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Development and Introduction of the Telemedical System into the Blood Transfusion Practice

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1. Introduction

The blood transfusion service is a distributed service. Blood products are delivered from the central blood bank to the final consumer – local hospitals. Before a blood transfusion is given, obligatory pre-transfusion tests are performed at the hospital laboratories for confirmation of the donor/patient compatibility. They are normally performed by specially trained personnel. Normally, these agglutination-based compatibility tests have straightforward results, enabling easy diagnostic decisions of the local staff. In approx 1-5% of tests, various serological difficulties and ambiguities occur (Rozman & Domanovic, 2006). In these cases, transfusion is delayed and an expert opinion is needed for the resolution of test results. In such cases, patient's blood samples are sent to the reference transfusion laboratory to a qualified immunohaematology expert by a courier. The expert performs additional tests and interprets them. The consultation between the expert and local technician is then performed by telephone or fax. Notably, this method is error prone procedure with a poor safety, quality and traceability performance, resulting in a time consuming and expensive operation.

In case of Slovenia, transfusion service is provided by two central national transfusion centres with reference laboratories and 9 hospital transfusion departments with their transfusion laboratories. Transfusion centres are expert centres coordinating all transfusion actions on national level. They are responsible for blood collection, testing, production of blood components and performing pre-transfusion tests. Hospital transfusion departments with their transfusion laboratories are responsible for blood collecting and pre-transfusion testing (Brič et al., 2010). On the average, transfusion service of Slovenia handles 400 transfusion cases per day (Rozman & Domanovic, 2006). Since it is impossible to predict when transfusion services are required, it is necessary to provide transfusion experts 24/7 in all hospitals depending on transfusion service. Therefore an adequate number of experts are required. It is difficult to satisfy these demands due to lack of the qualified experts and lack of funds. Furthermore, in smaller hospitals only a few transfusions per day occur. In these hospitals transfusion expertise is provided without dedicated personnel by expanding a set of assignments of other on duty doctors. These doctors attended additional transfusion medicine training course. They are able to solve straightforward cases occurring during their shift, when dedicated transfusion specialist is not present. But these doctors solve

relatively small amount of transfusion cases and an obvious problem is lack of practical experience of these *multipurpose* doctors.

The core problem, addressed by our telemedical system is the remote readout and interpretation of the agglutination tests, performed prior each blood transfusion (pre-transfusion tests), following the EU Directive 2002/98/EC that introduced quality management and haemovigilance into the practice of the current blood supply (Faber, 2004). The ability to perform remote readout and interpretation of pre-transfusion tests solved the problem of the delayed pre-transfusion procedure in cases of ambiguous cases which required attendance of reference laboratories. Another problem addressed by the system is provision of remote immunohaematology expertise to laboratories with insufficient personnel resources. Furthermore, the law requires issue of a signed document as a result of the pre-transfusion test. Since the telemedical system does not transmit signed paper documents, our system had to provide legally sound documents. To provide documents, legally equivalent to their signed paper counterparts, a digital signature infrastructure was introduced into the system.

2. Existing solutions

Regarding the mode of operation, two main models of telemedical systems for exchange of expertise between health care experts exist. These models are “store-and-forward” model and “real-time” model.

Store-and-forward telemedical system approach is asynchronous interaction. A query can be transmitted by the referrer and then answered by a specialist at later time. It is used in various forms and on various fields of medicine (Harnett, 2006). Many authors report successful store-and-forward telemedical implementations using common e-mail service (Bonnardot & Rainis, 2009; Wotton, et al., 2010). Telemedical solutions using e-mail as baseline technology platform are relatively easy to implement, since most of the infrastructure already exists, therefore investment into equipment is relatively low. These solutions use existing widespread applications for e-mail exchange. These applications and underlying communication protocols are mature and are relatively reliable. More advanced solutions use different PACS systems as their baseline technology platform. Store-and-forward service is capable of transmitting diagnostic data that can be digitalized or is already created in digital form. The most common store-and-forward applications using e-mail service are tele-ECG and still image transfer for dermatology or wound care. System using PACS are mainly tele-radiology systems (Bahaadinbeigy, et al., 2010).

On the other hand in cases where immediate response is required, real-time telemedical systems are used. They provide real-time communication between communicating parties, providing consulting side with immediate consultant expertise. Using the real-time system, it is possible to provide expert tele-presence. Expert consultant can interactively guide the consulting personnel through the patient treatment procedure. The majority of real-time telemedical systems transmit voice, and video image of the communicating parties. Several studies have shown, that it is important for the in communication participating persons to see each other, since a lot of information is exchanged through visual communication. Videoconferencing real-time approach can also be used to transmit diagnostic images of patients, their conditions and other objects. Several reported real-time telemedical systems are built using of the shelf videoconferencing equipment. Addition to relatively standard videoconference communication is transmission of other patient diagnostic data such as

real-time ECG. The most common real-time telemedical application areas employing videoconferencing are education, wound care and psychiatry (Bahaadinbeigy, et al., 2010). Comparing both widely used approaches of telemedical systems, store-and-forward model of telemedical service provides better accuracy and traceability, compared to real-time systems. Better accuracy is provided because the consultant does not have to work under constant pressure of swift decisions since he/she can take time to handle the cases. Better traceability is provided because the model by its definition provides track of performed actions. Data is exchanged in a condensed form. Data exchanged usually consists of diagnostic data, patient health record data and refined question to the consultant, awaiting refined response. On the other hand the real-time system provides its users with quick resolution of their problems. It enables additional data exchange through real-time interaction on specific topics needed to resolve the problem (Wootton 2006). Regardless of many telemedical systems in existence no publication about the telemedical system, other than ours, supporting the blood transfusion was found.

3. Our solution

Our system enables remote interpretation of pre-transfusion tests performed on gel-cards. Considering advantages of both store-and-forward and real-time approach a hybrid telemedical system was developed using store-and-forward as base mode of operation with possibility to switch to real-time mode when necessary. In real-time mode audio/video communication between its users is offered. A special device Gelscope was developed to capture images of gel-cards.

Our system follows high level of security, user identification and data protection requirements. The result of the system usage is prompt exchange of immunohaematology expertise in form of legally valid electronic document containing the pre-transfusion test readout, interpretation and diagnose.

4. Background: pre-transfusion serological testing

Our telemedical system is based on the pre-transfusion serological testing consisting of ABO blood grouping, cross matching, antibody detection and specification (direct and indirect antiglobulin tests) (Lapierre et al., 1990; Langston et al., 1999). These tests are based on the detection of red cell antigen-antibody reactions, resulting in the agglutination of red blood cells. Although several agglutination methods exist, the micro-tube gel method with the DiaMed® gel-cards is probably the most widely used. Gel-cards are plastic cards with 6 embedded micro-tubes, filled with a mixture of sephadex gel, buffer and reagent. For each pre-transfusion test a different combination of the reagents is used in the gel-card test tubes. Figure Fig. 1 depicts the image of commonly used serological test ABO Rh gel-card with agglutinates fixed, ready for the readout and interpretation. During the test a suspension of red blood cells or a mixture of the red blood cells and diagnostic antibodies is centrifuged through the gel under standardized conditions. If no agglutination occurs, the red blood cells penetrate the gel and sediment at the bottom of these micro-tubes (negative result). In cases when agglutination occurs, agglutinates are trapped on the surface of the gel (positive result).

