



ITU-T Kaleidoscope 2009

Innovations for Digital Inclusion

TOWARDS...

“DIGITAL BLOOD-BANKING”

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Background

- The Transfusion of Blood and Blood components are essential for health-care service delivery.
- Important instruments for the safety improvement of the Blood and Blood products supply constitute:
 - First, clinical Guidelines that lead the Transfusion practice.
 - Second, an inspection system to control the compliance to the guidelines.
 - Finally, a Haemovigilance program that supervises the Blood supply chain, and offers counter actions to eventual threats for the safety of Blood product recipients.
- Obviously, for the achievement of these goals the employment of Clinical and Laboratory Information Systems based on mutually and reliably communicating computer networks is indispensable.

The aim of the presentation

- The diversity of the legal and social background of Transfusion Medicine in the numerous countries and transnational groupings world wide, and consequently, the multifarious missions of the corresponding Blood establishments, have not allowed yet a generally acceptable modus of accessibility and interoperability, between the Blood-Bank Information and Communication Systems of different countries or regions.
- It is the purpose of this paper to present the attempts and the results of our group, during the last decade, to contribute to the design and the implementation of a universal Information System with integrated Web-Services, covering the most important:
 - ◆ Medical-Managerial.
 - ◆ Clinical and Laboratory Quality Assurance.
 - ◆ Hemovigilance,
 - ◆ Financial-Managerial,
 - ◆ Educational,
 - ◆ and Continuity of Careaspects of contemporary Transfusion Medicine.

Supporting Medical-managerial aspects

- There are still a lot of Blood Banks worldwide that although they employ locally some Laboratory application software, however, their activities are still based on manually filled up pre-printed template paper forms.
- A typical Hospital Blood Bank administration schema comprises of the **manual documentation and management** of various routine functions.
- We have investigated the employed paper-forms in major Hospitals, as well as, their specifications in national and transnational legal documents, and we have developed a MS Access based related Databases system that allows for:
 - First, the reproduction of the familiar to the personnel lay-out of the employed paper-forms.
 - Second, the digital archiving of all transactions.
 - Third, the transmission of demands and responses through electronic mail.
 - Finally the full searchability of the system.

