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A Point of Care Clinical Decision Support System for the Diagnosis of Neonatal Jaundice by Medical Field Personnel

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Abstract: This study reports the design and successful implementation of a decision support system for use by a multi-purpose health worker or in any situation where there is no immediate pediatric or neonatal care. Furthermore to aid in future decision making and service deployment as also for state of health evaluation and administration the decision support system is augmented by a networking architecture for connection over an internet or intranet using the Microsoft's. NET framework. In all there were 39 cases in a span of 4 months out of which 33 were correctly diagnosed and appropriate follow-ups were scheduled. The high percentage of success is indeed very promising for further enhancements to the knowledgebase, the user interface, system setup and deployment. The high percentage of success in the decision making aspects of the system is promising for further modifications and enhancements to the setup and architecture. Making it available for developing countries where the disease conditions exist but where neonatologists are rare, would indeed be a much needed change.

Key words: Jaundice, expert systems, health care information systems, Microsoft.NET

INTRODUCTION

Jaundice of the newborn occurs not only due to physiological causes but also due to a variety of pathological causes too (Johnson and Bhutani, 1998). Specifically with term infants the onset of jaundice due perhaps to non-physiological causes might lead to fatal results if not promptly detected and treated by a field expert (Newman, 1999). Indeed clinical symptoms if detected should be immediately followed by appropriate tests to confirm the presence or absence of jaundice in such cases. However in rural places and in villages or towns of third world countries such experts might be scarce or unavailable. It is imperative therefore that the healthcare field worker needs to have suitable point of care support to promptly detect, setup appropriate tests and analyze the results either in conjunction with or without a remotely located pediatric specialist.

Newborn infants appear jaundiced when the serum bilirubin levels are greater than 7 mg dL^{-1}. The normal serum bilirubin level is less than 1 mg dL^{-1}. Adults appear jaundiced when serum bilirubin levels are greater than 2 mg dL^{-1}. Jaundice of the newborn occurs not only due to physiological causes but also due to a variety of pathological causes. Each year approximately 60% (of full-term infants and 80% of pre-term infants) of the 4 million newborn in the United States alone become clinically jaundiced (Moses, 2004). Furthermore some studies have shown that in recent years, *Kernicterus* the most severe and potentially fatal form of complication in clinical jaundice, has increased in incidence as post-partum hospital stays have become shorter (Lock and Ray, 1999; Maisels and Kring, 1998; Malkin *et al*., 2000). However no such numbers are available from those of third world countries excepting a few studies confined to specific regions (Kumar *et al*., 2002). Especially in rural places of such countries many term infants die from lack of prompt detection by a specialist. The health care worker in such countries typically doesn't have the clinical expertise to quickly evaluate the onset of jaundice symptoms leading to a higher degree of infant mortality. This can be obviated however by equipping these workers with appropriate decision support systems installed in an inexpensive PDA or a hand-held computer. Furthermore it would be worthwhile if such devices could also be used to upload the necessary information to be later employed by the district and/or metropolitan health care administration or pediatricians, field specialists and the like as also a knowledgebase to help aid in future decision making. The latter implies the requirement for a database juxtaposed with the decision support system ready to be connected to a remote site over an internet or

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intranet. In this context this study reports the use of the latest advances in the arena of Web Services specifically the Microsoft's.NET framework for the deployment of the decision support and data management aspects of the project (Anonymous).

