Mounting Evidence Implicates Zika Virus In Microcephaly And Guillian-Barre Cases

Firm Proof Awaits Results From Case-Control And Cohort Studies

The lack of understanding about Zika virus, and especially the lack of certainty about the cause of the reported increases in microcephaly and Guillian-Barre Syndrome cases in Brazil and other parts of the Americas, have prompted the World Health Organization to declare a global public health emergency.

According to WHO’s Bruce Aylward quoted in the Washington Post, “This is classic ‘building your boat while you sail it’. People said that about Ebola and that was trying to get a bigger sail on the boat. Here we’re still stitching the sail, and we’re not quite sure what kind of sails you really need.”

Also quoted was David Heymann, London School of Tropical Medicine and Hygiene epidemiologist, who contrasted Zika with Ebola saying the Ebola epidemic was an emergency because of what was known about the disease, whereas Zika is an emergency because of what is unknown.

- Zika continues on next page

Critics Of Counterfactual Movement In Epidemiology Say “Pragmatic Pluralism” Is Better Approach To Causal Inference

“We wish to forestall the emergence of a ‘hardline’ methodological school within epidemiology, one which we feel would damage the discipline if it became the dominant paradigm.” This is how authors Jan Vandenbroucke, Alex Broadbent, and Neil Pearce express their reason for writing a critique of the counterfactual movement in an advance access article of the International Journal of Epidemiology in January.

Non-trivial Damage

And the damage the authors foresee is not trivial since the restricted potential outcomes approach (RPOA)

- Causal continues on page 8
Burden of Disease

Zika Virus Infections:
The Brazilian Ministry of Health (MOH) has estimated that as few as half a million or as many as 1.5 million infections have occurred in that country. Columbia has reported more than 31,000 suspected cases and Cape Verde more than 7,000. Overall, some experts estimate 3-4 million cases will occur over the next year.

According to WHO, the geographic range of the virus has increased significantly in 2015-16 especially in the Americas with 28 countries or territories now affected.

Cases of Microcephaly:
Brazil has reported approximately 5,280 cases of microcephaly or central nervous system abnormalities as of February, including 108 deaths.

Cases of Guillain–Barre syndrome:
Five countries in the Americas have reported increases in Guillain–Barre syndrome in association with the Zika virus outbreak. These cases in adults have been reported in much lower numbers than the microcephaly cases. The largest number is from Venezuela with 252 cases.

Proving Causality

While it is established that Zika virus is transmitted by the aedes species of mosquito, and that prevention of Zika is theoretically possible with effective mosquito control and/or effective protection against mosquito bites, the cause of the microcephaly and GBS cases is less firmly established.

To truly pin down the role of Zika virus in microcephaly, a collaborative case-control study between CDC, Brazil, and possibly other scientists will be carried “to look in more depth at different factors that the mothers were exposed to, and to look at laboratory tests from the mothers and babies, and really get a better idea of what proportion, if any, of these birth defects can be specifically linked with the Zika virus,” according to CDC’s Anne Schuchat.

Smoking Gun

A critical ingredient will be hammering out a good case definition of microcephaly since right now there are reports of over-reporting and misdiagnosis among the approximately 5,000 officially reported cases. The study has begun as of mid-February despite the strong conviction among Brazilian health authorities that Zika is the cause of the microcephaly cases. The circumstantial evidence or “smoking gun” is very strong and the Minister of Health has been quoted saying “We have no doubt that the epidemic of microcephaly that we are seeing in Brazil is caused by the Zika virus outbreak.”

Favoring Causality

Arguments in favor of a causal link between Zika and microcephaly are: 1. There appears to be a significant increase in microcephaly cases since 2015 in association with an increase in Zika cases in Brazil. Initial
"Every item on the Centers for Disease Control and Prevention’s (CDC) list of great public health achievements of the twentieth century can be attributed in part to legal interventions.” This striking CDC conclusion is highlighted in a recent article entitled “A Transdisciplinary Approach to Public Health Law: The Emerging Practice of Legal Epidemiology” by Temple University researcher Scott Burris and colleagues in the Annual Review of Public Health.

