Bridging the gap between evidence and practice in asthma management by developing a mobile-based clinical decision support system for GINA asthma guideline

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Research article

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Posted Date: May 10th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-25364/v1

Title page:

Bridging the gap between evidence and practice in asthma management by developing a mobile-based clinical decision support system for GINA asthma guideline

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Abstract:

Background: Physicians' compliance with clinical practice guidelines (CPG) remains insufficient. Guideline-based clinical decision support systems (CDSSs) can be beneficial to address this challenge. The principal objective of this research is to translate the Global Initiative for Asthma guideline (GINA) into a mobile-based CDSS to improve its utilization as a clinical decision-making tool.

Methods: Designing and development of our expert system were conducted in an iterative and stepwise approach by the multidisciplinary expert team. Translating and extracting the embedded knowledge in GINA was done according to the Knowledge to Action framework. Next, extracted knowledge was converted to decision tree models to design the knowledge-base of the desired system. The accuracy and proficiency of the expert system were calculated based on the predefined scenarios. The expert system usability was evaluated by the think-aloud protocol and the GUIDES questionnaire.

Results: Based on the analysis of the GINA guideline, more than 220 rules and 336 knowledge statements were extracted. Our knowledge-based expert system was devised based on production rules. After modification with feedback from six experts, the system was developed in the Android platform. The overall accuracy and efficiency of our CDSS were 100% and 100%, respectively.

Conclusion: The *ginasthma* mobile-based CDSS was developed for android smartphones to improve the adherence of health care providers to GINA guideline with high accuracy and efficiency. Further investigation is needed to evaluate the efficacy of this app in real practice.

Keywords: Clinical decision support systems, Asthma, GINA, Guideline

Background:

Asthma is a complex multi-faceted condition encompassing a variety of phenotypes and endotypes with an estimated 300 million affected people worldwide[1]. Establish a proper treatment plan and timely diagnosis could control symptoms, reduce the risk of asthma attacks, and allow patients to return normal activities [2-4]. Regarding the complexity of its diagnosis and management, clinical practice guidelines (CPG) produced to enhance asthma care based on the best evidence to support clinicians in decision-making [2].

In 1995, the Global Initiative for Asthma (GINA) guideline was published and has been updated annually as the principal guideline for clinicians to manage asthmatic patients based on the best current evidence. Despite tremendous efforts, the GINA strategy usually is not fully implemented in real practice [5, 6].

Guidelines implementation is a complex process that is influenced by many factors, including the physician's knowledge, attitudes, experiences and guidelines' properties[7]. Many guidelines have not been followed, even those that are widely accepted [8, 9]. In addition to other limiting factors to implementing CPG, paper-based guidelines are still time-consuming to read [10, 11]. Practical strategies are needed to address barriers to the implementation of clinical guidelines [9].

Adopting of paper-based clinical guidelines into routine practice is very slow. Given the dramatic advances in computer science in recent years, the clinical decision support systems (CDSSs) have been emerged to support the clinician in complicated decision-making processes [12, 13]. It has been considered as one of the best strategies to improve guideline compliance in routine clinical practice [14]. Implementing asthma management guidelines in the form of CDSS has been proposed to fill the gap between evidence and practice [15].

Mobile-based health applications have the potential to enhance the acceptance of CPG and facilitate implementing CDSS in point of care [16, 17]. To improve the GINA adherence among physicians and healthcare providers and increase its accessibility, we decided to develop guideline-based CDSS on a mobile platform.

The main objectives of this work were: (1) to translate the embedded knowledge in GINA guideline to CDSS platform, (2) to describe the process of design and development of our ginasthma application, (3) to evaluate the usability of our expert system.

Methodology

GINA guideline 2019 was selected as the source of knowledge to be implemented. The iterative test-build-redesign approach was applied in analysis, knowledge translation, development, evaluation, and redesign phases. It enabled us to get feedback from the experts and improve the performance and usability of our application. The applied model of our methodology is shown in Fig 1.

Setting:

This study was conducted by Thoracic Research Center, Tehran University of Medical Sciences. The expert team consists of four pulmonologists, one pharmacotherapist, and a medical informatics specialist.

Analysis:

First, a literature review was conducted to select the appropriate model and platform of the desired system. Then, the research requirements of this study, framework, and requirements of the expert system were derived from the paper-based GINA guideline by initial evaluation and qualitative analysis of the guideline. The findings were examined at different meetings with experts to identify the main sections that should be included in the mobile app.

