



SPECIAL ARTICLE

Technical and functional standards and implementation of a clinical information system in intensive care units[☆]

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Abstract

Introduction: Clinical information systems (CIS) are becoming a useful tool for managing patients and data in the ICU. However, the existing CIS differ in their capabilities and technical requirements. It is therefore essential for intensivists, as the end clients of these applications, to define the suitable minimum specifications required in order to be operative and helpful.

Objectives: The Spanish Society of Intensive Care Medicine and Coronary Units, through its Organization and Management Workgroup, has designated a group of clinical and software experts to draft a document with the recommendable technical and operating requirements of these systems.

Methods: The group was formed by ten people supported by managers or engineers from the five principal industries producing CIS in Spain. The project involved the following phases:

- Completion of a check list. This step was considered necessary in order to establish the precise current situation of CIS applications.
- Discussion of the results by the group of experts in a meeting and in online format.

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PALABRAS CLAVE

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Results: The requirements were grouped into four sections: technical, functional, safety and data management. All requirements were classified as basic and optional in order to allow the end user to choose among different options according to the existing budget, though ensuring a minimal set of useful characteristics. A chronogram for the installation process was also proposed.

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Estándares técnicos y funcionales, y proceso de implantación, de un sistema de información clínica en unidades de cuidados intensivos

Resumen

Introducción: Los sistemas de información clínica están convirtiéndose en una herramienta útil para la gestión de los pacientes en la unidad de cuidados intensivos (UCI). Sin embargo, los sistemas disponibles en el mercado difieren en cuanto a capacidades y requerimientos técnicos. Por tanto, es necesario que los intensivistas, como clientes finales de estas aplicaciones, definan los mínimos para que estas sean operativas y útiles.

Objetivos: La Sociedad de Medicina Intensiva Crítica y Unidades Coronarias, a través de sus Grupos de Trabajo de Internet y Nuevas Tecnologías, y de Organización y Gestión, encargó a un grupo de expertos clínicos e informáticos la redacción de un documento que recogiera los requerimientos técnicos y funcionales mínimos que deberían de reunir los sistemas de información en las UCI.

Métodos: El grupo de expertos estuvo formado por diez personas y contó con la colaboración de representantes e ingenieros de las principales cinco compañías fabricantes de estos sistemas en España. El proyecto presentó las siguientes fases:

- a) Realización de una encuesta técnica que recogiera la situación actualizada para cada sistema.
- b) Discusión presencial y on-line de los resultados, y formulación de estándares por el grupo de expertos.

Resultados: Los estándares se agruparon en cuatro categorías: técnica, funcional, datos y seguridad. Todos los estándares fueron clasificados en básicos y opcionales para permitir que el usuario final pueda decidir entre diferentes posibilidades, pero asegurando un mínimo básico de características útiles. También se propuso un cronograma de implantación del sistema.

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Introduction

The objective of an information system in an intensive care unit (ICU) is to favor improvement of the healthcare processes and resource management, with a view to secure a competitive advantage for the Unit, increase the added value in the care of critically ill patients, and improve professional work quality.

In the last few years there has been a spectacular development in information and communications technology (ICT) in healthcare settings. Although such advances have been incorporated to the daily activities of many business sectors, the healthcare setting is characterized by a notorious delay in their application and exploitation as a resource for improving patient care.¹ ICT is commonly used in the hospital administrative and management setting, warranted by studies that regard it as an essential tool for improving patient care and for reducing errors,^{2,3} and as a means to ensure greater adherence to the clinical practice guides.

Departments of Intensive Care Medicine (DICM) represent a highly specialized healthcare area with a broad range of devices that generate a large volume of data and registries

on the admitted patients – reaching up to 1300 data elements per patient and day of stay.⁴ This particularity defines such departments as a natural setting for the incorporation of ICT.

The use of clinical information systems (CIS) in the DICM aims to improve the end results of the healthcare process, optimizing safety and quality, and collaborating to improve DICM management. The care of critically ill patients consumes approximately 30% of the resources available for the management of acute patients, and accounts for 8–12% of the hospital monetary costs – representing over 2400 million € a year in Spain alone.⁵ The introduction of tools that can help to better manage the care processes of these patients can generate a more efficient distribution of the healthcare resources, since CIS offer timely information for optimizing clinical decision taking and more effective and safe healthcare management.

The association of all these potential benefits derived from the presence of increasingly sophisticated information systems in the DICM primarily seeks to optimize patient care. However, the penetration of such systems is still limited. In Spain, according to updated information from the

industry (personal communication of May 2011), it can be estimated that close to 32% of all ICU beds (1183 out of a total of 3683 registered in the latest census of the Spanish Society of Intensive Care Medicine and Coronary Units [*Sociedad Española de Medicina Intensiva y Unidades Coronarias*, SEMIUC]) are equipped with a CIS or have been licensed for the installation of such a system in the near future. In a survey published by Lapinsky on the presence of ICT in ICUs in Ontario (Canada), most of the Departments were equipped with some electronic system offering access to laboratory test data (98%) and images (76%). However, the implementation of electronic medical prescription dropped to 22%, and the prevalence of direct data capture from monitoring devices, perfusion systems and mechanical ventilation equipment varied between 6 and 14%.⁶ In the United States, in the year 2003, between 10 and 15% of all ICUs were equipped with CIS. In turn, countries such as Australia⁷ have generically implemented ICT use.

