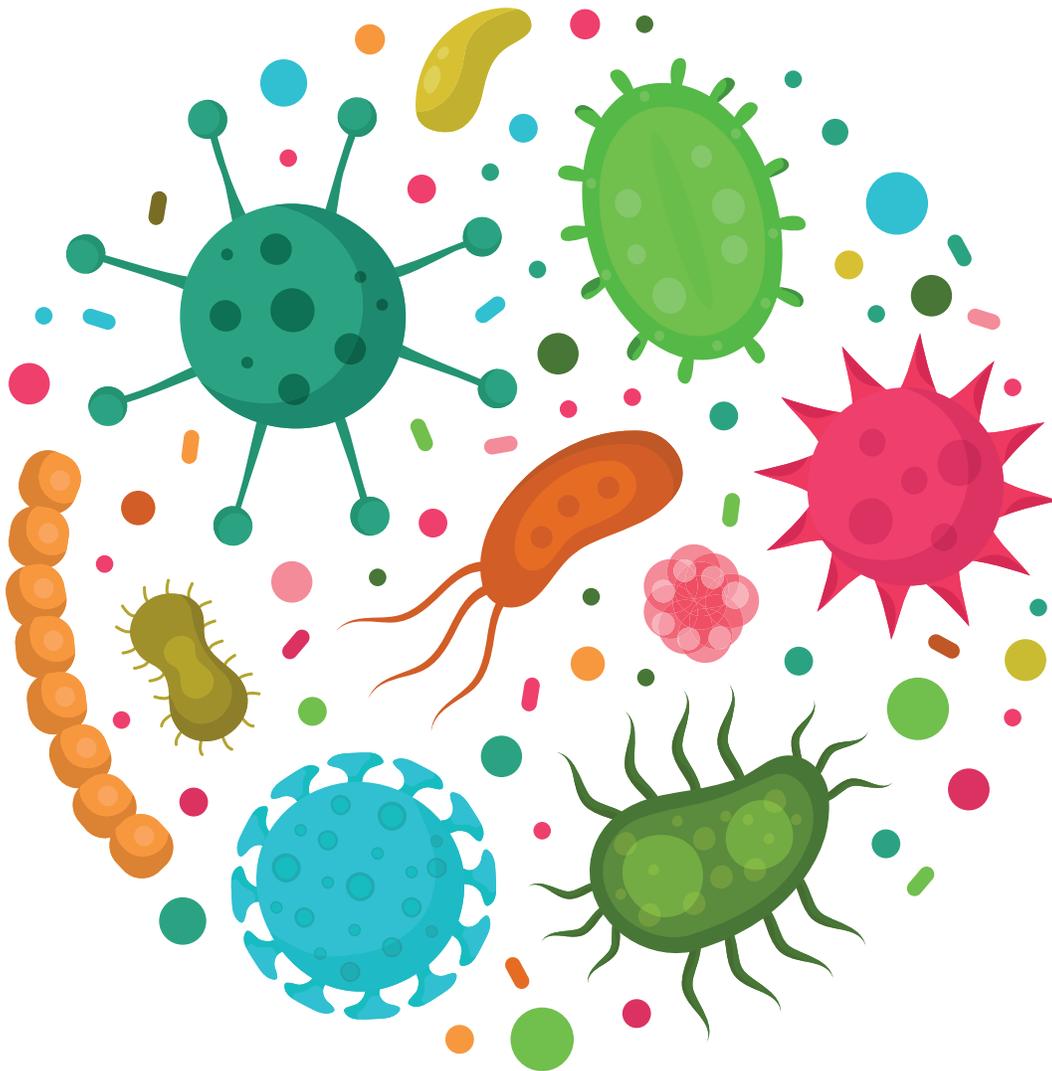


Delaware Journal of

Public Health

A publication of the Delaware Academy of Medicine / Delaware Public Health Association

Communicable Diseases



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3 | In this Issue

Omar A. Khan, M.D., M.H.S.,
Timothy E. Gibbs, M.P.H.

4 | Comments on the Communicable Disease Issue

Neal D. Goldstein, Ph.D., M.B.I. and
Deborah Kahal, M.D., M.P.H., F.A.C.P.

6 | Delaware Faces Immunization Challenges Head-on

Jim Talbott, M.P.A. and
Paul Hess

12 | Pertussis Outbreak in an Amish Community: Kent County, Delaware, 2018

Paula Eggers, R.N.
Tabatha N. Offutt-Powell, Dr.P.H., M.P.H.,
Lisa Henry, M.S.H.A.
Rick Hong, M.D.

18 | Vaccination is the Most Effective Strategy for HPV Prevention

Margot Savoy, M.D., M.P.H., F.A.A.F.P.,
F.A.B.C., C.P.E., C.M.Q., F.A.A.P.L.

20 | Management of Hepatitis C in Delaware Prisons: Approaching Microenvironmental Eradication

William P. Mazur, M.D.

30 | Global Health Matters

Fogarty International Center

42 | Hepatitis C in Pregnant Women and Their Children

Stephen C. Eppes, M.D.

46 | Delaware and Hepatitis C: Is it Time for Universal Screening?

Navin Vij, M.D., M.S.H.P.

50 | Statewide Antibiotic Stewardship: An eBrightHealth Choosing Wisely Initiative

Marci Drees, M.D., M.S.
Kimberly Fischer, B.S.N., R.N.
Loretta Consiglio-Ward, M.S.N., R.N.
Janelle Caruano, PharmD, B.C.I.D.P.
Shannon Chan, PharmD
William Chasanov, D.O., M.B.A.
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Alexander Kashmanian, PharmD, B.C.P.S.,
B.C.I.D.P.
Jillian D. Laude, PharmD, B.C.P.S.
Nicole Harrington, PharmD, B.C.P.S.
AQ-ID
Elizabeth A. Richardson, M.S.N., M.P.H.,
R.N.
Arezoo Zomorodi, M.D.
Robert Dressler, M.D., M.B.A.

60 | Low Incidence and High Profile: Tuberculosis Control in Delaware

Joanna S. Suder, J.D.

64 | Four Decades of Epidemiologic Science on HIV Infection and Disease, and Its Impact on Public Health Practice and Policy for Sexual and Gender Minority Persons

Nguyen K Tran, M.P.H., and
Seth L Welles, Ph.D., Sc.D.

74 | Access to HIV Medication in the Community Versus a Nursing Home for the Medicare Eligible HIV Population

Brianne L. Olivieri-Mui, M.P.H.

80 | Communicable Disease Lexicon of Terms

81 | Communicable Disease Resources

82 | Index of Advertisers



COVER

“Communicable disease” means an illness caused by an infectious agent or its toxins that occurs through the direct or indirect transmission of the infectious agent or its products from an infected individual

or via an animal, vector or the inanimate environment to a susceptible animal or human host. New York, N.Y., 24RCNY Health Code § 11.01 (2010).

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IN THIS ISSUE



Omar A. Khan, M.D., M.H.S.
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This is truly a milestone moment for the Delaware Academy of Medicine / Delaware Public Health Association. At our Annual Meeting this year (the 89th), our keynote address was delivered by David Heymann, M.D., D.T.M.&H., C.B.E., speaking about a lifetime combating global communicable diseases. Select images from the event are on pages [71–73](#). The entire collection is available online at <https://delamed.org/images-from-the-89th-annual-meeting-of-the-academy-dpha/>.

Immediately before Dr. Heymann’s presentation, we recognized the extraordinary work of the William J. Holloway Community Program at Christiana Care Health System. Now expanded to include sites throughout the state, their efforts have been a part of the success story regarding HIV—seeing it go from being a fatal illness, to a manageable chronic disease. The award was accepted by Dr. Susan Szabo and Arlene Bincsik R.N., M.S., C.C.R.C., A.C.R.N. Arlene was thanked in particular, for her 40 years of advocacy, care, and education. For more on the story, see: <https://news.christianacare.org/2019/05/william-j-holloway-program-honored-by-delaware-academy-of-medicine/>

The timing of this issue on Communicable Disease could therefore not be better. It follows the day-long Holloway Infectious Disease Symposium and the spectacular events and awards above. We are indebted to our expert guest editors, Neal Goldstein, Ph.D. and Deborah Kahal, M.D. for their guest editorship of this issue.

We also recognized the work of Sherman L. Townsend, Chair of the Delaware Institute for Medical Education and Research (DIMER), with the 2019 Lewis B. Flinn President’s Award. His leadership of DIMER, which along with the Delaware Branch Campus at Christiana Care acts as Delaware’s medical school, has been assuring spots for Delaware students at our Philadelphia medical school partners for nearly 50 years. We take this opportunity to thank the Sidney Kimmel Medical College of Thomas Jefferson University and the Philadelphia College of Osteopathic Medicine for their continued partnership in helping serve Delawareans’ health needs through a well-trained workforce.

To those of you who have read the Delaware Journal of Public Health from the start in 2015, you’ll notice a change in the layout and readability of this issue. This is a result of reader feedback; as a result we have improved viewability and readability of graphics and text on mobile devices.

We hope that you like the change, and as always, keep the comments coming!

Comments on the Communicable Disease Issue

by the Guest Editors

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The focus on infectious diseases in public health ebbs and flows. Students of the field are taught that developed countries have undergone an epidemiological transition whereby morbidity and mortality from non-infectious diseases has eclipsed that of infectious causes.¹ Nevertheless, infectious etiologies of disease remain a substantial threat to the public's health. The last decade has seen a re-emergence of vaccine preventable diseases,² including pertussis and measles; an increase in sexually transmitted infections (STIs) most notably syphilis among gay, bisexual, and other men who have sex with men³; a worsening Hepatitis C infection (HCV) crisis in the setting of the opioid epidemic⁴; and the ongoing struggle to control the HIV epidemic well into its fourth decade.⁵ To that end, we have solicited a wide range of experts in infectious disease epidemiology, public health practice, and clinical medicine to contribute insightful, and at times, provocative discussions of important infectious diseases within Delaware. Globally, nationally, and locally, healthcare systems face many challenges related to infectious diseases, from creating the infrastructure and microenvironments to support responsible antibiotic prescribing practices to immunization advocacy (and rapid response to complications stemming from a lack of adequate vaccination coverage) to ongoing efforts to test and treat for STIs. This issue of the *Delaware Journal of Public Health* tackles these broad issues.

Certainly, we are all cognizant of the on-going debate surrounding vaccinations in our country. With the recent measles outbreak in Washington and elsewhere,⁶ public health is in the challenging position of advocating for vaccination while responding to disease outbreaks from those who choose to abstain from this remarkable preventive intervention. James Talbot and Paul Hess review the state of immunization in Delaware and how the Delaware Division of Public Health (DPH) has responded to recent vaccine preventable disease outbreaks. A pertussis outbreak in the Amish community in Delaware, as highlighted in the article by Paula Eggers et al., provides a local example of the repercussions of low vaccination rates. Margot Savoy enriches the immunization discussion with a closer examination of human papillomavirus vaccination and a call to action for us all to work collaboratively toward improved vaccination acceptance rates. A common theme throughout these articles is an emphasis on the importance of public health practitioners closely engaging with communities that have lower vaccination rates.

HCV presents a multi-faceted story of incredible therapeutic success and implementation challenges. There is much work still to tackle as we strive to meet the four goals of the national Viral Hepatitis Action Plan in 2020:

1. Prevention of new hepatitis infections,
2. Reduction of death and improvement in health of those living with hepatitis,
3. Reduction of viral hepatitis health disparities, and
4. Effective implementation of viral hepatitis activities.⁷

Continuing with the engagement of the community by public health professionals, William Mazur describes caring for patients with HCV who are incarcerated in Delaware's correctional facilities. With recent advances in HCV therapeutics, treating individuals in an institutionalized setting represents an opportune time to improve the patient's health and provide treatment as prevention of forward HCV transmission subsequently reduces the community HCV burden. Stephen Eppes highlights the unique opportunities surrounding HCV amongst women of childbearing potential and their children, while Navin Vij shares his profoundly personal story with HCV. While Eppes and Vij offer different perspectives, both share compelling arguments in support of universal HCV screening for all pregnant women and adults, respectively.

We have also included several articles that focus on the programmatic

management of infectious diseases in Delaware. Vital statewide efforts to improve antimicrobial stewardship are eloquently outlined by Marci Drees et al. The eBrightHealth Choosing Wisely Initiative emphasizes the importance of sustainable multidisciplinary collaboration in working toward appropriate antibiotic utilization in upper respiratory tract infections in inpatient and ambulatory settings. Joanna Suder tackles the sometimes difficult task of public health in the prevention, isolation, and quarantine of individuals who have tuberculosis, focusing on the medicolegal implications.

This issue would be incomplete without including several articles focusing on HIV, both the successes and ongoing opportunities for improvement. Nguyen Tran and Seth Welles detail how understanding the epidemiology of HIV among sexual and gender minority communities, who have been particularly affected by HIV, is used to inform public health policy and action. As they discuss, the epidemiology of HIV has drastically changed since the disease was first recognized in the early 1980s. In large part due to the increase in HIV screening, reduction in stigma, and the development and roll-out of antiretroviral therapy (ART), HIV has transitioned from a death sentence to a chronic infection. Consequently, we are seeing an aging population with HIV, the focus of Brianne Olivieri-Mui's article which considers a Medicare-eligible HIV population and implications for ART access in a nursing home setting.

In closing, we hope you enjoy this issue and give pause to consider both the remarkable achievements of public health in reducing infectious disease sequelae and serious challenges that lay ahead. Lastly, we wish to express our sincere gratitude to the invited contributors who have devoted considerable time and energy to making this issue of the *DJPH* a success.

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Delaware Faces Immunization Challenges Head-on

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Abstract

This article explores the recent history of under immunized vaccine preventable diseases, along with recent outbreaks and how the Delaware Division of Public Health has responded to each. Delaware's vaccination efforts for children have achieved high coverage rates for all of the vaccine preventable diseases, leading to low incidences rates in the state. The main reason for these high rates is the law for mandated immunization for children entering kindergarten. As children age out of primary school, vaccination uptake declines. HPV vaccination rates are a prime example, as even though Delaware's rates as compared to the National average are better, they fail to meet Healthy People 2020 standards of 80% vaccinated. To get to the heart of an under immunized population, a study to determine where the lower vaccinated rates are, along with the surveillance rates to cross match the results must be undertaken. It is understood that for communities where vaccination rates are lower, risk for disease is greater, with several recent outbreaks corroborating this. A pertussis outbreak in the Delaware Amish community was managed by the State with education and outreach in the community, with mixed results. Hepatitis A is an epidemic in a number of states, and Delaware has taken steps to try to protect our vulnerable population, using outreach, education and vaccination clinics to prevent the outbreak from occurring locally. While work continues, resources will need to be continually applied to ensure that vulnerable populations have the means to access the services needed. DPH continuously monitors State vaccine coverage level data and disease outbreaks within and outside Delaware's borders and has implemented the above-mentioned public health initiatives to promote immunization awareness and address community health concerns.

INTRODUCTION

Vaccination efforts save countless lives and billions of dollars each year in avoidable medical expenses. Since 1993, the Vaccines for Children Program has enabled the government to vaccinate uninsured and underinsured children. In its first 20 years, this program saved an estimated \$295 billion in direct health care costs and over \$1 trillion in societal costs, such as lives and work hours saved.¹

Delaware's vaccination efforts for children have achieved great results. The State of Delaware requires that children in licensed daycare centers and entering kindergarten through grade 12 at public, private, and home schools be immunized against certain communicable diseases before enrolling in school. Delaware Administrative Code 4202, "Control of Communicable and Other Disease Conditions," requires immunizations against measles, mumps, and rubella (MMR); tetanus, diphtheria, and pertussis/whooping cough (Tdap); polio (IPV or OPV); hepatitis B; and chickenpox (varicella).² These diseases can be fatal or have serious complications that can result in blindness, deafness, and developmental delays.

Each year, the Centers for Disease Control and Prevention's (CDC) National Center for Immunization and Respiratory Diseases (NCIRD) sponsors the National Immunization Survey (NIS). The NIS is a group of telephone surveys used to monitor vaccination coverage among children 19-35 months and teens 13-17 years, along with flu vaccinations for children 6 months to 17 years. In 2017, Delaware's rate for the series 4:3:1:3:3:1:4 (4+DTaP, 3+Polio, 1+MMR, 3+Hib, 3+HepB, 1+Varicella, and 4+ PCV) was 77.1%, higher than the national average of 70.4% and close to the Healthy People 2020 goal of 80%.³

Due to the successes of vaccination, fewer health care providers and parents have witnessed the serious and sometimes life-threatening consequences of vaccine-preventable diseases. Yet small numbers of cases can lead to the re-emergence of vaccine-preventable diseases, especially if there are increasing numbers of unvaccinated people. Disease outbreaks sporadically surface nationally and in Delaware, and the State's challenge is to respond quickly to outbreaks to prevent them from spreading rapidly. We describe challenges and opportunities in vaccination and vaccine-preventable disease in Delaware by focusing on three case studies: pertussis, human papillomavirus, and hepatitis A. We conclude with discussion of vaccination availability in Delaware through the Vaccines for Children (VFC) Program.

PERTUSSIS CHALLENGE

Occasional outbreaks of whooping cough (pertussis), a highly contagious respiratory disease, occur in Delaware. Typically, pertussis outbreaks have occurred among Kent County's Amish community, a population that is largely unvaccinated. The Amish community practices separation from the world through group solidarity and caring for their own. Though their religious doctrine does not prohibit vaccination, coverage levels for routine childhood vaccination remain low for various reasons, including misinformation about the safety and/or content of vaccines and a strong belief in naturally acquired immunity.

While Delaware has seen an improvement in coverage rates in pertussis, identified cases are still being reported every few years. Pertussis in Delaware has ebbed and flowed, with reported

case spikes in 2014 and 2018. In 2014, 202 cases of pertussis — the state’s largest caseload since 2005 — were reported to the Division of Public Health (DPH); most were due to an outbreak among the Amish. In May 2018, DPH learned of a new pertussis outbreak among the Amish. As of December 31, 2018, the case count for that outbreak was 183 total cases, with 74 confirmed and 109 considered probable. Most reported cases were in individuals 10 years of age and younger. For comparison with other years, there were 20 pertussis cases in Delaware in 2015, 15 in 2016 and 9 in 2017 (Delaware Health and Social Services [DHSS], 2019). For all years, the actual number of cases was likely higher due to underreporting and misdiagnosis.

