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EDITORIAL

Registering a clinical trial

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The results of clinical trials are a basic source of information used in clinical practice, in the development of clinical guidelines and evidence-based patient information, in systematic reviews and health technology assessments, in the work of institutional review boards, and within medical education [1]. The research community relies on the unrestricted flow of data from these trials, but some remain unpublished and hidden, particularly if they do not serve the interests of the sponsors or the authors, leading to selective publication.

Since 2004, there has been a push from governments and international organizations including the International Committee of Medical Journal Editors (ICMJE) [2] and the World Health Organization (WHO) to make clinical trial information more widely available and to standardize registries and processes of registering. Trial registration is currently the best strategy for countering selective publication, making it suitably transparent, and strengthening the validity and value of the scientific evidence base [1, 2] (http://www.who.int/ictrp/en/). Registration of clinical trials in a comprehensive, computerized database should reduce publication bias by improving the ability to identify trials on an intervention and decreasing the likelihood of studies being missed. The registries are supposed to provide credible and comprehensive information on medical interventions, and to ensure that a complete view of research is accessible to all those involved in healthcare decision making.

Selective publication or reporting means that not all trials are disclosed. Selective publishing in favor of a positive trial or statistically significant results, together with a reduced willingness to publish negative or inconclusive studies, may lead to imbalance in the scientific literature, overestimation of potential benefits and underestimation of the harm of a treatment [1, 3]. Systematic reviews of the literature further magnify this bias and distortion in medical literature by combining these favorable studies to obtain greater statistical power at the clinical level, and such reviews are often the source for clinical guidelines [4]. Thus, selective publication has a negative impact on patient health and may interfere in the decisions of ethics research boards and funding agencies which are based on the available data [1].

Currently, the *International Urogynecology Journal* encourages the registration of randomized and controlled clinical trials with a public clinical trials registry prior to commencing patient recruitment. The IUJ editors have decided to move the journal forward by taking another step on the road to full transparency of all relevant information about a particular trial. From now on, the IUJ will require registration of all prospective interventional clinical trials that are to be considered for publication. "Ongoing" studies for which the investigators are still collecting, cleaning or organizing data also require registration (even retrospectively) before submission to the IUJ. The IUJ will defer the application of the policy of mandatory prospective registration (registration of clinical trials with a public trials registry made at or before the time of first patient enrollment as recommended by the ICMJE) for 2 years to allow investigators, trial sponsors, and regulatory bodies time to plan for their implementation.

We believe anyone should be able to learn of any trial's existence and its important characteristics, irrespective of its outcomes, or the benefit and potential harm of the intervention under investigation.

Following the criteria of the ICMJE and WHO, the IUJ will accept registrations with any one of the registries listed below. They are accessible to the public at no charge, open to all prospective registrants, managed by a not-for-profit

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organization, have a mechanism to ensure the validity of the registration data, and are electronically searchable.

- Australian New Zealand Clinical Trials Registry (ANZCTR) (http://www.anzctr.org.au)
- Brazilian Clinical Trials Registry (ReBEC) (http://www.ensaiosclinicos.gov.br)
- Chinese Clinical Trial Registry (ChiCTR) (http://www.chictr.org.cn)
- Clinical Research Information Service (CRiS), Republic of Korea (https://cris.nih.go.kr/)
- Clinical Trials Registry - India (CTRI) (http://ctri.nic.in)
- Cuban Public Registry of Clinical Trials (RPCEC) (http://registroclinico.sld.cu)
- EU Clinical Trials Register (EU-CTR) (https://www.clinicaltrialsregister.eu/)
- German Clinical Trials Register (DRKS) (http://www.drks.de)
- Iranian Registry of Clinical Trials (IRCT) (http://www.irct.ir/)
- UMIN Clinical Trials Registry, Japan (UMIN-CTR) (http://www.umin.ac.jp/ctr)
- Thai Clinical Trials Registry (www.clinicaltrials.in.th)
- The Netherlands Trial Register (www.trialregister.nl)
- UK ISRCTN registry (http://www.isrctn.com)
- US ClinicalTrials.gov ClinicalTrials.gov
- Pan African Clinical Trial Registry (PACTR) (http://www.pactr.org/)
- Sri Lanka Clinical Trials Registry (SLCTR) (http://www.slctr.lk/)

The success of the process of registration depends on the combined efforts of ethics committees, funding bodies and journal editors, but investigators are primarily responsible for allowing public access to their results.

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