There are a number of reasons for this delay. Firstly, there is conflicting evidence on the true usefulness of these systems as tested at the patient bedside. Some studies have reported no positive impact,^{8,9} though the reasons for such negative findings are attributable to inadequate implementation or even to patent alterations in the normal working dynamics of the Unit. Nevertheless, other studies do report beneficial effects with the use of CIS in terms of the optimization of time and resources. The study carried out in the DICM of Ospedali Riuniti (Ancona, Italy) shows that the use of a software system results in a substantial reduction of the time spent by the personnel in document processing, compared with the traditional paper-format based protocols (3 ± 2 min/day versus 37 ± 7 min/day, respectively, $p < 0.001$), and is moreover well accepted by the medical and nursing personnel.¹⁰ Likewise, the study carried out in San Camillo-Forlanini Hospital (Italy) concluded that the use of an information system in the ICU results in a significant reduction in medication error (from 3.69% to 0.86%), particularly as referred to potentially fatal errors (2.34% versus 0%)—a fact that increases patient safety.¹¹ In this same line, Colpaert et al. report that informatization implies a decrease in the frequency and seriousness of errors attributable to medication. These authors found the cost range attributable to medication error to vary between 10 USD in the case of harmless errors to over 5000 USD in the case of an adverse event.¹²

Other reasons hampering the generalization of these systems are their high cost and the reluctance of clinicians to change.¹³ However, a clear factor of uncertainty in the final decision as to whether to implant a CIS or not is the lack of standardization, which precludes definition of the characteristics required of these systems in order to be clinically useful, and makes it difficult to decide whether a given commercial product satisfies these requirements. In this context, inadequate presentation of the information can overburden the clinician with useless data, prolonging the time dedicated to the system, increasing the difficulty of patient evaluation, and raising the possibility of error.¹⁴ This shows that although the technology has been sufficiently developed, there is a gap or fracture between the developers of commercial applications and the hospital information services and needs of daily clinical practice. Information flow among these sectors is essential for the future

development of systems capable of offering not only genuine improvements in clinical care but also a solidly based and necessary change in the cultural attitudes of the healthcare personnel.

Based on the above considerations, and knowing the advantages, inconveniences and barriers against the incorporation of CIS, it is seen as absolutely necessary for the professionals – as end users of these applications – to have the capacity to state their opinion on the minimum required characteristics for useful installation of these systems in their Units. To this effect, a series of basic standards is needed, allowing clinicians to guide and fundament their opinion. The objective of this expert consensus document is to establish the standards required by a CIS for application in a DICM, and the optimum process for implementing such a system.

Methods

In order to reach the proposed objective, the SEMICYUC, through its Working Groups in Internet, Information and Communications Technology, and Planning, Organization and Management, gathered a group of experts with the purpose of developing a document addressing the minimum technical and operative specifications applied to clinical practice and which could be required for such clinical information systems. This group of 10 people (8 physicians – one of which was also an engineer in computer science – and two nurses), all reputed experts in the utilization of CIS, in turn received the collaboration of the five main industries in the sector in Spain (Phillips, Drager, IMD Soft, General Electric, Picis), which through their managing personnel and engineers contributed ideas and helped to clarify doubts.

The project comprised the following phases:

- 1) Elaboration of a template (modified from a Canadian questionnaire)¹⁵ of technical and operative standards required of a CIS for incorporation to a DICM, including data exploitation and security. This template was presented to a member of the group of experts (an advanced user of each application) for completion together with an advising engineer.
- 2) The results of this template were tabulated, discussed and clarified in a joint meeting of the group of experts and the industry. On the occasion of the meeting, each company separately answered the doubts and proposals of the clinicians related to the shortcomings, strong points and potential future development of each application. Also discussed was the need for both parts, society and industry, to closely collaborate in order to allow clinicians to become aware of the need to introduce these systems.
- 3) The group of experts then divided the requirements and relevant standards into groups, and classified them as either basic or optional. This division was based on the need on one hand to establish a recommended minimum series of options for the selection, implementation and basic operation of the applications, and on the other to offer a package of ideal options – some of them already present in some systems – and which can help decide clinician and funding entity opinion in favor of one

choice or other, according to the existing needs and budget limitations. These optional requirements are already available in some solutions, and as admitted by the industry, they are technically viable – though some require joint development with the clinicians. It is clear that a minimum series of specifications should be established in the next few years, with editing of the document, given the interest shown by the different agents implicated in its implementation and development.