RESPONSE TO PERTUSSIS OUTBREAKS

These re-occurring outbreaks demonstrate the challenges of addressing disease in the Amish population. DPH has served generations of the Amish and over the past 45 years has strived to gain their trust. Amish leaders and midwives serving the population have educated DPH staff about their homeopathic approach to treating disease. Some within this community do not consider immunization necessary to prevent diseases from occurring, or in response to outbreaks. Instead they view getting some diseases and getting over them naturally without the intervention of a vaccine, a ‘rite of passage’. Similarly, a 2017 study sought to determine the knowledge, beliefs and attitudes among Amish communities in Ohio. Through it, some respondents shared fears of having too many recommended immunizations and that immunizations would overwhelm a child’s own natural immune system⁴.

In response to the 2018 pertussis outbreak, DPH initiated a multi-pronged effort to control the spread of the disease. One of the early activities was to set up a meeting between the DPH Director, key staff and the Amish leadership (Bishops). During this meeting, DPH staff learned that the primary drivers behind low vaccination rates were misinformation about the makeup and safety of the vaccine, perceived pain and distress to the children during vaccination, and a belief that if you let the disease run its course that children could not be re-infected. The Bishops were happy that DPH expressed concern about the community’s well-being and indicated they would be willing to distribute educational materials within the community.

These educational materials included flyers highlighting the symptoms of pertussis, the benefits of seeking and completing antibiotic treatment, and the benefits and safety of vaccination. Distribution of materials occurred at Amish owned businesses, as well as businesses frequented by members of the community, physician’s offices, and schools. Generally, the distribution of the flyers was well received, however, DPH did encounter resistance to its distribution of information in the schools from some parents. Amish schools in Delaware are not part of the public school system and so distribution of materials from outsiders must be approved by the community’s leadership. For this reason, DPH was asked to stop using the school system to distribute information.

An important aspect of DPH’s outbreak response was epidemiological surveillance and direct contact with the community. DPH spent weeks conducting door-to-door case finding and a contact investigation campaign to maximize active surveillance and control measures. Teams of DPH epidemiologists and clinic nurses visited homes of community members where reports of pertussis had been confirmed, and asked questions to determine if there were other close contacts at risk. From a treatment perspective, updated standing orders allowed for the distribution of antibiotics for treatment and prophylaxis in households where DPH identified symptomatic persons and their contacts. The Delaware Immunization Program also made field visits to offer vaccine and antibiotics at the Public Health Clinics throughout the State.

During visits, information gained through administering survey questions informed DPH’s response. Some of those who had received immunizations in the past, or had their children vaccinated for various reasons, but who subsequently stopped getting vaccinated said it was because DPH no longer conducted immunization clinics in their community. In the past, DPH conducted immunization clinics in the community but stopped due to lack of attendance.

It is apparent that since this community is hesitant to seek and find vaccinations, DPH must offer immunizations where the Amish are most receptive to receiving them. Another way DPH addressed this issue was to work with a midwife who sees pregnant Amish women to provide pertussis vaccines in accordance with the Advisory Committee on Immunization Practices (ACIP). The midwife is a trusted source of medical guidance for Amish women in the community. DPH is providing the midwife with Tdap vaccine so she can vaccinate her clients during their well visits, if the women agree. DPH also contacted, and provided information, to chiropractors, who are another source of medical advice for this population.

DPH also reached out to Holmes County General Health District in Ohio for public health approaches that were successful with their Amish communities. Holmes County provides health clinics in the Amish community that offer immunizations, health screenings, and other services. They also help organize an annual Amish Health and Safety Day, which provides another opportunity to share information. In addition to Ohio, DPH reached out to the State of Pennsylvania, who has a large Amish populations to understand how they faced vaccine-preventable disease outbreaks.

DPH’s educational outreach was not limited to the Amish community, because ultimately pertussis spread to the non-Amish population in Delaware. In the 2018 outbreak, 10 pertussis cases occurred among non-Amish individuals. DPH issued a press release to the public through media contacts, and on August 27, 2018 informed health providers by issuing a Health Alert (<https://healthalertde.org/>) through the Delaware Health Alert Network (DHAN). In addition, DPH created and distributed a flyer to all licensed medical providers in Kent County and asked them to share it with their patients. The flyer

announced the outbreak to help engage patients in conversations about receiving Pertussis vaccinations and other ways they could protect themselves and their families.

Through these multi-faceted measures, DPH has re-established open lines of communication with the Amish community, and hopes that it will encourage more of these individuals to reach out to the Agency in the event of future outbreaks.

HUMAN PAPILLOMAVIRUS

According to the CDC, every year 33,700 women and men are diagnosed with a cancer caused by human papillomavirus (HPV) infection. HPV vaccination could prevent more than 90% of these cancers (31,200 cases ever year) from ever developing.⁵ HPV vaccinations coverage levels remain low across the nation. In 2017, only 49 percent of adolescents were up to date on the HPV vaccine, and 66 percent of teens ages 13-17 years received the first dose to start the vaccine series.⁶ According to the 2017 National Immunization Survey (NIS), 58 percent of Delaware adolescents were up to date on the HPV vaccine, and 75 percent received the first dose to start the vaccine series.⁷ Although Delaware's HPV coverage rates are above the national average, HPV vaccination rates are much lower than for other adolescent-recommended vaccines within Delaware, such as Tdap (89.6%) and Meningococcal (90.5%), both recommended at the same time as the HPV vaccine (Delaware HPV Vaccination Report, December 2018).

The lower vaccination rates are not due to lack of vaccine or vaccine availability. In the fiscal year beginning July 1, 2017 to June 30, 2018, medical providers in Delaware ordered 31,745 doses of HPV. In the current fiscal year that began on July 1, 2018, medical providers in Delaware have ordered 13,103 doses as of January 8. The CDC estimates that Delaware will have ordered enough vaccine to vaccinate all of the 11-year-olds in Delaware this year. Yet while sufficient doses are ordered, some providers are not reporting administered doses to the State Immunization Information System (IIS) suggesting that the true vaccination rate is higher than what is reported.

To address the issue of low HPV rates, the Delaware Immunization Program recently collaborated with the Delaware Cancer Prevention program and the Delaware Cancer Consortium to identify and implement activities designed to promote HPV awareness and increase immunization rates. The Cancer Prevention program provided funding to support three projects in order to increase lagging HPV rates within the state. These activities included initiating an HPV media campaign, continuing state Immunization Information System (IIS) reports training for Vaccines for Children (VFC) providers, and continuing HPV-education workshops for local providers.

The HPV education for VFC provider's project involved contracting with a vendor to conduct this training for approximately 100 VFC providers. DPH established a contract with a vendor to recruit and train these providers from November 1, 2018 thru June 30, 2019. The vendor developed a HPV training curriculum using the CDC's "You Are the Key to HPV Cancer Prevention" guide.⁸

These training sessions range from small groups to one-on-one encounters with providers. Topics include the benefits of vaccinating at an early age, role play activities to appropriately address parental safety concerns with the HPV vaccine, and utilizing reports within the IIS (i.e. coverage level, Not Up-To-Date, Patient Roster, and Reminder Recall reports), to improve vaccination rates.

The DPH also entered into a contract with another vendor to offer VFC providers training on the Delaware's IIS reports module to assist them through the Assessment, Feedback, Incentive and Exchange (AFIX) process and help providers increase their immunization coverage rates.

The providers receive training on the following reports:

1. AFIX Snapshot – Report allows providers to run immunization coverage levels for specific age cohorts within their practice.
2. Patient Roster reports – Report allows the provider to identify all the patients within their practice who are currently active in the IIS.
3. Patient Inactivation reports — Report allows the provider to inactivate any patients in the patient roster report that are no longer active within their practice.
4. Up-To- Date reports – Report allows the provider to identify patients that require additional immunizations to be compliant with immunization recommendations.
5. Recall reports – Report allows the provider to generate a list of all their patients that require additional immunizations and print out post-card reminders to mail to these individuals.

The primary objective is to attempt to mirror the immunization coverage data from a provider's medical record with the Immunization Program's IIS and the NIS to get a true picture of the HPV coverage rate in Delaware. Since implementation of the IIS report training, the IIS HPV coverage rate rose to 68.7% for the first dose, an increase of 1.5% from June 1, 2018. The up-to-date coverage for the series completion reflects a 2% increase from December 13, 2017.

The DPH Cancer Prevention and Control Program contracted with a vendor to develop and implement a statewide marketing campaign that encourages parents of children ages 11 or 12 to have their children receive the HPV vaccine in the same visit when they are vaccinated for other serious diseases, like meningitis and whooping cough. This campaign consists of print, radio, social media, and digital ads; direct mail; and social influencers targeting parents of 11-12 year olds. There is a social media plan for Facebook and Instagram that includes live chat events with physicians, school nurses, or parents speaking on the advantages of getting children vaccinated for HPV, and polls that engage parents using facts and statistics about HPV and the HPV vaccine. A private school outreach plan encompasses HPV presentations at parent events; HPV messaging in parent newsletters or emails; parent/child HPV vaccination videos; and posters and other printed resources to promote HPV awareness.

The Immunization Program continues to conduct AFIX provider site visits to all VFC providers within the state as part of the federal requirements for the VFC program. During the initial site visits, a DPH staff member reviews the current immunization coverage levels for the provider's practice and discusses issues or barriers contributing to any lower rates. The staff also works with the provider to develop quality improvement activities that they can incorporate into their existing workflow to increase their immunization coverage rates. Special attention is given to their HPV coverage rates at this visit and the staff offer the provider educational materials on HPV and encourage them to offer this vaccine in the same way and on the same day that they offer other vaccines at the 11 and 12-year-old well visits.

Providers are also encouraged to take the IIS Reports training class. DPH provides registration information during the site visit. DPH conducts a follow-up visit six months later to discuss changes in their coverage rate and the progress made on the quality improvement activities. The Immunization Program saw increased coverage levels in providers who had received these visits and completed the IIS Reports training.

HEPATITIS A

Since March 2017, several state and local health departments have battled hepatitis A outbreaks that spread through person-to-person contact. The outbreaks are occurring primarily among persons who use injection and non-injection drugs, and/or among persons who are homeless and their close direct contacts.

Hepatitis A outbreaks have occurred in California, Utah, Arkansas, Missouri Michigan, Ohio, Kentucky, West Virginia, Tennessee, North Carolina and the city of Philadelphia. Those outbreaks compelled the ACIP on October 24, 2018 to recommend that "all persons at least 1 year old who are experiencing homelessness should be routinely immunized against hepatitis A".⁹

DELAWARE'S HEPATITIS A RESPONSE

Since the beginning of October 2018, DPH has contacted homeless shelters, transitional housing organizations, and outpatient facilities to provide Hepatitis A vaccinations to persons experiencing homelessness. A questionnaire distributed to homeless and residential shelters asked for the number of residents, their ages, if they are required to leave each morning, and what would be a good time for DPH to hold a hepatitis A vaccination clinic there, if interested. If a facility expressed interest in hosting a vaccination clinic, the Delaware Immunization Program shared that information with DPH's Northern and Southern Health Services teams, who would reach out to schedule one that would fit everyone's needs. Since homeless individuals are transient, a continuous presence at these sites should occur with further vaccination clinics scheduled.

For other agencies with homeless clients, but without the capability to provide the hepatitis A vaccine, DPH created an educational flyer to give to individuals at intake to start the

vaccination conversation. DPH also provides vaccination at State Service Centers located throughout Delaware. It is DPH's hope that the shelters will include hepatitis A immunizations as part of their intake policy. This will protect not only the residents of these shelters, but the community at large as the residence interact in their communities.

Brandywine Counseling and Community Services (BCCS), a leading outpatient care provider in Delaware, has sites throughout the state and caters to the population that DPH has focused on to prevent the spread of hepatitis A. DPH collaborated with BCCS to provide hepatitis A vaccine at their facilities. The agreement calls for BCCS to screen their clients when they arrive to determine their immunization status for hepatitis A. If clients are not up to date on their hepatitis A coverage, BCCS will vaccinate them and schedule a date and time for the final dose. If this initiative is successful, and with appropriate budgets and staff support, DPH can visualize an effort to immunize all homeless individuals with all vaccines recommended for adults.

SECTION 317 VACCINE

Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. Over its 50-year history, Section 317-purchased vaccine was directed to priority populations. Most recently, this included underinsured children ineligible for VFC and uninsured adults. Section 317 discretionary funding also supports immunization program operations at the local, state, and national levels.¹⁰

In Delaware, while VFC vaccine covers most, if not all children, Section 317 vaccine is used in two areas: pandemic response exercises, and uninsured and underinsured adults and children. Each year, every state health department is required to perform a Point of Dispensing Exercise (POD). The POD allows DPH staff to practice immunizing a large population in a timely manner. Since 2015, DPH has operated its largest flu clinics as PODs, a maneuver with several benefits. Combining efforts allows the State to purchase more influenza vaccine to vaccinate those in the general population, and it enables DPH to practice their required POD duties.

Also in 2015, DPH provided Section 317-purchased vaccines to ten local Federally Qualified Health Centers (FQHCs) and one non-profit provider clinic to assist with immunizing their under- and uninsured adult populations. These vaccines include: tetanus, diphtheria and pertussis/tetanus diphtheria (Tdap/Td); hepatitis A and B; measles, mumps, and rubella (MMR); human papillomavirus (HPV), varicella, meningococcal B (Men B), meningococcal ACWY (MCV4), pneumococcal conjugate (PCV13), pneumococcal polysaccharide (PPSV23), and influenza. DPH continues to provide these above-mentioned clinics with all adult vaccines as recommended by the ACIP with the exception of the zoster vaccine. In Fiscal Year 2019, the State of Delaware received approximately \$167,000 in Section 317-vaccine funding, an amount equal to Fiscal Year 2018.

In 2018, DPH was able to supply all needed vaccine to these clinics and utilized all funding by the end of the fiscal year. Just two months into Fiscal Year 2019, DPH processed 23 adult 317 vaccine orders and spent 18% of the budget. As of December 2018, 3,560 doses of influenza vaccine were distributed using 317 vaccine funds which was a 22% increase from the number of influenza doses distributed by December 2017. These doses were distributed as follows; 1,400 doses were used for POD activities and 2,160 doses were delivered to Section 317 providers. These partnerships allow more underserved at-risk adults to receive the immunizations they need. Vaccination data is reported to the State Immunization Information System (DelVAX).

CONCLUSION

The DPH diligently monitors State vaccine coverage level data and disease outbreaks within and outside Delaware's borders. As a result, DPH has collaborated with stakeholders throughout the State to:

- implement HPV provider trainings and a state-wide media campaign designed to promote HPV awareness and increase coverage levels,
- establish hepatitis A vaccination clinics in sites that provide services for at-risk populations (i.e. Homeless shelters, Drug Treatment Centers), and
- rapidly responded to a pertussis outbreak by conducting field case investigations, educational outreach, and medical management (antibiotics and vaccinations) as appropriate within the Amish community.

In addition; DPH issued a public Health Alert regarding the outbreak, distributed Pertussis flyers to medical providers in Kent County to share with their patients in order to increase awareness and promote vaccinations, and reached out to other states to identify public health approaches that were successful within their Amish communities.

RESOURCES FOR READERS

For more information on immunizations for children, adults, and health care providers, visit DPH's immunizations website, <http://www.dhss.delaware.gov/dhss/dph/dpc/immunize.html>, or call the Immunizations Hotline at 1-888-282-8672 weekdays between 8:00 a.m. and 4:30 p.m. Children without medical insurance may receive free vaccines through the VFC program. For details, call the hotline or visit <http://www.dhss.delaware.gov/dhss/dph/dpc/immunize.html> to learn more.

The CDC's website, <http://www.cdc.gov/vaccines/>, offers additional information such as the recommended immunization schedule. Health care providers can view the immunization schedule on tablets or smart phones by downloading the CDC Vaccines Schedules app at www.cdc.gov.

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CONTRIBUTORS

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DPH launches My Healthy Community

Delawareans can now assess the overall health of their communities on one central platform. The My Healthy Community data portal, launched by the Division of Public Health (DPH), delivers neighborhood-focused population health, environmental, and social determinant of health data. Users can navigate the data at the smallest geographical area available, and explore factors that influence health.

Air quality data, asthma incidence data, public and private drinking water results, and drug overdose and death data are currently available. Additional categories and data indicators will be added over the next several months.

"The portal will allow communities, governments and stakeholders to better understand the issues that impact our health, determine priorities, and track progress," said Delaware Department of Health and Social Services (DHSS) Secretary Dr. Kara Odom Walker.

"Addiction, air quality, chronic disease and drinking water quality impact every one of us," said DPH Director Dr. Karyl Rattay. "When communities become aware of the level at which these issues are occurring in their neighborhoods, it can spur action that can improve the quality of life for current and future generations."

My Healthy Community came to fruition through a partnership between DPH, the Department of Natural Resources and Environmental Control, the Division of Substance Use and Mental Health (DSAMH), and the Delaware Health Care Commission.

Access the My Healthy Community data portal at MyHealthyCommunity.dhss.delaware.gov.



DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health

Behavioral Health Consortium seeks to eliminate mental health and addiction stigmas with campaign

May is Mental Health Awareness Month. In Delaware, more than 30,000 adults, over 9,000 adolescents, and greater than 82 percent of the state prison population, struggle with mental health or addiction issues, according to the Behavioral Health Consortium (BHC).

A new communications campaign by the BHC aims to help Delawareans struggling with mental health challenges or addiction connect with resources and support services.

DHSS Secretary Dr. Kara Odom Walker, DSAMH Director Elizabeth Romero, New Castle County Police, and others joined BHC Chair Lieutenant Governor Bethany Hall-Long when the campaign was unveiled May 6 at Christiana Mall.

"Approximately every 22 hours we are losing a Delawarean to a fatal overdose," said Lt. Governor Hall-Long. "We all know someone who is affected by mental health challenges or addiction, and each day we feel the impact that they make on the well-being and future prosperity of Delaware. We have to take measurable action if we want to reverse these disheartening statistics, and start saving lives. The bottom line is no one has to struggle alone."

The campaign includes signage, posters, and floor and bathroom clings at supermarkets, liquor stores, bars and restaurants; bus shelter cards, and print, radio and social media ads.

Materials carry the powerful message, "Mental health and addiction don't discriminate. We have the resources to help."