The readout and interpretation of the test is performed by visual interpretation of the agglutination pattern in six micro-tubes. It consists of two steps. In the first step, the

strength of agglutination is determined for each of the six micro-tubes, ranging from 0 to 4+. Typical agglutination patterns ranging from 0 to 4+ are shown on Figure Fig. 2. An ambiguous agglutination pattern is also shown and is marked by (?). In the second step of the pre-transfusion test interpretation, the result is interpreted based on the agglutination pattern in six micro-tubes. By capturing the image of the gel-card, it is possible to electronically capture the result of the pre-transfusion test.

The gel test method of pre-transfusion serological testing, when performed by standardized procedures, yields sensitive, specific and reproducible results. The final visual read out and interpretation of the gel-card represents the most important step affecting the accuracy of the medical diagnosis (Lapierre et al., 1990; Langston et al., 1999). It requires engagement of highly qualified and experienced personnel. In addition, access to the patient’s medical history is required during the diagnostic procedure for an accurate diagnostic decision.

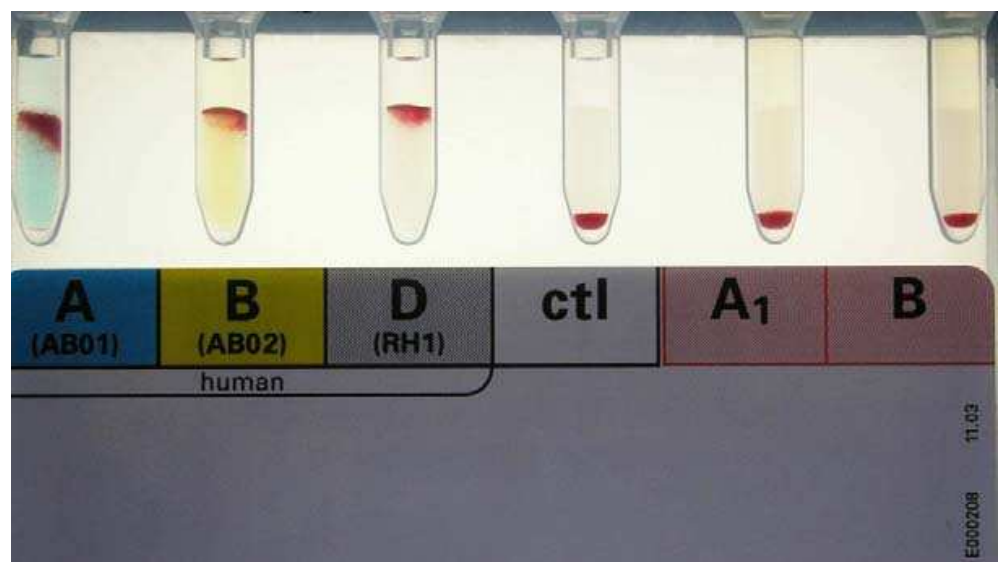


Fig. 1. ABO Rh gel-card after centrifugation with agglutinates trapped in the gel. The image is obtained from the working telemedical system.

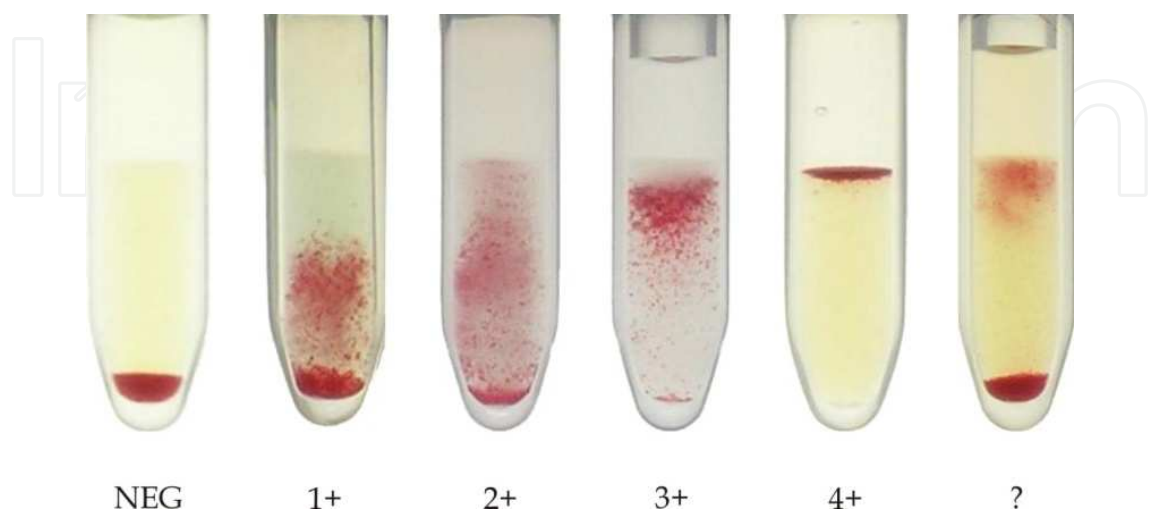


Fig. 2. Possible gel-card test tube classifications, ranging from negative result (NEG) to positive result (4+). Ambiguous test tube is marked with question mark (?).

5. User requirements acquisition

As already mentioned, the blood transfusion service of Slovenia is provided by 2 large blood transfusion centres and 9 hospital-associated transfusion departments with laboratories, which supply hospitals with blood products and obligatory pre-transfusion serological testing. Provisioning of these services in Slovenia requires 24 hours per day, 7 days per week availability of at least one immunohaematology expert in each institution (Rozman & Domanovic, 2006). To rationalize these needs, several requirements for the telemedical system for a remote read-out and interpretation of pre-transfusion tests were identified. Prospective users of the telemedical system were involved into the system design from its beginning. At the start it was not possible to generate detailed system specification; therefore the process of developing the telemedical system was iterative. In the first iteration use case scenarios of the system were discussed with prospective system users – immunohaematology experts and technicians from transfusion laboratories. Based on discussed use case scenarios high level user requirements of the system were obtained. These user requirements were used to create detailed set of technical specifications, based on which a prototype system demonstrating the basic functionality was build. The prototype system was then evaluated by the prospective users who provided refined user requirements set. Refined user requirements were then used in another iteration of the development cycle. The whole procedure was then repeated until the system was in the production ready state.

Current condensed set of high level user requirements of the telemedical system is as follows. The telemedical system should provide (Meza, et al., 2007):

- capturing of high resolution images of DiaMed® gel-cards;
- transmission and archiving of the captured gel-card images;
- magnification of the gel-card images for detailed observation of agglutinates;
- 24-hour availability of expertise from the reference laboratory to the remote hospital laboratories;
- a store-and-forward telemedical model for non-urgent transfusion cases;
- exchange of corresponding medical data of patients and blood donors;
- permanent on-line connection to the national data bases of blood donors and patients for the provision of the transfusion and anamnestic data;
- real-time interaction between the technician in the local hospital laboratory and the expert in the reference laboratory in urgent cases;
- audio and visual communication between its users;
- complete traceability of all procedures;
- scalable system design;
- notification of users via SMS;
- reliable, safe, secure and encrypted data transmissions.

Since users of the telemedical system were involved into the system design, they adopted the system as their project, which helped to the system success. Common problems did not deter them from using it. According to the authors (Broens, et al., 2007) technical problems are among the main barriers for successful telemedical system implementations. Involvement of users of the system into the system's development also lead to quick resolution of technical problems, since they were quickly identified, and thoroughly described to the development team.

Use case scenario, describing the system usage is presented in the next section.

