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Improving Quality Through Clinical Registries in Urology

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Abstract

Purpose of review—In this review, we highlight the use of clinical registries for quality improvement and research purposes in urology. We focus on national and regional clinical database registries, such as the the National Surgical Quality Improvement Program (NSQIP), the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE), the Michigan Urological Surgery Improvement Initiative (MUSIC), and the American Urological Association Quality Registry (AQUA) program.

Recent Findings—It is widely known that claims-based and institutional databases are limited in their capacity to provide granular, real-time data for quality improvement purposes. As a result, clinical registries have emerged as an attractive alternative given their ability to capture large amounts of data across networks of health records. Another added benefit of Federally Qualified Clinical Data Registries (QCDRs) is the ability to meet emerging Medicare quality reporting standards, such as Physician Quality Reporting System (PQRS) and Meaningful Use (MU). Despite the enthusiasm for QCDRs in the field of urology, however, myriad challenges remain in their implementation and widespread adoption including integration of existing health-information technology infrastructure, the accurate measurement of quality measures, and the availability of clinically relevant quality measures in sub-specialty practices.

Summary—Quality measurement and improvement have become important aspects of modern clinical practice. Advances in health information technology have ushered in new tools, such as clinical registries, that simultaneously improve the quality of scientific research and clinical care while assisting eligible professionals in meeting federally mandated reporting requirements.

Keywords

Clinical registries; quality improvement; quality collaborative

Introduction

Effective quality measurement and improvement in urology are not possible without reliable and meaningful clinical data. Up until recently, administrative databases were the workhorses for quality improvement research and reporting. Yet, claims-based data were never intended for this purpose. Limitations of claims-based data for QM/QI include

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questions of coding accuracy, lack of clinically relevant covariates for adjustment, lack of granular outcome measures, and lack of patient-reported outcomes. Furthermore, a substantial body of literature suggests that administrative data is actually quite inaccurate when it comes to outcomes reporting.[1–4] The utility of claims data may be limited to measuring compliance with process measures in situations in which the at-risk population can be defined through claims data. In response to these limitations, clinical registries have been established to accurately record valuable clinical data for quality improvement and reporting purposes.[5*] These databases include process and outcomes measures such as unplanned readmissions after surgery, infection rates after procedures, and antibiotic compliance. While the primary goal has always been quality improvement through performance benchmarking and feedback, qualified databases may also provide a seamless mechanism whereby eligible professionals can meet Medicare reporting requirements, thereby avoiding downward payment adjustments under the newly legislated Merit-Based Incentive Payment System.[6]

The purpose of this narrative review is to summarize the details of the existing clinical registries in urology within the context of three specific objectives: (1) to identify regional and national clinical registries and outline their structure; (2) to individually describe how these registries have been used for quality measurement and improvement with recent examples, where possible, from the published literature; and (3) to highlight limitations of these registries.

Clinical Registries in Urology

While there are numerous high-quality multi-institutional prospective clinical databases in Urology, there are primarily four clinical registries that are specifically designed for quality improvement and public reporting purposes: the National Surgical Quality Improvement Program (NSQIP), the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE), the Michigan Urological Surgery Improvement Initiative (MUSIC), and the American Urological Association Quality Registry (AQUA) program. Table 1 describes the structural characteristics of each registry including inception date, data points captured, stated mission, and whether the registry is federally qualified for PQRS and MU reporting.

National Surgical Quality Improvement Program (NSQIP)

The largest and best-known program for assessing and reporting surgical outcomes in the U.S. is NSQIP – a program that began in the Veteran’s Health Administration but is now run by the American College of Surgeons. Since 1994, data from NSQIP has been leveraged to study risk-adjusted postoperative outcomes which has in turn provided benchmarks intended to encourage local and regional quality improvement efforts to produce improved outcomes. [7] Advantages of NSQIP include the fact that it is a prospectively collected clinical database designed by surgeons with routine and spot audits that ensure high quality data.[8] Another advantage is that deidentified NSQIP data are also publically available for secondary data analysis. In the urologic literature, for example, these data have been used to describe complication rates after cystectomy,[9] the effect of adjusting for case mix on

mortality and length of stay after cystectomy [10], and venous thromboembolism after a wide spectrum of urological surgery.[11]

