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Facilitating Prospective Registration of Diagnostic Accuracy Studies: A STARD Initiative

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Guest:
Dr. Daniel Korevaar is from the Department of Clinical Epidemiology, Biostatistics and Bioinformatics at Academic Medical Center in Amsterdam.

Bob Barrett: This is a podcast from *Clinical Chemistry,* sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I am Bob Barrett.

Despite the altruism of millions of volunteers who have participated in clinical trials to advance medical diagnosis and treatment, and an ethical responsibility of investigators to publish the findings, results of these studies often fail to get reported. Recent evidence shows that this is a major issue among diagnostic accuracy studies. Approximately half of these studies never reached full-text publication. This raises concerns that studies with positive and optimistic findings are being published more often and more rapidly than those with disappointing results, which could lead to misplaced enthusiasm regarding the performance of tests and clinical practice.

The August 2017 issue of *Clinical Chemistry* includes a special report addressing this topic in which Dr. Daniel Korevaar and colleagues argue that all diagnostic accuracy studies should be registered so unpublished studies can be easily identified. Dr. Korevaar joins us in this podcast. He is from the Department of Clinical Epidemiology, Biostatistics and Bioinformatics at Academic Medical Center in Amsterdam.

So, Dr. Korevaar, over the past years, multiple policies have been launched that aimed to improve prospective registration of studies in clinical trial registries, such as ClinicalTrials.gov. Since 2005 for example, the International Committee of Medical Journal Editors (ICMJE) has required that all clinical trials are registered before initiation. Doesn't this also apply to diagnostic accuracy studies?

Dr. Daniel Korevaar: Well no, unfortunately not. We recently evaluated registration rates among published diagnostic accuracy studies and we found that only 15% had been registered in a trial registry such as ClinicalTrials.gov. Studies that were registered were often registered after the study has already been finished and the registered data was often very scarce

with limited information on the outcomes of primary interest, eligibility criteria for patient inclusion, and other crucial information regarding study methodology. And one reason maybe that these studies are rarely registered, maybe the fact that registration policies have had so far mainly addressed randomized trials of interventions, whereas many considered diagnostic accuracy studies to be observational studies. And we believe that there's an urgent need to start registering these studies and these diagnostic accuracy studies as well.

Bob Barrett: Why is that? Why is registration of diagnostic accuracy study so important?

Dr. Daniel Korevaar: Well, there are numerous reasons why perspective registration of trials in general is beneficial. And these reasons, I think, fully apply to diagnostic accuracy studies as well. In my opinion, the most important reason lies in the fact that we have recently shown that many completed diagnostic accuracy studies never get published. This is a problem because it represents a waste of research investments and may lead to unnecessary duplication of research, and it could also lead to bias in systematic reviews when studies with more optimistic results get published more often than those with disappointing results, and perspective registration of studies will facilitate the identification of unpublished studies and results. But there are numerous other reasons as well, why such a policy could be beneficial.

So perspective registration will allow journal editors and peer reviewers to prevent others from selectively reporting on some outcomes while leaving out other outcomes. And registration may also allow researchers to identify research gaps and to facilitate collaboration with colleagues and to facilitate participant recruitment, and full disclosure of study materials, including study protocol as more and more being seen in the scientific community as an ethical obligation towards study participants. And this is also illustrated for example by the fact that the Declaration of Helsinki now states that every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

Bob Barrett: Now currently, there are no registries available for diagnostic accuracy studies. So where should researchers register their diagnostic accuracy studies?

Dr. Daniel Korevaar: So currently, no central register exists that focuses specifically on diagnostic accuracy studies. However, in our study published in *Clinical Chemistry*, we did a survey among 16 existing trial registries that are considered as primary registries by the World Health Organization, the

WHO, because these 16 registries, they meet specific criteria for quality.

And in this survey, we asked the representatives from these registries if they accept registration of diagnostic accuracy studies. And 13 responded, of whom 8 indicated that they would always accept registration of a diagnostic accuracy study. One of these eight, for example, was ClinicalTrials.gov. And for the other five registries that responded, indicated that they would register diagnostic accuracy studies in some cases. So, researchers can register their diagnostic accuracy studies in existing trial registries. We believe that there's no need to develop a registry specifically designed for this type of study.

Bob Barrett: So, are there any guidance documents available on how researchers can register their diagnostic accuracy study in an informative way in existing trial registries?

Dr. Daniel Korevaar: Well, we've recently developed such guidance. The main problem with registering diagnostic accuracy studies in the existing primary trial registries is that such registries mainly focused on trials of therapeutic interventions. And because of this, some protocol information is requested by these registries that does not really apply to diagnostic accuracy studies, whereas some protocol information that is really specific to diagnostic accuracy studies is not requested by these registries. But we believe that registering diagnostic accuracy studies can be as straightforward as registering a randomized trial of a new drug.

So with the help of an international group of 85 experts in the field of diagnostic accuracy studies, we developed explicit instructions for registering diagnostic accuracy studies in these existing trial registries in an informative manner. And these instructions are reported in our article published in *Clinical Chemistry*.

Bob Barrett: Finally doctor, what can readers of *Clinical Chemistry* do to improve the situation?

Dr. Daniel Korevaar: We hope that researchers start registering their diagnostic accuracy studies in one of the major trial registries that are willing to host them. In our own experience, we know that the time investment of registering a study is really minimal. It generally takes less than 30 minutes which is, well, fairly limited amount of time of course, considering the large amount of time spent on a complete study. And we also hope that journals that publish large amounts of diagnostic accuracy studies such as *Clinical Chemistry* will strongly start encouraging researchers and others to register their study before study initiation.

Bob Barrett: Dr. Daniel Korevaar is from the Department of Clinical Epidemiology, Biostatistics and Bioinformatics at Academic Medical Center in Amsterdam in the Netherlands. He has been our guest in this podcast from *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.