

ROMANIAN ELECTRONIC REGISTRIES FOR PATIENTS WITH EXTRACORPOREAL SUPPORT OF VITAL FUNCTIONS

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ABSTRACT: Patient registries are being developed worldwide in response to the increasing demands of healthcare providers, for both clinical and research benefits. We describe the development and operation of the first national registries implemented for patients with extracorporeal support of vital functions, by hemofiltration and artificial lung, respectively. The registry development was accomplished under the auspices of the Romanian Society of Anesthesia and Intensive Care (SRATI). The registries are currently in use, serving a multicentric network of hospitals in Romania. The National Artificial Lung Registry is available on the website novalung.srati.ro, while the Hemofiltration National Registry is available on the website hemofiltrare.srati.ro. The beneficiaries are the Intensive Care Units medical staff, researchers and patients themselves. This also results in improved healthcare services and allows translation towards larger scale registry networks, at national and international level, by implementing standards defined in CEN 13606 and HL7.

KEYWORDS: electronic patient registry, multicentric registry, hemofiltration, artificial lung, extracorporeal support, intensive care unit.

1. INTRODUCTION

Electronic processing of patient data is a concept dating from the 1970s. Initially it was proposed on small scale, in a hospital or clinical department, for specific data sets, as in an automatic system of analysis of electrocardiograms. Further developments led to defining key principles in implementing registries, registry purposes and design.

Nowadays patient registries encompass patient-related data, selected by a certain clinical manifestation, diagnosis, medical or surgical procedure. Registries have become a useful tool in research, as they can be used to follow the natural history of a disease, to evaluate clinical effectiveness and safety of therapies, to study large scale heterogeneous groups of patients, to determine the level of access to healthcare and the standards of

medical care. A specific study design has evolved to meet the research needs, the registry-based observational study [R+15]. The main advantages of such study type are lack of bias and enlarged scope, among its drawbacks could be the need for a specific registry and the non-interventional character. In Romania, the unicentric registry created at Floreasca Clinical Hospital Bucharest in 1995 for ST elevation myocardial infarction (STEMI) patients, transformed into multicentric registry in 1997, numbers among the first successful patient registries, in use for over 10 years [C+15].

The registries development for patients with extracorporeal support of vital functions is aiming to fulfill the unmet needs in critical patients care at national level. The registries we describe are based on data available from Intensive Care Units (ICU) in Romania, with data input and storage on a single platform. A potential problem at this stage would be Internet connectivity for all the participating Units, which had already been solved beforehand.

The registry development was accomplished under the auspices of the Romanian Society of Anesthesia and Intensive Care (SRATI). The relevant fields for registry development were identified in SRATI board meetings and confirmed in a general meeting of its members. Registry operation is beneficial for the clinical staff in the ICU at the participating hospitals, by direct access to a management tool for the critically ill patient. It will also enable the medical community to perform research by using the recorded data. The patients will benefit from analysis of morbidity and mortality indices, with further lowering of these rates, as well as a decrease in recovery time for patients following the implementation of infections surveillance and monitoring.

These registries, built with interoperability standards, also aim to facilitate translation towards larger scale national and international trials.

2. RATIONALE

Complex biochemical and pathophysiological imbalances lead to significant impact on survival rate among the critically ill patients admitted in ICU. The most frequent death-related mechanisms are the systemic inflammatory response syndrome (SIRS), acute respiratory distress syndrome (ARDS) and multiple organ dysfunction syndrome (MODS). Besides these, the critically ill patient also bears other conditions which can be induced and augmented by the critical status. It is documented that in an acute kidney failure setting, but also in respiratory failure, cumulated with septic status, the patient can develop MODS, in up to 90% of cases, which quickly leads to death [LC07].

The extracorporeal systems for supplanting renal clearance, as well as those for blood oxygenation and CO₂ removal, were developed to address these aggravating factors - the renal and respiratory impairment - in the critically ill patients. The only studies available in Romania with data from the Intensive Care Units, up to the development of these two registries, were performed retrospectively, limited in time, geographically and in clinical scope. Another limiting factor was the human resource, with a finite amount of time available for both the clinical duties and research activities, also taking into account the human resources deficit in the healthcare system. There was no unified national system for reporting and monitoring renal and pulmonary impairment assisted by extracorporeal systems. Internationally there were also few implemented electronic registries, the majority of them encompassing one ICU, at local level. The registries' development is driven by the increased worldwide trend to assess health issues and investigate possible solutions by means of information stored in computerized databases.

The registries developed under SRATI auspices address these information deficits and allow for real time input of patients vital data, with a synthesis of clinical parameters and laboratory values, with a

patient file being prepared in a custom format that can be visualised locally or in other centers. User feedback is also an important indicator for assessing registry functionality. The severity and prognostic scores are automatically computed, thus facilitating medical interventions.