However, there are several drawbacks to NSQIP; chief among them is the relatively short duration of follow-up and the absence of some clinical variables that are of interest to urologists. For example, while 30-day stroke or heart attack complications after robotic prostatectomy are indeed important, these are relatively rare complications and are, at best, of tangential interest to urologists. Urologists are obviously far more concerned about 3- or 5-year biochemical free survival rates or incontinence rates, neither of which are available in NSQIP. Secondly, NSQIP does not report on process measures that might be of interest to urologists such as receipt of prophylactic heparin prior to major cancer surgery or antibiotic compliance prior to prostate biopsy. Nonetheless, there is collaboration between NSQIP and AUA on developing additional data points of interest to urologists, such as urine leak after lower urinary tract surgery, and the NSQIP program has been quite successful in providing comparative performance feedback to participating hospitals for the past two decades. [Smaldone R, personal communication]

Michigan Urological Surgery Improvement Collaborative (MUSIC)

MUSIC is a quintessential example of how to thoughtfully leverage outcome data into interventions that lead to improvements in patient care. MUSIC is a physician-led quality improvement collaborative comprised of a consortium of urology practices across the state of Michigan. Established in 2011, the MUSIC aims to foster regional collaboration between key stakeholders such as hospitals and surgeons, to identify variations in process and outcome measures, and to implement targeted improvement activities and evaluate their effectiveness. It funds several centralized functions related to data audit, analysis, and reporting as well as regular meetings of the participants for feedback and review. Because another article within this edition of *Current Opinions* reviews quality collaboratives in greater detail, we will limit our discussion to recent interesting findings from the collaborative and potential limitations.

A key feature of a quality collaborative, at least compared to a program like NSQIP, is the ability to provide concurrent feedback regarding performance. In a recent study of National Comprehensive Cancer Network (NCCN) guideline concordance for follow-up surveillance testing among active surveillance patients, MUSIC investigators reported wide variations in guideline compliance (10 to 68%) – a finding that the investigators then leveraged to reduce variations in these services.[12**] Other recent interesting findings from MUSIC include the variation in the use of prostate biopsy among men with limited life expectancy[13]; variation in the use of postoperative radiotherapy among high-risk men following radical prostatectomy[14]; variation in anastomotic and gastrointestinal events after radical prostatectomy[15]; and variation in the use of active surveillance for prostate cancer patients.[16] While these variations in and of themselves are indeed thought provoking, the real value of these studies, and by extension the quality collaborative, is the ability to use these findings as the basis for quality improvement interventions that result in tangible reductions in outcome variation.[17] While this innovative regional collaborative has demonstrated promising results, it's reproducibility in markets without the financial support

of the dominant insurer, the collegial interplay between community and academic urologists, and the committed time and support of clinical thought leaders is yet to be determined.

Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE)

CaPSURE was established in 1995 with the goal of reporting prostate cancer epidemiologic trends, patterns of practice, survival and quality of life outcomes. Over 40 primarily community based urologic practices participate. CaPSURE collects over 1000 clinical and patient-reported endpoints including baseline clinical data, biopsy and pathology data, staging tests, treatment results, subsequent procedures, performance status, and medications. Patients are treated according to their physicians usual practice and are followed longitudinally until time of death or withdrawal from the study. While the principal advantage of CaPSURE is that the dataset represents “real-world” practice data, it is not population-based, there is a relative underrepresentation of minority populations, and it exclusively focuses on prostate cancer.[18]

Despite these limitations, CaPSURE investigators have contributed over 200 publications to the urologic literature including recent validation of the new prognostic grade group system[19]; the effect of immediate versus delayed hormone therapy for biochemically recurrent prostate cancer[20]; the impact of age on quality of life outcomes after treatment[21]; and long-term patient reported quality of life outcomes after localized treatment for prostate cancer.[22] Not unlike MUSIC, CaPSURE has mechanisms in place for practice improvement interventions though as of late, most of the CaPSURE studies seem to focus on the estimation of treatment effects or measures of associations rather than provider and practice feedback for quality improvement purposes.

American Urological Association Quality Registry (AQUA) program

The American Urological Association Quality Registry (AQUA) program is nationwide informatics-enabled clinical registry for urologic diseases that is designed to measure and report healthcare quality indicators and patient outcomes at the organizational- and urologist-specific level. The AQUA registry extracts data directly from an electronic medical record minimizing the administrative burden on participating practices.

The clinical data points currently captured by AQUA will position AQUA to be a highly relevant tool in comparative effectiveness research. At present, AQUA is collecting prostate cancer data from various stages of clinical care including the pre-diagnostic phase, the cancer diagnosis and staging phase, treatments, follow-up tests, cancer recurrence or cure, mortality and patient-reported outcomes. A database this rich in patient-, physician-, and organizational-level outcomes will obviously facilitate the study of several endpoints of interest to health service researchers and policy analysts alike, such as treatment and outcome associations, patient safety, costs of care, and system effectiveness.

