To IRB or Not to IRB—Can There Be Any Question?

James O’Barr

To assure that the highest quality health care is provided to migrant and seasonal farmworkers and their families, both the practice of evidence-based medicine and the utilization of practice-based research are essential. When humans are the subject of study, Institutional Review Boards (IRBs) are charged with the responsibility for reviewing, approving, and monitoring the research to assure their protection and ethical treatment. However, research with mobile, marginalized populations requires particular vigilance to ensure that appropriate safeguards are in place to protect their rights, safety, and welfare, and to see that such elements as cultural differences, language barriers, and literacy levels are taken into account in research design. Conventional IRBs, whether linked to academic or community institutions, are rarely conversant with what is needed to work effectively with migrant, low-literate populations, and with the unconventional methods that must often be employed to ensure informed consent. Fortunately, the Migrant Clinicians Network, long committed to serving farmworkers and other mobile poor with just such methods, stepped into the breach, creating its own IRB in 1999.

When MCN took that step, Institutional Review Boards were still a recent innovation, and it is worth considering the sordid history that preceded their introduction. Since antiquity, and across different cultures, healers have been revered as persons with special knowledge of the mysteries of life and death, and the relationship between patient and physician has held deep moral and religious significance. Over time, the concept of medicine as a profession has taken hold, and science replaced religion as the basis of medical practice. Nevertheless, even as that practice has evolved, the moral and ethical aspects of medicine have remained central to the understanding of what it means to be a member of a health profession. In the twentieth century, however, the explosive growth of scientific knowledge, the increasing involvement of government support for research, and the callous disregard for human life in scientific research that culminated most notoriously in the Nazi concentration camp medical experiments, lent urgency to the need for outside regulation and informed consent when human beings are the subjects of research. In 1964, the World Medical Association made recommendations, later codified and periodically revised as the Declaration of Helsinki, that would govern international research ethics and define rules for research combined with clinical care, as well as for non-therapeutic research. Two years later, Dr. Henry Beecher, a Harvard Medical School anesthesiologist, authored an article in the New England Journal of Medicine examining 50 studies published in the U.S. since 1945 that were what he called “examples of unethical or questionably ethical studies.” One study that Dr. Beecher did not include, because it was a closely guarded secret, was the infamous Tuskegee Study of Untreated Syphilis in the Negro Male, which was conducted by the U.S. Public Health Service from 1942 to 1972. Terminated only as a result of a leak to the press, the Tuskegee Study led to the Belmont Report in 1979, and the establishment of the Office for Human Research Protections in the Department of Health and Human Services. It also led to federal regulations requiring Institutional Review Boards for protection of human subjects in studies funded by DHHS.

For Americans, with our famously short attention spans, the Tuskegee Study may seem like ancient history. Certainly the words of the national director of the study, attempting to justify the refusal to provide treatment once penicillin was discovered in the 1940’s, are from another era, if not another ethical universe: “The men’s status did not warrant ethical consideration.”...
cal debate. They were subjects, not patients; clinical material, not sick people.” History, yes, but not ancient—when President Clinton formally apologized for the Study at a ceremony honoring the Tuskegee participants at the White House in May, 1997, five of the survivors were there. And the harm done is still with us, in the form of distrust by poor African Americans of public health efforts, their reluctance to seek routine preventive care, and their unwillingness to participate in medical trials.

As the careful language of medical science proposes, the IRB’s most basic function is to minimize the potential for harm in human subject research, enable and protect individual autonomous choice about participating in that research, and promote the pursuit of new knowledge. IRB members must be skilled in reviewing research protocols and consent documents, and be able to evaluate compliance with applicable regulations and ethical guidelines. The added value brought to the process by members of the MCN IRB includes a broad range of experience and expertise in successfully dealing with the challenges of working with the marginalized, mobile poor, and the ability to help researchers develop research designs that take those challenges into account.