A Medical - Administrative Text and Image Library

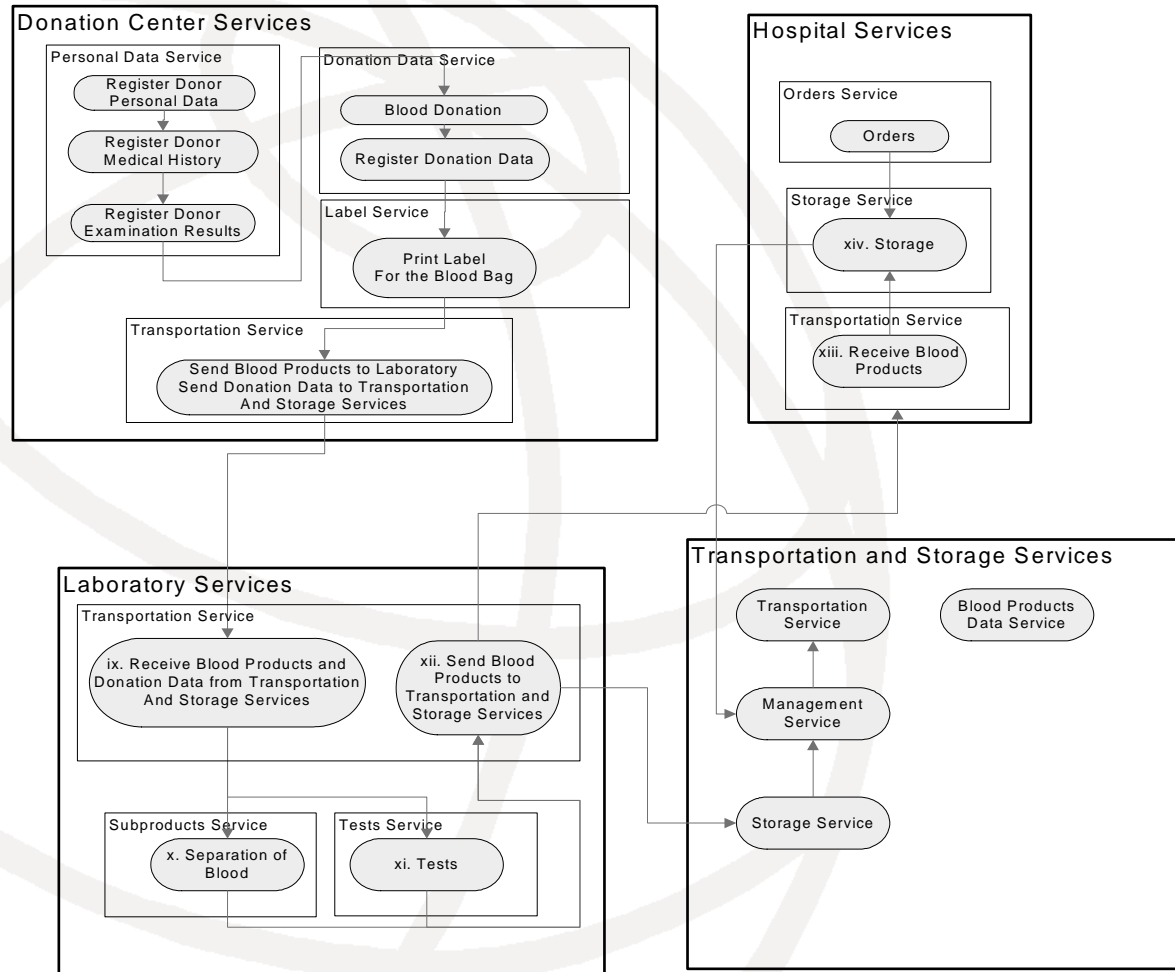
- A secure password protected Internet-accessible **Dynamic Medical and Administrative Text and Image Library** that supports remote Regional Routine Administration, as well as, Crisis and Disaster management, completes the system.
- A workstation connected first, to an Optical Microscope, equipped with a Digital Camera, second, to a Hematology Automatic Analyzer, and finally, to an Electrophoresis System, allows for the acquisition and the posting on the Digital Library, of diagnostic images concerning interesting and rare cases of transfused patients, of examined donors, cases of haemoglobinopathy etc.
- The system allows for the **gradual formation** of a very useful **knowledge-base** supporting Transfusion Medicine related clinical decisions.

ISBT 128 compliant Web-Service prototype for Blood-Bank product management

- We have developed an **ISBT 128 compliant prototype of interface descriptions**, in Web Service Definition Language (WSDL), for Blood products management.
- The developed Web service is a software system designed to support **interoperable machine-to-machine interaction** over a network.
- It has an interface that is described in a machine processable format such as WSDL.

| The ISBT 128 specified entities of the Webservice | |
|---|--|
| <i>Activity Description</i> | <i>Activity Description</i> |
| Donation numbering system that ensures globally unique identification. | Bar coding system for information transfer upon the product label. |
| Information to be transferred, using internationally agreed reference tables. | Standard layout for the product label. |
| International product reference database. | A standard reference for use in electronic messaging. |
| Data structures in which this information is placed. | |

Schematic representation of the work flow of a typical Blood Donation Centre



Clinical transfusion guidelines

- **Clinical transfusion guidelines** are tools used to aid clinicians to make a clinical assessment of a specific patient's condition and appropriate laboratory parameters.
- We have developed software that aims to support clinical personnel decision making, through the retrieval of appropriate transfusion related medical guidelines, elaborated by the World Health Organization (WHO), Blood Transfusion Safety, Geneva.
- The user interacts with the program through its main menu, which gives him the ability to switch to different screens, reflecting factors determining the **need of transfusion**, or detailed **information related to Specialties** using the Blood most frequently.
- The transfusion audit is a quality improvement process that seeks to improve patient care and outcomes, through the systematic review of the use of transfused Blood components against transfusion guidelines.
- A MS-Access based data-base supports the **elementary assessment** of Transfusion practice and outcome, employing the set of Blood Bank and Specific Blood Product Assessment Parameters.

