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Sonja van Rees Vellinga
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info@croesoffice.org

MISSION

Through worldwide collaboration, CROES seeks to assess, using evidence based scientific methodology, the various aspects of clinical endourology.

VISION

By applying rigorous scientific evaluation to the field of clinical endourology, CROES will enable all urologic surgeons to bring to their patients the most effective and efficient care possible.

PROJECTS

- Global PCNL study
- Global URS study
- Global GreenLight Laser study
- Global Renal Mass study
- Global NBI study

CONTACT

For more information please contact Sonja van Rees Vellinga (info@croesoffice.org).



CROES GLOBAL PCNL PROJECT: COMPLETING THE PUZZLE OF QUALITY

Jean de la Rosette, Sonja van Rees Vellinga, and Stavros Gravas

In the era of evidence-based endourology, it has been universally recognized that there is still plenty of room to further improve the quality of our research. It has been underlined that the quality of our scientific work may be regarded as an audit of our clinical work and consequently reflects our scientific integrity. The initiative of the Endourological Society to establish the Clinical Research Office of the Endourological Society (CROES) is a good step in the right direction. In line with this, CROES has become the premier platform for global endourologic research.¹ As such, CROES promotes and supports international research in endourology, provides the necessary infrastructure to support and conduct high quality studies, and can serve as a platform for technologic developments in partnership with industry.

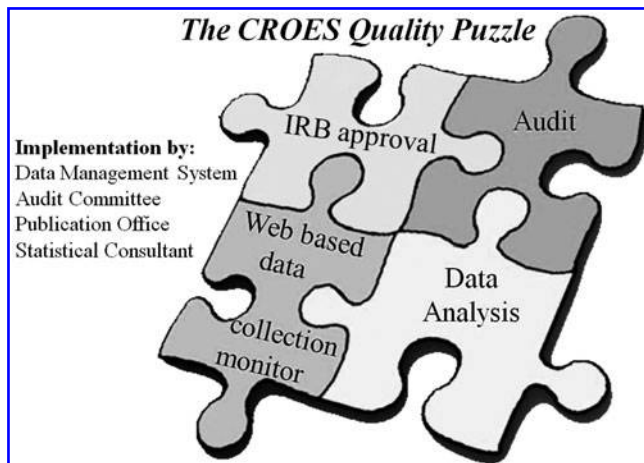
Research quality represents a puzzle that challenges our scientific and organizational skills. In a basic puzzle, one is intended to put together pieces in a logical way to come up with the desired solution. Solutions to puzzles may necessitate recognizing patterns and creating a particular order.

The Four Pieces of Quality Puzzle and the right assembly order

1. The need for Institutional Review Board (IRB) approval. All research undertaken by CROES' approved investigators is subject to the rules set forward by (inter)national healthcare authorities.² Therefore, IRB approval or a letter from the principal investigator of the study site assuring the quality and ethical standards of data collection is requested to participate in the CROES' projects. The chairman of the participating department and the primary investigator are responsible.

2. Web-based data collection and monitor. Data of the CROES clinical studies is collected centrally through of a web-based data management system (DMS). This reliable and user friendly program consists of several parts, among which is the main program, the "heart" of the system, which enables users to connect and to enter data with a single username and password for all CROES studies.³ In addition, all data entered by the users, login activity, and history files are defined in multiple data bases. Dedicated data managers are responsible for checking and securing all incoming data. The DMS contains a program that generates inclusion overview reports and a program that automatically runs queries to check for inconsistencies in the data collected. These programs enable the CROES team to constantly monitor the progress of the study and the individual centers to ensure a reliable dataset. The data managers communicate with the researchers in case of questions, inconsistencies, or missing data.

3. Audit. To validate the accuracy of all study data, the possibility of an independent audit of submitted data is implied in every CROES agreement. Self-reported data characterize the initial CROES studies; therefore, the need to monitor and validate the data by an independent source has been acknowledged. Auditing of the data can be performed either electronically (thanks to some special features of the unique web-based DMS) or on site (either randomly or based on the information



The Four Pieces of Quality Puzzle and how to solve it.

the data is performed guided by the objectives of the study. The Global PCNL Study was the first study launched and, at present, close to 25 manuscripts have been accepted for publication or are under review. Because it was a true global study, there were some inherent limitations, including the heterogeneity of centers and surgeons and local conditions that urge the need for high quality statistical support. For this reason, CROES sought advice from an established and very well recognized expert in this field who works closely with the publication office that has been established to support the preparation of manuscripts and secure the unobstructed and timely flow of data publication.

The last two CROES articles that have accepted for publication in *European Urology* represent an excellent example of the quality data provided by CROES.^{5,6} The first article explicitly investigates the relationship between case volume and outcome of PCNL for the first time.⁵ Analysis was based on the guidelines for executing reliable volume-outcome studies.⁷ The outcome of PCNL in terms of stone free, complication rates, and length of hospital stay was evaluated simultaneously while risk adjustment for known confounders of the outcomes under study was performed. Furthermore, the case volume was used as a continuous variable, which gives a clearer relationship with outcomes instead of using arbitrary cutoff volumes according to Hong and associates.⁸ It was found that centers that perform large numbers of PCNLs (>120 per year) achieve higher levels of team efficiency, leading to better efficacy and safety results.

The idea behind the second article was to evaluate the agreement of interurologist rating of PCNL complications to the Clavien score and to guide assignment of specific complications to Clavien score categories based on the large dataset of the CROES PCNL project.⁶ The regression models contained the following factors: Presence of staghorn stone, preoperative urine culture status, operative time, and the presence of nephrostomy tube postoperatively, whereas, by including the identity of the centers, the models also adjusted for systematic differences in hospital stay between the participating centers. Thanks to the high quality data, this article will be extremely helpful for urologists to standardize reports of adverse outcomes of PCNL, resulting in improvement of comparability between studies of complications and specific morbidities in PCNL.

The ultimate goal of the Global PCNL project is to further improve our daily practice, implementing what we have learned from our own real-life work. Moreover, the findings will help us to understand the limitations of our surgical tools and work in close collaboration with our partners from industry to further improve them. Consequently, we will be able to provide the absolute best, least invasive, quality of care for all our patients.

References

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provided). The CROES council has discussed this issue with the Executive Council of the Endourological Society, and it was decided to install the Audit Committee comprised of six international members of high standing under the chairmanship of Dr. Glenn Preminger.⁴ The tasks of the committee include the preparation of audit guidelines, supervision of the audits, and reports on the audit outcome to the CROES council, the steering committees of each study, and consequently to all participants.

4. Data analysis. The three previous pieces of the Quality Puzzle have been presented extensively in the past.^{2–4} Data analysis is the last necessary piece to produce the complete picture of quality. Once the database is locked and the validity of the data confirmed, the analysis of

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- The Global PCNL observational study was closed in December 2009.
- The Global Ureteroscopy study and the Global Renal Mass Study were closed for initiating new sites in January 2011. The Global GreenLight Laser study was closed for initiating new sites in April 2011.
- Ongoing project: Trandomized study on Narrow Band Imaging *vs* White Light Imaging.
- For further information please visit: www.croesoffice.org or contact the Executive Director of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).