Ask the Expert – Closing session at CAREB 2016 National Conference

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Discuss 2 case studies
Open discussion to the audience
Q&A for other hot issues

Case Study #1: Re-evaluation of Minnesota Coronary Experiment

For over 40 years, the public has been warned that dietary cholesterol and saturated fat are bad for them and they should be using unsaturated vegetable oils instead. Much of this advice has been based on epidemiologic research, with only two large-scale randomized clinical trials. The larger of the two was known as the Minnesota Coronary Experiment and involved over 9400 patients living in mental institutions and nursing homes in Minnesota between 1968 and 1973. It was believed that this "captive population" would enable researchers to follow them closely over an extended period of time to see long term effects of the two diets and corresponding morbidity and mortality rates. Participants were not given the opportunity to provide written consent, but were told about the study and that they could decline participation or withdraw at any time. The participation rate was close to 100%. Contrary to expectation, participants could not be followed continuously over long periods of time, as they were routinely discharged and readmitted, so in fact the researchers were only able to follow participants for an average of one year. This limited the results; however, the researchers concluded in a 1989 paper that the data they had supported their hypothesis that vegetable oil lowered cholesterol and hence reduced the risk of cardiovascular disease and death.

In 2016, it was determined that not all of the data obtained in the study had been analyzed to come to this conclusion. The missing data were reintroduced and the study was reanalyzed by a different research team (the PIs had since died). The researchers came to a different conclusion from that of the original publication. Although the diet high in vegetable oils did decrease cholesterol levels, this did not result in a reduced risk of cardiovascular disease, and, in fact, increased the risk of overall mortality.

1. Should the original study have been approved, considering the population (institutionalized, potential lack of capacity) and lack of individual-level written consent? Does the answer change if using a 1968 lens compared to today?
2. How would the omission of data (accidental or on purpose) be viewed at the time of publication (1989) compared to now? How should the omission be handled or viewed? Should the original paper be retracted?
3. Discuss the impact of erroneous data analysis on public policy.

Case Study #2: Key Haven Project

The Zika virus has been determined by the World Health Organization to be a "public health emergency of international concern". The mosquitoes known to carry Zika can be found in South American and southern North American countries. It has been shown to be transferred through the blood and through sexual contact. Zika is believed to cause microcephaly in foetuses of pregnant women who have contracted the virus, as well as Guillain-Barré syndrome (GBS).

Oxitec, a British company, creates genetically modified sterile male mosquitoes to combat mosquito-borne diseases such as Dengue fever. They have now created a variety specific for the species that transmits Zika and want to conduct a field test of the GM mosquito in Key Haven, FL. It is expected that by having the GM sterile male mosquitoes mate with wild type females to create non-viable offspring, the mosquito population will be reduced by 80-90%.

While the intention is to release only the GM sterile male mosquitoes, there is a risk of 1/10,000 mosquitoes released being female. Only females bite, so this is a very minor safety risk. The benefits to the human population are significant, including fewer mosquitoes (and therefore mosquito bites), less chance of contracting Zika or other mosquito-transmitting viruses. The US FDA centre for veterinary medicine has concluded that the study will be safe to humans.

Local residents of Key Haven are concerned with genetically modified organisms and many are fighting against their unvoluntary "participation" in this study. While the field test has been explained to them and their questions have been answered, a vocal minority continues to protest the use of their community for the testing. A non-binding vote of the residents has been scheduled.

Questions:

1. Is this human participant research, environmental research, or both? Would this study require ethics review?
2. To what extent should residents' wishes be considered?
3. How should the harms and benefits be evaluated in light of residents' concerns?
4. What other considerations are there?