Laboratory Quality Assurance

- The **Laboratory Quality Assurance** system of an organization ensures that internal processes adhere to current requirements, **including policies, internal standard operating procedures, or working documents.**
- Blood establishments should take all necessary measures to ensure that a **quality system**, for instance according to ISO 9000:2000, is implemented and maintained and should be supported by a quality assurance function in fulfilling quality assurance.
- We have developed a MS-Access based **related database system** that allows for the on-line management and compliance with the **guidelines, procedures, instructions and controls** prescribed by a quality system.
- For our prototype application the Quality System is set up according to ISO 9000:2000, and the annex "Quality system standards and specifications" of the Commission Directive 2005/62/EC.
- However, the system can easily be modified to comply with equivalent standards in the case of **Blood Establishments in third countries.**

Haemovigilance

- Haemovigilance comprises of a set of **organized surveillance procedures** relating to **serious adverse or unexpected events** or reactions in Blood donors or recipients and the epidemiological follow-up of donors, codified, for example, by **Directive 2005/61/EC** implementing **Directive 2002/98/EC** as regards traceability requirements and notification of serious adverse reactions and events.
- We are presently developing Haemovigilance software that allows for:
 - First, the reproduction of the lay-out of the defined paper-forms.
 - Second, the digital archiving of all transactions.
 - Third, the transmission of reports and responses through electronic mail.
 - Finally the full searchability of the system.

Issues defined and addressed by the Directive 2005/61/EC

| The most important issues defined and addressed by the Directive 2005/61/EC that lay the foundation of the developed system | |
|--|--|
| Traceability | Notification of serious adverse events |
| Verification procedure for issuing Blood or Blood components | Requirements for imported Blood and Blood components. |
| Record of data on traceability | Annual reports. |
| Notification of serious adverse reactions | Communication of information between competent authorities |

Financial-managerial aspects of Blood-banking

- Financial-managerial aspects pertain to the overall policy of a **Blood establishment** and in particular,
 - ◆ First, to matters of allocation of resources.
 - ◆ Second, concerning the efficiency and the efficacy of its operation, and the reliability of the various procedures involved.
- Most Hospital or centralized Blood Banks employ locally some **application software**.
- However, a regional or national standardized approach is not yet universally constituted; neither for the regional Transfusion Medicine networks administration and crisis management, nor as far as the operational cost of the Hospitals' Blood Bank is concerned.
- We attempted to **design and partially implement** an on-line **Blood Bank administration and operational cost-monitoring model**.

The developed Blood-Bank administration module

- The developed model comprises of first, a **typical Blood Bank administration module**, including documentation and management of all the routine functions, such as Volunteer Donors Recruitment and Incentives, Blood Donation, in site Transfusion, Blood Processing and Conservation, Blood Serology, screening for Infectious Diseases, Hematology Laboratory related to Transfusion Medicine demands, and screening for Abnormal Hemoglobin.
- Second, a data-base management system that enables high-speed access to and processing of data related to reagents, consumables, disposable and other components of functional cost, financial and administrative figures, safety and quality control statistics, and information concerning manufacturers and local representations.
- And, finally, a **Patient, Procedure and in vitro Laboratory Test Classification System**, outfitted with a set of **Cost Calculation Algorithms** that allows for the rational approximation of the overall expenditure, and the quasi real-time on line Blood Bank operational cost monitoring.

The Cost Calculation Algorithms

- The system is designed to record, on-line or manually, the **annual human and material resources employed in a Blood-Bank** that is equipment cost, reagents and disposable material consumption, building-leasing, energy, and infrastructure-maintenance expenditures, and finally man-power employed.
- An in house developed algorithm enables the allocation of the input resources consumption to the final Blood-products administered during the same period, in order to create a reliable cost per unit approximation.
- Another refined algorithm, takes advantage of a **denotative set of provider price indexes** in order to, first, account for **price inflation**, second, follow up the **annual cost evolution** of the Blood-Bank products and services, third, **ascertain additional cost changes**, as a result of improved quality, of introduction of new procedures, or for other reasons.
- Finally, the system allows for, the sorting of the units administered, by Clinic or by Department, according to the primary diagnosis of the patient, or by other criteria, and proposes a relevant DRGs assignment for each case.