6. Use case scenario – system usage workflow

The system usage workflow can be explained on the following use case scenario. Let us assume that in a hospital transfusion laboratory there is no immunohaematology expert present and a need for pre-transfusion testing emerges. Since no expert is present, a remote pre-transfusion test interpretation is required. Users involved into the process are divided into two roles. Users belonging to the role *consulting user* are laboratory technicians. These are users requesting the remote interpretation. Users belonging to the *consultant* role are immunohaematology experts. They are legible to issue legally valid pre-transfusion test interpretations. Technicians as well as consultants both use the terminal with the teleconsulting application. Screenshot of the teleconsulting application can be observed on Figure Fig. 5. All users must log into the application using their unique credentials. Based on the credentials the system determines user's role and rights to access different data. Roles and rights for each user are defined on the teleconsulting server. On Figure Fig. 3, a laboratory setup of the technician side is photographed.



Fig. 3. Laboratory setup of the telemedical system. Main application window can be observed on the terminal. Gelscope device is visible right next to the terminal monitor. Videoconference call is not established.

At first the laboratory technician prepares the required samples according to the protocol of the pre-transfusion testing (Langston et al., 1999). Result of sample preparation is a series of gel-cards with administered blood samples after centrifugation with agglutinates fixed in the gel of gel-cards. After gel-cards are prepared, the laboratory technician sets up a teleconsulting session by setting up a question. Teleconsulting session consists of a question and if answered of the answer to that question.

Setting up the teleconsulting question is divided into several steps. The first step is entering a blood sample number into the teleconsulting application. It is accomplished by capturing the blood sample number from the sample vial, using the barcode reader. Sample number

record exists in the existing hospital information system along with patient's details, transfusion history and anamnesis. After capturing the sample number, patient's data is automatically obtained by the teleconsulting application and appended to the teleconsulting question. In the next step, the technician uses the Gelscope device to capture images of all gel-cards used in the test. For each gel-card, card type is selected and inserted into the teleconsulting application from provided dropdown menu. Users can add up to 10 gel-cards to each question. In the next step of the question setup, the case specific question is typed into the teleconsulting application. Then the available immunohaematology expert - the consultant is selected from the list of available consultants. After all question data has been entered, the technician finishes question data entry. The teleconsulting application then relays the entered data to the teleconsulting server.

All teleconsulting applications continuously pool the server for any new questions/answers. When a new question to the currently logged consultant emerges, the teleconsulting application immediately notifies the consultant about the incoming interpretation request. Notification is accomplished by displaying an alert window on the terminal and by sending an SMS to the consultant's mobile phone. Using the telemedical application, consultant reviews the question. He/she interprets the test results for each of the gel-cards and enters them into the telemedical application. After all gel-cards are interpreted, consultant determines and types the answer to the test case specific question set by the technician. After all data has been entered, the consultant can decide to digitally sign the answer. In case of digital signature the answer becomes signed document, which is legally equal to the paper document required for the blood transfusion procedure. After data has been entered into the teleconsulting application it relays it to the teleconsulting server.

Since all active teleconsulting applications pool the server for new questions/answers, a new answer to his/her question is noticed by the technician's teleconsulting application. When new question is noticed, the telemedical application immediately notifies the technician about the incoming answer by displaying an alert window on the terminal screen. It also sends an SMS message to his/her mobile phone. Technician then reviews the consultant's answer along with the question. He/she can then verify the digital signature of the document and proceeds with the transfusion procedure as if the consultant was actually present in the laboratory and has signed the paper document.

In cases, when immediate response is needed and verbal discussion is required between the technician and the consultant, users can establish a videoconference call using the telemedical application. Either user can establish a videoconference call. It is established by selecting online person from the list of users currently logged to the telemedical system. After selecting the person user wants to establish videoconference call with, the calling teleconsulting application sends videoconference request directly to the called user's teleconsulting application. Called application notifies the user about the incoming videoconference call by displaying a notification window. Called user can either accept or decline the incoming videoconference call. If accepted, a bidirectional videoconference call is established from both teleconsulting applications. Either side can then break the call after the videoconference connection is no longer needed.

Since videoconference call can be established only in a point-to-point mode, users currently in video call procedure are marked as busy in the list of for the videoconference available users and cannot be called by other users. Regardless of videoconference availability status, store-and-forward telemedical questions can still be relayed to busy users.

7. System architecture

The basic telemedical system architecture is client-server architecture. The system consists of several components, illustrated on Figure Fig 4. The first component of the system is the telemedical terminal, comprising of a personal computer, running the MS Windows XP SP3, running the telemedical application. Screenshot of the telemedical application can be observer on Figure Fig. 5. Telemedical terminal component is used at the hospital laboratories (consulting side) and at the transfusion centre (consultant side). Along with standard PC peripherals, the telemedical terminal is equipped with special propose hardware for capture of gel-card images – Gelscope device, shown on Figure Fig. 7, web camera, headphones with microphone, bar code reader, colour laser printer and VPN router. Existing hospital information system also exists in all hospital laboratories and is also shown in Figure Fig 4. Since consultant side does not need the equipment for question set up, terminals are lacking the Gelscope device and the connection to the existing hospital information system.

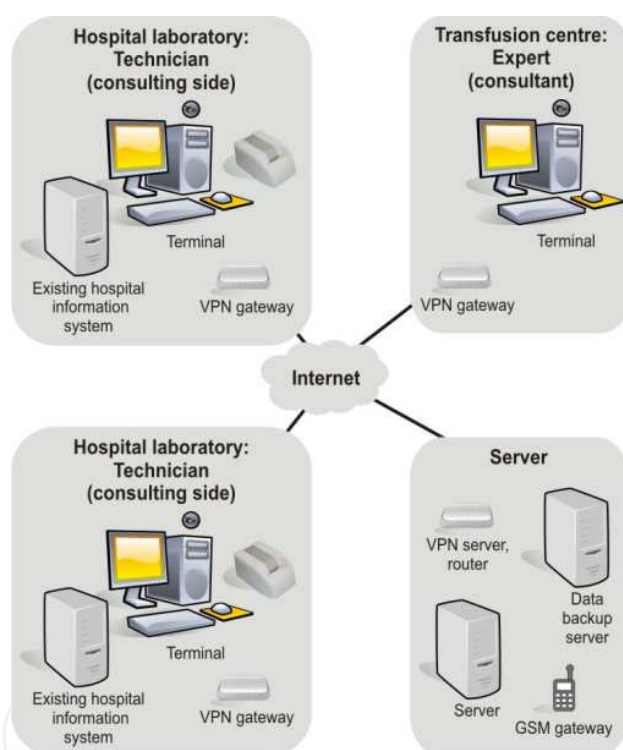


Fig 4. Teleconsulting system structure. Three terminal setups, server setup and connecting infrastructure are illustrated.

The second component is the server side of the system with main server running Debian Linux operating system, running the telemedical server application, certificate authority server application and database. The server also has GSM module attached to it and runs SMS notification application. The server side also includes VPN server – router.

All nodes of the system are securely connected through the secure virtual private network (VPN) tunnels via the public Internet established by the VPN gateways and the VPN server. The telemedical system is integrated with the existing hospital information system through a special integration module to obtain patient basic data (name surname, birth date, and blood type), previous patient anamnesis and patient transfusion history.

Basic operation mode of the telemedical system is a store-and-forward mode. If required, users can switch to the real-time mode by establishing a videoconference call. Videoconference calls are established using the videoconference module which is a part of the telemedical application.

A digital signature infrastructure was also developed and integrated into our telemedical system. Therefore through system issued readouts, interpretations and diagnoses have the same legal value as their signed paper counterparts.