Those struggling with mental health or addiction should:

- Visit HelpsHereDE.com
- Call 800-652-2929 in New Castle County or 800-345-6785 in Kent and Sussex counties.
- Call 800-345-6785 in Kent and Sussex counties.

Pertussis outbreak in an Amish Community: Kent County, Delaware, 2018

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Abstract

The Amish lead a very simplistic lifestyle free of modern conveniences. They have unique perceptions and beliefs regarding health and illness and generally do not adhere to conventional preventive measures such as immunizations, which can result in un- or under-immunized populations. Populations with low vaccination coverage are at greater risk of outbreaks compared to vaccinated populations as a result of low herd immunity. Over the past two decades, the Delaware Division of Public Health (DPH) has recorded three distinct outbreaks of pertussis in Delaware's Amish community. The third, and most recent, outbreak was detected in May 2018. DPH conducted an outbreak investigation in the Amish community to identify cases, estimate the burden of disease in the community, and implement control measures including vaccination, treatment, and post-exposure prophylaxis. Through the conduct of active surveillance activities, DPH interviewed 134 families and identified 181 confirmed and probable cases of pertussis. The majority of pertussis cases (77%) occurred among children ≤ 10 years of age, of which 87% were unvaccinated. DPH engaged the Amish community in meetings, distributed educational materials, and provided medication and vaccines in the community to encourage prevention and implement control measures. DPH officially closed the outbreak investigation on December 20, 2018 following three full incubation periods (63 days) without any new pertussis cases identified in the community.

INTRODUCTION

Kent County Delaware, just outside the city limits of Dover, is home to a picturesque and serene Amish community. Numerous buggy signs alert drivers to the presence of the Amish, cautioning vehicles to maintain slow speeds when passing buggies. Children play on traditional Amish scooters while plow teams of the gentle, giant Percheron horses work the fields.

The Amish lead a very simplistic lifestyle free of modern conveniences. Their faith calls for a life of hard work, discipline, humility, and avoidance of any form of self-expression. The family is the foundation of the Amish way of life. Large families are considered a gift from God. When its members live together, work together, worship together, and socialize together, the family is stronger. The wisdom of the elders and grandparents is a treasured asset, and their advice is often sought and followed from one generation to the next.

In Kent County the Amish are involved in a variety of trades including carpentry, masonry, furniture building, blacksmithing, farming, and sawmilling. They also successfully operate a number of community shops for items such as dry goods and quilts. Eleven one-room Amish schools within the community teach students in grades one through eight. After their education, Amish boys typically learn a trade, and girls acquire the skills necessary to raise children and maintain a home.

The Amish have unique perceptions and beliefs regarding health and illness, and pass many customs to their children and grandchildren. They generally do not adhere to conventional preventive measures such as immunizations. The Amish avoid health practices customary to the general population because they view them as actions that put man before God. Many families prefer to take responsibility for their own health by using herbs and natural remedies to mend injuries and care for sick loved ones.

BACKGROUND

Pertussis is a highly contagious respiratory disease that can cause severe illness in persons of any age; however, children under one year of age are at highest risk of complications or more severe disease.^{1,2} Primary prevention methods include vaccination of persons of all ages.^{2,3} Vaccinations protect individuals and populations from the spread of infectious diseases by activating the body's immune response (i.e., active immunity).⁴ As the percentage of the vaccinated population increases, herd immunity provides indirect protection to more effectively limit the spread of the disease to susceptible persons.⁵ To meet the herd immunity threshold for pertussis, or the "minimum proportion to be immunized in a population for elimination of infection,"⁵ vaccination coverage levels of at least 92% are required. Vaccination coverage in the Amish population has been documented as sub-optimal to provide herd immunity (<10%).⁶

Delaware reports cases of pertussis to the Centers for Disease Control and Prevention (CDC) annually. Between 2005 and 2018, the median number of reported pertussis cases reported in the state was 17 (Figure 1). Over the past two decades, the Delaware Division of Public Health (DPH) has recorded three distinct outbreaks of pertussis in Delaware's Amish community.⁷ The third and most recent outbreak was detected in May 2018. This report describes the public health investigation of the third outbreak of pertussis in the Amish community and opens the discussion to identify new approaches to increase vaccination and reduce the burden of disease in under- and unimmunized populations.

METHODS

In May 2018, an Amish mother contacted a nurse at the DPH Kent County Health Unit (KCHU). She informed the staff that her child had been coughing for an extended period of time

and asked to have her child tested for whooping cough. During her visit, she shared that other families in the community had children who were coughing or had whooping cough. The child tested positive for pertussis. At that time, it became clear that the likelihood of a potential outbreak existed in this population.

OUTBREAK INVESTIGATION

To confirm the presence of an outbreak and to quantify the magnitude and spread of the disease throughout the community, DPH initiated active surveillance of pertussis in the Amish community. Active surveillance activities consisted of door-to-door contact investigation. DPH formed two-person field teams that included an epidemiologist and a clinic nurse that investigated reported cases, initiated contact tracing, conducted active case finding among the community, and initiated control measures. The clinic nurse carried nasopharyngeal (NP) swabs during home visits to collect specimens from ill individuals. A state courier transported specimens to the Delaware Public Health Laboratory where they were tested for *Bordetella pertussis* using polymerase chain reaction (PCR). Additionally, Amish families also directly contacted KCHU regarding ill children. Each family that presented to the clinic with a coughing child and symptoms compatible with pertussis were tested, and an epidemiologic case investigation was initiated.

CASE DEFINITION AND CLASSIFICATION

DPH epidemiologists developed a case definition and modified the pertussis investigation questionnaire used in the 2013-2014 Amish outbreak. For this outbreak DPH used the National Notifiable Diseases Surveillance System (NNDSS) 2014 case definition for case classification. The case definition included clinical, laboratory, and epidemiologic linkage criteria. A case was defined a person living in Kent County with cough illness lasting greater than or equal to two weeks with onset between January 2018 and October 2018, and without other apparent cause. A confirmed case was defined as a clinical case of pertussis that: 1) was laboratory confirmed by PCR for *B. pertussis*; or 2) had an epidemiologic link to a laboratory-confirmed case in the same household residence or Amish community (e.g., school, church) with at least one of the following signs or symptoms: paroxysms of coughing, inspiratory 'whoop,' post-tussive emesis, or apnea (with or without cyanosis)(for infants aged <1 year only).⁸ A probable case was defined as meeting clinical criteria without laboratory confirmation or epidemiologic linkage. A primary case was defined as the first case in a household. A co-primary case was defined as a case with onset of symptoms within six days of a primary case. Secondary household transmission was defined as cough onset seven to 42 days following contact with a primary or co-primary case.

CONTROL MEASURES

In addition to active surveillance activities, DPH instituted control measures. On their visits to Amish homes, DPH field teams carried travel kits with vaccine to provide on-site vaccinations, as well as medications for treatment and/or prophylaxis to deliver to accepting families. Standing orders were written to enable dispensing of azithromycin during field visits for the duration of the outbreak.

COMMUNITY OUTREACH

In addition to clinic staff, DPH's Community Health section consists of health educators known as the Community Engagement Team (CET). The CET conducted intensive community outreach and education using epidemiologic data provided by the field team epidemiologists. They distributed educational pamphlets and information sheets to Amish families during home visits. CET members distributed flyers to many businesses within the geographic area of the Amish population in Kent County. The team focused its resources on Amish-owned businesses as well as public and Amish schools to increase knowledge in the community about the current outbreak, treatment, and ways to prevent the disease. To ensure that outreach was conducted in areas where known disease transmission was most prevalent, the team used maps to compare outreach locations with pertussis case locations. Lastly, the lead epidemiologist and a CET member visited each Amish school and delivered flyers for students to take home to their parents about the prevention of, and treatment for, pertussis.

RESULTS

DPH teams interviewed 134 families representing 67 households with confirmed/probable cases (Table 1). Seventy-four cases were confirmed through laboratory testing (n=21) and epidemiologic linkage (n=53). An additional 107 probable cases were identified. Sixty-nine individuals received azithromycin for treatment or prevention of pertussis. Additionally, 28 individuals were vaccinated at the KCHU due to known exposure or to prevent illness.

Primary and co-primary cases accounted for approximately 51% of all cases. Secondary household transmission and second primary household transmission accounted for approximately 40% and 9% of cases respectively (Figure 2). Of the five non-Amish cases associated with the outbreak, all had direct, household contact with the Amish. One infant was hospitalized in May 2018 for pneumonia. This child was not tested for pertussis during the hospitalization but had clinically consistent illness and met the case definition for pertussis. No deaths were reported during the outbreak.

Of the 181 confirmed and probable cases, the majority of cases (77%) occurred among children ≤ 10 years with 40% of cases among children aged 1 to 5 years (Figure 3). A smaller percentage of cases (14%) were ≥ 15 years (Figure 4).

During epidemiologic interviews, DPH asked family representatives about the vaccination status of all household members. Of the 181 cases, 10.5% reported being fully vaccinated against pertussis (5 doses), 4.4% reported being partially vaccinated (≤ 3 doses), and 85% reported having never received any pertussis vaccinations. Beginning October 23, 2018, DPH added two additional questions to the outbreak questionnaire to assess attitudes and beliefs regarding the use of antibiotics and vaccinations. Fear of side effects was the most common reason for choosing not to vaccinate or accept antibiotics. The CET distributed educational materials to over 50 businesses, local public schools, and Amish schools.

The last documented cough onset was October 18, 2018. DPH officially closed the outbreak investigation on December 20, 2018 following three full incubation periods (63 days) without any new cough illnesses identified in the community.

Table 1. Characteristics of pertussis cases in an Amish community outbreak, Kent County, Delaware, January 2018 – October 2018

Characteristic	Cases n(%)	Primary/Co-Primary Cases n(%)	Secondary/Second Primary Cases n(%)
Sex			
Male	88 (49)	45 (25)	43 (24)
Female	93 (51)	47 (26)	46 (25)
Age group (yrs)			
<1	9 (5)	5 (3)	4 (2)
1-5	73 (40)	41 (23)	32 (18)
6-10	57 (31)	29 (16)	28 (16)
11-14	18 (10)	9 (5)	9 (5)
15-19	10 (5.5)	4 (2)	6 (3)
20-29	8 (4.4)	2 (1)	6 (3)
>30	6 (3.3)	2 (1)	4 (2)
Vaccination status			
Vaccinated	19 (10.5)	11 (6)	9 (5)
Partially vaccinated*	8 (4.4)	4 (2)	3 (1.6)
Unvaccinated	154 (85)	77 (43)	77 (43)

Source: Delaware Division of Public Health, Delaware Electronic Reporting and Surveillance System

* Partially vaccinated is defined as receipt of ≤ 3 doses of vaccine against pertussis.

DISCUSSION

In general, pertussis outbreaks in under- or unimmunized populations can be difficult to manage. The primary goal of pertussis outbreak control efforts is to decrease morbidity and mortality among infants; a secondary goal is to decrease morbidity among people of all ages. Fortunately, during this outbreak, only one hospitalization and no deaths were reported.

In contrast to the current outbreak, the previous two outbreaks that occurred in 2004 to 2005 and 2014 were defined by increasing numbers of cases during the late fall and winter months. The 2018 outbreak was defined by increasing numbers of cases in the early to late spring months. DPH hypothesized that the outbreak may have peaked in late April to early June of 2018. Similar trends in age groups and vaccination coverage were recorded in the previous outbreaks. Although DPH conducted the outbreak investigation upon identification of the index case, case ascertainment was incomplete despite extensive active surveillance activities in the Amish community. Disease transmission and exposure to unvaccinated children perpetuated the outbreak given the close social interaction of ambulatory children and the general lack of social distancing among the community. There were only five non-Amish pertussis cases documented in this outbreak signifying that spread outside the Amish population was limited to individuals with direct close contact with Amish cases.

During its response, DPH encountered potential barriers to

vaccination and treatment. The DPH CET and clinic staff attempted to overcome access barriers by having surveillance teams bring vaccines and antibiotics to the home visits. There was limited uptake of medication. It is unclear whether these same individuals would have visited the local clinic or other healthcare provider to obtain antibiotics. In addition, surveillance teams noted that the Amish community were less receptive to home visits as compared to more positive interactions during previous outbreaks.

To gain further insight, DPH met with leaders within the community and contacted a local health department in Ohio that had experience with outbreaks within Amish communities. The discussion focused on providing accurate information to the Bishops on pertussis, vaccination, and antibiotic therapy. Additionally, the team discussed non-medical activities that the community could do to help decrease disease transmission; most importantly, the idea of social distancing. The Bishops welcomed the conversation and agreed to support DPH by providing education to their church members. In addition to focusing on the current outbreak, the conversation included ways for the DPH team to build and strengthen an ongoing partnership with the Amish community. Suggestions included meeting school officials after classes and contacting leaders directly to disseminate information. An interesting finding during the meeting was that many of their beliefs were not rooted in religion or faith. Residents researched non-evidence-based medical interventions through publications and periodicals, many of which promoted certain diets and avoidance of vaccination.

The local public health department in Ohio provided a similar perspective. It experienced similar challenges related to the community's concerns and beliefs. It successfully gathered community preferences through surveys and maintained a presence by operating a clinic within the Amish community. Its community clinic strengthened relationships with the residents and improved access to medical care. DPH previously operated a clinic within the Amish community, which may in part weakened DPH's relationship with the community, leading to some of the present challenges.

CONCLUSION

The pertussis outbreak investigation closely paralleled the previous pertussis outbreak in this community in 2004-2005. The same challenges and limitations of the previous outbreaks were present in the 2018 outbreak, including low vaccination rates, poor adherence to antibiotic treatment and/or prophylaxis, and poor compliance with social distancing. The current outbreak uncovered an interesting finding that religion is not the primary

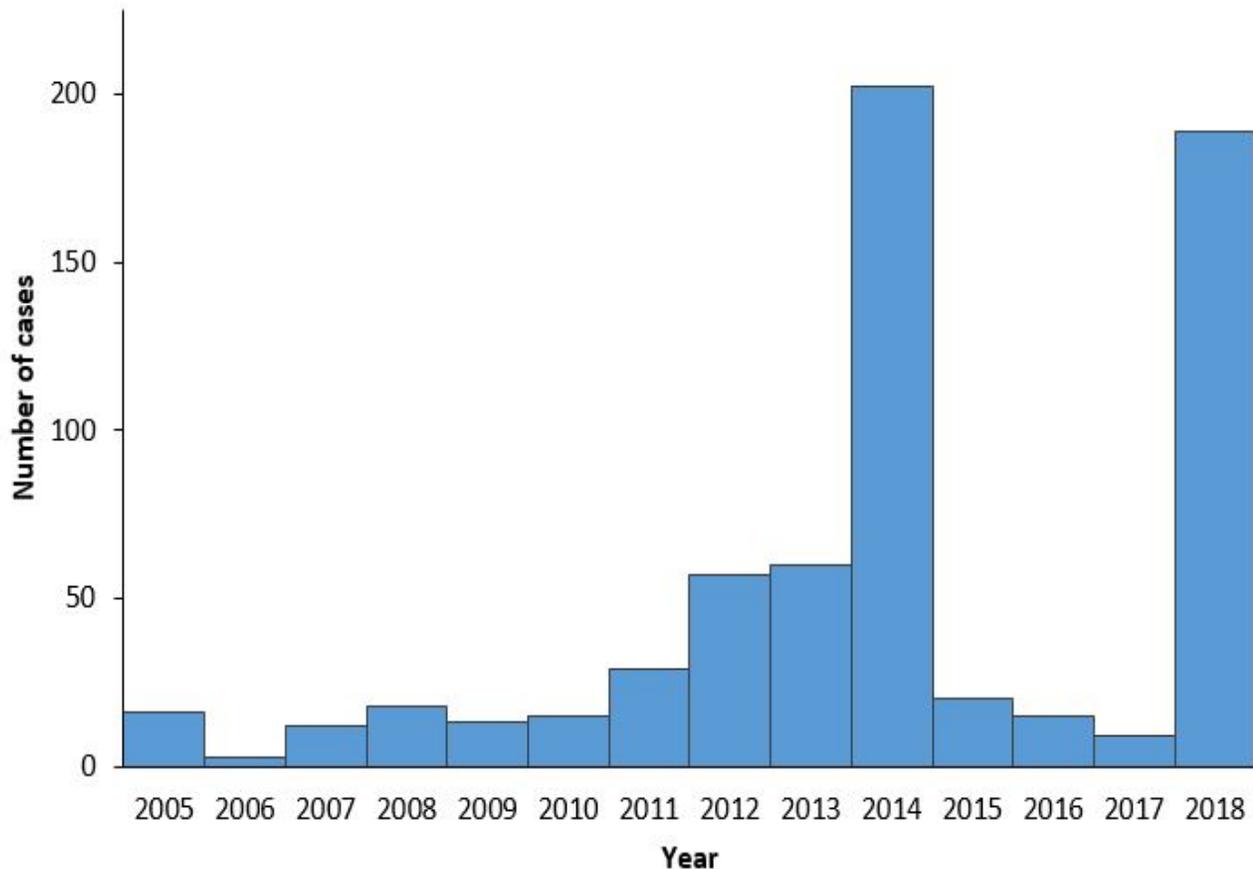
basis of their health beliefs. Many Amish avoid vaccinations because of their adherence to non-evidence-based medical interventions. These challenges hindered traditional prevention and control efforts. The low vaccination coverage and previous documented pertussis outbreaks in this community suggest that continued periodic circulation of *B. pertussis* is likely.

DPH recommends ongoing educational outreach to this susceptible community including: those at highest risk for serious illness, vaccination safety, and protective benefits of vaccination during pregnancy and possible complications.

