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PUBLIC HEALTH *Reports*

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The AIDS Memorial Quilt was conceived in 1987 by a small group of people in San Francisco as a way to memorialize those who had died from AIDS. Today, the Quilt includes more the 94,000 names and is approximately 1.3 million sq. ft. in size. For more information on the Quilt, visit www.aidsquilt.org.

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A Message from the Editor

Public Health Reports (*PHR*) has been reporting on infectious diseases since its inception in 1878. Through the years, our focus has shifted from the now mostly eradicated "communicable" diseases of the day, such as cholera and typhoid, to modern-day infectious diseases, such as human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), as well as historically difficult diseases such as hepatitis, which still present public health challenges despite significant progress.

In this issue, *PHR*'s focus on infectious diseases continues with articles on HIV/AIDS, varicella, hepatitis, and influenza. In the *Executive Perspective* column, and in concert with World AIDS Day on December 1, Dr. Ronald Valdiserri maintains that achieving an AIDS-free generation could be possible if we focus on "implementation science"—i.e., making sure that research findings and evidence-based interventions are actually integrated into health-care policy and practice. In a related article, Baral and colleagues describe a system—the Highest Attainable Standard of Evidence (HASTE)—for evaluating evidence specifically to assess HIV prevention interventions. The authors describe how practitioners and policy makers can use the HASTE system to facilitate the evaluation of biomedical, behavioral, and structural approaches for prevention interventions targeting the most-at-risk populations for HIV.

Since the introduction of the varicella vaccine in the 1990s, full-blown chicken pox—a once ubiquitous childhood disease—is becoming so uncommon that breakthrough cases are often mistaken for other conditions, thus delaying control measures and sometimes even resulting in school outbreaks. Daskalaki et al. surveyed pediatric health-care providers about laboratory testing practices for breakthrough varicella and concluded that as this disease becomes less common, laboratory confirmation will be even more critical for appropriate diagnosis. The authors' findings suggest that providers need more education regarding laboratory confirmation, containment, and reporting of breakthrough varicella.

Surveillance is the foundation for all public health actions, especially in identifying and tracking new and continuing pathogens. Focusing on the surveillance of acute hepatitis A, B, and C, Iqbal et al. found that while there have been successes in the electronic reporting of these three infectious diseases, providing adequate resources for such surveillance improves the quality of viral hepatitis surveillance data overall. Surveillance for viral hepatitis is critical, not only to measure the burden of disease, but also to identify and control outbreaks and facilitate targeted vaccination and other prevention initiatives.

While vaccination is one critical method of preventing infectious disease outbreaks, other prevention efforts can be just as important in minimizing the spread of disease. In their article on nonpharmaceutical strategies for minimizing the spread of influenza, Barrios and colleagues describe lessons learned during the 2009 H1N1 pandemic. They then present a framework for local and state public health officials and other community stakeholders to follow in selecting nonpharmaceutical strategies to minimize disease spread during such a pandemic.

This notion of prevention is also critical to improving the heart health of our nation. In her *Surgeon General's Perspectives* column, Dr. Regina Benjamin describes Million Hearts™, an initiative started last year by the Department of Health and Human Services and a number of public and private partners to prevent one million heart attacks and strokes by 2017. The initiative focuses on preventing cardiovascular disease, which is the leading cause of death in the U.S. Partners in the effort to raise awareness and educate consumers about heart health include federal agencies, state and local health departments, private health-care systems, and groups such as the American Heart Association and the YMCA. Of course, as public health practitioners, you can be doing your part to promote heart health. To find out how you can help prevent one million heart attacks and strokes by 2017, go to http://millionhearts.hhs.gov/be_one_mh.html.

Janice Huy, MS
Captain (Ret.), U.S. Public Health Service

Surgeon General's Perspectives

THE MILLION HEARTS™ INITIATIVE: PROGRESS IN PREVENTING HEART ATTACKS AND STROKES

VADM Regina M. Benjamin,
Surgeon General

We have good tools to prevent and treat heart disease and stroke, but they're not used enough. That is why, a year ago, the Department of Health and Human Services (HHS) along with a number of public and private partners launched Million Hearts™, an initiative that aims to prevent one million heart attacks and strokes by 2017.[1]

The initiative has taken strong aim at cardiovascular disease, including heart disease and stroke, which is the leading cause of death (responsible for one of every three deaths) in the United States. Together, heart disease and stroke kill more than 800,000 Americans and cost the nation approximately $444 billion each year. One out of every six dollars spent on health care is for treatment of cardiovascular disease, but those who are treated aren't "cured." Many continue to suffer from serious illness, disability, and decreased quality of life.[2–4]

Fortunately, Million Hearts is attacking this burden of illness and the associated social and economic costs through the approach to better health and well-being of the National Prevention Strategy—integration of clinical and community preventive services, empowered people, and elimination of health disparities. This comprehensive effort also emphasizes strong public/private collaboration. The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services are co-leaders of the initiative within HHS, working alongside other federal agencies including the Administration on Community Living, National Institutes of Health, Agency for Healthcare Research and Quality, Food and Drug Administration, and Veterans Administration. Private partners include the Y (YMCA), American Heart Association, America's Health Insurance Plans, American Pharmacists Association, Ohio State University, American College of Physicians, and American Nurses Association.

In its first year, the Million Hearts initiative has made tremendous progress in raising awareness among health-care professionals, patients, and communities about how they can help reach the goal of preventing one million heart attacks and strokes by 2017. Emphasis continues in two areas:

1. Reducing the number of Americans who need blood pressure or cholesterol treatment by empowering them to make healthy choices, including:
   - Not starting to smoke,
   - Being more physically active, and
   - Reducing their intake of sodium and transfats
2. Improving care for people who need treatment by focusing on the "ABCS" of heart attack and stroke prevention:
   - A—Aspirin therapy as appropriate
   - B—Blood pressure control
   - C—Cholesterol management
   - S—Smoking cessation

Controlling blood pressure was a primary focus in the initiative's inaugural year, which included the following activities:

- In May, Million Hearts promoted the Community Preventive Services Task Force's new recommendation that team-based care improves blood pressure control. The Task Force's review of 77 studies showed that patients' control of blood pressure

improved when their care was provided by a team of health professionals—including nurses and pharmacists—rather than by a single physician.[5]

- In September 2012, CDC published the latest data on the toll that hypertension takes among Americans. *Vital Signs: Awareness and Treatment Among U.S. Adults with Uncontrolled Blood Pressure* stated strongly that putting blood pressure control "front and center" for individuals, health-care providers, and health-care systems is the key to better control and reduced risk for heart attack and stroke.[6]
- Also in September, CDC launched the Team Up, Pressure Down campaign in support of Million Hearts to increase the number of pharmacists who provide advice, especially tips on taking blood pressure medications as prescribed, to their customers with high blood pressure. In addition, it aims to increase customers' awareness about the importance of asking the pharmacist for help with taking medications.

In 2012, public and private partners of Million Hearts emphasized a variety of the initiative's elements, ranging from educating consumers about heart health to sharing best practices of state health departments, private health systems, and others.

- The American Heart Association continued to support monitoring progress in achieving the initiative's goals and to offer consumers access to heart health management tools, including Heart 360®, My Life Check™, and the Heart Attack Risk Calculator.
- The Commonwealth of Virginia launched Million Hearts™ VA, a statewide approach to preventing heart attacks and strokes. Health districts, organizations, hospitals, providers, pharmacists, and Virginians were challenged to screen blood pressures in one million people during the month of May to highlight the importance of controlling hypertension—to prevent heart attacks and strokes—in Virginia.
- The Association of State and Territorial Health Officials is convening a series of webinars that share best practices and technical assistance from state health officials, chronic disease directors, and heart and stroke disease prevention leaders in their states.
- The National Consumers League incorporated Million Hearts goals into the activities of Script Your Future, a national campaign to raise awareness of medication adherence that features coordinated national communications and targeted outreach in six cities.
- The Virginia Health Quality Center and Virginia Department of Health's Heart Disease and Stroke Prevention Program (HDSP) led a session modeling how quality improvement organizations, HDSPs, and other Million Hearts partners can work together to enhance the state's capacity to plan, implement, track, and sustain population-based interventions to address heart disease, stroke, and related risk factors.
- The Virginia Pharmacists Association and Virginia Commonwealth University School of Pharmacy collaborated with employers to support the Virginia Health Commissioner's goal of screening one million Virginia residents for high blood pressure. Pharmacists and pharmacy students screened and counseled employees.
- The WomenHeart organization's support networks used educational materials developed by the Preventive Cardiovascular Nurses Association to educate women and families using a network of peer mentors on hypertension.

These examples are just a few of the contributions and progress that Million Hearts supporters are making toward preventing heart attacks and strokes. To be successful, we must continue to educate health professionals and the public about improving their ABCS and the benefits for individuals and society of living a healthier lifestyle.

I urge all public health professionals to learn more about the Million Hearts initiative and work within their own organizations and communities to sustain these efforts to prevent heart disease and stroke. Together, we can prevent more than one million heart attacks and strokes.

Regina M. Benjamin, MD, MBA
VADM, U.S. Public Health Service
Surgeon General

RESOURCES

Million Hearts (http://millionhearts.hhs.gov/index.html)

Heart 360® (https://www.heart360.org/Default.aspx)

My Life Check™ (http://mylifecheck.heart.org)

Heart Attack Risk Calculator (http://50.56.33.51/hart01/main_en_US .html)

Script Your Future (http://scriptyourfuture.org)

National Prevention Strategy (http://www.healthcare.gov/prevention/nphpphc/strategy/index.html)

REFERENCES

1. Department of Health and Human Services (US). Million Hearts: the initiative [cited 2012 Feb 12]. Available from: URL: http://millionhearts.hhs.gov/index.html
2. Department of Health and Human Services (US). Million Hearts: about heart disease & stroke: consequences and costs [cited 2012 Feb 12]. Available from: URL: http://millionhearts.hhs.gov/abouthds/cost-consequences.html
3. Roger VL, Go AS, Lloyd-Jones DM, Adams RJ, Berry JD, Brown TM, et al. Heart disease and stroke statistics—2011 update: a report from the American Heart Association. Circulation 2011;123:e18-209.
4. Heidenreich PA, Trogdon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation 2011;123:933-44.
5. Community Preventive Services Task Force. Cardiovascular disease prevention and control: team-based care to improve blood pressure control [cited 2012 Jul 31]. Available from: URL: http://thecommunityguide.org/cvd/RRteambasedcare.html
6. Centers for Disease Control and Prevention (US). Vital signs: awareness and treatment among U.S. adults with uncontrolled blood pressure [cited 2012 Jul 31]. Available from: URL: http://www.cdc.gov/VitalSigns/CardiovascularDisease/index.html

Letters to the Editor

USING ICD-9-CM E-CODES IN ADDITION TO CHIEF COMPLAINT KEYWORD SEARCHES FOR IDENTIFICATION OF ANIMAL BITE-RELATED EMERGENCY DEPARTMENT VISITS

We read with interest the article by Bregman and Slavinski demonstrating the use of emergency department (ED) data for animal bite surveillance.[1] Currently, the North Carolina Division of Public Health (NC DPH) utilizes statewide ED visit data for animal bite surveillance. Our experience has been that using International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) external cause-of-injury codes (E-codes), in addition to chief complaint and triage note keyword searches, enhances animal bite surveillance.

The North Carolina Disease Event Tracking and Epidemiologic Collection Tool (NC DETECT) is a statewide syndromic surveillance system created in 2004 by the NC DPH in collaboration with the Carolina Center for Health Informatics at the University of North Carolina Department of Emergency Medicine. Currently, more than 99% (115 of 116) of acute care hospitals in North Carolina submit ED visit data daily to NC DETECT, including chief complaints, triage notes, and up to 11 ICD-9-CM final diagnosis codes or E-codes. NC DETECT reports that are available to authorized users include an Animal Bite Keyword Report that contains ED visits with animal bite-related keywords in chief complaint or triage note fields and an Animal Bite ICD-9-CM Report that includes ED visits coded as E906 (Other injury caused by animals), E906.0 (Dog bite), E906.1 (Rat bite), E906.3 (Bite of other animal except arthropod), E906.5 (Bite by unspecified animal), and/or E906.9 (Unspecified injury caused by animal).

Animal bite surveillance using both ICD-9-CM E-codes and chief complaint keyword searches may result in increased surveillance sensitivity. From January 1, 2008, through December 31, 2010, there were 26,353 NC DETECT ED visits made by North Carolina residents with a dog bite E-code (E906.0). A chief complaint keyword search similar to that used by Bregman and Slavinski was employed on a 10% random sample (n=2,636) of the dog bite E-coded visits. There were 1,833 (69.5%) sample visits that contained the word "dog" or a common misspelling (e.g., dob or bog) and the word "bite" or some derivation (e.g., bit or bitten) in the chief complaint field. The word "animal" or a recognized mammalian animal (e.g., cat) and the word "bite" or some derivation of the word were found in the chief complaint fields of 281 (10.7%) sample visits. However, 522 (19.8%) dog bite E-coded sample visits would not have been identified as animal bite-related ED visits using only this keyword search criteria. In 411 (78.7%) of those 522 visits, the chief complaint field contained a description of the injury or its sequelae (e.g., a facial laceration or abscess), rather than specifying a bite.

Animal bite surveillance using ED visit data may vary by public health agency due to syndromic surveillance system capabilities, availability of ICD-9-CM codes, and the desired balance of surveillance sensitivity and specificity. However, ICD-9-CM final diagnosis codes and E-codes are considered part of a minimum dataset for syndromic surveillance systems using ED visit data.[2] Therefore, we encourage agencies that collect this data element to consider using animal bite-related ICD-9-CM E-codes in addition to chief complaint keyword searches for identification of animal bite-related ED visits.

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The Institutional Review Boards of the University of North Carolina at Chapel Hill and the North Carolina Division of Public Health approved this study. The North Carolina Public Health Data Group and NC DETECT do not take responsibility for the scientific validity or accuracy of the methodology, results, statistical analyses, or conclusions presented.

REFERENCES

1. Bregman B, Slavinski S. Using emergency department data to conduct dog and animal bite surveillance in New York City, 2003–2006. Public Health Rep 2012;127:195-201.
2. International Society for Disease Surveillance. Final recommendation: core processes and EHR requirements for public health syndromic surveillance, January 2011 [cited 2012 Apr 9]. Available from: URL: http://www.syndromic.org/meaningfuluse/EDdata

ERRATA

The article by Ayala et al., "Actions to Control High Blood Pressure Among Hypertensive Adults in Texas Counties Along the Mexico Border: Texas BRFSS 2007" in the March/April 2012 issue of *Public Health Reports*,[1] contained two typographical errors.

In Table 1 on page 176, the prevalence of taking antihypertensive medication among hypertensive males was inadvertently reported as 77.9% with a standard error of 0.9, the same values as for the total prevalence of adults in Texas taking antihypertensive medication. The correct prevalence for hypertensive males in Texas taking antihypertensive medication is 74.5% with a standard error of 1.6.

A second error also occurred on page 176, where it was incorrectly reported that "Hispanic adults were 40 times less likely to take action to control their hypertension (OR=0.6, 95% CI 0.5, 0.8) than non-Hispanic people." The correct statement is that "Hispanic hypertensive adults were 0.6 times as likely, or 40% less likely, to take action to control their hypertension (OR=0.6, 95% CI 0.5, 0.8) compared with non-Hispanic hypertensive adults." The authors and *PHR* regret the errors.

REFERENCE

1. Ayala C, Fang J, Escobedo L, Pan S, Balcazar HG, Wang G, et al. Actions to control high blood pressure among hypertensive adults in Texas counties along the Mexico border: Texas BRFSS 2007. Public Health Rep 2012;127:173-85.

Executive Perspective

World AIDS Day will be celebrated on December 1. The World AIDS Campaign sponsors this day, which promotes an international commitment to fighting AIDS through policy, practice, and resource allocation. Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases, U.S. Department of Health and Human Services, is a nationally recognized public health physician who has worked tirelessly to promote sound public health approaches to HIV/AIDS. In this column, Dr. Valdiserri provides insight into the challenges of achieving an AIDS-free generation. For more information on World AIDS Day, please visit http://www.worldaidscampaign.org/world-aids-day.

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ACHIEVING AN AIDS-FREE GENERATION: IT'S THE DETAILS THAT MATTER

Ronald O. Valdiserri, MD, MPH

The commemoration of World AIDS Day on December 1, 2012, provides an opportunity to remember those who have been lost to the epidemic of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) and an occasion to honor the individuals and communities that continue to work in pursuit of its eventual end. In the speeches and remarks delivered at multiple ceremonies, events, and observances, we are certain to hear about the phenomenal scientific progress that humankind has brought to bear against this brutal viral foe—scientific advances so profound that we have actually begun to talk, in practical terms, about achieving an "AIDS-free generation." We have every reason to anticipate a generation without the burden of AIDS as well as celebrate our hard-won progress in the fight against this disease—a fight that has returned spectacular dividends in terms of improved longevity, reduced mortality, and substantial hope where once there was only fear and despair.

But as we reflect on how far we've come since those early days of the epidemic, taking pride in our achievements and marveling at the sophistication of the scientific enterprise that has added such amazing tools to our AIDS armamentarium, we would do well to keep in mind the following caution. No matter the elegance of the controlled trial, the statistical significance of the results, or the superiority of the science, we must confront this inevitable reality: We will never be able to take full advantage of our progress in HIV clinical and prevention science until we develop and sustain the human, organizational, and structural capacities necessary to implement these new scientific breakthroughs. If we fail to attend to the "on-the-ground" details of implementation, we risk dissipating the promise of new drugs, novel therapies, and enhanced interventions that could, in fact, lead us to an AIDS-free generation.

A recent Institute of Medicine report on the integration of primary care and public health highlighted five key principles for successful integration: (*1*) focus on improving population health, (*2*) engage the community in defining and addressing health needs, (*3*) align leadership to foster continuity and manage change, (*4*) build infrastructure for enduring value and impact, and (*5*) actively share and use data to achieve health goals.[1] These broad principles were not identified in the context of a categorical disease issue such as HIV/AIDS. Instead, they were developed in response to the cross-cutting question, "How can the two major sectors of our health-care system better align their efforts and resources to improve health outcomes?" But a similar question can be posed in an AIDS-specific context: "What must we do, across all sectors of society, to promote the uptake and integration of proven and emerging research findings into existing systems of prevention and care in such a way that we can reduce new HIV infections, improve access to quality HIV care, and eliminate the existing disparities in health outcomes that have been well documented in the American HIV/AIDS epidemic?"[2]

Admittedly, this is not a new question. In the realms of both HIV prevention[3] and treatment,[4] analysts have observed that the adoption of new scientific findings and other technical innovations is usually not immediate, nor is it necessarily thorough. More typically, the uptake of scientific advances into policy and practice is influenced by myriad factors: biological, social, organizational, environmental, and contextual. And any

one of these factors—sometimes several—can exert a profound impact on implementation.[5] That is why the study of how best to integrate research findings and evidence-based interventions into health-care policy and practice—namely, implementation science—is being recognized more and more as a critical element of our societal response to the HIV/AIDS epidemic.[6]

What must we do to achieve a generation free of AIDS? We must begin by accepting the premise that if we support scientific inquiry *without* attending to the details of downstream implementation, we will fall short of our goal. The five principles of successful integration, outlined previously, can be repurposed so as to emphasize this bedrock tenet.

1. ***Address the social determinants that fuel the HIV/AIDS epidemic.*** What worth has a new therapy, no matter how effectively it halts viral replication, if the people most in need of treatment are unable to remain adherent because of unstable housing or other chaotic life circumstances?
2. ***Engage communities in finding solutions to HIV/AIDS.*** If we accept the fundamental premise that health is much more than the absence of disease, then we must commit to engaging communities in defining health as they see it and supporting their efforts, along with technical experts, to design and deliver successful HIV prevention and care programs.
3. ***Align leadership across various sectors to overcome HIV/AIDS.*** We cannot successfully address HIV/AIDS in our nation if we persist in treating it solely as a medical or public health problem. The complexity of this challenge calls for everyone to be involved: educators, parents, ministers, entrepreneurs, and entertainers.
4. ***Engineer public health and medical systems so they can incorporate emerging HIV research findings.*** Stated more plainly, we must build the infrastructure necessary to deliver the product! Selling a product, no matter how worthy, doesn't begin and end with its manufacture. The same can be said about actively promoting scientific advances. Our systems, processes, and workforce must be actively prepared to incorporate and support emerging findings—otherwise, the new science lies fallow.
5. ***Anticipate and adapt to changes in the epidemic.*** Our response to HIV/AIDS must be dynamic. It's not just science that evolves over time. Changes in demographics, economics, social norms, and practices—even the virus itself—can influence the trajectory of HIV prevention and care programs. Anticipating these trends requires that we collect, share, and use data proactively.

Hyperbole aside, we are closer than ever before to seeing an AIDS-free generation. Certainly, there are gaps in our knowledge base—not the least of which is the lack of a curative treatment or a vaccine to prevent HIV infection. But the knowledge and tools we do have at hand to curb the epidemic are formidable.[7] And we can make a difference. That is, if we are willing to pay attention to the details of implementation.

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The findings and opinions expressed in this article are those of the author and do not necessarily represent the official position of the U.S. government.

REFERENCES

1. Institute of Medicine. Primary care and public health: exploring integration to improve population health. Washington: National Academies Press; 2012.
2. White House Office of National AIDS Policy. National HIV/AIDS strategy for the United States. July 2010 [cited 2012 Jul 5]. Available from: URL: http://www.whitehouse.gov/administration/eop/onap/nhas
3. Valdiserri RO. Technology transfer: achieving the promise of HIV prevention. In: Peterson JL, DiClemente RJ, editors. Handbook of HIV prevention. New York: Kluwer Academic/Plenum Publishers; 2000. p. 267-83.
4. Markson LE, Cosler LE, Turner BJ. Implications of generalists' slow adoption of zidovudine in clinical practice. Arch Intern Med 1994;154:1497-504.
5. Madon T, Hofman KJ, Kupfer L, Glass RI. Public health. Implementation science. Science 2007;318:1728-9.
6. Schackman BR. Implementation science for the prevention and treatment of HIV/AIDS. J Acquir Immune Defic Syndr 2010;55 Suppl 1:S27-31.
7. Valdiserri RO. Commentary: thirty years of AIDS in America: a story of infinite hope. AIDS Educ Prev 2011;23:479-94.

Selecting Nonpharmaceutical Strategies to Minimize Influenza Spread: The 2009 Influenza A (H1N1) Pandemic and Beyond

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ABSTRACT

Shortly after the influenza A (H1N1) 2009 pandemic began, the U.S. government provided guidance to state and local authorities to assist decision-making for the use of nonpharmaceutical strategies to minimize influenza spread. This guidance included recommendations for flexible decision-making based on outbreak severity, and it allowed for uncertainty and course correction as the pandemic progressed. These recommendations build on a foundation of local, collaborative planning and posit a series of questions regarding epidemiology, the impact on the health-care system, and locally determined feasibility and acceptability of nonpharmaceutical strategies. This article describes recommendations and key questions for decision makers.

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In preparation for a severe influenza pandemic, the Centers for Disease Control and Prevention (CDC) issued *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions* in February 2007.[1] This document described tiers of nonpharmaceutical measures (e.g., dismissing students from school and using facemasks) that could be used for different pandemic severity levels, but primarily focused on measures for a 1918-like severe influenza pandemic. As influenza A (H1N1) pdm09 (hereafter, pH1N1) outbreaks began in the United States in April 2009, CDC released new guidance on nonpharmaceutical measures to state and local public health agencies and communities, and updated this guidance every three to four days based on rapidly changing epidemiologic and laboratory information as well as feedback from public health and education sector partners.

By May 2009, emerging data suggested that the pH1N1 outbreak was not as severe as the 1918 pandemic. Providing advisory measures that were well matched to the severity of the pandemic in the first few weeks proved challenging for several reasons: decisions were needed before much was known about the severity of the pandemic, pre-pandemic planning did not focus sufficiently on middle-range severity pandemics or how to use nonpharmaceutical strategies in a limited fashion, and communities varied widely in their experiences with pH1N1 and, accordingly, in their willingness to implement more disruptive measures. To address these concerns, during the summer of 2009, CDC held discussions with influenza experts, the U.S. Department of Education, and state and local public health and education officials to understand their concerns and inform further guidance.

