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Quality assurance in surgery—a moral obligation

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Summary
Background Quality assurance (QA) in surgery is crucial, ensuring patient safety, improving outcomes, and maintaining the highest standards of care. Structured medical documentation is a key component in generating valid data that can be used to achieve QA goals. Unfortunately, digital systems for surgical documentation that are simultaneously clinically oriented, appropriately comprehensive, and user friendly are currently lacking.
Methods For this reason, the Department of Visceral, Transplant, and Thoracic Surgery at the Medical University of Innsbruck has established its medical documentation platform as a quality-controlled registry (qcRegistry).
Results This paper gives an overview of quality assurance measures in medicine, especially in surgery. It describes the essential requirements for the data of a registry, the tools to achieve quality-controlled data, and its implementation in routine without significantly disturbing the daily clinical routine.
Conclusion Despite complex conditions inherent to medical quality-controlled documentation, it has been shown that a quality-controlled, audit-capable registry (qcRegistry) can be successfully implemented across all aspects of surgical practice in a tertiary care surgery department.

Keywords Documentation · Registry · Outcome quality · Process quality

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Main novel aspects

- Despite the high complexity of surgical diseases and their treatment, comprehensive quality-controlled documentation that meets the criteria of randomized controlled trials (qcRegistry) is implementable at an institutional level.
- Specific attributes embed the qcRegistry into the clinical workflow, enabling validated data collection (outcome quality) in the shortest possible time and generating process quality.

Introduction

Quality assurance (QA) in surgery is a systematic approach to maintaining and improving the quality of surgical care. It includes clinical guidelines and protocols that standardize surgical procedures (standard operating procedures [SOPs]) and ensure that state-of-the-art principles are followed. QA tools can be divided into general and specific measures, the latter established at the departmental level. General measures include peer review processes, which in Austria correspond to the Austrian Inpatient Quality Indicators (A-IQI) [1], in which surgical outcomes are evaluated and discussed by third parties on an equal footing to identify improvement areas. For this purpose, preexisting data of the *Leistungsorientierten Krankenanstaltenfinanzierung* (performance-oriented hospital financing; LKF) [2], which was developed for the reimbursement of inpatient hospital costs and has been in use in several modifications since 1997, are utilized. In addition, the instruments of the Morbidity and Mortality Conferences (M&MC) and the Critical Incident Reporting System (CIRS) [3] play an essential role in QA. At M&MCs, all deaths and cases with "near misses" are discussed with all staff members [4]. In a structured process, the focus is on identifying sys-

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temic errors, which are then disseminated and thus corrected through result protocols, and, secondly, on staff education [5]. The above-mentioned continuing education of surgeons is also part of quality assurance, at least within the framework of relevant internal and external events and congresses.

However, the pursuit of quality in surgery is as old as surgery. "*Primum non nocere, secundum cavere, tertium sanare*," the moral basis of medical action enshrined in the Hippocratic Oath, is, however, attributed to Scribonius Largus at the court of Emperor Tiberius Claudius around 50 AD [6]. The beginnings of modern quality assurance measures are found in the meticulous bookkeeping introduced by Billroth, i.e., surgical documentation, including his surgical results and the relentless publication of statistics on successful and unsuccessful surgical innovations. In Zurich, he laid the foundation for "scientific surgery" and thus was later called the *Naturforscher im Kittel des Chirurgen* (naturalist in the surgeon's smock) [7]. He is considered the founder of modern quality control in surgery. Other milestones in quality assurance in surgery include the introduction of the first Morbidity and Mortality Conferences (M&MC) by Ernest Amory Codman [8, 9], one of the founding members of the American College of Surgeons (ACS) [10]. He is also considered the initiator of the so-called outcome management, which evaluates the quality of medical care based on the patient's long-term outcome. He thus laid the groundwork for registries. Finally, Avedis Donabedian introduced the established concepts of structure, process, and outcome quality [11]. Quality controlled surgical documentation is now understood to be the adequate, comprehensible recording and transparent data maintenance of information during an inpatient stay, particularly concerning surgical procedures. It includes patient master data, surgical techniques, pre- and postoperative care, complications, and adverse events.