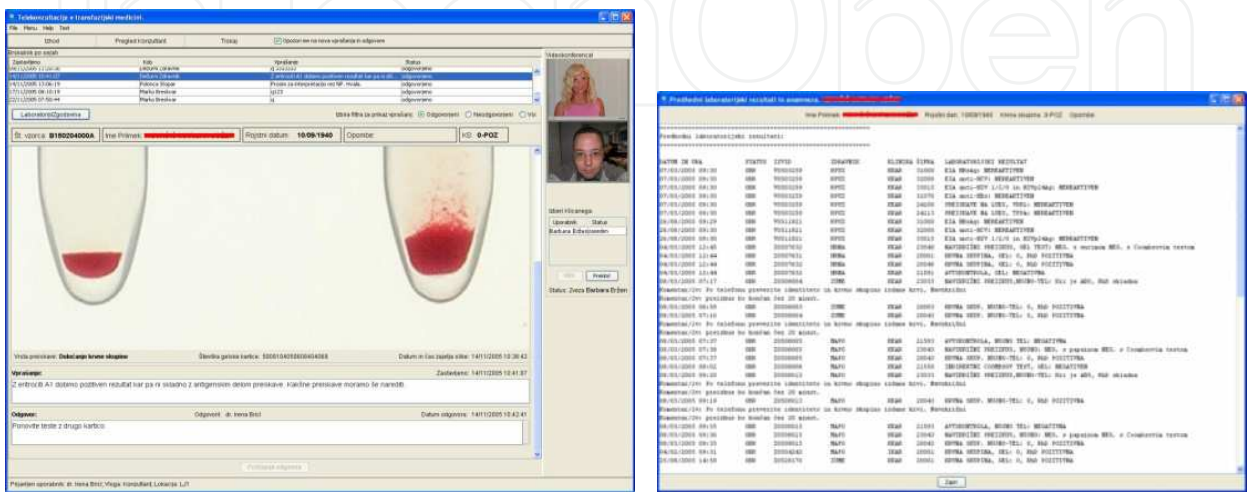


Fig. 5. Telemedical application user interface. Left shows main user interface window with a videoconference in progress; right window shows patient data obtained from existing hospital information system.

8. Telemedical system modules

8.1 Telemedical application – client

The telemedical application is the front-end of the telemedical system to its users. One of the main functionalities of the telemedical application is acquisition of the telemedical data from various sources and presentation of that data to the users. Consulting users (laboratory technicians), consultants (immunohaematology experts) as well as system administrators all use the same application. The telemedical application is running on the terminal PC. It is a client part of the telemedical system. It was developed in the Java programming language. The application user interface changes accordingly to the user level, using the system. There are several levels of users. The main difference between levels is a set of to the user allowed actions. If for example, a certain user has a role of a consulting person, than he/she is only allowed to set up questions, and he/she is not allowed to answer them. Therefore only options for setting up the question and browse them are available to that user. If user has a role of consultant, only options for answering the questions are available to that user. If user has a role of administrator, only administrative options are available to that user. Combined user roles are also possible.

The teleconsulting application screenshot is shown on Figure Fig. 5. The left window shows typical view of the telemedical application for consultant, answering the question. In the top of the window, a table with list of questions to consultant is displayed. Following below is the area where the patient basic data (name surname, birth date, blood type and medical remarks) is displayed. In the middle of the window the magnified view of the gel-card is

displayed along with gel-card image metadata. Below are question and answer entry fields. On the right side of the main teleconsulting application window a videoconference interface is shown. The top window shows incoming video stream and the bottom one is showing the outgoing stream. Below is the list of for the videoconference available users with videoconference control buttons. The right window of the Figure Fig. 5 shows screenshot of the window for display of patient data obtained from the existing hospital information system. This window is shown only on request, since there is not enough space on the monitor to simultaneously display both the main and the patient detail display window all the time.

The telemedical application communicates with the telemedical server. None of the data required for work is stored locally. All within the system existing data is obtained from the server and all newly generated data is immediately stored to the server. This enables absolute portability of the users between terminals.

There are three main modes of the common operation of the telemedical application. Not all modes are available to all users, since users have different privileges. The first mode of operation is question setup, the second one is question answering and the third one is answer review. Each mode has specific user interface. Mode switching is intuitive.

In the question setup mode, which is intended for consulting users, the application provides users with user interface for entering all question data. In this mode the application listens to the events from the attached Gelscope device. When a gel-card is inserted into the Gelscope device, it notifies the application, which commences immediate gel-card image capture. Captured gel-card images are appended to the telemedical question being set up. After a gel-card image is captured user is required to enter gel-card specific data – type of the gel-card and optionally read the gel-card serial number using the barcode reader. The gel-card images belonging to current question are shown on the ribbon as image tiles. User can select specific gel-card image for display by clicking on its tile on the ribbon. Selected gel-card can be seamlessly zoomed in or out using intuitive user interface. When image is enlarged and only a portion of the gel-card is displayed, users can pan the image view using the mouse.

In the question setup mode, the telemedical application also communicates with the existing hospital information system to obtain patient details, transfusion history and anamnesis based on the blood sample number which is read by the barcode scanner.

After all data has been entered and recipient of the question selected, the application performs data entry control and sends the data to the telemedical server.

In the question answering mode, which is intended for consultants, the telemedical application provides users with the question browser and answer entering data fields along with all question data. Using this mode of operation, users review question data and enter answers. They thoroughly examine all gel-card images and performs readout and interpretation which is entered into the provided data entry fields for each gel-card image. A patient history and anamnesis is also available. After all gel-cards are read and interpreted and patient history and anamnesis is examined, the final decision about the pre-transfusion test is made and typed into the answer field. After all data has been entered, the users can decide whether to digitally sign the answer.

In case of digital signature, the application digitally signs all question and answer data using the user's digital certificate. After the signature, neither question nor answer data can be changed without breaking the signature. After the question has been answered, the answer data is sent to the telemedical server.

In third mode of the telemedical application operation, the answer review mode, which is indented for consulting users, the application provides users with the question browser. It displays all question data entered during the question setup and in case, the question has been answered all answer data. If the answer was digitally signed, the digital signature can be verified.

Telemedical application provides its users with option to establish videoconference call with any available user of the telemedical system regardless of the current mode of the operation. In case of videoconference call audio video communication is established. Outgoing and incoming video streams are displayed in the application window.

Telemedical application is able to print question/answer data to obtain hardcopy paper documents.

The telemedical application continuously pools the telemedical server for any new questions/answers to the logged user. If a new question/answer emerges it notifies the user by displaying alert window and sending an SMS message to the logged user mobile telephone.

The telemedical application is also used to manage the users. If logged user has administrator privileges, he/she can add or change new system users, generate, register and revoke user certificates.

8.2 Existing hospital information system access module

Existing hospital information system access module is used to obtain patient data from the system and include it into the telemedical questions. It consists of two parts. The first part is a script for collecting and serving required patient data. The script is running on the existing information system. The second part is the script initiation system and data parser.

The data, obtained from the system is textual data, structured into several data fields. These are: patient details (name, surname, birth date, blood type, and medical remarks), patient transfusion history and patient anamnesis. All transfusion hospital laboratories in Slovenia use the same in-house developed information system named DATEC comprising of a UNIX running server and in FoxPRO written application. For placement of the existing information system placement within the telemedical system see Figure Fig 4. The information system DATEC was originally designed to be accessed to by its users using a terminal interface. The communication protocols, provided are telnet and FTP protocols, which were also used in our access module.

