An infrastructure for quality assessment in intensive care. Prognostics models and terminological systems

de Keizer, N.F.

Citation for published version (APA):

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: http://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.
Chapter 1

General Introduction
1.1 Introduction

The topic of this thesis is quality assessment of intensive care. We explore, design and implement conditions for quality assessment of intensive care from two perspectives: a clinical epidemiological perspective concerning data analysis, and a medical informatics perspective concerning the structuring of information towards diagnoses. The clinical epidemiological perspective is described in part one of this thesis. It presents the organisational infrastructure for a quality assessment program for Dutch intensive care units (ICUs) and the assessment of quality of ICUs by using prognostic models. Special attention is devoted to scoring systems and prognostic models, the performance of these models in the Dutch situation, and the added value of refined diagnostic information in the prognostic models to estimate hospital mortality for adult intensive care patients.

One of the starting hypotheses from the medical informatics perspective is that unambiguous and structured diagnostic information is essential to define patient categories within the intensive care population and to stratify patients accordingly. The second part of this thesis therefore describes conditions to arrive at valid instruments to collect and manage data for quality assessment of intensive care. It pays special attention to terminological systems which facilitate structured registration of diagnoses and retrieval of diagnostic information to enable unequivocal patient selection and stratification.

This chapter is organised as follows. Section 1.2 gives a short history of the medical domain of interest in this thesis: intensive care. Section 1.3 is a general introduction to quality assessment in intensive care. Section 1.4 introduces Patient Data Management Systems (PDMSs), which are important tools to collect data that can be used for quality assessment. Section 1.5 gives an introduction to terminological systems, and section 1.6 describes the objectives and outline of this thesis.

1.2 Intensive Care

Intensive Care has been defined as “a service for patients with potentially recoverable conditions who can benefit from more detailed observation and invasive treatment than can safely be provided in general wards or high dependency areas” [1]. Intensive care is mainly concerned with patients with vital organ failure. The origin of intensive care goes back to some developments in the treatment of vital organ failure started several decades ago. In the early 1950s, the poliomyelitis epidemic in Copenhagen led to the use of ventilation technology and resuscitation techniques in the clinic. These techniques were brought to the clinic from the operating room by anesthesiologists, to sustain polio victims which experienced respiratory failure due to the paralytic seizures [2-4]. The development of intensive care was also stimulated by the awareness that caring for severely ill patients in a specific area of the hospital in which expertise is concentrated, could be life saving and is more efficient compared to caring for these patients across different wards [3]. Following the success of treating life threatening respiratory insufficiency, a significant advance occurred in treating renal failure. In 1960 an artificial kidney center was opened in Seattle. This clinic was the first that applied a machine, which had been developed by Willem Kolff in the Netherlands during the early 1940s, to replace the kidney function [3]. The last important inducement for intensive care was the initiative in North America in 1962 to set up special
Chapter I

units for continuous monitoring and support of patients with acute myocardial infarction [3, 5].

These events all contributed to the development of the intensive care unit as a treatment concept in almost all western hospitals nowadays. In university hospitals, special ICUs, next to general ICUs, exist for surgical patients, cardiothoracic patients, neurological and neurosurgical patients, pediatric, and neonatal patients. In the Netherlands there are approximately 120 ICUs varying from one room 4 bed ICUs to big departments with up to 60 beds in university and teaching hospitals. Approximately 127,000 patients are admitted in Dutch ICUs every year. It is hard, however, to provide the exact number of ICU admissions, ICUs or ICU beds because beds labelled as ‘ICU beds’ in one hospital may be considered medium or high care in others. Internationally, the number of ICU beds varies widely from 1-2% of total hospital beds in the United Kingdom to 3-4% in the Netherlands [6] and 20% in the United States [4]. Again, international variation may partially rest on different definitions of an ICU.