In no way did the representatives of the industry participate in drafting the document, though they were given the opportunity to review the completed text and to offer non-binding suggestions referred to concrete points – some of which have been incorporated by the group of experts in the final text. Once drafted, the document was approved by the Scientific Committee of the SEMICYUC on 26 May 2011.

The final document has been divided into sections, the order of which reflects the logical CIS implementation process: from review of the hospital informatics structure and the technical standards required of the system to allow integration within the mentioned structure, to the actual implementation process, the operative requirements classified according to work flow with the patient, and final system data exploitation.

This document is addressed not only to the DICM professionals or supervisors but also to hospital management, regional health authorities, and the industry itself. For the clinical professionals, the document will be a guide for initiation, information and counseling in the installation of a CIS, and will help establish the best choice according to the existing needs – comparing the requirements with the offer made. In the case of the supervisors, the purpose is similar, though the clinical vision of the document attempts to ensure that the CIS is chosen not only according to its price or maintenance characteristics but also considering a series of features that make it user-friendly for clinicians and a useful tool in their work setting. Lastly, the document will serve as a reference for the industry, allowing it to adapt to the requests of the clinicians, improve its products for the immediate future, and gain a favorable position in competing for sales.

The standards grouped by categories are presented below, with a brief description of each of them. A more detailed description of each item can be obtained from the complete document, which can be accessed on the SEMICYUC website: <http://semicyuc.org/temas/semicyuc/documentos/estandares-systems-informacion>.

Technical specifications

The technical requirements are summarized in [Table 1](#).

Information transmission standards

Basic requirements:

- 1) The CIS must be able to interact with other hospital information systems using an HL7 protocol. In this sense it is advisable for the HL7 version to be 2.4 or higher.

Optional requirements:

- 1) Compliance with the *Integrating the Healthcare Enterprise* standards (IHE, <http://www.ihe.net/>), with conversion to *Connectathon*, with a positive evaluation. The *Connectathon* is a periodic meeting held to test and certify the integration characteristics of different products and devices with respect to the standards advocated by the IHE.
- 2) It also would be advisable for the CIS to be able to adapt to the *Clinical Document Architecture* standard (CDA, <http://hl7book.net/index.php?title=CDA>) in the generation of documents and reports.
- 3) Possibility of parameterizing the HL7 messages to adapt them for connection to other systems using different sub-versions or parameter specifications.
- 4) Possibility of automatically generating summaries of configurable data (minimum basic data set (MBDS), indicators, etc.) in XML format that can be sent via web or e-mail to centralized registries for benchmarking, quality control, SEMICYUC statistics, etc.

Integration engine

Basic requirements:

- 1) Integration engine (proprietary or configurable), allowing the introduction of new connections with other systems in a flexible manner, using a well defined communication protocol available for those in charge of conducting future integrations. This integration engine must be included in the technical support.

Optional requirements:

- 1) Integration engine allowing input and output connections via HL7 and XML in a configurable manner.

Architecture

Basic requirements:

- 1) The architecture, whether client-server or web, must allow utilization of the system from all the work areas, and the analysis of data as required.
- 2) Statistical data exploitation must be possible in parallel to normal operation of the application, without data loss of any kind over time. Under no circumstance or condition can the manufacturer cease to afford access to all the stored patient data.

Optional requirements:

It would be advisable for the system to allow its integration within a service-oriented architecture, as either producer or consumer.

It also would be advisable for the system to allow transparent access to other Department or general applications without requiring repeat password entry.

Table 1 Technical requirements.

	Basic	Optional
Transmission of information	Protocol HL7 or other protocol guaranteeing intercommunication	Comply with IHE standard ^a Comply with CDA standard ^b Parameterize HL7 messages Data summary in XML format
Integration engine	Proprietary or other engine for flexible connection with external applications. If there is a previous engine, ensure full integration with it	Connection input and output with HL7 and XML Access to DICOM and external applications via URL web links
Architecture	Multi-post use Simultaneous data exploitation Possibility of access to parameterization of all functions, according to capacity	Service-oriented architecture Access to other applications directly, and if possible without passwords
Functional modules	Specify type and number of independent modules	
Versions	Specify notification, cost and procedure of installation with data security	Advisable at least once every 2 years Incorporation of user-suggested improvements
Maintenance	Clear conditions Physical presence or remote, according to type of failure to safe keep data Collaboration with Informatics Department Permanent counseling of clinical administrators	
Training	Sufficient for daily tasks Time specified in contract Functionality and parameterization Advanced user (clinical administrator)	Periodic upgrading according to new functions Possibility of channeling user suggestions
Tolerance of malfunction and crises	Protocol for protection of previous data and inclusion of those generated during malfunction Possibility of correction of erroneous data with registry of changes	Re-send and receive messages produced during malfunction See previous information of patients via local caches or web redundancy architecture
Performance	Short response time. The hospital must ensure server sufficiency, bandwidth and web Maintenance should not affect response	Mirror, cluster, virtualization, load balanced servers
Storage	Sufficient to avoid losses. At least 5 years	Possibility of importing data from previous applications, in case of product change

^a IHE standard: Integrating the Healthcare Enterprise.