In order to gain access to patient data from the existing information hospital system DATEC to the telemedical system, a special data query script to run on the information system was developed. When run, the script requests for the blood sample number which is then used to query the internal database for all patient data. Obtained data is then stored as a text file with separators used to separate distinctive data fields on the internal DATEC's file system, accessible through the FTP protocol.

When patient data is required by the telemedical application, it establishes a telnet connection to the information system. Then it starts the data query script and provides it with the sample number. After the script finishes its execution, the telemedical application breaks the telnet connection and establishes a FTP connection instead. Using the FTP connection the file containing the patient data is obtained from the DATEC's file system. The file is deleted afterwards. After the file is obtained the data is parsed into the telemedical application's data container, which is then displayed to the telemedical application's user and appended to the telemedical question. See Figure Fig. 5, right.

8.3 Gel-card image capturing device

The images of gel-cards are captured using specially for this purpose developed hardware – Gelscope, designed to be easy and simple to use. Gelscope provides standardized and repeatable capturing of images required for the correct read-out and interpretation of the pre-transfusion tests. Image capture is standardized in means of position, illumination and other optical deformations of the gel-card. The captured high resolution images (24-bit, true-colour 3.2 mega pixels) can be magnified up to 20-times without any visible degradation of the image. Hence, the observation and interpretation of the agglutinates is easy compared to the standard visual reading by the naked eye (Meza et al., 2007).

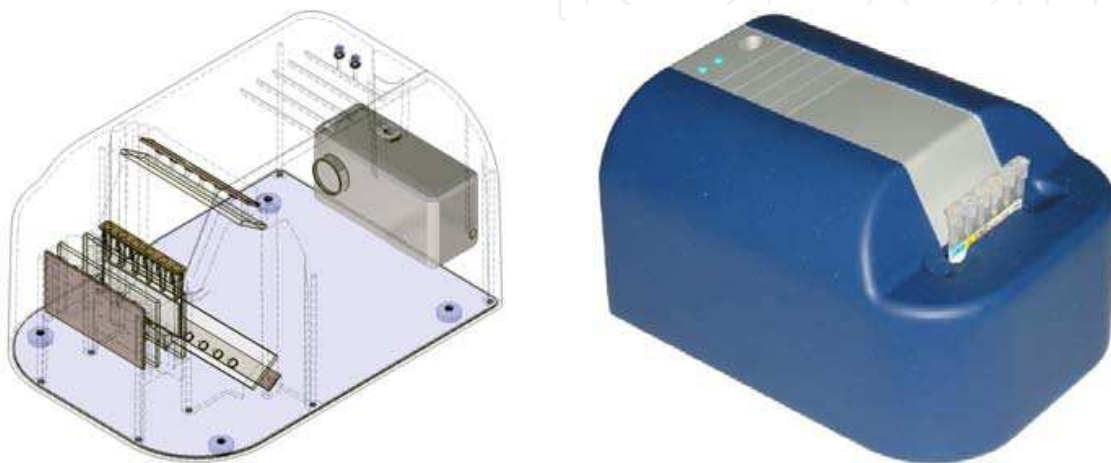


Fig. 6. Special purpose hardware for capture of gel-card images, Gelscope 32 -version 1.

To capture the image of the gel-card, it must be correctly illuminated using the white spectrum light. Due to specific requirements for gel-card image capture, the gel-cards must be illuminated from the front and from the back side to effectively illuminate all important gel-card components. They are: gel-card label and gel-card's micro tubes with their content. In our design three illuminators were used. They were made of an array of white LEDs and a light diffuser, made of white diffuser glass. The image of the gel-card is captured by the off shelf digital camera, built into the device. The setup of the illuminators, the gel-card and the camera is illustrated in Figure Fig. 8. Two illuminators are used to illuminate the front side of the gel-card and the third illuminator is used to backlight the transparent gel-card. Using this illuminator setup an efficient illumination of all gel-card components is achieved. The front illuminators must not cause any with built in camera visible reflections of the gel-card. This request is satisfied if the front illuminators illuminate the gel-card at a steep enough angle. Figure Fig. 8 depicts the worst angles of the reflections with dashed lines. It is obvious, that the gel-card, illuminator and camera locations cause no reflections to the camera lens (Meza & Kosir, 2009).

Two versions of the Gelscope device were developed. The first one named Gelscope 32 is shown on Figure Fig. 6. X-ray view of the device is also shown. During the pilot testing of the system some design flaws of the device were identified. To mention some they were: uneven gel-card illumination, deterioration of illuminators due to inappropriate heat dissipation, possibility to insert and capture the image of gel-card slightly rotated, visible visual artefacts of the Gelscope device mechanics in the captured gel-card images. These flaws were remedied in the development and production of the second version of the gel-card image capture device named Gelscope 80, shown on Figure Fig. 7. Gelscope 80 has



Fig. 7. Special purpose hardware for capture of gel-card images, Gelscope 80 - version 2.

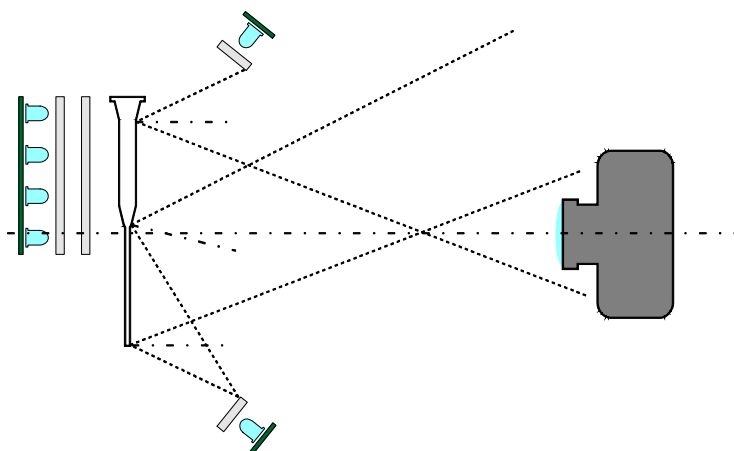


Fig. 8. Schematic display of the Gelscope device regarding illumination, gel-card and camera positions. From the left: rear illuminator, gel-card, front illuminators and camera.

further improvements to the Gelscope 32 among which are: better and more intuitive design, better quality of captured image due to higher resolution camera with better optics. Gelscope devices need individual calibration. In the Gelscope 80 the calibration data resides in its non-volatile memory, which has drastically simplified service of the telemedical terminals. In case of the Gelscope 80 device failure a service technician can simply replace the failed device with a new one without the need to enter new calibration data in the system.

8.4 Digital signature

Digital signature assures that the document was created by the known user and that it was not altered after it was signed. Our digital signature solution was implemented as combination of a digital signature module, running within the telemedical application, and a certificate authority server. Our solution is responsible for key management, digital signature of the documents and for digital signature verification. It is based on the public/private key infrastructure employing the MD5/SHA message digest algorithm and the RSA algorithm for creating and verifying the signature. The procedure of creating digital signature of the document and verifying it is illustrated on Figure Fig. 9.