In it the authors describe the rich history of public health law for over a century, but note “Four major Institute of Medicine (IOM) reports over 25 years have lamented the state of public health laws, the practice of law, the training of public health officials in law, and the access of health officials to quality legal advice.”

Why the neglect?

Neglect

Despite the continued and growing importance of the field, many of those who practice public health law have an entrenched, antiquated view of its scope - seeing the field only as applying legal knowledge to regulate health agencies, according to Burris and colleagues. They add, another important dimension of public health law has developed through the rigorous, scientific study of how public health laws affect public health. However, scientists and even lawyers engaged in this type of research have not historically classified the work as “public health law”.

Burris et al. argue “The view that public health law is the province only of lawyers misses the fact that public health laws are commonly conceived, promoted, administered, and evaluated by public health professionals and others without JD degrees.” Further, a lack of unification between public health law and the study of public health will inevitably lead to gaps in health policy.

Solutions and Definitions

The proposed solutions for this neglect?

To remedy the situation, the authors propose a multidisciplinary conceptual model of public health law consisting of two branches - public health law practice and legal epidemiology. They define legal epidemiology as “the scientific study of law as a factor in the cause, distribution and prevention of disease and injury in a population.”

In this model, public health law practice remains defined as it has been historically - applying
professional legal skills to develop health policy through counsel, representation and research. However, also included within this model are three components of legal epidemiology: legal prevention and control, legal etiology, and policy surveillance.

1. Legal prevention and control is the study of the effect of legal interventions on public health. Research in this area is critical to insure that public health laws actually increase positive health outcomes and do so efficiently.

2. Legal etiology in turn studies how laws can themselves be the causes of disease or have unintended health consequences.

3. Lastly, policy surveillance is the monitoring, assessment and circulation of information on laws and policy important to health.

**Training Needs**

While the growth of JD/MPH programs is producing more public health minded lawyers, according to the authors, they believe “future public health practitioners and researchers need a solid grounding in legal epidemiology.” MPH graduates will need improved legal training not restricted simply to a cohort of legal specialists within the field of public health. The goal of this training they argue should be to have all social and behavioral researchers willing and prepared to study the law as a factor affecting health. As such, they suggest the development of JD/PhD programs to train researchers that can take the lead in further growing the field of legal epidemiology.

**Better Health Faster**

Ultimately, a transdisciplinary approach linking public health law and legal epidemiology would connect research, advocacy and practice so that the transition from innovation or new findings to adoption or into public health practice can move faster and more smoothly. In short, the new model has the potential to produce “better health faster,” say the authors.

**Links to articles:**


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"...the new model has the potential to produce “better health faster,”"
In his 2015 State of the Union address, President Barack Obama announced the Precision Medicine Initiative (PMI), an ambitious plan to advance the emerging field of precision medicine through research and development of technology and policies that improve individualized care. Precision medicine is a personalized approach to disease treatment and prevention that is tailored to individuals based on specific genomic, environmental and lifestyle data.

**Topic Areas of Interest**

The PMI will look at genomic, environmental and lifestyle data to achieve a better understanding of disease risk, mechanisms of disease and individual response to therapeutics. As the White House describes it in an official statement, the overarching goal of the PMI is to “leverage advances in genomics, emerging methods for managing and analyzing large data sets while protecting privacy, and health information technology to accelerate biomedical discoveries.” More specifically, NIH director Francis Collins has written in a perspective in the New England Journal of Medicine that the initiative will have a “near term focus on cancers and a longer-term aim to generate knowledge applicable to the whole range of health and disease.”

**Key Component**

A central component of the PMI involves the development of a longitudinal research cohort of at least 1 million U.S. participants from diverse social and ethnic backgrounds, all ages and all health conditions. However, just months before the President announced his plans for the PMI, the government was forced to shut down the National Children’s Study (NCS) before enrolling a single child despite spending 14 years and $1.3 billion on planning and pilot testing. As the NIH is now preparing to begin enrolling volunteers for the PMI research cohort in early 2016, some remain skeptical of the feasibility of large-scale population studies.