While having safeguards in place to minimize harm and protect autonomy satisfies critical ethical and moral concerns, promoting new knowledge is especially important when those being studied are uprooted and unsettled. Those who are out of sight tend also to be out of mind, and our knowledge about them is often lacking. The MCN IRB is devoted to enabling the contributions of more practitioners and researchers to the body of knowledge about “migration health,” in the process rendering the men, women, and children living and working in the shadows more visible.

The MCN IRB meets monthly, and responds to applications accepted for review within 45 days. All projects submitted receive a set of recommendations that provide advice and counsel on the protection of human subjects, and on research design. Currently serving on the MCN IRB are Chairperson Loretta Heuer, PhD, RN, North Dakota State University; Lawrence Li, MD, Community Health Centers of the Central Coast (CA); Andrew Morris, MD, Margaret R. Pardee Memorial Hospital (NC); George Davis, MD, Callan Family Care, (NY); Alice Larson, PhD, Larson Assistance Services (WA); Giulia Earle Richardson, PhD, NY Center for Agricultural Medicine and Health; and, James O’Barr, MSW, Hudson River HealthCare (NY). MCN staff support is provided by Deliana Garcia and Ann Marie Wilke.

To find out more about MCN’s IRB, and to download the complete application, go to the MCN website homepage, www.migrantclinician.org, and click on MCN Services. You can also reach MCN at (512) 327-2017.
Neurobehavioral Effects of Pesticide Exposure in Children

Diane S. Rohman, Center for Research on Occupational and Environmental Toxicology, Oregon Health & Science University

There is increasing concern that the use of pesticides in agriculture may be adversely affecting farmworker communities, including children. And this concern is well-founded. Detectable levels of agricultural pesticides have been documented in home dust, primarily in agricultural areas, where farmworkers transport pesticides from their clothing and hands into the home. Moreover, biological markers of pesticides have been documented in adults and children in agricultural communities, and levels of exposure are higher in residents of agricultural communities than non-agricultural communities. Furthermore, many farmworker families do not recognize the seriousness of pesticide exposures, have limited resources to pay for preventive health care and do not trust health care or government systems.

Organophosphate pesticides are of greatest concern due to their well-characterized neurotoxic effects and persistence once in the home. While the neurotoxic effects of acute organophosphate pesticide exposure are well established, chronic low-level exposure is poorly characterized in adults, and even more so in children. It is presumed that children of farmworkers are exposed to pesticides throughout development, which may produce subtle health effects that would not be detected by clinical examinations nor recognized by parents.

An ongoing research project conducted through the Pacific Northwest Agricultural Safety and Health Center is examining the health effects from chronic exposure to organophosphate pesticides in children to determine if they are associated with current home pesticide exposure and lifetime exposure measures. Methods to assess neurobehavioral functioning in school-age children and a measure of lifetime exposure to pesticides have been developed. Children’s exposure to pesticides from the parent’s work or residence in an agricultural community will be measured through dust samples collected from the home. Children will complete the neurobehavioral test battery a second time one year later to obtain longitudinal data that will be used to characterize developmental progress and relate that progress to exposure estimates.

Children More Vulnerable

Children can have greater exposure to toxicants than adults due to behaviors, such as crawling on the floor and increased hand-to-mouth contact, as well as to their greater surface area relative to body weight. Significant changes occurring in the brain during early development through adolescence make children especially vulnerable. Evidence from animal studies clearly demonstrates adverse effects of pesticides on neurodevelopment.

Evaluating Risk from Exposure

To assess risk to children it is necessary to associate measures of exposure with adverse outcomes, establishing a dose-response relationship. Studies examining pesticide exposure in children have used a variety of methods to classify exposure, including: environmental monitoring of indoor air, dust samples, and surface wipes; maternal and child exposure measures, such as urinary metabolites and acetyl cholinesterase level; and pesticide source information, including pesticide use, home inventory, proximity to agricultural fields, and parental occupation.

Pesticide Effects in Children

A variety of methodologies have been developed to evaluate the health effects of pesticides in populations ranging in age from prenatal to adolescent, and with varying exposure to pesticides, including acute poisoning incidents and chronic lifetime exposure.

