35th Annual International Conference of the IEEE EMBS
Osaka, Japan, 3 - 7 July, 2013

Adapting the design of Anesthesia Information Management Systems to innovations depicted in Industrial Property documents

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Abstract— **The purpose of this paper is to present the design and the current development status of an Anesthesia Information Management System (AIMS). For this system, the physical and technical advances, depicted in relevant, recently published Industrial Property documents, have been taken into account. Additional innovative sensors create further data-load to be managed. Novel wireless data-transmission modes demand eventually compliance to further proper standards, so that interoperability between AIMS and the existing Hospital Information Systems is being sustained. We attempted to define, the state-of-the-art concerning the functions, the design-prerequisites and the relevant standards and of an "emerging" AIMS that is combining hardware innovation, real-time data acquisition, processing and displaying and lastly enabling the necessary interoperability with the other components of the existing Hospital Information Systems. Finally, we report based on this approach, about the design and implementation status, of our "real-world" system under development and discuss the multifarious obstacles encountered during this still on-going project.**

I. Introduction

Anesthesia Information Management Systems are acquiring, processing and displaying the patient's vital Biosignals during anesthesia for surgical procedures. They are recording eventual physiological changes and adverse events, and they are also monitoring the administration of pharmacological substances. They are storing digitally all crucial data, during the perioperative period, in an anesthesia record, enabling, thus, the accurate reconstruction of the entire procedure postoperative, if necessary. Obviously, the significance of the employed anesthesia machines, of their components and of the other recording equipment is very important for the successful outcome of the operation. Therefore, aiming to present in this paper, the design and the current development status of an Anesthesia Information Management System (AIMS), we have to take into account, the physical and technical advances, not only published in trustworthy peer-reviewed journals and conference proceedings, but also the ones depicted in relevant, recently published Industrial Property (IP) documents.

In this paper, we attempted to define, first, the state-of-the-art concerning the functions, the design-prerequisites and the relevant standards and of an "ideal prototype" of an AIMS that is combining hardware innovation, real-time data acquisition, processing and displaying and lastly enabling the necessary interoperability with the other components of the existing Hospital Information Systems. And second, to report based on this approach, about the design and implementation status, of our "real-world" system under development and discuss the multifarious obstacles encountered during this still on-going project.

II. Defining the State of the Art by Searching relevant IP-Documents

We have searched all major relevant International (IPC) and European (EPC) Patent Classification categories, by employing the on-line esp@cenet search-engine of the European Patent Office (EPO). By sorting and evaluating the over 2500 retrieved Patent Documents, an overall "mapping" of Anesthesia Technology has been created. An excerpt the results is presented in following Table.

TABLE I. Recent IP-Docs relevant to Anesthesia Vaporizers

Nr.	Publication Date	Publication Year	Patent Office
1	WO2012106523(A1)	2012	US
2	WO2012094223(A1)	2012	US
3	WO2012084042(A1)	2012	SE
4	KR20110068561(A)	2011	KR
5	CN201308700(Y)	2009	CN
6	CN201244267(Y)	2009	CN
7	CN101496925(A)	2009	CN
8	US2008236580(A1)	2008	US
9	WO2008048947(A2)	2008	WO
10	RO123438(B1)	2012	RO
11	DE102005012340(B3)	2006	DE
12	WO2006094172(A2)	2006	WO
13	US2011056491(A1)	2011	US
14	CN101061088(A)	2007	CN
15	US2006032502(A1)	2006	US
16	US2005072420(A1)	2005	US
17	CA2419103(A1)	2003	CA
18	CA2326822(A1)	2001	CA
19	EP1044700(A2)	2000	EP
20	EP0911052(A2)	1999	EP

*Research has been co-funded by the European Union (European Social Fund) and Greek National resources under the framework of the "Archimedes III: Funding of Research Groups in TEI of Athens" project of the "Education & Lifelong Learning" Operational Programme.

