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Awareness of clinical trial registration among healthcare professionals: An observational study

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Abstract

Aim: Prospective registration in a freely accessible public platform is a key step in the ethical conduct of clinical trials. Little is known of the awareness of clinical trial registration among the scientific community. This study aimed to assess awareness of clinical trial registration among participants attending a medical congress in Sri Lanka.

Methods: Knowledge of trial registration was assessed using a self-administered questionnaire, which spanned domains such as involvement in research, and knowledge and perceptions regarding trial registration. A knowledge score was calculated and correlated with demographic variables.

Results: Of 251 survey respondents, 53.4% were male, 74.9% were below the age of 40 years, and 56.6% were currently engaged in research. Registration was considered necessary for trial publication by 73.3%, and 70.5% agreed that trials should be registered prospectively. Most achieved a knowledge score of 'Acceptable' (41%) or 'Good' (19.9%). Mid- or advanced career stages, postgraduate training, current involvement in research, and recent research publications/presentations were correlated with higher knowledge scores ($P < 0.05$). Beneficial effects considered to be associated with trial registration were access to findings of all trials (61.4%), access to negative results (47.8%), preventing trial duplication (69.3%), and preventing multiple publications (70.1%). Increasing research workload (49.8%), additional restrictions on research conduct (52.2%), and the possibility of 'intellectual theft' (56.2%) were seen as potential negative effects.

Conclusions: Most participants were aware of the need for prospective registration as a requirement for publication of clinical trials. Concerns were expressed regarding several perceived negative effects of trial registration.

KEYWORDS
awareness, biomedical research, clinical trials, registries, Sri Lanka

1 | INTRODUCTION

Prospective registration in a publicly accessible platform is considered an important step towards improving transparency in the conduct and reporting of clinical trials.[1–5] A mechanism for this has been created with the establishment of several national, regional, and disease-specific trial registries.[3,6] The World Health Organisation (WHO) has developed the International Clinical Trials Registry Platform (ICTRP), with a Registry Network of primary and partner registries, and a search portal facilitating access to trial data.[7] The need for clinical trial registration and the establishment of various trial registries have been well documented.[1–3,6,8] The number of clinical trials registered worldwide has increased sevenfold from 2004 to 2013, and it is believed that national and regional clinical trial registries and the ICTRP have made a significant contribution towards the success of the global drive for clinical trial registration.[9]

Notwithstanding the growing acceptance of the importance of prospective trial registration, many trials continue to be registered

retrospectively. Evaluation of randomly selected trial records registered with the ICTRP in 2008/2009 and in 2012/2013 has revealed that approximately half of the clinical trial registrations are retrospective.[10,11] In another study of clinical trials published in a group of medical journals in 2013, only 31% of published trials had been prospectively registered.[12] Lack of awareness regarding trial registration may be a key factor contributing to this, resulting in investigators realizing the need for trial registration only at publication stage. As many as one-third of researchers with previous experience in publishing clinical trials have cited lack of knowledge as a primary reason for failure to register trials prospectively.[13]

Little is known regarding awareness of clinical trial registration among the scientific community. The aim of the present study was to assess awareness of clinical trial registration among participants attending a medical congress in Sri Lanka. Data on awareness of clinical trial registration among the medical research community would be useful in developing strategies to improve prospective trial registration.

2 | METHODOLOGY

We conducted a survey among participants at the Annual Scientific Congress of the Sri Lanka Medical Association (SLMA) held in 2010. The SLMA is the national professional medical association in Sri Lanka, and its annual scientific congress is the main forum for the presentation of medical research in the country. An annual congress is a gathering place for researchers, academics, and practicing clinicians from all disciplines and from all parts of the country.

We distributed an anonymous self-administered questionnaire to all participants at the congress and related workshops. Several steps were taken to improve the response rate, such as the projection of slides in between presentations reminding participants to complete and hand over the questionnaire, and verbal reminders at exit points from symposia halls during tea and lunch breaks. Boxes were provided at each exit point to deposit the completed questionnaires. No incentives were given for completion.