METHODS

CDC and the U.S. Department of Education hosted a meeting with 19 education sector national nongovernmental organizations, the U.S. Department of Agriculture, and the U.S. Department of Defense Education Agency in Washington, D.C., on June 29, 2009, to address recommendations on the dismissal of students from schools. On July 1 and 2, 2009, CDC and the Council of State and Territorial Epidemiologists (CSTE) held a joint meeting in Atlanta, Georgia. This meeting was followed by weekly conference calls with CSTE and the Association of State and Territorial Health Officials (ASTHO) membership. These calls were used to present draft guidance and receive CSTE and ASTHO input. Additional input was sought from and provided by federal agencies including the Environmental Protection Agency, U.S. Department of Homeland Security, U.S. Department of Labor, Administration for Children and Families Office of Head Start, U.S. Small Business Administration, and U.S. Department of Commerce. Based on this feedback, CDC released new guidance documents in August 2009 on selecting and implementing nonpharmaceutical measures for schools, colleges/universities, child care programs, and employers.[2–5] These new guidance materials established a framework for flexible decision-making based on outbreak severity, allowing for the uncertainty inherent in this type of decision-making process. The centerpiece of the guidance documents was a set of key questions to determine which nonpharmaceutical strategies to use and when.

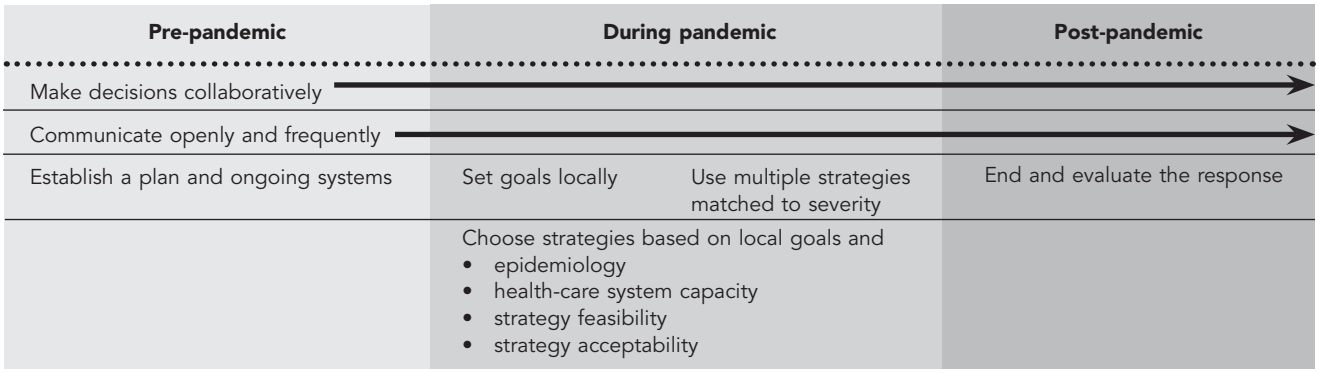
Beginning in fall 2009, CDC provided technical assistance to the Harvard School of Public Health as its staff conducted repeated polls assessing public perceptions and acceptance of community mitigation guidance.[6,7] In addition, during fall 2009 and winter 2010, CDC conducted opinion leader calls and focus groups with administrators, staff, and families from K–12 schools, institutions of higher education, and early childhood programs, as well as with employers representing both large and small businesses.

CDC used the findings from these formative evaluation activities to finalize the framework presented in this article. The framework is intended for use by state and local public health officials in collaboration with appropriate stakeholders such as education officials or large local employers.

A FRAMEWORK FOR SELECTING NONPHARMACEUTICAL STRATEGIES TO USE DURING AN INFLUENZA PANDEMIC

Nonpharmaceutical measures are critical components of the earliest response to a developing pandemic, prior to distribution of an effective vaccine. While they remain important after vaccine introduction to continue to assist in slowing the spread of influenza, their impact is likely to be greater when used in combination with pharmaceutical measures, such as vaccines or antiviral medications. The severity of a pandemic is unlikely to be known early in a response, and local priorities and conditions are likely to vary. To be effective in responding to a pandemic, planners must engage a variety of partners, collaborate effectively to develop a plan, make explicit the goals of their response, select strategies in a thoughtful process based on those goals and data, and evaluate the response for lessons learned (Figure). Although some aspects of this work

Figure. A framework for selecting nonpharmaceutical strategies to use during an influenza pandemic



NOTE: Planners should engage a variety of partners, collaborate effectively to develop a plan, explicitly define goals, select strategies based on goals and data, and evaluate their response. Although some components occur before, during, or after a pandemic, much of the strategy involves concurrent data collection, discussion, and iterative reassessment.

must occur before, during, or after a pandemic, much of any response involves concurrent data collection, discussion, and iterative reassessment.

Make decisions collaboratively

The key to successful implementation of a chosen course of action is that stakeholders understand and support the recommendations made. The best way to achieve stakeholder support is to include, in a collaborative decision-making process established in advance of a pandemic, representatives of groups who will implement or be affected by the course of action. State and local public health officials should collaborate with staff from other government agencies, such as education, transportation, and emergency response, to decide which strategies to implement and when, collect and share data, and disseminate emerging guidance. Neighboring states or other jurisdictions should communicate regularly to ensure that differences in response plans across jurisdictions are well understood and communicated to the public and other stakeholders. Other likely stakeholders include representatives of local businesses, health-care providers, community- and faith-based organizations, and families and representatives of targeted settings (e.g., schools, universities, child care programs, and nursing homes.) These groups bring multiple data sources, perspectives, and values; including these groups makes for a richer decision-making environment. Collaborative decision-making, based on shared values, allows for more consistent action by all stakeholders.[8] The need for rapid decisions in emergencies can limit opportunities for collaborative decision-making, especially if relationships and processes are not already well-established.

Elected and appointed officials, which are a specific type of stakeholder, often feel tremendous pressure to act immediately in a crisis. This inclination runs counter to the scientist's natural preference for more data. Officials prefer to be given a single recommendation with clear outcomes; scientists may prefer to provide pros and cons of various choices. Given these competing demands, scientific decision makers should avoid promising specific outcomes. Instead, they should explain how and why decisions will be made and how further data will be used to close the gap between the recommended action and the expressed goal. Most importantly, state and local public health officials should establish trust with elected and appointed officials before a pandemic. A trusting relationship can help ensure that decisions made during a pandemic are based on the best available scientific information.

Communicate openly and frequently

Frequent, open communication with the public, other government agencies, state and local partners, and community stakeholders is essential to effective implementation. The consequences of over- or under-reacting should not be underestimated. If CDC, state, or local agencies overreact by recommending or instituting very disruptive measures, communities and families can incur great costs with only minimal benefits, and the agencies' future recommendations could be perceived as less credible. If these agencies under-react, more people might become ill, including severely ill, or die. Ultimately, the success of nonpharmaceutical strategies depends on individual and collective actions of community members. For example, employers need to understand that if their sick-leave policies align with

public health policies, ill people may be more likely to stay home during a pandemic, benefiting both the business and the community. The public must understand the rationale for recommendations and be willing to accept disruption based on perceived risk.

Relationships with local media should be established before a pandemic. During a pandemic, state and local public health officials should work with media and trusted sources in communities to (*1*) describe the nonpharmaceutical strategies being implemented and dispel rumors, (*2*) clarify goals and rationale, (*3*) inform the public when and why response strategies change, (*4*) disseminate clear information about what the public should and should not do, and (*5*) communicate uncertainty as well as the likelihood for changing course as new information emerges.

Establish a plan and ongoing systems before a pandemic

Decisions about nonpharmaceutical strategies to use during a pandemic should be based on an existing plan and within the context of a standard emergency response framework, such as the Incident Command System.[9] Given inevitable uncertainty, it is critical that plans avoid a locked-in fixed response and be flexible enough to respond to uncertainty and, ultimately, to evolving pandemic scenarios of different severities. Planning assumptions in underlying scenarios must be explicit so that they can be evaluated against the reality of an emerging event. Plans should frequently be reviewed, tested, and revised (as needed) in collaboration with partners and stakeholders and as part of ongoing emergency preparedness activities. Plans should address legal authorities and policies, including which agencies or officials are authorized to implement measures such as closing schools, and which decision makers need to be involved in planning and implementation. Plans also should describe the methods that will be used to evaluate whether selected measures meet the goals set by the state or community.

A strong, ongoing influenza surveillance system, capable of providing timely data for a range of age groups, is critical for decision-making during a pandemic but must be established in advance. Information on seasonal influenza-related illness, doctor's office visits, hospitalizations, emergency department visits, intensive care unit (ICU) admissions, workplace and school absenteeism, and deaths can greatly help the state or community determine the impact of the pandemic over and above seasonal influenza.

Set goals locally

CDC will monitor an evolving pandemic, look for changes in illness severity and the virus itself, and share what is learned with state and local agencies and the public. However, communities are likely to be affected differently and at different times. Communities also may set different prevention and mitigation goals. Feasibility and acceptability of intervention strategies will vary across communities as well. Therefore, local decisions should be based on local circumstances and not national data alone.

Decision makers should explicitly set, prioritize, and communicate the goals they hope to achieve by implementing nonpharmaceutical strategies whether that be reducing overall transmission of the influenza virus or reducing transmission in certain settings. For example, depending on illness severity and the age groups most affected, a community might place a higher priority on implementing strategies in schools or nursing homes. Decision makers likely will need to decide which population groups most need protection. They could select strategies likely to reduce overall transmission or place a higher priority on those at increased risk for serious complications from influenza (e.g., people with chronic medical conditions). Decision makers must balance the risk of influenza transmission, impact of disease, and community functioning. They should consider how much the pandemic is disrupting community functioning and the health outcomes of those who become ill and examine whether (further) disruption is necessary and tolerable when selecting measures.

Use multiple strategies matched to outbreak severity

Decision makers should understand the types of nonpharmaceutical strategies available to them and consult the best available implementation, policy analysis, and evaluation science. Using multiple strategies early and in a coordinated fashion may be more effective in reducing transmission than using a single strategy.[10,11] Specific strategies are designed to affect influenza transmission at different times in the transmission process and in a pandemic. For example, social distancing measures (e.g., school dismissals) are intended for preemptive use and must be applied early and comprehensively throughout a community to be most effective.[12] Once disease is in a community, aggressive monitoring of symptoms and swift isolation at the beginning of symptoms, as well as antiviral prophylaxis for household members might delay community transmission.[13–15] Hand hygiene and cough etiquette may reduce the likelihood of transmission from an infected person to someone else. The availability of

pharmaceutical strategies such as vaccines and antiviral medications will influence which nonpharmaceutical strategies to implement as well. Because each strategy works in a different way, the effectiveness of the overall response would be expected to be greater when multiple strategies are simultaneously used. Appropriate matching of the intensity and type of intervention to the severity of a pandemic is important to maximize the public health benefit that may result from using these measures while minimizing untoward secondary effects. Decision makers should answer the following questions to help set goals locally and make collaborative decisions about the best strategies to use.

Examine the epidemiology. Federal, state, and local data can be used in combination to generate an epidemiologic picture of a pandemic and its likely local effects. It is unlikely that most states or cities will be able to answer all of the questions listed subsequently. Additionally, data on outbreaks that begin outside the U.S. might be contradictory, difficult to interpret, or of questionable validity for the U.S. context. The following are questions for state and local health officials to consider:

- What is the extent of the spread of influenza-related illness? Regional? National? Global?
- Who is most affected? Consider age groups, regions, and vulnerable populations.
- What is the course of the disease? Do people become severely ill soon after symptoms arise?
- What is the number/rate of outpatient visits for influenza-like illness? What proportion of those visits is due to confirmed influenza?
- What percentage of people with influenza-like illness are hospitalized?
- What percentage of hospitalized patients need ICU, advanced care, or respirators?
- How many deaths are occurring and among which groups?
- How are populations at increased risk for serious complications from influenza distributed within the jurisdiction? What is the likely effect on these populations?

Health officials are not the only potential sources of useful information to assess the extent of the pandemic. Education agencies, child care licensing offices, universities, pharmacies, businesses, and chambers of commerce also are potential sources of valuable data. For example, education agencies might be able to share their student and staff absenteeism rates, school health office visits, and numbers of students and staff with influenza-like symptoms leaving during the school day. Large local employers may be able to report trends in employee absenteeism.

Consider health care. A pandemic can overburden the health-care system. This occurs when there are not enough health-care providers, hospital beds, emergency room capacity, ICU spaces, ventilators, or medicines available to provide adequate care for influenza- and non-influenza-related medical conditions. During a severe pandemic, ill people, as well as people who are not ill but worried, may be more likely to seek medical care. When health-care systems cannot provide adequate care, mortality and costs are likely to increase. The impact of influenza on the health-care system will influence decisions about the types, numbers, and timing of nonpharmaceutical strategies. Questions to consider include the following:

- Are health-care providers and hospitals able to accommodate the increase in influenza-related visits they are receiving or may receive?
- Are there enough resources such as staffed hospital beds, medications, and ventilators?
- Is there enough capacity in emergency departments and ICUs to accommodate an increased demand?
- Is absenteeism increasing among health-care workers due to influenza-like illness in themselves or their family members?
- Is there enough antiviral medicine to treat people at increased risk for influenza-related complications or who have more severe illness?
- Are effective vaccines available? If not, when will they be available in the state or locality and how will they be distributed?

Determine feasibility. Decision makers need to consider implementation-related issues that can limit their available strategy options. Balancing information on severity, spread, affected populations, and local goals with a critical examination of the feasibility of each strategy option requires asking questions such as the following:

- Do strategies need to be implemented in a particular order? If so, what should be done first?
- Are changes to legal authority or policy needed? If so, how feasible are these changes?
- How long will specific strategies take to get started? For how long can they be sustained?
- What resources (e.g., funds, personnel, equipment, and space) are needed and available to implement the strategies?

- What obstacles could decrease the effectiveness of the strategies?
- What can be done to improve adherence to nonpharmaceutical strategy recommendations?

Determine acceptability. Community support is critical to strategy implementation. Although the most disruptive nonpharmaceutical strategies (e.g., prolonged school dismissals or child care facility closures) are unlikely to be used in less severe pandemics, several strategies can have negative secondary effects, disrupting families and communities.

Strategies are more likely to be implemented fully and effectively if the public is prepared, if they perceive the same level of severity of influenza-related illness as decision makers, or if they believe that the strategy will be effective. Risk perceptions can vary across time and place and be influenced by media attention.[16] Polling might be an effective tool for gathering information about risk perceptions and strategy acceptability in a time frame that is useful for decision-making.[6,7] The following questions can guide analyses of strategy acceptability and methods for increasing acceptability:

- What are public concerns about the influenza pandemic? Do people believe they are likely to be infected? Do they believe many people could become seriously ill or die?
- Do social norms and public opinion support or reject specific strategies under consideration?
- What communication efforts can be used to explain the need for the strategies to the public? What can be used to minimize or dispel rumors and misinformation and spread correct information? Who should be the spokesperson to communicate with the public?
- How should guidance be adapted for use with multiple audiences?
- How can expected benefits be measured and shared with the public?
- What negative effects (e.g., detrimental effects on child nutrition, job security, financial support, or educational progress) could occur? How could negative effects be reduced?
- What can be done to increase community buy-in and support?
- What can be done to increase the public's self-efficacy for implementing protective actions?

End and evaluate the response

Careful monitoring of the evolution of a pandemic allows for detection of changes in severity or waning of the outbreak. Knowing when and how decisions will be made about stopping strategies is as important as knowing when to start them. Planning for ending and evaluating a response should happen early in the response process, engaging the same stakeholders in a collaborative decision-making process. Discussions should encompass criteria for removing nonpharmaceutical strategies and returning to normal operations, and should take into account how difficult it will be to stop each implemented measure. Plans should address whether some strategies should be continued for a longer period of time.

Evaluation activities, for example, after-action reviews, should address both processes (i.e., how well strategies were implemented) and outcomes (i.e., how effective they were in achieving the goals). Evaluation should not be an academic exercise: care should be taken to determine how lessons learned will be applied to future planning.

CONCLUSIONS

It is impossible to predict when the next influenza pandemic will occur or what its severity will be. Decision makers must be flexible and willing to change course based on information about the virus, epidemiology, and the acceptability of responses as new information becomes available. Decision-making in a pandemic is an ongoing process—not a one-time activity. Current plans should be reviewed and revised based on lessons learned during the pH1N1 pandemic.[6,7,17–22] However, as that experience illustrated, we can never conceive of all possible scenarios ahead of time, will always want additional information, and need a flexible framework for making and communicating decisions. Despite advances in vaccine production and distribution, it is unlikely that a well-matched vaccine will be available at the onset of the next pandemic. Nonpharmaceutical strategies will be needed to help slow the spread of influenza in conjunction with other measures; the judicious use of these measures may yield the best results. Using a standard framework, such as the one described in this article, can provide a structure for making decisions.

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REFERENCES

1. Centers for Disease Control and Prevention (US). Interim pre-pandemic planning guidance: community strategy for pandemic influenza mitigation in the United States—early, targeted, layered use of nonpharmaceutical interventions. Atlanta: CDC; 2007. Also available from: URL: http://www.flu.gov/planning-preparedness/community/community_mitigation.pdf [cited 2012 Mar 8].
2. CDC (US). CDC guidance for state and local public health officials and school administrators for school (K–12) responses to influenza during the 2009–2010 school year. Atlanta: CDC; 2009. Also available from: URL: http://www.cdc.gov/h1n1flu/schools/schoolguidance.htm [cited 2012 Apr 11].
3. CDC (US). CDC guidance for responses to influenza for institutions of higher education during the 2009–2010 academic year. Atlanta: CDC; 2009. Also available from: URL: http://www.cdc.gov/h1n1flu/institutions/guidance [cited 2012 Apr 11].
4. CDC (US). CDC guidance on helping child care and early childhood programs respond to influenza during the 2009–2010 influenza season. Atlanta: CDC; 2009. Also available from: URL: http://www.cdc.gov/h1n1flu/childcare/guidance.htm [cited 2012 Apr 11].
5. CDC (US). Guidance for businesses and employers to plan and respond to the 2009–2010 influenza season. Atlanta: CDC; 2009. Also available from: URL: http://www.cdc.gov/h1n1flu/business/guidance [cited 2012 Apr 11].
6. SteelFisher GK, Blendon RJ, Bekheit MM, Lubell K. The public's response to the 2009 H1N1 influenza pandemic. N Engl J Med 2010;362:e65.
7. Parental attitudes and experiences during school dismissals related to 2009 influenza A (H1N1)—United States, 2009. MMWR Morb Mortal Wkly Rep 2010;59(35):1131-4.
8. Snowden DJ. The paradox of story: simplicity and complexity in strategy. Scenario and Strategy Planning 1999;1:16-20.
9. Federal Emergency Management Agency (US). Incident Command System review material. Washington: FEMA; 2008. Also available from: URL: http://www.training.fema.gov/EMIWeb/IS/ICSResource/assets/reviewMaterials.pdf [cited 2010 Dec 1].
10. Markel H, Lipman HB, Navarro JA, Sloan A, Michalsen JR, Stern AM, et al. Nonpharmaceutical interventions implemented by US cities during the 1918–1919 influenza pandemic [published erratum appears in JAMA 2007;298:2264]. JAMA 2007;298:644-54.
11. Halloran ME, Ferguson NM, Eubank S, Longini IM Jr, Cummings DA, Lewis B, et al. Modeling targeted layered containment of an influenza pandemic in the United States. Proc Natl Acad Sci 2008;105:4639-44.
12. Davey VJ, Glass RJ, Min HJ, Beyeler WE, Glass LM. Effective, robust design of community mitigation for pandemic influenza: a systematic examination of proposed US guidance. PLoS One 2008;3:e2606.
13. Bell DM; World Health Organization Working Group on Prevention of International and Community Transmission of SARS. Public health interventions and SARS spread, 2003. Emerg Infect Dis 2004;10:1900-6.
14. Van Gemert C, Hellard M, McBryde ES, Fielding J, Spelman T, Higgins N, et al. Intrahousehold transmission of pandemic (H1N1) 2009 virus, Victoria, Australia. Emerg Infect Dis 2011;17:1599-607.
15. Pang X, Yang P, Li S, Zhang L, Tian L, Li Y, et al. Pandemic (H1N1) 2009 among quarantined close contacts, Beijing, People's Republic of China. Emerg Infect Dis 2011;17:1824-30.
16. Ibuka Y, Chapman GB, Meyers LA, Li M, Galvani AP. The dynamics of risk perceptions and precautionary behavior in response to 2009 (H1N1) pandemic influenza. BMC Infect Dis 2010;10:296.
17. Nicoll A, Coulombier D. Europe's initial experience with pandemic (H1N1) 2009—mitigation and delaying policies and practices. Euro Surveill 2009;14:pii 19279.
18. Chao DL, Halloran ME, Longini IM Jr. School opening dates predict pandemic influenza A (H1N1) outbreaks in the United States. J Infect Dis 2010;202:877-80.
19. Chu CY, Li CY, Zhang H, Wang Y, Huo D, Wen L, et al. Quarantine methods and prevention of secondary outbreak of pandemic (H1N1) 2009. Emerg Infect Dis 2010;16:1300-2.
20. De Serres G, Rouleau I, Hamelin ME, Quach C, Skowronski D, Flamand L, et al. Contagious period for pandemic (H1N1) 2009. Emerg Infect Dis 2010;16:783-8.
21. Gift TL, Palekar RS, Sodha SV, Kent CK, Fagan RP, Archer WR, et al. Household effects of school closure during pandemic (H1N1) 2009, Pennsylvania, USA. Emerg Infect Dis 2010;16:1315-7.
22. Wu JT, Cowling BJ, Lau EH, Ip DK, Ho LM, Tsang T, et al. School closure and mitigation of pandemic (H1N1) 2009, Hong Kong. Emerg Infect Dis 2010;16:538-41.

The Highest Attainable Standard of Evidence (HASTE) for HIV/AIDS Interventions: Toward a Public Health Approach to Defining Evidence

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ABSTRACT

Objectives. Evidence-driven decisions have become a standard for health interventions, policy, and programs. While randomized controlled trials (RCTs) are encouraged for public health interventions, there are limitations with RCTs as the gold standard of evidence for HIV interventions. We developed a novel system of evaluating evidence for assessing HIV preventive interventions termed the Highest Attainable Standard of Evidence (HASTE).

Methods. The HASTE system focuses on triangulation of three distinct categories of evidence: efficacy data, implementation data, and plausibility. We conducted systematic reviews, including experimental and observational data, to assess all available interventions for men who have sex with men (MSM). We collected implementation and programmatic data using a global electronic consultation, Internet searches, and in-person consultations. We assessed plausibility with expert analyses of both biological and public health evidence.

Results. HASTE includes four grades of evidence: Strong (Grade 1), Conditional (Grade 2), Insufficient (Grade 3), and Inappropriate (Grade 4). We used the HASTE system to evaluate the evidence for HIV interventions for MSM in low- and middle-income countries. Several differences emerged in the strength of recommendation with the use of the HASTE system, including strong recommendations for voluntary counseling and testing and for structural interventions.

Conclusions. The HASTE system addresses a need for an evidence evaluation tool that is specific for HIV interventions and facilitates an evaluation of biomedical, behavioral, and structural approaches using the highest standard of attainable evidence. HASTE represents a tool that balances scientific integrity and practicality in assessing the quality of evidence of preventive interventions targeting the most-at-risk populations for HIV.

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Evidence-based decision-making has become a global standard for health interventions, policy, and programs. In the human immunodeficiency virus (HIV) arena, this methodology has been a welcome trend. While randomized controlled trials (RCTs) with HIV endpoints are encouraged for public health interventions, there are limitations with using RCT as the gold standard of evidence for HIV interventions.[1–3] These limitations include the very high cost of efficacy trials, the relative scarcity of populations with sufficient incidence in which to mount trials, and the ethical imperative to compare experimental treatments with ever more potent control conditions, which can mitigate the ability to assess efficacy. In addition, some interventions have never been formally evaluated with RCTs but have demonstrated significant impact from implementation and observational research, making RCTs now either unfeasible or ethically challenging. An example of this limitation is the use of needle and syringe exchange programs for injecting drug users (IDUs), for which many would argue the window of opportunity to conduct an RCT has long passed.[4]

Within the realm of clinical medicine, evidence-based medicine (EBM) is now considered the basis by which to define standards of clinical care. Defining packages of clinical services has been predicated on systematic reviews of individually randomized double-blinded placebo-controlled trials of medications and/or services for patients with varying clinical conditions. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system has been widely endorsed as the most effective method with which to grade the current state of evidence for a variety of clinical interventions.[5,6] The GRADE system was designed for individual-level clinical interventions in which the traditional hierarchy of evidence is applied. Specifically, the highest-quality evidence is derived from double-blinded placebo-controlled RCTs, followed by unblinded RCTs, prospective cohort studies, case-control studies, clinical case series, and consensus among experts. Additional weight is given to appropriately executed systematic reviews and meta-analyses of studies with little heterogeneity among participants, methods, and results.