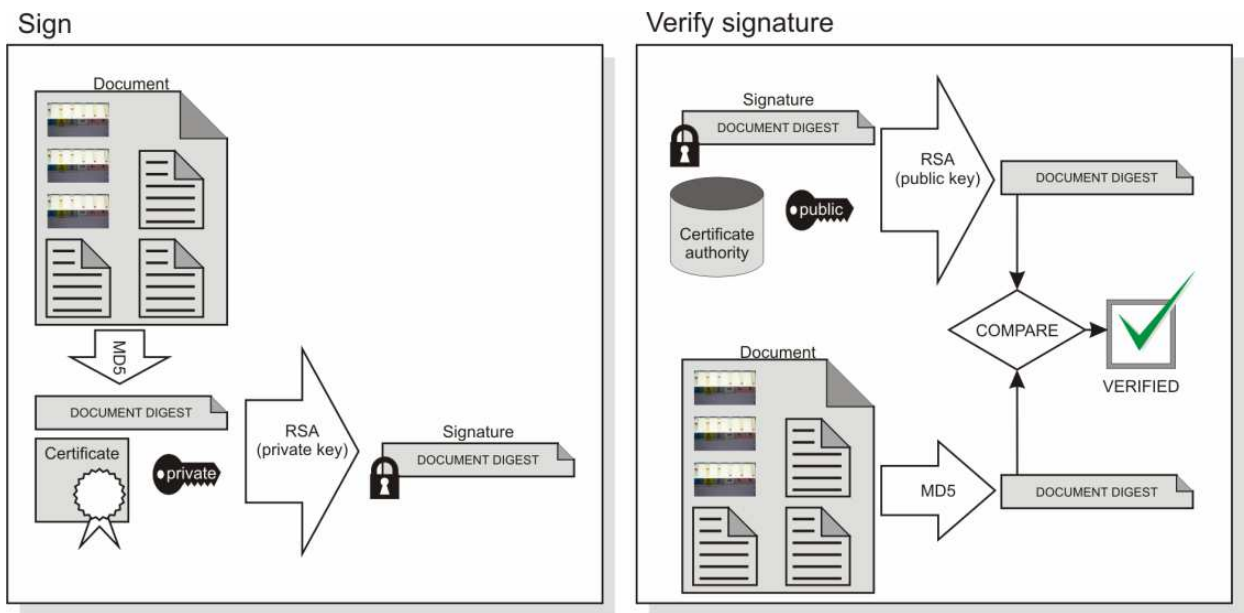


Fig. 9. Signing document with private key from certificate and verifying signature with public key obtained from certificate authority.

When signing a document, the signing user is asked to provide the telemedical application with his/hers certificate, containing the certificate serial number, user credentials and public/private key pair. After correct certificate password has been entered by the user (certificate keys are encrypted using symmetric cryptography using 3DES encryption algorithm) the private key from the key pair is obtained.

The document to be signed consists of several data objects. They are: question text, gel-card images with readout data, patient history and anamnesis, diagnosis and answer to the question. All these data objects combined represent the document to be signed. Message digest function MD5 is used to calculate 128 bit hash value of the document. Hash value of the document is then encrypted using the RSA encryption algorithm with signing user's private key. Resulting encrypted hash value can be decrypted only with user's public key, which is stored along with user's credentials on the certificate authority server.

Encrypted hash value which represents actual digital signature of the document is then attached to the document which then becomes digitally signed document. Two issues are solved this way. If anybody would change the document, the hash of the document would also change. Since only the signing user has the private key, he and only he could have used it to sign the document. This way, it is assured, that the document was not changed and that it was signed by the specific user.

Signature of the document can be verified by anybody, who has access to the user's public key, which can be obtained from the certificate authority server located at the secured location within the server of the telemedical system.

Signature verification is performed by obtaining the public key of the user claiming the signature from the certificate authority server. This key is used to decrypt the encrypted hash of the signed document. The MD5 message digest function is used to compute hash of the signed document. Decrypted and computed hash values are then compared. If they match the digital signature is valid and the document is pristine. If not, either the document was tampered with either the claiming user did not sign it.

If the digital signature matches, the artwork displayed in Figure Fig. 10 is printed on the hardcopy of the answer along with the actual digital signature string. This is a cosmetic measure, allowing quick diversification of the signed documents with verified signatures from non-signed ones.



Fig. 10. Digital signature artwork, printed on the document following the digital signature string.

8.5 Videoconference module

Videoconference module is used to establish real-time audio/video communication between users of the telemedical system. It was implemented using the JMF (Java Media Framework) framework. It is a part of the telemedical application. It consists of two major components. The first one is call control/notification component (call control). It is used to control the calls, notify the user about call status and notify the server about the user availability status changes. The other component is audio video encoding/decoding and transmission component (AVT component) which captures audio and video streams from the terminal attached microphone and camera, encodes/decodes them and transmits them via the network. Only point to point calls are supported.

When user logs on to the telemedical system through the telemedical application, the telemedical application call control sends the terminal computer's IP address to the telemedical server. The telemedical server records the address into the database along with user details and availability status. All logged users have default status available for videoconference. Other possible videoconference user statuses are busy – a status assigned to user in ongoing videoconference call, and offline – a status of all offline users. When the telemedical application starts it runs call control component which continuously listens to the incoming videoconference calls on the special videoconference control port.

When a user in the system wants to establish a videoconference call to the other user, his/her telemedical application's call control obtains called user's terminal IP address. It then prepares the grounds for call by opening four ports for videoconference communication. These ports are incoming audio stream data and control ports and incoming video data and control ports. Then a special videoconference call message, containing callers credentials, and callers terminal IP address is sent to the called terminal's IP to videoconference control port, polled by the call control. The server is also notified about the user status change to busy. Called user is notified about the incoming videoconference call which can be either accepted or rejected. If rejected, a reject message is returned to the calling telemedical application which upon reception of the message notifies its user, closes the incoming audio video ports and notifies the server about user status change to available. If accepted, the caller's call control opens the incoming audio and video ports and returns call accepted message to the caller and notifies the server about user status

change to busy. After the connection initiation, the AVT component starts transmitting the audio stream from the terminal's microphone and the video stream from the terminal's camera to the caller's incoming data ports. When called call control receives call accepted message it also initiates AVT component to start transmitting audio and video streams to the calling telemedical application.

AVT component uses G.711 (U-law) 8 kHz codec for audio transmission. For video transmission H.263 in SQCIF resolution (128x96) codec is used. QCIF (176x144) and CIF (352x288) resolutions are also supported. RTP (Real Time Protocol) and RTCP (Real Time Control Protocol) protocols are used to transmit audio and video data streams and to control them.

When either of users in the videoconference call decides to break the connection the call control notifies other side about the break connection and both sides stop transmitting video. On that event both call controls notify the server that the user's videoconference availability has changed to available.

8.6 Server application

The server side is the core element of the telemedical system. It comprises of several components. They are main server running the telemedical application modules, database and management tools, VPN server with router, backup data storage and GSM module.

Current main server hardware is a server computer with redundant power supply (2x hot swappable + UPS) and redundant disk storage (RAID 5, hot swappable), located in a protected and climate-controlled server room at the Blood Transfusion Centre of Slovenia. The server is running Debian Linux distribution. The server side of the telemedical system consists of in Java written servlets, listening to the incoming POST and GET messages from telemedical applications – clients. Servlets are served by the Apache Tomcat application server. Running servlets are the main telemedical servlet, certificate authority servlet and SMS notification servlet.

The main telemedical servlet is responsible for the user authentication, receiving and storing of the telemedical data from client telemedical applications and serving the telemedical data to the telemedical applications. All communication in the system is initiated by the telemedical applications through sending specially formed messages to the telemedical system servlets. Messages contain data containers with action commands. Main servlet is functioning according to the user rights matrix which contains definition of rights for each user of the system.

Certificate authority servlet is responsible for storing and serving public keys of user certificates along with user details and certificate details such as validity and revocation status.