The questionnaire was developed after several rounds of discussion among three of the authors (UKR, AdA, and LCR). It comprised two main parts: Part A recorded demographic data (seven questions, Table 1); Part B assessed knowledge (five questions, Table 2) and perceptions (three questions, Table 3) of participants regarding clinical trial registration. A scoring system was developed to quantify the knowledge of the participants. The five questions assessing knowledge consisted of a total of 30 possible responses that included both correct and incorrect responses; 11 of these which were considered unequivocally correct regarding clinical trial registration were scored. Three items addressing mandatory registration of clinical trials, and identification of international trial registries as well as the SLCTR as mechanisms available for trial registration were given a score of 2 points each; the other eight items were each assigned a score of one (Table 2). Out of a total of 14, a score of 0–6 was equated with 'Poor knowledge', 7–10 with 'Acceptable knowledge' and 11–14 with 'Good knowledge'. Scores were correlated with the demographic variables of the respondents. Data were entered into a custom designed spreadsheet and analyzed using MS Excel 2016. Our study was descriptive, and data has been summarized as numbers and percentages. Differences between groups were expressed as a P value, and the significance level was set at a P value of less than 0.05.

3 | RESULTS

Of 714 registered participants at the congress and workshops, 251 (35.2%) returned completed questionnaires. None of the questionnaires were excluded from analysis due to incomplete data. About three-fourths of the respondents (74.9%) were below the age of 40 years, 53.4% of them were male, and nearly half (49%) had less than five years of professional experience. A majority were employed in a government hospital (37.5%) or a university (39.4%). Many (56.6%) were currently engaged in research, and 42.6% had been an author or a co-author of a research paper or a scientific presentation during the last three years (Table 1).

An overwhelming majority (97.6%) considered registration of clinical research to be important. Many agreed on the need to register clinical trials evaluating drugs (67.3%), diagnostic tests and procedures (62.5%), lifestyle modification interventions (49.8%), and behavioral interventions (47.8%). However, some respondents were of the opinion that case series (30.7%), observational studies (29.5%), and clinical audits (19.9%) too should require registration. Most respondents considered that registration was a requirement for trial publication (73.3%), presentation of trial findings at scientific meetings (56.2%), and for ethics committee approval (54.6%). Over 70% agreed that trials should be registered prospectively. Nearly half (49%) were not aware of an existing mechanism for registration of clinical trials conducted in Sri Lanka, and only 31.5% had heard about a Sri Lankan trial registry (Table 2).

A large majority felt it was beneficial to have research findings freely available to other researchers (81.3%), clinicians (84.5%), and research participants (76.7%). Fewer respondents considered it important to make research findings available to the pharmaceutical industry (48.2%), patients (55.8%), or the public (56.6%). Potential beneficial effects of trial registration perceived by the participants included improving access to findings of all trials (61.4%), improving access to negative results (47.8%), preventing trial duplication (70.1%), and preventing multiple publications of the same study (69.3%). Adding to the burden of research conduct by increasing workload and placing additional restrictions, and enabling possible 'intellectual theft' of research methods and protocols were seen as potential drawbacks (Table 3).

Knowledge was rated as 'Good' in 50 responders (19.9%) and as 'Acceptable' in 103 (41%). Over one-thirds (n = 98, 39%) were noted to have 'Poor' knowledge. Correlation with demographic variables revealed higher scores among respondents in mid- or advanced career stages ($P < 0.001$), those with postgraduate training ($P < 0.001$), or current engagement in research ($P = 0.003$), and in those who had published or presented a paper within the preceding three years ($P = 0.003$) (Table 1).

TABLE 1 Participant data and summated test scores

Factors		Number	%	Summated scores		
				Poor	Acceptable	Good
Gender distribution						
	Male	134	53.4	49	59	26
	Female	115	45.8	48	43	24
	Not responded	2	0.8	1	1	0
Age distribution						
	21–30 years	104	41.4	56	39	9
	31–40 years	84	33.5	24	33	27
	41–50 years	35	13.9	11	19	5
	51–60 years	17	6.8	5	7	5
	61–70 years	8	3.2	0	4	4
	>70 years	3	1.2	2	1	0
Number of years as a doctor/professional						
	<5 (includes undergraduates)	123	49	62	49	12
	6–10	43	17.1	11	14	18
	11–20	42	16.7	12	22	8
	>20	40	15.9	10	18	12
	Not responded	3	1.2	3	0	0
Current designation						
	Consultant	33	13.1	4	15	14
	Postgraduate trainee	69	27.5	19	28	22
	Medical officer (intern, pre-intern, other)	62	24.7	36	20	6
	Scientist	11	4.4	5	5	1
	Administrator	2	0.8	1	0	1
	Family physician	13	5.2	3	8	2
	Medical/Physiotherapy undergraduate	43	17.1	19	20	43
	Other	18	7.2	11	7	0
Current place of employment						
	Government hospital	94	37.5	38	35	21
	University (includes undergraduates)	99	39.4	34	49	16
	Private hospital	13	5.2	4	4	5
	Family practice	14	5.6	5	6	3
	Other	31	12.4	17	9	5
Current involvement in research						
	Yes	142	56.6	43	64	35
	No	107	42.6	54	39	14
	Not responded	2	0.8	1	0	1
Authorship of a paper /presentation during the past three years						
	Yes	107	42.6	43	64	35
	No	142	55.8	54	39	14
	Not responded	2	1.6	1	0	1