^b CDA standard: Clinical Document Architecture.

Functional modules

Basic requirements:

- 1) The manufacturer must offer clear specification of the independent functional modules conforming the program (both basic and optional), their dependencies and the expected frequency of revision and upgrading.

Version upgrades

Basic requirements:

- 1) The manufacturer must clearly specify the procedure for notifying the availability of new version, the economical conditions for the upgrading of versions, the procedure to be followed for upgrading, the approximate upgrading time, and its impact upon functioning of the system.

Optional requirements:

- 1) It would be advisable for the product to have a major version upgrading frequency of at least once in every two years.
- 2) User access to improvement plans and new functional options of the manufacturer shall be made easy.
- 3) The upgrading process must be accompanied by new formation if new functional options are introduced, or if there are modifications in the use of the existing functions.

Maintenance**Basic requirements:**

- 1) The conditions of maintenance must be clearly specified in the contract, and it must be possible to establish paid agreement for a sufficiently rapid response or reaction time to guarantee the continued operability of the system.
- 2) The manufacturer must collaborate with the Informatics Department of the center to facilitate maintenance, the execution of easily configurable backup copies at regular intervals (in all cases to be established by each hospital), and integration of the system with other Department or general applications.
- 3) The manufacturer will provide permanent advisory service for the clinical administrator or administrators of the CIS.

Training**Basic requirements:**

- 1) Acquisition of the system entails the obligation of the supplier to provide sufficient training for all users of the system, in order to allow correct handling of all the functions required in their daily working activities.
- 2) The training period must be established in the contract.
- 3) Training must cover both the functions of the CIS and the configuration and parameterization of the system.

Optional requirements:

Periodic upgrading courses imparted by the manufacturer.

Tolerance of malfunction and crisis situations**Basic requirements:**

- 1) A malfunction response protocol must be available, allowing posterior full recovery of the system and of the previous data, as well as posterior inclusion of the data generated during the malfunction period or interval.
- 2) It must be possible to correct erroneous data and introduce previous data, keeping a complete registry of the changes in all cases, in accordance with the current legal guidelines in this field (Spanish Data Protection Act).

Optional requirements:

- 1) It must be possible to re-send and receive the messages produced during the malfunction period, from and to other systems of the Department and center: monitorization, interfaces with other devices (respirators, pumps), laboratory, hospital information system (HIS), etc.
- 2) After web malfunction, the system must allow continued visualization of the information of a given patient through local memory caches or web and server redundancy architecture, as well as local storage of the information generated in the client, in order to allow its transmission once system function has been restored.

Performance**Basic requirements:**

- 1) The system response time must be sufficiently short to not interrupt the normal user working rhythm. This implies immediate system response, or a delay of no more than a few seconds in the case of more complex tasks.
- 2) The hospital will guarantee that the available hardware in clients and servers, and the web capacity, are sufficient for ensuring correct system operation to meet the above mentioned specification.
- 3) The hospital also will ensure that the bandwidth is sufficient.
- 4) The administrative and maintenance activities within the system should not slow it down excessively.

Optional requirements:

It would be advisable to use mirror, cluster or load balanced servers, virtualization or other server enhancement mechanisms and client equipment to guarantee security and efficiency in the functioning of the system.

Storage**Basic requirements:**

- 1) The patient data storage capacity must be sufficient to avoid losses as time elapses following patient discharge. The clinical information stored in the CIS database must be available for at least five years after the last patient visit or admission, as specified by the Data Protection Act.
- 2) It must be possible to recover the information on previously discharged patients to incorporate or at least visualize the data during a new admission.

Optional requirements:

Possibility of importing data from other previous applications in the case of a change in product.

Implementation of the clinical information system

The incorporation of a CIS to an ICU is a complex process requiring close collaboration between the technical

Table 2 System implementation timelines.

Time	According to supplier
Project team	Director: supplier or hospital personnel (depending on the case) Team supervisor supported by physicians and nurses Technical supervisor of the supplier, or designated by the hospital (Informatics)
Starting phase	Check inter-operability between CIS and other hospital systems Installation of hardware First meeting
Development phase	Installation of product Training in configuration Configuration by project supervisor and team. Approved by supplier
Test phase	Connections to devices, HIS and configurations
Activation phase	Establish by supplier and hospital. Paper format co-existing period before go-live
Maintenance phase	Configuration changes through clinical team Ideally done through test system
CIS upgrades	Performed with shortest possible stop time, and through test system

team of the supplier of the system and the team assigned by the Unit and hospital for managing the system. Different factors intervene in this process, as specified in Table 2.

