

Ivor Benjamin:

Welcome to this podcast on the 2020 AHA ACC Consensus Conference Report on Professionalism and Ethics, with a specific focus on conflicts of interest, relationships with industry and expert testimony.

I'm Dr Ivor Benjamin The co-Chair of the conference on professionalism and ethics jointly sponsored by the American Heart Association and the American College of Cardiology and we're about to produce a report called the ACC consensus conference on professionalism and ethics, a consensus report. There are three main items that I think will be covered in this particular task force that address conflicts of interests relationships in industry and expert testimony. The first is as professionals, the public really demands that we declare our conflict of interests, because this is the foundation of establishing trust.

The second is that as peer reviewers, we need to be transparent, because that trust is embedded with having a process to adjudicate relationships and conflicts.

And the third as recent events have been able to exemplify is the whole issue around expert testimony where there really needs to be an approach by which the Community is able to really identify individuals that we will call experts and find a way in which.

We in general can feel good and wholesome, particularly when expert tends to me is directly relevant to the broader context of justice, including social justice so welcome to today's podcast and thank you so very much for joining.

I am joined today by Dr. Bob Harrington, an esteemed colleague and friend. Dr. Harrington was a lead author of the paper and is a past President of the American Heart Association. Dr. Harrington is also the Arthur L. Bloomfield Professor of Medicine and Chair of the Department of Medicine at Stanford University. Thank you, Dr. Harrington, for joining us for the second podcast in our series of six podcasts focusing on the 2020 AHA ACC Consensus Conference Report on Professionalism and Ethics. Tell our readers about your role and on Task Force 1.

Robert Harringt...:

I was involved with Task Force 1, which was really setting the stage as we got beyond the opening sections of the paper that

dealt with a lot of the principles of ethics in a profession to try to then get into some specific situations around navigating conflicts. This really spans the relationship with industry, but moves beyond that into intellectual relationships and potential conflicts, institutional relationships and potential conflicts. With that, we covered a broad array of topics, ones that you might expect, things like, how do you deal with conflicts of interest when working in a research project sponsored by industry? How does one think about conflicts in our daily care of patients?

But as we move into some, I would say, less obvious topics, like how do you think about serving as a peer reviewer for publications? For grants? How do you think about philanthropy and relationships with other entities? And just how does that issue of philanthropy interface with our patients? And then finally, as you've outlined in your opening, the whole issue of expert testimony. I think that there's a lot of things, and you said it well in the opening of the paper itself, the pandemic has brought a lot of these issues to the forefront and maybe we'll talk about that. But some of the recent issues, like the George Floyd trial, really brought to forefront some of the issues around expert testimony. So I look forward to our discussion, Dr. Benjamin.

Ivor Benjamin:

So provide us with a little bit more context as to why navigating conflict is important for addressing, in a consensus report, focus on professionalism and ethics.

Robert Harringt...:

I think it's nicely, again, set out in the paper, that talks about the concept of we having primary interests and secondary interests. Primary interests are really the task at hand, taking care of a patient, reviewing a manuscript, enrolling a patient in a clinical trial, reviewing a grant. The secondary interest is really the tricky part and where the conflicts might arise. I'll emphasize the word, might, because not all relationships result in a conflict. Or, if they result in a potential conflict, that conflict might be able to be managed. And the secondary interest though, might include things like a consulting relationship with a medical products company. It might include a position of authority at an institution or an association.

These are the things that we need to be first transparent about so that the concept of the buyer beware can be evoked. But we also need to be transparent, because we need to make sure, as a trusted profession, that, in fact, the public has trust in us. The public really, I think, wants to know and needs to know what are our relationships. Might those relationships matter in this

particular situation? How are those relationships being managed? Who has oversight of that management?

Ivor Benjamin:

Let's take an even deeper dive, because I really, absolutely love the direction where you're going. Specifically outline for our communities with respect to the guidance that you will give with respect to conflict of interest.

Robert Harringt...:

The guidance that we've given is first off, let's call these relationships, again, maybe they're relationships with industry, which is the more common one that people talk about, but also as I've noted, intellectual conflicts, institutional conflicts, association conflicts. That has to be disclosed. Every activity that involves research, education, things like reviewing manuscripts, reviewing grants, those really need to have four things take place, one of which is disclosure. Each organization, in this case, the AHA, needs to, and does have, a mechanism by which those relationships can be disclosed on a regular and ad hoc basis. Secondly, there needs to be an institutional way for a group like AHA or our colleagues in this, the ACC, to review and to understand those relationships as to whether or not they constitute a true conflict. Is it a secondary interest that would interfere with the conduct of the primary interest?

I'll give you an example. A physician has a consulting relationship with a pharmaceutical manufacturer around a specific product. That investigator would like to do a clinical trial that involves human subjects research and, in particular, involves the consenting and enrolling of a patient in a clinical trial that involves that same medical product. There's both a relationship and a potential conflict. There needs to be a group that tries to make that link. Is there a conflict here that is either prohibitory? Doctor, you cannot participate in human subjects research with this consulting relationship. Or, might they say you can participate in certain aspects of the research with that relationship? It needs to be disclosed and then assessed.