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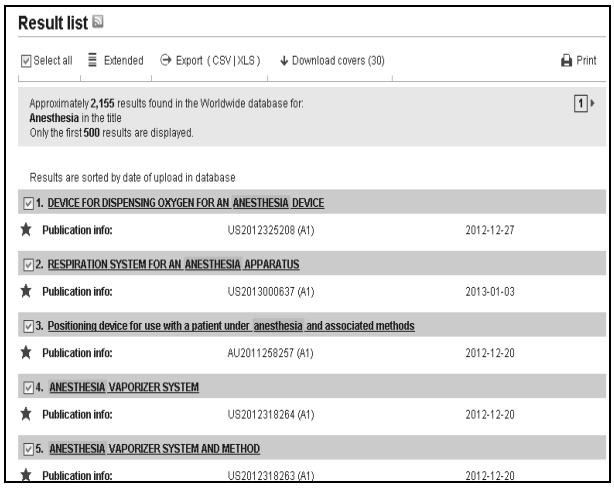

Figure 1. An exerpt of the esp@cenet search-report indicating Patent Application published during the year 2012 relevant to Anesthesia.

We have ordered the anesthesia machine components, the sensors, the novel services offered, the software demands arising etc. that appeared in the Patent-map into the following major groups:

- According to vital parameters monitored (Biosignals).
- According to their clinical significance for the patient.
- According to their medical-managerial benefits.
- According to their ability to support medical-decision.
- According to their interoperability demands & solutions.

Figure 1 displays an excerpt of the esp@cenet search-report, Table I presents indicative recent IP-Documents, relevant to the important technical component Anesthesia Vaporizer, and Table II summarizes all Parameters claimed to be monitored perioperative, according to the IP-search results.

TABLE II. VITAL ARAMETERS MONITERED PERIOPERATIVE ACCORDING TO THE RESULTS OF THE IP-DOCS SEARCH

Biosignal category	Biosignal type	Remarks
Electrical	Electrocardiogram ECG Electroencephalogram EEG Heart rate HR	Anesthesia Depth
Electro-Chemical	Oxygen Partial Pressure PO_2 Carbon Dioxide PP PCO_2 End-Tidal CO_2 ET-CO2	Capnography
Mechanical	Airway Pressure AP Airway Resistance AR Blood pressure BP Central venous pressure VP Pulm. Artery Pressure PAP Lung Compliance LC Respiratory Rate RR Tidal Volume TV	Ventilation specific Auxiliary Invasive Arterial Pressure Ventilation specific
Mass Spectrometry	Anesthetic Concentration AC N_2O Concentration/PP PN_2O	~ 200 AMU (Daltons)
Opto-Chemical	Pulse Oximetry PO N_2O Concentration/PP PN_2O Anesthetic concentration AC	Alternative Method
Thermal	Temperature T	Various points

In this Table, the presently available or emerging sensors are prearranged, according to the most frequently monitored vital parameters and they are adequately reflecting the Anesthesia-related equipment state-of-the-art and the sensors currently employed reveal their clinical significance for the patient upon the operating table. On the other hand, the continuous introduction of the properly formatted equipment data-output into an appropriately designed AIMS, leads to inferences, related to eventual medical-managerial benefits, concerning the improvement of Anesthesia related clinical pathways and the optimization of the management of human and material resources, involved in its perioperative delivery.

III. THE DESIGN PREREQUISITES AND THE RELEVANT STANDARDS OF THE AIMS SYSTEM UNDER DEVELOPMENT

The increased AIMS functionality reflecting the Anesthesia-related equipment state-of-the-art is only one component of the advances, during the last decade. Both, relevant patents and excellent recent publications [1-4] indicate the potential of these systems to improve the overall operating room clinical-care offered, as well as, the managerial efficiency and efficacy of this delivered care.

The clinical component includes the real-time intra-operative monitoring, the documentation of the parameters monitored, enabling thus timely medical decision support, especially in the case of adverse events appearance and the upgrading of the overall anesthesia practice, by refocusing the clinical personnel to the patient rather than to his or her vital signs.

On the other hand, the managerial improvement allows for the patient scheduling and the throughput optimization, the rationalization of drugs and other materials employed and the accurate and detailed record-keeping, enabling the compliance with regulatory issues, the traceability of the details of each operation and the creation of searchable and retrievable medical records that constitute the valuable starting point for the future updates of Guidelines relevant to Anesthesia delivery.

More specific, the employment of more sophisticated AIMS, offers the possibility for an increasing number of Hospitals, to form regional, national and even international networks, sharing anonymized Anesthesia data in a common and collectively accessible inventory. Thus, evidence based Anesthesia administration and clinical research will be promoted, especially if systematically is being focused on adverse events reporting, evaluating and taking measures for the diminishing their occurrence.