Knowledge translation:

This study adopted the Knowledge to Action (KTA) conceptual framework was introduced by Graham (2006) to translate the GINA guideline [18]. This model suggested by Boulet et al. [19] as the best framework to translate GINA guideline. According to this model, the first step is knowledge creation. Knowledge inquiry and extraction were done based on in-depth analysis of guideline context.

Recommendations and protocols of the guideline were extracted based on the predefined core elements of the system. Next, all of the protocols, concepts, and scenarios refined into structured algorithms. All of the necessary algorithms, processes, and actions translated into the machine-understandable format. Then, these scenarios were represented in the form of decision tree models by the knowledge engineer. Clinical experts verified all of the algorithms and decision tree models. To creating a knowledge-base (KB), the decision tree models were written in the form of production rules or “if-then" structures. So, the expert system can interpret the results using the inference engine and the rules embedded in KB.

CDSS development and programming:

The CDSS, which we named the “*ginasthma*”, is an application that can be run on mobile devices. According to the popularity of Android applications across the world [20], The Android platform was chosen for CDSS development. We used Java Android language in the Visual Android studio platform. Based on the iterative approach that was considered in this study, programmers redesigned the different prototypes of the system with expert consultation to achieve the final goal.

System evaluation:

The usability and knowledge evaluation of our system were estimated by designing thirty-two scenarios regarding all possible conditions might occur in asthma management. Each clinical scenario was defined as a hypothetical story that helps the person to imagine and think about a clinical problem or case easily [21].

Knowledge and performance evaluation:

The proficiency scores of algorithms were calculated by comparing the results of the designed decision models with the results obtained from the paper-based GINA using predefined scenarios. If the results were identical to the guidelines’recommendation, the module was scored “+1” but if the results were different the module was scored “-1”. The proficiency and efficiency values were calculated according to the following formulas[21]:

$$Proficiency = \frac{Sum\ of\ +1'\text{s and } -1'\text{s scores}}{Total\ number\ of\ +1'\text{s}}$$

$$Efficiency = \frac{Number\ of\ +1'\text{s}}{Total\ number\ of\ \text{choices}}$$

Then sensitivity, specificity, and accuracy of our mobile-based app were calculated in this phase.

Usability evaluation:

The usability of our CDSS assessed in the two phases, heuristic evaluation, and questionnaire-based method. The heuristic evaluation was done based on the think-aloud protocol. Through the think-aloud strategy, users are asked to express aloud their suggestions when they are working with the system [22, 23]. By applying this method, the thoughts, interactions, and cognitions process are verbalized while the tasks are completed [24]. The usability sessions were conducted by representing written scenarios that described patients with different conditions to participants [25, 26].

Six participants were selected for usability testing[27]. The participants asked to work with all of the sections of the *ginasthma* app. After the tasks were terminated, the users were asked to say their recommendations to improve system performance and usability. Each session lasted between 20 and 30 minutes. All of the suggestions were recorded and written by the evaluator.

After the think-aloud session, participants were asked to complete the Likert-based GUIDES checklist consists of 16-factors in four domains. This standard questionnaire was developed to support researchers to evaluate the effectiveness of CDSS systems in 2018. It evaluates context, content, system and implementation factors of the system [20].

Results:

The findings of this study led to devising a new expert system for on-site application of GINA guideline.

Expert panel:

The participants in this research consist of six experts whose demographic characteristics were represented in Table 1.

Table 1. The demographic characteristics of the expert panel

	DATA	FREQUENCY
SPECIALTY	Pulmonologists	4(67%)
	Pharmacotherapist	1(17%)
	Medical informatics specialist	1(17%)
AGE	30-40	1(17%)
	40-50	4(67%)
	>50	1(17%)
EXPERIENCE	<5 years	1(17%)
	5-10 years	2(33%)
	>10 years	2(33%)

Analysis:

The key finding of the analysis phase is determining the “stand-alone and rule-based knowledge-base” model for developing our CDSS. In stand-alone CDSS, the physician voluntarily enters essential clinical information and the system interprets the results based on the entered data and the knowledge embedded into the system.

