: Which are the most important journals/conferences?

Table 1 shows a classification of most important journals and conferences based on number of citations.

For each journal, we analysed the SCImago Rank (Arencibia-Jorge, et al., 2008), which measures the scientific influence of journals. This parameter assumes four values: Q1 (the highest value), Q2, Q3 and Q4 (the lower value). All journals have the highest value; this means that this topic has high importance in prestigious journals.

Name	*JOUR/ CONF*	*SCImago Rank*	*# citations*	*# publications*
Artificial Intelligence in Medicine	JOUR	Q1	255	3
International Journal of Medical Informatics	JOUR	Q1	136	2
Lecture Notes in Computer Science	CONF	N/A	95	35
Proceedings of the IEEE	JOUR	Q1	36	1
IEEE Transactions on Software Engineering	JOUR	Q1	36	1
Journal of Biomedical Informatics	JOUR	Q1	33	3
Proceedings of the 8th ACM International Conference on Embedded Software, EMSOFT'08	CONF	N/A	26	1
Computer	JOUR	Q1	26	1
Proceedings of the ACM SIGCHI Symposium on Engineering Interactive Computing Systems	CONF	N/A	26	2
Annals of Internal Medicine	JOUR	Q1	22	1
IEEE Robotics and Automation Magazine	JOUR	Q1	21	1
Biomedical Optics Express	JOUR	Q1	20	1
Journal of Pharmaceutical and Biomedical Analysis	JOUR	Q1	20	1
Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability, HCMDSS/MDPnP 2007	CONF	N/A	20	2

Table 1: The list of Conferences and Journals with most citations

RQ4: How many papers about this topic have been written by the same author?

Figure 5 shows the number of publications per author. The most obvious thing is that the majority of authors (about 84%) have published only once about this topic and 10% of authors have two publications. Only 1.16% of authors have more than five publications (see Table 2). Analysing this value shows that there are many occasional contributors. Another explanation could be that this topic is new in the scientific community and authors are starting their activities in these years.

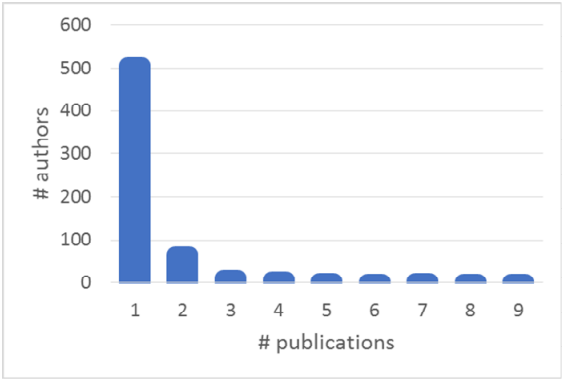

Figure 5: Publications per author

Author	*# publications*
Jones, P.L.	9
Curzon, P.	8
Mangharam, R.	8
Jiang, Z.	7
Masci, P.	7
Thimbleby, H.	7
Pajic, M.	6

Table 2: Authors with most publications

RQ5: Which are the most cited publications?

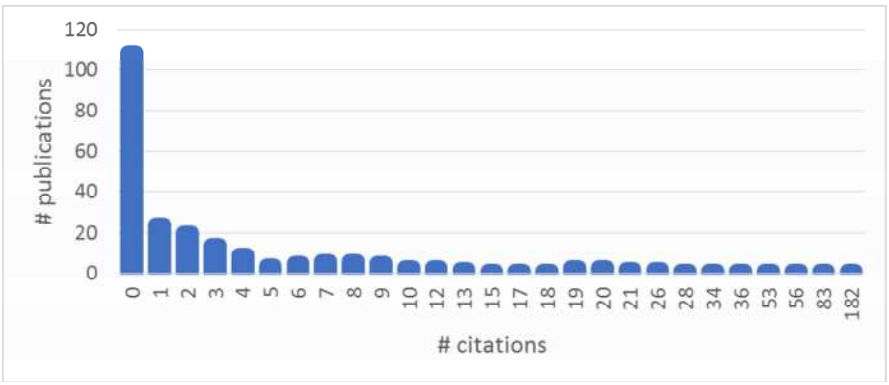

Figure 6: Citations per publications

Before introducing which are the most cited papers, we analysed the general behaviour of the number of citations[7] (see Figure 6). Overall, about 50% of publications do not have citations. About 40% of publications have less than ten citations, 6% have less than twenty citations and the same percentage have more than twenty citations. This low percentage of citations could be due to the novelty of this topic in the scientific community.

Table 3 shows the most cited publications. The publication with most citations is one of the first applications of formal methods in the medical field. It presents a formal specification language for representing medical procedures, decision, knowledge, and patient data. Paper two presents a framework for the design of a distributed and interoperable health information system. In 2006, another paper about improving medical protocols by formal methods has been written and it is one of the most cited papers (the number three in the Table). Paper four introduces a formal language developed to map different researches results into a default model. Paper number five defines a testing environment based on model-based testing and put emphasis on the lack of a formal methodology to test a medical device within the closed-loop context of patient. Paper number six is about Satisfiability Modulo Theories (SMT) solvers of embedded software. Paper number 7 applies formal methods to improve completeness and accuracy of biomedical terminologies. Paper number 8 advocates the Food and Drug Administration (FDA) defined process to evaluate the safety of medical software based on formal methods. The last paper in Table 3 is about a formal method applied to biomedical sensor networks. The authors have defined the model, have simulated the system behaviour and have applied a model checking tool to verify critical properties.