Future considerations for community outreach and education with this community include:

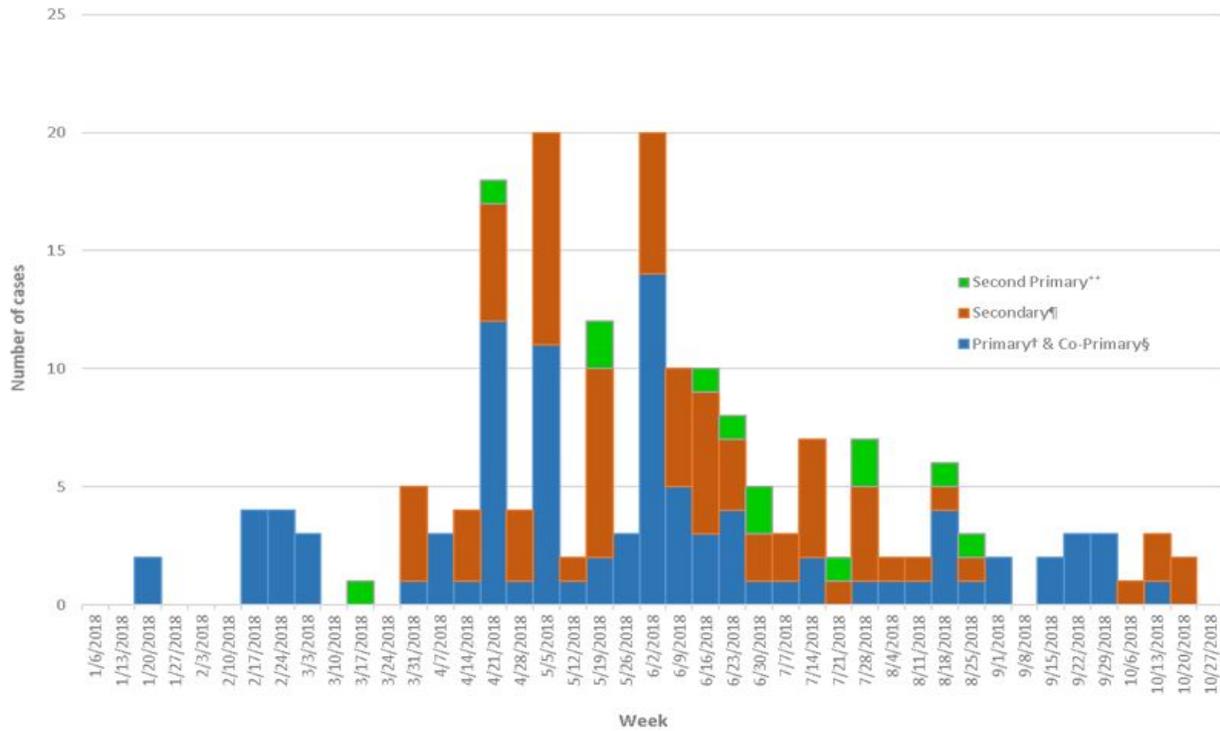
- Consistency of DPH's presence by reinstating DPH vaccination clinics in the community.
- Hosting a health and safety fair to provide health and safety information that is of interest to Amish residents.
- Educational outreach through the frequent provision of flyers and other educational information on a variety of health topics.

Figure 1. Reported number of pertussis cases, Delaware, 2005 – 2018*



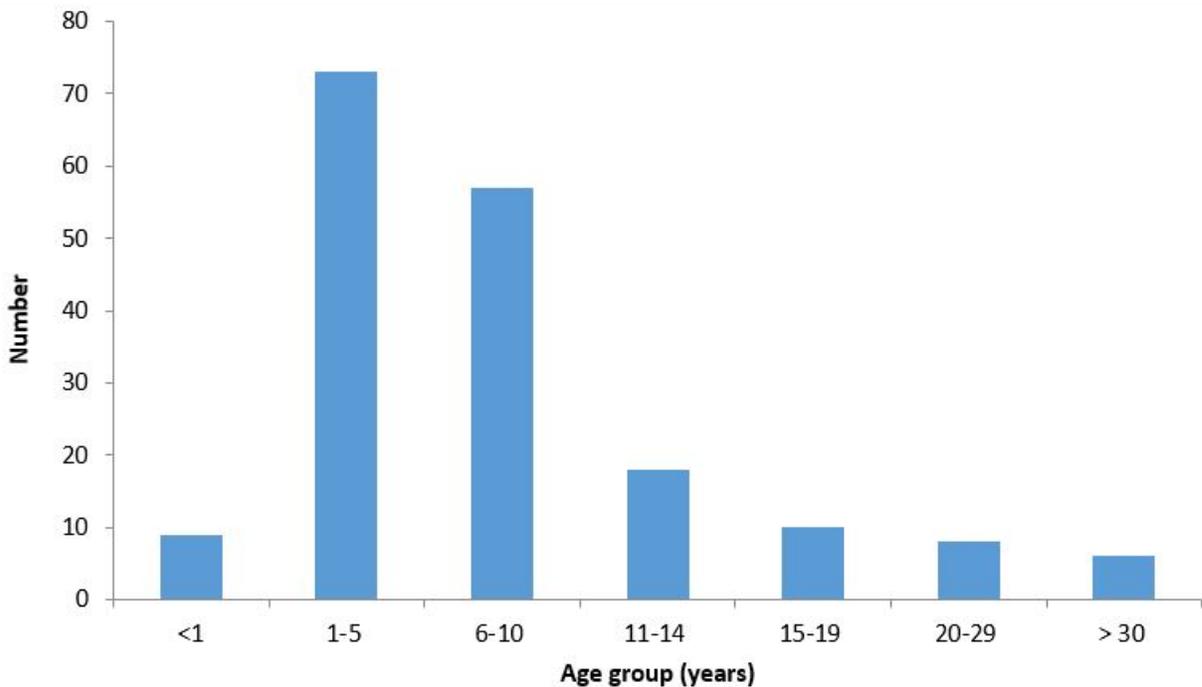
Source: Delaware Division of Public Health, Delaware Electronic Reporting and Surveillance System;
*2018 case counts are provisional and subject to change.

Figure 2. Number of pertussis cases in an Amish community outbreak, Kent County, Delaware, January 2018 – October 2018



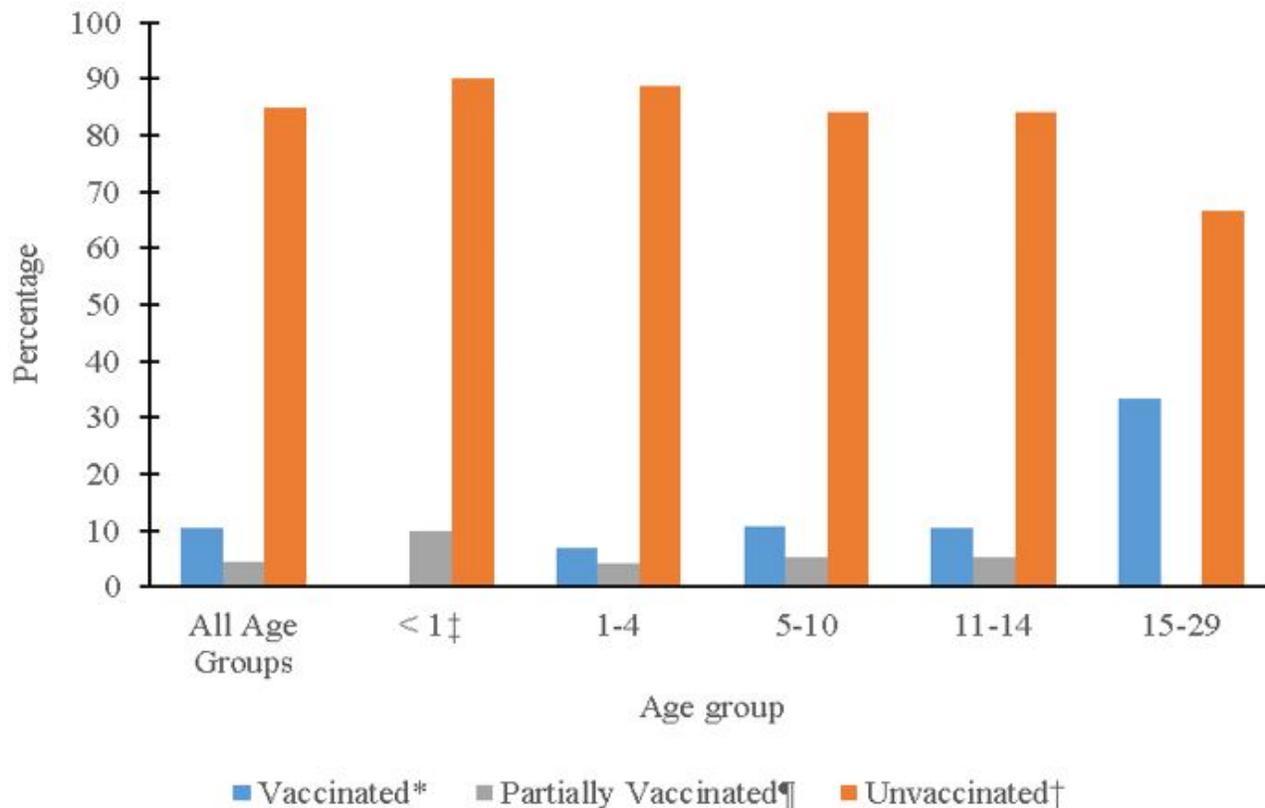
Source: Delaware Division of Public Health, Office of Infectious Disease Epidemiology;
 † Primary - First case in household; § Co-Primary - Cough onset within 6 days of Primary case;
 ¶ Secondary - Cough onset 7-42 days after Primary case;
 ** Second Primary - Cough onset >42 days after Primary case

Figure 3. Number of pertussis cases in an Amish community outbreak by age group, Kent County, Delaware, January 2018 – October 2018



Source: Delaware Division of Public Health, Office of Infectious Disease Epidemiology

Figure 4. Vaccination status of pertussis cases in an Amish community outbreak by age group, Kent County, Delaware, January 2018 – October 2018



Source: Delaware Division of Public Health, Office of Infectious Disease Epidemiology

* Received ≥ 4 doses of vaccine against pertussis;

¶ Received ≤ 3 doses of vaccine against pertussis;

‡ Infants per ACIP recommendations; † Received no vaccination against pertussis;

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Vaccination is the Most Effective Strategy for HPV Prevention

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ABSTRACT

Human Papillomavirus (HPV) remains the most commonly sexually transmitted-infection (STI) in the world. During 2013 to 2014, the prevalence of genital infection with any HPV type was 42.5% among adults aged 18 through 59 years in the United States.¹ Although many will be asymptomatic, most sexually active people will be infected with one of the 40 types known to infect the genital area in their lifetime. HPV types are not equally dangerous. Types 16 and 18 are known to be highly oncogenic and cause a wide range of cancers including cervical, penile, vulvar, vaginal, anal, and oropharyngeal cancers and precancers, but a number of additional strains (types 31, 33, 45, 52, and 58) are known to be oncogenic as well.^{2,3} While HPV types 7 and 11 do not appear to cause cancer they account for nearly 90% of genital warts and cause other medical issues like respiratory papillomatosis.^{2,3}

VACCINATION IS THE MOST EFFECTIVE HPV PREVENTION STRATEGY

As skin-to-skin contact is all that is necessary to transmit HPV, abstaining from sexual intercourse and consistent use of latex condoms does not completely eliminate the risk of infection. Vaccination is a safe and effective method of preventing infection with the HPV types most likely to cause cancers and genital warts. Despite the vaccine's effectiveness, four out of ten adolescent girls and six out of ten adolescent boys have not started the HPV vaccine series, and remain vulnerable to cancers caused by HPV infections.⁴ In Delaware, 40% of all adolescents completed their first HPV shot in 2016 (up from 26% in 2013); however, we continue to struggle with vaccine series completion.⁴ Approximately 17% of teens received the third dose of HPV vaccination in 2016, which represents an increase from 7.3% in 2013. Needless to say, we have a lot of work to do to reach the Healthy People 2020 goal of 80%.⁵

ACIP RECOMMENDATION FOR HPV VACCINATION

The Advisory Committee on Immunization Practices (ACIP) is the committee that reviews immunization data and makes recommendation to the Centers for Disease Control and Prevention (CDC) about immunization schedules. HPV vaccination appears on both the infant, child and adolescent and adult schedules. HPV is routinely recommended for adolescents at ages 11-12 years old.² One major benefit to providing the vaccine on time is the use of a two-dose series (0, 6-12 months). If the first dose of HPV vaccination is provided before the 15th birthday,

only one additional dose is required to complete the series. The vaccine can be given as early as 9 years old, and catch-up vaccination can occur up to age 21 years in men (26 years amongst men who have sex with men) and 26 years in women.² Older adolescents and young adults starting the series after 15 years old should continue to receive the traditional three dose series (0, 1-2, 6 months). Recently the 9vHPV vaccine was approved by the US Food and Drug Administration for administration to adults up to age 45 years; however, no recommendation has been made from the ACIP yet.⁶

STRATEGIES TO IMPROVE HPV VACCINATION RATES

MAKE A STRONG RECOMMENDATION

There are some key strategies for communicating a strong recommendation. Firstly, use a presumptive approach: expect that the patient is open to hearing your recommendation rather than anticipating there will be a disagreement or resistance. Use clear language and consider employing a bundled approach to clearly delineate that you are recommending HPV vaccine the same way as other adolescent vaccinations. Aim to have a recommendation that stresses administration of vaccines on the same day. Common wording that has been shown to be effective includes "I strongly recommend 3 shots during today's visit: Tdap, HPV and Meningitis," or "You are due for 3 shots today - Tdap, HPV and Meningitis. I strongly recommend you receive all three." The CDC has a series of videos called "How I Recommend" that you may find valuable as you develop your personal recommendation style.⁷

ADDRESS CONCERNS ABOUT SIDE EFFECTS AND SAFETY

While there is a robust national conversation about vaccines, some of this information is inaccurate. Parents and teens may have concerns or fears about the safety of a vaccine and/or potential exposure to harm. You should be prepared to answer common questions about vaccine side effects and safety. CDC resources are available to assist in the education of teens and their guardian(s).⁸ Additionally, the CDC campaign website for “You are the Key to Cancer Prevention” includes resources for health care professionals and patients.⁹ Some clinicians may overreact to minor questions with defensiveness or the provision of massive amounts of safety data. This is not an ideal approach as it overwhelms the parent and teen and, at times, leads to delays or refusals for immunization.

LEVERAGE THE WISDOM OF YOUR PRACTICE TEAM

Immunizations should not be limited to the clinician domain. Office staff can be incredibly supportive and instrumental in creating an atmosphere of vaccine acceptance. Consider selecting an *Immunization Champion* for your practice. This champion can serve as the point person who organizes your practice workflow around vaccinations, stays up-to-date on changes and recommendations, and ultimately helps your practice excel in immunization delivery. Encourage administrative staff to remind patients of upcoming immunizations through reminder-recall strategies (for example, sending post cards to remind patients of appointments or using patient portals to recall them back to the office when the time for the next dose has passed) or when scheduling routine appointments. Institute a standing order policy to reduce barriers to immunizing during rooming (and saving the patient the 15 minute wait at the end of the visit). Some practices even leverage daily huddles and care gap reviews to identify and encourage vaccination during visits. The National HPV Roundtable has a resource library and a dedicated provider education resource page that includes a variety of tools to help you improve your HPV vaccination rates, including a set of action guides with targeted approaches that have been shown to be effective.¹⁰

CONCLUSION

HPV vaccination represents an opportunity to prevent not only a STI but to prevent cancer. Delaware has the opportunity to be a leader in the nation by continuing to increase our immunization rates among males and females. We can all play a major role by stocking, strongly recommending, and advocating for on time HPV vaccine at 11 and 12 years old. Use the wide variety of resources to educate yourself and your patients about HPV. If you find that you have questions about 9vHPV (or any other vaccine), the CDC welcomes you reaching out to them at NIPINFO@cdc.gov.

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Management of Hepatitis C in Delaware Prisons: Approaching Micro-environmental Eradication

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Abstract

The management of chronic hepatitis C virus (HCV) infection has been transformed due to the arrival of HCV-specific Direct-Acting Antivirals (DAAs), which are safer, more effective, and better tolerated than the interferon-based therapies that preceded them. Compared with community healthcare systems, many prison healthcare systems have been slower to adopt the routine use of HCV DAAs despite the fact that HCV infection disproportionately affects individuals in correctional institutions. In 2015, the Delaware Department of Correction (DDOC) launched a treatment program that prioritized treatment for patients who were at greatest risk of disease complications. To date, 327/345 (95%) of eligible current HCV patients have initiated DAA therapy. A total of 196/199 (98.4%) patients who have initiated treatment and who have post-treatment data available have achieved sustained virologic response, defined as undetectable HCV viral load 12 weeks after treatment. Applying a concept of micro-environmental eradication, it can reasonably be concluded that DDOC is approaching this benchmark with regard to chronic HCV infection and will soon enter a "maintenance phase," during which it will be feasible to treat new cases of HCV in real time. Correctional systems with significant numbers of untreated hepatitis C patients may want to consider implementing HCV treatment programs that focus on cost-effectiveness and prioritize treatment for patients who are at greatest risk of disease complications.

INTRODUCTION

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States.¹ Approximately one-quarter of patients infected with hepatitis C spontaneously clear the infection, but the rest develop chronic infection, which usually results in progressive liver fibrosis (i.e., scarring) and may lead to cirrhosis, liver cancer, and liver failure.² It has been estimated that 20%-30% of people with untreated chronic HCV will develop cirrhosis within 25-30 years of becoming infected.³ Hepatitis C infection and its complications impose a substantial healthcare utilization and cost burden, which increases as HCV-associated liver disease advances.⁴ HCV is curable with antiviral therapy, and achieving sustained virologic response (SVR) with HCV antiviral therapy has been shown to reduce adverse liver-related health outcomes and all-cause mortality.⁵

The seroprevalence of HCV infection in the general population is estimated to be approximately 1.0% (see Figure 1).⁶ Injection drug use (IDU) is the most common mode of HCV transmission and is reported by 20% to 55% of inmates,⁷ so it is not surprising that HCV infection disproportionately affects individuals in correctional institutions. A review of pooled published studies during 2003-2010 reported the HCV seroprevalence among incarcerated persons in the United States to be between 17.4% and 23.3%.⁸ It has been estimated that nearly one-third of all Americans with hepatitis C spend at least part of the year in a correctional facility.⁹

The management of chronic hepatitis C has undergone a remarkable transformation in recent years due to the arrival of HCV-specific Direct-Acting Antivirals (DAAs), which are safer, more effective, and better tolerated than the interferon-based therapies that preceded them. Expert guidelines recommend that all patients living with hepatitis C should be treated.¹⁰ Compared with community healthcare systems, many prison healthcare systems have been slower to adopt the routine use of HCV DAAs.