Interestingly, participants currently involved in research were better aware of the existence of a Sri Lankan trial registry, compared to those who reported no current involvement (38.7% vs. 20.6%, P = 0.02). They were also more likely to consider that clinical trial registration would enable free access to findings of all conducted trials (69.0% vs. 52.3%, P = 0.007). Both groups, however, agreed that registration should be done before commencing a trial (74.7% vs. 64.5%, P = 0.08). There was also consensus that mandatory registration would

TABLE 2 Knowledge regarding registration of clinical research

Factor	Number	Percentage
Is registration of clinical research mandatory at present?		
Yes**	98	39
No	62	24.7
Do not know	84	33.5
Not responded	7	2.8
What type of study requires / should require registration?		
Case series	77	30.7
Observational studies	74	29.5
Audit	50	19.9
Clinical trials on drugs*	169	67.3
Trials on diagnostic tests / procedures*	157	62.5
Field trials*	101	40.2
Lifestyle modification trials*	125	49.8
Behavioral intervention trials*	120	47.8
Phase I or II drug trials*	127	50.6
Do not know	24	9.6
Why is registration of clinical research a requirement?		
For publication of research findings*	184	73.3
For the presentation of research findings	141	56.2
To obtain ethics committee approval	137	54.6
To obtain funding	88	35.1
Legal requirement	121	48.2
Do not know	21	8.4
When should registration take place?		
Before starting trial*	177	70.5
After starting the trial, but before completion	13	5.2
Before completion	10	4
After completion, but before research presentation	19	7.6
After completion, but before publication	18	7.2
Do not know	23	9.2
Mechanisms available for registering clinical research		
International Trial Registry**	47	18.7
WHO trial registry	36	14.3
Sri Lankan trial registry**	79	31.5
No mechanism available	13	5.2
Do not know	123	49

Items considered for scoring are marked with* (* = 1 mark, ** = 2 marks).

prevent duplication of trials (73.9% vs. 65.4%, P = 0.15), and multiple publications of the same trial (69.7% vs. 69.2%, P = 0.92) (Supplementary Tables S1 and S2).

4 | DISCUSSION

Knowledge regarding the need for clinical trial registration, and the mechanisms available, would greatly influence the success of the drive for prospective trial registration. Our results indicate that a large number of participants at a medical congress, including many active researchers, had inadequate knowledge on clinical trial registration.

To our knowledge, this is the first study of awareness on clinical trial registration among a group of healthcare professionals. Two studies have reported the attitudes of researchers with previous experience in a trial publication on their willingness to register trial information on a publicly available database. Reveiz et al. surveyed the corresponding authors of PubMed indexed clinical trial publications regarding their views on international guidelines on clinical trial registration.[13] In 2011, White et al. used a similar methodology to determine the views of trialists conducting interventional research in Argentina.[14] Our results showed that although most of the respondents agreed on its importance, awareness was deficient regarding the requirements for and the mechanisms available for clinical trial registration. This is in keeping with previously reported findings, where about one-thirds of the participants cited lack of knowledge as a primary reason for nonendorsement of prospective trial registration.[13] Many participants in our study had concerns regarding several perceived negative effects of trial registration such as administrative overburden and challenges from competing investigators, similar to the findings from these two studies.[13,14] The present study provides insights into the knowledge and perceptions regarding trial registration among a group of healthcare professionals in a developing country.