Methods

A review of the recent literature on the topic using PUBMED and the Internet was conducted. Statistics have not been applied.

Results

Quality assurance as a corporate culture and a prerequisite for translational research

Today, quality assurance should be indispensable as part of the corporate culture of a clinical department [12]. There is almost a moral obligation to generate quality-controlled clinical data, considering that therapies and treatment recommendations are derived from translational research. As a result, data transparency plays an essential role. The ability to validate and possibly correct clinical documentation through regular checks in the clinical process (monitoring) is an integral part of quality assurance and quality management since the results can be acted upon. Regular audits of surgical documentation, surgical processes, and, for example, infection or pain control measures would help to identify and correct deficiencies. In addition to this clinical aspect, QA includes patient safety initiatives, such as surgical checklists [13] and handovers, to prevent errors and increase patient safety [14]. Furthermore, third parties (auditing) should be allowed to verify the data based on the original documents, such as the physician's letters and operating room reports.

However, monitoring and especially auditing clinical data in a medically oriented documentation system is hardly established in any institution. Lack of data transparency is one of the primary sources of scientific fraud [15]. Analyses show that 72% of researchers know someone in their immediate professional environment who has manipulated data on a small or large scale [16]. It is a fact that data in translational and clinical research are predominantly opaque. Verifiable and transparent data must replace the "mere" trust in presenters and authors regarding data quality. Top journals have already responded by increasingly requiring original data sources for publication [17]. Internal departmental and supraregional registries in health services research, including those run by the state, often show considerable quality deficits [18]. This is not least because too little importance is attached to clean and controlled data documentation, which is a medical task. It has been shown that only 80% of adverse events are documented by physicians [19]. Furthermore, the Swedish Rectal Registry published deficiencies in crucial parameters, such as the rate of anastomotic dehiscence, because the collection and documentation were delegated to non-physician personnel [20]. The establishment and maintenance of multi-institutional registers is exceptionally complex [18]. Therefore, there are several calls for registries to include quality assurance measures similar to those established in clinical controlled trials, including monitoring and auditing. These registries are called quality-controlled registries (qcRegistries), and statistical methods—including randomization—can be used to obtain results from them (registry-embedded clinical trials) that are equivalent to and should be considered additive to controlled randomized trials (CRT). Statistical methods include propensity score analysis, paired analysis, trials within cohorts (TwiCs) designs (rCRT), and batch randomization [21]. These can remove biases inherent to CRT, such as the age of the patients enrolled.

Quality assessment

Quality in medicine is fundamentally challenging to measure. For this reason, it has become common