According to a recent Washington Post article, up to 97 percent of inmates in the U.S. with hepatitis C have not been treated.¹¹ Many states cited high drug prices as the reason for denying treatment. This article may have underestimated the percentage of incarcerated patients who have been treated, but it seems clear that much more needs to be done to increase treatment of hepatitis C in prison populations. In 2015, the Delaware Department of Correction (DDOC) launched a treatment program based on a prioritization approach and, since then, has treated nearly all of its identified cases of hepatitis C.

HEALTHCARE IN THE DELAWARE DEPARTMENT OF CORRECTION

The Delaware Department of Correction (DDOC) is comprised of the Office of the Commissioner, Bureau of Administrative Services, Bureau of Correctional Healthcare Services, Bureau of Prisons, and Bureau of Community Corrections. Unlike most state correctional systems, the Delaware Department of Correction is a unified correctional system, which manages offenders from pre-trial detention through incarceration and community supervision. The Department supervises between 5,500 – 7,000 inmates within its correctional facilities and approximately 17,000 probationers within the community. Within the unified system, Delaware maintains a five-level system of supervision for offenders:

- Level V - 24-hour incarceration (jail/prison) *
- Level IV - Work Release Centers, Home Confinement (electronic monitoring), Residential Drug Treatment, Violation of Probation Centers
- Level III - Intensive Probation Supervision
- Level II - Standard Probation

- Level I - Administrative Supervision

**Jail describes those offenders serving one year or less.*

The Bureau of Correctional Healthcare Services (BCHS) provides management and oversight of the daily medical care, substance abuse, and behavioral health operations of the contracted medical and mental health providers to ensure that the standards of the National Commission on Correctional Health Care are continuously met and maintained. Offenders under the DDOC custody in Level 5 and Level 4 facilities have access to medical primary care services through Intake Screening, Sick Call and Chronic Care Clinics staffed by Registered Nurses (RN), Advanced Practice Registered Nurses (APRN), Physician Assistants (PA), and Primary Care Physicians (PCP), as well as comprehensive behavioral health and general dentistry services.¹²

HEPATITIS C MANAGEMENT IN DDOC

In the DDOC, hepatitis C is managed in accordance with current guidelines, in particular HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA).¹⁰ Since 2011, the management of DDOC patients with chronic hepatitis C has been supervised by an Infectious Disease (ID) specialist who is employed part-time by the medical contractor and who is the sole prescriber of hepatitis C medications. Most inmates are screened for hepatitis C during their medical intake (see below). Patients who have a positive screening test or who report a history of hepatitis C are referred by the primary care providers to the facility Infection Control Nurses (ICN); approximately 20-30 new cases are identified per week. The ICNs inform the ID specialist about the new cases of HCV. Patients with confirmed chronic hepatitis C receive appropriate counseling and education and undergo baseline evaluation, including medical history and physical examination. Baseline lab tests include: quantitative HCV RNA (HCV viral load), HCV genotype and subtype, staging of hepatic fibrosis, hepatitis A and B serologies (HAV Ab, HBsAb, HBsAg, HBcAb) complete blood count (CBC), international normalized ratio (INR), hepatic function panel (i.e., albumin, total and direct bilirubin, alanine aminotransferase [ALT], aspartate aminotransferase [AST], and alkaline phosphatase levels), and calculated glomerular filtration rate (eGFR).

The ID specialist utilizes serum measurement of biochemical markers for noninvasive assessment of liver fibrosis status. FibroTest, known as FibroSure in the U.S., is a biomarker test that uses the results of six serum tests to generate a score that is correlated with the degree of liver damage in people with a variety of liver diseases. It has been validated for use in the setting of chronic hepatitis C infection and is considered to have the same prognostic value as a liver biopsy. FibroTest and ActiTest permit the non-invasive evaluation of individuals with hepatitis C for the presence of liver fibrosis and liver inflammation, respectively. FibroTest and ActiTest scores are calculated based on patient age, gender and concentrations of serum of γ -glutamyl transferase (GGT), total bilirubin (TB), a-2 macroglobulin, haptoglobin, apolipoprotein A1 and alanine aminotransferase (ActiTest). FibroTest and ActiTest Scores, on a scale of 0.0 to 1.0, are assigned a Metavir scale indicating the level of fibrosis or inflammation present.¹³ (see Figure 2 and Figure 3)

Before 2015, the standard of care for treatment of hepatitis C was interferon-based therapy, which was available for DDOC patients. These treatment regimens had cure rates of only approximately 50% and had significant safety and tolerability drawbacks. The arrival of HCV DAAs, which were expected to be much safer, more effective, and more tolerable, was anticipated for years and it became common practice in community healthcare settings to recommend deferral of treatment for most patients in order to take advantage of the improved safety and efficacy of DAAs. Deferral of treatment was presented as an option to DDOC hepatitis C patients, most of whom agreed with this approach.

Successive waves of increasingly effective DAAs have transformed HCV treatment. The first generation of DAAs was approved by the U.S. Food and Drug Administration (FDA) in 2011 and included two HCV protease inhibitors. Cure rates were slightly higher, but these medications required coadministration of interferon, and therefore did not result in significant safety benefits. In 2013, the FDA approved a third protease inhibitor and the first HCV polymerase inhibitor, which raised cure rates to higher than 80% and also shortened the duration of treatment to as little as 12 weeks. However, the drawbacks for all four of the first-generation DAAs was that they still required most patients to be treated with interferon. In addition, they were very expensive. For these reasons there was very little utilization of these early DAAs by DDOC. However, their arrival did increase anticipation for interferon-free treatment among community and DDOC patients living with hepatitis C and their advocates, and when this possibility finally arrived the department was poised for progress. In late 2014 and 2015, several new DAA were approved that did not require interferon, finally ushering in the current paradigm of interferon-free therapy for hepatitis C. Additional DAAs arrived in 2016 and 2017, providing prescribers with several treatment options for all types of HCV infection, all of which have excellent safety profiles and cure rates as high as 99%.

HCV TREATMENT IN DDOC DURING THE DAA TREATMENT ERA: A MULTI-LEVEL PRIORITIZATION APPROACH

In addition to the constant influx of new patients, by 2015 there was a large volume of existing HCV cases awaiting treatment. To assure that patients who were at highest risk for disease complications got evaluated and treated as quickly as possible, baseline testing was prioritized according to the patient's age; this was based on the presumption that older patients may have had HCV longer and may, therefore, have more advanced hepatic fibrosis. Baseline evaluation was also expedited for DDOC HCV patients with shorter sentences to assure that they get evaluated before they get released.

In 2015, AASLD/IDSA Guidance recommended treating patients who have advanced illness before treating those with less advanced disease in settings where resources limit the ability to treat all patients immediately.¹⁴ Resource limitations exist in virtually every healthcare setting, including prisons and jails. Accordingly, the Federal Bureau of Prisons (FBOP) has established priority criteria for treatment based on several clinical measures, most notably the degree of hepatic fibrosis.¹⁵ In keeping with this guidance, a prioritization approach based on risk of disease complication was developed for DDOC. Under this scheme, patients with cirrhosis were the first to

receive treatment with HCV DAAs. These cirrhotic patients were further stratified by Child-Pugh classification, a widely used tool to assess prognosis in patients with chronic liver disease and cirrhosis. Once the initial cohort of cirrhotic patients was treated, which took about 18 months, patients with stage F3 hepatic fibrosis were offered treatment, then patients with F2 fibrosis, and so on. Patients with F3 through F0 fibrosis were further prioritized according to their necroinflammatory scores based on the understanding that higher necroinflammatory scores are associated with faster disease progression. Within each fibrosis category, patients with comorbidities which have been associated with faster disease progression, such as HIV or chronic Hepatitis B infection, were prioritized for treatment before those who did not have such comorbidities. While awaiting treatment, FibroTest assessment was repeated annually to monitor for disease progression. The prioritization scheme was flexible, and newly identified patients with fibrosis scores higher than the current treatment level were expedited.

DAA SELECTION AND COST-EFFECTIVENESS CONSIDERATIONS

Several factors went into the selection of HCV DAAs for each patient who received treatment, most notably the safety and efficacy. AASLD/IDSA HCV Guidance recommends DAA regimens based on scientific evidence and expert opinion.¹⁰ Each recommendation includes a Roman numeral (I, II, or III) representing the level of the evidence that supports the recommendation and a letter (A, B, or C) representing the strength of the recommendation. Recommended regimens are those that are favored for most patients in a given group, based on optimal efficacy, favorable tolerability and toxicity profiles, and treatment duration. Alternative regimens are those that are effective but, relative to recommended regimens, have potential disadvantages, limitations for use in certain patient populations, or less supporting data than recommended regimens. In certain situations, an alternative regimen may be an optimal regimen for an individual patient. For most patients, there are several treatment regimen options that are recommended with the highest possible rating (I, A).

The high cost of HCV DAAs has resulted in significant barriers to access in both community and correctional settings. DDOC is determined to provide HCV treatment despite the high prices of these medications. Several recent studies have demonstrated the economic value of HCV treatment and made it clear that HCV therapy is cost-effective,^{16,17} including in prisons.^{18,19} According to AASLD/IDSA Guidance, when given a choice between recommended HCV DAA regimens, the less costly regimen is preferred as a more efficient use of resources (even if it requires multiple tablet dosing).¹⁰ Because of the similar efficacy of most DAA regimens, cost becomes the critical factor driving cost-effectiveness. DDOC endeavors to maximize cost-effectiveness while providing treatment in accordance with the community standards and current guidelines. The DDOC maintains a contractual arrangement with an institutional pharmacy service provider (PSP) to administer its pharmaceutical activities. The PSP engages in ongoing negotiations with pharmaceutical manufacturers to obtain the best possible prices for medications, including HCV DAAs, therefore prices are always subject to change. To stay abreast of current DAA prices, the ID specialist maintains ongoing communication with the PSP.

After consideration of pertinent clinical information (e.g. HCV genotype, fibrosis level, treatment experience, potential drug interactions, etc.), there usually are several AASLD/IDSA Recommended regimens with Level I, A ratings from which to choose. From this list of options, the ID specialist typically selects the most cost-effective (least expensive) option for each patient. DAAs with lower AASLD/IDSA ratings are not selected over DAAs with higher ratings for any reason, including cost. By selecting DAAs based on cost-effectiveness it was possible to treat more patients each year for less total cost. This is evidenced by the decreasing cost per treatment each year since 2015 (see figure 3).

SENTENCE TIME CONSIDERATIONS

Interferon-based HCV treatment regimens required six to twelve months of therapy, and when they were the standard of care the Federal Bureau of Prisons and most state correctional systems included sentence duration of up to 18 months as a criterion for treatment eligibility in order to avoid treatment interruptions.²⁰ Most HCV DAA treatment courses are only 8 or 12 weeks, which makes it feasible to treat patients with much shorter sentences, and some correctional systems have shortened their minimal sentence requirements.²¹

Currently, while there is no official minimal sentence time requirement to receive treatment for hepatitis C while in DDOC, there does need to be a reasonable expectation that the patient will remain in the system long enough to complete both the treatment and post-treatment evaluation. Accordingly, treatment is routinely offered for patients with sentences of at least six months. Patients whose sentence time is long enough to complete treatment but not post-treatment monitoring may be offered treatment if there is a reasonable expectation that the patient will follow up for post-treatment evaluation in the community after release. Patients with very short sentences are not treated, but are encouraged to follow up with the ID specialist in the community after release. Many of these patients have, in fact, done so and have been successfully treated post-incarceration.

Jails, which are usually run by local law enforcement and/or local government agencies, are designed to hold inmates awaiting trial or serving a short sentence. As mentioned above, the DDOC is a unified correctional system that includes detainees who are awaiting trial in addition to inmates who have been sentenced. DDOC HCV patients who are awaiting sentencing undergo baseline evaluation and receive contact information for community care. HCV treatment has been historically uncommon in jails, primarily because of the short duration of incarceration.²² A recent observational cohort study demonstrated the feasibility of initiating and completing DAA HCV treatment in a jail setting.²³ In this study, 104 detainees in the New York City jail system received DAA treatment; most completed treatment successfully but some were released before post-treatment viral load testing could be completed. A small number of DDOC HCV patients who were not yet sentenced, but who were expected to remain in DDOC long enough to complete treatment, have been treated. Most of them successfully completed treatment, however, some of them were released sooner than expected - several before the treatment was completed - and have been lost to follow up. The ID Specialist regularly monitors for the possible return of these individuals; a few have recidivated and have completed post-treatment testing.

HEPATITIS C SCREENING, PREVENTION, AND LINKAGE TO CARE

Many HCV-infected individuals, including those in correctional facilities, are unaware of their infection.²⁴ The high prevalence of hepatitis C, coupled with the fact that up to 30% of all persons with HCV infection in the U.S. spend at least part of the year in a correctional institution,^{9,25} suggest that correctional facilities may provide an excellent opportunity to offer screening to a large population of at-risk individuals. Several HCV management guidelines recommend screening for all incarcerated individuals.^{10,16} However, recent surveys of state prison medical directors and department of corrections health authorities indicate that although some form of HCV testing is performed in the majority of prisons, only a minority of them screen for HCV universally or routinely (i.e., HCV screening is included in normal health assessments for all patients and not based on risk).^{18,26}

DDOC offenders are offered screening for hepatitis C in accordance with recommendations from the Centers for Disease Control, including adults who were born between 1945 and 1965; report history of risk behaviors and/or exposures, and other circumstances (e.g. HIV infection, unexplained chronic liver disease and/or chronic hepatitis). HCV screening consists of HCV-antibody testing followed by confirmatory HCV-RNA testing if antibody-positive. Chronically infected individuals receive counseling and education about HCV infection. Individuals who may be released before they get evaluated and/or treated are provided linkage to follow-up community healthcare for further evaluation and treatment of HCV upon release.

Currently, screening for HCV in DDOC is not universal, however, efforts are being made to increase screening by educating providers on current screening recommendations. In addition, the DDOC is in the process of converting to opt-out screening for HCV in its facilities. Universal opt-out HCV screening in prisons has been demonstrated to be highly cost-effective and would be expected to reduce HCV transmission and HCV-associated diseases primarily in the outside community (See Figure 4).²⁷

In the United States, at least 95% of incarcerated individuals, including those with HCV infection, will be eventually released into the community.²⁸ It has been estimated that individuals released from the criminal justice system may account for up to 29% to 43% of the 2.7 million to 3.9 million persons infected with hepatitis C in the United States.²⁴ The criminal justice system may be an ideal setting to efficiently identify and cure the greatest number of HCV-infected people.²⁹

In an effort to reduce risk factors and decrease the potential for spread of HCV, the DDOC has taken steps to address injection drug use predominantly related to opioid addiction. The DDOC has historically provided substance use rehabilitation and counseling programs on a volunteer basis or to fulfill sentencing requirements. More recently, a Medication Assisted Treatment program for opioid use disorder has been launched and continues to expand. This program lies parallel to a robust discharge planning and re-entry process to connect inmates with a history of substance abuse to community service providers after incarceration.

DE DOC HEPATITIS C TREATMENT DATA

As of March 2019, there were 371 DDOC patients with confirmed chronic HCV infection and complete baseline evaluations; this number includes patients who were previously identified and were awaiting treatment when the DAA treatment program began

in 2015. Of these patients, 345 are/were eligible for treatment based on sentence duration. There are twenty-six current DDOC patients who have been evaluated but have sentences that are too short to complete treatment or have not yet been sentenced; all of these patients have received referrals for community follow up and have been encouraged to follow up there in the event they get released. Unsented patients who receive sentences that are long enough to complete treatment will be offered treatment. A total of 327 patients have initiated treatment; this represents approximately 95% of eligible current HCV patients. All of the remaining eighteen patients have stage F0 fibrosis and are scheduled for treatment initiation by May 2019. Twelve current DDOC HCV patients have refused lab evaluation; they have been scheduled to meet with the ID specialist to discuss management options.

Of the 327 patients who have initiated treatment, 196 have achieved sustained virologic response (SVR), defined as an undetectable HCV viral load 12 weeks after treatment. Eighty-five patients are either still on treatment or have recently completed treatment so have not yet had a post-treatment viral load measurement. Data is missing for thirteen patients: eleven were released, one transferred to another state, and one patient died while on treatment (unrelated to HCV). There have been ten treatment failures (See Figure 5): seven have successfully achieved SVR following retreatment; two patients were recently retreated and are awaiting SVR labs; one patient was released soon after the post-treatment viral load was drawn and is currently lost to follow up. To date, there are 199 patients who have initiated treatment and who have SVR data available; 196 of these have achieved SVR (98.4%).

MICRO-ENVIRONMENTAL ERADICATION OF HEPATITIS C

Prison-based screening and treatment may be a highly effective strategy for reducing the burden of human immunodeficiency virus (HIV), tuberculosis, HCV, and some sexually transmissible infections among prisoners and the general community.³⁰ The concept of a prison micro-environment that provides a promising location to intervene in the care of blood-borne transmitted diseases is compelling, since this population carries a high prevalence of disease, commonly engages in high-risk behaviors, and could be readily accessible by providers for testing and treatment. Prisons are a particularly attractive microenvironment for HCV treatment considering that DAA regimens require only 8–12 weeks to achieve cure.³¹

As outlined above, all of the identified, eligible (sentenced) cases of chronic hepatitis C in DDOC will have been treated by May 2019. Applying this concept of microenvironmental eradication to the DDOC experience, it can reasonably be concluded that the system is rapidly approaching this benchmark with regard to chronic HCV infection. Clearly, it will never be possible to completely eradicate all hepatitis C from the DDOC because there will always be an influx of new inmates, many of whom are already chronically infected. Also, the current achievement may prove to be just a preliminary state of microenvironmental eradication, as additional cases are likely to be discovered among the existing population. If this occurs the newly identified cases will be treated expeditiously. Perhaps more interesting is the notion that moving forward, the DDOC will enter a “maintenance phase”, during which it will be feasible to treat all new cases of HCV in real time, regardless of their severity of disease progression.