The majority of studies have focused on the effects of chronic pesticide exposure, whether from parental occupation or living in an agricultural community. These studies were conducted in several countries and used a variety of methods, but all demonstrated deficits in performance, including increased behavioral problems as reported by parents, slower response speeds, visual motor and visual spatial deficits, and deficits in memory and learning.

Because of the rapid growth and development of children, there is a need for longitudinal studies to assess functional changes over time. Moreover, functional effects of early exposure may not become apparent until later in life. Three longitudinal birth cohort studies examining early exposure to pesticides are currently underway: the Mt. Sinai Children’s Environmental Health Study, the Mothers and Newborns Cohort Study at the Columbia Center for Children’s Environmental Health, and the University of California Berkeley Center for the Health and Assessment of Mothers and Children of Salinas. Both the Mt. Sinai and the Columbia Centers are focused on residential pesticide exposure in cohorts in New York City. The CHAMACOS study follows Latino mothers and children living in agricultural communities in California, where 75% of the homes have at least one household member working in agriculture. Although there are inconsistencies between the three studies when associations between exposure and outcomes are examined, more recent evidence demonstrates a convergence of findings across studies. Two studies have reported an association between prenatal exposure and pervasive developmental disorder assessed by the Child Behavior Checklist.

Conclusions

The methods used to measure pesticide exposure and assess development and performance in children varies across studies. Although there are methodological inconsistencies, the evidence suggests that pesticide exposures are associated with performance deficits and an increased reporting of developmental and behavioral problems in children. The current study will help to identify health effects associated with pesticide exposure in children living in agricultural communities.

References


Addressing the Need for Real Information about Highly Mobile Populations: 

Results of the Migrant and Seasonal Farmworkers Descriptive Profiles Project

Ann Marie Wilke, Migrant Clinicians Network

Migrant Health Centers (MHC) consistently need to document and report the characteristics of their target population, both for federal reporting purposes and to assist in planning services. Information such as family size, language needs, and frequency of migration is critical in planning for services. Due to a variety of factors, it is often the case that information is gathered, and responsive action taken, reactively rather than proactively, leaving MHC staff running to catch up.

An innovative project that tested various methods of gathering timely, accurate information about the migrant and seasonal farmworker (MSFW) population was initially featured in the February 2009 issue of Streamline. MCN staff and research consultant Alice Larson, PhD set out to develop a system for rapid access to data to aid Migrant Health Centers in planning and health care service delivery. Project results indicate that there are indeed self-sustaining methods that can provide continual, timely updates about the MSFW population at local, regional and national levels. Additionally, these methods foster collaboration between service providers to further enhance services of all agencies.

THE PROJECTS

Much of the work in the MSFW Profiles Project was to determine whether these methods of rapid information collection were feasible and would yield results in a broader, ongoing process. The project protocol was submitted for IRB review and approved.

Briefly, the three concepts piloted were:

1. Querying knowledgeable individuals who work frequently with the MSFW population through a key informant sentinel network, direct interviews, and small focus groups, can yield an accurate profile of MSFWs and identify changes in the population.

2. Strategic collection and comparison of utilization data from a consortium of local, federally-funded MSFW service agencies (e.g. Migrant Head Start) can be conducted periodically to yield a current profile of MSFWs.

3. Documentation of change factors for local agricultural and agricultural worker characteristics can inform service design and delivery.

RESULTS

The systems piloted successfully gathered current and informative data. The picture for MSFWs is fairly consistent nationally. A variety of national trends were identified including the pervasive negative effect of anti-immigrant practices and policies, which were significant factors in all regions. Another trend was a decrease in continued migration of many seasonal workers and families, as more and more MSFWs choose to settle in one location. Additionally, respondents queried indicated that they see more men migrating independently of their families, rather than families traveling together.

There were also regional differences identified. For example, there is more indigenous representation in the Western U.S. with corresponding language challenges. More individuals were seeking agricultural work in the East. However, there was a greater labor shortage in the West. Agricultural data gathered indicates industry shifts such as a decrease in hand labor crops occurring in some areas, while they are increasing in others (particularly the West), which could in turn have an affect on labor needs in those regions.