To further standardize the presentation of evidence in clinical interventions and meta-analyses, criteria including the Consolidated Standards of Reporting Trials (CONSORT) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were developed, which have facilitated the grading of evidence.[7,8] Given the nature of individual-level clinical interventions, the GRADE system has facilitated the development of clinical practice guidelines and other clinical practice tools to promote the practice of EBM.[9] The GRADE system is also relevant, as it integrates the potential for a separation between quality of evidence and strength of recommendations based on extenuating circumstances, such as cost-efficacy, risk-benefit, and contextual factors.[10]

While there is general acceptance of the use of the GRADE system in clinical medicine, there has been no widely accepted standard for grading public health interventions, although a series of different algorithms and hierarchies of evidence have been proposed.[1,11–13] Varying algorithms of evaluating public health interventions are also in use by the International Agency for Research on Cancer, the United States Preventive Services Task Force (USPSTF), the newly revived Canadian Task Force on Preventive Health Care (CTFPHC), and the National Institute for Health and Clinical Excellence in the United Kingdom, among others. While Hill's criteria for causality, including strength of the relationship, dose-response, temporality, experimental evidence, analogy, and biologic plausibility, still apply to public health interventions, it is more difficult to demonstrate efficacy using traditional evaluation strategies.[14] One reason for this difficulty is that public health interventions tend to be context-specific, including geographic and socioeconomic contexts, and are generally multifaceted. Moreover, primary prevention strategies targeting at-risk populations may be subject to the prevention paradox first described by Rose.[15] The prevention paradox describes a situation in which an effective population-level public health intervention may provide only little benefit at the individual level while being significant at the population level, thereby complicating the measurement of effectiveness or efficacy.[16]

There is an emerging awareness of the significant roles the key or most-at-risk populations (MARPS) may play in HIV epidemics. Many country epidemics began as concentrated epidemics among MARPS including gay men and other men who have sex men (MSM), sex workers, and IDUs, and then transitioned to more generalized epidemics. The role of MARPS in concentrated epidemics is relatively uncontroversial. However, in generalized epidemic settings, the initial presentation of numerous HIV epidemics was among MSM.[3,4] With the emergence of generalized epidemics, the role of these three MARPS and other country-specific MARPS, such as truckers, internally displaced people, and victims of gender-based violence, has been given less attention. However, there is a growing evidence base of disproportionate risk among MARPS including sex workers, MSM, and IDUs in these settings.[17,18] Recent assessments of global HIV prevention suggest that few

HIV/acquired immunodeficiency syndrome (AIDS) prevention, treatment, and care programs include targeted programming for these populations.[19] Given this lack of funding, infections continue to increase in the context of slowing epidemics in the general population and, with the exception of IDUs, there has been limited progress in defining the optimal package of services for MARPS in low- and middle-income settings.

In response to this lack of progress, our multidisciplinary team worked to develop a novel system of evaluating evidence for HIV interventions targeting decreasing HIV risk specifically among MSM. We propose the use of the term the "Highest Attainable Standard of Evidence" (HASTE). HASTE was initially used to define a package of services for preventing HIV infection among MSM in low- and middle-income countries (LMIC). Other derivatives of the GRADE system have been suggested, including by Tang et al.[13] When stigma affecting MARPS is compounded with the difficulties and limitations of RCTs evaluating public health intervention with biological endpoints, the evidence base for any HIV intervention supporting these vulnerable populations is limited. Thus, while our initial intent was to use the GRADE methodology to evaluate individual interventions, it became clear that the system required modifications to include assessment of what we termed HASTE. HASTE deliberately echoes the language of human rights conventions on the right to health, which accept that what can realistically be attained in resource-constrained environments can still serve as life-saving aspirational goals.[20,21] The aspiration was to develop a system that balances scientific integrity with the need to make recommendations for prevention programming and policies for an understudied and underserved population.

METHODS

The HASTE process

The HASTE system proposed in this article is specific to HIV interventions among MSM and focuses on the triangulation of three main characteristics: efficacy data, implementation data, and biological and public health plausibility, although it may be adaptable to other public health areas and disciplines. The inclusion of a review of efficacy data is a common denominator across all systems evaluating levels of evidence. However, the response to preventing HIV infection has differed compared with most other clinical conditions in that implementation of these preventive measures is generally managed by civil society and not-for-profit nongovernmental institutions rather than health-care facilities. Although RCT data from interventions are often unattainable, these interventions constitute a predominant majority of HIV prevention services in LMIC. Thus, our group considered capturing these implementation data that are crucial in informing the optimal package of services for MSM.

Hill's criteria for causality remain as the most relevant set of determinants of whether a risk factor causes disease or an intervention causes prevention or mitigation of a disease. One of these criteria is plausibility, and our group considered this criterion vital, similar to others before us.[13] However, in considering the public health plausibility of an intervention, we assessed whether a preventive intervention with limited demonstrated efficacy in preventing HIV as a biological endpoint was within the causal pathway of another intervention that does have demonstrable effectiveness in preventing HIV infection. We will use the example of the role of voluntary counseling and testing to illustrate the importance of public health plausibility for the HASTE system (Figure 1).

To review the evidence for effective interventions to prevent HIV among MSM, we used a process first proposed by the Centers for Disease Control and Prevention's (CDC's) Community Preventive Services Task Force when developing an evidence-based guide to public health interventions.[10] This process included forming a multidisciplinary team, developing an approach to assessing the evidence for interventions, selecting which interventions would be included in the review, developing systematic search strategies for each intervention, implementing these search strategies, assessing and summarizing the quality of evidence using a standardized abstraction tool, and then translating this evidence into a set of recommendations for including interventions into a combination HIV prevention/interventions package. Finally, through the global consultation for implementation data describing interventions supporting the needs of MSM in LMIC, we considered information and data outside the realm of effectiveness, and have identified and summarized research gaps (Figure 2). Two reviewers independently abstracted data from the identified reports using a standardized abstraction tool. Conclusions were presented to a multidisciplinary group for review before final adoption of the recommendation.

Efficacy data

We used a scoping review as defined by Arksey and O'Malley to determine individual components of the package of preventive services for MSM.[22] In brief, the scoping methodology is focused on mapping literature relevant to HIV preventive interventions for MSM without assessing the quality of included studies. These

Figure 1. A HASTE assessment of the importance of VCT programs for combination HIV prevention interventions for MSM in low- and middle-income countries

HASTE characteristics	*Assessment*
Efficacy data	The demonstrated efficacy of VCT interventions in preventing HIV infection has been limited.[a]
Implementation data	A large body of consistent implementation data highlighting the importance of VCT as a point of interaction with the health-care system that may result in the provision of a series of reproductive health and preventive services, including sexually transmitted infection diagnosis and care as well as mental health counseling, among other preventive services. A critical step in the pathway for preventive interventions based on knowledge of HIV status.
Plausibility	HIV prevention technologies are increasingly dependent on knowledge of HIV status, including oral and topical ART chemoprophylaxis for those not living with HIV and early ART for those living with HIV/AIDS to decrease onward transmission and community viral load.
	There is evidence of behavior change post-VCT for women living with HIV and also for men living with HIV.[a–c] Normalizing testing can also reduce stigma associated with HIV status, which can increase uptake of ART.[d,e]
	Interventions to increase awareness of HIV serostatus have public health plausibility.[f–i]
Rating	Strong recommendation

[a]Holtgrave D, McGuire J. Impact of counseling in voluntary counseling and testing programs for persons at risk for or living with HIV infection. Clin Infect Dis 2007;45 Suppl 4:S240-3.

[b]Hayes R, Sabapathy K, Fidler S. Universal testing and treatment as an HIV prevention strategy: research questions and methods. Curr HIV Res 2011;9:429-45.

[c]Ojo O, Verbeek JH, Rasanen K, Heikkinen J, Isotalo LK, Mngoma N, et al. Interventions to reduce risky sexual behaviour for preventing HIV infection in workers in occupational settings. Cochrane Database Syst Rev 2011;(12):CD005274.

[d]Kawichai S, Celentano D, Srithanaviboonchai K, Wichajarn M, Pancharoen K, Chariyalertsak C, et al. NIMH Project Accept (HPTN 043) HIV/AIDS Community Mobilization (CM) to Promote Mobile HIV Voluntary Counseling and Testing (MVCT) in Rural Communities in Northern Thailand: modifications by experience. AIDS Behav 2012;16:1227-37.

[e]Sweat M, Morin S, Celentano D, Mulawa M, Singh B, Mbwambo J, et al. Community-based intervention to increase HIV testing and case detection in people aged 16–32 years in Tanzania, Zimbabwe, and Thailand (NIMH Project Accept, HPTN 043): a randomised study. Lancet Infect Dis 2011;11:525-32.

[f]Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med 2010;363:2587-99.

[g]Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011;365:493-505.

[h]McGowan I. Rectal microbicides: can we make them and will people use them? AIDS Behav 2011;15 Suppl 1:S66-71.

[i]Das M, Chu PL, Santos GM, Scheer S, Vittinghoff E, McFarland W, et al. Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco. PLoS One 2010;5:e11068.

HASTE = Highest Attainable Standard of Excellence

VCT = voluntary counseling and testing

HIV = human immunodeficiency virus

MSM = men who have sex with men

ART = antiretroviral therapy

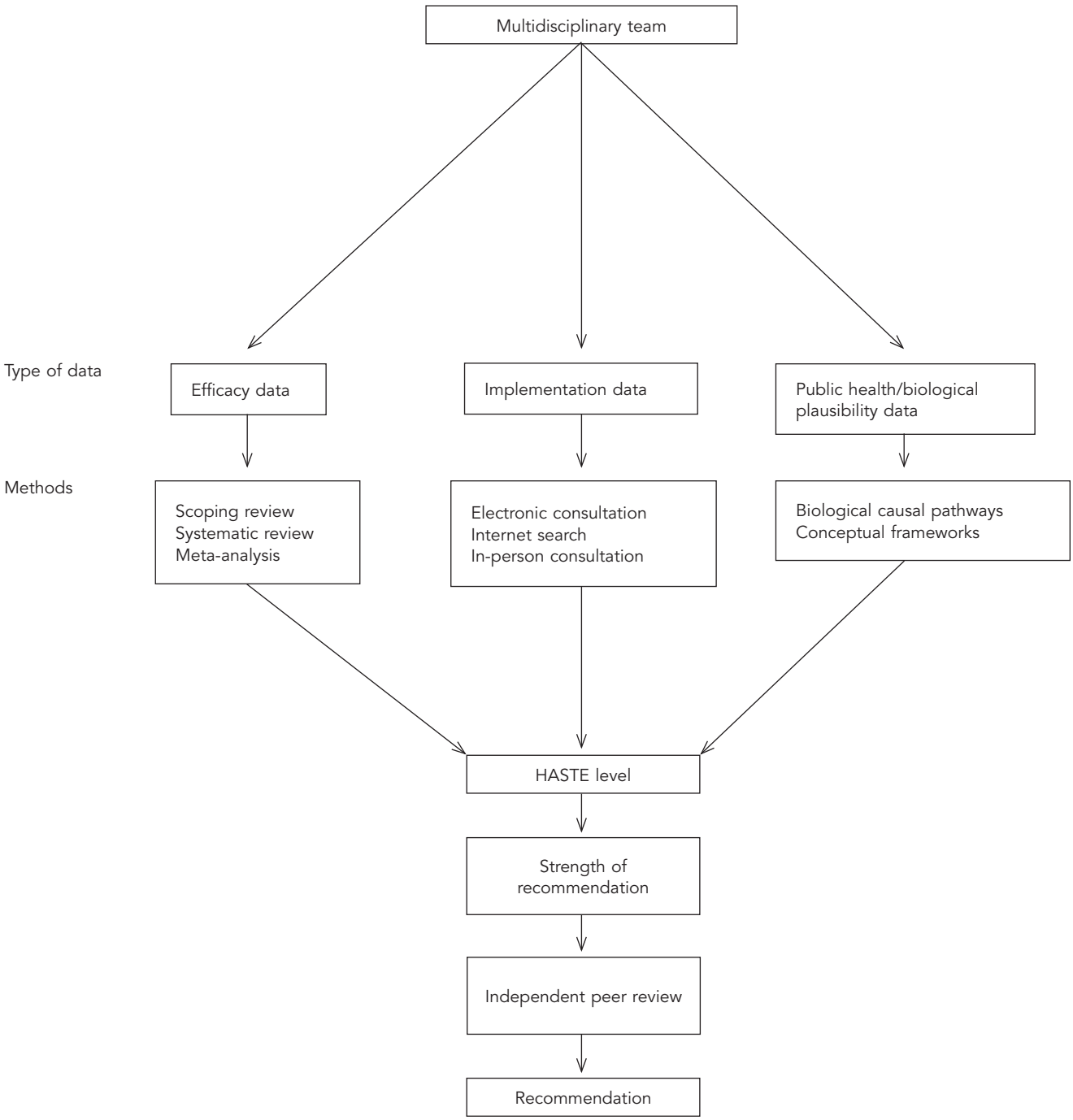
AIDS = acquired immunodeficiency syndrome

reviews included the development of a specific search protocol with selection criteria, but did not include tracking the numbers of included studies. We used sensitive search terms to facilitate the development of an overview of the state of prevention sciences to help facilitate decisions on which prevention methods were to be further assessed. Once we defined the potential components of the package of services, we completed an umbrella review of systematic reviews if systematic reviews of the efficacy of individual components had been previously completed, such as assessing the efficacy of behavioral interventions to decrease HIV risk among MSM.[23] However, each individual article used in the systematic reviews was collected to assess specific inclusion and exclusion criteria.

We completed novel systematic reviews with defined search protocols when previous systematic reviews were not harnessed on individual components of HIV prevention for MSM. When quantitative outcomes were available, such as changes in self-reported unprotected

anal intercourse secondary to targeted interventions, we completed a meta-analysis. If meta-analysis was not possible, either because there was only one study or there was significant intra-study variation in design, relevant data were abstracted with the aforementioned tool, conclusions on efficacy were made by three different investigators, and results were compared until consensus was reached.

Figure 2. HASTE system for HIV interventions process



HASTE = Highest Attainable Standard of Evidence

HIV = human immunodeficiency virus

Implementation data

We used several different methods to harness implementation data.[24] The majority of small implementers with limited scope do not have websites to post these data, but they do produce digital reports of their programs for their funders. As such, an electronic global consultation was completed in October 2009. Letters requesting information on epidemiology, rights contexts, and programming for MSM were sent out using dedicated listservs in Asia, Africa, Latin America and the Caribbean, and Eastern Europe. These letters were also sent out by key funders of related initiatives including the American Foundation for AIDS Research (known as amfAR) with its MSM Initiative to its grantees, the MSM Global Forum for HIV, and key United Nations (UN) agencies including UN Development Programme (UNDP) and UNAIDS. In addition, we contacted key informants in 28 countries requesting information specific to their country. In total, we retrieved implementation data from 68 LMIC pertaining to MSM. To attain implementation data from larger implementers, we searched Google and Bing using similar keywords to what was used for the systematic searches. In addition, we individually searched the websites of large international HIV prevention implementers known to provide services for MARPS for further documentation of programs and outcomes.

Separate from this search, a global consultation was held after the umbrella review, separate systematic reviews, and further review of electronic documents describing implementation data. This consultation included representation from several UN agencies including the UNDP, UNAIDS, World Health Organization, and the UN Populations Fund, in addition to key informants from 15 countries where a member-checking and results-validation session was completed. We presented the package of services using the framework of biomedical, behavioral, and structural interventions along with the evaluation approach. As this consultation was held early in the process of developing this set of recommendations, the feedback for the process and content of this package facilitated appropriate changes being made to the package of recommendations and evaluation system. One of the key changes was the need to review the evidence supporting conversion or reparative therapies, whose focus is to try and change sexual orientation, as these interventions form the base for many interventions targeting MSM in LMIC with a focus on regions in the Middle East and North Africa.[25]

While there is no common evaluation framework used by HIV implementers large or small, our group used the Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM) framework, which has five key components in assessing programmatic reach; efficacy or effectiveness; and measures of adoption, implementation, and maintenance to assess the relative importance of key interventions.[26] The RE-AIM framework is well established for non-randomized processes and program evaluations.[27–29]

Reach functions as a measure of program scale and can be measured in several ways, including the number or percentage of the target audience being reached. Because the denominator or true population size of MSM is rarely known, programs describe the absolute number of people reached as the most common characterization of scale. Generalizability of the population reached in the particular program is also included under reach.

Efficacy or effectiveness is measured by assessing the changes in a set of appropriate outcomes, the impact on the quality of life of participants, and any potential adverse effects of the program. Adoption is measured by assessing the proportion of those targeted by the intervention who actually participated in the intervention. It can also be considered as a measure of acceptability of this program with impact on ultimate program uptake. Implementation-related issues include a feasibility assessment of the program with key components, including a proprietary assessment, program evaluability, resource needs for the program (e.g., fixed and marginal costs), and legality. The assessment of program implementation also evaluates whether the program was consistently delivered episodically or in different geographic regions.

Finally, maintenance of the program represents sustainability of the programmatic outcomes generally assessed with cutoffs of either six months or one year. The non-randomized study or program data abstraction tool focused on extracting quantitative and qualitative data from programmatic studies under each of the realms of RE-AIM. While the abstraction tool and framework for evaluation included the potential for assessing all components of RE-AIM, most programmatic descriptions did not report each of these elements.

Plausibility

We applied the biological plausibility criterion to assess biomedical interventions using current levels of knowledge of biological causal pathways. We assessed public health plausibility using conceptual frameworks of HIV risk among MSM developed by members of the team akin to the analytic frameworks used by the Guide to Community Preventive Services.[30]

Independent peer review

The aforementioned global consultation meeting served as an interim validation and review of the recommendations suggested in the package of services. A separate process for ensuring the appropriateness, akin to the GRADE values and preferences process, of the conclusions included peer review by HIV/AIDS prevention experts not connected with the study.[6] The external reviewers included both academic experts in HIV/AIDS epidemiology and targeted interventions for MSM, as well as experts in implementation of interventions for MSM in high-, middle-, and low-income settings.

RESULTS

HASTE for HIV interventions

The HASTE process for HIV/AIDS interventions was modified from several tools used to evaluate public health interventions including ones developed by USPSTF, CTFPHC, and GRADE to evaluate the quality of evidence of HIV interventions for MSM. The HASTE system gives the highest weight of efficacy evidence to RCTs, systematic reviews, and meta-analyses of RCT studies where attainable. The differentiating factors for this system are that other experimental studies, such as non-randomized controlled studies and pre- and post-assessments of interventions, were also included in RCTs pending an assessment using the RE-AIM framework.

This approach generated four grades of evidence for HASTE—Strong (Grade 1), Conditional (Grade 2), Insufficient (Grade 3), and Inappropriate (Grade 4)—depending on the amount of efficacy trial and implementation data available for a given intervention (Figure 3). Grade 1 (i.e., strong) recommendations are given when there are available efficacy or implementation data that the benefit of an intervention clearly outweighs the potential risks, or there are data that the intervention addresses a known causal risk factor of HIV risk among MSM using the approach of assessing plausibility.

Grade 2 (i.e., conditional) recommendations are given when there is potential efficacy for an intervention, but further research or implementation data are required to make a strong recommendation. Conditional recommendations may be given when there is not a large body of implementation data and limited quality of experimental research evaluating a particular intervention. Specifically, for Grade 2a (i.e., probable) interventions, there may be limited or no efficacy data, but there are plausibility and consistent implementation data highlighting the importance of this intervention. For Grade 2b (i.e., possible) interventions, there are limited or inconsistent efficacy data, plausibility, but only limited implementation data from non-randomized studies or programmatic data. The most common difference between interventions receiving probable or possible recommendations is the amount of non-randomized data available for

Figure 3. Highest Attainable Standard of Evidence (HASTE) system for HIV interventions—four grades of evidence

Grade level	*Strength of recommendation*	*Explanation*
Grade 1	Strong	• Efficacy is consistent • High plausibility • Large body of consistent implementation data
Grade 2	Conditional	
Grade 2a	Probable	• Limited efficacy data • Plausibility • Consistently effective from implementation data
Grade 2b	Possible	• Limited or inconsistent efficacy data • Plausibility • Limited but consistent implementation data
Grade 2c	Pending	• Ongoing efficacy trials • Plausibility
Grade 3	Insufficient	• Inconsistent data • Undefined plausibility • Inconsistent or paucity of implementation data
Grade 4	Inappropriate	• Consistent data demonstrating lack of efficacy • Consensus from implementation data of inappropriate intervention

HIV = human immunodeficiency virus

assessment using the RE-AIM framework. In addition, for some interventions such as circumcision, Grade 2b recommendations were given if the intervention had the potential to be beneficial for a small subset of MSM, such as those who have high insertivity ratios and multiple female partners.[31] Separately, for some interventions, Grade 2c (i.e., pending) recommendations are given when there are ongoing efficacy trials among MSM.

Grade 3 (i.e., insufficient) is applied when there is inconsistent evidence for the efficacy of a particular intervention, the causal pathway is unclear or not well defined, and there are limited non-randomized study or programmatic data about a particular intervention. Grade 4 (i.e., inappropriate) is given when there is evidence of no efficacy or effectiveness of an intervention, where there are efficacy or consistent implementation data suggesting harm, where risks outweigh potential benefits, or where there is consensus from implementation data that this is an inappropriate intervention.

Combination HIV prevention interventions for MSM

We used the HASTE system to evaluate the evidence for individual HIV-related interventions for MSM in LMIC. The results of this process are presented in Figure 4, although the complete information and rationale for selection are available in the World Bank report by Beyrer et al.[32] Figure 4 also presents an analysis of which interventions are supported by RCTs in both high-income countries and LMIC, as defined by the World Bank Atlas Method.[33] The only interventions evaluated using RCTs in LMIC are individualized risk-reduction counseling, brief client-focused counseling, community-level interventions, and preexposure prophylaxis. Of these interventions, only a single HIV intervention, preexposure prophylaxis, has been evaluated as an RCT among MSM in a generalized HIV epidemic. Thus, these are the only interventions that would be awarded four points as a starting point based on type of evidence under the GRADE system, whereas all observational studies would be given a starting value of two. Moreover, only the oral chemoprophylaxis study included an objective outcome of HIV seroincidence, involved blinding, and had high retention rates; thus, the others would lose between two and three points based on quality of evidence. Directedness of generalizability of all studies but oral chemoprophylaxis is limited given that it was the only one with efficacy completed in an LMIC. Finally, effect size as graded by having a measure of association greater than two or five would also be a limitation, as no HIV intervention has been shown to decrease HIV incidence with this magnitude. With this scoring framework, where a numerical value of four or higher is associated with a high strength of recommendation—three being associated with medium, two being associated with low, and one or lower being associated with a very low-strength recommendation—only oral chemoprophylaxis would receive a strong recommendation for MSM in LMIC.