Figure 1. Hepatitis C is a disease of the marginalized. Adapted from Edlin BR. Perspective: Test and treat this silent killer. *Nature* Volume 474, pages s18–s19 (09 June 2011).⁶

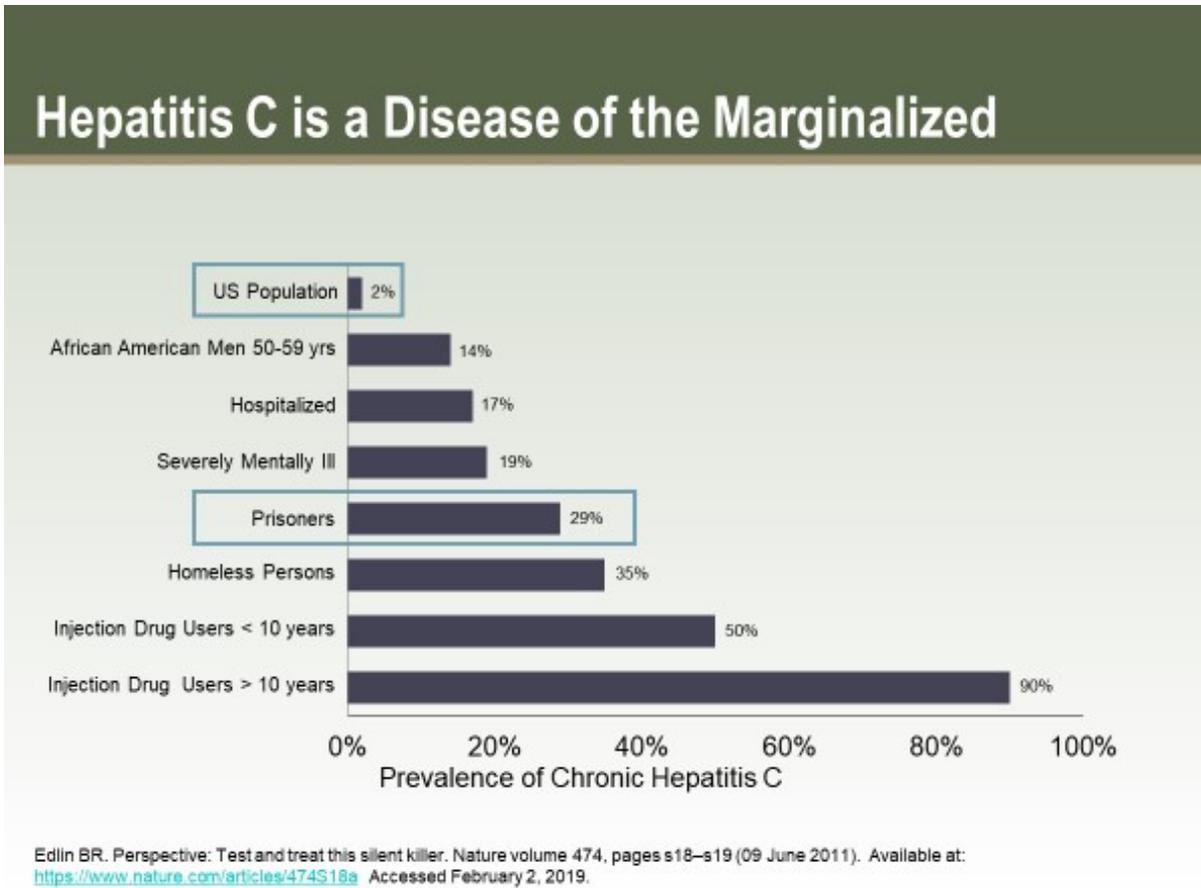


Figure 2. (left panel). FibroTest scores range from 0.00 to 1.00 and correlate with METAVIR fibrosis stages. (right panel). Sample FibroTest/ActiTest report. This sample demonstrates stage F3-F4, Activity stage A1-A2.

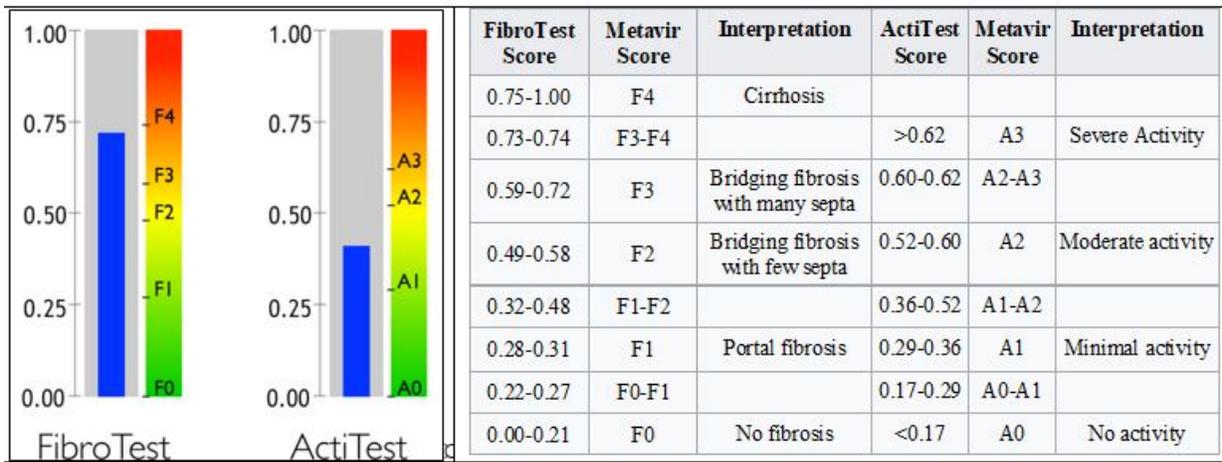
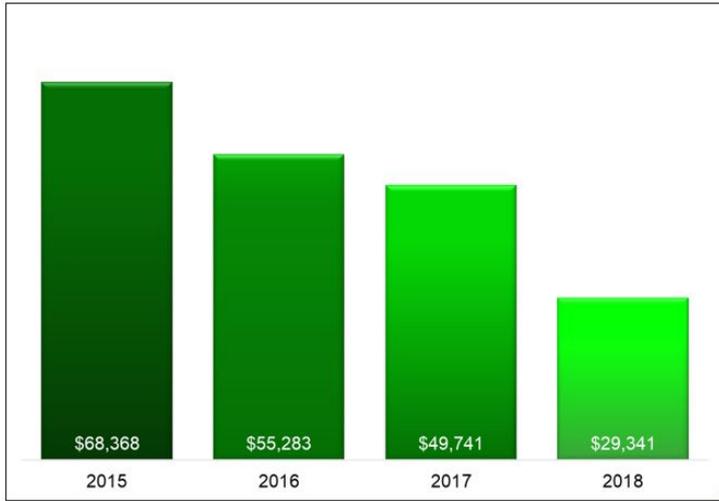


Figure 3. Average HCV Cost per Patient 2015 – 2018.



Courtesy of Correct Rx Pharmacy Services, Linthicum, Maryland.

Figure 4. (left panel). Model schematic of HCV disease transmission and progression in prisons and in the general population. (right panel). Projected reduction of hepatitis C virus (HCV) transmission.

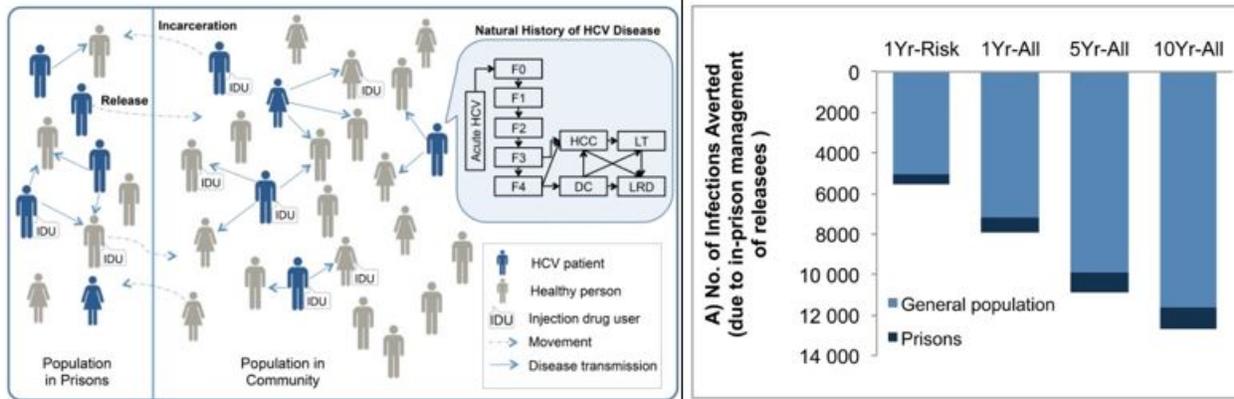
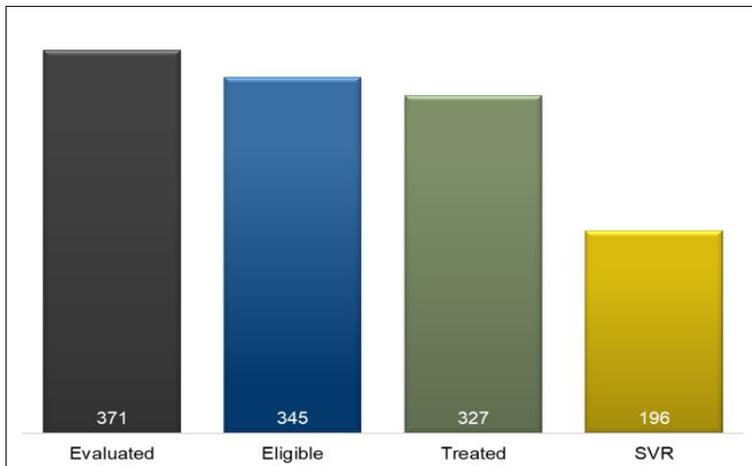


Figure 5. DDOC HCV Patient Disposition as of March 31, 2019.



DISCUSSION

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States and disproportionately affects correctional populations, including the Delaware Department of Correction. Several years ago, the Department responded to this situation by deciding to treat patients with hepatitis C in accordance with community standards. A prioritization approach was developed to assure that the patients who were at highest risk of attributable morbidity and mortality would receive treatment as quickly as possible. As of the time of this writing, nearly all of the identified, treatment eligible (sentenced) hepatitis C patients have been treated and the remaining cases, all of whom have no hepatic fibrosis, are expected to initiate treatment by May 2019. Including successful re-treatment of initial treatment failures, 98.4% of patients with available post-treatment data have achieved SVR. There are several important factors that have contributed to the success of the DDOC experience, but three key elements warrant discussion: 1) the emphasis on maximizing cost-effectiveness; 2) the involvement of a small group of healthcare professionals; and 3) treatment prioritization.

The high cost of HCV medications has been a significant barrier to treatment both in and out of prisons. The DDOC has been committed to meet the challenge of HCV treatment head on despite these barriers. Prices of DAAs have decreased considerably over time, but some are still very expensive. Fortunately, treatment of HCV has been demonstrated to be very cost-effective. By maintaining strict adherence to AASLD/IDSA Guidance, all DDOC patients are assured community standard treatment. And by routinely selecting the most cost-effective treatment options, the overall cost of treatment has remained reasonable and the average cost-per-treatment has steadily decreased.

As previously noted, a single, part-time ID specialist treated all of the HCV patients with the help of a few dedicated staff employees at each facility. This small group of individuals spends a significant portion of their time working on HCV, and therefore is very focused. They continuously review the referral and evaluation processes, which are unique for each site, and make frequent refinements in order to provide excellent care as efficiently as possible. Since 2015, these processes have become much more streamlined, which has resulted in an acceleration in the rate of treatment. A less specialized, less focused management approach would be less likely to have evolved as much and as quickly.

Several years ago, AASLD/IDSA Guidance removed language recommending prioritizing patients with advanced fibrosis for treatment, suggesting that all patients who have chronic hepatitis C should be treated immediately. Although most community healthcare systems operate with resource limitations, this may be feasible. However, in a semi-closed environment with significant resource limitations, such as a prison system, there are potential advantages to prioritizing treatment based on hepatic fibrosis. This is evidenced by current FBOP Clinical Guidance for HCV management, which recommends treatment for all sentenced inmates with chronic HCV infection but continues to endorse priority criteria based on severity of disease.¹⁶ Arguably, the most significant advantage of such an approach is that patients who are

at highest risk of experiencing morbidity or mortality receive the benefits of SVR as quickly as possible. The alternative would be to treat patients on a “first come first served” basis. If the DDOC had taken this approach, patients with advanced fibrosis could be among those who are still waiting for treatment, all the while remaining at risk of disease related adverse events. Instead, all DDOC patients with advanced fibrosis were treated by early 2017. Since then, newly identified patients who were found to have advanced fibrosis have received expedited treatment.

Some readers may attribute the success of this treatment program to the small size of the DDOC relative to other state prison systems. The DDOC operates with similar resource limitations as other prison systems, including staffing, clinical space, time, and of course, financial. Despite these limitations, a small, focused team has successfully treated nearly all known cases of HCV within a few short years. All of this could be replicated on a larger scale and so is generalizable to larger systems. Correctional systems with significant numbers of untreated HCV patients at all levels of hepatic fibrosis may want to consider implementing HCV treatment programs that focus on cost-effectiveness and prioritizing treatment for patients who are at greatest risk of disease complications.

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Call to Action to Promote the All of Us Research Program to People with Disabilities

WHY SHOULD YOU PARTICIPATE IN THE ALL OF US RESEARCH PROGRAM?

“Nothing About Us Without Us”: This slogan is used to communicate the notion that no policy or practice, which affects the disability community, should be created without full and direct participation of members of the disability community. Historically, people with disabilities have been **excluded** and **ignored** from research studies. That ends **NOW** because of the [All of Us Research Program](#)!

Congratulations! The [All of Us Research Program](#) is **YOUR** chance to make an impact and get involved in direct, cutting-edge research to find solutions that could help people with disabilities. For the first time, people with disabilities are being encouraged to participate and are being asked to enroll in a study that can directly impact how health care is received in the future. If we truly believe in the concept of “nothing about us without us,” then **we must answer the call** when asked to participate.

What is this Call to Action? The American Association on Health and Disability (AAHD) is calling on **YOU** to learn more about and consider involvement in the National Institutes of Health’s (NIH) [All of Us Research Program](#). If you are interested in participating in the research program, enroll at <https://www.JoinAllOfUs.org/together>.

What is the [All of Us Research Program](#)? The NIH has created a nationwide research program focused on precision medicine, also known as personalized medicine, to help researchers understand more about why people get sick or stay healthy. The [All of Us Research Program](#) plans to **recruit one million** or more people to share their health and lifestyle data. The program recognizes the importance of recruiting traditionally underrepresented populations living in the United States (U.S.), providing the disability community a unique opportunity. When you join the program you will be contributing to an effort to improve the health of future generations while also advancing precision medicine and learning more about your own health, through better testing, better medicine and more information presented to you.



The [All of Us Research Program](#) will provide researchers more information about people’s health and habits. By looking for patterns in biological, environmental and behavioral factors, researchers may learn more about what affects people’s health and, in turn, the best way to treat them. Currently, all eligible adults over the age of 18 who live in the U.S. can join the [All of Us Research Program](#).

What is precision medicine? Health care has traditionally followed the same approach using a “one—size—fits—all” method, by prescribing treatment for diagnoses based on the average patient. Now, thanks to recent precision medicine initiatives, physicians are working toward tailoring treatment plans to the individual. For instance, many medical conditions, such as high blood pressure, are treated with a standard medication given to all patients and then trial and error is used to determine the best medication and/or dosage. Imagine a scenario where the individual’s treatment is already customized for the person based on factors known about them, including any disabilities. This research program **will advance precision medicine and focus on the individual.** Precision medicine ensures that lifestyle, environment and genetic factors are considered when physicians determine the course of treatment in order to provide the best possible care for each patient.



What is the connection between *All of Us*, precision medicine and people with disabilities? The program is looking at a diverse group of people with a variety of health statuses, who will aid in moving the health care profession toward a more comprehensive, individualized approach. As a community engagement partner with *All of Us*, AAHD is focusing outreach efforts on educating people with disabilities about the importance of participating in the [All of Us Research Program](#). Researchers are emphasizing the importance of recruiting traditionally underrepresented populations living in the U.S., providing the disability community a unique

opportunity to improve the health of people with disabilities. No one understands “underrepresented and underserved” like the disability community. Participation is especially important when you consider that people with disabilities have been previously left out of biomedical research either because researchers did not actively recruit them, or they were not prepared to provide the accommodations people with disabilities need to participate.

Why should people with disabilities participate in *All of Us*? People with disabilities know all too well that health status isn’t just dependent on a medical diagnosis. The “one—size—fits—all” method is not effective, as each person is unique and requires individualized care and treatment. There are many physical and environmental barriers that are unique to the disability community, and the presence of secondary conditions and health disparities is often overlooked by health care providers. A visit to a health care provider can become an all-day event if a bus’s wheelchair lift is broken. A medication can be taken incorrectly if the instructions aren’t written in a format that a person can read, such as braille or large print. A serious medical condition can be misdiagnosed if a physician isn’t trained to understand all aspects of the primary and/or secondary condition. These issues can be detrimental to the health of people with disabilities. **This is YOUR chance to change how medicine works. YOUR chance to solidify the slogan, “nothing about us without us.”**



For more information about how you can get involved in the *All of Us* Research Program, please visit the American Association on Health and Disability website <https://www.aahd.us/initiatives/all-of-us-research-program/> or visit the program’s website <https://www.JoinAllOfUs.org/together>.



FOGARTY INTERNATIONAL CENTER • NATIONAL INSTITUTES OF HEALTH • DEPARTMENT OF HEALTH AND HUMAN SERVICES

CUGH examines implementing solutions for impact

By Ann Puderbaugh

CHICAGO—With a mandate to improve health across the planet, attendees of the 10th annual meeting of the Consortium of Universities for Global Health (CUGH) were encouraged to unleash the unique power of their institutions to enhance the translation and implementation of knowledge so the world’s underserved can benefit. “We know that putting what works into scale will save millions of lives,” said CUGH chair, Dr. Ann Kurth, in her opening address. “We need to work together across borders and across ideologies,” she said, encouraging attendees to synergize efforts to improve health for all.

More than 1,750 academics, practitioners, administrators, students and others, representing 50 countries, attended the gathering. In keeping with the conference’s implementation science theme, Fogarty’s Center for Global Health Studies (CGHS) organized a panel discussion to explore ways to advance the field.

“We need a more coordinated approach to implementation science capacity building that identifies the most useful content for stakeholders,” said Dr. Rohit Ramaswamy of the University of North Carolina. He’s been developing a multi-tiered concept to provide different, but complementary, levels of training for researchers, implementers, policymakers and those involved in care delivery. It’s not helpful if trainees return home ready to put implementation science theories into practice but their stakeholders don’t understand what they’re talking about, Ramaswamy noted.