Accordingly, the interactive and stepwise approach was selected to design the system as defined in requirements engineering. Seven main sections were identified based on the guideline content. These sections include initial diagnosis, determining the level of asthma control, exacerbation management, adjusting treatment, management of uncontrolled asthma, and differential diagnosis.

To a better understanding of drug characteristics and easier access to useful drugs regarding asthma control, a separate section was dedicated to introducing medicines which are suggested by GINA guideline. Different drug groups and pharmaceutical information were considered in this section. The initial model of system is shown in Fig 2.

Knowledge translation:

Knowledge extraction:

The embedded knowledge at the guideline was converted into decision tree models and algorithms. For each section and subsection that determined in the analysis phase, the decision trees and algorithms were designed separately.

Textual contents of the GINA guideline were converted to knowledge statements to design decision tree models. In total, more than 336 knowledge statements were extracted. We extracted 45 statements in initial diagnosis, 18 statements in the level of asthma control, 25 statements in exacerbation management, 65 statements in adjusting treatment, 85 statements in management of uncontrolled asthma, and 98 statements in differential diagnosis (in three age groups) sections.   Based on these extracted bits of knowledge, 28 decision tree models were designed. The two samples of algorithms and decision models of the GINA guideline are shown in Fig 3 and Fig 4.

In this phase, the input and output of each category were determined. Since the most proper model of the output is a recommendation, the output of each algorithm based on the guideline was translated into recommendations.

In an iterative cycle, all of the extracted knowledge in the form of algorithms and decision trees assessed and refined through more than 13 focus group discussions to achieve the accurate decision model.

Designing knowledge-base:

The knowledge-base (KB) is the brainpower of the expert systems. It contains all of the rules and the essential facts. Based on the decision models, more than 220 rules were determined in this stage. The rules were extracted from the eight main sections based on the 28 decision models. In the following, some rules are represented:

a. if (((wheeze==true) or (shortness of breath==true)) and (symptoms variatin==true)) then related asthma symptoms=true
b. if ((reliever needed==0) and (night symptoms==0) and (activity limitation==0) and (daytime symptoms==0)) then asthma=well controlled
c. if (level of asthma control==1) && (treatment type==2) then Step up
d. if ((reinfection==true) &&(productive cough==true)) then probability of bronchiectasis=1

Most of the designed rules were devoted to the "differential diagnosis section (36%)". The least number of rules were devoted to "determine the level of asthma control section" (8%). However, in the asthma control section, twenty percent of the rules were repeated in adjusting treatment.

CDSS design and Development:

According to previous phases, the overall model of the system and process were designed based on the functional requirements. The overall model of the expert system is shown in Fig 5. After an expert team confirmed the obtained model, we entered the programming phase.

The overall function of the system is described in the following. After logging on to the system, the user should select the desired section from the seven main parts of the system. In each section, according to defined scenarios, the user is asked to list the patient's clinical signs or symptoms among the existing items in the system. The system makes suggestions and recommendations to the physician using the combination of patient's information and embedded knowledge in its knowledge-base. In some cases, the user may be asked to do more actions to achieve the appropriate result. In CDSSs, the final decision should be made by physicians.

According to functional requirements and decision rules, the system was programmed by a software engineer. In the developmental phase, the different prototypes of the system were developed iteratively under expert supervision to achieve the best interface design and performance.

Regarding developing a user-friendly system, the checklists and drop-down lists were utilized for entering signs and symptoms, and the results of each section are shown in the form of recommendations and alerts. To raise the smartness of our system, if the user needs to shift to another part of the program for better performance, the system will guide the user logically.

Evaluation:

Knowledge evaluation:

The scores of knowledge were calculated based on the standard formula. The overall proficiency and efficiency of the translated knowledge were 100% and 100%, respectively. The high efficiency showed that the developed algorithms were working in accordance with the guideline's recommendations. High proficiency determines the powerful performance of an expert system.

Evaluation of the performance and diagnostic characteristic:

The gold standard in this evaluation was guideline recommendations. The sensitivity, specificity, and accuracy of the mobile-based app were 100%, 100%, and 100 %, respectively. The results and characteristics of the diagnostic tool based on the scenarios displays in Fig 6.

Usability evaluation:

The heuristic evaluation was done based on the think-aloud protocol in this phase. Thus, we can determine to what extent the system is usable in practice in addition to identify the user's expectations. All of the recorded problems and errors that were found by the evaluator are classified and listed in Table 2.

