

Report 87: Making environmental health-related laboratory assays robust and cheap enough for use in large human population research studies

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Brief History: There are many existing laboratory assays that assess biologic levels of environmental agents or their metabolites in human biospecimens or early effects of these agents that were developed for testing scientific hypotheses in small studies in carefully controlled settings; often highly skilled staff are needed to perform these assays correctly. However, it often takes a long time for these assays to be useable in epidemiologic and other field studies (or for health surveillance) because the assays are too expensive, take too much biospecimen or biospecimens that are difficult to obtain, or are too sensitive to the procedure for acquiring the specimen, how it is transported, and analyzed. Often there are few incentives for principal investigators to scale up existing assays to be more robust, cheaper, and easier assays. This is because existing funding mechanisms reward discovery and hypothesis testing research, not the types of methods research needed to solve these technical methodologic problems. In addition, sometimes existing assays are not adequately described in the published literature making it difficult for scientists who want to take and improve the method for use in large human studies. Reference materials are usually not available to make sure that any new method that is purportedly cheaper or more robust meets the standards of original assays. Some existing types of funding opportunity announcements, such as Small Business Innovation Research grants have been used in the past to help address some of these problems; however, much more needs to be done to facilitate and speed the process and provide the tools to perform assays cheaply and easily enough for use in large human population studies. Finally the scientists who do the large population studies usually don't have the expertise to develop these robust assays, and scientists who develop the assays for use in smaller discovery studies aren't aware of the constraints of large population studies.

Discussion Highlights:

Develop more assays that are robust enough to be done "in the field". This is sometimes necessary due to human subject issues, rapid deterioration of the analyte involved, transportation problems, and mandates in some countries that biospecimens cannot be sent out from that country.

Assays used in large population studies need to be able to be completed as quickly as possible in order to be able to get another biospecimen if the original one is compromised, insufficient, lost, etc.

Speeding scaling up and ramping up of assays will require fostering partnerships with businesses and academics with the capacity to do this type of methodologic work.

Assays used in large scale studies typically need to either require very small quantities of biospecimens or the assays need to be heavily multiplexed because specimens are hard to get and must be used for to detect multiple environmental exposures and early effects in addition to use in assessing nutrients, inflammatory biomarkers, immunologic biomarkers, etc. Tools and methods developed have to measure as many analytes as possible.

Recommendations:

NIEHS should develop the infrastructures and incentives needed to ensure that laboratory assays for environmental health-related analytes that show promise for understanding exposure levels and early health effects in human populations are rapidly and efficiently scaled up to be cheap, easy, and robust enough for use in human population research.

NIEHS should ensure that reference materials are developed and maintained that can be used to determine the analytical validity of newly developed laboratory procedures that have the desired properties of being cheap, easy to do, are multiplexed and/or require smaller biospecimen samples.

NIEHS should ensure that the methodologies used to do the original assay and the better, cheaper, more robust assay are properly and extensively documented

NIEHS could consider using CRADAs, Small Business Innovative Research methods, and FOAs such as NCI's IMAT (Innovative Methods for ... and Technology or something like that) that can incentivize and foster this type of important methodologic research.

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