**Problems and Solutions**

The NCS intended to study environmental influences on child health and development by tracking 100,000 U.S. children from before birth until the age of 21. By collecting biological specimens, environmental samples from homes and data from the families, scientists hoped to gain insight into the impact of these factors on the development of disorders such as asthma and autism. While there is no simple explanation for why the NCS study failed, there were a number of significant problems with the study that NIH officials are hoping to avoid with the PMI.

1. **The PMI must move quickly**

One of the major issues with the NCS

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"...some remain skeptical of the feasibility of large-scale population studies."

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"...there is no simple explanation for why the NCS study failed..."
was that it simply moved far too slowly. The NIH spent 7 years and $54 million on planning alone, as debates and internal arguments over study design as well as how to recruit and enroll participants dragged on for years. Pilot studies, which accounted for the majority of the $1.3 billion spent, took more than 9 years to even begin. These delays crippled the study, as NIH director Francis Collins told the website STAT, “Science changed drastically during that time, and so the design that had been put together didn’t really fit the scientific opportunities by the time it was ready to get started.”

**Enrollment Strategies**

To address this issue the PMI will be utilizing different enrollment strategies, both allowing individual Americans to volunteer directly as well as collaborating with large health care provider organizations such as the Geisinger Health System, Veteran’s Affairs and Kaiser Permanente who serve diverse populations and already have electronic health records and stored biosamples for millions of people.

Aided by the advent of electronic health records, this strategy should be significantly faster and more cost-efficient than the door-to-door recruitment strategy employed during the NCS. The NIH’s PMI working group estimates that the recruitment goal of 1 million participants could be reached in 4 years with this methodology.

2. The PMI must have consistent and empowered leadership

Throughout the course of the study, the NCS went through multiple directors and was continuously undermined by inconsistent and ineffective leadership. Researchers and administrators went back and forth on fundamental aspects of the study design and implementation, culminating in a letter written to the NIH by 5 lead investigators involved in the study in which they argued “the present direction and conduct of the study places it at high risk of scientific failure”.

The PMI Working Group specifically addressed the need for consistent and empowered leadership in their report to director Collins, recommending that the NIH appoint a director with “institutional authority, professional expertise and structural support to lead the effort”.

3. PMI must avoid funding issues

In the case of the NCS, funding for the full study was delayed for years and the initial funding had to be reauthorized by Congress every year. Cost projections began to increase significantly beyond the initial total budget and the NIH eventually dramatically cut funding.

The NIH hopes these funding issues can be avoided with the PMI due to strong political support from both Republicans and Democrats. The PMI already has a 2016 budget of $215 million, $130 million of which is designated for the development of the research cohort. In addition, by learning from the mistakes of the NCS, the NIH believes they can utilize more cost-effective recruitment strategies to keep expenses under control.

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"...the design that had been put together didn’t really fit the scientific opportunities..."
estimates are that the country averaged only about 163 microcephaly cases per year prior to 2015 but has reported approximately 5,000 in the last few months. In the northeastern state of Pernambuco, microcephaly cases surged last year when only 9 cases are found in a typical year.

2. Zika was actually detected in 41 babies among 462 confirmed cases of microcephaly in Brazil. A total of at least 508 microcephaly cases have been confirmed to date.

3. A review of birth data from the Zika outbreak in French Polynesia in 2013-14 indicated that the number of congenital abnormalities was increased there as well from 0-2 annually to 18 in 2014-15, including 9 microcephaly cases. Four of the mothers later tested showed evidence of having had Zika.

4. A baby born in Hawaii in December had a serologically confirmed Zika infection. The mother had experienced symptoms compatible with Zika in the second trimester.

5. The fetus of a baby in Slovenia had the virus isolated after pregnancy termination.

Favoring Other Etiologies

Arguments against a causal link:

1. Other viruses besides Zika such as dengue and chikungunya are circulating. Also, other known non-viral causes of microcephaly have not been ruled out.