Intensive care is expensive. The technologies to treat and monitor organ failure of critically ill patients, are not only costly as consequence of equipment costs, they also require a large number of skilled personnel to maintain and use these technical facilities 24 hours a day, 7 days a week. The nurse to patient ratio (nurse:patient) in the Netherlands varies between 1:1 for level 1 ICUs (very complex and ill patients) and 1:2 to 1:4 for level 3 ICUs (monitoring and treatment of critically ill patients with risk for organ failure) [7]. ICU nurses have completed a specialist-training program after the general nursing training. The same applies to the medical staff. Although medical care formerly was provided on a consultancy basis with one consultant in charge as the clinical director, a growing number of ICUs in the Netherlands have fulltime intensivists. A special training program of 12-24 months, after the specialization as an anesthesiologist, surgeon or internist, is necessary to become a certified intensivist [8]. Most Dutch intensivists have an anesthesiology or internal medicine background.

Research shows that a relatively large proportion of hospital resources is spent on ICUs [7] although accurate figures are hard to provide. The mean cost per day on a Dutch ICU ward in different sources [9-11] varied between €415 and €1150 in the years 1992-1998 depending on the type of hospital and the calculation methods used, for example depending on whether overhead costs are included.

Intensive care undoubtedly improves the outcome of critically ill patients. However, many questions arise about the effectiveness and efficiency of intensive care. The work described in this thesis provides a basis to address these questions by developing an infrastructure for continuous quality assessment in intensive care.

1.3 Quality assessment and quality assurance in Intensive Care

Although intensive care obviously reduces mortality and morbidity for many patients, few research has evaluated its overall effectiveness and efficiency in a systematic way. Budgetary constraints, insurance regulations and professional ambitions now have prompted physicians and managers to assess the performance of ICU treatment. To enable quality assessment of ICU several initiatives, national as well as international, were born. Quality assessment can be defined as the critical appraisal of the measured results of a health care program, in comparison with the formulated objectives [12]. In quality assessment three aspects can be distinguished: efficacy, effectiveness and efficiency. Efficacy can be defined as the measure
in which the health care program achieves the objectives under ideal circumstances [13].

**Effectiveness** can be defined as the measure of agreement between the objective and the result of a health care program for a defined population under average circumstances in general daily practice [13]. Effectiveness is a more appropriate measure than efficacy in quality assessment of intensive care because actual daily practice is considered. Commonly used outcome measures for the effectiveness of health care are the five “d’s”: death, disease, disability, discomfort and dissatisfaction [14]. The last three “d’s” are sometimes summarized with the concept *quality of life*. In this thesis we restrict our outcome measures to ICU and hospital mortality, because death is a sensitive and objective outcome measure and it has regrettably a relatively high frequency, making it a suitable indicator.

**Efficiency** of a health care program can be defined as the achievement of the objectives under an optimal use of resources [13]. To appraise efficiency, costs of care should be added as an additional outcome measure and should be related to the clinical outcome measures. Independent of efficacy, effectiveness and efficiency, labour satisfaction is also a growing outcome measure in quality assessment, but this will not be considered in this thesis.

It is unethical to evaluate the effectiveness and efficiency of ICU treatment in a randomised trial in which one group of patients is treated in a general ward and one in the ICU. Furthermore, ICU treatment often consists of many therapies which can not be evaluated separately from each other. Therefore, to enable quality assessment of intensive care several regional or (inter)national intensive care databases were developed [15-21], of which the ICNARC national database [22] is probably the best-known. Information from these databases enables appraisal of the effectiveness and efficiency of the care process by comparing outcome data with the expected outcome values on the basis of the input of the care process.

The patient population admitted to ICUs is a heterogeneous group of patients displaying many different diseases and varying severity of the diseases. It forms a part of the input of the care process (see Figure 1.1).

**In consequence of these case mix differences, it is not useful to directly compare outcome of different ICUs. A 30% mortality rate in an ICU located in a large university hospital compared to a 20% mortality rate in an ICU located in a small general hospital does not necessarily indicate better care at the general hospital. The reverse may be true e.g. in [13]. It could be the case that the patients admitted to the first ICU are more severely ill than patients admitted to the second ICU. Adjustment for these differences in as far as they exist prior to admission is called case mix adjustment. Case mix adjustment is necessary before outcome of different ICUs can be compared among themselves or with some standard. Existing case mix adjustment methods for estimation in intensive care mainly concern mortality by using the**
Standardized Mortality Ratio, the ratio between the observed mortality and the expected case mix adjusted mortality calculated with a prognostic model. Case mix adjustment for other outcome measures such as quality of life and cost of care is rare. In paediatric ICUs a method for case mix adjusted quality of life, by standardised health ratios, is developed in analogy with standardised mortality ratios [23]. The TISS, Therapeutic Intervention Scoring System, is often used as an approximation of costs of ICU treatment [24-26] and could be used to compare real costs with estimated costs.