Respondents to the sentinel network and interviews also identified several challenges to successfully meeting the needs of their MSFW clients. They cited financial challenges, such as a loss of complementary funding (e.g. Medicaid). Cultural challenges included language differences and varying cultures of health. Overall, there seemed to be a pervasive sense of gloom concerning the availability of, and access to, health care for migrant and seasonal farmworkers.

CONCLUSIONS

There is a need for real-time, accurate information about the MSFW population. Respondents identified the assistance in planning and forecasting needs provided by the results as principal benefits of the systems piloted. They indicated that information yielded from these systems would allow them to anticipate need and proactively plan for both short and long term needs. Respondents were eager and willing to continue participation in data collection projects.

FUTURE PLANS AND POTENTIAL OUTCOMES

The continuation and expansion of the Sentinel Network of key informants could provide regular updates about the MSFW population. For example, during the initial H1N1 outbreak last year, such a network could have prepared clinicians to respond to potential needs.

Information gathered through these methods can make MHCs more proactive to the needs of mobile patients, resulting in more efficient and expeditious care. Additionally, the use of these systems to collect data can pinpoint areas of need to inform funding allocation and guide retention, and further recruitment of, healthcare professionals.

To view the February 2009 Streamline where this project was originally described, please visit: http://www.migrantclinician.org/files/MCN%20JanFeb09_f%20LR.pdf. For more details regarding this project, please contact Ann Marie Wilke, at 512-579-4509, or awilke@migrantclinician.org.
The U.S. Environmental Protection Agency (EPA) is taking action to end all uses of the insecticide endosulfan in the United States. Endosulfan, which is used on vegetables, fruits, and cotton, can pose unacceptable neurological and reproductive risks to farmworkers and wildlife and can persist in the environment.

New data generated in response to the agency’s 2002 decision have shown that risks faced by workers are greater than previously known. EPA also finds that there are risks above the agency’s level of concern to aquatic and terrestrial wildlife, as well as to birds and mammals that consume aquatic prey which have ingested endosulfan. Farmworkers can be exposed to endosulfan through inhalation and contact with the skin. Endosulfan is used on a very small percentage of the U.S. food supply and does not present a risk to human health from dietary exposure.

Makhteshim Agan of North America, the manufacturer of endosulfan, is in discussions with EPA to voluntarily terminate all endosulfan uses. EPA is currently working out the details of the decision that will eliminate all endosulfan uses, while incorporating consideration of the needs for growers to timely move to lower-risk pest control practices.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA must consider endosulfan’s risks and benefits. While EPA implemented various restrictions in a 2002 re-registration decision, EPA’s phase-out is based on new data and scientific peer review, which have improved EPA’s assessment of the ecological and worker risks from endosulfan. EPA’s 2010 revised ecological risk assessment reflects a comprehensive review of all available exposure and ecological effects information for endosulfan, including independent external peer-reviewed recommendations made by the endosulfan Scientific Advisory Panel.

Endosulfan, an organochlorine insecticide first registered in the 1950s, also is used on ornamental shrubs, trees, and herbaceous plants. It has no residential uses.

The 2010 National Summit of Clinicians for Healthcare Justice

The National Summit of Clinicians for Healthcare Justice, September 23-25, 2010 is a one-of-a-kind event sponsored by many of the major safety-net clinician organizations across the United States. The 2½ day event will attract clinicians and advocates from all over the country who will come together to celebrate, acknowledge and highlight the work frontline clinicians do to serve disenfranchised populations in need of basic healthcare in our country. The conference provides an opportunity for clinicians and others to explore cutting edge solutions and to be a part of the vital efforts to make quality health care for the underserved a reality.

The following are just a few of the many exciting speakers we are honored to have at the 2010 National Summit of Clinicians for Healthcare Justice.