MATERIALS AND METHODS

Rule based decision support system: A clinical decision support system supports the definition, storage, retrieval and management of clinical information throughout the clinical decision making process and thus, is an essential component in almost all health care undertakings. In such settings the decision making environment encompasses a broad range of activities and players including diagnosis, findings and treatments among clinical experts, decision makers, patients, etc. A typical clinical decision making process consists of medical professionals and patients gathering information and exploring potential diagnosis for various treatments and services and post healthcare activities. The decision making part of such systems are typically rule based which serves to mimic the reasoning process experts (in this case the clinical specialist) use to solve problems and which could be put to use by a non-expert (a health care worker or medical resident) to aid in an environment devoid of having very few experts. Such systems effect decision making based on the assumption (non-trivial) that clinical activity can be analyzed using many simple rules and that the decision process of the specialist can be modeled by sets of such rules. Essentially these systems are used to propagate scarce knowledge resources for improved and consistent results. Several rule based systems are becoming very popular in the area of clinical decision making and are typically distinguished based on their mode of acquiring knowledge be it using artificial neural networks or fuzzy logic and/or combinations of them and traditional statistical techniques as well (Luger and Stubblefield, 1999; Marion, 1999). In this study we report the development of a rule based system for use by paramedical personnel in the domain of neonatology. Figure 1 shows the beginning screen shot of a new case to be evaluated.

This system has three important components-Inference engine, Knowledge base and Static knowledge in the form of rules and facts. The methodology involved here is to build a branched tree with various rules and goals. The input parameters are each given a confidence level between 0 and 10 (0 being NO CONFIDENCE and 10 the HIGHEST). Once the model is developed it has to be validated and checked for possible errors.

Non-physiologic causes of jaundice may not be easy to distinguish from physiologic jaundice and thus requires a field expert to correctly distinguish one from the other (Watchko and Oski, 1992). Some of the situations that such experts consider as non-physiological jaundice requiring further investigation are given below.

General conditions like onset of jaundice within first 24 h of life and persistence of jaundice over prolonged period, signs of underlying illness in infants like vomiting, lethargy, poor feeding, excessive weight loss and temperature instability. The above mentioned symptoms are non-specific. A detailed family history regarding the following should be obtained: history of jaundice, anaemia, gall bladder disease, liver disease, sibling with jaundice or anaemia, maternal illness during pregnancy,