Table 2- The identified problems and recommendations through the think-aloud protocol

The main sections or the subsections of the system		The identified problems and suggestions
Initial diagnosis	Sign and symptoms	Change comorbidity to combo box instead of a checklist
	Recommendation	Adding a description of comorbidity

Determine the severity of asthma	Results	Show the results of the assessment in different colors based on DX
Stepwise treatment	Determine risk factors	Determine risk factors in a different form
	Show additional information	Representing additional information about allergens and risk factors
	Determine treatment	Used drugs can be shown in the form of checklists
	Action plan	Show action plan based on peak flow meter and meaningful colors
Emergency situation	Recommendation	Show additional information in the pop-up box
Differential DX	Age groups	Show results based on different age groups
Extra section	Images	Adding a different section in the main menu to show essential algorithms and needed images of GINA

Heuristic evaluation continued with evaluating the effectiveness of our expert system using a questionnaire. The mean and standard deviation of the scores given to the GUIDES questions are represented in Appendix A. The total mean score of the survey was estimated at 6.30 (±0.36). The highest-rated domain of 16 items belonged to the "CDSS context" with 6.50. The mean score for "CDSS content" and "CDSS system usefulness" were 6.25, and 5.75, respectively.

Discussion:

Through this study, a clinical decision support system based on the GINA guideline was developed successfully by the researchers. To our knowledge, this study is the first attempt to implement the GINA into mobile-based CDSS in a stepwise approach. This study describes all of the phases related to designing, developing, and evaluating our system. The evaluation of embedded knowledge and system performance indicated that the developed application is quite following the GINA strategies.

Recently, interest in using smart aid tools in disease management and control of chronic diseases has been increased because they can improve the possibility of early and accurate diagnosis. Additionally, The results of other studies support the idea of that CDSSs have the potential to enhance the adherence of physicians to CPG in clinical practices. Recent evidence suggests that using health-IT based solutions could reduce the gap of adherence to GINA strategies[19].

Despite the interest in CDSSs development regarding asthma in recent years, Matui et al. [28] believed that most developed CDSSs did not improve asthma outcomes because they rarely used during the actual clinical process. This problem might be due to they are not available all over time, and clinicians can't utilize them in daily clinical practice. Thus, a mobile platform was selected in this study to improve its accessibility and portability. Moreover, we have no matter for technical installation based on the mobile-based platform. Additionally, according to WHO reports, mobile health interventions could strengthen clinical practices.

The strength of this study lies in a structured methodology. The iterative approach applied in this study enabled the researchers to refine the system continuously. As noted by Trafton et al.[29], using the iterative process for developing CDSS leads to meet the expert's expectations, and convert written CPG to an actionable expert system. This method was combined with the KTA model to achieve the best way to translate knowledge into action. Boulet believed that the KTA model could be the best strategy applied for translating knowledge of the GINA guideline [19]. Using expert consultation at all developmental stages is another strength of our study. Consulting with the multidisciplinary expert team led to various aspects of GINA guideline could be considered and analyzed. Went et al. believed that this is the best strategy to create convenient and user-friendly systems.[30]

Most recently, Khalifa (2014) proposed the most notable strategies to ensure the success of the CDSS [31]. Therefore, we tried to follow the Khalifa's suggestions as much as possible during system development. In his view, providing valid information based on the scientific reference is the key factor to success in these systems. Our ginasthma app is based on GINA guideline as the principal guideline for management of asthmatic patients based on the best current evidence. Another important strategy in ensuring the success of CDSS is providing accurate, valid, and reliable information in the most straightforward language. Together, we achieved seven out of ten success factors through this research. Utilizing a scientific approach based on merging the last medical informatics advances and clinical expertise could differentiate this study from similar studies.

Regarding the validation and accuracy of our system, using different evaluation methods at different levels ascertained the research team from the validity of the invented algorithms, and the robust performance of CDSS. Furthermore, defining different scenarios based on real patient cases with various clinical conditions has enabled us to evaluate the accuracy and specificity of the system. Patient-based clinical scenarios could mimic real patient cases and help researchers to test different situations [32]. So, examining and evaluating the significant parts of the system is possible. Regarding its high accuracy and high efficiency, ginasthma app could be expected to use in routine clinical practice by healthcare providers.