Timelines

The time needed to incorporate the CIS depends on its complexity and on the integrations required. It is advisable to follow the recommendations of the supplier in this sense.

Project team

- a) It is advisable to assign a project director in charge of integration of the CIS within the ICU. The project director will be a technician of the company supplying the CIS, or a qualified person designated by the hospital, and will be accompanied and advised by the necessary technicians to ensure full incorporation of the system in accordance to the purchased products.
- b) On the part of the hospital, it is advisable to designate a project team composed of a technical supervisor and a clinical supervisor: the former will be in charge of the technical aspects of the project, while the latter will supervise the clinical configuration of the product. Both supervisors in turn will be assisted by the opportune hospital professionals. It is advisable for the clinical supervisor to have the support of physicians and nurses willing to lead implantation of the CIS in the Unit and to keep it up to date from the clinical perspective. It is strongly recommendable for the professionals participating in implantation of the CIS to have the necessary time to carry out their assigned duties, freeing them fully or in part from those healthcare activities which they may have during the system introduction period.

Phases of the project: start, development, tests and activation

Starting phase. Before acquiring or installing a CIS, it is essential to analyze its bidirectional operativeness with other hospital systems—fundamentally the HIS, or specific Department applications (pharmacy, laboratory, radiology, etc.), defining the components needed to cover these activities (both hardware and software).

Development phase. The supplier will install the acquired product or products, and will be in charge of integrating them with other applications and connections to the different medical devices as agreed. The development phase comprises modification of the standard configuration and the hospital-specific modifications of tables and files that will guide functioning of the application. The project team of the hospital will construct the application with the counseling and the training afforded by the project team of the supplying company.

Test phase. During this phase, tests will be made of the established integrations, connections with devices, and all the clinical configurations. Those points that fail to operate as expected or for which new changes are suggested must be corrected or incorporated in this phase. Posteriorly, training of all ICU personnel will start, under the supervision of the previously trained clinical team.

Activation phase. After having checked the entire system (components, integration and parallel validation), and having trained its users, the decision relating to activation or non-activation will be taken jointly by the supplier and the hospital. It is advisable for the start of activity with the CIS to be simultaneous to cessation of activity in paper format.

Maintenance phase. Once the CIS is operational, the technical and clinical teams of the hospital will supervise clinical maintenance of the application, modifying the templates and the configuration as required. It is advisable for the DICM to have at least one physician and a nurse to listen to the user suggestions and propose changes in the configuration accordingly.

Table 3 Functional requirements.

Parameter	Basic	Optional
Patient data	Demographic, allergy	Relevant history data (relevant antecedents, explorations, tests, clinical judgment) Nursing diagnoses, access to laboratory and radiology, drugs before admission, data on previous ICU admission if not abandoned hospital
Report	Tool for report preparation with word processor characteristics Easily configurable by administrators	Daily objectives sheet
Drug prescription	Configurable drug library (group, name, presentation, route, dose) Alert of potential conflicts with allergies	Edition without need for new prescription Alerts according to interactions, or clinical, pharmacological or laboratory test criteria
Connection to devices	Monitors, ventilators, cardiac output monitors, pumps (at least drip rate)	Pumps: drug libraries, with doses and volumes Extrarenal filtration equipment Discrimination and filtering of imported anomalous or incorrect data Generation of alerts referred to these data
Guides and plans	Medical and nursing plans according to type of patient. Includes measures/care, drugs, fluids, and assessments Program clinical protocols according to guides	Daily objectives and problems sheet
Alerts and notifications	Allergies	Previously specified critical clinical or laboratory test values Sentinel indicators reflecting important deviations from protocol or guidelines Deviations of quality indicators Potential adverse effects Simple «If... then...» type programming Transmission of information to wireless devices

Clinical information system upgrades. The application upgrades will be programmed in terms of time and resources by the hospital and the supplier in such a way as to ensure minimum interruption of clinical practice. In this phase it becomes more necessary to have a test system in order to evaluate the upgrades before introducing them to clinical activity.

Operative standards

Once the technical and training requirements for installing the CIS have been reviewed, the fundamental or core part of its functioning is addressed. This refers to the functional or operative standards allowing the essential clinical work which the system must be able to cover quickly and reliably. In our opinion, the requirements included under this point are the most important, since they speak of the current basic mission of these applications.

In order to describe the standards in a logical and orderly manner, we have used the criterion of following the basic patient work flow from admission to discharge. Each of these steps comprises a group of specific requirements which are detailed in [Tables 3 and 4](#).

The areas covered are the following:

1. Patient data.
2. Creation of the admission report and planning.

3. Prescription.
4. Connection to monitorization systems.
5. Modeling of patient course. Specific techniques and care.
6. Scales, reports and coding.