Several differences emerge in the strength of recommendation with the use of the HASTE system compared with a classical RCT-driven evaluation system. These differences were strong recommendations for voluntary counseling and testing and for structural interventions. An example of the abbreviated HASTE analysis for voluntary counseling and testing is shown in Figure 1. Structural-level risk interventions among MSM have not been evaluated with an RCT, partly because of the complexity of the study designs required to characterize the efficacy and effectiveness of these interventions, and partly due to logistical and cost considerations. However, there are convincing public health plausibility and implementation data that highlight the importance of these interventions to facilitate the development and delivery of HIV services for MSM in LMIC.[32]

DISCUSSION

Among MSM in LMIC, there is a confluence of high HIV-related risk practices at the individual level with structural barriers to HIV preventive services including stigma, discrimination, and criminalization. Drivers of HIV risk among MSM occur at multiple levels including the individual, social, and sexual networks; community; and public policy realms. Together, these factors have resulted in a disproportionate burden of HIV disease among MSM wherever studied, including generalized epidemics.[18] The imperative to mount evidence-based and comprehensive responses to this disproportionate risk is urgent, as more than three decades into the epidemic most LMIC have no dedicated services for MSM. The initial systems for evaluating evidence to define recommendations, including the GRADE system, were initially designed for individual-level clinical interventions. Moreover, the available systems in the literature evaluating public health interventions did not include detailed assessments of implementation data, which comprise a large component of the evidence base in the field of HIV/AIDS prevention. There is significant variability in organizations focused on implementing HIV prevention service delivery, ranging from small community-based organizations to large not-for-profit institutions active in a number of countries spanning multiple continents. Many of the smaller community-based organizations serving the needs of MARPS tend to be led by members of these same populations that

Figure 4. Strength of recommendations for inclusion of specific prevention components in combination HIV prevention intervention packages for MSM

Intervention	*Components*	*HASTE level*	*Strength of recommendation*	*RCT in HIC*	*RCT in LMIC*
Condoms and water- or silicone-based lubricants	Effective distribution	Grade 1	Strong		
	Counseling and education about condoms and lubricants	Grade 1	Strong		
	Thicker condoms	Grade 2b	Possible		
	Female condom	Grade 2b	Possible		
Behavioral interventions	Individualized risk-reduction counseling	Grade 2a	Probable	Yes[a–o]	Yes[p,q]
	Conversion or reparative therapy	Grade 4	Inappropriate		
	Didactic teaching	Grade 2b	Possible	Yes[h,r,s]	
	Brief client-focused counseling	Grade 2a	Probable	Yes[t–z]	Yes[aa]
	Community-level interventions	Grade 1	Strong	Yes[bb–mm]	Yes[nn,oo]
Antiretroviral therapy	Method of secondary prevention	Grade 1	Strong		
	Primary prevention	Grade 2a	Probable		
	Address substance use and mental health disorders to increase adherence	Grade 2a	Probable	Yes[pp–ss]	
	Rectal microbicides	Grade 2a	Pending		
	Postexposure prophylaxis	Grade 2a	Probable		
	Preexposure prophylaxis	Grade 2a	Probable	Yes[tt]	Yes[tt]
Voluntary counseling and testing	HIV testing	Grade 1	Strong		
	Rapid testing for HIV	Grade 2a	Probable		
	LGBT sensitization	Grade 1	Strong		
Circumcision	Medical male circumcision	Grade 2b	Possible		
Syndromic STI treatment	HSV-2 suppression	Grade 4	Inappropriate	Yes[uu]	Yes[uu]
	Screening and treatment of all genital ulcerative diseases	Grade 2a	Probable		
Vaccination	HPV	Grade 2a	Probable		
Structural interventions	Government-sponsored anti-homophobia policy, community systems strengthening, and health sector training	Grade 1	Strong		

[a]Imrie J, Stephenson JM, Cowan FM, Wanigaratne S, Billington AJP, Copas AJ, et al. A cognitive behavioural intervention to reduce sexually transmitted infections among gay men: randomised trial. BMJ 2001;322:1451-6.

[b]Carballo-Diéguez A, Dolezal C, Leu CS, Nieves L, Díaz F, Decena C, et al. A randomized controlled trial to test an HIV-prevention intervention for Latino gay and bisexual men: lessons learned. AIDS Care 2005;17:314-28.

[c]Cleary PD, Van Devanter N, Steilen M, Stuart A, Shipton-Levy R, McMullen W, et al. A randomized trial of an education and support program for HIV-infected individuals. AIDS 1995;9:1271-8.

[d]Valdiserri RO, Lyter DW, Leviton LC, Callahan CM, Kingsley LA, Rinaldo CR. AIDS prevention in homosexual and bisexual men: results of a randomized trial evaluating two risk reduction interventions. AIDS 1989;3:21-6.

[e]Kelly JA, St. Lawrence JS, Hood HV, Brasfield TL. Behavioral intervention to reduce AIDS risk activities. J Consult Clin Psychol 1989;57:60-7.

[f]Dilley JW, Woods WJ, Sabatino J, Lihatsh T, Adler B, Casey S, et al. Changing sexual behavior among gay male repeat testers for HIV: a randomized controlled trial of a single-session intervention. J Acquir Immune Defic Syndr 2002;30:177-86.

[g]Chesney MA, Chambers DB, Taylor JM, Johnson LM, Folkman S. Coping effectiveness training for men living with HIV: results from a randomized clinical trial testing a group-based intervention. Psychosom Med 2003;65:1038-46.

[h]Koblin B, Chesney M, Coates T. Effects of a behavioural intervention to reduce acquisition of HIV infection among men who have sex with men: the EXPLORE randomised controlled study. Lancet 2004;364:41-50.

[i]Wolitski RJ, Gomez CA, Parsons JT. Effects of a peer-led behavioral intervention to reduce HIV transmission and promote serostatus disclosure among HIV-seropositive gay and bisexual men. AIDS 2005;19 Suppl 1:S99-109.

[j]Rotheram-Borus MJ, Swendeman D, Comulada WS, Weiss RE, Lee M, Lightfoot M. Prevention for substance-using HIV-positive young people: telephone and in-person delivery. J Acquir Immune Defic Syndr 2004;37 Suppl 2:S68-77.

[k]Wolitski RJ, Parsons JT, Gomez CA, Purcell DW, Hoff CC, Halkitis PN. Prevention with gay and bisexual men living with HIV: rationale and methods of the Seropositive Urban Men's Intervention Trial (SUMIT). AIDS 2005;19 Suppl 1:S1-11.

[l]Patterson TL, Shaw WS, Semple SJ. Reducing the sexual risk behaviors of HIV+ individuals: outcome of a randomized controlled trial. Ann Behav Med 2003;25:137-45.

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Figure 4 (continued). Strength of recommendations for inclusion of specific prevention components in combination HIV prevention intervention packages for MSM

[m]Berg R. The effectiveness of behavioural and psychosocial HIV/STI prevention interventions for MSM in Europe: a systematic review. Euro Surveill 2009;14:19430.

[n]Gore-Felton C, Rotheram-Borus MJ, Weinhardt LS, Kelly JA, Lightfoot M, Kirshenbaum SB, et al. The Healthy Living Project: an individually tailored, multidimensional intervention for HIV-infected persons. AIDS Educ Prev 2005;17(1 Suppl A):21-39.

[o]Myers T, Tudiver FG, Kurtz RG, Jackson EA, Orr KW, Rowe CJ, et al. The Talking Sex Project: descriptions of the study population and correlates of sexual practices at baseline. Can J Public Health 1992;83:47-52.

[p]Zimmerman MA, Ramirez-Valles J, Suarez E, de la Rosa G, Castro MA. An HIV/AIDS prevention project for Mexican homosexual men: an empowerment approach. Health Educ Behav 1997;24:177-90.

[q]Toro-Alfonso J, Varas-Díaz N, Andujar-Bello I. Evaluation of an HIV/AIDS prevention intervention targeting Latino gay men and men who have sex with men in Puerto Rico. AIDS Educ Prev 2002;14:445-56.

[r]Peterson JL, Coates TJ, Catania J, Hauck WW, Acree M, Daigle D, et al. Evaluation of an HIV risk reduction intervention among African-American homosexual and bisexual men. AIDS 1996;10:319-25.

[s]Robert B, Rosser S. Evaluation of the efficacy of AIDS education interventions for homosexually active men. Health Educ Res 1990;5:299-308.

[t]Picciano JF, Roffman RA, Kalichman SC, Rutledge SE, Berghuis JP. A telephone based brief intervention using motivational enhancement to facilitate HIV risk reduction among MSM: a pilot study. AIDS Behav 2001;5:251-62.

[u]Richardson JL, Milam J, McCutchan A, Stoyanoff S, Bolan R, Weiss J, et al. Effect of brief safer-sex counseling by medical providers to HIV-1 seropositive patients: a multi-clinic assessment. AIDS 2004;18:1179-86.

[v]Hospers HJ, Debets W, Ross MW, Kok G. Evaluation of an HIV prevention intervention for men who have sex with men at cruising areas in the Netherlands. AIDS Behav 1999;3:359-66.

[w]Roffman RA, Picciano JF, Ryan R, Beadnell B, Fisher D, Downey L, et al. HIV-prevention group counseling delivered by telephone: an efficacy trial with gay and bisexual men. AIDS Behav 1997;1:137-54.

[x]Picciano JF, Roffman RA, Kalichman SC, Walker DD. Lowering obstacles to HIV prevention services: effects of a brief, telephone-based intervention using motivational enhancement therapy. Ann Behav Med 2007;34:177-87.

[y]Coates TJ, McKusick L, Kuno R, Stites DP. Stress reduction training changed number of sexual partners but not immune function in men with HIV. Am J Public Health 1989;79:885-7.

[z]Choi KH, Lew S, Vittinghoff E, Catania JA, Barrett DC, Coates TJ. The efficacy of brief group counseling in HIV risk reduction among homosexual Asian and Pacific Islander men. AIDS 1996;10:81-7.

[aa]Sampaio M, Brites C, Stall R, Hudes ES, Hearst N. Reducing AIDS risk among men who have sex with men in Salvador, Brazil. AIDS Behav 2002;6:173-81.

[bb]Community-level HIV intervention in 5 cities: final outcome data from the CDC AIDS Community Demonstration Projects. Am J Public Health 1999;89:336-45.

[cc]AIDS community demonstration projects: implementation of volunteer networks for HIV-prevention programs—selected sites, 1991–1992. MMWR Morb Mortal Wkly Rep 1992;41(46):868-9, 875-6.

[dd]Hays RB, Rebchook GM, Kegeles SM. The Mpowerment Project: community-building with young gay and bisexual men to prevent HIV1. Am J Community Psychol 2003;31:301-12.

[ee]Flowers P, Hart GJ, Williamson LM, Frankis JS, Der GJ. Does bar-based, peer-led sexual health promotion have a community-level effect amongst gay men in Scotland? Int J STD AIDS 2002;13:102-8.

[ff]Jones KT, Gray P, Whiteside YO, Wang T, Bost D, Dunbar E, et al. Evaluation of an HIV prevention intervention adapted for black men who have sex with men. Am J Public Health 2008;98:1043-50.

[gg]Miller RL, Klotz D, Eckholdt HM. HIV prevention with male prostitutes and patrons of hustler bars: replication of an HIV preventive intervention. Am J Community Psychol 1998;26:97-131.

[hh]Kelly JA, St Lawrence JS, Diaz YE, Stevenson LY, Hauth AC, Brasfield TL, et al. HIV risk behavior reduction following intervention with key opinion leaders of population: an experimental analysis. Am J Public Health 1991;81:168-71.

[ii]Kegeles SM, Hays RB, Pollack LM, Coates TJ. Mobilizing young gay and bisexual men for HIV prevention: a two-community study. AIDS 1999;13:1753-62.

[jj]Harding R, Bensley J, Corrigan N, Franks L, Stratman J, Waller Z, et al. Outcomes and lessons from a pilot RCT of a community-based HIV prevention multi-session group intervention for gay men. AIDS Care 2004;16:581-5.

[kk]Kelly JA, Murphy DA, Sikkema KJ, McAuliffe TL, Roffman RA, Solomon LJ, et al. Randomised, controlled, community-level HIV-prevention intervention for sexual-risk behaviour among homosexual men in US cities. Community HIV Prevention Research Collaborative. Lancet 1997;350:1500-5.

[ll]Operario D, Smith CD, Arnold E, Kegeles S. The Bruthas Project: evaluation of a community-based HIV prevention intervention for African American men who have sex with men and women. AIDS Educ Prev 2010;22:37-48.

[mm]Williamson LM, Hart GJ, Flowers P, Frankis JS, Der GJ. The Gay Men's Task Force: the impact of peer education on the sexual health behaviour of homosexual men in Glasgow. Sex Transm Infect 2001;77:427-32.

[nn]Amirkhanian YA, Kelly JA, Kabakchieva E, McAuliffe TL, Vassileva S. Evaluation of a social network HIV prevention intervention program for young men who have sex with men in Russia and Bulgaria. AIDS Educ Prev 2003;15:205-20.

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Figure 4 (continued). Strength of recommendations for inclusion of specific prevention components in combination HIV prevention intervention packages for MSM

[oo]Amirkhanian YA, Kelly JA, Kabakchieva E, Kirsanova AV, Vassileva S, Takacs J, et al. A randomized social network HIV prevention trial with young men who have sex with men in Russia and Bulgaria. AIDS 2005;19:1897-905.

[pp]Stall RD, Paul JP, Barrett DC, Crosby GM, Bein E. An outcome evaluation to measure changes in sexual risk-taking among gay men undergoing substance use disorder treatment. J Stud Alcohol 1999;60:837-45.

[qq]Shoptaw S, Reback CJ, Peck JA, Yang X, Rotheram-Fuller E, Larkins S, et al. Behavioral treatment approaches for methamphetamine dependence and HIV-related sexual risk behaviors among urban gay and bisexual men. Drug Alcohol Depend 2005;78:125-34.

[rr]Sorensen JL, Dilley J, London J, Okin RL, Delucchi KL, Phibbs CS. Case management for substance abusers with HIV/AIDS: a randomized clinical trial. Am J Drug Alcohol Abuse 2003;29:133-50.

[ss]Kelly JA, Murphy DA, Bahr GR, Kalichman SC, Morgan MG, Stevenson LY, et al. Outcome of cognitive-behavioral and support group brief therapies for depressed, HIV-infected persons. Am J Psychiatry 1993;150:1679-86.

[tt]Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med 2010;363:2587-99.

[uu]Celum C, Wald A, Hughes J, Sanchez J, Reid S, Delany-Moretlwe S, et al. Effect of aciclovir on HIV-1 acquisition in herpes simplex virus 2 seropositive women and men who have sex with men: a randomised, double-blind, placebo-controlled trial. Lancet 2008;371:2109-19.

HIV = human immunodeficiency virus

MSM = men who have sex with men

HASTE = Highest Attainable Standard of Evidence

RCT = randomized controlled trial

HIC = high-income country

LMIC = low- and middle-income countries

LGBT = lesbian, gay, bisexual, and transgender

STI = sexually transmitted infection

HSV-2 = herpes simplex virus-2

HPV = human papillomavirus

recognize the vulnerable state and disproportionate burden of HIV risk and disease among their peers.

Given limited resources, human and financial resources are focused on service delivery rather than sophisticated evaluation strategies. Larger HIV prevention service implementers often evaluate interventions using process indicators of HIV prevention rather than the measurement of biological endpoints. Moreover, HIV implementers rarely submit the results of their programs for publication in peer-reviewed journals. This publication dearth is likely because smaller-scale implementers lack the inherent technical capacity to do so and because larger implementers do not allocate resources to this activity. The HASTE system presented in this article was developed to be able to comprehensively assess all forms of evidence relating to HIV prevention for MARPS and was not developed as a tool to evaluate evidence relating to all public health interventions. Rather, this tool was used to develop recommendations for combination HIV preventive interventions for MSM in LMIC. The full HASTE analysis supporting Figure 4 is included in the World Bank report, "The Global HIV Epidemics Among Men Who Have Sex with Men."[32] Figure 4 summarizes the interventions assessed, demonstrating that few of these interventions have been tested with RCT, although many are considered the standard of care rendering RCT level of evidence unattainable. Even fewer of these interventions have been tested in LMIC, where the risk environment is often heightened because of stigma and discrimination. Consequently, if RCT-level evidence is held as the standard by which one can make strong assertions of evidence efficacy, there would be few interventions that would receive a strong recommendation. As such, we believe that the HASTE tool can also be used to define an appropriate package of HIV services for other vulnerable populations including sex workers, IDUs, victims of gender-based violence, and internally displaced or other migrant populations.

Limitations

There were clear limitations to the HASTE system presented in this article. For one, there is no common evaluation framework for HIV/AIDS implementers, and the evaluation of these programs tends to be specific to the identified needs of the funders focusing on process rather than outcome indicators. While we used the RE-AIM system that has been previously used to evaluate health sector programming, a standardized system of evaluating and reporting non-randomized research studies was suggested by CDC and termed Transparent Reporting of Evaluations with Non-Randomized Designs (TREND).[34] However, this system has not yet been widely adopted by HIV implementing

organizations. Standardizing the evaluation and reporting of HIV interventions would likely increase the availability of evidence in the peer-reviewed literature. In addition, when including implementation data from a series of organizations, there is inconsistency in the quality of these data, given that the primary purpose of these programs is to provide services rather than to conduct research.

To compensate for these limitations, the HASTE system combines implementation data with efficacy data and plausibility analysis. Observational studies and analysis of implementation data do not allow for analysis at the level of the individual, thereby making interpretation subject to ecological fallacy. Additionally, reproducibility of the HASTE system for MSM in LMIC may be difficult, as it involves retrieving implementation data that are not all indexed in the public domain. Significant effort would be required to retrieve these data. Finally, the HASTE system purposefully does not assign a numerical score to different components of the assessment, which may be perceived as being less objective than score-based systems such as GRADE. The development team decided that the assignment of abstract numerical values to evidence attributes also represents a subjective judgment assessment. However, we believe that despite these limitations, the system presented represents a tool that balances scientific integrity and practicality in assessing the quality of evidence of HIV/AIDS preventive interventions targeting MARPS for HIV.

CONCLUSIONS

In the context of a slowing HIV pandemic, HIV incidence and prevalence continue to increase among MARPS. HIV interventions for these populations have been inconsistently implemented, which is likely secondary to inadequate political motivation to address vulnerable populations, insufficient targeted funding, and the lack of a means to define an optimal package of services in resource-constrained settings. We have developed the HASTE system to define an appropriate package of HIV services including biomedical, behavioral, and structural approaches using the highest standard of attainable data. This system can be used to advocate for a package of HIV prevention, treatment, and care services for MARPS in low- and middle-income settings, allowing advocacy for the appropriate scale-up of these services in response to evidence-based need.

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REFERENCES

1. Rychetnik L, Frommer M, Hawe P, Shiell A. Criteria for evaluating evidence on public health interventions. J Epidemiol Community Health 2002;56:119-27.
2. Wolfe D, Carrieri MP, Shepard D. Treatment and care for injecting drug users with HIV infection: a review of barriers and ways forward. Lancet 2010;376:355-66.
3. Vandenbroucke JP. Observational research, randomised trials, and two views of medical science. PLoS Med 2008;5:e67.
4. Degenhardt L, Mathers B, Vickerman P, Rhodes T, Latkin C, Hickman M. Prevention of HIV infection for people who inject drugs: why individual, structural, and combination approaches are needed. Lancet 2010;376:285-301.
5. Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. Going from evidence to recommendations. BMJ 2008;336:1049-51.
6. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924-6.
7. Moher D, Altman DG, Liberati A, Tetzlaff J. PRISMA statement. Epidemiology 2011;22:128; author reply 128.
8. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA 1996;276:637-9.
9. Ansari MT, Tsertsvadze A, Moher D. Grading quality of evidence and strength of recommendations: a perspective. PLoS Med 2009;6:e1000151.
10. Briss PA, Zaza S, Pappaioanou M, Fielding J, Wright-De Agüero L, Truman BI, et al. Developing an evidence-based Guide to Community Preventive Services—methods. The Task Force on Community Preventive Services. Am J Prev Med 2000;18(1 Suppl 1):35-43.
11. Petticrew M, Roberts H. Evidence, hierarchies, and typologies: horses for courses. J Epidemiol Community Health 2003;57:527-9.
12. McQueen DV. The evidence debate. J Epidemiol Community Health 2002;56:83-4.
13. Tang KC, Choi BC, Beaglehole R. Grading of evidence of the effectiveness of health promotion interventions. J Epidemiol Community Health 2008;62:832-4.
14. Hill AB. The environment and disease: association or causation? Proc R Soc Med 1965;58:295-300.
15. Rose G. Sick individuals and sick populations. Int J Epidemiol 1985;14:32-8.
16. John S. Why the prevention paradox is a paradox, and why we should solve it: a philosophical view. Prev Med 2011;53:250-2.
17. Strathdee SA, Hallett TB, Bobrova N, Rhodes T, Booth R, Abdool R, et al. HIV and risk environment for injecting drug users: the past, present, and future. Lancet 2010;376:268-84.
18. Beyrer C, Baral SD, Walker D, Wirtz AL, Johns B, Sifakis F. The expanding epidemics of HIV type 1 among men who have sex with men in low- and middle-income countries: diversity and consistency. Epidemiol Rev 2010;32:137-51.
19. Global HIV Prevention Working Group. Global HIV prevention: the access, funding, and leadership gaps. Washington: Global HIV Prevention Working Group; 2009.
20. United Nations. The Universal Declaration of Human Rights. Paris: UN General Assembly; December 10, 1948.
21. Office of the United Nations High Commissioner for Human Rights. International Covenant on Economic, Social and Cultural Rights. New York: UN General Assembly; January 1976.
22. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005;8:19-32.
23. Johnson WD, Diaz RM, Flanders WD, Goodman M, Hill AN, Holtgrave D, et al. Behavioral interventions to reduce risk for sexual transmission of HIV among men who have sex with men. Cochrane Database Syst Rev 2008(3):CD001230.
24. Padian NS, Holmes CB, McCoy SI, Lyerla R, Bouey PD, Goosby EP. Implementation science for the US President's Emergency Plan for AIDS Relief (PEPFAR). J Acquir Immune Defic Syndr 2011;56:199-203.
25. Abu-Raddad LJ, Hilmi N, Mumtaz G, Benkirane M, Akala FA,

Riedner G, et al. Epidemiology of HIV infection in the Middle East and North Africa. AIDS 2010;24 Suppl 2:S5-23.
26. Donabedian A. An assessment of the criteria approach to medical care evaluation. Hosp Med Staff 1976;5:1-9.
27. Allen K, Zoellner J, Motley M, Estabrooks PA. Understanding the internal and external validity of health literacy interventions: a systematic literature review using the RE-AIM framework. J Health Commun 2011;16 Suppl 3:55-72.
28. Glasgow RE, Dickinson P, Fisher L, Christiansen S, Toobert DJ, Bender BG, et al. Use of RE-AIM to develop a multi-media facilitation tool for the patient-centered medical home. Implement Sci 2011;6:118.
29. Shubert TE, Altpeter M, Busby-Whitehead J. Using the RE-AIM framework to translate a research-based falls prevention intervention into a community-based program: lessons learned. J Safety Res 2011;42:509-16.
30. Zaza S, Wright-De Agüero LK, Briss PA, Truman BI, Hopkins DP, Hennessy MH, et al. Data collection instrument and procedure for systematic reviews in the Guide to Community Preventive Services. Task Force on Community Preventive Services. Am J Prev Med 2000;18(1 Suppl):44-74.
31. Sanchez J, Sal Y Rosas VG, Hughes JP, Baeten JM, Fuchs J, Buchbinder SP, et al. Male circumcision and risk of HIV acquisition among MSM. AIDS 2011;25:519-23.
32. Beyrer C, Wirtz AL, Walker D, Johns B, Sifakis F, Baral SD. The global HIV epidemics among men who have sex with men. Washington: World Bank Publications; 2011.
33. World Bank. Gross national income per capita 2008, Atlas method and PPP. Geneva: World Bank; 2009.
34. Des Jarlais DC, Lyles C, Crepaz N. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. Am J Public Health 2004;94:361-6.

Knowledge, Attitudes, and Practices for Diagnosing Breakthrough Varicella in the Outpatient Setting

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ABSTRACT

Objectives. We assessed provider knowledge, attitudes, and practices for the management of breakthrough varicella and identified barriers to implementation of laboratory testing and reporting.

Methods. We surveyed 145 health-care providers (HCPs) from 30 pediatric practices in Philadelphia who did not have a history of laboratory testing for breakthrough varicella. The self-administered survey instrument collected information on clinicians' practices for management of children presenting with rash, infection-control strategies, reporting to public health agencies, and laboratory testing.

Results. Among the 144 HCPs who completed the survey, 73 (51%) had practiced for more than 10 years. While 115 HCPs (80%) would elect to evaluate a child with rash in the office, only 19 (13%) would submit diagnostics. When patients had a known recent exposure to varicella, 84 HCPs (58%) would use laboratory tests: 40% would use direct fluorescent antibody staining on a specimen from a cutaneous lesion, 24% would use polymerase chain reaction on a lesion specimen, 21% would use acute and convalescent serology, and 10% would use other tests. While waiting for test results, 82 HCPs (57%) would advise that the child be kept at home, 39 (27%) would notify the local health department, and 33 (23%) would inform the school nurse.