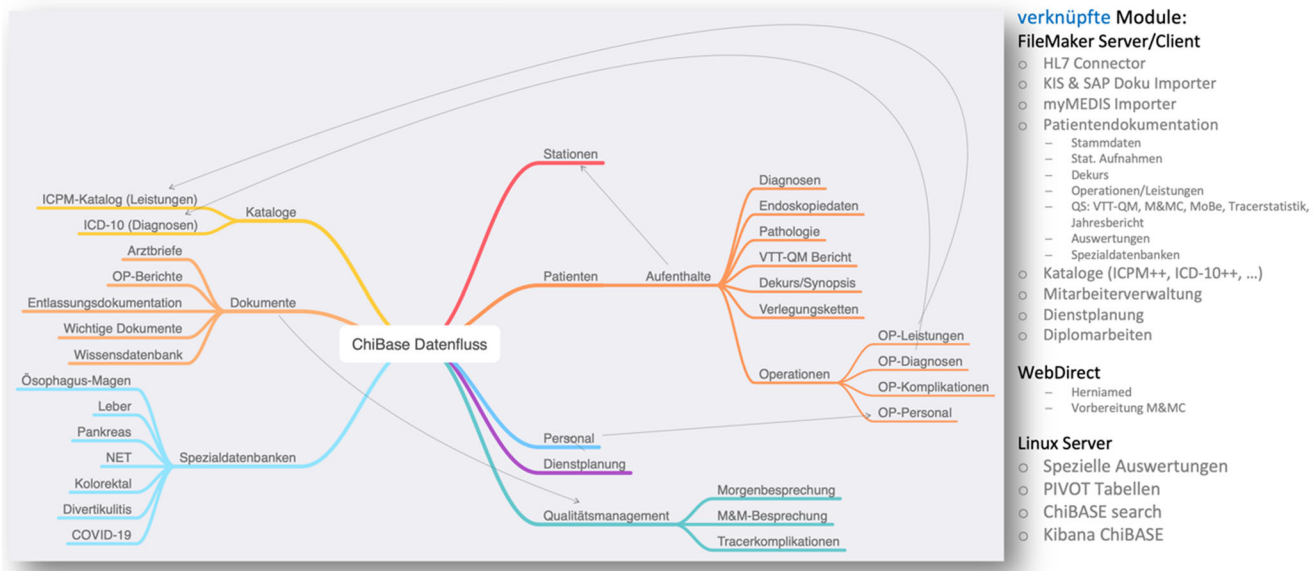

Fig. 1 Data stream and modules in ChiBASE, courtesy of B. Schulz, Salzburg

practice to measure quality in medicine using surrogate parameters. Ideally, these quality indicators (QIs) should be multifactorial (composite QI). Depending on their characteristics, they provide a graded distinction between excellent and poor quality. The requirements for QIs, the so-called QUALIFY criteria [22], include relevance, scientificity, and practicability. According to the medical field, quality indicators are defined by professional societies, for example, by the *Studien, Dokumentations- und Qualitätszentrum* (StuDoQ) [23] of the German Society for General and Visceral Surgery (DGAV) for the Rectal Cancer Registry, or by expert committees, or by departments themselves. Established QI examples are failure to rescue, textbook outcome, postoperative in-hospital, 30-day, and 90-day mortality, and other preferable composite QIs. The analysis of QI based on quality-assured documentation forms the framework for assessing the quality of services provided. For example, it can be clarified whether a goal was achieved, partially met, or missed, or a comparison with other hospitals can be made. In the case of registries, this comparison is made anonymously concerning all participating hospitals. This comparison is different from benchmarking in the narrower sense. The basic principle does not compare with the average of achievable results but with the best postoperative results that can be achieved under multifactorial, real-life conditions. The difficulty lies in identifying the "frontrunner(s)," the "leader in the class," in determining generally valid parameters [24, 25], and in the quality of accessible databases of selected cooperating hospitals, which do not always have quality-controlled data that can be audited. In principle, however, this would be an interesting aspect in the field of quality management in that benchmarking promotes the intrinsic striving, the imperative must of surgeons, for perfection, rather than assessing the performance of the center or the surgeons [26–28].

From a vision to ChiBASE

From what has been described so far, it is clear that valid and thus controlled and transparent data, which third parties can verify, is a central, obligatory factor in all quality management areas. These so-called quality-controlled registries (qcRegistries), whether set up at a departmental, supra-regional, or international level, do not exist in the quality described. Regarding the vision of a registry-embedded clinical trial, it is undisputed that surgical documentation can increase knowledge to better treat patients. The strategy is, therefore, to develop a comprehensive, department-wide, quality-controlled registry for medical documentation. This strategy was realized in Innsbruck with the proprietary documentation system ChiBASE, which provides quality-controlled data over several levels in clinical routine, which can be verified from within the program by third parties using unalterable original documents. ChiBASE was developed because there is currently no alternative to approach the vision of a registry-embedded clinical trial [29, 30]. Previous systems for clinical documentation were almost exclusively derived from other industries and were only modified for medicine, with the main focus on economic aspects. Mainly due to the documentation of surgical services using the LKF coding in Austria, these systems are unusable for the goals of quality-controlled surgical documentation. Many surgical services do not have a unique code. Another inherent problem is the complexity of surgical conditions, which makes it challenging to develop commercially available systems suitable for surgical documentation. The development effort is disproportionate to the size