SMS notification servlet is responsible for relaying messages to user's mobile telephones via to the server attached GSM module.

All actions of the system are logged in log files, to provide complete system usage traceability.

On the server several support processes also run. These are telemedical system maintenance program responsible for the maintenance of user statuses (if user has not properly logged off from the system this process cleans after unclean user logoff. Unclean user logoff occurs in cases of shutting down the telemedical terminal without logging off). Another support process is a process for regular backup of the data to the external data storage. It periodically performs a complete system backup to the external data storage media. For

implementation of backup AMANDA package is used. Further support process running on the server is server status and load monitoring process MUNIN which is used to supervise server's operational parameters.

Another part of the server setup is a VPN server – router. It is responsible for handling all incoming VPN connections and routing of the traffic within the telemedical network.

8.7 SMS notification

Short text messages (SMS messages) are used to notify users about system events through their mobile phones. Our SMS notification system comprises of a GSM module connected to the server via the serial cable and a SMS notification servlet. When a need for sending an SMS occurs in the system, a SMS send request message is sent to the SMS notification servlet. These messages are sent by telemedical applications, when it is necessary to notify the users about telemedical system events requiring their attention. Notified events are “question received” and “answer received” respectively. The message sent from the telemedical application to the SMS notification servlet contains authentication data, recipient mobile's number and actual message. The servlet interprets the message and via AT command set communicates the attached GSM module to send the message. Alternative to this approach would be a direct link to the mobile telephony operator, but this approach would need a direct connection to the internet from the telemedical system, which would be a security issue.

8.8 Database

All data of the telemedical system is stored centrally on the server data storage. Data storage consists of two modules. The first one is the relational database and the second one is the file system. The relational database is used to store all telemedical system data except images of gel-cards. Images of gel-cards are stored on the server's file system and references to these image files are recorded in the database.

The database engine used in the current version of the telemedical system is MySQL database, version 4.1.11. It contains various tables for different data objects such as gel-card image meta-data, question data, answer data, user details along with their rights, patient data and public keys of user certificates along with their details.

Files of gel-card images are stored on the file system under unique names, which are determined centrally to avoid file name collisions from sessions originating from different clients.

All data is daily backed up. Since system is online constantly it would be impossible to make system backup by just copying database files. To make a successful backup of the database a database dump operation is performed. Database dump creates a single file containing all database data at the moment of the dump. Dump file is then be backed up along with the gel-card image files. Several versions of system backups are stored enabling system rollback.

8.9 Communication

Telemedical network was established to provide data transfer between system nodes. It consists of a public packet switched data network Internet as a baseline communication network, routers with VPN gateways and a VPN server.

Internet was chosen mainly for economical reasons. Since public network Internet does not provide any level of security, VPN technology was used to create encrypted tunnels through

the public network. All nodes of the system are equipped with routers with VPN gateways. Routers are configured to automatically establish a tunnel, connecting to the VPN server. Therefore connectivity is assured even if the Internet connection of certain node has been dropped and re-established. The VPN server serves as a hub for all traffic between system nodes. All traffic generated in the system passes through it. Because of the client-server architecture of the system the majority of data transfer is accomplished in direction from client to server and vice-versa. A teleconsulting system server is collocated with the VPN server. They are connected by a fast local network connection. Therefore this, on top of the Internet imposed star topology setup, does not introduce data transfer bottlenecks. Usage of the VPN technology ensures encrypted data transfer, hiding all data from unauthorized parties. It also assures terminal and server authentication, eliminating the man-in-the-middle attack possibility. All terminals are connected to the VPN ports of the routers to which only VPN traffic is routed. Therefore the terminals are invisible from the public network thus eliminating the security threats in form of worms which lurks in the public Internet.

The majority of data between system nodes is transmitted through HTTP protocol's POST messages. Exchanged POST messages contain serialized data containers and are used to transmit data between terminals and server. Data containers contain proprietary data fields for data such as patient name and surname, birth date, gel-card images, question data, answer data, etc.

Videoconference data is transmitted through RTP protocol via UDP connections, established through the telemedical network.

Communication between existing hospital information system and telemedical applications is established through combination of the telnet and FTP protocol.

Communication between the server and the MySQL database is established using the standard SQL language queries. SQL queries are relayed to the database through Java language specific API library JDBC.

Communication between teleconsulting applications and SMS notification server is accomplished using HTTP protocol's GET messages.

Network operation is constantly monitored by a special monitoring application, residing on server side of the system, which constantly checks if all nodes of the teleconsulting system are reachable through the telemedical network. If any of the nodes cannot be reached, the monitoring application notifies the maintenance personnel about the communication failure. Notification messages are sent via SMS and via e-mail messages.

9. System usage analysis

Since all data of the telemedical system is stored in the central server's database, the system usage analysis was relatively simple. Used database MySQL can be queried using SQL queries through on the server installed database management system phpMyAdmin. Since the telemedical system must be online constantly it was not acceptable to perform system usage analysis on the live database due to possibility to make an error, which could corrupt the data. Therefore the data was extracted from the live database by executing a database dump. Resulting dump file was then used to create an offline database clone on which the analysis was then performed. Analysis was performed using for this purpose formulated SQL queries. A of number of telemedical sessions, number of signed telemedical sessions and number of transmitted images of gel-cards was analysed through time.

10. Results

The pilot version of the telemedical system was first developed and installed into the National reference immunohaematology laboratory within the Blood Transfusion Centre of Slovenia and into the transfusion laboratories of two hospitals (60 and 80 km distance, respectively). This pilot setup was intended to test and validate the telemedical system before the production version is installed into every transfusion laboratory.

Validation was performed using a series of 99 cases taken from the everyday routine. During the validation procedure immunohaematology experts first performed the read-out of the pre-transfusion tests on gel-cards by using the telemedical system. These read-outs were then repeated by independent experts using the standard visual method. There were no statistically significant differences between the proportions of correct read-outs and final result interpretations using the telemedical system and using the standard visual method (Meza et al., 2007).

After a successful pilot installation and validation all transfusion laboratories in Slovenia were equipped and connected into the telemedical system. A new organisation structure was introduced. Figure Fig. 11 illustrates the organisation of the telemedicine in transfusion of Slovenia. Two expert centres are offering 24/7 immunohaematology expertise to the hospital transfusion laboratories. In some of the shown hospital transfusion laboratories the afternoon and night shifts does not have immunohaematology expert present. These hospitals rely solely on the expert from one of the expert centres (Bricl et al., 2010).

Currently the system is in operation for 4 years and was used for 6300 consultations. During these consultations 17200 images of gel-cards were transmitted and analyzed. Of 6300 consultations, 4900 were digitally signed and can therefore be considered as valid diagnoses. Using the system, the time required for the pre-transfusion test interpretation of ambiguous cases was significantly decreased. In majority of cases, the time was decreased from several hours (required for the courier delivery of the samples to the reference laboratory) to only a few minutes.