Patient data

Basic requirements:

- 1) Patient demographic data (first and last names, birth date, sex, address, telephone number, history number, admission number) acquired via direct importing of the HIS through ADT.
- 2) Importing of allergies.

Optional requirements:

- 1) Clinical history: importing of the most relevant patient history data to avoid duplications of the information contained in the HIS.
- 2) Nursing diagnoses (NANDA) and planning of care through interventions (NIC or Nursing Interventions Classification) and nursing objectives (NOC or Nursing Outcomes Classification).
- 3) Integration, or rapid access to laboratory test and radiology results.

Table 4 Functional requirements.

Graphic plots	Patient grid with relevant information Configurable multiparameter graph formats Drugs in graphs Configurable trending Introduce events and marks	Link to request system of the HIS Time synchrony of data, therapy and care
Techniques	Menu for each specific or relevant technique in ICU	Execution date and duration counter Report of techniques and type according to user (teaching interest)
Clinical notes	Configurable templates according to type and purpose Easy configuration by administrator	
Scales	Included by defect At least one severity scale. Must be able to import data Nursing burden	Tool for design of new scales (administrator-friendly)
Reports	Too for preparation of reports Administrator-friendly use and configuration. Exportation of relevant data to HIS	Importing of fields directly from CIS to report template Exportation to external databases using accepted specific formats SNOMED classification
Codification	Incorporate MBDS Coding via ICD9-10	
Nursing (specific)	Report of daily nursing activity and care. Planning of care. Codification of nursing diagnoses Tool for preparation of exportable report at discharge Easily configurable by administrators	Planning of care using NANDA, NIC and NOC taxonomies (inter-relation)

- 4) Drugs received in the ward prior to admission to the ICU, via XML or HL7, specifying drug substance, dose, timing and start (ideally).
- 5) It must be possible to incorporate data corresponding to a previous and recent admission to the ICU, particularly when the patient has not abandoned the hospital.

Creation of the admission report and planning

Basic requirements:

Tool for preparing admission reports. This tool must be able to generate texts in different formats and allow the use of macros, abbreviations or other elements assisting in writing. This function must be simple to use for the clinical administrators. In some cases, it may be replaced or complemented by the reporting tools of the HIS.

Optional requirements:
Daily objectives sheet.

Prescription

Drug prescription

Basic requirements:

- 1) A drug library that can be easily configured and amplified by the clinical administrator of the application.

Optional requirements:

- 1) Editing and modification of dose, timing and frequency, without having to prescribe the drug again – though specifying that changes have been made, to the effects of clinical control.
- 2) Possibility of generating configurable alerts in case of interactions or possible side effects, according to pharmacological, clinical or laboratory test criteria.

Prescription of care plans, protocols and guides

Basic requirements:

The system must offer possibilities for programming by an advanced user:

- 1) Clinical protocols according to the clinical guides: by type of patient, including general measures, drugs and assessments (scales).
- 2) Nursing care plans: individualized and/or standardized, with programming and time correspondence, and evaluation.

Connection to monitorization systems

Basic requirements:

- 1) Monitors: ideally, it should be possible to capture all the monitoring signals which the device can register through all its channels.

- 2) Ventilators: capture of all the information allowed by the communication protocol and data output of each apparatus.
- 3) Cardiac output monitors.
- 4) Perfusion pumps: drip rate.

Optional requirements:

- 1) Perfusion pumps: importing of drug libraries, accumulated volumes and doses.
- 2) Connection to extrarenal filtration machines.
- 3) Bar code reading systems.
- 4) Discrimination, based on pre-established rules, of possible anomalous data attributable to monitoring device error or to actual patient measured values.
- 5) Alerts and alarms corresponding to these deviations for checking and correction, as required.

Modeling of patient course. Specific techniques and care

Care plans and guides

Basic requirements:

The CIS should allow the incorporation of clinical guides and care plans, in both the medical and nursing settings. The system should offer the possibility of programming clinical protocols according to clinical guides, based on:

- i. Patient type.
- ii. Contents: general measures, drugs, fluids and assessments (scales).

Optional requirements:

- 1) Daily objectives and problems sheet (to be included as an editable medical and nursing note).
- 2) Relational integration between nursing care planning and the graphic plot. This entails the internal relation between the information appearing in both sections of the registry (plot-care plans).

Alerts and notifications (meta-alerts)

Basic requirements:

The use of alert systems in the CIS is necessary in order to maintain patient safety and quality criteria. These systems may help the professionals to reduce the most common adverse events.

- 1) The CIS should generate alerts corresponding to anomalous monitorization data.
- 2) Notifications and alerts should be used to indicate the possibility of adverse drug reactions (allergies) in the prescription, though this would not be essential if the HIS satisfies this requirement in a prescription module.

Optional requirements:

- 1) Critical clinical or laboratory test values, according to disease.
- 2) Parameters (sentinel indicators) showing deviations from protocol or clinical guidelines.