On-line Blood-product Refrigerators

- A weak point, concerning efficiency, especially in small and medium size Hospital Blood-Banks, is the **Blood-product Refrigerators** that usually remain **off-line**.
- We have designed and implemented a simple, ultra low-cost, on-line **Blood-product Refrigerators' Inventory Management System** based on **Radio Frequency Identification (RFID)** tagging that offers additional safety and can be employed, either as a "stand alone" system, or as linked to any already available **Blood- Bank Information Management System (BBIMS)**.
 - The hardware of the developed system comprises of one or more **RFID Readers** to read passive **RFID transponder tags** up to 7.5 cm.
 - The **RFID Reader** is controlled by a commercial controller, and may be directly connected to a **PC RS232 input**, or wirelessly be linked to a remote **PC**, by employing a **433.92 MHz RF Transmitter/Receiver coupling**, allowing for a line-of-sight range of approximately **180m**.
 - After the completion of the registration and the labeling of a **Blood-product unit** in a **Blood-Bank**, by employing any already existing **BBIMS** and codification (**ISBT 128** or any other codification), a **RFID tag** is attached to the unit, is passed through the reader and it is positioned to a refrigerator in the booth.
- **Custom developed software** allows for the **registration** of the permanent **10-digit serial number** of **each detected transponder tag** and its correlation to the **unit's unique classifier**, assigned by the employed **BBIMS**.

Post-Transfusion Continuity of Care Aspects

- In an effort to increase **accessibility and convenience of care** of the patients, and to **decrease the associated costs**, several **post-Transfusion therapies** are now occasionally given in **patient's home or in physician's office**.
- Erythrocyte-concentrates transfusion, Factor VIII/IX concentrates infusion, administration of certain Chemotherapy-schemata, self-testing and self-management for patients receiving long-term Warfarin therapy, through International Normalized Ratio (INR)-monitoring etc. are among the most frequent cases.
- Nevertheless, as we move towards this **decentralized model**, well argued concerns are raising about the **fragmentation of patient's relevant information**, and the **discontinuity in the delivered care**.
- Furthermore, in transitions from hospital to homecare, crucial questions emerge, concerning the way this specific kind of care will be medically supervised and financially reimbursed.

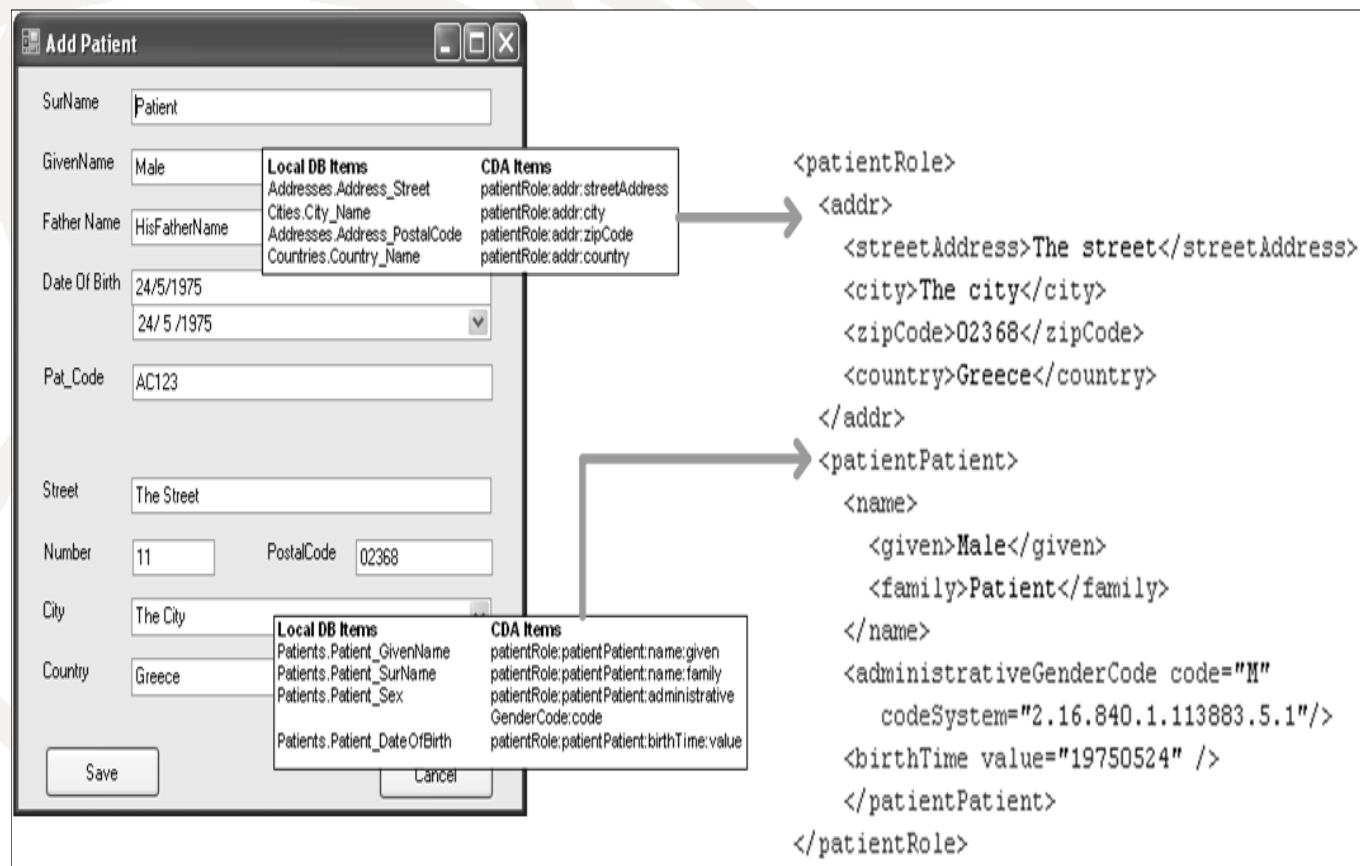
The Continuity of Care Record (CCR)