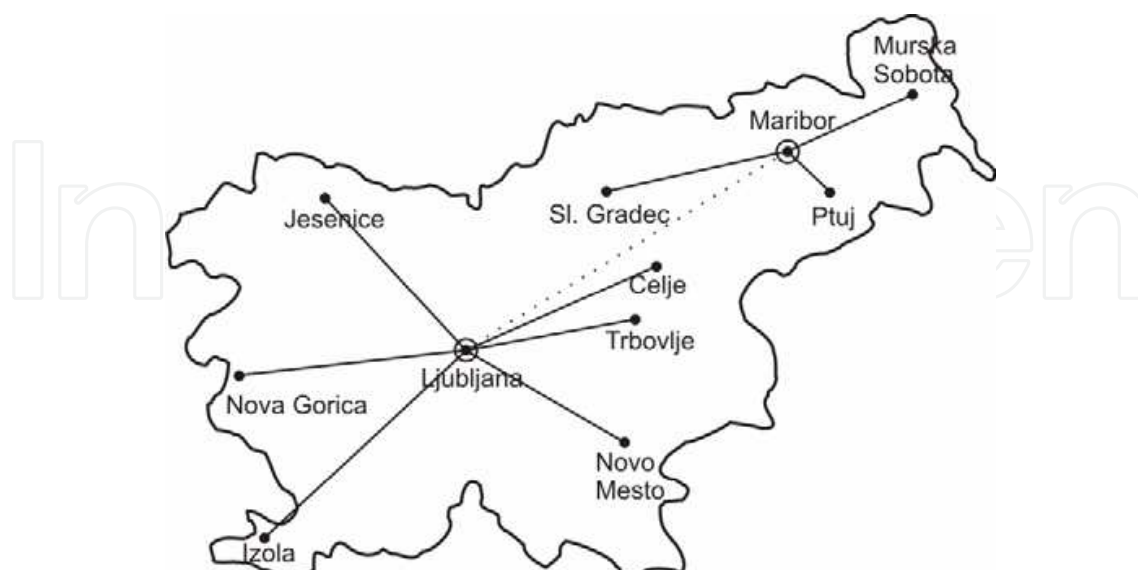


Fig. 11. Organisation of the telemedicine in the blood transfusion service of Slovenia. Two expert centres are providing blood transfusion expertise through telemedical system to the hospital transfusion laboratories.

Smaller transfusion laboratories were also relieved of the requirement for 24/7 on duty transfusion specialists, since the expertise needed is provided through the telemedical system. Their operation can now be sustained even if transfusion specialist is not present only by the laboratory technician. Therefore, the system has introduced substantial savings to the national blood supply. Exact data about savings is matter of other study, which results will be published shortly.

11. Discussion

Telemedical system was introduced into the transfusion practice of Slovenia. Slovenian transfusion practice follows EU transfusion directives (Rozman & Domanovic, 2006). Therefore solutions, working in Slovenia are likely to work in other countries, following same directives. Since Slovenia is relatively small country, compared to other European countries, it is ideal test field for new approaches.

Our telemedical system supports remote interpretation of the pre-transfusion tests which is, as far we are aware, a new approach in the field of transfusion medicine. The system is based on the detection of the red cell antibody reactions resulting in direct red cell agglutination. Currently, the system supports agglutination detection, performed using the most widely used Diamed® micro tube gel-cards. The system can easily be modified to support other micro tube gel-cards. With further modifications, the system can also support other red blood cells agglutination detection methods. Using the system, the most important phase of the test – visual readout is performed remotely by immunohaematology expert.

The system enables detailed and integrated patient transfusion treatment by providing the patient's previous anamnesis and transfusion history, obtained from the existing hospital information system. To provide the integration, the current information system, supporting transfusion service of Slovenia was studied and integration module was implemented. Since this information system was custom built, it would be necessary to repeat this process in case the system would be installed into other transfusion service.

The language of the system's user interface is Slovenian; therefore the system should be translated into other language if required.

Since EPR (electronic patient record) standards and widespread systems did not exist during the time of system development in future it will be necessary to develop data interchange module between our system and EPR systems.

Overall, the telemedical system was relatively well accepted among its users, regardless of quite a few problems during its initial pilot phase. We believe this is due to the involvement of its users into early stages of the system development. By including users into the development process, they have adopted the system as their own project and have tolerated higher number of errors, which would otherwise deter them from using the system. Another factor affecting the acceptance level is well organized education of the users and quick resolution of the problems they encounter.

At first the system was intended to serve as a consultation tool in ambiguous cases, but it evolved into a system enabling operation of the transfusion laboratory without immunohaematology expert present. This sprouted the need to provide legally sound electronic documents, which was satisfied by the digital signature infrastructure.

The system is relatively new with many modules, which were not jet long term stress tested. Since some laboratories sometimes depend solely on the remote immunohaematology expert available through the telemedical system, flawless system operation has become

critically important. To provide flawless system operation a process of identification and duplication of system critical components was started in order to provide redundancy and increase overall system's reliability. On the top of everything a procedure protocol prescribing manual work without the functional system was also established.

Another interesting fact observed, was usage of the system as the digital magnification glass. Since the system enables up to 20 times magnification of gel-card images without any visible distortions, users use the system just to capture images of gel-cards to magnify them and observe and interpret them magnified.

12. Future work

Sometimes the interpretation of pre-transfusion tests is mundane and tiring. After whole day shifts mistakes can easily slip in. A welcoming upgrade of the telemedical system would be a system that automatically interprets the pre transfusion tests in parallel to human. If human determined results differ from the automatically generated ones, the system would warn the user. Through the use of the telemedical system a significant dataset of diagnostic data and corresponding interpretations was accumulated. Acquired data was used to build the model of the human interpretation process using the machine learning methods. A set of suitable methods was chosen through evaluation of the accuracy of the model built by those methods. Future research will be focused on the model improvements and introduction of the model into the production version of the telemedical system. The model will be used for error control of human actions.

Another future research focus is planned on identification of other types of diagnostic medicine, where the developed approach could be used. Prospective are diagnostic methods, based on visual interpretation of diagnostic data, where creation of diagnostic data is straight forward and does not require examiners interaction like in the process of ultrasound examination. Prospective candidates are x-ray imaging, CT imaging, etc...

Another focus of the future work will be support of one of the standards for medical record exchange. Currently prospective standard is open specification for interoperable, electronic health record, specified by the non-profit Foundation openEHR.

The system functionality will also be extended to serve as an archiving tool for all pre-transfusion tests, not only for those which required remote interpretation.

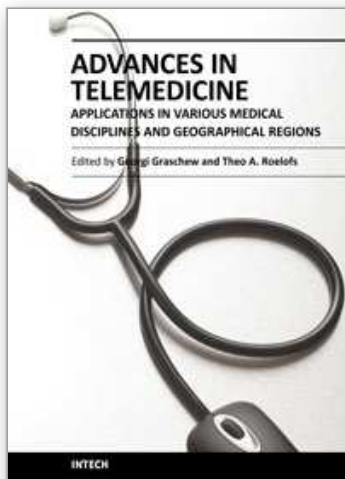
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Innovative developments in information and communication technologies (ICT) irrevocably change our lives and enable new possibilities for society. Telemedicine, which can be defined as novel ICT-enabled medical services that help to overcome classical barriers in space and time, definitely profits from this trend. Through Telemedicine patients can access medical expertise that may not be available at the patient's site. Telemedicine services can range from simply sending a fax message to a colleague to the use of broadband networks with multimodal video- and data streaming for second opinioning as well as medical telepresence. Telemedicine is more and more evolving into a multidisciplinary approach. This book project "Advances in Telemedicine" has been conceived to reflect this broad view and therefore has been split into two volumes, each covering specific themes: Volume 1: Technologies, Enabling Factors and Scenarios; Volume 2: Applications in Various Medical Disciplines and Geographical Regions. The current Volume 2 is structured into the following thematic sections: Cardiovascular Applications; Applications for Diabetes, Pregnancy and Prenatal Medicine; Further Selected Medical Applications; Regional Applications.

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