Conclusion. As varicella becomes increasingly uncommon, laboratory confirmation becomes more critical for appropriate diagnosis, similar to poliomyelitis and measles. Our findings suggest that HCPs need further education regarding laboratory confirmation, containment, and reporting of breakthrough varicella.

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In the post-varicella vaccine era, a dramatic reduction in the overall number of varicella cases has been documented, with the proportion of previously vaccinated cases increasing as the number of vaccinees has increased.[1–4]

While, historically, varicella diagnosis was made clinically, given the distinctive appearance of classic varicella in unvaccinated individuals (i.e., a generalized vesicular rash with lesions in different stages preceded by fever and malaise), breakthrough varicella is usually mild, with fewer lesions, fewer or no vesicles, and no fever, and usually lacks the characteristic evolution of the rash in "crops or waves."[3–9] As a result, its rash can be confused with other conditions (e.g., herpes simplex infection, scabies, poison ivy, and even insect bites), and is more challenging to diagnose clinically.[6,9,10] Remarkably, school outbreaks have occurred because of delayed recognition of breakthrough varicella cases and postponed implementation of control measures.[3,5,11–15]

Varicella (but not herpes zoster) was added to the list of nationally notifiable diseases in 2003, and most states, including Pennsylvania, are mandating the report of varicella cases to a public health agency. To monitor the changing epidemiology of varicella disease after vaccine licensure, the Philadelphia Department of Public Health (PDPH) has conducted active surveillance for varicella and herpes zoster in the area of West Philadelphia since 1995. In the remaining areas of Philadelphia, passive surveillance has been conducted for varicella and herpes zoster because both conditions are reportable by local regulation. To support clinical management and disease surveillance of varicella and herpes zoster, PDPH has encouraged collection of specimens for testing by the National Varicella-Zoster Virus (VZV) Laboratory at the Centers for Disease Control and Prevention by advertising these laboratory services (which are free of charge) through newsletters and on-site in-service sessions, especially in the West Philadelphia active surveillance area. Although more than 50 practices throughout the city routinely utilize these services, only 30% of the suspected breakthrough varicella cases from the West Philadelphia area in 2007 had laboratory testing performed.

The purpose of this study was to assess knowledge, attitudes, and practices regarding the diagnosis, clinical management, and especially the role of laboratory testing for varicella by health-care providers (HCPs) in Philadelphia.

METHODS

In 2009, an in-person self-administered survey was given to HCPs in 30 practices in Philadelphia, outside the West Philadelphia active surveillance area. All staff within each practice, including physicians, physician assistants, nurse practitioners, and nurses, were encouraged to attend the educational session. The survey was offered only to staff who were present the day of the educational session and was selectively scheduled on a day when most physicians would be present at the practice. Information on physicians or nurse practitioners not present on the day of the session was not collected. We selected practices based on a criterion of 600 or more pediatric (<19 years of age) patients registered. The survey was followed by an educational session. We targeted practices that had not submitted specimens since 2007 or did not have a history of testing breakthrough varicella cases reported to PDPH, as we thought these practices could benefit from the educational session following the survey.

The survey instrument comprised 11 closed-ended multiple-choice questions. The first questions were based on a clinical scenario of a 2-year-old child who was previously vaccinated with one dose of varicella vaccine and who presented with maculopapular rash after being exposed to an uncle diagnosed with herpes zoster. A picture of the rash was projected while the survey respondents were answering questions about the case history. Following the questions based on the clinical scenario, the survey collected information on clinician recommendations for parents of children with rash, containment strategies, collection of laboratory specimens, varicella diagnostics, and reporting responsibility for varicella and herpes zoster to the local health department.

After HCPs completed the survey, PDPH staff provided an educational session on site, focusing on varicella disease in the post-vaccine era. To prevent the introduction of bias, PDPH staff did not reveal the specific survey and educational session objectives to the participating HCP offices when scheduling the sessions and, after the survey was completed, responses were collected before beginning the formal educational presentation. Study analyses were conducted to identify gaps in knowledge and barriers to implementation of VZV laboratory testing. Our main analyses were limited to physicians and nurse practitioners. The survey responses were entered into a Microsoft® Access database, and analyses were conducted using SAS® version 9.1.3.[16]

The study introduced no significant risks to the participants, and the Institutional Review Board of the Philadelphia Department of Public Health determined it to be exempt from full review and granted a waiver of informed consent for participation.

RESULTS

All 30 practices that were approached for the survey and educational session participated. Of the 145 HCPs who were offered the survey, 144 completed it; the survey respondents' characteristics are shown in the Table. The median number of children younger than 19 years of age served by the participating practices was 1,700 (mean: 1,965; range: 600–4,500). Information on socioeconomic and insurance status of the children served by the practices was not collected.

Of the 144 HCPs who participated in the survey, 115 (80%) would advise the parent of a preschool attendee with maculopapular rash (described in the clinical scenario of the survey) to bring the child to the office for evaluation, but only 19 (13%) would order laboratory tests to confirm or rule out diagnoses from their differential diagnosis list. Once the HCPs were informed of a clear exposure to VZV in the following survey question, 84 HCPs (58%) indicated they would order laboratory tests to confirm the diagnosis (Table).

While the majority (57%) of respondents would advise that a child be kept at home while a test result for VZV was pending, 40 HCPs (28%) did not select any answer addressing advice for school attendance. Only 39 HCPs (27%) would report a possible varicella case to the local health department, and 33 HCPs (23%) would inform the child's school nurse. Even when the case of the clinical scenario was confirmed as breakthrough varicella, only 42 of 144 HCPs (29%) said they would report it to the local health department, despite the fact that the majority of HCPs (n=110, 76%) recognized varicella as a reportable disease in Philadelphia.

Table. Characteristics of Philadelphia health-care providers who completed a survey on knowledge, attitudes, and practices in handling breakthrough varicella in the outpatient setting, 2009 (n=144)

Characteristic	N *(percent)*
Health-care provider type	
Physician	128 (89)
Nurse practitioner	16 (11)
Gender[a]	
Female	86 (60)
Male	57 (40)
Years practicing[b]	
<1	15 (11)
1–5	42 (30)
6–10	11 (8)
>10	73 (51)

[a]Missing one response

[b]Missing three responses

Also, 97 HCPs (67%) were aware that varicella should be reported to the state public health system, and 85 (59%) were aware that it should be reported to the national public health system. Fewer HCPs (n=69, 48%) identified herpes zoster as a reportable disease in Philadelphia, whereas 57 (40%) erroneously thought that herpes zoster was reportable in Pennsylvania, and 50 (35%) mistakenly thought it was reportable nationally (data not shown).

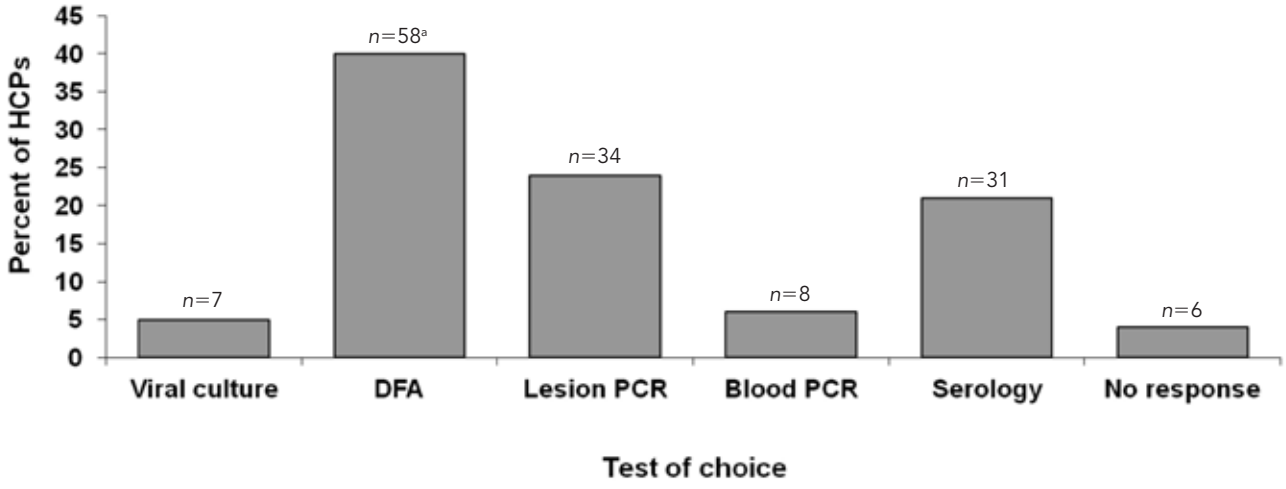
The tests HCPs said they would conduct for laboratory confirmation of breakthrough varicella are shown in the Figure. Stratification by HCP years of practice showed that 15 (18%) of the 84 HCPs with >5 years of practice said they would conduct laboratory testing for a maculopapular rash vs. three (5%) of the 57 HCPs with ≤5 years of practice (p=0.03). After exposure to varicella was provided in the history, 67% of HCPs practicing for >5 years said they would test lesions for VZV, compared with 33% of those practicing for ≤5 years (p=0.02). Selection of test for confirming breakthrough varicella did not differ by HCP years of practice. Reporting to PDPH differed by years of practice as well; 64% of those practicing for >5 years said they would report a possible or confirmed varicella case to PDPH, compared with 46% of those practicing for ≤5 years (p=0.03). Ninety-three percent of HCPs practicing for >5 five years recognized varicella as reportable in Philadelphia vs. 75% of HCPs practicing ≤5 years (p=0.004) (data not shown).

DISCUSSION

While the epidemiology and clinical presentation of varicella disease have changed dramatically post-vaccine implementation,[1] our results suggest that management of varicella cases in the outpatient setting is still mostly based on clinical judgment, at least in our area. After implementation of the second dose of the varicella vaccine, further declines in varicella incidence were reported.[17] However, elimination is not expected, and outbreaks have occurred in populations with high two-dose coverage.[14] Pockets of susceptible individuals in the population remain for various reasons, including limitations on administration of live-virus vaccines to some immunocompromised individuals, erroneous perception of varicella being a relatively benign disease, religious or philosophical objections to vaccination, and residence in institutional facilities from a young age.[18]

We advocate for increased awareness regarding the use of available laboratory tests for varicella. An effort to educate physicians on the importance of laboratory confirmation of potential breakthrough varicella cases

Figure. HCP test of choice for laboratory confirmation of breakthrough varicella: survey of Philadelphia HCPs on knowledge, attitudes, and practices in handling breakthrough varicella in the outpatient setting, 2009 (*n*=144)



[a]*n*=31 when excluding providers of a hospital-based ambulatory clinic where DFA is readily available and recommended by the hospital infectious diseases group

HCP = health-care provider

DFA = direct fluorescent antibody

PCR = polymerase chain reaction

is crucial as, frequently, its nonspecific appearance can be confused with other rashes of noncommunicable diseases.[6,9,10] As with other exanthematous vaccine-preventable diseases (e.g., measles and rubella) that are now rare in the United States and with clinical presentation modified by immunization, we believe that clinical identification alone for breakthrough varicella is not reliable. We suspect that the diagnostic challenge is even greater for younger physicians who train in the post-vaccine era and rely mostly on textbook descriptions of vaccine-preventable viral exanthems. Our study shows that physicians practicing for ≤5 years are not as likely to test for breakthrough varicella as physicians with >5 years of practice, even when an exposure to varicella is provided in the history. Although one could expect that younger physicians would have less trust in their clinical judgment in making the diagnosis and be more prone to test, we speculate that many might have a low index of suspicion for breakthrough varicella.

Survey participants were not alerted to a diagnosis of VZV by the description of the rash as maculopapular even though a lack of vesicles and predominance of maculopapular lesions have been described with breakthrough varicella in both clinical trials and post-varicella vaccine licensure studies.[3,4,6,8,9] While a clear exposure history to VZV prompted most HCPs to consider breakthrough varicella, it is doubtful that exposure information would be available in daily practice, as most source cases would also have a modified clinical appearance and may not be recognized as varicella. The contagiousness of breakthrough varicella is lower than varicella in unvaccinated individuals, depending also on the number and type of lesions, but can still be spread to close contacts.[19] In addition, exposure to herpes zoster may go under recognized because there is only moderate awareness that herpes zoster is contagious via airborne droplets and not only from direct contact with skin lesions.[18,20–22] There is no doubt that various causes of maculopapular rashes exist and some of them are noninfectious. While it is not feasible to test every patient with a maculopapular rash for a variety of reasons, we believe that once varicella is suspected, one should test to confirm the diagnosis, because of the related public health implications.

The survey results indicate that there is uncertainty about which test should be selected for laboratory confirmation of breakthrough varicella. Three different tests were equally popular among clinicians for this purpose (Figure): direct fluorescent antibody (DFA), polymerase chain reaction (PCR), and serology (comparison of acute and convalescent immunoglobulin G [IgG] titers). DFA has been used to diagnose varicella and differentiate it from herpes simplex-related rashes, but its performance relies on adequate specimen collection, and it is also less sensitive than PCR.[23] PCR is both highly sensitive and specific and has recently

been recognized as the test of choice for diagnosing breakthrough varicella.[23,24] Measurement of serum IgG antibody against varicella is only useful to provide proof of immunity to natural infection and does not have adequate sensitivity to detect change in IgG antibody titer of vaccinated individuals after breakthrough varicella.[25]

The limited availability of the PCR test for varicella may explain in part the fact that many HCPs did not select PCR as their first-choice test. We believe that PCR for varicella should be made readily available so that HCPs are encouraged and empowered to laboratory confirm suspected cases, as it is taught with other vaccine-preventable diseases and diseases with public health consequences. As a component of their bioterrorism preparedness programs, state public health laboratories were given the capability to test for varicella along with the necessary training, as varicella is the first diagnosis in the differential for smallpox.[26] Although a specific funding mechanism will be needed to support the continued use of VZV laboratory services, having these public health laboratories process specimens collected to rule out breakthrough varicella may provide a solution and facilitate diagnosis and management. Use of these laboratory services on a regular basis could also help the technicians in these laboratories maintain skills related to testing for orthopoxviruses. While PCR is a relatively costly test, control of outbreaks resulting from missed diagnoses is also very labor- and resource-intensive. A cost-benefit analysis was outside the scope of this study but should shed some light on the use of PCR as a confirmatory test in the future.

Notably, 28% of the clinicians would not advise a patient's family on school attendance when a child has an exanthematous illness. The reluctance of the survey participants to weigh in on school attendance is corroborated by the fact that most would not report a possible case of varicella to a public health agency and would not notify the school. Physicians' underreporting of communicable diseases to public health agencies has been documented previously.[27] We believe there is significant lack of recognition on the important role primary HCPs can play in protecting and promoting public health. By notifying public health agencies, outbreaks can be prevented and contained, and individuals at greater risk for morbidity and mortality can be protected. We advocate that suspicion of breakthrough varicella should prompt physicians to report their suspicion to public health, conduct a confirmatory test, and offer counseling on containment strategies until the test rules in/out the diagnosis, as is the case for other vaccine-preventable diseases (e.g., measles and pertussis).

Limitations

Our study had certain limitations. We surveyed a small subset of HCPs in Philadelphia, and results may not be generalizable to other areas. Because West Philadelphia has been an active surveillance site for varicella and zoster for several years, we would have expected greater awareness and knowledge about optimal management of breakthrough varicella cases than would be found in other locations. While the responses provided by HCPs in the survey might not reflect their actual actions in daily practice, the testing history and the survey responses of these practices seem consistent. We performed analysis on HCP responses without controlling for the effect of providers working in the same practice. A cost analysis to determine cost-effectiveness of the use of PCR as the confirmatory test for suspected varicella cases was beyond the scope of this study.

CONCLUSION

While further reduction of varicella cases has been seen after widespread implementation of the second varicella vaccine dose,[17] continuous efforts to educate physicians on reporting to public health agencies, responsibility for containing potentially communicable patients, and laboratory confirmation of breakthrough varicella will allow more accurate measurements of the impact of vaccination and improve our understanding of the evolving epidemiology of varicella.

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REFERENCES

1. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2007;56(RR-4):1-40.
2. Varicella outbreak among vaccinated children—Nebraska, 2004. MMWR Morb Mortal Wkly Rep 2006;55(27):749-52.
3. Lopez AS, Guris D, Zimmerman L, Gladden L, Moore T, Haselow DT, et al. One dose of varicella vaccine does not prevent school outbreaks: is it time for a second dose? Pediatrics 2006;117:e1070-7.
4. Guris D, Jumaan AO, Mascola L, Watson BM, Zhang JX, Chaves SS, et al. Changing varicella epidemiology in active surveillance sites—United States, 1995–2005. J Infect Dis 2008;197 Suppl 2:S71-5.

5. Outbreak of varicella among vaccinated children—Michigan, 2003. MMWR Morb Mortal Wkly Rep 2004;53(18):389-92.
6. Bernstein HH, Rothstein EP, Watson BM, Reisinger KS, Blatter MM, Wellman CO, et al. Clinical survey of natural varicella compared with breakthrough varicella after immunization with live attenuated Oka/Merck varicella vaccine. Pediatrics 1993;92:833-7.
7. Galil K, Lee B, Strine T, Carraher C, Baughman AL, Eaton M, et al. Outbreak of varicella at a day-care center despite vaccination. N Engl J Med 2002;347:1909-15.
8. Vázquez M, LaRussa PS, Gershon AA, Steinberg SP, Freudigman K, Shapiro ED. The effectiveness of the varicella vaccine in clinical practice. N Engl J Med 2001;344:955-60.
9. Watson BM, Piercy SA, Plotkin SA, Starr SE. Modified chickenpox in children immunized with the Oka/Merck varicella vaccine. Pediatrics 1993;91:17-22.
10. Chaves SS, Zhang J, Civen R, Watson BM, Carbajal T, Perella D, et al. Varicella disease in vaccinated persons: clinical and epidemiological characteristics, 1997–2005. J Infect Dis 2008;197 Suppl 2:S127-31.
11. Dworkin MS, Jennings CE, Roth-Thomas J, Lang JE, Stukenberg C, Lumpkin JR. An outbreak of varicella among children attending preschool and elementary school in Illinois. Clin Infect Dis 2002;35:102-4.
12. Tugwell BD, Lee LE, Gillette H, Lorber EM, Hedberg K, Cieslak PR. Chickenpox outbreak in a highly vaccinated school population. Pediatrics 2004;113:455-9.
13. Haddad MB, Hill MB, Pavia AT, Green CE, Jumaan AO, De AK, et al. Vaccine effectiveness during a varicella outbreak among schoolchildren: Utah, 2002–2003. Pediatrics 2005;115:1488-93.
14. Gould PL, Leung J, Scott C, Schmid DS, Deng H, Lopez A, et al. An outbreak of varicella in elementary school children with two-dose varicella vaccine recipients—Arkansas, 2006. Pediatr Infect Dis J 2009;28:678-81.
15. Nguyen MD, Perella D, Watson B, Marin M, Renwick M, Spain CV. Incremental effectiveness of second dose varicella vaccination for outbreak control at an elementary school in Philadelphia, Pennsylvania, 2006. Pediatr Infect Dis J 2010;29:685-9.
16. SAS Institute, Inc. SAS®: Version 9.1.3. Cary (NC): SAS Institute, Inc.; 2007.
17. Kattan JA, Sosa LE, Bohnwagner HD, Hadler JL. Impact of two-dose vaccination on varicella epidemiology: Connecticut—2005–2008. J Infect Dis 2011;203:509-12.
18. Lopez AS, Burnett-Hartman A, Nambiar R, Ritz L, Owens P, Loparev VN, et al. Transmission of a newly characterized strain of varicella-zoster virus from a patient with herpes zoster in a long-term-care facility, West Virginia, 2004. J Infect Dis 2008;197:646-53.
19. Seward JF, Zhang JX, Maupin TJ, Mascola L, Jumaan AO. Contagiousness of varicella in vaccinated cases: a household contact study. JAMA 2004;292:704-8.
20. Josephson A, Gombert ME. Airborne transmission of nosocomial varicella from localized zoster. J Infect Dis 1988;158:238-41.
21. Sawyer MH, Chamberlin CJ, Wu YN, Aintablian N, Wallace MR. Detection of varicella-zoster virus DNA in air samples from hospital rooms. J Infect Dis 1994;169:91-4.
22. Yoshikawa T, Ihira M, Suzuki K, Suga S, Tomitaka A, Ueda H, et al. Rapid contamination of the environments with varicella-zoster virus DNA from a patient with herpes zoster. J Med Virol 2001;63:64-6.
23. Leung J, Harpaz R, Baughman AL, Heath K, Loparev V, Vázquez M, et al. Evaluation of laboratory methods for diagnosis of varicella. Clin Infect Dis 2010;51:23-32.
24. Ozcan A, Senol M, Saglam H, Seyhan M, Durmaz R, Aktas E, et al. Comparison of the Tzanck test and polymerase chain reaction in the diagnosis of cutaneous herpes simplex and varicella zoster virus infections. Int J Dermatol 2007;46:1177-9.
25. Schmid DS, Jumaan AO. Impact of varicella vaccine on varicella-zoster virus dynamics. Clin Microbiol Rev 2010;23:202-17.
26. Kim M, Terashita D, Borenstein L, Mascola L. Responding to suspected smallpox cases in the Los Angeles County from 2002 to 2006: identifying areas for education. Am J Emerg Med 2009;27:55-62.
27. Konowitz PM, Petrossian GA, Rose DN. The underreporting of disease and physicians' knowledge of reporting requirements. Public Health Rep 1984;99:31-5.

Comparison of Acute Viral Hepatitis Data Quality Using Two Methodologies, 2005–2007

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ABSTRACT

Objective. We compared the quality of data reported to the Centers for Disease Control and Prevention (CDC) from sites that received funding for acute viral hepatitis surveillance through CDC's Emerging Infections Program (EIP) with sites that have electronic infrastructure to collect data but do not receive funding from CDC to support viral hepatitis surveillance.

Methods. Descriptive analysis was conducted on acute hepatitis A, B, and C cases reported from EIP sites and National Electronic Disease Surveillance System (NEDSS)-based states (NBS) sites from 2005 to 2007. Data were compared for (*1*) completeness of demographic and risk behavior/exposure information; (*2*) adherence to CDC/Council of State and Territorial Epidemiologists (CSTE) case definition for confirmed cases of acute hepatitis A, B, and C; and (*3*) timeliness of reporting to the health department.

Results. Data reported for sex and age were at least 98% complete for both EIP and NBS sites and race/ethnicity was more complete for EIP sites. For acute hepatitis A, B, and C, case reports from EIP sites were more likely than those from NBS sites to include a "yes" response to at least one risk behavior/exposure variable and were more likely to meet the CDC/CSTE case definition. EIP sites received case reports in a more timely fashion than did NBS sites. The case definition for acute hepatitis C proved problematic for both EIP and NBS sites.

Conclusions. Data from the EIP sites were more complete and reported in a more timely way to health departments than data from the NBS sites. Funding for follow-up activities is essential to providing surveillance data of higher quality for decision-making and public health response.

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One of the main objectives of national hepatitis surveillance is to measure the burden of this disease in the population. Since 1966, the Centers for Disease Control and Prevention (CDC) has monitored viral hepatitis through the National Notifiable Diseases Surveillance System (NNDSS).[1] This system enables all states to collect and report valuable data on demographic, laboratory, clinical, and exposure history on cases of acute viral hepatitis identified in their states. However, because data needs shift over time, the attributes of surveillance systems should be periodically evaluated to ensure the best use of scarce public health resources.[2]

Surveillance for viral hepatitis is critical, not only to measure the burden of disease, but also to identify and control outbreaks and facilitate targeted vaccination and other prevention initiatives. Various aspects of viral hepatitis pose unique challenges to conducting population-based surveillance, including the lack of signs and symptoms for many infections, the large number of laboratory positive results indicating potential infections, and the complexity of the viruses causing viral hepatitis. Hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV) cause most viral hepatitis infections in the United States; however, these viruses have differing modes of transmission, necessitating unique prevention strategies. In 2008, more than 8,000 cases of acute viral hepatitis A, B, and C were reported to CDC; however, CDC estimates that more than 30,000 people were newly infected.[3] Infection with HBV and HCV can develop into chronic infection, leading to substantial morbidity and mortality. Although acute infection can result in clinical disease and mortality, most severe health outcomes are associated with persistent or chronic infection. People infected with HBV and HCV are typically asymptomatic; therefore, chronic infection can persist undetected for decades before causing life-threatening liver disease, including cirrhosis and cancer.