Even considering only these nine papers, it is apparent that some of them are only marginally relevant within the declared scope of our research. For instance, the paper number 7 is an interesting application of formal methods in the medical field, but has only a potential impact over the design and validation of medical software and systems. We found this the greatest limitation of the systematic approach we adopted: the use of keywords and words in titles identify also papers that fall under our criteria but

[7] Note that Scopus cannot identify self-citations in the number of citations of a given paper, so using this value as a measure of impact is not completely fair.

are not very relevant. Sometimes, we observed that papers were included only because the authors choose a wide range of keywords or because Scopus added some extra keywords. This caused the inclusion of papers that do not fit well with the goal of our SRL.

N°	*Publications*	*# citations*
1	Fox, J., Johns, N., & Rahmanzadeh, A. (1998). Disseminating medical knowledge: the PROforma approach. *Artificial intelligence in medicine*, *14*(1), 157-182.	182
2	Lopez, D. M., & Blobel, B. G. (2009). A development framework for semantically interoperable health information systems. *International journal of medical informatics*, *78*(2), 83-103.	83
3	Ten Teije, A., Marcos, M., Balser, M., van Croonenborg, J., Duelli, C., van Harmelen, F., ... & Seyfang, A. (2006). Improving medical protocols by formal methods. *Artificial intelligence in medicine*, *36*(3), 193-209.	56
4	Maldonado, J. A., Moner, D., Boscá, D., Fernández-Breis, J. T., Angulo, C., & Robles, M. (2009). LinkEHR-Ed: A multi-reference model archetype editor based on formal semantics. *International journal of medical informatics*, *78*(8), 559-570.	53
5	Jiang, Z., Pajic, M., & Mangharam, R. (2012). Cyber–physical modeling of implantable cardiac medical devices. *Proceedings of the IEEE*, *100*(1), 122-137.	36
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Table 3: Publications with most citations

4 Limitations and Future Work

During our research activity we were able to identify several limitations and threats to validity of our results. We have been able to solve some of these issues by adapting our strategies, but for some of them we can only indicate our plans for the future in order to address them.

First, we have used only one source (Scopus) which we believe provides a very good mix between the number of papers included in the repository and values of the venues in which the papers have been published. For the future, we plan to consider other sources like ISI Web of Science (ISI-WoS), ACM digital library, IEEE explore, Springer Online Library, NLM's MEDLINE, Wiley Inter Science, Google Scholar, and others. After a preliminary analysis we have noticed that not all the available sources provide a good "advanced search" feature as Scopus and this can limit the introduction of a new source because we cannot easily extract information we are interested in. For example, some sources do not provide a specific language for queries. Furthermore, other sources, like Google Scholar, contain large quantity of documents and it is difficult to select those important (for example to include only those peer reviewed).

The use of words in titles and in keywords has allowed us to automatically select the papers of interest. However, we found that this makes our results very sensitive to authors' choices in terms of title words they used and of keywords they selected. Sometimes titles and keywords were matching, but the content of the paper was not in the scope of our research. On the other hand, we may have

missed interesting papers because the authors had selected particular words we did not include in our queries (for example the name of a tool or of a case study). As a future work we are planning to understand why this happens and how we can include these papers by adjusting our SLR process. One solution will be to extend the research to other sources that allow more general semantic queries. Another solution will be to manually check whether interesting papers cited in our selected papers are already included in our collection and if not, find queries to include them. With this process we will include also papers that have used different keywords to express the same concept of our SLR objective.
In general, being a preliminary analysis, we were able only to perform analysis that require a low degree of human interaction and were mainly based on the use of fields in the bibliographic entries (like year, type of publication, affiliation, citations, and so on). This has limited the results of the current analysis. To address this problem, we plan to extend the research questions with new ones that require a deeper analysis of paper contents. Examples of analysis we are interested in, are:

- What is the goal of the use of formal methods in medical field?
- Which are the notations used?
- Which are the tools used?
- Which are the methodologies applied?
- Which are the typical case studies?

We have used very simple metrics to measure impact like the number of citations and h-index. There is a general agreement on the significance of such metrics; however, some readers may find this too simplistic. We will introduce new metrics like the measure for citations using individual h-index, which normalizes the number of citations for each paper by dividing the number of citations by the number of authors for that paper, and then calculate the h-index of the normalized citation counts.
Another limitation we found in this preliminary analysis is that some journal papers are extended versions of conference papers and these should probably not contribute to the number of publications per authors. To solve this, we will manually analyze the papers with same (or similar) authors and same (or similar) titles and we will group them. After that we will keep only one paper for each group, in this way we will remove papers with the same content.

5 Conclusions

In this paper, we presented a systematic literature review about formal methods applied to medical devices. We ran several complex queries on Scopus, combined the results, and we obtained 238 publications. We performed a set of analysis (see Section 3) to provide information that can help researchers working within this domain. The number of publications per year is still growing and the researchers publish more in journals than conferences (although the difference is not big). Considering the cited papers for each journal/conference, the journal papers have more citations than conference papers. In addition, authors published in journals with high SCImago Rank (measurement of scientific influence of journals). There are a lot of authors that have published only once, and only a few authors have published more than two papers. While analysing the most cited papers (see RQ5), we found some marginally relevant papers. After a further investigation, we noticed that Scopus adds some extra keywords that do not fit well the content of the paper. As a future work, we plan to analyse in details the keywords and consider only those inserted by the authors. This allows excluding the publications that do not fit our research topic. The analysis presented in this paper is a result of a preliminary investigation.

6 References

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