2. Cases of microcephaly outside of Brazil have not been reported. Reasons given to explain this unexpected finding if Zika is a true cause include the possibility that other affected populations have not been large enough to produce the explosive spread possible in a large non-immune population such as Brazil. This assumes the incidence rate among pregnant women is low, and that previous outbreaks could not create a detectable or highly visible “cluster” of microcephaly cases. Or there may be other co-factors unique to Brazil that have helped make the outbreak of neurological outcomes possible and apparent.

Expected Future Wave of Cases

Another reason given by CDC Director Tom Frieden is that “we’re not surprised not to see cases of microcephaly in other countries because of the time frame between infection and delivery.” This assumes Brazil was one of the earliest affected areas and that a wave of cases will occur as time passes in other parts of the Americas.

There is a suspicion that these numbers may include over-reporting and misdiagnosis so that the correct number is still in doubt. Another recent report on the WHO data portal suggests there has been significant under-reporting of cases prior to 2015. Their best estimate of the background rate is some 10 times higher than official estimates or 2,725 cases annually with a minimum incidence of 92 per 100,000. This would make the current outbreak less extraordinary than initially believed.
they criticize limits, in their view, the questions that epidemiologists can ask, the designs they can create, the evidence they consider acceptable for determining causality, and consequently the evidence acceptable for scientific and public health decision making.

Concerns

According to the authors, the counterfactual movement is becoming dominant in theoretical epidemiology but it takes a too narrow view of causality and fails to take into account the contributions that can be made from diverse forms of evidence. Interestingly, the authors differentiate “practical” causal inference from a presumably more theoretical one which underlies the counterfactual approach. They describe the historical practice of epidemiology as “incredibly rich and successful” and believe that the principles that are associated with the counterfactual or RPOA approach “bear little resemblance” to the public health problem solving that epidemiology has contributed to so usefully.

Formula 1 Cars

To make their point more colorfully, the authors employ the metaphor of Formula 1 cars.

“Formula 1 cars may be the best in the idealized environment of a racetrack, but to say that they are the ‘best cars’ would be misleading, since they are useless in almost every other situation.”

Problems With RPOA

The criticisms of the RPOA approach for both the theory and practice of causal inference in epidemiology are described in detail in the paper. In summary, they are:

1. Restricting epidemiology to study feasible human interventions misses the chance to study those which are not humanly feasible such as heat waves or being born with two X chromosomes.

2. States such as “obesity” cannot be studied as causes.

3. Claiming that causation is well defined only when interventions are well specified is problematic because the term “well-specified intervention” itself is in need of definition.

4. RPOA ranks evidence in a way that ignores the context-dependence of evidence.

5. RPOA does not make provisions for ruling out alternative hypotheses.

6. It does not help in the use of different kinds of evidence to arrive at one verdict about causality.

Pragmatic Pluralism

In place of RPOA, Vandenbroucke et al. argue for a pragmatic pluralism which is less tied to a single concept of causality. They state “…it is very plausible that we think about causation in more than one way.”
They lay out a blueprint for teaching epidemiology and what students should learn, namely:

1) that causal inference remains a judgment based on integration of diverse types of evidence,

2) to use diverse strategies to assess causality by ruling out alternatives

3) about the elements of all types of epidemiological study designs, inclusive of those types of design that do not match the ideal counterfactual situation

4) to reflect critically on whether potential biases matter

Links to related articles:

1. https://tinyurl.com/j8bq45c
2. https://tinyurl.com/ktoka69
3. https://tinyurl.com/zxxao7q

Residential Summer Course in Epidemiology, Florence, 20 June – 8 July 2016
Contact: eepe@eepe.org and http://www.eepe.org

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Pre-Course week, 13 June – 17 June 2016. Two independent courses on: Genetic and Molecular Epidemiology, and GIS (Geographic Information Systems) in Epidemiology.