This study is encountered by some limitations. The expert panel is limited to six experts. However, we benefited from experienced healthcare professionals. Pulmonologists have participated in this survey had more than ten years of experience in asthma management. Also, the expert system is not implemented in a real clinical environment. Further investigation is needed to evaluate the efficacy of this app in real patients to assess its actual performance in routine practice.

Conclusion:

The present study is an attempt to improve the adherence of health care providers to the GINA guideline by developing a mobile based CDSS. Expert system knowledge was evaluated to determine whether the knowledge of the algorithms and decision models are in accordance with the knowledge of the paper-based guideline. The results showed the high accuracy of our system in accordance with the GINA guideline. This expert system can deliver the GINA recommendations to users based on the entered patient's signs and symptoms without limitations of time and space. Additionally, it can decrease the complexity of clinical decision making in asthma management.

List of abbreviations

CPG: Clinical practice guideline

CDSS: Clinical decision support systems

GINA: Global Initiative for Asthma guideline

KTA: Knowledge to Action

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Declarations:

Ethics approval:

The study protocol was reviewed and approved by the ethical committee at the Tehran University of medical sciences (IR.TUMS.VCR.REC.1397.115).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding:

This project was funded by Tehran University of Medical Sciences (No: 96-04-211-37171).

Authors' contributions:

H.A, M.G, and M.A contributed to the conception and design of the project. M.G and M.A extracted knowledge of the guideline and analyzed it. M.G and S.A designed the algorithms, decision models by H.A consultation. H.A and S.A validated the decision models. M.G implemented guideline application and knowledge-base. H.A, S.A, and M.G evaluated the expert system. The final application evaluated by all M.G, M.A, H.A, and S.A. H.A, M.G and S.A drafted the manuscript, and all authors reviewed, provided input, and approved the final manuscript.

Acknowledgments:

The authors also thank all the experts of expert panel.

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Availability of data and materials

All data generated or analysed during this study are included in this published article and its supplementary information files.

Figure Legends:

Fig 1. The methodology model of guideline-based CDSS

Fig 2. The main sections of the GINA mobile app

Fig 3. The decision model of initial diagnosis of asthma

Fig 4. The decision tree of differential diagnosis of asthma for 6-11 years patients