Then it needs to be managed. Who's watching out over that? Who's making sure that the primary interests are protected? Again, the AHA has mechanisms to do this. Then I think we put forward an important fourth step which is, where is the larger oversight of that management process at every institution, whether it's a university or an association like the American Heart Association? How is that overseen? By what body? Is it some subset of the Board of Directors? Is it another group? So four steps, Ivor. I think that those can be applied to many of the situations that we're talking about. There's some other things that we get into, I think, which are a little trickier. So for

example, when one reviews a manuscript for a peer review journal, we put forward the notion that one needs to be both aware of and disclosing of one's own potential biases. Again, relationships with industry would be important here. But also intellectual biases.

Secondly, we need to approach that review in a fair and transparent manner, meaning that we need to say, "Well, I understand what the author is saying, but I have this other perspective." We need impartial jurors, in this case, editors, who'll look at those comments from the reviewers in the context of their potential biases and are able to balance all of that to provide an appropriate and high-quality peer review. So there's some trickiness there that isn't quite as clear as just the four steps of disclosure, assessment, management and oversight.

Ivor Benjamin:

Thank you, Bob. I want to link it to what you mentioned at the top of this podcast with relationship to the George Floyd, not only murder, coupled with Chauvin's trial, but link that to expert testimony. I know we're going to run out of time, but you can do it.

Robert Harringt...:

Well, I'll try to be quick here. This is not my specific area of expertise, but these were good discussions as a Task Force. Really, I think the Task Force tried to lay out, what should be the criteria for expert scientific and clinical testimony in legal proceedings? Then take it a second step, which would be, could we have a system that, in a sense, was peer review around expert testimony? Not post hoc, which is what happens now, but before that testimony takes place so that we know it's reliable and credible. So that we know it stands up to the rigors of the legal process. So that we know it's something that might reduce the risk of appeals, because the expert testimony has been vetted even before getting to the courtroom and can raise the trust not only of the clinical and scientific community, but of the legal process that involves those parties.

Ivor Benjamin:

Another question I would like to ask is how you see this consensus report being utilized best applied to the ACC AHA joint guideline process?

Robert Harringt...:

There is already a lot of scrutiny and a lot of attention paid to our guidelines, both internally and externally. We have, for many years, adhered to a very high level of disclosure and a requirement, for example, that at least 50% plus one of the writing group have no relationships with industry. And that the Chair of that committee be completely free of relationships with

industry. That has served us well. I think it's in line with the Institute of Medicine and National Academy of Medicine's approach to best practice for guidelines. I see this as an area where we need to double down on to make sure that our guidelines are going to be trusted and put together by the best people.

Now, some might say there should be no individuals on the committee with relationships with industry. But what we're really trying to do though is balance getting their expertise with the potential of conflict, so we have a number of procedures and policies in place for the level of discussion that someone can participate in whether or not they can vote on certain things that they might be involved with. Again, I think we have a pretty good system. And with our guideline modernization process that's been going on over the last couple of years, I think that'll be even further strengthened. Our guidelines are used by practitioners. They're used by health systems. They're used by scientists. They're viewed by the public. We need to make sure they're trustworthy.

Ivor Benjamin:

So as you think about the various areas of recommendations, what specific aspect do you think that comes to mind that Task Force 1 address, that when revisited in the future, is likely to be really key and important?

Robert Harringt...:

One we've already talked about. That's expert testimony. We've put forward a construct which is not used today. And we'd like to see it used. How that evolves over the coming years, I think, will be a point of discussion, let's call it, in the next version. The second, which I've not mentioned yet, but I've mentioned the pandemic, during the pandemic we have relied, as a scientific community, on open access and pre-prints. Pre-prints by their nature are not yet peer reviewed. We did not have a discussion about, what is the responsibility of disclosure and management of potential conflicts in the pre-print phase? There is not an editor. There's not peer reviewers, by definition. At least not yet. I think, Dr. Benjamin, that is going to be a really important area for discussion and contemplation over the coming years, because pre-prints are here to stay. They help move the science faster, but there's some tricky issues that we need to, as a scientific community, grapple with.

Ivor Benjamin:

As we look to the future, we want to be sure that the recommendations remain agile yet relevant and allow for guidance in perceived conflict challenges facing the scientific medical and basic scientist communities. As healthcare professionals, we must be committed to the high standards of

ethical behavior expected from our patients, as well as those with whom we work, educate and, of course, the scientific community. On behalf of the American Heart Association and American College of Cardiology, a consensus conference report was developed to address professionalism and ethics. This process addresses conflict-of-interest compliance to ensure the mechanism by which we, as healthcare professionals, can provide for the cardiovascular healthcare delivery, research and education that's grounded, of course, in ethical foundations.

We have four more podcasts planned, so please return to HeartBEATS Series for additional podcasts in this series, covering diversity, equity, inclusion and belonging, clinician wellbeing, patient autonomy, privacy and social justice in healthcare and, of course, the modern healthcare delivery system. Also, please visit the AHA's Lifelong Learning platform for a webinar recording of the round table discussion led by our esteemed Dr. Bob Harrington. Thank you so very much, Dr. Harrington, for sharing your time and expertise with us today.