**Dr. Linda Rae Murry, MD, MPH**  
Chief Medical Officer  
Ambulatory and Community Health Network  
Dr. Murray has spent her career serving the medically under served. She has worked in a variety of settings including practicing Occupational Medicine at a Workers Clinic in Canada, Residency Director for Occupational Medicine at Meharry Medical College, Bureau Chief for the Chicago Department of Health under Mayor Harold Washington.  
More recently Dr. Murray served as Medical Director of the federally funded health center, Winfield Moody, serving Cabrini Green Public Housing Project in Chicago. Dr. Murray has been an active member of a wide range of local and national organizations including serving as a member of the Board of Scientific Counselors for the Agency for Toxic Substances and Disease Registry (ATSDR), and the Board of Scientific Counselors for the National Institute of Occupational Safety and Health (NIOSH) and the Board of Directors of Trinity Health (a large Catholic Health system).

**Dr. David Satcher, MD, PhD, FAAP, FACPM, FACP**  
16th Surgeon General of the United States; Current Director, Center of Excellence on Health Disparities and the Satcher Health Leadership Institute of Morehouse School of Medicine  
Dr. Satcher served simultaneously in the positions of Surgeon General and Assistant Secretary for Health from February 1998 through January 2001 at the U.S. Department of Health and Human Services. In June 2006, Dr. Satcher established the Satcher Health Leadership Institute (SHLI) of Morehouse School of Medicine as a natural extension of his experience in improving public health policy for all Americans and his commitment to eliminating health disparities for minorities, the poor and other disadvantaged groups.

**Dr. Alvin D. Jackson, MD**  
Director  
Ohio Department of Health, Ohio’s Doctor  
Alvin D. Jackson, M.D., became director of the Ohio Department of Health (ODH) June 4, 2007, following his appointment by Gov. Ted Strickland in January. Dr. Jackson brings to ODH his holistic approach, the chronic disease prevention model of health care - a model in which patients are partners with their physicians in maintaining good health and charting courses of treatment when needed.  
Fluent in Spanish, Dr. Jackson comes to ODH from Community Health Services in Fremont, Ohio, where he provided primary medical care to rural residents and migrant workers since 1993 and served as medical director since 1995. Under Dr. Jackson’s leadership, Community Health Services expanded its reach from three counties to 12; reduced its no-show rate from 21 percent to 9 percent; opened a pediatric suite; and expanded its in-the-field care services, with the addition of a mobile clinic, for migrant workers.

**Maria E. Rosa**  
Vice President  
Institute for Hispanic Health  
Overall strategic and operations responsibility for the Institute for Hispanic Health program areas, which include diabetes, cardiovascular diseases, cancer, HIV/AIDS/STDs, Medicare, Alzheimer’s, genetics, reproductive health, and nutrition and exercise; co-directs the NCLR-CSULB (California State University, Long Beach) Center for Latino Health, Evaluation and Leadership Training, a joint initiative between NCLR and CSULB.

**Dr. Eduardo J. Sanchez, MD, MPH**  
Vice President and Chief Medical Officer  
Blue Cross and Blue Shield of Texas  
Eduardo J. Sanchez, M.D., M.P.H. serves as Vice President and Chief Medical Officer for Blue Cross and Blue Shield of Texas. Prior to this, he was the Director of the Institute for Health Policy at The University of Texas (UT) School of Public Health. Dr. Sanchez served as Commissioner of the Texas Department of State Health Services from 2004-2006 and the Texas Department of Health from 2001-

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**The National Summit of Clinicians for Healthcare Justice**

"Celebrate, Acknowledge and Highlight the Work of Frontline Clinicians"

Come together to celebrate, acknowledge and highlight the work of frontline clinicians who serve disenfranchised populations in need of basic healthcare.  
An opportunity to explore cutting edge solutions and to be a part of the vital efforts to provide quality health care for the underserved.

[www.allclinicians.org](http://www.allclinicians.org)

Let’s Make our Voices Heard!

September 23-25th, 2010  
DoubleTree Hotel Crystal City  
Washington, D.C.