The clear benefits to the HSR community notwithstanding, the AQUA registry will also be leveraged for many other useful purposes that broadly fall under the quality improvement umbrella. Participating physicians, for example, will receive individualized feedback regarding their individual- and practice-level performance on a range of quality measures, such as incontinence rates after prostatectomy. These data will also be benchmarked against

their peers at a regional and national level, something that is not currently possible with this level of granularity. Indeed, while CaPSURE and MUSIC capture regional data, the AQUA registry covers providers from 33 states from solo practices to large integrated health care systems. Taken together, these data will be leveraged not just for quality improvement but also professional development, evidence based decision-making, and guideline improvement. While the initial focus of AQUA was on prostate cancer, the repertoire has been expanded to include benign prostatic hyperplasia, cryptorchidism, hypogonadism, and prostate biopsies among others. Eventually, AQUA will capture and report on the full spectrum of urological disease.

Aside from quality improvement, AQUA – as well as MUSIC – ostensibly serve another useful purpose: helping eligible professionals meet new Medicare reporting requirements. New regulatory and financial pressures have given rise to a complex network of reporting requirements for physicians and group practices, including the Physician Quality Reporting System (PQRS) and Meaningful Use (MU). To avoid downward payment adjustments, eligible professionals must now meet and report “generic” quality standards to Medicare – even if we feel that these standards are not clearly pertinent to everyday urologic practice. Nevertheless, in 2016, AQUA applied for, and received, Qualified Clinical Data Registry (QCDR) status allowing users to more easily submit quality measures to Medicare for reimbursement purposes. Some examples of the PQRS measures that are supported by AQUA include overuse of staging bone scan for low risk prostate cancer patients, medication reconciliation post discharge, and annual care planning for women with urinary incontinence.

Limitations to Registries—While registries solve some of the aforementioned problems with administrative data, the main limitation is cost, which limits scalability. Registries like MUSIC and NSQIP rely on paid registrars to hand abstract data – which is an expensive process. Others, like AQUA, try to automate data abstraction, but there are known limitations of the accuracy of natural language processing and other automated data abstraction methods, not to mention the cost of programming for each different electronic medical record and each different practice. While other registries such as the Urological Surgical Improvement Collaborative and the Movember Prostate Cancer Outcomes Registry are in development, for the sake of brevity we do not review them in detail in this review.

Conclusions

Clinical registries aim to overcome limitations of claims-based data by adding granularity for risk adjustment, by improving the accuracy of quality measurement, by expanding the focus of quality measurement to include valuable endpoints that are meaningful to urologists, and by establishing a framework for local interventions to address quality gaps. Federally qualified registries such MUSIC and AQUA also allow participants to avoid downward payment adjustments by satisfying PQRS and MU requirements under the newly legislated Merit-Based Incentive Payment System. Taken together, clinical registries, while relatively recent developments, are likely to play increasingly dominant roles in quality improvement and produce studies that will constitute a large share of the urologic literature given their distinction advantages over claims-based administrative data.

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Key Points

- Clinical registries aim to overcome limitations of claims-based data by adding granularity for risk adjustment, by improving the accuracy of quality measurement, by expanding the focus of quality measurement to include valuable endpoints that are meaningful to urologists, and by establishing a framework for local interventions to address quality gaps.
- Federally qualified registries such MUSIC and AQUA also allow participants to avoid downward payment adjustments by satisfying PQRS and MU requirements under the newly legislated Merit-Based Incentive Payment System.
- Merely knowing the outcomes does not necessarily provide the solution to actually improving them. This requires contextualization of these outcomes through the development of local guidelines and best practices which is only possible with strong local leadership on behalf of the key stakeholders, and of course, funding

Table 1

Clinical Registries in Urology

Registry	Inception	Data Elements	Follow-up	Scope	Public Reporting	Audit	Function	QCDR
NSQIP	1994	Postoperative complications	30-days	National	Voluntary	Yes	Development and validation of risk models for outcomes	No
CaPSURE	1995	All stages of prostate cancer diagnosis, management, and follow-up	Indefinite	Regional	NA	Yes	Expand knowledge of prostate cancer prediction, diagnostic trends, treatment patterns, outcomes, and quality of life	No
MUSIC	2011	All stages of diagnosis, management, and follow-up	Indefinite	Regional	Voluntary	Yes	Foster regional collaboration between key stakeholders such as hospitals and surgeons, to identify variations in process and outcome measures, and to implement targeted improvement activities and evaluate their effectiveness	Yes
AQUA	2014	All stages of diagnosis, management, and follow-up	Indefinite	National	Voluntary	Yes	Designed to measure and report healthcare quality indicators and patient outcomes at the organizational- and urologist-specific level	Yes