- We attempted to develop a Continuity of Care Record (CCR) complying with the American National Standards Institute (ANSI) E2369-05 Standard Specification improving Continuity of Clinical post-Transfusion therapies related Home-Care.
- The CCR covers the need to organize and make transportable a set of basic patient information consisting of the most relevant and recently facts about a patient's condition.
- The structure of the CCR fits to the needs of home-care, both, the administrative and the medical ones, and it is designed to be technology and vendor neutral for maximum applicability.
- The CCR is being developed on the eXtensible Mark-up Language (XML) platform in order to offer multiple options for its presentation, modification, and transmission.

Post-Transfusion home-care plan

- We have fitted-out the CCR with a specialized module appropriate for the creation of a **post-Transfusion therapy home-care plan**.
- This module allows for every Blood-Bank or Hematology-Clinic, to individually assign an appropriate set of homecare nursing activities, classified according to the Nursing Interventions Taxonomy of the Clinical Care Classification (CCC), first, to any relevant disease and procedure of the International Classification of Diseases Version 9 (ICD9), for medical treatment purposes, and second, to the Australian Refined Diagnosis Related Group (AR-DRGs), for eventually reimbursement purposes.
- The system is currently being **successfully tested in our laboratory**, with an EHR system that has been also developed by our team.
- The implementation indicates, so far, that the system, whether interfaced to an EHR or not, provides an effective tool for the formation of, both, a CCR and a homecare plan, enabling also a reliable approximation of the individual case cost.