Benchmarking, the process of comparing the data of one entity with a reference [27], is a commonly used technique in quality assessment, which has also been applied in intensive care. In intensive care, benchmarking often uses the national average of an outcome as the reference point. The measurement of effectiveness and efficiency in a quality assessment program by comparing the outcome of individual ICUs with the national average outcome, clinical or related to resources, is just the starting point for quality assurance. Quality assurance can be defined as the critical appraisal of the measured results of a health care activity in order to identify whether the formulated objectives of that activity are being achieved, and in case of a discrepancy, quality assurance implies a response to reduce the deviations from the objectives [28]. An operational quality assurance program searches for determinants of the difference between achievements of an individual participant (ICUs) and the objectives, for example the average of the two best performing ICUs.

1.4 Patient Data Management Systems

To enable quality assessment, data about the input and outcome of the ICU is essential (see Figure 1.1). During the last years a number of ICUs have implemented a Patient Data Management System (PDMS) as a solution to manage the large amount of information produced by monitoring instruments, laboratories and care activities in intensive care. A PDMS is a computer-based information system which facilitates the collection, integration, retrieval and interpretation of the multi-source, multi-variant data found in ICUs [29-31]. With a lot of data collected during patient care, including data about demographic features, the disease and the severity of illness, the PDMS is a valuable source of information for management, research questions and hence also for quality assessment. Currently a manual Case Record Form (CRF) is often used as an alternative for electronic data collection with the aim of quality assessment. However, the PDMS or in general the Electronic Patient Record seems to be a certainty for the future and there are several reasons to prefer electronically data collection above manually collected data: a) rules and definitions in help functions improve non-ambiguous and consistent data collection; b) the quality of data directly imported from bedside equipment, hospital and laboratory information systems is expected to be of better quality due to the avoidance of human errors; c) the quality of other (manually entered) data in the PDMS is expected to be high because they also play an important role in the daily treatment of the patient; d) in theory it does not take additional effort when the data set has to be expanded for as long as it concerns data already routinely collected in the primary care process; e) data collection and extraction does not give (much) additional workload to nurses and physicians as the data are (part of) the data in use for the primary care process. There are also some disadvantages in using current PDMS compared to manual data collection: a) PDMSs are very costly; b) it takes a lot of effort to configure a
PDMS so that it is suitable for the extraction of the desired data set in the right format; c) due to the complex database structure of any PDMS, and due to the lack of expertise on informatics in the ICU, and the lack of accessible data extraction tools, most ICUs are dependent on the PDMS supplier for the extraction of the desired data set; d) data analyses on non-validated data can be erroneous, e.g. an automatically imported body temperature of 20 degrees due to the disconnection of the thermometer should not be used in data analysis. Besides these disadvantages one has to be aware of the fact that due to the high frequency of sampling (physiological) data by a PDMS the probability of detecting extreme values, e.g. blood pressure, is larger. This requires adaptation of the prognostic models derived from such “worst value in first 24-hours” data [32].