Jargon	ICPM++	ICPM	MEL	working group	wound classification	training procedure	Austria account
Narbenkorrektur	5-894.1	5-894.1	QZ030	General Surg	1	Yes (GA)	1
Nicoladoni	5-898.9a	5-898.9	QZ620	General Surg	3	Yes (GA)	1
Nagelextraktion	5-898.5a	5-898.5	QZ630	General Surg	3	Yes (GA)	1
Organentnahme nur Leber	5-920.0a	5-503.0	XY999	Transplant	1	Yes (Tx module)	8
Organentnahme nur Pankreas	5-920.1a	5-525.4	XY999	Transplant	1	Yes (Tx module)	8
Hepatektomie im Rahmen einer Multiorganentnahme	5-920.y6	5-920	XY999	Transplant	1	Yes (Tx module)	8

Fig. 2 So-called jargon catalog of procedures (ICPM++ codes). *ICPM* International Codes of Procedures in Medizine, *MEL* Medizinische Einzelleistung, *SURG* suergery

of the market. In addition, ChiBASE delivers not only quality of results but also quality of processes, in that the program accompanies the daily clinical routine so that the processes are mapped and checked for completeness and plausibility. The result of 30 years of development is a modular system. In addition to the possibilities of quality-controlled recording of procedures, postoperative morbidity, adverse events, and the history of the clinical course, a tool for personnel development and deployment, a recording of teaching and publication performance, a reporting of critical data and key point indicators (KPI), a knowledge database, a content database for standard operating procedures (SOP), a blog, handovers for services, and much more are available (Fig. 1). As the modules interlock like gears, they open up unprecedented dimensions of interrelationships. Basically, a medical documentation system requires six dimensions of data quality: completeness, accuracy, consistency, validity, uniqueness, and integrity [31]. All problems related to these parameters in uniform coding and assignment have been solved in ChiBASE. Completeness is ensured by the establishment of a "minimal dataset" and by the introduction of closure routines. Unambiguity is ensured by integrating jargon catalogs relating to surgical services (ICPM++) and diagnoses (ICD-10++). The surgical procedures have been modified in wording according to the International Codes of Procedures in Medicine (ICPM) [32] (one "plus" stands for this, and the second "plus" stands for additional procedures that do not appear in the ICPM). The same applies to diagnoses, where complications had to be mapped more precisely in the ICD-10++ catalog. Currently, the ICPM++ comprises 1056 procedures and the ICD-10++ 15,144 diagnoses. Another problem was the specific automatic assignment of postoperative morbidity to operations or procedures. Understandably, with more than 100,000 operations at present, this cannot be done manually. The solution is to define a leading operation and its procedures when checking an operation with several operations during an inpatient stay, and to define the leading procedure for an operation within several procedures. Thanks to the special user-friendly tools included in the program, this can be done in a few seconds and does not interfere with the checking process in any way. The modified terminology catalogs (ICD-10++ and ICPM++) ensure uniqueness, which can be considered a table, where the first column contains the terminology text with numerous synonyms, followed by several other expressions. The international code, the wound class according to Cruse [33], the affiliation of the service to the Surgical Training Certificate, the responsible working group, and so on (see Fig. 2), are such additional characteristics. This makes it possible, for example, to stratify wound infection rates according to wound classification or to provide trainees with an up-to-date overview of their training status.

Discussion

The primary goal of quality assurance in surgery is to enhance patient safety, optimize surgical outcomes, promote continuous improvement in surgical care delivery, and provide sufficient clinical data for translational research. Despite complex conditions inherent to medical quality-controlled documentation, it has been shown that a quality-controlled, audit-capable registry (qcRegistry) can be successfully implemented across all aspects of surgical practice in a tertiary care surgery department. Specific attributes embed the digital documentation program into the clinical workflow and enable validated data acquisition in the shortest possible time without disrupting everyday clinical practice. Outcome parameters are used in various ways, and the close link to clinical routine generates process quality, too, and has become an integral part of everyday clinical practice. Future publications will consider this quality-controlled data in clinical and translational research. In addition, studies on the effects of quality control on the actual registry data are expected.

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Conflict of interest D. Öfner declares that he has no competing interests.

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