Evening Distinguished Lectures: Rodolfo Saracci, Jørn Olsen and Nino Künzli
Epidemiology’s Joint Policy Committee Granted Official Non-Profit Organization Status

Group Now Seeking Donations To Combat Misuse Of Epidemiology

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Operating at the interface of scientific inquiry and policy, we aspire to be an ethical and effective counter-weight to the misuse of epidemiology. In particular, when vested interests manufacture doubt, the IJPC-SE aims to provide independent evidence and correct what is scientifically wrong. Any action that is designed to foment uncertainty in the minds both of the public and policy-makers can result in delayed health policy with consequent harm to people and other living systems. We aim to minimize delays in policy and consequent harms to health when the evidence justifies so doing. Work at the interface of research and policy is called “translational science” by some and “consequential epidemiology” by others.

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Core values are held in common among the member societies and associations of epidemiology comprising the IJPC-SE. These values anchor us in our role as professionals engaged with communities in the study of disease and health patterns. We value the production of valid scientific evidence for the advancement of science and to inform policy. We recognize that along with the privilege of our position comes responsibility for protecting the public interest with the values of respect, equity, integrity and transparency.

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The International Joint Policy Committee of the Societies of Epidemiology exists to promote the effective and unbiased use of epidemiology. It strives to bring clarity to the science underlying policies to protect public health, according to a recent release by the group.

The organization has now completed its long process of qualifying as a non-profit corporation in the United States. It is now able and anxious to receive donations from epidemiologists everywhere who are supportive of its important mission.

The following information about the Committee has been released for those wishing to better understand the composition and work of the group.

What Is The Joint Committee

Founded in 2006, the International Joint Policy Committee of the Societies of Epidemiology (IJPC-SE) is a global, not-for-profit consortium of more than 18 national and international epidemiology organizations spanning five continents.

What Does The Committee Do?

When important health issues or controversies arise in assembling or using epidemiological information, we work collaboratively and transparently to host forums and develop position statements with recommendations to protect and improve public health.

...to provide independent evidence and correct what is scientifically wrong."

"...we aspire to be an ethical and effective counter-weight to the misuse of epidemiology."
NEW FEATURE: What We’re Reading

[Ed. Note
If it interested us, it will interest you! That’s the thinking of our epidemiologist mind in creating a new feature for the newsletter entitled What We’re Reading. The concept is to share with our readers some of the best articles we come across or give readers more opportunities to learn about topics we were not able to report on. We hope you will benefit from this new addition and send us some of your own “best articles” to share with readers. Send your suggestions and links to epimon@aol.com ]

How A Medical Mystery In Brazil Led Doctors To Zika
“One of those who flew in to help in the detective work was Dr. Laura C. Rodrigues, an epidemiologist at the London School of Hygiene and Tropical Medicine on contract to the Pan American Health Organization.

‘It was the kind of call where you dropped everything,” she said. “There had never been a congenital malformation by mosquito before, not ever. It was totally outside our experience.’”

https://tinyurl.com/hxqw7v4

Science For Sale
The Center for Public Integrity has launched a series of exposes under the framework of “Science for Sale”. It is a revealing and troubling look at the influence of money in science and science data. Below are the first four articles in the series.

Meet Rented White Coats Who Defend Toxic Chemicals
https://tinyurl.com/jko4uv1

Making A Cancer Cluster Disappear
https://tinyurl.com/jkf8pd

Ford Spent 40 Million To Reshape Asbestos Science
https://tinyurl.com/jlcntve

Brokers of Junk Science
https://tinyurl.com/zsxmx7a
**Notes on People**

**Named:** Michelle Williams, as Dean of the Harvard Chan School of Public Health starting in July. Dr Williams is currently the Chair of the Department of Epidemiology at Harvard. The President of Harvard told the Harvard Gazette, “Michelle Williams is an eminent epidemiologist, an outstanding teacher and mentor, and an energizing leader and institutional citizen, impassioned about the power of public health to change people’s lives for the better.”