Finally, a cardinal design prerequisite to attain these objectives is ensuring the interoperability among various AIMS. There is presently no official “universal” standard covering this important issue, however, there are promising approaches ensuring interoperability by employing semantics, based on standard terminologies (e.g. SNOMED), not only in the field of Anesthesia. Almost all these approaches, adopt the Health Level 7 (HL-7), Version 3 clinical document architecture (CDA).

IV. Present Design and Implementation Status of the System under Development

The employment of Anesthesia Information Management Systems in the Hospitals of the Greek National Health System, as well as, in the private health-care sector is very incomplete and most of the employed systems are limited to custom made Anesthesia record, fed partially with data manually, with the exception of those vital-signs already integrated in anesthesia machine purchased recently. Due to the present economical crisis in the country, the perspective of the implementation of really up-to-date integrated AIMS, either by purchasing a commercially available system or by custom developing one, is rather unlikely. Although we know that a functional and reliable AIMS implementation necessitates resources beyond our expected funding, we have started a "modular" design and development of a low-budget prototype that is taking into account all above mentioned technological innovations, however, their implementation is following both, the limited R&D funds available and the influence of the present shortage of all health-care providers to support us.

This on-going project comprises of three discrete work-packages that are also reflecting the three major innovation components of all modern AIMS:

- Acquisition, processing, display and documentation of frequently monitored vital parameters.
- Development of an Anesthesia Record capable to handle the huge amount of real-time equipment output-data.
- Interoperability of the AIMS with the Hospital Information System and other critical ICT loci i.e. data exchanged between Anaesthesia records and other proximal or distal systems, are mutually recognized and they preserve their unique semantic values.

A. The vital-signs monitoring approach

Concerning the multifarious vital-signs monitoring equipment, we are trying to reduce the cables around the patient by miniaturizing sensing-units and by introducing digital wireless transmission modules.

A first module has already been designed and implemented to acquire the Electrocardiogram (ECG), the Non-Invasive arterial Blood Pressure (NIBP) and the arterial Oxygen Saturation (SpO2) of the patient. Data communication was performed with an Xbee 802.15.4 module [5], which operates within Industrial, Scientific and Medical (ISM) radio bands. The details are presented elsewhere [6]. Various other typical parameters may also be introduced into the AIMS, provided that the corresponding devices have at least a serial output (RS-232, USB etc.).

B. The Anesthesia Record

We have developed two versions of Anesthesia Records, in order to accommodate the different demands of users with various levels of needs and of training in Information Technology. The first version of our developed application is mainly a simple data-base approach, needs only an installed copy of Microsoft Office for Windows (XP or later versions) or a corresponding open-source free package.

The second version is still under development and employs Extensible Markup Language (XML) to allow for compliance with the Health Level 7 Version 3 (HL-7 v.3) Clinical Document Architecture (CDA), combined with valuable elements of the excellent approach by Nickalls et al. [7], regarding the set-up of an open-source Anaesthesia Linux workstation.

Both systems enable Anesthesia administration record-keeping, patient managing, drugs & disposable management, and any vital-signs manual or quasi real-time documentation, depending on the digital-output features of the corresponding Anesthesia Machine components.

Presently, only Version II allows for real-time ECG, NIPB and SpO2 acquisition. Further functions included in both versions is the management of Quality Assurance in Anesthesia and Surgery, Adverse Events Reporting and a custom developed Cost Estimation method, helpful for a realistic enumeration of a DRGs classes.

C. Interoperability issues

No standard vocabulary for the domain of anaesthesia was available, however, most available classifications and nomenclatures although elements of such as ICD-9, ICD-10, SNOMED CT, LOINC etc. included at least parts of a useful Anesthesia vocabulary.

Since 2003 the especially founded International Organization for Terminology in Anaesthesia (IOTA) has set-up an Anesthesia specific Terminology [8], [9]. We have selected to adopt both, the WHO ICD-10 and the IOTA vocabularies in our project. For the vital-signs representation, the CEN/ISO/IEEE 11073 Terminology and Domain Information Model (DIM) have been selected.