There are several limitations to this study. First, this was conducted among participants attending a medical congress, and our results may not reflect awareness of the Sri Lankan medical scientific community in general. However, the SLMA congress is the premier health-related scientific gathering in the country, most of the respondents had an active interest in research, and it is likely that they would have had some exposure to the concept of clinical trial registration. It is disconcerting that awareness was found to be deficient in several areas even in this group, in whom a higher level of awareness would have been expected; it is unlikely that awareness would be better among the scientific community at large. Second, the response rate to the questionnaire was poor, in spite of several methods employed to improve the yield. The poor response rate, however, may itself be a reflection of a lack of interest in the concept of clinical trial registration. It is pertinent to note that only 22% of academic researchers involved in the conduct of clinical trials responded to a previous survey on opinions regarding clinical trial registration.[15]

The SLCTR was established in 2006 and is a Primary Registry of the WHO–ICTRP Registry Network.[16,17] It has completed ten years of existence as the national clinical trials registry in Sri Lanka.[18] Over the years, it has taken several steps to inform the Sri Lankan scientific and clinical community on the need for clinical trial registration and the availability of the SLCTR as a national platform to facilitate this. These steps have included: letters to all universities, ethics committees, funding agencies, and professional organizations; circulars from the Department of Health to all healthcare institutions; presentations at annual scientific meetings of the SLMA and regional medical organizations; and articles published in the Ceylon Medical Journal (CMJ), the leading medical journal in the country that is distributed free of charge to members of the SLMA.[16,19,20] The SLMA and the CMJ insist

TABLE 3 Perceptions regarding registration of clinical research

	Yes (%)	No (%)	No response (%)
Is registration of clinical research important?	245 (97.6)	5 (2.0)	1 (0.4)
	Good (%)	Bad (%)	No response (%)
Is it good or bad to have research details available to the following?			
Other researchers	204 (81.3)	12 (4.8)	35 (13.9)
Clinicians	212 (84.5)	9 (3.6)	30 (12.0)
Patients	140 (55.8)	60 (23.9)	51 (20.3)
Research participants	170 (76.7)	36 (14.3)	45 (17.9)
The public	121 (48.2)	72 (28.7)	58 (23.1)
Possible effects of registration of clinical research			
Access to findings of all trials	154 (61.4)	59 (23.5)	38 (15.1)
Access to negative results	120 (47.8)	67 (26.7)	64 (25.5)
Intellectual theft	49 (19.5)	141 (56.2)	61 (24.3)
Prevents multiple publications of same trial	174 (69.3)	24 (9.6)	53 (21.1)
Prevents duplication of trials	176 (70.1)	21 (8.4)	54 (21.5)
Makes research more difficult by placing additional restrictions	51 (20.3)	125 (49.8)	75 (29.9)
Makes research more difficult by increasing work load	41 (16.3)	131 (52.2)	79 (31.5)

on proof of registration before considering clinical trials for presentation at academic meetings and publication. Ethics review committees in the country grant only conditional approval for clinical trials pending trial registration. In spite of these measures, nearly half of the respondents were not aware of any mechanism available for registration of clinical trials conducted in Sri Lanka, and only 30% were aware of the SLCTR's existence. This finding highlights the need for more intensive measures in improving awareness on clinical trial registration. Following the study, the SLCTR has renewed its efforts in keeping the Sri Lankan scientific community better informed, and it is hoped that current levels of awareness would be comparatively higher. National regulatory authorities and funding agencies are ideally placed to enforce prospective trial registration in Sri Lanka, and the SLCTR needs to work more closely with them and take advantage of this opportunity to ensure more comprehensive trial registration in the country.

Our findings point to a clear need to improve awareness on clinical trial registration. Admittedly, these data do not represent a cross-sectional view of the scientific community of the country at large, and findings are likely to vary among different groups of healthcare professionals. It would be interesting to compare these findings with similar studies among the healthcare community in other countries. The global landscape of clinical trials is rapidly changing with increasing participation of developing countries such as Sri Lanka,[21] and robust mechanisms are needed to ensure the safe and ethical conduct of clinical trials in these resource-limited settings. We believe improving awareness of researchers and potential researchers on clinical trial registration would facilitate the safe, ethical, and transparent conduct of clinical trials.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

Authors' contributions

All authors made substantial intellectual contributions to the paper. UR conceived the study. UR, AA, and CW planned the study. AA and MW collected and entered data. AA, MW, and LR analyzed the data. UR wrote the first draft of the manuscript. UR, AA, CW, and CG revised the manuscript. All authors read and approved the final manuscript.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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