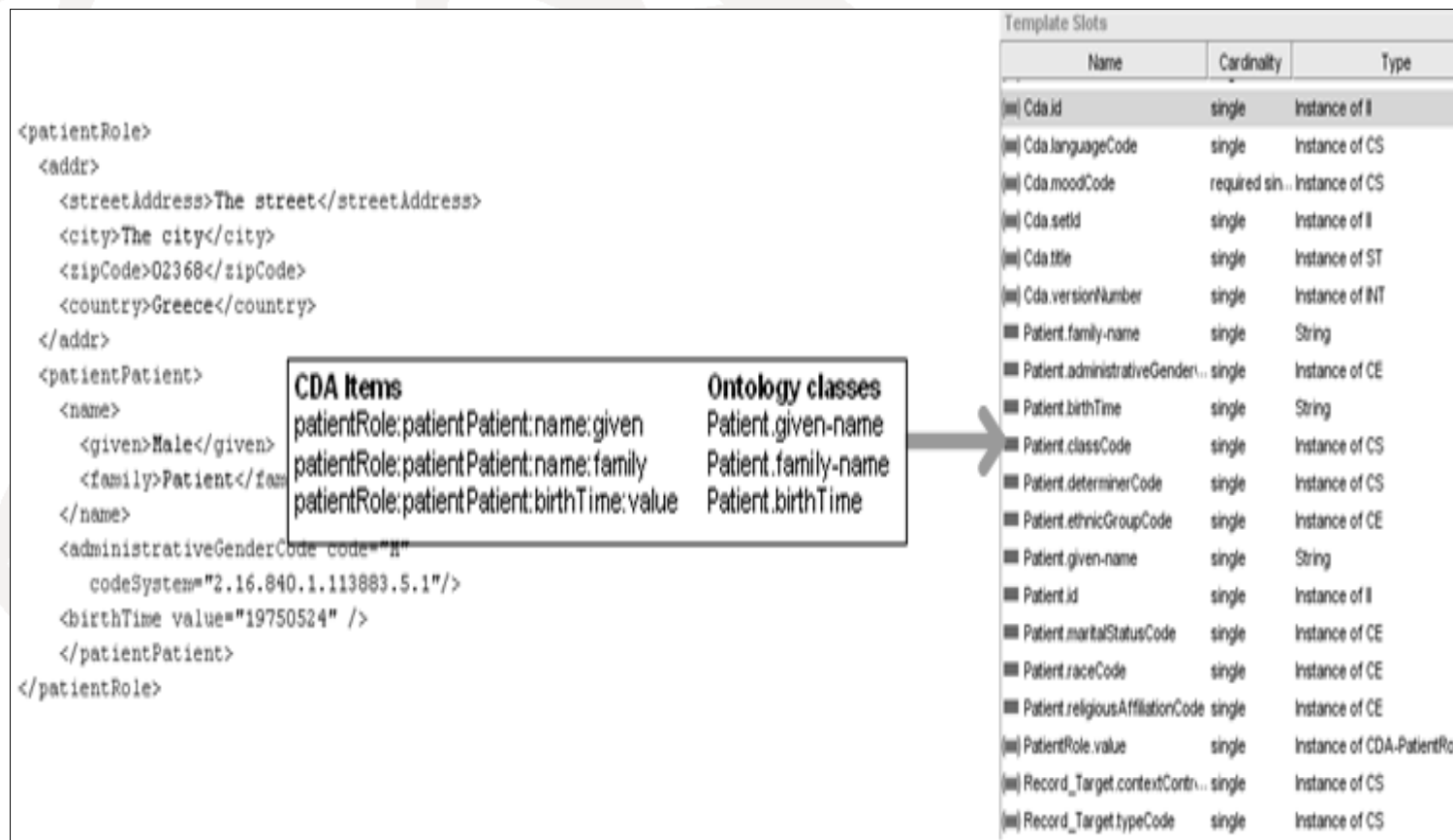
Transformation of Local Database items to CCR components



A semantic-web based system for Clinical information exchange among various points of care

- The last task for the completion of the support of the Continuity of post Transfusion Care is the implementation of a semantic-web-based system, to facilitate the exchange of Clinical information among various points of care.
- We have designed a solution that provides for the shared understanding of Referrals and Imaging Data between diverge information systems.
- The proper representation of the concepts of these documents, in terms of an ontology, developed with freeware tool "Protégé", provides for the shared understanding of the document, and allows for the creation of appropriately designed semantic Web Services, exceeding the problems of, both, incompatible formats in messages, and that of the use of diverse vocabularies.
- The prototype ontology is based upon the HL7–CDA, an application that converts the referral documents into a CDA–compliant format and the contents of the CDA – compliant documents into ontology instances.
- An appropriately designed semantically annotated Web service is responsible for the distribution of the documents over the network, by discovering existing instances of the ontology upon demand.

The contents of the CDA – compliant referral documents are converted into ontology instances



Concluding remarks

- In this paper we attempted to report **the efforts of our group during the last decade**, to contribute to the design and the implementation of a **universal Information System with integrated Web-Services**, covering the most important Aspects of modern Transfusion Medicine, i.e. Medical-Managerial and Educational issues, Clinical and Laboratory Quality Assurance, Haemovigilance, Financial-Managerial topics, and finally, post Transfusion Continuity of Care.
- Although the system components described **do not yet fulfill the demands for clinical employment**, they constitute a low-cost suggestion towards semantically annotated Web Services supporting bidirectional Exchange of Transfusion relevant medical and managerial Data, among **various Points of care** over an integrated Blood and Blood Product Network.