This forms the base for developing a decision support system for clinicians, with potential of improving the specific morbidity and mortality indices. The standardized data input and information storage will allow further access and integration with international databases created in compliance with CEN 13606 and HL7 standards [D+06, S+06, TKK13].

3. REGISTRY OPERATION

The following hospitals are currently enrolled in the multicentric registries: Emergency Clinical County Hospitals in Cluj Napoca, Oradea, Timisoara as well as the Emergency Hospital of the Internal Affairs Ministry in Bucharest. The Artificial Lung National Registry is available on the website novalung.srati.ro, while the Hemofiltration National Registry is available on the website hemofiltrare.srati.ro. Preliminaries included infrastructure set-up (server configuration, domain reservation, web page creation). User names and passwords have been generated for ICU staff in the hospitals, to facilitate data input into the registry and retrieval thereof. The designated operator in a hospital's ICU uses his credentials to log in to the respective website (fig. 1,2).

The main registry page allows for visualizing the data entries for existing patients' datasets, adding a new entry, searching by a specific string (diagnosis) or performing basic statistics on the available information.

Summary parameters (origin hospital, patient ID coded as initials or chart number, admission date and complete diagnosis) are provided for each database entry. Password change and exit for the current user are also possible (fig. 3, 4).

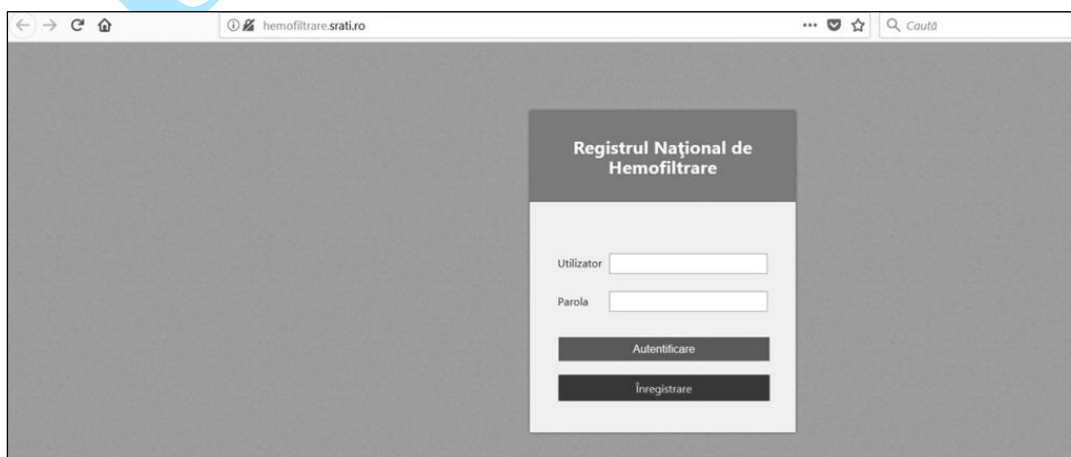


Fig. 1. Homepage of the Hemofiltration National Registry



Fig. 2. Homepage of the Artificial Lung National Registry

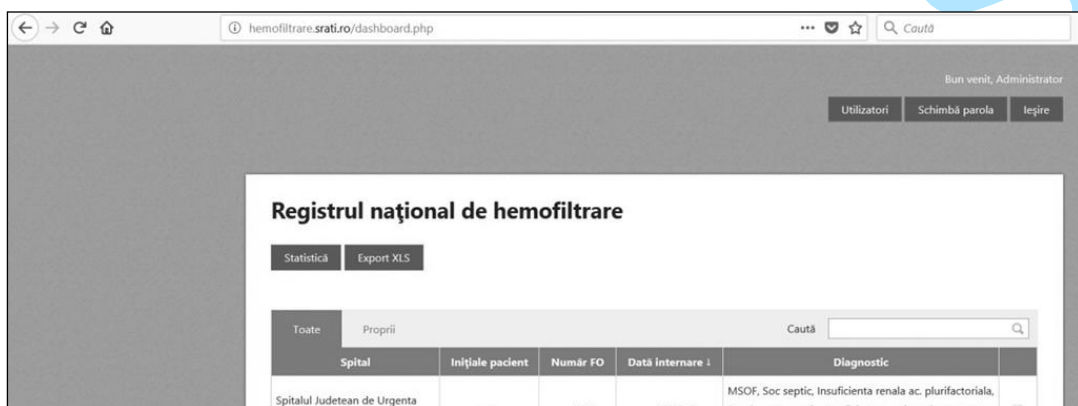


Fig. 3. Main page of the Hemofiltration National Registry



Fig. 4. Main page of the Artificial Lung National Registry

The patient's chart is initialized with demographical, clinical and laboratory data after their ICU admission. During their stay, the patients are monitored and specific values are updated in the registry. Upon the patient's transfer or death, the registry is updated with representative data such as:

- demographical data (age, sex, weight, height),
- type of mechanical ventilation that was employed,
- admission time in the ICU,
- hospitalization time,
- time and cause of death
- associated conditions developed after admission,
- extracorporeal therapy duration,
- vasopressor and diuretic medication duration,
- diuresis,
- sepsis incidence,
- acid-base balance parameters,
- oxygen and carbon dioxide status,
- lung imaging changes, other specific laboratory tests,
- MODS incidence,
- clinical status of the patient upon discharge (fig. 5).