1.5 Terminological systems

PDMSs in Intensive Care become important tools to collect, integrate, retrieve and interpret the large amount of data of ICU patients. One aspect of the total data collection in intensive care concerns the collection of reasons for ICU admission during ICU stay. The ‘reason for admission’, but also other diagnostic information such as complications occurring during ICU stay, is essential to set up and adapt treatment in daily care practice. It is vital to select patient groups or to stratify the patient population in a research or management setting. Integration and interpretation of multi-source data in an information system or PDMS are only possible when the data are structured. Until now there has hardly been any systematic and structured registration of reasons for admission during stay in the ICU. This is largely attributed to the lack of an appropriate terminological system for describing diagnoses of patients admitted in intensive care. A terminological system is a system that, based on a specification of concepts (entities of thought) in a domain, e.g. diagnoses in intensive care, and their interrelationships, provides information services such as providing the terms that denote these concepts. At this moment none of the PDMSs used in Dutch ICUs, enable structured collection of diagnoses. At best an enumerative list with diagnoses (primarily based on ICD-9 or ICD-10 [33]) is used. The International Classification of Diseases (ICD) is perhaps the best known terminological system used in medicine, originally intended for statistical abstraction of mortality data. The first “ICD” was developed in 1893, and through a hundred years it evolved into the ICD-10 [33], which was published in 1993. Although the ICD is primarily developed for mortality registration its use has widened to use in a general clinical setting. For example the ICD-9-cm (clinical modification of ICD-9) [34] was developed for morbidity registration and is currently in use in most countries. Some countries already use ICD-10 now, but mostly for mortality registration only.

During the last decades many terminological systems have been developed [35-39] each with its own domain and structure to support an unambiguous description of medical concepts. Figure 1.2 represents the role of a terminological system in relation to the PDMS and the users. The arrows represent the data flow between the information sources. For example, the reasons for admission or complications during ICU stay can be entered into the PDMS by nurses and physicians, managed by the terminological system. These data can be looked up by all people involved with the care and treatment of the patient and by people involved with intensive care research or management.

A terminological system related to the PDMS should (1) support the ICU physicians and nurses to describe the patient’s health problems as part of the care process and (2) support researchers and managers to aggregate the ICU population in relevant patient groups. To
enable the first objective, the expressiveness of the terminological system, i.e. the possibility to express the things one wants to say, should be adequate. This means among others that the level of description detail should not be restricted and that it should be possible to refine concepts in the terminological system by making attribute values explicit, e.g. it should be possible to refine ‘myocardial infarction’ into ‘acute myocardial infarction’ or ‘old myocardial infarction’. Because in daily care practice users denote a concept with different terms, the terminological system should also support the use of synonyms, e.g. ‘heart attack’ and ‘myocardial infarction’.

Refinement of concepts should be possible but in a controlled way. This implies the need for syntax rules to avoid insensible or ambiguous concepts. For example, when the concept ‘disease’ can be refined by giving the related concept ‘aetiology’ a value without rules and restrictions, it is possible to define a new concept ‘pneumonia caused by hepatitis B virus’. When for example the relation between the concepts ‘diagnoses’ and ‘treatment’ is not made explicit, it is impossible to interpret whether the disease is treated by e.g. medication or is rather the complication of the medication.

To support both objectives of a terminological system in IC (to support communication in daily care practice, and research), the generation of concepts should be restricted by formalising rules based on explicit representation of concepts and their relationships.

Figure 1.2 The relation between PDMS, Terminological System and their users
1.6 Objectives and outline of this thesis

The objective of the study described in this thesis is to describe the design and implementation of a quality assessment program for Dutch intensive care. Design and implementation are viewed from a clinical epidemiological perspective and a medical informatics perspective. From the epidemiological perspective the following objectives can be distinguished:

1. To analyse the possibilities and limitations to set up an organizational infrastructure, including a national database intensive care, to enable quality assessment of Dutch intensive care (chapter 3).

2. To assess the performance of prognostic models to predict hospital mortality for Dutch intensive care patients, and to improve one of the prognostic models (the SAPS II) to use it in quality assessment comparison of Dutch ICUs (chapter 4).

3. To examine the additional value of refined diagnostic information to estimate hospital mortality taking APACHE II, a well-established prognostic model as an example (chapter 5).

From the medical informatics perspective our focus is on designing, applying and evaluation of instruments for describing and structuring data in terms of a terminological system in order to facilitate data collection and management. We have the following objectives:

4. To give an overview of the measure in which current PDMS configurations in Dutch ICUs satisfy the Dutch specifications for information systems in intensive care, and especially the possibilities and limitations of using these systems to extract a minimum data set for the national database intensive care (chapter 6).

5. To set up a framework for understanding terminological systems and describe our experiences with applying this framework to some well-known medical terminological systems (chapter 7 and 8).

6. To design, implement and evaluate a terminological system for intensive care diagnoses (chapter 9 and 10).
Chapter I

References