Fig 5. The overall model of the system

Fig 6. The diagnostic characteristic of ginasthma app

Figures

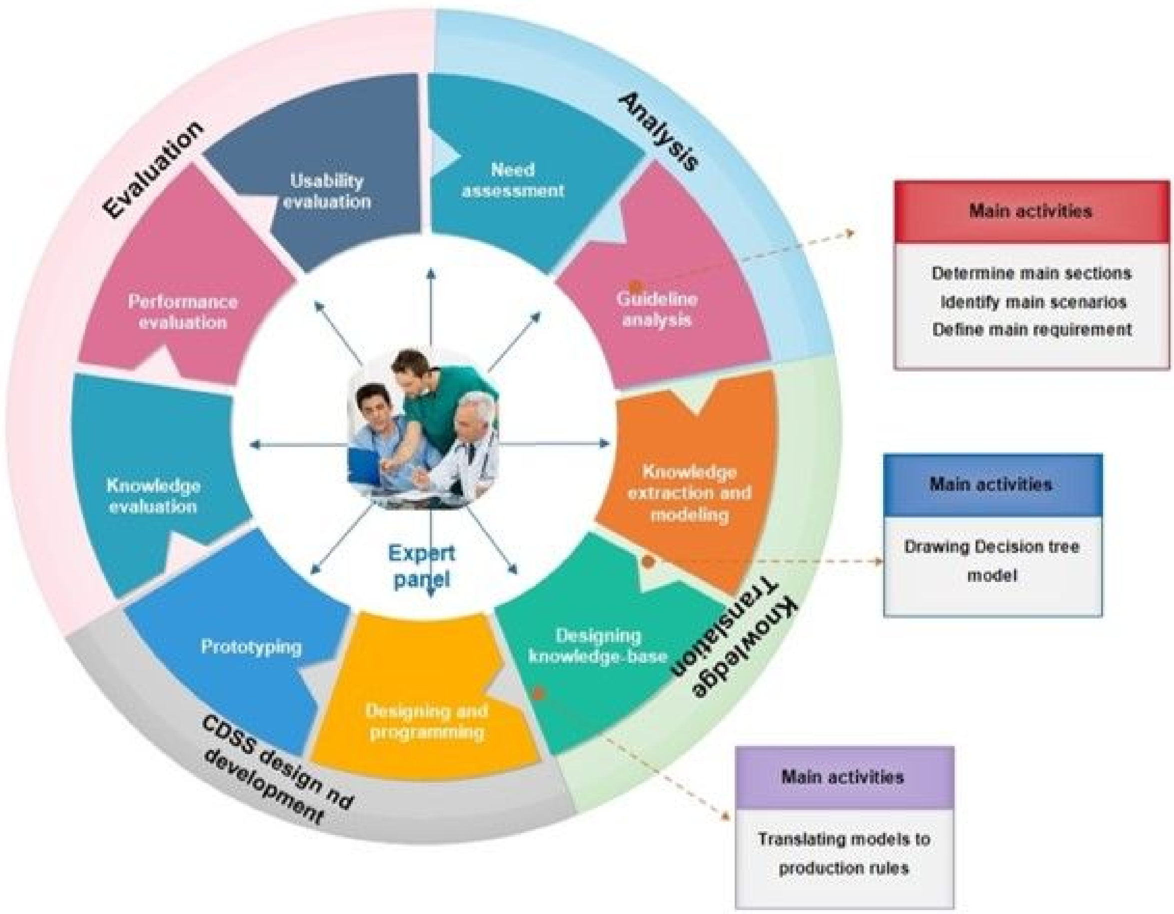

Fig 1.

Figure 1

The methodology model of guideline-based CDSS

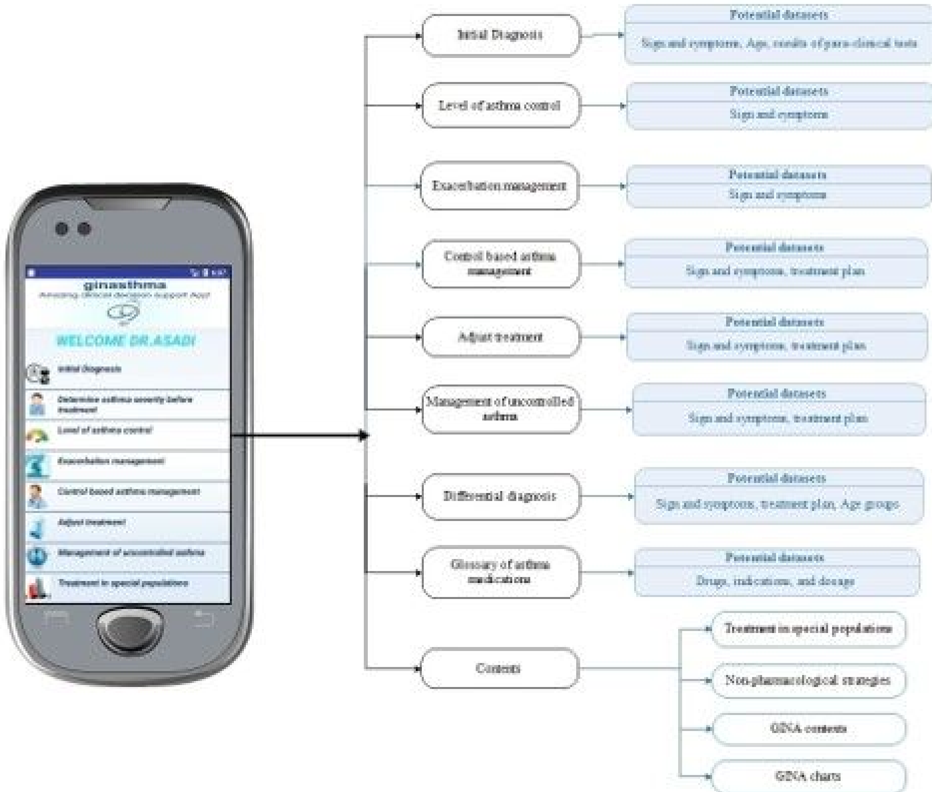

Fig 2.

