CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGICAL SOCIETY

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Editorial

A Platform for Global Endourological Research

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The Endourological Society is one of the major urological societies and was established to facilitate scientific dialogue among endourologists worldwide. The society especially supports the global diffusion of knowledge and skills in the broad field of endourology: engineering in urology, urologic endoscopy (i.e. percutaneous, ureteroscopic, and laparoscopic), urologic robotic surgery, emerging uro-technologies, noninvasive image guided therapies (e.g. shock wave lithotripsy and HIFU) and urologic diagnostic imaging. Within this framework, it is of great importance to advance further in these fields and to implement the highest level of basic and clinical research inside the Endourological Society. It is therefore logical to establish a Clinical Research Office of the Endourological Society (CROES) that is responsible for organizing, structuring and facilitating a global network for endourological research.

CROES was founded during the World Congress of Endourology meeting in 2008 in Shanghai and thus has been operational for almost one year. It is at this very point in time that I want to take the opportunity to share with you some considerations about the significance of the endourological network and its global potential. For this I want to present the objectives set by this office and address them critically one by one.

Promote and Support International Research in Endourology

With the introduction of an increasing number of innovative surgical techniques and devices over the past 30 years, the urological community has witnessed the blossoming of endourology. Indeed, endourology and its related fields have now evolved into the main body of urological surgery. Parallel to these developments, a certain flow of urological research has similarly developed. However, general clinical research today faces many limitations. In this regard, Swanson et al surveyed a large group of urologists to ascertain their attitudes about clinical research, with a goal of gaining insights into how to increase patient enrollment in prostate cancer clinical trials. This survey explored perceptions of the organizational and environmental context in which trials are conducted.[1] The respondents indicated that clinical trials build scientific knowledge, are beneficial to their patients, and keep them better informed regarding the value of current practices, thereby benefitting their practice.

However, despite these favorable views, clinical research remains hampered by significant limitations. Randomized controlled trials (RCT) are considered the reference standard for evaluating therapy alternatives and establishing standards of care in diagnostics and treatment. However, the rate of accrual to RCT often remains low[2] and frequently does not reflect real life practice.[3] In contrast, high quality clinical databases offer an alternative approach, with the potential to bring research closer to daily practice while providing for wide ownership and high generalizability through the participation of

many clinicians, relatively low costs per study, the ability to generate large samples rapidly, the opportunity to collect a significant sample of a rare condition or nonstandard intervention and the provision of accurate information for clinical practice, audit, and administration.

As proof of concept, the initial CROES study on percutaneous stone removal (PCNL) was highly instructional. In this study more than 100 sites from Asia, Europe and the Americas participated; in one year these sites entered almost 5000 patients. Data from this study are currently being mined to answer multiple questions with regard to PCNL. These questions cover the entire spectrum of clinical research from learning curves to efficacy of different treatment modalities.

Since the initiation of CROES, four other projects have been defined and are now in their initiation phases. These studies include: an observational study on KTP laser for treating benign prostatic hyperplasia, renal mass treatment, ureteroscopy for urinary stones and narrow band imaging in the diagnosis and treatment of bladder cancer.

Creation of a Global Network

In the next decade there will be many challenges and threats to health care. What can international organizations do to meet these challenges successfully and overcome the potential threats? In view of the challenges that affect health care directly and indirectly, priorities and choices must be made. By drawing on the expertise, experience, and catalytic potential of researchers, the urological community can fully capitalize the diverse intellectual resources to make lasting contributions to global health. We believe that CROES can provide a platform for such an international endourological network, thereby enabling a critical analysis of current patterns of practice and providing data upon which decisions can be made for the fiscally responsible, future delivery of effective health care.

The cornerstone for the creation of this global network is the already established fellowship training sites.

From our initial work with PCNL, we learned that most participating investigators had been exposed to clinical research by their prior or current academic mentors and had been encouraged to enroll patients into the trial. Accordingly, the rich history of the society's fellowship programs and the mentors of these programs, along with other participating members of the Endourological Society, create a powerful collaborative global network that can perform large scale clinical studies in the field of endourology.

Infrastructure to Support and Conduct Studies

All research undertaken by CROES' approved investigators is subject to the rules set forward by (inter)national health care authorities. These rules mandate institutional review board (IRB) approval of any research with human subjects. Though both 'research' and 'human subjects' might seem self-explanatory, they are defined in a relatively specific manner. Research is defined as 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge'. Under federal rules in the United States, human subjects are defined as 'living individuals about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.'

Most importantly, though, this process is intended to advance scientific knowledge while ensuring the privacy patients deserve.[4]

The benefits of developing high quality clinical databases have long been recognized; however, until recently, little progress has been made. While lack of progress has partly been the consequence of lack of interest on the part of the clinicians, managers, and researchers, it has also reflected the demanding requirements of creating a high quality database. Such a database must include individual data on all consecutive cases, use standard definitions of conditions and outcomes, ensure data are complete and accurate, and include data on all known patient characteristics that might affect outcome.

CROES fully endorses these recommendations and aims to conduct all studies according to the highest standards of ethics and quality. The structure of CROES facilitates the key conditions necessary to obtain clinical studies with reliability and of scientific credibility due to the development of large patient databases by CROES researchers.

Initial concerns about a global research effort through the Endourological Society included burdensome paperwork, complicated trials that could be overly difficult to implement, and practical as well as logistical difficulties. We believe we have been able to overcome these difficulties by capitalizing on a paperless, centralized web-based data collection system. This should greatly facilitate entry of patient data at each CROES site.

Platform for Technological Development in Partnership with Industry

Globalization has many faces. In a recent article by Glickman et al it is argued that globalization is increasingly acknowledged as a force that is changing many aspects of life.[5] As health care organizations expand and move into global markets, they face many challenges. It comes as no surprise that pharmaceutical and device companies have embraced globalization as a core component of their business models, especially in the realm of clinical research. This phenomenon raises important questions about the economics and ethics of clinical research and the translation of trial results to clinical practice. It is at this crossroad that founding CROES was a logical consequence. Since the Endourological Society is the leading organ embracing new technologies it is obvious that our goals can be best achieved in close collaboration and in partnership with industry.

We underscore the conclusion made by Glickman et al that long-term solutions to problems arising from the globalization of clinical research will require input from stakeholders in academia, industry, and regulatory agencies around the world. Consequently, we must ensure the ethical and scientific integrity of clinical research globally, promote harmonization of international research, and provide information about the benefits and risks of new drugs and devices among populations and environments worldwide. With your contribution, CROES will be able to help each of us reach the ultimate goal of our professional career: to provide the absolute best, least invasive, quality of care for all patients. The time is now – with CROES, the ability is yours.

References

1. Swanson GP, Carpenter WR, Thompson IM, Crawford ED. Urologists' attitudes regarding cancer clinical research. Urology 2007;70:19–24.
2. Sateren WB, Trimble EL, Abrams J, Brawley O, Breen N, Ford L, McCabe M, Kaplan R, Smith M, Ungerleider R, Christian MC: How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. J Clin Oncol 2002;20:2109–2117.
3. Black N. Why we need observational studies to evaluate the effectiveness of health care. BMJ 1996;312:1215–1218.
4. World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research involving human subjects. Available from: www.wma.net/e/policy/b3.htm
5. Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, Schulman KA. Ethical and Scientific Implications of the Globalization of Clinical Research. NEJM 2009;360:816–823.