CDC funds select sites for viral hepatitis surveillance through its Emerging Infections Program (EIP), a network comprising state health departments, academic institutions, local health departments, and other federal agencies.[4] Since 2004, EIP sites have been conducting enhanced population-based surveillance for acute infection with HAV, HBV, and HCV. Surveillance efforts include follow-up on cases and outbreak investigations to collect basic clinical and demographic information and information regarding risk behaviors and exposures.[5] Sites submitted a cumulative dataset of cases without personal identifying information to CDC's Division of Viral Hepatitis (DVH) on a monthly basis via a secure file transfer protocol site.

In 2003, CDC developed the National Electronic Disease Surveillance System (NEDSS), a passive, patient-centric surveillance system characterized by an Internet-based infrastructure for public health surveillance data exchange that employs specific data standards.[6] By 2007, 15 states were using NEDSS to conduct viral hepatitis surveillance. While none of these NEDSS-based states (NBS) received viral hepatitis surveillance funding from CDC, the NBS sites voluntarily transmit case reports to CDC on a weekly basis via NNDSS, which has the capacity to receive the same information as the EIP-funded hepatitis surveillance sites. Case reporting forms for both EIP and NBS sites are identical and allow for the collection of demographic data, clinical information, laboratory information, and risk exposures.

The federal government has provided few resources—in the form of guidance, funding, and oversight—to local and state health departments to perform surveillance for viral hepatitis.[7] To optimize use of available funding and resources, the adequacy of existing viral hepatitis surveillance mechanisms must be evaluated. This article assesses and compares CDC EIP-funded and non-funded surveillance mechanisms, with a focus on three core attributes of viral hepatitis surveillance: (*1*) completeness of demographic data (i.e., sex, age, and race/ethnicity) and risk behavior/exposure information; (*2*) adherence to the CDC/Council of State and Territorial Epidemiologists (CSTE) case definition for a confirmed case of acute hepatitis A, B, and C; and (*3*) timeliness of reporting to the health department.

METHODS

We selected laboratory-confirmed cases of acute hepatitis A, B, and C reported from six EIP demonstration sites (n=2,273 cases reported from Colorado, Connecticut, Minnesota, New York City, 34 counties in New York State, and Oregon) and 15 NBS sites (n=6,314 cases reported from Alabama, Idaho, Maine, Maryland, Montana, Nebraska, Nevada, New Mexico, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, and Wyoming), all of which had collected at least one full year of data from 2005–2007. Ratio estimates were calculated and tested for completeness of demographic and risk information and proportion of cases meeting the case definition to measure the effect and describe the strength of association between EIP sites and NBS sites. Calculated p-values of <0.01 were considered statistically significant. All analyses were conducted using SAS® version 9.2.[8]

Completeness of demographic and risk information

We assessed completeness of reporting for sex, age, and race/ethnicity by calculating the percentage of reported cases with a valid response for these variables. Responses for sex were considered valid if either "male" or "female" was indicated on the reporting form. For age, responses that included a date of birth were considered valid, and for race/ethnicity, responses were valid only if "yes" was marked on the reporting form to indicate American Indian/Alaska Native, black, white, Asian/Pacific Islander, other race, or Hispanic race/ethnicity. Cases with any other response regarding demographics (e.g., unknown or missing) were excluded.

Completeness of reporting for risk behavior/exposure information (Table 1) was classified in one of three ways: (*1*) case reports indicating at least one risk behavior/exposure (i.e., at least one "yes" response to a risk behavior/exposure variable), (*2*) reports indicating no identified risk behavior/exposure (i.e., responses to all questions about risk behavior/exposure variables were "no"), and (*3*) reports with either unknown or missing information for all risk behavior/exposure variables. We determined the percentage of cases within each category and compared them using ratio estimates and 95% confidence intervals (CIs).

Meeting the case definition

We evaluated cases of acute viral hepatitis reported from EIP and NBS sites to determine whether they

Table 1. Percentage of viral hepatitis case reports with complete demographic and risk behavior/exposure information—EIP demonstration sites[a] and NBS sites,[b] 2005–2007

Characteristic	*EIP sites (n=2,273 cases) Percent*	*NBS sites (n=6,314 cases) Percent*	*Ratio estimate (95% CI)*	*P-value*
Demographic information				
Sex	99.9	99.0	1.0 (1.0, 1.0)	<0.01
Race/ethnicity	89.7	68.4	1.3 (1.3, 1.3)	<0.01
Age	99.8	98.3	1.0 (1.0, 1.0)	<0.01
HAV-risk information[c]				
At least one "yes" response	55.3	30.5	1.8 (1.7, 2.0)	<0.01
No identified risk	37.0	37.8	1.0 (0.9, 1.1)	0.65
Missing or unknown	7.7	31.7	0.2 (0.2, 0.3)	<0.01
HBV-risk information[d]				
At least one "yes" response	64.9	27.9	2.3 (2.2, 2.5)	<0.01
No identified risk	24.1	41.8	0.6 (0.5, 0.7)	<0.01
Missing or unknown	11.0	30.4	0.4 (0.3, 0.4)	<0.01
HCV-risk information[d]				
At least one "yes" response	71.1	43.4	1.6 (1.4, 1.9)	<0.01
No identified risk	14.1	19.7	0.7 (0.5, 1.0)	0.05
Missing or unknown	14.8	36.9	0.4 (0.3, 0.5)	<0.01

[a]The six EIP sites used in this analysis were Colorado, Connecticut, Minnesota, New York City, 34 counties in New York State, and Oregon.

[b]The 15 NBS sites used in this analysis were Alabama, Idaho, Maine, Maryland, Montana, Nebraska, Nevada, New Mexico, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, and Wyoming.

[c]Risk behavior/exposure variables two to six weeks before symptom onset for HAV included being a household, sexual, or other contact of someone diagnosed with HAV; having multiple sex partners; being a man who has sex with men; being a child in daycare or a daycare employee; traveling outside the United States and Canada or having a household contact with such travel three months before symptom onset; and having been exposed as part of a common-source outbreak, foodborne or waterborne.

[d]Risk behavior/exposure variables for HBV (six weeks to six months before symptom onset) and HCV (two weeks to six months before symptom onset) included having sexual, household, or other contact with an infected person; using injection drugs or non-injection street drugs; having multiple sex partners; being a man who has sex with other men; undergoing dialysis; having received a needlestick or blood transfusion; being employed in the medical field or public safety; having received a tattoo, piercing, dental work, or surgery; and being a resident of a long-term care facility.

EIP = Emerging Infections Program

NBS = National Electronic Disease Surveillance System-based states

CI = confidence interval

HAV = hepatitis A virus

HBV = hepatitis B virus

HCV = hepatitis C virus

met the CDC/CSTE definition for a confirmed case. For hepatitis A, we used the 2000 case definition; for hepatitis B and C, the 2004 case definitions were used. Case definitions for all three types of acute viral hepatitis share the following clinical criteria: acute illness with (*1*) discrete onset of symptoms and (*2*) jaundice or elevated serum alanine aminotransferase (ALT) levels. For acute hepatitis A and B, elevated ALTs are defined as two times the upper limit of normal; for acute hepatitis C, ALT levels of >400 International Units per liter are considered elevated. Laboratory criteria, however, vary by type of viral hepatitis. Only those cases of acute hepatitis A with a positive assay for immunoglobulin M (IgM) antibody to hepatitis A virus meet laboratory requirements, and acute hepatitis B requires a positive IgM antibody to hepatitis B core antigen or positive hepatitis B surface antigen. Acute hepatitis C laboratory requirements include a positive antibody to a hepatitis C virus (anti-HCV) screening test (repeat reactive), verified by results from an additional, more specific assay (e.g., recombinant immunoblot assay for anti-HCV, nucleic acid testing for HCV ribonucleic acid, or a positive anti-HCV screening test with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay).

Cases meeting both the clinical and laboratory criteria associated with the CDC/CSTE case definition were considered confirmed. Cases that did not meet the case definition were further assessed to determine gaps in information, including missing data for acute onset of symptoms, clinical criteria, and laboratory testing. The percentage of cases meeting the definition and the reasons that cases did not meet the definition were determined and compared using ratio estimates and 95% CIs.

Timeliness of reporting

We assessed timeliness of case reporting by calculating the number of days between the date of diagnosis and the date the health department received the case report. To be considered valid, both the diagnosis date and the report-received date were required to have non-missing date responses. The percentages of cases reported within one week and within 30 days were determined and compared for EIP and NBS sites.

RESULTS

Completeness of reporting

Data reporting for sex and age were 99.9% and 99.8% complete, respectively, for EIP sites and 99.0% and 98.3% complete, respectively, for NBS sites. Although reporting for race/ethnicity was more complete for data reported from EIP sites (89.7%), NBS sites maintained 68.4% completeness. EIP sites were 1.3 times as likely as NBS sites to have complete race/ethnicity data (Table 1).

For hepatitis A, B, and C, case reports from EIP sites were more likely than those from NBS sites to include a "yes" response to at least one risk behavior/exposure variable (1.8, 2.3, and 1.6 times as likely for HAV, HBV, and HCV, respectively) (Table 1). However, when examining the percentage of case reports with a "no" response to all risk behavior/exposure variables, results varied by type of viral hepatitis. EIP and NBS sites were equally likely to report cases of HAV infection with no risk behavior/exposure, whereas for HBV and HCV infections, reports from EIP sites were less likely to have a "no" response to all risk behavior/exposure variables (0.6 and 0.7 times as likely for HBV and HCV, respectively). For all three types of viral hepatitis, case reports from EIP sites were less likely to have missing or unknown information about risk behaviors/exposures (0.2, 0.4, and 0.4 times as likely for HAV, HBV, and HCV, respectively) (Table 1).

Meeting the case definition

Compared with NBS sites, cases of hepatitis A, B, and C reported through EIP sites were more likely to meet the CDC/CSTE case definition (1.6, 2.3, and 3.3 times as likely, respectively) (Table 2). Failure to meet the case definition was attributable to different factors, depending on the type of viral hepatitis and surveillance program. For both EIP and NBS sites, reports of HAV and HBV infections were excluded from the case definition primarily because of missing information regarding clinical characteristics (i.e., data on ALT levels and jaundice). For NBS sites, absence of information regarding acute onset of symptoms also caused reports of HAV and HBV infections to be excluded from the case definition. Regardless of surveillance site, the reason most cases of HCV infection failed to meet the case definition was the absence of required laboratory testing data.

Timeliness of reporting

Timeliness of reporting could be determined for 69% of the case reports from EIP sites and 49% of the cases received from NBS sites (i.e., reports contained both the diagnosis date and the date a case was reported) (Table 3). For all three types of viral hepatitis, health departments within EIP sites received case reports more quickly than did those in NBS sites. For EIP sites, most cases of HAV, HBV, and HCV infection were reported within seven days of diagnosis (median of four, zero, and six days, respectively). For NBS sites,

although about one-half of all HAV infection cases were reported within seven days of diagnosis, reporting time was slower for cases of HBV and HCV infections (14 and 16 days, respectively). Health departments in both surveillance systems received more reports of all types of viral hepatitis by 30 days after diagnosis. For EIP sites, 94.1% of HAV, 97.6% of HBV, and 80.1% of HCV cases were reported within 30 days of diagnosis. In NBS sites, 85.3% of HAV, 66.4% of HBV, and 70.4% of HCV cases were reported within 30 days of diagnosis.

DISCUSSION

For the three categories examined in this study, the quality of data was higher for EIP sites than NBS sites. Compared with NBS sites, demographic and risk behavior/exposure data were more completely reported, significantly more cases met the case definition, and reporting was more timely in EIP sites. The success of any effort to measure the burden of viral hepatitis, identify and respond to outbreaks in a timely fashion, and develop and evaluate prevention strategies hinges

Table 2. Percentage of viral hepatitis cases meeting the case definition[a] of viral hepatitis and reason why cases did not meet the case definition[b]—EIP demonstration sites[c] and NBS sites,[d] 2005–2007

Type of hepatitis/case definition	*EIP sites (n=2,273 cases) Percent*	*NBS sites (n=6,314 cases) Percent*	*Ratio estimate (95% CI)*	P-*value*
HAV				
Case definition met				
Yes	87.5	53.9	1.6 (1.6, 1.7)	<0.01
No	12.5	46.1		
Reason case definition not met				
Missing acute onset of symptoms	58.7	72.3		
Missing clinical information (LFT or jaundice)	79.7	84.7		
Missing laboratory testing	48.3	8.3		
HBV				
Case definition met				
Yes	96.5	41.3	2.3 (2.2, 2.4)	<0.01
No	3.5	58.7		
Reason case definition not met				
Missing acute onset of symptoms	30.0	88.9		
Missing clinical information (LFT or jaundice)	73.3	87.2		
Missing laboratory testing	6.7	6.6		
HCV				
Case definition met[e]				
Yes	55.3	17.0	3.3 (2.6, 4.1)	<0.01
No	44.7	83.1		
Reason case definition not met				
Missing acute onset of symptoms	0.8	41.9		
Missing clinical information (LFT or jaundice)	6.3	22.7		
Missing laboratory testing	92.9	90.7		

[a]Elevated aminotransferase levels (ALTs) are defined as two times the upper limit of normal.

[b]Not mutually exclusive; multiple reasons could explain why the case definition was not met.

[c]The six EIP sites used in this analysis were Colorado, Connecticut, Minnesota, New York City, 34 counties in New York State, and Oregon.

[d]The 15 NBS sites used in this analysis were Alabama, Idaho, Maine, Maryland, Montana, Nebraska, Nevada, New Mexico, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, and Wyoming.

[e]The case definition used for acute HCV was a modified version of the 2005 Centers for Disease Control and Prevention/Council of State and Territorial Epidemiologists case definition. ALTs were elevated at >400 International Units per liter.

EIP = Emerging Infections Program

NBS = National Electronic Disease Surveillance System-based states

CI = confidence interval

HAV = hepatitis A virus

LFT = liver function test

HBV = hepatitis B virus

HCV = hepatitis C virus

Table 3. Timeliness of reporting cases of viral hepatitis from diagnosis date to reporting to the state health department—EIP demonstration sites[a] and NBS sites,[b] 2005–2007

Site and event	Median (days)	Range (days)	Percent ≤7 days	Percent ≤30 days
EIP[c]				
HAV	4	0–726	72.9	94.1
HBV	0	0–229	87.6	97.6
HCV	6	0–1,646	56.0	80.1
NBS[d]				
HAV	7	0–391	51.9	85.3
HBV	14	0–432	36.9	66.4
HCV	16	0–687	28.2	70.4

[a]The six EIP sites used in this analysis were Colorado, Connecticut, Minnesota, New York City, 34 counties in New York State, and Oregon.

[b]The 15 NBS sites used in this analysis were Alabama, Idaho, Maine, Maryland, Montana, Nebraska, Nevada, New Mexico, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, and Wyoming.

[c]69% of case reports from EIP sites had both diagnosis date and report date.

[d]49% of case reports from NBS sites had both diagnosis date and report date.

EIP = Emerging Infections Program

NBS = National Electronic Disease Surveillance System-based states

HAV = hepatitis A virus

HBV = hepatitis B virus

HCV = hepatitis C virus

on the availability of (*1*) complete, accurate, and reliable de-duplicated case data; and (*2*) the consistent application of case definitions, which provide uniform criteria for reporting cases that increase the specificity of reporting and improve the comparability of disease reports from different geographical areas.[9] Timeliness of reporting is also an integral surveillance component, particularly for outbreak detection, to enable prompt public health response to changes in disease occurrence.[10]

The case definition for acute hepatitis C proved problematic for both surveillance programs. Slightly more than half (55.3%) of cases reported through EIP sites and only 17.0% of cases from NBS sites met the case definition for acute hepatitis C. Several factors contribute to case-definition challenges, including lack of a laboratory marker to distinguish between acute and chronic HCV infections. In the absence of such a marker, acute and chronic cases can only be distinguished by clinical information. Further, for both EIP and NBS sites, more than 90.0% of acute hepatitis C case reports were missing the laboratory test information needed to meet the case definition (e.g., signal-to-cutoff ratios) (Table 2).[11] Lack of clinical information also is problematic—a substantial number of case reports did not include the basic clinical data needed to determine whether the case definition was met. Health departments are tasked with conducting follow-up for these case reports, which can be burdensome and particularly challenging for those with scarce resources.

The overwhelming number of laboratory reports of hepatitis C received by health departments serves as another barrier to reporting. Because chronic hepatitis C is highly prevalent in the United States, health departments process four laboratory reports for every new case of HCV infection.[12] With numerous laboratory results and limited electronic laboratory reporting (ELR), health departments have a difficult time entering cases into their data systems. This difficulty is particularly problematic for EIP sites, which are in need of an enhanced infrastructure for electronic reporting. Although NBS sites have an adequate electronic infrastructure in place for collecting multiple laboratory results through ELR, lack of federal funding has rendered these sites understaffed to provide needed follow-up on potential cases.

A recent Institute of Medicine report suggested that completeness of reporting for hepatitis C could be improved by eliminating clinical requirements from the case definition.[7] Such an approach would facilitate the identification of all HCV infections, regardless of whether they are symptomatic. This approach would be helpful in identifying chronic cases, as clinical symptoms are not a criterion in the case definition. However, because clinical characteristics are the only criteria used to differentiate acute from chronic cases, excluding clinical information from the case defini-

tion would compromise efforts to identify new cases of hepatitis C. Early recognition of HCV infection is critical to the health outcome of infected individuals because treatments for viral hepatitis are more effective when taken during the acute phase of infection.[13]

Limitations

The findings in this article are subject to several limitations. The results only represent cases reported from selected sites, and data quality and timeliness may not be comparable to other U.S. populations, who may have varying viral hepatitis surveillance resources. Also, there may be differences in overall population coverage between the two types of sites; however, these differences were not assessed. Additionally, we did not assess the qualitative process, such as case ascertainment and follow-up methods, used by NBS sites, as there were no site visits or follow-up with NBS sites on their specific methods used for viral hepatitis surveillance. Differences in qualitative processes between the two surveillance programs, therefore, could not be determined. For both EIP and NBS sites, data were not evaluated by specific site; consequently, observed variations in data between the two reporting systems may reflect data collection at certain sites rather than the system as a whole. Furthermore, to facilitate comparison of the two surveillance methods, only data obtained from the reporting forms were analyzed in this study. Although both EIP and NBS sites use the same forms to collect viral hepatitis data, NBS sites routinely collect additional information that might have provided further insight on acute viral hepatitis in these states.

CONCLUSIONS

Overall, viral hepatitis surveillance data from EIP sites were more completely reported; more often met the CDC/CSTE case definitions for hepatitis A, B, and C; and were reported in a more timely way than comparable surveillance data from NBS sites. Additional efforts are needed to better understand the factors that promote the timely collection of quality viral hepatitis data in the U.S. For instance, since 2009, two NBS sites began receiving viral hepatitis surveillance funding through EIP; analyses are needed to determine how additional funding affects data quality and completeness of reporting. Another important next step would be to evaluate the criteria required to meet the case definitions, modify the current case report forms as appropriate, and analyze the impact of a new case definition on case reporting. Finally, because electronic data systems provide increased opportunities for efficient data collection, development and expansion of electronic infrastructure are critical components of future viral hepatitis surveillance efforts. Providing funding for surveillance sites such as NBS that already have the electronic infrastructure in place would be beneficial. Taken together, all of these steps can help improve the quality of viral hepatitis surveillance data, even among sites with limited resources.

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REFERENCES

1. Daniels D, Grytdal S, Wasley A. Surveillance for acute viral hepatitis—United States, 2007. MMWR Surveill Summ 2009;58(3):1-27.
2. German RR, Lee LM, Horan JM, Milstein RL, Pertowski CA, Waller MN. Updated guidelines for evaluating public health surveillance systems: recommendations from the Guidelines Working Group. MMWR Recomm Rep 2001;50(RR-13):1-35.
3. Centers for Disease Control and Prevention (US). Estimates of disease burden from viral hepatitis. Atlanta: CDC; 2008. Also available from: URL: http://www.cdc.gov/hepatitis/PDFs/disease_burden.pdf [cited 2012 Jul 3].
4. Schuchat A, Hilger T, Zell E, Farley MM, Reingold A, Harrison L, et al. Active bacterial core surveillance of the emerging infections program network. Emerg Infect Dis 2001;7:92-9.
5. Klevens RM, Miller JT, Iqbal K, Thomas A, Rizzo EM, Hanson H, et al. The evolving epidemiology of hepatitis A in the United States: incidence and molecular epidemiology from population-based surveillance, 2005–2007. Arch Intern Med 2010;170:1811-8.
6. Status of state electronic disease surveillance systems—United States, 2007. MMWR Morb Mortal Wkly Rep 2009;58(29):804-7.
7. Institute of Medicine. Hepatitis and liver cancer: a national strategy for prevention and control of hepatitis B and C. Washington: National Academies Press; 2010.
8. SAS Institute, Inc. SAS®: Version 9.2. Cary (NC): SAS Institute, Inc.; 2008.
9. Wharton M, Chorba TL, Vogt RL, Morse DL, Buehler JW. Case definitions for public health surveillance. MMWR Recomm Rep 1990;39(RR-13):1-43.
10. Thacker SB, Choi K, Brachman PS. The surveillance of infectious diseases. JAMA 1983;249:1181-5.
11. Alter MJ, Kuhnert WL, Finelli L. Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. MMWR Recomm Rep 2003;52(RR-3):1-13, 15.
12 Klevens RM, Miller J, Vonderwahl C, Speers S, Alelis K, Sweet K, et al. Population-based surveillance for hepatitis C virus, United States, 2006–2007. Emerg Infect Dis 2009;15:1499-502.
13. Jaeckel E, Cornberg M, Wedemeyer H, Santantonio T, Mayer J, Zankel M, et al. Treatment of acute hepatitis C with interferon alfa-2b. N Engl J Med 2001;345:1452-7.

Law and the Public's Health

This installment of *Law and the Public's Health* examines the raw milk controversy and the implications of two federal court decisions for both U.S. Food and Drug Administration enforcement efforts and the ongoing role of state public health agencies in assuring the safety of intrastate consumption of raw milk.

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RAW MILK IN COURT: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

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Although only about 3% of the U.S. population drinks raw—or unpasteurized—milk, in recent years, the raw milk movement has erupted into an impassioned and increasingly public debate between public health authorities and consumers.[1] In 2012, even as a raw milk outbreak in Pennsylvania sickened 80 people in four states and a new Centers for Disease Control and Prevention (CDC) study reaffirmed the link between foodborne illness risks and raw milk consumption, several states considered legislation that would legalize raw milk sales within their borders, and two federal court decisions involving the regulation and sale of raw milk—*U.S. v. Allgyer*[2] and *Farm-to-Consumer Legal Defense Fund (FTCLDF) v. Sebelius*[3]—added fodder to the arguments on both sides.

This installment of *Law and the Public's Health* examines the debate regarding raw milk regulation and sales in the United States and the implications of *U.S. v. Allgyer* and *FTCLDF v. Sebelius* for public health practice and policy.

BACKGROUND

The past several years have witnessed an increased consumer demand for "whole," locally grown and produced foods, particularly produce, meat, and dairy. Commensurate with this increase, heated debate has evolved regarding the sale of raw milk between a growing number of consumers on the one side, and state and federal food safety and public health officials on the other. Although the U.S. Food and Drug Administration (FDA) regulations prohibit the interstate sale of unpasteurized milk for human consumption, 30 states allow raw milk sales within their borders with varying restrictions.