Figure 2

The main sections of the GINA mobile app

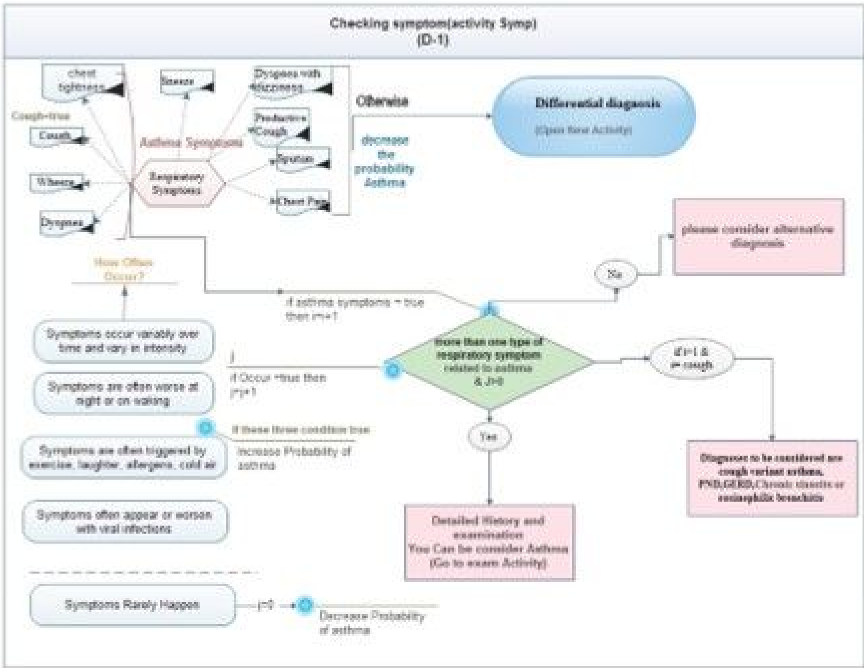

Fig 3.

Figure 3

The decision model of initial diagnosis of asthma

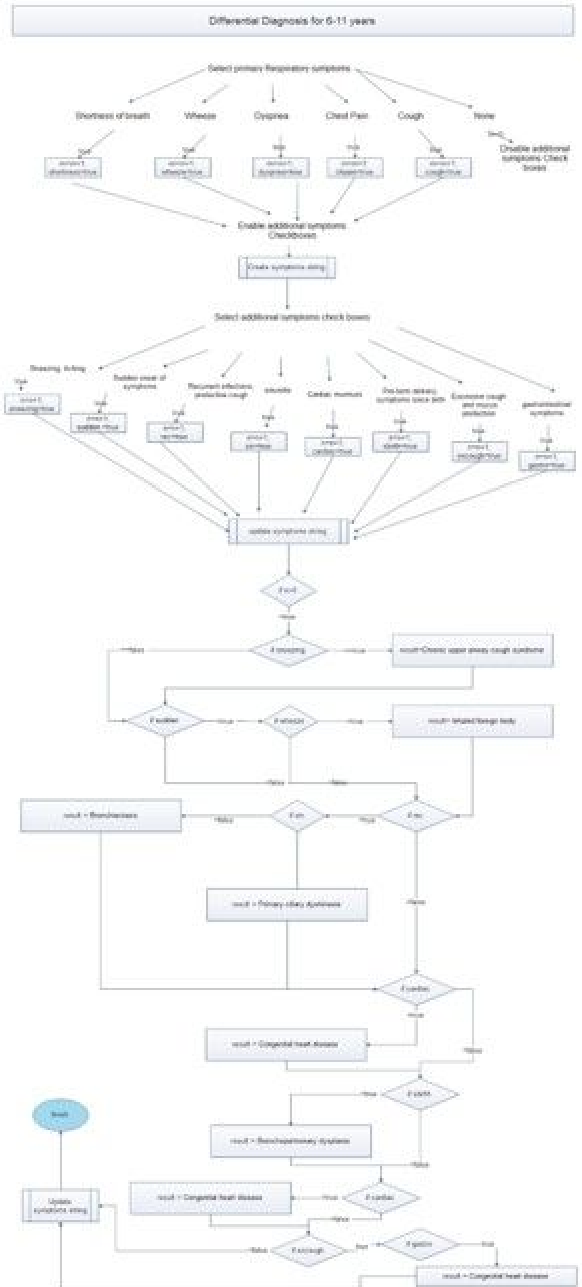

Fig 4.

