

Recommendations of the NHLBI Council/BEE Working Group on Epidemiology

Webinar: Friday, October 24, 2014 ♦ 11:30am (EST)

Summary of Dr. Michael Lauer's comments regarding the Working Group's recommendations:

Hello and thank you. It is important to understand the process for handling of the report. The Working Group represents a body of experts independent of the NHLBI, appointed, and charged by the NHLBI Council. The draft Report and recommendations were submitted to and unanimously accepted by Council for the NHLBI to finalize the report after taking account Council's comments and then to submit to the NHLBI Director for consideration. The Council praised the efforts of the Working Group as thorough and thoughtful.

Process aside, I know that I can speak on behalf of Dr. Gary Gibbons and the entire NHLBI leadership in saying that once the Report is rendered to the Institute, the NHLBI will carefully and very thoughtfully consider the Report Recommendations and how best to move forward. In so doing, we will seek the ongoing support and engagement of the research community, strive for fairness in our approach to working through any challenges, and commit to collaborating to create something even better for the science of the future.

NHLBI's cohort studies have been tremendously productive and have made great contributions to science. Now is the time to look at the potential for a new vision and direction for these studies that will allow their proud legacies to continue and grow. Within each of the recommendations just presented by Dr. Roger rests a

deal of complexity with respect to feasibility and implementation alternatives. Each warrants careful and thoughtful consideration in order to ensure that the best science moves forward in a manner that optimized the investments we have to bear.

Finally, I would like to thank Dr. Roger and the entire Working Group for their tremendously efforts over this past year in generating these recommendations.

Questions & Answers to Which Dr. Lauer Addressed:

About the inter-institute collaboration – have the other NIH Institutes been brought into this discussion?

Response: Other NIH Institutes and Centers have been wrestling with the same issues. One of the webinars involved reaching out to the National Cancer Institute to see how they are addressing their cohort studies. We hear loud and clear from the Working Group that this needs to be a process that occurs with other partners. The implementation will involve a trans-NHLBI program and for sure trans-NIH in several aspects as well.

What is the NHLBI's implementation process, and will that process be sufficiently timely to inform the participants during the transition so they are aware of future plans?

Response: Our concerns are your concerns. We are aware of potential lapses in funding and will take these into account as we develop our timeline.

Implementation will be a continuously evolving process. There are some things that will evolve sooner than other things. We will be putting in place tentative

timetables over the next several months but the implementation will surely be something that occurs over time. It is best to consider this as evolutionary not revolutionary as it relates to process – it won't evolve over night, it will likely take years.

What are the plans for staging and operationalizing these seven recommendations?

Response: As I mentioned earlier, we will be working on the timeline to implement these recommendations. Engaging the community of stakeholders, exploring all possible options and alternatives, maintaining flexibility given the ever changing environment in which we now operate, and assuring that we are able support the best science while expanding use of large data sets are just a few of the principles we wish to maintain. We will be reaching out to you, the external investigators, to help us deliberate many of these questions.