Two case studies of HIV-related implementation science projects that were shepherded by Fogarty’s CGHS were presented. With adolescents identified as a key population for disease transmission in Africa, a collaboration has been established to enhance effective



Consortium of Universities for Global Health Chair Dr. Ann Kurth opened the 2019 annual meeting with a call for action to advance implementation science.

Photo courtesy of CUGH

use of evidence to improve HIV prevention, screening and treatment of young Africans, aged 15-24. The Adolescent HIV Prevention and Treatment Implementation Science Alliance (AHISA) provides a space to facilitate dialogue and exchange of ideas among researchers, implementers and decision makers, said Fogarty’s Dr. Rachel Sturke, who manages the program.

An initiative to prevent mother-to-child-transmission of HIV—another CGHS project—resulted in formation of the Nigeria Implementation Science Alliance (NISA), a national effort to coordinate research and capacity building efforts among stakeholders. Established in 2015 with a focus on research productivity and development of independent investigators, NISA has already generated two funded NIH

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FOCUS



Fogarty programs build capacity and spur NCD research

- Evaluation shows 600 researchers trained, 982 publications produced
- Broad range of diseases and conditions studied across the lifespan
- Ongoing challenges and unmet needs require continued support

Read More on pages 35 - 38

CUGH examines implementing solutions for impact

... continued from previous page

grant proposals and more than seven published research papers. Projects are always multi-site, multi-partner and involve issues that have potential for national scope and impact, said Dr. Nadia Sam-Agudu, of Nigeria's Institute of Human Virology.

To strengthen NIH's global mental health initiatives concerning children, the National Institute of Mental Health (NIMH) co-hosted a workshop during the conference to gain insights that will inform its future programs. Eighty-five percent of the world's youth live in low- and middle-income countries (LMICs), where access to diagnosis and treatment is lacking. "Youth mental illness is one of the most urgent mental health problems worldwide," according to NIMH Director Dr. Joshua Gordon. "Early interventions can improve outcomes," he said, yet there has been little research on how to apply existing knowledge and practices for use in low-resource settings. Proven diagnostic techniques—such as using mobile devices to track eye contact in young children—could be adapted for use in LMICS so that diagnosis and treatment of autism could begin earlier, he said. Using cellphones or other portable devices to administer such tests "is imminently implementable worldwide."

But implementation without maintaining quality of care is also an enormous problem in LMICs. In a session organized by Fogarty, panelists presented the results of a recent U.S. National Academies of Sciences, Engineering and Medicine (NASEM) report that shows up to 8 million deaths occur each year from lack of access and poor quality of care in developing countries—more than HIV, TB and malaria combined. The study examined what an ideal health system would look

like and recommended a shift in focus and ownership of health to the communities, said Dr. Marcel Yotebieng, an author of the report and faculty member of Kinshasa University and Ohio State. NIH funds a broad range of studies on how to improve quality of care through 18 grants in 14 LMICs, said Fogarty's Dr. Linda Kupfer, who helped coordinate NIH's participation in the NASEM report.

Photo courtesy of CUGH



Fogarty's Dr. Ken Bridbord was awarded CUGH's highest honor by its director, Dr. Keith Martin. (see page 11)

At another session, Fogarty Fellows and Scholars shared their stories of their early-career experiences at NIH research sites and the positive outcomes that resulted. The program's first landscape architect, Dr. Leann Andrews of the University of Washington, presented her successful efforts to improve a Peruvian slum community's health by working with residents to construct gardens full of herbs, medicinal plants, fruits and vegetables. By making their surroundings safer and more attractive, boosting food security and access to medicines, and improving water quality, she found residents reported a decrease in depression and gastrointestinal illness, as well as fewer falls and injuries.

Other Fogarty Fellows presented their studies of cervical cancer in Malawi, mental illness in Kenya, HIV/AIDS

in Peru and TB in Tanzania. Fogarty Director Dr. Roger I. Glass said he was encouraged by the caliber of these emerging global health leaders. "I'm so proud of you all and to see that by investing in youth, through the impact of this program, we are launching careers that will endure for 30 years."

Mentoring—essential for early-career scientists—is not often part of the culture at LMIC research institutions. That was the topic of a session to launch a supplement published by the journal of the American Society of Tropical Medicine and Hygiene (ASTMH) that provides recommendations and case studies to spur mentorship programs in low-resource settings.

"This is a call to action, not just an academic discussion," said ASTMH CEO Karen Goraleski, who introduced the session. "We have to change the way business is being done." LMIC scientists need a mentoring approach tailored to their unique circumstances, which often include very divided gender roles, respect for hierarchy and seniority, and a colonial history that has left a legacy of authoritarian attitudes, said Dr. Willy Lescano, a co-author and professor at Peru's Cayetano Heredia University.

The publication was inspired by a series of "Mentoring the Mentor" workshops hosted in LMICs by faculty of Fogarty's Global Health Program for Fellows and Scholars. "We spend a tremendous amount of our time, resources and thought in training the next generation of global health leaders," said Glass, "so we really do have an investment in doing this better, in developing a mentoring roadmap for the future, to ensure the satisfaction and success of our trainees, and to keep them on the research track."

RESOURCES

<http://bit.ly/cugh2019>

Scientists urge cross-cutting stigma research

By Karin Zeitvogel

Stigma is a barrier to better health for vulnerable populations worldwide, despite many new interventions and scientific discoveries making strides against stigmatized conditions ranging from HIV/AIDS to depression. In a series of articles published in *BioMed Central (BMC)*, scientists are calling for stigma research to be broken out of silos that focus on a single condition or population and instead develop approaches that cut across illnesses, demographics and scientific disciplines. Effective solutions will require the expertise of researchers, practitioners, policymakers and community members, and transdisciplinary teams of scientists from public health, medicine, psychology, sociology, anthropology and other fields, working together, according to the authors of the “Collection on Stigma Research and Global Health.”

Making such changes to stigma research would help to advance understanding of the drivers, manifestations and outcomes of stigma, and lead to a unified response to it, the collection says. The impact of such a shift in stigma research focus would be felt worldwide, the researchers note, because, although the burden of stigma is heaviest in low- and middle-income countries (LMICs), it also occurs in developed countries, including the U.S.

“Breaking down disease silos and working across disciplines and scientist-community member boundaries would allow us to effectively address health-related stigma and enhance health equity globally,” said Fogarty advisory board member and grantee, Dr. Gretchen Birbeck, who edited the collection. “While medical advances put better health within reach of many, stigma deters care-seeking, which generates or perpetuates health inequities,” added Birbeck, a University of Rochester professor who spends most of her time providing clinical care and conducting research in Zambia.

Often ingrained in cultural norms and institutional policies, stigma is a powerful barrier to better health for all. Community, cultural and institutional attitudes to people with stigmatized conditions, along with internalized stigma that an individual might feel, and the prejudice, discrimination and stereotyping they face, must be addressed by research, according to the BMC collection, which was inspired by a 2017 workshop convened by Fogarty’s Center for Global Health Studies.

During three days of meetings, U.S. and LMIC experts



brainstormed how to reduce health-related stigma across disease areas, populations and settings, and refined the agenda for global stigma research. “The collection reflects the challenges, priorities and opportunities identified during the workshop—including dealing with the ethical challenges we face when conducting stigma research, developing strategies to engage stakeholders and community members, determining how to study stigma across conditions, and deciding which interventions are the most effective at reducing stigma,” said Birbeck. “Ultimately, the aim of the workshop and the collection of articles is to improve lives around the world by catalyzing new research approaches and collaborations that help to move the critical field of stigma research forward.”

The workshop also informed a stigma research program launched by Fogarty in 2018, aimed at improving HIV/AIDS prevention, treatment and care in LMICs. This effort builds on the Center’s previous stigma program, begun in 2002, that awarded \$17 million through 18 awards.

For stigma science to continue to advance, scientists must focus on developing, securing funding for, implementing and scaling up interventions, said Birbeck. These interventions must take into account new challenges. For example, as treatments for HIV improve, people with the virus are living longer and are at greater risk of becoming disabled or developing cancer, epilepsy or another noncommunicable disease that also carries a burden of stigma. “The next stage for stigma science has to be the development and implementation of scalable interventions that address the intersectionality of stigma,” said Birbeck. “Not only would this complement the understanding that scientists already have of the causes, manifestations and outcomes of stigma, but it could improve the health of millions worldwide.”

RESOURCE

<http://bit.ly/stigmaBIOMED>

PROFILE

Fogarty Fellow fights cholera in Bangladesh

By Karin Zeitvogel

Dr. Eric Nelson still vividly remembers the distraught father he met in Dhaka when he was a Fogarty Fellow in 2005-06. “Holding his daughter in his arms, he gripped my arm and implored, ‘Doctor, I have three children. Two died yesterday from cholera. Please save this child,’” Nelson recalled.

“In 2005, no one should have been dying of cholera,” Nelson said. “To me, this simple meeting expressed failings at so many levels and crystallized my purpose as a researcher and clinician.”

Nelson was paired with Dr. Ashraf Khan from Bangladesh for the year-long Fogarty fellowship. After training together at NIH, the two researched different topics in Bangladesh, with Nelson focusing on cholera transmission in mice.

Nelson’s days started before dawn, when he would pump water from a Dhaka pond into a barrel on the back of a flatbed rickshaw and then accompany the rickshaw to the hospital. Throughout the day, he would run between the “mouse-house,” the hospital and lab, always making time to study and analyze what was going on around him. “As a Fellow, I learned how to be a good observer and how to act on those observations, such as building tools that improve care in challenging environments,” Nelson said.

As often happens in science, one project or idea led to another. For weeks, as he watched the Bangladeshi lab technician who was studying samples under a darkfield microscope to see which ones contained cholera and which didn’t, Nelson mentally calculated that around half were autoclaved, meaning they were cholera-free. That discovery eventually led to published papers in which Nelson identified key factors that contribute to the understanding of cholera transmission. “One was starvation of *Vibrio cholerae* in nutrient-limited pond water, and the second was predation by little viruses called phages that infect and kill the *V. cholerae*,” Nelson explained. “About half the samples that were autoclaved had these viral particles.”

As he continued his research, Nelson found antibiotics in the majority of cholera patients who insisted they



Eric J. Nelson, M.D., Ph.D.

Fogarty Fellow: 2005-2006

Fellowship at: Int’l Center for Diarrheal Disease Research, Bangladesh

U.S. partners: Massachusetts General Hospital, Harvard Medical School, Tufts University School of Medicine

Research areas: Cholera transmission

hadn’t taken the drugs. What this said to Nelson was that scientists studying cholera transmission have to think not only about how phage particles affect cholera transmission but also about how antibiotics do. That finding, in turn, led Nelson to help create a tool, which seeks to change antibiotic prescription habits among doctors. Thirteen years after the fellowship, Nelson and Khan officially conducted their first project together in 2018, running a clinical trial to test whether this tool was more effective in paper form or as a mobile phone app at changing the behavior of doctors managing diarrheal disease in challenging environments. The trial, which looked at doctors’ decision-making processes when ordering fluid replacement and prescribing antibiotics, not only achieved some significant outcomes but also exemplified the “international collaboration that the NIH and Fogarty make possible, and the huge return on investment that Fogarty gets when it supports early-career researchers,” Nelson said.

Nelson was recruited during his Fogarty fellowship by then-director of icddr,b, Dr. David Sack, to collaborate on a method to rapidly train personnel to manage cholera and shigellosis outbreaks in resource-poor settings. Called Cholera Outbreak Training and Shigellosis (COTS), the method he helped to devise has since been used globally. An updated version is part of an immersive one-week outbreak response course Nelson leads in Haiti.

Nelson attributes the innovative projects he’s been involved with to the support he got from Fogarty and NIH as an early-career scientist. “Every aspect of my research has been positively impacted by Fogarty, in ways that are still declaring themselves,” he summarized. “Had Fogarty not put me at the bench for a year in Bangladesh, my portfolio would either be empty or filled by traditional bench science.”

Photo courtesy of Dr. Eric Nelson

JONATHAN SAMET, M.D., M.S.

Dr. Jonathan Samet has spent decades researching the health risks of inhaled pollutants, including secondhand smoke and particles in outdoor air such as those in vehicle exhaust. A longtime Fogarty and NIH grantee, he has conducted research around the world, including in China, Latin America and Africa. A pulmonary physician and epidemiologist, Samet was named dean of the Colorado School of Public Health in 2017. Previously, he was the director of the University of Southern California (USC) Institute for Global Health, and a professor and chair of the department of epidemiology at Johns Hopkins University's Bloomberg School of Public Health.



What impact has your tobacco research had?

The Fogarty-supported tobacco projects I've been involved with have seeded many important things. When I first went to China in 1995, for instance, there was one person doing tobacco control with a tiny budget. There were smoke-free zones in the airport and everyone would be smoking in them. That has changed, and work funded by Fogarty, the Bill & Melinda Gates Foundation and, more recently, the Bloomberg Initiative, has played a big role in bringing about those changes. Today, social norms around secondhand smoke have shifted, and an increasing number of Chinese cities, including Beijing and Shanghai, have restrictions on smoking in public places.

Fogarty support also helped to start the tobacco control program at the National Institute for Public Health of Mexico, which has become a regional leader in tobacco research and training. But there's still work to do because there's always a new issue in tobacco control. Who was talking about vaping three years ago? That crept up on us, and today, it's hugely popular among young people.

What is your current Fogarty project?

As part of the GEOHealth Hubs program, supported by Fogarty, the National Institute of Environmental Health Sciences (NIEHS), CDC and Canada's International Development Research Centre, we're putting in place monitors for airborne particles in the capital cities of Ethiopia, Kenya, Rwanda and Uganda, to try to understand what air pollution levels are.

Our focus is on capacity building and helping to develop scientists in East Africa who do environmental health work and want to advance policy through research. Fogarty's aim is to develop researchers who can generate the evidence needed to affect policy, and be willing to step in and talk with policymakers about what their evidence shows. We're giving them the tools to do that.

What has this research achieved so far?

In Kampala and Addis Ababa, we've completed a complicated assessment of child respiratory health in relation to air pollution. After identifying schools with a range of air pollution levels, we put an air quality monitor in each of 10 schools in both cities. We've collected data about respiratory health and measured lung function in about 1,000 children—100 from each school. We've also installed centrally located monitors in each city.

What challenges have you faced?

When we started this work five or six years ago, there were very limited monitoring data available in Africa, there were some people involved in air pollution research and control, but no real enforcement capacity. The sources of air pollution in major cities are themselves complicated—things like trash burning, factories spewing out smoke, diesel vehicles. A lot of the world's older diesel vehicles—the ones that blast out black smoke when they go down the street—have ended up in Africa. There are the problems that arise from using fuels that pollute indoors and outdoors, whether it's burning wood or biomass, charcoal or animal dung. While the problem is well recognized, what to do about it is a challenge.

Communication of risk is another challenge. With air pollution, people know it's bad when the levels are extraordinary. Your eyes burn, you can't see, there's no question that it's harming you. But as levels go down, people learn to live with pollution.

What can the US learn from this research?

Although the U.S. has made great progress in bringing down air pollution, it remains a global issue. The pollution generated in China, for example, circulates around the world. So when there's control as a result of research in China or Africa, there are benefits to Americans. Steps that are taken to reduce air pollution locally also are expected to have benefits in terms of greenhouse gas emissions.

Fogarty programs build capacity and spur NCD research

By Shana Potash

At the start of the century, as the threat of noncommunicable diseases (NCDs) in the developing world was emerging, Fogarty launched a series of programs to prepare local scientists to address the looming crisis, which claims 32 million lives each year. Between 2001 and 2017, Fogarty and its NIH partners invested nearly \$80 million to establish NCD research partnerships between U.S. and low- and middle-income countries (LMICs) institutions, and build related research training programs.

Under the Fogarty programs, more than 600 investigators have received long-term NCD research training and, along with their mentors, have addressed a variety of topics from

Noncommunicable diseases (NCDs) claim 32 million lives in developing countries each year. To help address the epidemic, Fogarty has supported NCD research and training programs since 2001.

cardiovascular disease to aging disorders, and mental health to environmental health, publishing nearly 1,000 articles. Researchers have examined NCDs across the lifespan; sought to understand how diseases interact with each other; and explored risk factors and other cross-cutting issues. In addition to research and training, the nearly 80 funded projects spurred the creation of curricula and degree programs, and new health practices and policies in countries throughout the developing world.

“Noncommunicable diseases are a complex problem, and research and training needs continue to evolve.”

– DR. ROGER I. GLASS, FOGARTY DIRECTOR

Three of Fogarty’s NCD programs were reviewed recently by the Center’s Division for International Science Policy, Planning and Evaluation to determine how the initiatives enhanced research collaborations and built sustainable research capacity in NCDs. The team examined grant and publications data, surveyed U.S. investigators and foreign collaborators, and interviewed Fogarty staff to determine the impact of the NCD programs. The findings have been posted online and include recommendations for future priorities.

The evaluation and the latest Fogarty funding opportunities for NCD research training programs come at a critical time. Heart disease, cancer, diabetes and other NCDs disproportionately affect people in poorer countries. More than three-quarters of all NCD deaths globally occur in LMICs, according to the WHO. Driven by an aging population, rapid urbanization, unhealthy lifestyles and other forces, the burden of these chronic diseases is expected to increase further unless proven interventions are implemented. Part of that challenge, as noted in a 2018 WHO report, is that many countries lack research capacity.

“Noncommunicable diseases are a complex problem, and research and training needs continue to evolve,” said Fogarty Director Dr. Roger I. Glass. “This evaluation shows the substantial progress we have made but also points out the tremendous need for continued support.”

Resources: <http://bit.ly/NCDResearchEval>

Photo by China Photos/Getty Images



Programs evolved to meet new challenges

Fogarty’s NCD research training programs began with 14 grants awarded through the International Clinical, Operational and Health Services Research and Training Award (ICOHRTA) in 2001. Several years later, after an update to the Global Burden of Disease Study highlighted the NCDs with the highest burden in developing countries, Fogarty launched another program focusing on cancer, lung disease, diabetes and cardiovascular disease, known as the Noncommunicable Chronic Diseases Research Training Program (NCoD). Those two programs were eventually consolidated into a new initiative when program officer Dr. Kathleen Michels recognized the need for a more holistic approach. The Chronic, Noncommunicable Diseases and Disorders Across the Lifespan Research Training Program (NCD-Lifespan), which began in fiscal year 2011 and continues today, emphasizes research across the aging continuum and aims to support the science needed to develop and implement evidence-based interventions.