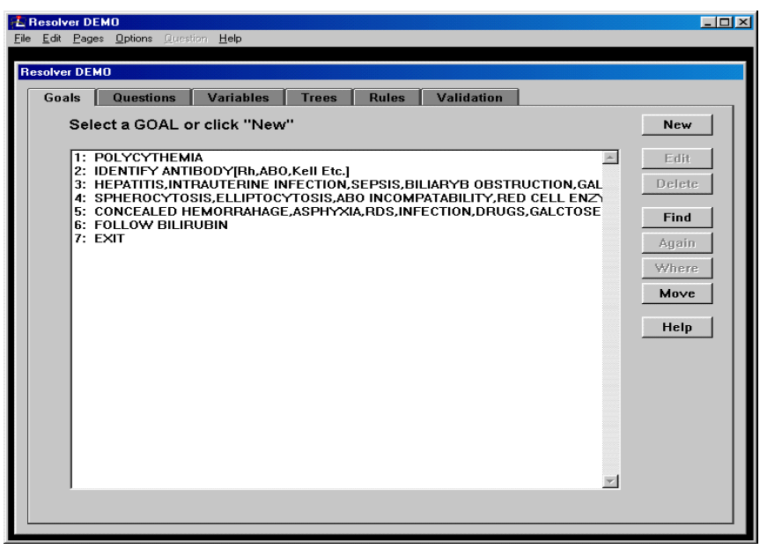

Fig. 1: The goals open to the paramedical personnel for field testing

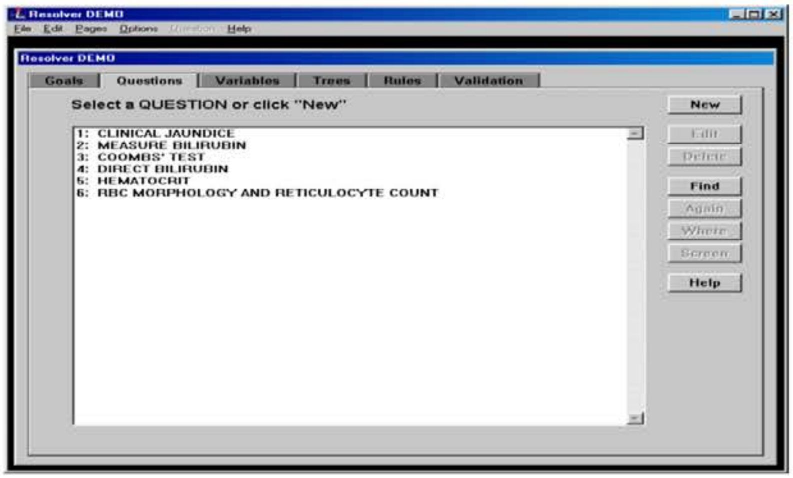

Fig. 2: The query page of the rule based system for the decision making process

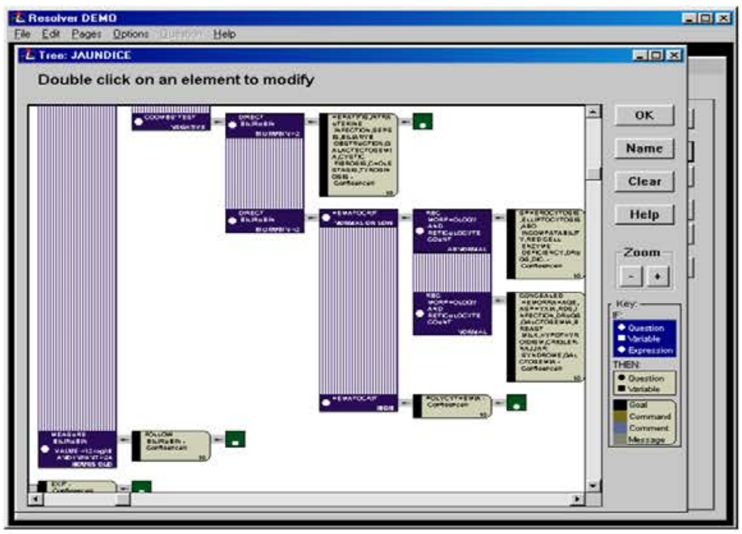

Fig. 3: Decision tree traversal for one specific case of neonatal jaundice

maternal drug intake, ethnicity, difficult labor or delayed cord clamping, history regarding breast feeding, delayed stooling and excessive vomiting (Anonymous, 1994). The physician assistant or the general practitioner should next proceed to a detailed physical examination and jaundice is looked for in the infant by blanching the skin with finger pressure to observe color of skin instead of looking for yellowish discoloration of conjunctive as in the case of an adult. Besides biomedical devices such as the transcutaneous bilirubinometer and card ictometer to assess the severity of jaundice there are quite a few pharmacological means to treat it (Tan, 1997; Alcock and Liley, 2003; Suresh *et al*., 2003).

The next step is to proceed to running a few tests on the infant and the following tests are indicated in the presence of non-physiologic jaundice.

- Total serum bilirubin, blood type, Rh and direct COOMBS' to test for isoimmune hemolytic disease.
- Infants of women who are Rh negative should have a blood type, Rh, COOMBS' test performed at birth. Blood typing and COOMBS' test should be done for infants who are discharged early especially if mother's blood group is type O. For the mother it is imperative to do blood type, Rh grouping and antibody screen during pregnancy and should be repeated at delivery.
- Perform peripheral smear for RBC morphology and reticulocyte count to detect causes of COOMBS' negative hemolytic disease, for eg. Spherocytosis. Identification of antibody on infant's RBC especially if results of direct COOMBS' is positive.

- Direct bilirubin estimation is necessary when jaundice persists beyond the first 2 weeks of life and when there are signs of cholestasis.
- In prolonged jaundice tests for liver disorders, congenital infection, sepsis, or metabolic diseases or hypothyroidism.
- A G-6-PD screen may be helpful especially in male infants of Asian, Mediterranean or Middle Eastern descent (Sinclair and Bracken, 1992).