TABLE III. Summary of the Development Status of our AIMS

Vital Signs Acquisition	Anesthesia Record	Interoperability Features
Wireless: ECG NIPB SpO_2	Anesthesia/Patient Management	Classification: ICD-10 Terminology: IOTA
Traditional: AP RR AR LC (on demand)	Drugs/Disposable Management	Vital-signs representation: ISO 11073 Terminology Domain Information Model (DIM)
Optical: PO PCO_2/PN_2O	Vital Signs on-line ECG NIPB SpO_2 Vital Signs off-line Any	Version II (under development) HL-7 v.3-CDA-RIM
E/Chemical: PO_2	Quality Assurance Adverse Events Reporting	Version I (implemented) Human-readable, No semantics, Text.
Thermal: T	Cost Estimation DRGs - viewpoint	Anonym outcomes for R&D purposes

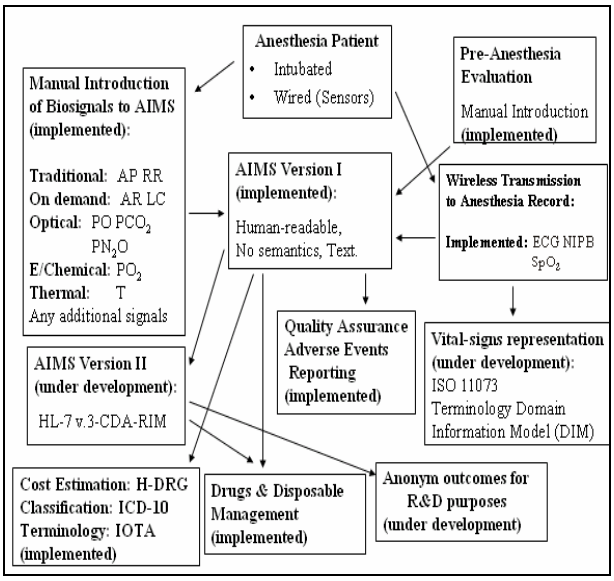

Figure 2. Interrelations of the modules of the AIMS under development.

The implemented Version-I ensures human-readability, employs no semantics and is based on text. Version II is still under development, and complies with the HL-7 V.3-CDA-RIM approach. An anonym outcome for R&D purposes can be extracted and transmitted. The CDA standard itself, and all components of a CDA document are rooted in the HL7 V3 RIM. The RIM is an object model created as part of the V3 methodology that represents HL7 clinical data (domains) and identifies the life cycle that a message or groups of related messages will carry. It is a shared model between all domains and, as such, is the model from which all domains create their messages [10], [11]. The RIM is an ANSI approved standard.

In order to create semantically enriched text output, it is necessary to "highlight" somehow the employed terminology by linking it to an appropriate ontology. By doing so, the system can be also used to support Medical Decision Making in Anesthesia. This terminology representation is facilitated by employing the Protégé-OWL ontology editor. The Protégé-OWL editor is an extension of Protégé that supports the Web Ontology Language (OWL), the most recent development in standard ontology languages [12, 13].

Table III provides an overview of the most important features of the presented system and Figure 2 displays the Interrelations of the modules of the AIMS under development.. Our software will be delivered free of charge to active Anesthesiologists expressing interest. Version I is appropriate for a gradual transition from manual to digital Anesthesia record-keeping, since Version II is addressed for Departments intending to acquaint their personnel with interoperability issues.

V. Conclusion

We attempted to define the state-of-the-art concerning the equipment, the functions, the design-prerequisites and the relevant standards, of an "emerging" AIMS that is combining hardware innovation, real-time data acquisition, processing and displaying and lastly enabling the necessary interoperability with the other components of the existing Hospital Information Systems. We have described the implementation status of our AIMS, and discussed the resources shortage and technical "environment" related obstacles, leading us to down-sized interim solutions. In the future, Anesthesia related equipment are expected to produce an increasing amount of mostly real-time data and their wireless transmission modes, will allow for a smoother operation.

Finally, compliance to appropriate standards, such as the combination of Vital-signs representation ISO-11073 Terminology to the Domain Information Model (DIM), contribute to further interoperability enhancement, between AIMS, Hospital Information Systems, Clinical Research Repositories and other relevant health-care systems.

Acknowledgment

This research project has been co-funded by the European Union (European Social Fund) and Greek National resources under the framework of the "Archimedes III: Funding of Research Groups in TEI of Athens" project of the "Education & Lifelong Learning" Operational Programme.

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