Figure 4

The decision tree of differential diagnosis of asthma for 6-11 years patients

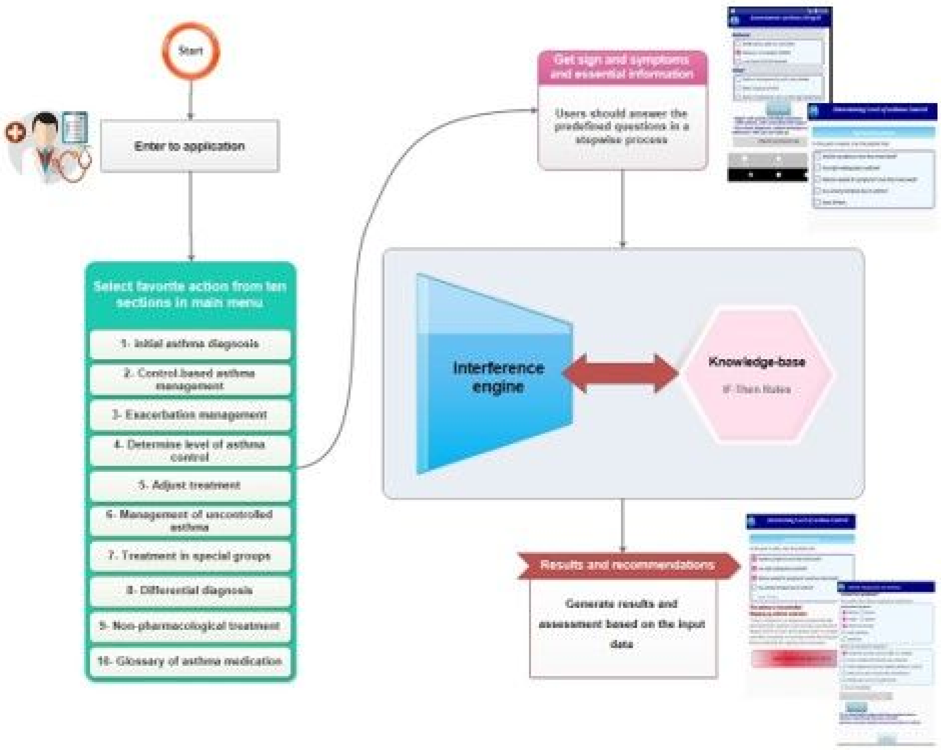

Fig 5.

Figure 5

The overall model of the system

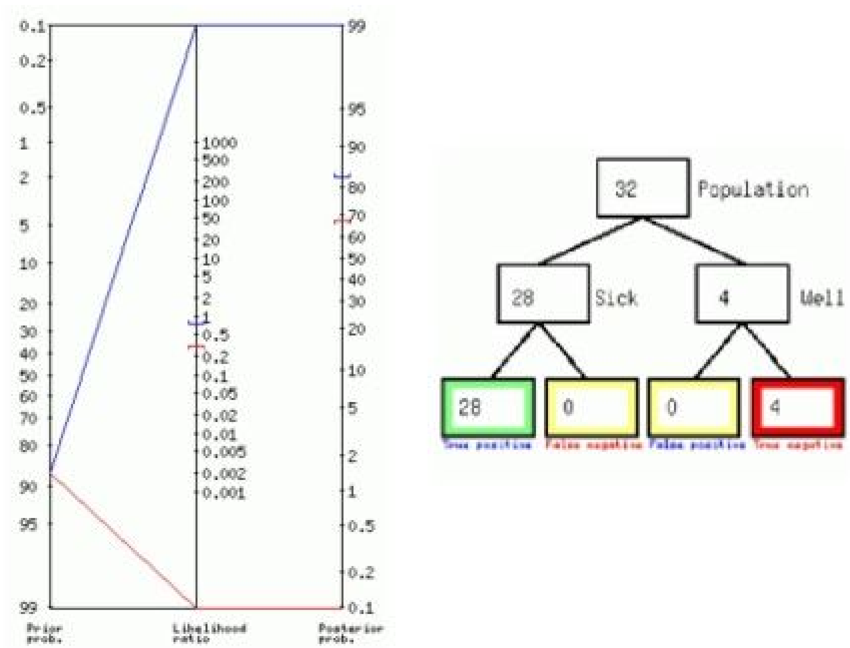

Fig 6.

Figure 6

The diagnostic characteristic of ginasthma app

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AppendixA.docx