- 3) Relevant quality indicator deviations.
- 4) Potential adverse effects according to clinical or laboratory test information that modify treatments (e.g., suspension of an antiplatelet drug in the presence of severe thrombocytopenia).
- 5) In their simplest version, these alerts and notifications should be programmed according to "If... then..." programming rules included in modules for this purpose.
- 6) Transmission of critical alert information to wireless devices, locators or mobile phones.

Graphic representations

Basic requirements:

- 1) Table-based patient visualizations (patient grids).
- 2) The CIS should allow visualization of any clinical, laboratory or fluid information in graphic and/or tabular form.
- 3) It should be possible to configure different types of graphic representations and their values – ranges, distribution, etc. – referred to different parameters and types of patients (by age or disease).
- 4) The drugs prescribed and administered are to be reflected on the graphic representations.
- 5) It should be possible for the user to configure graphic and tabular trends and tendencies.
- 6) It should be possible to enter events and time marks.

Optional requirements:

- 1) Placement of requests from the system or capacity to link to the requests system of the HIS.
- 2) All prescribed treatments, as well as nursing care, are to be reflected in the graphic representation, in order to join on the same timeline the patient data (monitorization, laboratory tests, etc.) and the provided treatment and care.
- 3) From the grid it should be possible to configure an alert panel referred to anomalous data, care deviations (failure to perform an evaluation), scales (marked score increments) and protocols.

Techniques

Basic requirements:

- 1) The CIS should be equipped with a module addressing about the most common techniques used in the ICU.

Optional requirements:

- 1) Possibility of including performance date and a daily duration counter in the techniques menus (e.g., days of line or catheter insertion).
- 2) The system should inform of what type and how many techniques are performed by the user.

Clinical notes

Basic requirements:

- 1) The CIS should allow the preparation of medical and nursing notes based on previously established templates.
- 2) The elaboration of these templates should be carried out with a tool that is simple to use for the administrator.

Scales, reports and coding

Scales

Basic requirements:

- 1) The system should include severity scales and assessment scales by organs, condition (pain, sedation, ulceration risk, etc.) or disease processes (sepsis, traumatism, pancreatitis, coronary disease, postsurgery, multiorgan failure, etc.), to facilitate calculation and analysis of the results. The system should be able to import demographic and clinical data to complete calculations.
- 2) Inclusion of nursing burden calculation scales (TISS, NAS, NEMS).
- 3) The scales programming module should allow the generation of proprietary scales of the Unit, or of scales published in the future.
- 4) This module should be user friendly for the advanced operator.

Reports

Basic requirements:

- 1) Availability of a tool for preparing reports allowing the configuration of different formats (techniques, procedures, discharge).
- 2) This tool should be easy to use for an administrator with only minimum training.
- 3) The CIS should allow the exportation to the HIS of relevant information on patient admission to the ICU.

Optional requirements:

- 1) Automatic importing of fields from the CIS (procedures, diagnoses, drugs, complications, etc.) to the exportable report template.
- 2) Capacity of data export to external databases based on specific formats (XML, Excel, coma values [CVS], etc.).

Codification

Basic requirements:

- 1) The system should allow patient classification by means of a minimum basic data set (MBDS) adapted to the ICU setting.
- 2) The system should allow codification of diagnoses, procedures and complications in accordance to versions ICD9-10.

Optional requirements:

Possibility of including the SNOMED (Systematized Nomenclature of Medicine-Clinical Terms) classification of diagnoses, procedures, results.

Nursing

In order to ensure operability of the CIS from the intensive care nursing perspective, the system must incorporate essential resources suited to the activities carried out. Specifically, in relation to nursing, the CIS must include tools for the planning of care, with the generation of care activity reports. These preferentially should focus on methodological standards based on validated taxonomies (NANDA, NIC and NOC languages), and on the modalities in which the information is structured or presented (relational criteria). In addition, the applications should allow new or autonomous codification, facilitating professional development and work with nursing procedures, and the opportune indicator reports (Table 5).

Data and security

Data analysis

The requirements of these sections are summarized in Table 5.

Basic requirements:

- 1) Any CIS installed in a DICM must be equipped with a tool for conducting searches and analyses of the data registered in the system.
- 2) If this tool does not come with the CIS package, the supplier may offer the task of data processing through an external application, provided it has been validated for the system and installed by the supplier.
- 3) With these tools, the CIS will elaborate reports on the variables conforming the Unit control panel. In addition, searches will be made for investigational studies or activity reports of certain user groups.