Fișă de înregistrare iLA			Nr. 4	
Spital:	Spitalul Județean Timișoara	Tipul secției ATI:	Interdisciplinară	
Localitate:	Timișoara	Număr de utilizări iLA:	>10/an	
1. Rezultat				
Internare în ATI:	16.01.2014	Externare din ATI:	27.01.2014	
Intubație:	20.01.2014	Traheostomie:		
Detubare/decanulare:		Start iLA:	17.01.2014	
Stop iLA:	22.01.2014	Deces pacient:	NU	
Scor APACHE la startul iLA:	26	Cauză deces:		
2. Date demografice				
Sex:	masculin	Vârsta:	55 ani	
Înălțime:	162 cm	Greutate:	80 kg	
		Greutate ideală:	65.7 kg	
3. Indicații și diagnostic				
Indicații iLA:	Insuficiență ventriculă stângă și insuficiență ventriculă dreaptă, insuficiență respiratorie hipoxică			
Diagnostic:	Insuficiență cardiacă, ARDS, Status post stop cardio-respirator, insuficiență respiratorie profundă rezistentă			
Boală cronică pulmonară:	NU			
4. Acces vascular				
4.1 Canule cu un lumen				
	Tipul de vas	Mărimea (Fr)	Lungimea (cm)	Produsul utilizat
Drenajul sângelui		0	0	
Reperuzarea sângelui		0	0	
4.2 Canule cu dublu lumen				
	Tipul de vas	Mărimea (Fr)	Lungimea (cm)	Produsul utilizat
Drenajul / Reperuzarea sângelui	Vena femurală	0	0	
5. Terapii adjuvante				
6. Anticoagulante				
Heparină: UFH	20	Acid Acetil Salicilic (ASA)	0	
7. Complicații				
Îndoirea (răsucirea) canulei	NU	Hemoragie la locul de puncție	NU	
Trombozarea canulei	NU	Ischemie la nivelul membrului	NU	
Embolism	NU	Dislocare de canulă	NU	
Alte complicații				

Fig. 5. Patient chart in the Artificial Lung National Registry

Once the data have been entered, there are statistics available for computing: primary statistics based on one variable among the ones recorded in the registry:

- demographical variables (sex, age),
- diagnostics, comorbidities (such as heart failure, diabetes, cirrhosis),
- clinical scores (APACHE, SOFA),
- renal status (with indicators like diuresis state, creatinine level, hyperkalemia),
- non-renal conditions (sepsis, pancreatitis, trauma, burns etc),
- employed techniques (plasmapheresis, CRRT types etc),
- treatment options (anticoagulants, diuretics etc),
- complications (such as hypotension, bleeding, arrhythmias, filter clogging)
- patient's evolution (fig. 6).

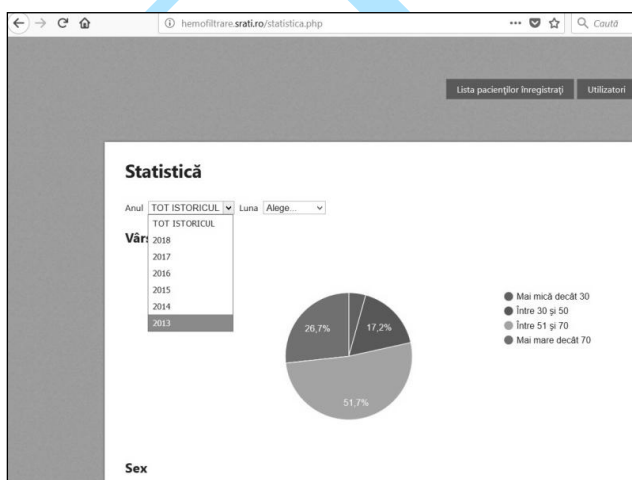


Fig. 6. Statistical tools for the Hemofiltration National Registry

4. CONCLUSIONS

There are 4 emergency hospitals with ICU enlisted to enter data into the two registries, thus creating the premises for expansion of these registries, by helping to eliminate challenges in routine collection of patient-related data and connecting clinical data to patient outcomes.

The two registries already contain over 150 entries of patients with extracorporeal support of vital functions, enabling further development for clinical and research use.

Undergoing research on patient outcomes is needed to determine the impact of registries of patients with extracorporeal support of vital functions on general and specific morbidity and mortality in the ICU admitted patient population.

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