Figure 2 shows the corresponding query page in the decision making system and Fig. 3 shows the decision tree traversed for one specific case.

NETWORKING

System requirements: Prior to the design phase a list of system requirements were identified which were as following:

- The backend database system being developed should be relational in nature
- The database system should be web enabled so that multiple testing sites can simultaneously enter and transmit data via the internet.
- User should be able to easily use the system. Standard and user friendly interface should be provided throughout the system.
- Since the system contains confidential medical records and data, application and system level security is a very important issue and only authorized user be allowed access to the relevant portions of the system.
- A log of users should be maintained.
- The system should be fault tolerant.
- Data should be validated to guarantee integrity and accuracy.
- The system should be easily modifiable and highly scalable.
- System should be simpler to maintain and extend.
- The cost of developing the system should be low. Use of inexpensive software and hardware.
- Data backups should be carried out everyday and backups stored at a remote location.
- A set of standardized reports (tables, frequencies, line lists) should be developed in order to provide data required for the appropriate state and/or federal or hospital reports.

System design and development-use of web services architecture: After carefully taking into consideration the system requirements and application development models it was decided to use the web services architecture to build and deploy as a secure and user-friendly web enabled system. The Web services architecture or platform has opened up the arena of communication across various systems irrespective of the programming language or operating system. In this context the Microsoft.NET platform, empowered with the Visual Studio.NET development environment, has not only created the support for Web services but also adheres to industry standards like SOAP (Box, 2001) and WSDL (Christensen, 2001) and UDDI (Bellwood, 2002) which facilitates the interoperability across various systems. The main concern that was holding up the adoption of Web services as an industry solution which was the security issue has since been obviated by the introduction of the ASP.NET (Basiura, 2002; Dournaee and Dournee, 2002) platform which in conjunction with.NET framework addresses various security concerns like authentication, authorization, confidentiality and integrity. Indeed besides general applications such as information portals (Ashby, 2001; Aversano, 2002) there are solutions already being developed for its use even in law enforcement (Slaski and Coleman, 2003) a very security-dependent application. Figure 4 shows the block diagram of the network architecture used.

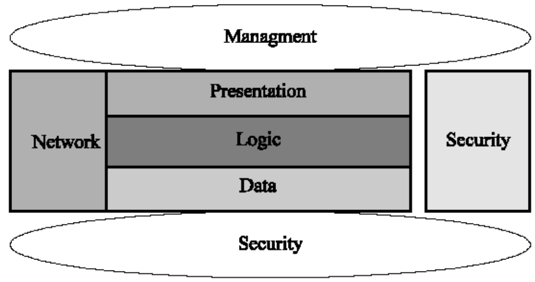

Fig. 4: Block diagram of network architecture used

In this study the Internet Information Server coupled with ASP.NET framework provides the web enabled application deployment infrastructure that collects the application input, performs business logic and data transactions and finally sends the output to thin web based clients (in this case mobile web browsers). As stated before, some of the ASPs also connect to the backend database using Microsoft's Jet Database Connectivity. The application server with the .NET framework provides the necessary setup to enforce complete application (both programmatic and declarative) security.

In essence the web enabled application architecture just described not only follows the traditional three-tier client/server architecture but also provides remote access to clients, session and transaction management, security enforcement and resource pooling. Using the MVC model,

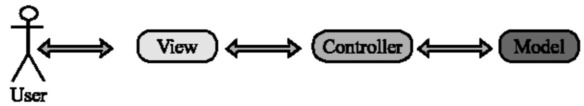

Fig. 5: Diagram of a model view controller

the business or application logic of application is separated from the data management and presentation portions and is allowed to execute separately thereby maintaining scalable and manageable application architecture.

System flow: In this project the application was designed using a modified Model-View-Controller (MVC) architecture for user and process flow driven applications using the ASP.NET (Active Server Pages) framework. In this setup, some Active Server Pages serve as views while others serve as Controllers and as Models (Fig. 5).