For more information call (530) 345-4806
Delivering childhood vaccines does not improve mental development.
New research that followed more than 1,000 children over the course of seven to ten years shows that delivering childhood vaccines doctors recommend does not improve their mental development. In fact, the study revealed that children who received their vaccines on time did slightly better on some speech and language tests than their peers whose parents delayed or declined vaccination. Dr. Michael J. Smith of the University of Louisville School of Medicine, who helped write the study explains, “Our study shows that there is only a downside to delaying vaccines, and that is an increased susceptibility to potentially deadly infectious diseases...” The study of kids and vaccines appears in the June edition of the journal Pediatrics.
http://www.npr.org/blogs/health/2010/05/25/127108384/delaying-childhood-vaccines-doesn-t-improve-mental-development

Agricultural Child Laborers Constitute a Largely Unprotected Workforce
According to a new report by the Human Rights Watch, the United States is failing to protect hundreds of thousands of children engaged in often grueling and dangerous farmwork. Their recent report by Human Rights Watch found that child farmworkers risked their safety, health, and education on commercial farms across the United States. For the report, Human Rights Watch interviewed 59 children under age 18 who had worked as farmworkers in 14 states in various regions of the United States.

The full 99-page report is available for download at http://www.hrw.org

Health Alert: Mercury Toxicity and Face Creams
California Department of Public Health, Division of Environmental and Occupational Disease Control has identified several cases of mercury toxicity linked to the use of adulterated, unlabelled face creams in the Latino community.

Officials turn a blind eye to the widespread abuse of migrants in Mexico
According to a new report by Amnesty International, Mexican authorities must act to halt the continuing abuse of migrants who are preyed on by criminal gangs while public officials turn a blind eye or even play an active part in kidnappings, rapes and murder. Rupert Knox, Mexican Researcher at Amnesty International explained that “Migrants in Mexico are facing a major human rights crisis leaving them with virtually no access to justice, fearing reprisals and deportation if they complain of abuses.” The full report is available in both English and Spanish at: http://www.amnesty.org

Nursing Workforce More Diverse
A new study by HRSA reveals the increasing diversity of the nursing profession. The survey found that the RN workforce is gradually becoming more diverse. In 2008, 16.8 percent of nurses were Asian, Black/African-American, American Indian/Alaska Native, and/or Hispanic; an increase from 12.2 percent in 2004. Published every four years by HRSA’s Bureau of Health Professions, the National Sample Survey of Registered Nurses is the pre-eminent source of statistics on trends over time for the nation’s largest health profession; a final report with the complete findings will be published in summer 2010.

http://www.hrsa.gov/about/news/pressreleases/100317_hrsa_study_100317_finds_nursing_workforce_is_growing_and_more_diverse.html

The 2010 National Summit of Clinicians for HealthCare Justice continued from page 6

Dr. Winston F. Wong, MD, MS
Dr. Margaret Flowers, MD
Dr. Margaret Flowers is a Maryland pediatrician with experience as a hospitalist at a rural hospital and in private practice. She is currently the Congressional Fellow of Physicians for a National Health Program, working on single-payer health care reform full time. In addition to her activity with PNHP, an organization of 17,000 doctors who support single-payer national health insurance, she is a member of Healthcare-Now! of Maryland and a co-founder of the Conversation Coalition for Health Care Reform. Dr. Flowers obtained her medical degree from the University of Maryland School of Medicine and did her residency at Johns Hopkins Hospital in Baltimore.
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calendar

Society for Nutrition Education 2010 Annual Conference
July 24-27, 2010
Reno, NV
www.sne.org/conference

National Summit of Clinicians for Healthcare Justice
September 23-25, 2010
Washington, DC
www.allclinicians.org

National Association for Healthcare Quality Educational Conference
September 30-October 3, 2010
Kansas City, MO

2010 East Coast Migrant Stream Forum
October 21-23, 2010
Charleston, South Carolina
http://www.ncchca.org/

20th Annual Midwest Stream Farmworker Health Forum
November 17-20, 2010
Austin, TX
http://www.ncfh.org/