Public health authorities have long noted the significant risk of serious foodborne illness associated with raw milk.[4] To protect against this risk, the vast majority of dairy products consumed in the U.S. today are pasteurized, a technique in which the milk is heated rapidly to a temperature high enough to kill most foodborne pathogens. Raw milk is not subject to this heating process and, therefore, is more likely to harbor harmful pathogens such as *Campylobacter*, *Salmonella*, *Escherichia coli* O157:H7, and *Listeria*, all of which would have been killed during pasteurization.[5]

Despite the reportedly small number of consumers who drink raw milk, most outbreaks among both pasteurized and unpasteurized milk are attributed to raw milk. In a recent CDC study, researchers found that, of the 56 fluid-milk reported outbreaks between 1993 and 2006, 46 (82%) involved raw milk, while only 10 were attributed to pasteurized milk. These 46 outbreaks led to 930 reported illnesses and 71 reported hospitalizations, with a disproportionate impact on people younger than 20 years of age.[6]

Notwithstanding the known risks of foodborne illness associated with consuming raw milk, the demand for raw milk appears to be increasing. While better taste is often cited as the primary reason consumers choose to drink raw milk, many proponents also believe that the pasteurization process depletes the milk of important properties that otherwise would confer health benefits, such as a reduction in asthma and allergies and improved infection-fighting capabilities.[7] Although public health authorities stress there is a lack of evidence to back these health-related assertions, state legislators, responding to constituent demand, have introduced a number of bills to legalize the sale of raw milk within their jurisdictions.

REGULATION OF RAW MILK

Federal regulation

FDA authority for regulating the interstate sale of raw milk is found in the commerce clause of the U.S. Constitution, which, in turn, gives Congress the authority to enact legislation affecting interstate commerce, including laws regulating food, drugs, and cosmetics under the Public Health Service Act (PHSA)[8] and the Food, Drug, and Cosmetic Act (FDCA).[9] The PHSA authorizes the FDA to adopt and enforce regulations that are necessary, in the agency's view, to prevent the introduction, transmission, or spread of communicable diseases—such as those caused by foodborne pathogens—from one state to another.[8] Pursuant to this authority, the FDA regulates the sale of milk in interstate commerce according to rules prescribed in its unpasteurized milk regulation, which provides that "no person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized. . . ."[10]

The FDA's authority with regard to raw milk is also found in the FDCA, which gives the FDA responsibility for protecting the public's health by ensuring that food entering interstate commerce is not adulterated or misbranded.[11] Raw milk harboring foodborne pathogens would be considered adulterated under the FDCA. But more often, raw milk is the subject of misbranding claims, because bottles of raw milk transported in interstate commerce do not conform to the FDA's "standard of identity" for milk, which requires that any beverage in final packaged form that is labeled as "milk" and sold in interstate commerce be pasteurized.[12]

The federal government's authority to regulate products such as raw milk in interstate commerce is broad and may extend to purely intrastate activities when necessary to make a regulation of interstate commerce effective.[13] Indeed, as a federal judge found in *Public Citizen v. Heckler*, "should it appear that the interstate sale of raw milk continues, it is within [the U.S. Department of Health and Human Services'] authority at that time to institute an intrastate ban as well . . . [if] . . . necessary to effectuate the interstate ban."[14] Moreover, in *Gonzales v. Raich*, which involved a federal ban under the federal Controlled Substances Act on locally grown and consumed marijuana, the U.S. Supreme Court held that actual movement of a regulated product into interstate commerce is not a necessary condition for federal intervention.[13] Rather, as Justice Scalia offered in his concurrence, federal laws can reach purely intrastate practices if such regulation is considered "necessary and proper" to a broader regulatory scheme affecting commerce.[15]

State regulation

Although the FDA prohibits the sale of raw milk across state lines, states retain authority through their police powers to regulate the sale of raw milk within their borders. Currently, 20 states and the District of Columbia prohibit the sale of raw milk, while the remaining 30 states allow sales of raw milk; state regulations vary widely.[16] Thirteen states permit sales only on the farm where the milk is produced, while 12 states permit sales of raw milk in retail stores separate from the farm. Five states maintain regulations that allow a combination approach, such as restricting sales to farmers' markets or to "owners" of the cow through "share" agreements.[16]

RECENT LITIGATION

With the growing demand for raw milk, consumers in states where such sales are prohibited often seek out other ways to obtain the milk. One approach is in-person purchases from out-of-state farms where raw milk is sold legally; another is entering into cow "shares" or private "buyers' clubs" in which groups of individuals buy or lease partial ownership of a cow and the milk it produces to avoid any interstate transaction involving raw milk. Two recent federal cases examined the legality of these practices under the FDA's unpasteurized milk regulation and the FDCA.

FTCLDF v. Sebelius

In 2010, the FTCLDF brought an action against the FDA challenging the constitutionality of its prohibition on interstate sales of raw milk.[3] Plaintiffs included individuals who sought to purchase raw milk in a state where sales were legal and transport it back to their home states—which did not permit such sales—for personal or family consumption. They also included an "agent" for a raw milk buyers' club who obtained raw milk legally from one state and delivered it to club members for personal or family consumption in states that prohibit sales, as well as a farmer who produced raw milk in a state where sales were permitted but knowingly sold to it customers who came into the state to make their purchase but resided in states that prohibit sales.

In the course of the litigation, the federal judge sought information from the FDA regarding the extent to which its unpasteurized milk regulation prohibited the types of sales in which plaintiffs were engaged. In its responses, the FDA generally asserted that all three

types of sales would violate its unpasteurized milk regulation by "causing milk to be delivered into interstate commerce." The agency further asserted that producers and buyers' agents who sell, ship, or transport raw milk to consumers in other states, or who solicit interstate sales, would be subject to FDA enforcement actions.[3] Notably, however, the FDA indicated to both the court and in separate public communications that it has "never taken, nor does it intend to take, enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption."[17] In March 2012, the judge dismissed the case against all plaintiffs for lack of standing on the grounds that none of them had actually been the subject of an FDA enforcement action under the unpasteurized milk regulation.[3]

U.S. v. Allgyer

In February 2012, the FDA emerged the victor in a suit against Daniel Allgyer, a dairy farmer in Pennsylvania. Allgyer had been shipping unpasteurized milk to buyers in Maryland, first through direct-to-consumer sales and later through a cow-share arrangement.[2] While raw milk sales are legal in Pennsylvania, they are prohibited in Maryland. The FDA filed suit against Allgyer, alleging that he had violated the PHSA, the FDA's unpasteurized milk regulation, and the FDCA. The agency sought an order from the court that he discontinue all interstate sales of raw milk.

The judge found that Allgyer's interstate sales of raw milk had violated both the PHSA and the unpasteurized milk regulation by "engaging in conduct that endangers the public health and safety by distributing in interstate commerce unpasteurized milk and milk products in final package form for human consumption." The court concluded that Allgyer's cow-share arrangement with his buyers was simply a sham method for continuing his interstate sales. The court further found that, because bottles containing raw milk that were delivered from Allgyer's Pennsylvania farm to consumers in Maryland were not labeled, the milk was misbranded within the meaning of the FDCA. As a result, the judge issued a permanent injunction prohibiting Allgyer from continuing to sell his raw milk products across state lines.

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

U.S. Supreme Court precedent grants the federal government broad powers to regulate both goods in commerce and wholly intrastate conduct that nonetheless has a substantial effect on commerce. With increasing interest in raw milk and the willingness of consumers to travel to neighboring states to obtain it, *U.S. v. Allgyer* and *FCLDF v. Sebelius* both provide an express legal basis for the FDA's actions while simultaneously offering greater clarity regarding the agency's enforcement intentions. Consumers living in states where raw milk sales are prohibited can continue to travel to other states where it is sold legally, and transport it back to their home states for personal and family consumption without fear of receiving a warning or worse from the FDA. At the same time, sellers of raw milk products cannot engage in practices that place their products in interstate commerce.

These cases do not in any way undermine the power of state public health agencies to regulate the sale of raw milk within their borders and suggest the importance of continuing efforts by state public health authorities to oversee the consumption of raw milk and educate residents about the associated foodborne illness risks, particularly in children, the elderly, and those with compromised immune systems. State public health agencies play a continuing and crucial role in monitoring raw milk production, responding to foodborne illness outbreaks, and educating state lawmakers regarding the health risks—to residents of their own states as well as other states—associated with raw milk consumption and laws that permit its sale.

At the same time, however, the *U.S. v. Allgyer* decision suggests that producers and buyers' agents will continue to be the focus of FDA investigations and enforcement actions aimed at curbing the interstate sale of raw milk. In this context, consumers who travel to other states to buy raw milk that is to be subsequently transported back to their own states may provide the evidence on which such enforcement actions will be based under federal law. This bifurcated policy approach—permitting purely local consumption of raw milk in states that allow it while regulating its interstate movement—represents a more tolerant approach than that taken by the federal government in the case of medical marijuana, balancing the authority of states to allow such practices within their borders with the role of the federal government in protecting the nation against unsafe commercial practices.

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REFERENCES

1. Centers for Disease Control and Prevention (US). Foodborne Active Surveillance Network (FoodNet) population survey atlas of exposures. Atlanta: CDC; 2006–2007. Also available from: URL: http://www.cdc.gov/foodnet/surveys/FoodNetExposureAtlas0607_508.pdf [cited 2012 Jul 31].
2. *U.S. v. Allgyer*, 2012 U.S. Dist. LEXIS 13257 (E.D. Pa., Feb. 2012).
3. *Farm-to-Consumer Legal Defense Fund v. Sebelius*, No. C 10-4018-MWB (N.D. Iowa, March 30, 2012).
4. Weisbecker A. A legal history of raw milk in the United States. J Environ Health 2007;69:62-3.
5. Food and Drug Administration (US). The dangers of raw milk: unpasteurized milk can pose a serious health risk [cited 2012 May 18]. Available from: URL: http://www.fda.gov/Food/ResourcesForYou/consumers/ucm079516.htm
6. Langer AJ, Ayers T, Grass J, Lynch M, Angulo FJ, Mahon BE. Nonpasteurized dairy products, disease outbreaks, and state laws—United States, 1993–2006. Emerg Infect Dis 2012;18:385-91.
7. Mendelson A. "In bacteria land": the battle over raw milk. Gastronomica (Berkeley Calif) 2011;11:35-43.
8. 42 U.S.C. §264(a).
9. U.S. Constitution. Art. 1, §8, cl. 3.
10. 21 C.F.R. Part 1240.61.
11. 21 U.S.C. §331(a).
12. 21 C.F.R. §131.110(a).
13. *Gonzales v. Raich*, 545 U.S. 1 (2005).
14. *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986).
15. *Gonzales v. Raich*, 545 U.S. 1 (2005) (Scalia concurring).
16. National Association of State Departments of Agriculture. NASDA releases raw milk survey [press release]; 2011 Jul 19 [cited 2012 May 18]. Available from: URL: http://www.nasda.org/cms/32211.aspx
17. Food and Drug Administration (US). Food safety and raw milk. November 1, 2011 [cited 2012 May 18]. Available from: URL: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm277854.htm

NCHS Dataline

In May 2012, the Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS) published its 35th annual "Health, United States" report. As in previous years, the 2011 edition reports on the nation's health in detailed trend tables, a chartbook, a smaller report of highlights, and a table summarizing the status of key indicators. This year, the special feature in the chartbook is on socioeconomic status and health. Also released in May 2012 were reports from NCHS presenting the latest data and trends on hospitalization for stroke and key indicators for oral health.

REPORT PROFILES HEALTH OF THE NATION

Each year, NCHS publishes "Health, United States" to report on the health of the nation. NCHS prepares the report for the Secretary of the Department of Health and Human Services to submit to the President and the Congress of the United States. Drawing on data from all of the NCHS data systems and other public and private sources, "Health, United States, 2011: With Special Feature on Socioeconomic Status and Health,"[1] presents 151 detailed tables with findings in four major areas: health status and determinants, utilization of health resources, health-care resources, and health-care expenditures and payers. The 45 charts in the chartbook highlight some of the findings in an easy-to-read format. This year's special feature in the chartbook examines the relationship between socioeconomic status, as measured by income and education, and health.

"Health, United States, 2011: In Brief"[2] is a standalone companion to the full report. This short report highlights trends in selected health statistics, each of which is presented in greater detail in the full report. "In Brief" contains summary information on the health of the American people, including mortality and life expectancy; morbidity and risk factors, such as cigarette smoking, overweight, and obesity; access to and utilization of health care; health insurance coverage; supply of health-care resources; and health expenditures. An "At a Glance" table, in both the full brief reports, summarizes some of these key indicators at the national level.

Highlights of the socioeconomic feature of the report included:

- In 2007–2010, higher levels of education among heads of households resulted in lower rates of obesity among children and adolescents 2–19 years of age. In households where the head of household had less than a high school education, 24% of boys and 22% of girls were obese. In households where the head of household had a bachelor's degree or higher education, obesity prevalence was 11% for males aged 2–19 years and 7% for their female counterparts.
- In 2007–2010, women 25 years of age and older with education less than a bachelor's degree were more likely to be obese than those with a bachelor's degree or higher education. Obesity prevalence among adult males did not vary consistently with level of education.
- In 2010, 31% of adults 25–64 years of age with a high school diploma or less education were current smokers, compared with 24% of adults with some college and 9% of adults with a bachelor's degree or higher education. Overall, in the same year, 19% of U.S. adults aged 18 years and older were current cigarette smokers, a decline from 21% in 2009.
- From 1996 to 2006, the gap in life expectancy at age 25 years between those with less than a high school education and those with a bachelor's degree or higher education increased by 1.9 years for men and 2.8 years for women. On average, in 2006, 25-year-old men without a high school diploma had a life expectancy that was 9.3 years less than those with a bachelor's degree or higher education. Women without a high school diploma had a life expectancy that was 8.6 years less than those with a bachelor's degree or higher education.
- From 2000 to 2010, the percentage of children with a family income below 200% of the federal poverty level (FPL) who were uninsured decreased from 22% to 11%–13%, the percentage of children with a family income at 200%–399% of FPL who were uninsured decreased from 9% to 7%, and the percentage of children with a family income at ≥400% of FPL who were uninsured decreased from 3% to 2%.

Other highlights from the report included:

- In 2010, half of adults 18 years of age and older failed to meet both the aerobic activity and the muscle-strengthening federal physical activity recommendations. Older adults were less likely than younger adults to meet the federal physical activity recommendations—39% of adults 18–24 years of age did not meet the recommendations vs. 70% of adults aged 75 years and older.
- The percentage of women 40 years of age and older who had a mammogram in the past two years remained steady at 67%–70% during the 10-year period from 2000 to 2010. During the same period, the percentage of adults aged 50–75 years with a recent colorectal test or procedure increased from 34% to 59%.

In addition to the tables and charts, the report includes useful information on data sources, definitions and methods, and an index. A technical notes section describes the methodology employed for statistical testing in the chartbook. The chartbook and trend tables are available on the site as downloadable PDFs and Microsoft® Excel spreadsheets. The site also includes Excel spreadsheets of additional years of data for selected trend tables and standard errors for selected estimates, as well as all the charts in PowerPoint format. For ease of locating data on specific topics, the charts and tables are also grouped by topics, such as older adults, racial/ethnic groups, and state data.

Data users can visit http://www.cdc.gov/nchs/hus/hus_electronic_mailing.htm to sign up for the "Health, United States" electronic mailing list and receive information about "Health, United States" activities, products, and release dates. List members also receive notices of updates to existing tables.

STROKE HOSPITALIZATION TRENDS

According to a new report, "Hospitalizations for Stroke in U.S. Hospitals, 1989–2009,"[3] the rate of hospitalization for stroke (cerebrovascular disease) per 10,000 population increased from 32.4 in 1989 to 34.9 in 1999, and then decreased to 31.8 in 2009. About 800,000 hospitalizations for stroke occurred in 1989, and nearly one million hospitalizations occurred during both 1999 and 2009. More than two-thirds of these hospitalizations were for patients aged 65 years and older; the average age of a hospitalized stroke patient was similar (70–71 years) in 1989, 1999, and 2009. The rate of hospitalization for those aged 65 years and older increased with age throughout the period, but all age groups experienced a decline from 1999 to 2009. In that decade, the stroke hospitalization rate decreased by 20% for those aged 65–74 years and ≥85 years, and by 24% for those aged 75–84 years. In 1989, 43% of patients hospitalized for stroke were males, but by 2009, the proportions of male and female stroke patients were similar.

The average length of stay for stroke patients was similar in 1999 (5.4 days) and 2009 (5.3 days), but was significantly shorter than the average hospital stay of 10.2 days in 1989. In all three years, most patients—approximately 60%—had a routine discharge, usually to their home. Smaller percentages of stroke patients were discharged to other short-term facilities (5%–7%) or long-term facilities (16%–18%). A smaller percentage of stroke patients died in the hospital in 2009 (5%) than in 1989 (8%) or 1999 (7%). Although stroke inpatients comprised only about 3% of total hospitalizations, they died at more than twice the rate of other patients in 1989, 1999, and 2009.

Data for this report are from the National Hospital Discharge Survey, a national probability sample survey of discharges from nonfederal, short-stay hospitals or general hospitals in the United States.

ORAL HEALTH INDICATORS

A new report presents data on key indicators of oral health: untreated dental caries, dental restorations (dental filling, crown, or other restorative material applied to the tooth), use of dental sealants, and loss of natural teeth in the United States by age, race/ethnicity, and poverty level in 2005–2008. Findings from "Selected Oral Health Indicators in the United States, 2005–2008"[4] are based on data from the National Health and Nutrition Examination Survey (NHANES), a continuing, nationally representative survey of the civilian, noninstitutionalized population using standardized physical exams, interviews, and laboratory testing to monitor the health of Americans.

Data from the NHANES show that more than one in five people had untreated dental caries in 2005–2008, with the lowest prevalence—about 13%—among adolescents aged 12–19 years. The prevalence of untreated dental caries varied significantly by poverty level, with those living in households with incomes below 100% of FPL being twice as likely as those with household incomes at ≥200% of FPL to have untreated dental caries. This income differential was present across all age groups. Differences by race/ethnicity were also documented. The prevalence of untreated caries was nearly twice as high among non-Hispanic black people (34%) compared with non-Hispanic white people (18%) in 2005–2008. Prevalence of untreated caries

was significantly higher for both non-Hispanic black and Mexican American people compared with non-Hispanic white children and adults.

As expected, the prevalence of existing dental restorations increased as individuals aged from childhood into adulthood and plateaued starting at 45 years of age and older. Thirty-nine percent of children aged 5–11 years and 52% of adolescents aged 12–19 years had a dental restoration. The prevalence of having a dental restoration increased to 79% for adults aged 20–44 years and then to nearly 92% for those aged 45–64 years. Dental restoration prevalence was 88% for those aged 65–74 years and 89% for those aged 75 years and older.

Twenty-seven percent of children and adolescents aged 5–19 years had at least one dental sealant. Thirty percent of non-Hispanic white children and adolescents had a dental sealant compared with 23% of Mexican American children and adolescents and 17% of non-Hispanic black children and adolescents. Dental sealant prevalence was significantly lower for children and adolescents aged 5–19 years living in households with incomes below 200% of FPL (20%–22%) compared with those living in households with incomes at ≥200% of FPL (32%).

Approximately 49% of adults aged 20–64 years had a full set of permanent teeth (excluding third molars). Tooth retention was higher among Mexican American (52%) and non-Hispanic white (51%) people, whereas only 38% of non-Hispanic black people had experienced no tooth loss due to dental disease. For adults aged 20–64 years living at ≥200% of FPL, 52% had not lost a permanent tooth; approximately 40% of adults living below 100% of FPL had retained all of their permanent teeth.

NCHS Dataline was prepared by Sandra S. Smith, MPH, Communications Consultant at the National Center for Health Statistics, Centers for Disease Control and Prevention.

REFERENCES

1. National Center for Health Statistics (US). Health, United States, 2011: with special feature on socioeconomic status and health. Hyattsville (MD): NCHS; 2012. Also available from: URL: http://www.cdc.gov/nchs/hus.htm [cited 2012 Jul 31].
2. National Center for Health Statistics (US). Health, United States, 2011: in brief. Hyattsville (MD): NCHS; 2012.
3. Hall MJ, Levant S, DeFrances CJ. Hospitalization for stroke in U.S. hospitals, 1989–2009. NCHS data brief no. 95. Hyattsville (MD): National Center for Health Statistics (US); 2012. Also available from: URL: http://www.cdc.gov/nchs/data/databriefs/db95.htm [cited 2012 Jul 31].
4. Dye BA, Li X, Beltrán-Aguilar ED. Selected oral health indicators in the United States, 2005–2008. NCHS data brief no. 96. Hyattsville (MD): National Center for Health Statistics (US); 2012. Also available from: URL: http://www.cdc.gov/nchs/data/databriefs/db96.htm [cited 2012 Jul 31].

On Academics

ADMISSIONS CRITERIA AS PREDICTORS OF STUDENTS' ACADEMIC SUCCESS IN MASTER'S DEGREE PROGRAMS AT THE NATIONAL INSTITUTE OF PUBLIC HEALTH OF MEXICO

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A competent public health workforce is a key element to ensure the advancement of research and the successful implementation of public health policy and programs, which, in turn, help ensure the health and wellness of the population. A century after the creation of the professional schools of medicine, public health, and nursing in Mexico, following the reports of Flexner,[1] Welch and Rose,[2] and Goldmark,[3] an effort is under way to modernize the education of health professionals. We need to reexamine the quality of the programs and institutions responsible for training leaders, practitioners, and researchers, all of whom are much needed to advance the public health agenda.

In this context, all of the schools and programs have admissions criteria to select the best candidates for their public health programs; however, we do not have enough evidence to support that each requisite or criteria specific for the programs is a predictor of academic success. Moreover, although some of the criteria are objective, much subjectivity is present during the admissions process.

The use of admissions criteria makes the implicit assumption that these indicators are predictive of a student's eventual good academic performance. Surprisingly, no widely known statistical evidence supports this assumption; as of August 31, 2011, a PubMed search yielded no scientific articles studying admissions processes in schools of public health (SPHs), and few articles dealt with the issue in other health-related professions such as medicine, pharmacy, and dentistry.[4–17]

The need for having a more objective evidence-based selection process has already been identified in undergraduate education. The National Association for College Admission Counseling[18] recommended that each educational institution perform research on the validity of the admissions tests and share its results with other universities. In light of this recommendation, it is striking that the field of public health, which tries to base its progress on rigorous scientific studies, does not apply this same rigorous approach to the selection of its students. The use of terms such as "evidence-based medicine" and even "evidence-based public health" is widespread, reflecting a positive trend to leave subjectivism behind. Why, then, don't SPHs have evidence-based admissions criteria?

The students in the National Institute of Public Health of Mexico (INSP [*Instituto Nacional de Salud Pública*]) come not only from Mexico, but from many other Latin American and Caribbean countries, as well as from the United States, Africa, and Europe. INSP offers primarily the 1.5-year-long Master of Public Health (MPH) and the two-year-long Master of Science (MSc) degrees, with diverse areas of concentration such as epidemiology, biostatistics, environmental health, behavioral and social sciences, health services administration, reproductive health, and nutrition. It also offers doctorate degrees and other diverse academic programs related to public health. Every year, approximately 150 students are admitted to the MPH and MSc programs at INSP.

INSP aspires to have an 80% graduation rate in its master's degree programs, which allows the school to maintain its certification from the U.S. Council on Education for Public Health (CEPH) and the Mexican government's National Council of Science and Technology (CONACYT), the latter of which offers scholarships to students in its certified programs. INSP has struggled to meet this 80% graduation rate, and although it eventually succeeded, students take overly long to graduate. It could take students up to four years or even longer to graduate, whereas the established

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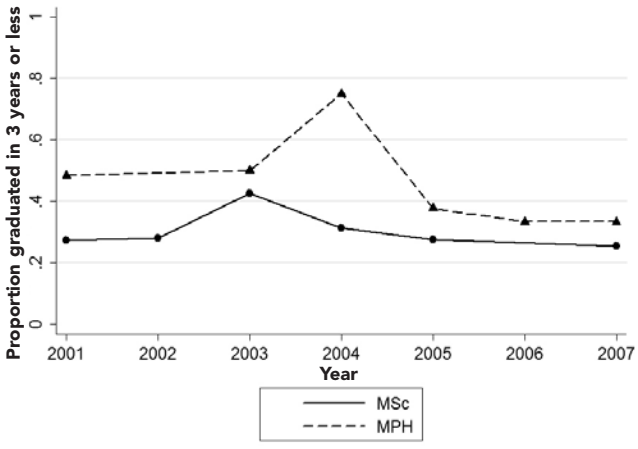
time for graduation is two years, with an extension possibility of one year if the thesis or project requires more time to conclude. To graduate, students must complete either a thesis or a scientific article in the MSc program, and a thesis or a Terminal Professional Project (which describes an intervention in the community and presents its results) in the MPH program. In all cases, students have an advising committee and, upon completing their thesis/project, must present an oral exam before a jury (different from the advising committee) comprising researchers from inside and outside INSP. In the case of an article/thesis, a research protocol must be first written and approved by the student's advising committee, as well as the INSP human subjects, biosafety, and research committees; only after this approval can the student begin to perform research activities, analyze data, and write the article/thesis.