Authorized users can log into the system using a username and a password. User authentication is performed across the database and user roles and privileges are used to control application security. Once the user has successfully logged with the proper rights and privileges in the system the user is presented with a choice of opening an existing record, creating a new record or querying the database to generate reports. If the user chooses to open an existing record, the user has to enter a combination of first name, last name and date of birth or first name, last name and social security number to derive a Master ID. A Master ID is a unique auto generated number assigned by the application to every record. The Master ID is finally used to open the patient record. The application then directs the user to a main menu where the user can select to view forms and make updates if necessary. If the user chooses to create a new patient profile the application will assign a new Master ID to that record. The user is then ultimately directed to the appropriate main menu either of the decision making system or of the administration and/or connection to the remote site. If it is the latter the user can query the database by inserting desired values in the search field. The user can further generate a report by clicking on the generate menu button. If it is the entry into the decision making part of the system then the rule-based system is invoked resulting in a series of question and answer session leading to a suggestion for decision or diagnosis.

Backup and recovery: At present the application is already configured to suitably store recorded data in the remote server location (district hospital or administrative offices). There are plans to implement load balancing and failover support in the future to provide higher availability.

RESULTS

After rigorous testing during the developmental stages the complete networked decision support system with its knowledge base was field tested in a district hospital in South India using three PDAs and a hospital web server system wherein the field personnel (nurses and clinical interns) were asked to (as part of their routine field trips) to use the rule-based system for diagnostic support. The clinical field personnel were aware of the recognition of the most basic symptoms of clinical jaundice but didn't have either the expertise or the extensive experience of the district neonatal specialist. Using assumed readings of 'typical' patients (obtained from the specialist) these field personnel were trained in the use of the system and to save the diagnostic results and upload it to the server. It was then taken on the field trips of the healthcare workers who routinely monitor the state of health of the local residents in the district. In all there were 39 cases of confirmed clinical jaundice in a span of 4 months. Using the system alone, 33 of these cases were correctly diagnosed and the conclusions and/or recommendations if any were verified by the specialist. The high percentage of success is indeed very promising for further enhancements to the knowledgebase, the user interface, system setup and deployment. The decision making system (whose screenshots-of the prototype system-have been illustrated in the figures thus far) was also used as a teaching tool to compare the decision making process of the clinical residents with those of a neo-natologist.

CONCLUSIONS

The main objective of this project was to develop a decision support system module that uses the clinical decision criteria of experts in the neonatology field to advice paramedical and semi-skilled personnel who require guidance to diagnose the etiology of neonatal jaundice. In this study we have used a rule-based system to build the decision tree that would aid the paramedical personnel to arrive at an appropriate etiology for hyperbilirubinemia in a neonate. By taking advantage of the pervasive nature of internet available even in third world countries, the application clearly illustrates the efficacy and practical usefulness of web based database applications by providing unified, efficient and secure applications for data collection, reporting and analysis in remote sites.

The high percentage of success in the decision making aspects of the system is promising for further modifications and enhancements to the setup and architecture. Some of these modifications would include the use of cellular phones and Pocket PCS as alternative to the PDAs used in this project. Furthermore networking on a district level basis with other hospital or clinics is also planned. As regards the rule-based system there is the problem that this system cannot train or learn by itself unlike an artificial neural network or better still a neuro-fuzzy system which is also considered as an alternative approach for future investigations. In summary, we have designed and validated this system for neonatal jaundice the disadvantage of this is that it does not have self-learning abilities as yet. The implementation of the rule base is completely based on the recommendation by AAP to aid in the evaluation and treatment of healthy term infants with jaundice. In these guidelines, the AAP has attempted to describe a range of acceptable practices, recognizing that adequate data are not available from scientific literature to provide more precise recommendations. Now by developing this system in such a way as to make it available for developing countries where the disease conditions exist but where neonatologists are rare, is indeed a much needed change.

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