**Elected:** Chen Chien-jen, as vice-president of Taiwan in mid-January. Chen is an epidemiologist who made a reputation for himself in the way he handled the SARS outbreak in 2003. He has carried out influential studies on arsenic and hepatitis according to Nature and is widely respected throughout the country in many different communities.

**Murdered:** Sandra Thomas-Trudo, Chief Epidemiologist of the Nashville Health Department. The Director of Nashville Public Health called her an intelligent, passionate public health professional and a valued member of our team.” According to press accounts, her husband implicated himself in the stabbing murder and was arrested. There was no known history of domestic violence.

**Named:** Paul VanVeldhuisen, as Chief Operating Officer of the Emmes Corporation, a research support company. He holds a PhD in epidemiology from George Washington University. The president of Emmes told FierceBiotech “Paul’s vision, leadership, and understanding of our business and culture make him an ideal COO, and I am looking forward to working with him in his new role.” In the same article, VanVeldhuisen, noted “What has stayed consistent during my 22 years here is our commitment to provide critical services that address important issues in public health...These are the kinds of challenges that inspire our staff to do their best. It’s the dedicated employees committed to Emmes’ mission that make this a remarkable place to work.”

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Epidemiology: Tenure-track or Tenured Faculty Positions in Epidemiology

Vanderbilt Epidemiology Center at Vanderbilt University Medical Center is accepting applications for multiple faculty positions at Assistant, Associate or Full Professor rank. More than 60 epidemiologists at Vanderbilt conduct clinical and population-based studies, including three large cohort studies in the U.S. and abroad with survey data and biological samples from approximately 225,000 study participants. Areas of ongoing research include diet and nutrition, health behaviors, environmental exposures, reproductive epidemiology, genetic and other biomarkers for disease risk and progression, and racial disparities in health outcomes. The center is particularly interested in expanding its research and training programs in chronic disease epidemiology.

Successful candidates will have a doctorate in epidemiology or a related field with additional training or experience in epidemiologic research, with demonstrated ability to develop and sustain an independent research program in chronic disease epidemiology. Vanderbilt fosters a rich environment of cross-disciplinary collaboration, providing exciting opportunities to work on cohort consortium projects and collaborate on ongoing research projects in epidemiology.

Vanderbilt University, is one of America’s premier private universities. Vanderbilt School of Medicine is ranked #14 (tied) on the US News and World Report 2016 list of top medical schools for research in the United States and in the Top 10 for NIH-funded research. Vanderbilt University is an Equal Opportunity/Affirmative Action Employer.

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To apply, email a cover letter, briefly describing research experience and interests, and curriculum vitae to mailto:kimkreth@vanderbilt.edu. Address the cover letter to: Dr. Wei Zheng, c/o Kim Kreth, Vanderbilt University Medical Center, 2525 West End Ave., 8th floor, Nashville TN 37203-1738.
The Department of Epidemiology at the Tulane University School of Public Health and Tropical Medicine is seeking a highly qualified candidate to fill a tenure track position at the assistant professor level in the area of obesity / nutrition epidemiology. Candidates with training and research experience in nutrition, obesity and/or clinical trials are encouraged to apply. Qualifications include a doctoral degree in epidemiology, or MD or PhD in nutrition with a master degree in epidemiology, post-doctoral experience, demonstrated potential to establish independent research programs, evidence of excellence in teaching, and interest in collaborative research. The Assistant Professor is expected to conduct independent research on the existing projects and to develop new research projects, and to teach graduate courses and provide academic service as needed. Applicants should send a letter of application with a statement about future research plans, a curriculum vitae, and three current letters of recommendation to:

Lu Qi, MD, PhD, HCA Regents Distinguished Chair and Professor, Director, Tulane University Obesity Research Center, Department of Epidemiology, Tulane University School of Public Health and Tropical Medicine, 1440 Canal Street, Suite 1724, New Orleans LA 70112, Email address: mailto:lqi1@tulane.edu

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For more information, see the job description (http://tinyurl.com/zyxym5jk) or contact Rebecca Brotman at rbrotman@som.umaryland.edu or 410-706-6767.

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