

The Clinical Research Office of the Endourological Society Audit Committee

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Abstract

The Clinical Research Office of the Endourological Society (CROES) conducts large-scale, international, multi-center clinical trials in the field of endourology. One of the major challenges that these trials pose is to ensure that data collected remotely and online within a very short time frame are valid and reliable. This editorial describes a formal process for auditing the data by the CROES Audit Committee. The audit process presented is largely based on an automatic scoring system, which takes into consideration several parameters to determine the quality of the data and of the participating institution. This process is dynamic in nature and offers live monitoring of both patient data and study centers.

Introduction

THE CLINICAL RESEARCH OFFICE of the Endourological Society (CROES)¹ is the premier Society-sponsored clinical research organization in the field of endourology. The primary objective of CROES is to implement large, multinational research studies that are designed to answer important clinical questions. The CROES Research Council is currently overseeing four active studies focused on ureteroscopic management of renal and/or ureteral calculi, management of renal masses, GreenLight™ laser prostatectomy, and narrow band imaging diagnosis of transitional-cell carcinoma of the bladder.

A CROES Audit Committee² has been established to conduct clinical data audits within the individual studies. This editorial briefly describes the functioning of the Audit Committee and the reason this process has been implemented: To ensure that data collected by CROES for any study are of high clinical standards,^{3,4} reliable, and validated within the possibilities of an audit process.

The CROES is currently collecting data from the four aforementioned studies through its own online Data Management System (DMS), with future studies currently under preparation. Data are remotely added at individual centers by different users (principal investigators or other study personnel such as fellows, residents,

medical students, or nurses). For every patient entered into each study, a set of clinical information is collected, varying in type, dimension, and volume. Below are the numbers of patients and centers involved in each study (as of July 15, 2011).

Ureteroscopy:	12,000 cases, 150 centers
Renal mass:	3500 cases, 120 centers
Narrow band imaging:	200 cases, 30 centers
GreenLight laser:	1000 cases, 30 centers

Each study has its own CROES data manager who oversees and coordinates the data collection process.

Data Quality

All studies contain data fields that are included for answering the scientific questions (study objectives). The Audit Committee recognizes that much of this information is “key data.” The collected data potentially present problems at two different levels: At the level of the single case, and at the level of the entire center/institution.

At the patient level the following issues might arise:

- No data entered
- Missing key data cases (eg, laboratory values or other fields missing)

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- Invalid key data (eg, wrong surgery dates)
- Outliers (data points largely deviating from the norm) or key data out of acceptable range

At the center level:

- Cases not entered at regular intervals (long periods between one surgery and the next—are key data being entered consecutively or selectively?)
- Unreliable (suspicious) key data (eg, very low complication rates across the set)
- Key data systematically missing or not available (ie, laboratory values or pathology reports)
- Low number of cases entered in the DMS
- Poor communication from centers with the data managers

Each of these issues raises questions on the validity of the data collected and increases the need for an immediate and resolute action aimed at:

At the patient level:

- Identifying data or set of data that are potentially invalid or do not conform to industry standards
- Checking data that are deemed as suspicious
- Amending, deleting, or approving and finally locking data that have been audited

At the center level:

- Identifying centers that have a poor record for quality of data
- Reviewing, approving, or excluding from the study centers that provide low quality data

Quality Score

The goal of the Audit Committee is that the assessments will result in a Quality Score (QS) for each center. The QS is a combination of two scores: One score assigned to each patient (Qp) and a score assigned to each center (Qc).

The Qp is calculated to identify cases with many missing data points or information that is not available (NA). The score is based on the calculation of the proportion of missing key data or NA key data over the total number of fields required.

The Qc is based on the calculation of a series of quality indicators: Total number of patients included by the center, rate of inclusion (how frequently patients are added to the database), missing or not available data over the total of patients included, and number of key data deemed as outliers. Each of these parameters can be weighted according to the Audit Committee's recommendations. This QS will be dynamic in nature: As the center increases the number of patients, the score will go up, signaling an improvement in the quality of data. The score can also go down; for instance, after a long period of inactivity, or if many key data are missing or contain outliers. This scoring procedure is, therefore, not just a final tool used by the Audit Committee to select centers for an audit, but also and most importantly, it is a monitoring tool that helps each center involved in the CROES activities to receive regular feedback on the quality of the data they provide, with the aim of keeping the highest possible standards.

Audit Process

The results are reviewed by the Audit Committee that determines which centers will be audited (for example, all centers with a Qp or Qc below a certain threshold).

Data auditing can be a complex and laborious process that requires collaboration from all parties involved and the necessary resources to conduct a large scale review of the information available. The CROES Office has developed in-house capabilities of validating key data and identifying centers with questionable quality.

The Audit Committee has begun to audit the data collected on the four currently active studies based on the QS, as well as selecting centers at random to undergo the audit process.

The formal CROES Audit consists of two phases:

- Phase 1. Generation of queries to be answered by the Center.
- Phase 2. Centers that do not answer the queries correctly will be required to submit source data that are then compared with the information entered in the CROES online DMS.

The Audit Committee realizes that all data cannot be audited at all centers. It will be possible for each center selected for an audit, however, to supply original data (eg, blood work, operative reports, pathology reports, etc) electronically to the data managers. Yet, some challenges will need to be addressed, such as documents that might need to be translated from their original language into English.

Based on the results of the random audit and the audit of the centers with low QS, the Audit Committee will make recommendations to the CROES Steering Committee about excluding data from certain centers that are considered unreliable. Such a process will ensure that data contained in the final database for each study provide the best possible information available for such a complex undertaking. This process will be dynamic, allowing the committee to lower or raise the criteria for auditing at any given time, based on online information.

Conclusions

The Audit Committee will be providing the CROES Council and the Endourological Society membership with routine updates of the audit process. Our goal is to validate, to the best of our ability, the quality of the studies performed by the CROES.

Respectfully submitted,

CROES Audit Committee

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Abbreviations Used

CROES = The Clinical Research Office of the
Endourological Society
DMS = Data Management System
NA = not available
QS = Quality Score
Qp = Quality Score for patient
Qc = Quality Score for Center