Although INSP's goal is that students graduate in 2.5 years, actual rates of graduation in this amount of time or less have been low (Figure 1), with an average of 30% for the MSc program and 40% for the MPH program. Graduation rates greatly improve with time and eventually reach the desired goal years later.

As part of the effort to find strategies that will improve graduation rates, we decided to perform a rigorous statistical analysis of the admissions criteria as predictors of academic success of INSP students in terms of not only graduation itself, but also the time it takes to obtain the degree, as well as students' academic performance as measured by average grades (or grade point average [GPA]).

Figure 1. Proportion of students graduating in three years or less after admission to the National Institute of Public Health of Mexico master's degree programs (MSc or MPH), according to year of admission



MSc = Master of Science
MPH = Master of Public Health

METHODS

Description of the current admissions selection process

One admissions criterion for prospective INSP students is a general knowledge test known as CENEVAL EXANI-III, which is used throughout the country for applicants to graduate programs. The test consists of three main components: verbal reasoning, mathematical reasoning, and English proficiency. Additional criteria for INSP admissions include a mathematics test covering themes in algebra, logarithms, and exponents; a curriculum evaluation; and an interview with two INSP professors. For the interview, a questionnaire is used that assigns points according to the perceived desirability of the applicant's answers. The final result is then expressed as a numeric index equal to the simple sum of these points. INSP only accepts applicants whose GPA from their bachelor's degree studies is at least 8.0 (on a scale of 0.0 to 10.0, which is the scale most widely used in Mexico). Information on other variables such as gender, age, place of residence, place of bachelor's studies, and marital status is also collected in forms completed by the applicant. A faculty committee in each area of concentration then gathers and votes on acceptance based loosely on the results of these criteria.

Study population

Our study population included enrolled students from the years 2001 through 2008 who entered the MPH or MSc program. The study design was a retrospective cohort. We obtained information from school records, which was entered into a Microsoft® Excel database and then transferred to STATA® for analysis.[19] The information gathered included date of admission; date of egress (defined as the conclusion of all mandatory courses); date of graduation or dismissal; grades in the CENEVAL EXANI-III global index as well as English, verbal, and mathematical reasoning indices; result of the interview (in a numeric index); and GPA of bachelor studies. Information was also retrieved on gender, age, type of bachelor studies, and number of children. Data identifying subjects were not included in the database to protect students' privacy. The original sample size was 579. However, due to large numbers of missing data, we excluded years 2001 and 2002 from further analysis, leaving us with a sample of 428 students; 54 additional students admitted in the year 2006 were excluded from regression models because the mathematics test was not applied that year, and

129 subjects were excluded because of missing values on covariates, leaving us with an analytical sample of 245 students.

Statistical analysis

Outcome variables were GPA (as a continuous variable) and an indicator variable for status of graduation (1 = graduated, 0 = otherwise); ordinary least squares (OLS) regression with robust standard errors and logistic regression models were fitted accordingly. All models were adjusted for age, gender, number of children, type of program (MPH or MSc), and year of admission as a second-degree polynomial. Numerical independent variables were standardized to make the magnitude of the coefficients comparable; the estimated beta coefficients represent the mean change in average grades for an increase of one standard deviation of the independent variable in the case of OLS regression and the proportional change in the odds of graduating in the logistic regression models.

We analyzed time from egress (credit completion) to actual graduation (in days), with the event being defined as graduation. We defined day 0 to be two years after admission to the school in the case of MSc students and 1.5 years after admission in the case of MPH students. Students who had not graduated on the day we collected the information, as well as those who were dismissed (expelled) from school, were defined as censored observations (end of follow-up time). In the case of students who had graduated or were dismissed before two years or 1.5 years from egress had passed for MSc and MPH students, respectively, we specified that the event had taken place at day 1 of the follow-up time. We obtained Kaplan-Meier survival estimates for MPH and MSc students, and Cox-proportional hazards models were fitted, adjusting for the same covariates as the linear and logistic models. In each modeling strategy, we tested for interactions between the numerical indices and the type of program (MPH or MSc).

RESULTS

Results from descriptive statistics are shown in Table 1. The average age of the applicants was 30 years, and a majority of them (67%) were female. All test results were consistently better, although by a small margin, for MSc students compared with MPH students. Conversely, MPH students scored better in the interview index.

Table 2 shows results from the GPA model. The general test result, the mathematics test, and the bachelor's studies GPA were all highly significantly predictive of the master's program GPA. Conversely, the interview did not show a significant association. The results of the model, which included the three components of the CENEVAL EXANI-III test as separate variables, showed that only mathematical reasoning was significantly predictive of average grades (p=0.04), whereas verbal reasoning and English were not (p=0.71 and p=0.40, respectively). Neither age nor gender was significantly associated with performance. Both models explained approximately 27% of the total variance of GPAs. Results of the logistic regression model of the odds of graduation are shown in Table 3; none of the admissions criteria was a significant predictor of graduation, and only gender was marginally associated, suggesting that women were 1.8 times as likely to graduate as men. The model featuring the three components of the CENEVAL EXANI-III did not show a significant association of any of the components with the odds of graduation (p=0.80 for English, p=0.92 for verbal reasoning, and p=0.68 for mathematical reasoning).

The Kaplan-Meier survival estimates for the MPH and MSc programs are shown in Figure 2. From these estimates, it is clear that MPH students graduate at a much faster rate than MSc students in the first few months after concluding their academic credits; however, approximately 1.5 years after this time, the rate stabilizes and graduation occurs very slowly from that point. The MSc survival curve shows a steadier rate of graduation until approximately 2.5 years after concluding academic credits, after which we observe the same phenomenon as in the MPH students, with graduations becoming extremely slow. The Cox proportional hazards models showed no evidence that any of the admissions criteria are predictive of the time to graduation, with, once again, only gender being marginally associated, suggesting that women are 50% more likely to graduate at any particular time than men (p=0.086), all other factors being equal.

There were no statistically significant interactions between the type of program (MSc vs. MPH) and any of the variables included in the model, so we decided to present a single model encompassing students from both programs.

DISCUSSION

The most intriguing finding of the study was the fact that admissions criteria are strong predictors of academic grades but not of graduation, which suggests that factors delaying graduation are not directly related to entry academic skills. A natural question was whether GPAs obtained in the MPH or MSc programs are related at all to the odds of graduation. To address this question, we fitted an additional OLS model using

Table 1. Descriptive statistics of a sample of students in the National Institute of Public Health of Mexico master's degree programs, 2003–2008

	Total			*Master of Science program*			*Master of Public Health program*		
Characteristic	N	*Mean*	*SD*	N	*Mean*	*SD*	N	*Mean*	*SD*
Age (in years)	426	30.2	7.0	234	29.0	6.6	192	31.8	7.2
Gender (percent of males)	428	33.2	NA	234	35.5	NA	194	30.4	NA
Number of children	423	0.3	0.7	234	0.3	0.7	189	0.4	0.7
CENEVAL index[a]									
Global	391	1,013.7	63.5	219	1,029.4	60.9	172	993.8	61.3
English	391	1,002.5	117.6	219	1,018.5	110.0	172	982.2	124.0
Verbal reasoning	391	1,015.7	86.3	219	1,031.7	82.7	172	995.3	86.8
Mathematical reasoning	391	1,024.2	98.4	219	1,053.1	88.7	172	987.5	98.1
Mathematics test[b]	332	64.8	18.8	198	69.0	16.3	134	58.6	20.5
Bachelor's studies GPA[c]	403	8.7	0.6	224	8.7	0.5	179	8.6	0.6
Interview index[b]	335	57.7	11.7	170	56.4	7.4	165	59.0	14.8
Master's studies GPA[c]	422	8.9	0.5	232	8.9	0.5	190	9.0	0.4

[a]On a scale of 700.0 to 1,300.0

[b]On a scale of 0.0 to 100.0

[c]On a scale of 0.0 to 10.0

SD = standard deviation

NA = not applicable

CENEVAL = CENEVAL EXANI-III test

GPA = grade point average

Table 2. Ordinary least squares regression model with robust standard errors of average grade at time of egress of the National Institute of Public Health of Mexico master's degree programs, 2003–2008

Variable	*β*	P-*value*	*95% CI*
CENEVAL index[a]	0.0929	0.005	0.0283, 0.1576
Bachelor's studies GPA[a]	0.1130	<0.001	0.0565, 0.1696
Mathematics test[a]	0.1168	0.001	0.0469, 0.1867
Interview index[a]	0.0282	0.223	–0.0172, 0.0736
Age (in years)[a]	0.0030	0.917	–0.0527, 0.0586
Gender (0 = female, 1 = male)	–0.0800	0.161	–0.1920, 0.0321
Number of children	0.0123	0.577	–0.0319, 0.0572
Program (0 = MSc, 1 = MPH)	0.2845	<0.001	0.1713, 0.3980
Time	0.6143	<0.001	0.3429, 0.8860
Time^2	–0.0607	<0.001	–0.0845, –0.0370

[a]Beta coefficients per increase of one standard deviation of independent variable

CI = confidence interval

CENEVAL = CENEVAL EXANI-III test

GPA = grade point average

MSc = Master of Science

MPH = Master of Public Health

the dummy for graduation as the outcome and GPAs as the independent variable. To our surprise, we found a very significant association ($p<0.001$) showing that students with higher grades were indeed much more likely to graduate. This apparent contradiction was explained when we took the percentage of variance explained by average grades (9%). The roughly 91% unexplained variability in the odds of graduation is likely due to factors related to the long process of writing the protocol/thesis/article and having it reviewed and approved by multiple committees, in a time when most students need to find a job.

The fact that the mathematical reasoning component of the CENEVAL EXANI-III test and the mathematics INSP test are the more predictive factors of average grades may reflect the fact that competencies in biostatistical analysis are among the most important competencies in the area of public health. The results of the survival analysis suggest that there are critical thresholds for graduation in terms of time after

Table 3. Logistic regression model of the odds of graduating from the National Institute of Public Health of Mexico master's degree programs, 2003–2008

Variable	*Odds ratio (95% CI)*	P-*value*
CENEVAL index[a]	1.191 (0.787, 1.805)	0.41
Bachelor's studies GPA[a]	1.189 (0.844, 1.673)	0.32
Mathematics test[a]	1.182 (0.745. 1.033)	0.48
Interview index[a]	0.882 (0.597, 1.304)	0.53
Age (in years)[a]	0.986 (0.658, 1.477)	0.95
Gender (0 = female, 1 = male)	0.541 (0.273, 1.070)	0.08
Number of children[a]	0.893 (0.612, 1.305)	0.56
Program (0 = MSc, 1 = MPH)	1.089 (0.527, 2.249)	0.82
Time	3.985 (0.659, 24.102)	0.13
Time^2	0.813 (0.688, 0.961)	0.02

[a]Odds ratios per increase of one standard deviation of the independent variable

CI = confidence interval

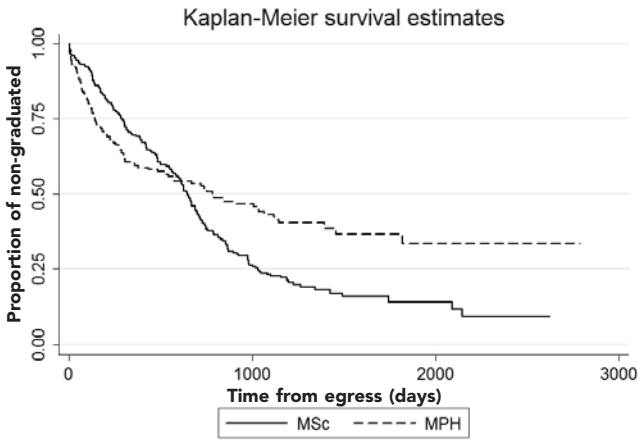
CENEVAL = CENEVAL EXANI-III test

GPA = grade point average

MSc = Master of Science

MPH = Master of Public Health

Figure 2. Time to graduation from the National Institute of Public Health of Mexico master's degree programs (MSc or MPH), 2003–2007



MSc = Master of Science
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concluding academic credits, so INSP should focus its efforts on this critical period to identify obstacles that delay students' graduation. Because stipends provided to students by CONACYT end after two years of admission to the school, we believe these critical windows reflect the fact that students begin to seek and eventually find jobs, which reduces the time available for work on their thesis, causing many of them to abandon all efforts toward finishing their degree. It is important to note that gender and age were not important predictors of grades, odds of graduation, or time to graduation. This finding emphasizes the importance of not taking these variables into account in the student selection process. The interview seems to have no relation to average grades, odds of graduation, or time to graduation. We cannot rule out that the interview is important for the selection process; however, it means that once a student is accepted, having had a good interview does not by any means guarantee that the student will have a favorable result at the end.

Although no similar studies in SPHs are published, some similarities were found in a study of a professional program in pharmacy. Houglum et al. found that the overall American College Test score and previous grades in mathematics were significantly related to academic success.[10] Similarly, in a study of time to graduation in a pharmacy PhD program, no variables were found to be predictive of the time to graduation with the exception of having previously taken advanced courses in biology.[12]

Limitations

The main limitation of our study was that rejected students were not contributing information to the estimation process. This limitation could cause a selection bias if unknown factors are associated both with the probability of admission and with the outcome, either average grades or graduation, as long as observed variables are correlated to these unknowns. Heckman selection models could be a solution, although the usual problem with this strategy is that an instrument is needed (in this case, a variable that is related only to the probability of selection, but not to average grades or to the probability of graduating), which is hard to find.[20] Because of the probability of selection bias, we recommend caution in using the results of this study to guide a modification of the selection process for the moment. However, even if selection bias is present, we could argue that the results we found are valid for those who are already admitted into the school, and they still convey valuable information.

CONCLUSION

Our findings suggest that although admissions variables are good predictors of GPAs, factors delaying graduation may instead be due to difficulties in the development of a student's thesis or final projects, or other related causes such as going back to work. This study constitutes our first attempt to scientifically investigate the factors behind academic success in an SPH. We plan to conduct future studies that will focus on the graduation process, which, according to our results, should be the most important measure. We hope that this study motivates other SPHs to scientifically delve into their admissions and graduation processes; such studies will surely promote advancements in the generation of educational knowledge that will contribute to evidence-based administrative decision-making and have a long-term impact on the education of health professionals and their competencies in the field.

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REFERENCES

1. Flexner A. Medical education in the United States and Canada bulletin number four (the Flexner report). New York: The Carnegie Foundation for the Advancement of Teaching; 1910.
2. Welch WH, Rose W; Institute of Hygiene. The Welch-Rose report: a report to the General Education Board of Rockefeller Foundation. Sleepy Hollow (NY): RF, Rg 1.1, Series 200L, Box 183, Folder 2201, Rockefeller Archive Center; 1915.
3. The Committee for the Study of Nursing Education. Nursing and nursing education in the United States: report of the committee and report of a survey by Josephine Goldmark. New York: The Macmillan Company; 1923.
4. Allen DD, Bond CA. Prepharmacy predictors of success in pharmacy school: grade point averages, pharmacy college admissions test, communication abilities, and critical thinking skills. Pharmacotherapy 2001;21:842-9.
5. Al-Rukban MO, Munshi FM, Abdulghani HM, Al-Hoqail I. The ability of the pre-admission criteria to predict performance in a Saudi medical school. Saudi Med J 2010;31:560-4.
6. Curtis DA, Lind SL, Plesh O, Finzen FC. Correlation of admissions criteria with academic performance in dental students. J Dent Educ 2007;71:1314-21.
7. Evans P, Wen FK. Does the medical college admission test predict global academic performance in osteopathic medical school? J Am Osteopath Assoc 2007;107:157-62.
8. Grillo JA, Latif DA, Stolte SK. The relationship between preadmission indicators and basic math skills at a new school of pharmacy. Ann Pharmacother 2001;35:167-72.
9. Holmes DC, Doering JV, Spector M. Associations among predental credentials and measures of dental school achievement. J Dent Educ 2008;72:142-52.
10. Houglum JE, Aparasu RR, Delfinis TM. Predictors of academic success and failure in a pharmacy professional program. Am J Pharm Educ 2005;69:283-9.
11. Lobb WB, Wilkin NE, McCaffrey DJ III, Wilson MC, Bentley JP. The predictive utility of nontraditional test scores for first-year pharmacy student academic performance. Am J Pharm Educ 2006;70:128.
12. McCall KL, Allen DD, Fike DS. Predictors of academic success in a doctor of pharmacy program. Am J Pharm Educ 2006;70:106.
13. McCall KL, MacLaughlin EJ, Fike DS, Ruiz B. Preadmission predictors of PharmD graduates' performance on the NAPLEX. Am J Pharm Educ 2007;71:5.
14. Meagher DG, Lin A, Stellato CP. A predictive validity study of the Pharmacy College Admission Test. Am J Pharm Educ 2006;70:53.
15. Meleca CB. Traditional predictors of academic performance in a medical school's independent study program. Acad Med 1995;70:59-63.
16. Renzi SE, Krzeminski MA, Sauberan MM, Brazeau DA, Brazeau GA. Prepharmacy years in college and academic performance in a professional program. Am J Pharm Educ 2007;71:69.
17. Sandow PL, Jones AC, Peek CW, Courts FJ, Watson RE. Correlation of admission criteria with dental school performance and attrition. J Dent Educ 2002;66:385-92.
18. National Association for College Admission Counseling. Report of the Commission on the use of standardized tests in undergraduate admission [cited 2010 Sep 2]. Available from: URL: http://www.nacacnet.org/PublicationsResources/Research/Documents/TestingComission_FinalReport.pdf
19. StataCorp LP. STATA® for Windows: Version 10.0. College Station (TX): StataCorp LP; 2009.
20. Baum CF. An introduction to modern econometrics using Stata. College Station (TX): Stata Press; 2006.

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College of Public Health – Chair, Department of Environmental Health The East Tennessee State University (ETSU) College of Public Health is seeking applications for a nationally recognized leader to serve as Chair in the Department of Environmental Health. ETSU has the only CEPH-accredited College of Public Health in Tennessee and has a rich history in environmental health with one of the oldest EHAC-accredited graduate programs in the United States. The College is one of five colleges in the Academic Health Sciences Center at ETSU. For over fifty years, the College has had a strong working relationship with a wide range of regional partners in northeast Tennessee and southwest Virginia and is a frequent partner with the community, local and state government and international organizations that are focused on providing public health training in areas of high need. An energetic and visionary leader is desired to continue with our considerable success in this arena.

With a strong regional focus, rich history and deep commitment to educational excellence, the department's educational programs include the B.S.E.H. with concentrations in Environmental Health and Occupational Health and Safety, the M.S.E.H. and M.P.H programs in Environmental Health, and the PhD in Environmental Health Sciences. An overview of the department and its programs can be found on the College website: http://www.etsu.edu/cph/eh.

Applicants should have a terminal degree in environmental health, environmental engineering, toxicology, microbiology or a related field. They should also possess a professional history consistent with appointment as associate or full professor in the department. Demonstrated administrative and leadership experience commensurate with leading an academic department is required. Significant experience with extramurally funded research is required. Applicants must also have an interest in the broader implications of their research as it relates to environmental health policy and practice. Applicants with relevant professional certifications, such as CIH, DABT, REHS, PE and graduates of ASPH-member schools are encouraged to apply.

East Tennessee State University is a comprehensive, Carnegie-designated Doctoral Research University, with a commitment to the Appalachian region. The University has approximately 13,000 undergraduates and 2,000 graduate and professional students. The Academic Health Sciences Center includes the College of Public Health, the College of Nursing, the James H. Quillen College of Medicine, the Bill Gatton College of Pharmacy and the College of Clinical and Rehabilitative Health Sciences. Johnson City, in the Tri-Cities region of east Tennessee, has close 60,000 residents and is consistently rated as one of the best small towns in the U.S., with affordable housing, excellent schools, and with outstanding cultural and outdoor recreational activities. Clinical care in Washington County has been ranked as the best in Tennessee two years in a row.

Interested candidates should upload a cover letter describing their research and teaching experience, listing of contact information for three references, and curriculum vitae at: http://jobs.etsu.edu.

The University of Georgia

College of Public Health

College of Public Health - Department of Health Policy and Management
Two Senior Faculty Hires in Obesity Policy

The University of Georgia Department of Health Policy and Management is accepting nominations and applications for two tenure-track, senior faculty positions in obesity policy.

(1) Full Professor: This position is for an expert in obesity policy who is a proven leader with a record of increasing administrative responsibility and successful program implementation. The full professor will be a mentor in the college, a subject expert and policy advocate in the public sphere, and a key leader for the university wide obesity initiative.

(2) Associate Professor: This position is for an active investigator with an established and growing research portfolio in obesity prevention, chronic disease management, health promotion, health services research, or health policy. The associate professor will bring a public health perspective to UGA interdisciplinary research initiatives in the obesity field.

Additional Qualifications for Both Positions: Both positions require extensive background in obesity and policy research with quality publications. A doctoral degree is required, such as a PhD in a public health discipline, a DrPH, or an MD with training and experience in health policy. Candidates for both positions must have a record of funded research in a relevant field such as public policy, health services research, health promotion, or epidemiology with a focus on chronic disease.

The College: The College of Public Health (CPH) received full CEPH accreditation in 2009 and has expanded rapidly. It now has four departments, four centers/institutes and over 900 students. Research funding per faculty member is currently the highest of any college at the university, and total annual research funding has risen to fourth among the University of Georgia's seventeen schools and colleges. Successful candidates for these two positions will join a growing and highly productive program. For more information: www.publichealth.uga.edu.

The UGA Obesity Initiative: With its evolving land grant responsibilities, a deep commitment to statewide public service and outreach, strong programs in the life sciences and nutrition, a rapidly developing college of public health and many other significant resources, UGA is positioned to undertake a major effort to help stem and reverse the epidemic of obesity in Georgia and the nation. The UGA Obesity Initiative was launched for this purpose in January 2012. UGA has assembled multidisciplinary research team sfrom its existing programs while adding new faculty with strategic hires dedicated to this effort. Visit http://obesity.ovpr.uga.edu.

The University: The University of Georgia, a land-grant/sea-grant university, is ranked among the top 25 American public universities in the most recent assessment by *U.S. News & World Report*. The University is recognized as a research intensive and community engaged institution by the Carnegie Foundation. Located in Athens, 70 miles northeast of Atlanta, UGA is the state system's most comprehensive research institution and has expanded its programs in recent years to include public health, engineering and medical education. Athens is a progressive and vibrant community that offers a rich cultural environment.

Application Process: E-mail submissions are preferred. Applications for the associate professor position should be sent to apcph@uga.edu. Indicate "Associate Professor Obesity Policy" in the subject line. Applications for the full professor position should be sent to fpcph@uga.edu. Indicate "Full Professor Obesity Policy" in the subject line. Applications must include: (1) a letter explaining your interest in the position, (2) a current CV and (3) contact information for four potential references (who will not be contacted without further correspondence with the applicant). Nominations and inquiries can be directed by mail to Dr. Eric Dahl, Associate Dean and Search Committee Chair, College of Public Health, 132C Coverdell Center, Athens, Georgia 30602; by e-mail to ericdahl@uga.edu; or by phone at 706-542-7759. The application review process will begin December 1, 2012, and the position will remain open until filled. The University of Georgia is committed to increasing the diversity of its faculty and strongly encourages applications from individuals in under-represented groups.

The University of Georgia is an Equal Opportunity, Affirmative Action Institution

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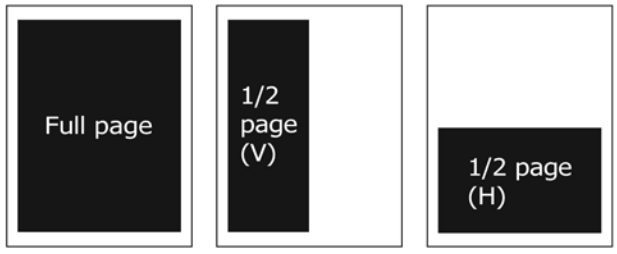

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