# Prof. Frederick Masoudi: challenges and opportunities in conducting research with observational data

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*Frederick Masoudi (Figure 1), MD, is the Professor of Medicine in the Division of Cardiology, University of Colorado with 260 publications in PubMed. His research interests focuses on practice patterns and health outcomes in older patient populations with heart failure and acute coronary syndromes. At the Chinese Heart Congress 2014 he gave us the speech on "Conducting research with observational data: challenges and opportunities". Annals of Translational Medicine (ATM) is honored to invite Prof. Masoudi for an interview to share his perspective on the observational data used in research and the role of the US National Cardiovascular Data Registries (NCDR) in this regard.*

**Figure 1** Professor Frederick Masoudi.

***ATM: What's the take-home message from your speech on "Conducting research with observational data: challenges and opportunities"?***

**Prof. Masoudi:** There are two things that I would like to emphasize. One is that observational Data plays a very important role in medical research as complement to other types of studies such as randomized controlled trials. It is important, though, that when we study and publish observational data, we are appropriately cautious about what the findings mean and consider important limitations about observational data, including potential confounding and bias. Further, in publishing observational data, authors should be careful about the language used to convey the results. Observational studies cannot prove causality, and we must be open about the limitations as well as the strengths of the studies that we performed with the observational data.

***ATM: Great effort has been made in Evidence-based research. As an expert in this field, what do you think is the role of evidence-based research and how to define the evidence?***

**Prof. Masoudi:** Well, the evidence is comprised of a broad range of studies. In some cases, it might just be a case series; in some cases, it may be a retrospective cohort study; in other cases, it may be a randomized trial. The evidence is multi-factorial and made up of a variety of different studies, not all randomized. It is important for us to recognize the strengths and limitations of different types of studies and understand that randomized trials are appropriately considered the gold standard to establish causal relationships between therapies and outcomes. But on the other hand, they don't tell us the entire story because they don't address treatment in patients that may not be eligible for conclusions in randomized trials. They often don't address issues of safety and they are not necessarily well suited to study all issues. There are places where the randomized trials are going to provide the best and clearest answers; there are other places where such studies are not practical or possible. So we have to have a broad view of what constitutes the evidence on the one hand, but also we have to be able to understand the key limitations of the various types of evidence that we are evaluating be it the randomized trial with its strengths and limitations or observational data, which also has their own strengths and limitations.

***ATM: We understand you are the senior medial officer***

***of National Cardiovascular Data Registry (NCDR), would you like to give a brief introduction for the NCDR programs?***

**Prof. Masoudi:** The NCDR is an important source of data on patients undergoing specific cardiovascular procedures or with specific cardiovascular conditions in the US. There are several different registry programs, including for example, coronary angiography and percutaneous coronary intervention (PCI), implantable cardioverter defibrillators, congenital heart disease, transcatheter aortic valve replacement, peripheral vascular interventions, acute myocardial infarction, and outpatient cardiovascular disease. Because of the broad reach of many of these registries, they serve as important sources of observational data for studies reflecting the care and outcomes of cardiovascular patients in the United States. They provide insights into treatment outcomes just not available from randomized trials. They provide important perspective on the level of the appropriate application of data from trials in real practice. They provide the basis of conducting observational comparative effective studies or temporal trends in care and outcomes. They do so in a population of patients receiving treatment in the real world. Some of the registry programs actually capture most patients that getting a particular treatment in the US so the data are potentially representative of clinical practice in the US.

***ATM: Where do you think is the trend of future research is leading? Will randomized controlled trial (RCT) or retrospective research predominate in the research arena?***

**Prof. Masoudi:** There are many opportunities as well as many challenges we are facing. One of the opportunities is the availability of big electronic data repositories that one may get through electronic health records (EHR). EHRs provide the opportunity to collect data from large numbers of patients of characteristic health problems above ages across the country. On the other hand, as I point out in my talk, the fact that we have more and more data doesn't means the concerns about the weakness of observational design go away. Those concerns persist. We always need to be careful, to consider the possibility of bias and confounding even in big data sets. The opportunity is that we will have more and more data available to us. We will be able to generalize insights more quickly on bigger populations of patients. But at the same time, we cannot be fooled to believe that these big datasets eliminate the concerns about the weaknesses of observational designs. Further, many available sources of "big data" do not include standardized data elements, which can limit their utility for research purposes. Without standard definitions, any source of data will be difficult to use, no matter how big.

***ATM: You are also dedicated to improving care in community settings. Would you like to share with us how do you launch the work of medical care with the registries?***

**Prof. Masoudi:** The NCDR is a very good example of this. The NCDR collects data in its heart-attack registry and CathPCI registry around the tissue timely reperfusion. And as a result of that there was a national effort led by Dr. Harlan Krumholz from Yale that focused on improving the timeliness of PCI in the US. The registry data identified a national gap in this process of care. Applying strategies from centers that performed best, a national program called D2B was implemented to improve door-to-balloon times for primary PCI. Now in the US, more than 90% of patients with ST segment elevation myocardial infarction (STEMI) who receive primary PCI are treated in a timely manner. That's a good example of how registry data that measure quality care can be used as a platform and the foundation for a national effort to improve the quality of care.

***ATM: Speaking of data collection, how does NCDR work in different cities?***

**Prof. Masoudi:** For example, in the Implantable Cardioverter Defibrillator (ICD) registry, almost every hospital in the USA that implants defibrillators uses the registry. For the CathPCI registry, about 80% of hospitals that care for 90% of patients that get percutaneous coronary interventions are included in the registry. So in those two cases, the registry is used in almost all US hospitals that perform these procedures. The other types of registry are somewhat more limited in terms of number of hospitals that participate, but at the same time, they are diverse in terms of location, size, and so on.

***ATM: After collecting all the data, who has the access to the data?***

**Prof. Masoudi:** The NCDR data are governed by the American College of Cardiology and its professional society partners, and analysis is performed analytic centers that work with NCDR. Although the data themselves are not

 

given to investigators, they can apply to do research using the registry. Their applications will be assessed in terms of feasibility, importance, and scientific rigor. Anyone submits a research or publication request, and if the application is approved as part of this process the data will be analyzed by the academic data analytic centers that work with NCDR.

This is an increasingly competitive process because of the potential strength of NCDR to answer important questions, and only a certain number of analysis can be done. It is critical that the research question is important, and that it has not already been addressed previously in the NCDR. It is important to understand very well what's data are in the registry and to understand the definitions, because this will determine the questions that can be answered and those that cannot. As I discussed in my talk, one of the keys about doing observational data is that when you are working with a dataset for which you haven't performed the data collection, you may not have a clear picture of what is available, what is not there, how complete the data are and so on.

***ATM: Thank you very much for sharing your insights!***

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