Optional requirements:

- 1) The CIS will generate statistical reports on relevant indicators and events in the activity of the ICU.
- 2) Storage, exploitation and data processing in Data Warehouse type databases, either proprietary or integrated in the HIS, and to which the CIS conveys the information. This database is defined by the following characteristics:
 - a) Topic oriented. The information is organized in such a way that the data relating to one same event or object in the real world (e.g., a clinical indicator) are inter-joined.
 - b) Variable over time. The time changes in the data are registered with a view to reflect these variations in future reports.
 - c) Non-volatility. The data are neither modified nor eliminated; once information has been stored, it becomes read-only information and is retained for future consultations.
 - d) Integrated. The database comprises all the data entered in the CIS for each patient, whether imported (demographic, MBDS, monitorization) or manually entered (codes, scales, techniques). The Data Warehouse of the CIS can inter-relate with the database

Table 5 Database and security requirements.

Parameter	Basic	Optional
Data analysis	Data search and analysis tool Can be application from other sources, but is always to be offered by supplier Capacity to prepare reports on variables of the Unit control panel	Reports on relevant quality indicators Data Warehouse with constitutive elements Protocol for extraction, filtering, and generation of models and reports
Database	Access limited to administrator Limit possibility of data erasure Based on security by database manager	
Safety		
Accesses	Identification by user name (login)/password with programmed expiry Ensure solidity of password Different levels of access or permission	Registry of failed accesses PKI (Personal Key Identifier)
Application	Back door block Data confidentiality protocol in maintenance activities Only administrators can carry out database edition and upgrading	Encrypting without limitation of exploitation
Remote access	Through private or virtual networks Connection to personal devices (telephones, PDA) through safe networks	
Audits	Report on connection time and type of activity per user User traceability through entry of erroneous information in registry Changes in password and failed accesses	

(Data Warehouse or otherwise) of the HIS for specific consultation on cost or other issues.

The advantages of databases of this kind are better and easier access to the data by the end users, an important help in the taking of decisions, based on consistent and integrated information on pilot indicators, and the identification of occult relations and trends among data with a view to developing clinical or management hypotheses allowing the understanding of past errors and future predictions according to the scenario involved. Their main disadvantage is high cost, though adequate exploitation and design can secure an important investment return.

- 3) As support to clinical management, with this or some other type of database, the following capacities must be available:
 - i. Extraction of the relevant information, data transformation and filtering.
 - ii. Data storage in raw and aggregated form for exploitation.
 - iii. Generation of the data model best suited to the desired exploitation, and which should be previously defined and implanted.
 - iv. Elaboration and presentation of the information in the form of control panels containing tables, indicators and graphic representations offering key aspects of the system considered globally, with the definition of alerts, and based on a navigable structure.
 - v. Generation of the statistics required for activity follow-up.
 - vi. Extrapolation of data and identification of incidents.

System security

Access control

Basic requirements:

- 1) All the systems are to require at least user identification by name and password, with a corresponding expiry date.
- 2) A subsystem to ensure solidity of the password is recommendable.
- 3) Access to the system should be configurable with the required levels of access or authorization, considering the different functions of the ICU healthcare team. Specifically, in nursing, if drug prescription is allowed (a common practice in the ICU setting), such authorization must abide with the specifications of current legislation (Act 28/2009 13).

Optional requirements:

- 1) Registry of failed accesses, as well as of block of access to the application after repeated unsuccessful attempts.
- 2) Authentication of access to these systems not only by name (login) and password, but also by the use of a PKI (Personal Key Identifier).

Application

Basic requirements:

- 1) The CIS should be equipped with a back door (access to the application or its databases in a way alternative to

that demanding a user name or login and corresponding password) or other intrusion blocking system.

- 2) Guarantee of data confidentiality during technical maintenance or system checks by technical personnel.
- 3) Guarantee that only the clinical administrators of the systems can make use of the upgrades or of database maintenance.

Optional requirements:

Data encrypting, without limitation of data exploitation in any case.

Remote access

Basic requirements:

Access through private virtual networks or web environments. The security of these networks must be checked, and access through them should be based on very solid passwords.

Audits

Basic requirements:

The CIS must be able to generate reports (audits) on the users, specifying time and type of activity, as well as changes in passwords and failed attempts to access the application, denial of services, or critical fields that have been edited.

Database

Basic requirements:

The controls to be applied for accessing the database can range from user (login) and password validation (but limiting the possibility of data erasure) to the granting (permission) of different levels of access to the data exploitation tool (read only, etc.).

Conflicts of interest

Dr. Vicente Gómez-Tello has been invited to two meetings organized by Dräger Medical, without remuneration.

Dr. Joaquin Alvarez-Rodríguez has been an invited speaker in different meetings organized by the PICIS, and belongs to the Advisory Board of the PICIS, with no remuneration for any of these activities.

Dr. Pedro Morondo has been invited to a European meeting of Centricity™ (General Electric) users, without remuneration.

Dr. Jose Maria Nicolas has been invited to several meetings organized by Dräger Medical, without remuneration.

Dr. Maria Calvete-Chicharro has been a remunerated clinical collaborator of IMD Soft up until the year 2010.

The rest of the authors declare no conflicts of interest.

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