While not part of the evaluation, Fogarty has also seeded the NCD researcher pipeline through other programs focused on brain disorders, trauma and injury, and tobacco cessation. In addition, the Center has broadened the disciplines included in its Fellows and Scholars program to include cardiology, diabetes, cancer, kidney disease and other NCD specialties.

NCD research training programs have impact

The three NCD programs combined provided substantial training for 660 scientists. Those opportunities, which lasted six months or more, included fellowships and certificate programs, master’s degrees, research and professional doctorate degrees, and postdoc positions. Nearly half of the long-term participants were in non-

NCD LIFESPAN PROGRAM OBJECTIVES:

- Strengthen research capacity of LMIC institutions so they can become national, regional and international centers of expertise in NCD research
- Support multidisciplinary research training across the research continuum
- Train a cadre of LMIC scientists in NCD research that will advance science and contribute to changes in clinical practice and public health policy
- Support training-related research that is directly relevant to the health priorities of the LMIC
- Integrate with existing NCD research and public health programs in the LMIC
- Strengthen core research support capabilities needed to manage grants at an LMIC institution.

NCD Lifespan program: 2011 to present

degree programs. While long-term activities were the core of the programs, most grants also offered workshops and other short-term opportunities to enhance skills in specific areas such as lab techniques, grant writing and research protocol development.

As signs of success, trainees and grantees were able to leverage their experiences to obtain funding for further research or research training projects. Half of the survey respondents reported having at least one trainee who

Top Categories of NCD Articles 2003-2015														
Note: Articles can focus on more than one research area. As such, a grant can be counted in more than one NCD category														
NCD category	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Grand Total
Mental Health/Behavioral Health		1	7	4	2	12	13	10	10	15	9	20	25	128
Risk Factors						4	6	8	11	17	25	27	22	120
Cardiovascular Diseases					2		2	1	6	14	15	16	35	91
Substance Abuse/Addiction			4	3	1	5	6	7	6	13	11	8	12	76
Cancers			1				1	10	8	11	13	7	11	62
Metabolic/Gastro/Digestive Kidney Disorders	1		2		3	1	2		1	6	11	10	18	55
HIV/STIs/Infectious Diseases			2	5	1	8	6	4	4	2	6	12	4	54
Trauma/Injury	1		2		3	3	5	4	6	7	6	5	10	52
Neurological/Developmental Disorders		1	3	3	3	2	2	2	3	6	9	5	5	44
Maternal/Child Health				1		2			1	2		2	9	17
Reproductive							2	2	1	2	3	1	1	10
Environmental/Occupational Health									2	1	2		2	7
Bone Diseases							1		1	2	1	1		6
Eye Diseases						1	2	1					1	5
Respiratory Diseases							1			2		1	1	5
Oral Health										1			1	2
Aging Disorders												1		1
Grand Total	2	2	21	16	15	38	47	49	60	101	111	116	157	735

Case studies demonstrate impact on NCD policy

The evaluation contains several cases studies representative of how findings from NCD research projects have influenced health policies and programs in developing countries.

The opioid Tramadol has become extremely popular in the Middle East, including Egypt where a dangerously toxic version is sold cheaply on the streets. A research training collaboration between Cairo University and the University of California, Los Angeles conducted a multi-country study of Tramadol addiction. Evidence from this study and others helped inform the WHO, and the governments of Egypt and the United Arab Emirates about the treatment needs of Tramadol users and promoted the approval of appropriate medications in the two countries. The research found that *grand mal* seizures occurred in 28.5 percent of study participants during prior withdrawal periods. Because of that, treatment centers in Egypt and the UAE have seizure prevention strategies as part of their withdrawal management plans.

Findings from a research project in Vietnam helped convince the Ministry of Health to make child mental health a priority, and the national health insurance started covering certain conditions. The research was the product of a collaboration between Vietnam National University and Vanderbilt University in the U.S. Investigators conducted Vietnam’s first nationally representative child mental health epidemiology survey. Among its findings, significant behavioral mental health problems were associated with an approximately 350 percent increase for risk of academic functional impairment.

This 5-year-old Vietnamese girl was a participant in a study that increased her country’s interest in child mental health services.

successfully obtained additional funding. Many former trainees now have positions in academia where, as the evaluation confirmed, their roles may range from “instructing the next generation of researchers, to leading clinical rounds at a university hospital, to conducting research in a lab.” Other alumni have assumed roles within the government or with not-for-profit organizations.

Building institutional capacity—creating a strong research environment—is another area where Fogarty’s NCD programs have made an impact. Grantees and collaborators from around the world provided dozens of examples of how their awards helped create courses or certificate and degree programs in topics that include cancer epidemiology, environmental sciences, nutrition, mental health, maternal and child health, and the ethics of clinical trials. Respondents also reported they had produced training materials and secured LMIC government commitments to increase staffing. The award, many said, enabled institutions to recruit or retain faculty interested in NCD research.

Outcomes include papers, protocols and products

Fogarty’s programs have added to the body of knowledge related to NCDs. The review found that 982 scientific publications citing an NCD grant were produced between 2003 and 2017. The three most common topics were mental health, risk factors such as obesity and nutrition, and cardiovascular diseases.

A bibliometric analysis examined, among other things, citation impact and collaborations. A key finding was that 69 percent of alumni grantees published at least three or more articles with an LMIC colleague after their NCD grant ended, signaling they had kept up the scientific relationship that was formed because of the program.

NCD Publications and Impact	
<i>Bibliometric indicator</i>	<i>Value</i>
Number of citations (times cited)	7,761
Mean citation count	13.13
Median citation count	7
<i>Bibliometric indicators for NCD articles supported by Fogarty programs, 2003-2015</i>	

“Overall the results of the bibliometric analysis and co-authorship network suggest that grantees and alumni are producing high quality scientific articles, continuing to foster collaborations between U.S. and foreign scientists, and have contributed to important empirical evidence to combat NCDs in LMICs,” as noted in the assessment.

Grantees and their collaborators have made other contributions to science. When asked what their project produced, 19 investigators—nearly half of those who responded—reported developing clinical protocols for use

Photo courtesy of Dr. Bahr Weiss



in LMICs. They include a clinical trial of a therapy targeting breast cancer and a protocol to manage sickle cell disease. Seventeen grantees reported building patient registries and databases; 11 created software and analytic tools; and four produced devices or prototypes.

Challenges and unmet needs

While progress has been made, tackling NCDs will require many more well-qualified researchers and mentors, according to the evaluation. Grantees and collaborators who were surveyed named a range of research topics that still require attention. “Adding to this need, the diversity of NCDs that make up the epidemic adds complexity to the process of building capacity. For example, a country may have built a critical mass of researchers in cardiovascular disease, but there remains a lack of experts that can manage the growing diabetes, trauma/injury or hypertension issues in the country,” the review stated.

Many grantees pointed to implementation science research as an area for growth, given its value in developing health policy guidelines and determining how to adapt or scale up interventions. Funding was an issue, with many grantees noting that even though LMIC governments may recognize the benefit of NCD research, their national budgets are too strained to support it. Creating protected time for research was also identified as an ongoing challenge, given that faculty at LMIC institutions often have competing interests.

When asked about hurdles they faced in building capacity, some grantees said that five years of funding, which is typical for the research training grant mechanism (known as D43), was not long enough to effect change in some countries. The biggest obstacles within the research infrastructure at LMICs were related to grant management and accounting, and institutional review boards that were either lacking or slow to give approval.

Recommendations and next steps

Recognizing that LMICs are facing the dual burden of NCDs and infectious diseases, the evaluation recommended collaboration between those scientific communities and suggested that future iterations of the NCD program consider how to prioritize the nexus between NCDs and infectious diseases. Encouraging such comorbidity research, the review noted, will help build a highly skilled and nimble research workforce.

Priority also should be given to research topics that cut across diseases, including prevention and implementation science, common risk factors, developmental origins, maternal and child health, and stigma. An emphasis also should be placed on research areas that so far have been under-

represented in research training such as metabolic disorders, hearing issues and chronic kidney diseases. Additionally, investigators may want to consider requiring each trainee to write and submit a grant proposal, because the process and feedback could help them take a critical step toward becoming an independent investigator.

Some of the evaluation’s findings have been incorporated into the newest funding opportunity announcements, which have deadlines in November 2019 and 2020. In a further effort to build institutional capacity, renewal applications funded solely by Fogarty must come from the foreign site. The move away from U.S.-led projects is intended to bolster LMIC institutions’ capacity to secure their own funding. New applications are expected to propose collaborations with a single LMIC institution as the major partner, thereby concentrating resources and training opportunities at one institution so a strong foundation is built.

Fogarty has additional funding opportunities to help NCD training program alumni and other early-career researchers make the transition to independent investigator. The Emerging Global Leader Award gives junior faculty at LMIC institutions financial support and protected time for research. And the Global Non-communicable Diseases and Injury Across the Lifespan: Exploratory Research program gives LMIC investigators the opportunity to jumpstart research programs related to NCDs, trauma and injury.

“These programs can prime the NCD research pipeline in LMICs by giving younger scientists additional opportunities to develop their research skills,” said Fogarty’s Dr. Glass. “It’s our hope these experiences will propel them toward becoming the scientific leaders in their countries who will in turn prepare future generations of researchers.”

Strong NIH support for Fogarty’s NCD programs

The NCD research programs have enjoyed broad support across NIH. Over time, Fogarty has had a dozen partners: the National Cancer Institute (NCI), National Center for Complementary and Integrative Health (NCCIH), National Institute on Aging (NIA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institute on Drug Abuse (NIDA), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Environmental Health Sciences (NIEHS), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Nursing Research (NINR), and the Office of Dietary Supplements (ODS).

New energy for global health is blossoming across NIH



There's a new wave of enthusiasm for global health sweeping across NIH. In addition to the continuing strong support from NIH Director Dr. Francis S. Collins, I'm pleased to have three new institute directors on campus who share our passion to build research capacity and fund studies to improve the health of the world's least fortunate. I was delighted to be joined in Kenya recently by

the relatively new directors of the institutes concerned with mental and child health research. There, they were able to see firsthand the impact their programs are having on the ground.

A visit to an innovative project in rural, western Kenya particularly impressed National Institute of Mental Health (NIMH) Director Dr. Josh Gordon. By enhancing irrigation and improving productivity of farmers living with HIV, researchers found it's more likely the farmers will adhere to their antiviral medication regimens and keep their clinic appointments. A few hours' drive away in Eldoret, Kenyan and U.S. researchers are studying how to keep adolescents with HIV on treatment using peer advisors and group therapy. They're also investigating how to treat depression and trauma to improve control of HIV infection, and alleviate mental health symptoms. I encourage you to read Dr. Gordon's full blog post about his travels, which he sums up with this observation, "Through cutting-edge research around the world, global efforts yield truly global impacts."

My colleague Dr. Diana Bianchi, director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), said it was "an unforgettable experience." Her visit included time at a busy public hospital in Nairobi, as well as rural sites in western Kenya. She reported being very impressed by the fact that post-partum mothers are housed and fed in the hospital for weeks and months after delivery of a premature baby, and are incorporated into the daily nursery routine by providing expressed breast milk and changing their babies' diapers. She was also struck at how clinical and implementation research is embedded in the overall culture and operations at Moi University, even more so than in many American academic medical centers.

She reported being moved by her interactions with children and families who are living with HIV/AIDS. She also said she was inspired by many of the women working to reduce HIV infections among adolescent girls and young women through the program called DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women). Administered by the President's Emergency Plan for AIDS Relief (PEPFAR), the DREAMS partnership includes the Bill & Melinda Gates Foundation and other private organizations.

Overall, the trip was a powerful demonstration of the impact NIMH and NICHD investments have made in advancing global health capacity and research, with a reminder that real people's lives depend on this vital work.

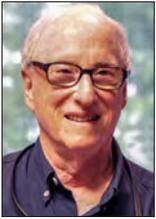
Back home in Bethesda, I was pleased to have Dr. Gordon and the new National Institute of Biomedical Imaging and Bioengineering (NIBIB) Director Dr. Bruce Tromberg join me for a discussion with Fogarty's advisory board. Both gave us valuable insights into how we might spur innovation in global health and build LMIC capacity in bioengineering and other related fields.

Arriving at NIH from the University of California, Irvine, Dr. Tromberg said many engineering schools now have improving human health as their top goal. Engineering is even being combined with medicine as a new discipline. For instance, his predecessor, Dr. Roderic Pettigrew, is now building the first such fully integrated national program at Texas A&M University. I was also excited to hear that Dr. Tromberg is a proponent of engineering capacity building, having led a two-week workshop in Côte d'Ivoire to teach entrepreneurship and innovation to African scientists. Indeed, he said the experience changed his life. Now that sensors and other components are inexpensive and more easily accessible in LMICs, technologies for health can be adapted to suit local needs, he said. Portable tools can be developed to reduce barriers to care, improve access and democratize human health.

With this wonderful energy and enthusiasm from my new colleagues, I'm more optimistic than ever that by working collaboratively across NIH, we can speed advances to improve the health of all people.

RESOURCES

<http://bit.ly/NIHglobalhealth>



Bridbord, Holmes lauded as global health leaders

Drs. Ken Bridbord and King Holmes are co-recipients of the Consortium of Universities for Global Health 2019 Distinguished Leadership Award, the organization's highest honor. As longtime director of Fogarty's extramural programs, Bridbord created initiatives that provided research training for 6,000 scientists in low- and middle-income countries. Now retired, Bridbord is a Fogarty senior scientist emeritus.



Holmes, a Fogarty advisory board member and grantee, is professor and founding director of the Department of Global Health (DGH) at the University of Washington. In his more than 50 years of global health research and training, Holmes has collaborated with over 170 trainees and mentees, and has produced some 800 publications.



NIH cancer director Sharpless moves to FDA

Dr. Norman E. "Ned" Sharpless, director of NIH's National Cancer Institute since 2017, has been tapped to become acting FDA commissioner in April. Previously, Sharpless directed the Lineberger Comprehensive Cancer Center at the University of North Carolina. Sharpless treated leukemia patients and conducted research on cancer and aging.



Swaminathan named WHO's chief scientist

Dr. Soumya Swaminathan, a former Fogarty trainee, has been appointed to a newly created WHO position, Chief Scientist, charged with strengthening the organization's core scientific work. She had been deputy director-general for programs. A pediatrician and clinical researcher, Swaminathan was director general of the Indian Council of Medical Research before joining WHO.



Richards-Kortum added to Inventors Hall of Fame

Former Fogarty advisory board member Dr. Rebecca Richards-Kortum is among the 2019 inductees into the National Inventors Hall of Fame. A professor of bioengineering and director of the Rice 360° Institute for Global Health at Rice University, Richards-Kortum develops medical devices for use in low-resource settings.



Oral cholera vaccine developer Clemens honored

Dr. John D. Clemens, executive director of Fogarty grantee institution the International Centre for Diarrhoeal Disease Research, Bangladesh, is a co-recipient of Thailand's Prince Mahidol Award. Clemens and longtime collaborator Dr. Jan R. Holmgren of Sweden were recognized for developing an oral cholera vaccine that has protected millions of people.



Abdool Karim awarded by Kuwait for HIV research

Longtime Fogarty grantee Dr. Salim Abdool Karim shares Kuwait's 2018 Al-Sumait Prize for Health, a Kuwaiti award honoring people and organizations that address challenges in Africa. Abdool Karim, director of the Centre for the AIDS Programme of Research in South Africa, was recognized for his contributions to HIV/AIDS treatment and prevention.

NIH releases plan for women's health

NIH has developed a strategic plan to advance science to improve women's health with a framework to integrate sex and/or gender influences into research, provide disease prevention and treatment tailored to women's individual needs, and ensure women in biomedical careers reach their potential. Full report: <http://bit.ly/NIHwomen>

Supplement improves infant outcomes

For women in resource-poor settings, taking a certain daily nutritional supplement before conception or in early pregnancy may improve growth of the fetus, according to an NIH-funded study. The supplement is fortified with vitamins and minerals, and provides protein and fat. Journal article: <http://bit.ly/NutritionForMoms>

WHO publishes malaria control guidelines

For the first time, WHO has published a comprehensive set of evidence-based guidelines for malaria vector control. The resource consolidates more than 20 sets of WHO recommendations and will be updated on an ongoing basis. Full report: http://bit.ly/WHO_malaria

WHO posts R&D spending by country

New analysis from the WHO Global Observatory on Health R&D shows that only 41% of 75 countries analyzed met their health R&D spending targets using the most recent data available. Some low-income countries allocated a higher percentage of their GDP on health than high-income countries. Website: http://bit.ly/WHO_benchmark

NIH, FDA host treatment collaboration tool

To encourage information sharing of treatment practices for neglected diseases and emerging or drug-resistant infections, the NIH and FDA have built a tool called Collaborative Use Repurposing Engine (CURE). The aim is to capture and centralize the global experience of new uses of approved medical products—both positive and negative. Website: <https://cure.ncats.io>

PAHO studies youth health in Americas

Half of all deaths of young people in the Americas are due to preventable causes such as homicide, traffic fatalities and suicide, according to a new report by the Pan American Health Organization (PAHO). The study examines various health aspects of the region's 237 million young people and provides recommendations for improvement. Full report: http://bit.ly/PAHO_youth

Funding Opportunity Announcement	Details	Deadline
Global Infectious Disease (GID) Research Training Program (D71) (D43) Clinical Trial Optional	http://bit.ly/IDtraining	July 25, 2019
Global Brain and Nervous System Disorders Research Across the Lifespan (R21) Clinical Trial Optional (R01) Clinical Trial Optional	http://bit.ly/NIHGlobalBrain	Nov 7, 2019
Emerging Global Leader Award (K43) Independent Clinical Trial Required (K43) Independent Clinical Trial Not Allowed	http://bit.ly/NIHGlobalLeader	Nov 7, 2019
Noncommunicable Diseases and Disorders Research Training Programs in LMICs (D43) Clinical Trial Optional	http://bit.ly/NCDtrain	Nov 12, 2019
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Poor quality drugs pose “health emergency,” study says

Photos by Nico Rametier/FDA



Poor quality and fake medicines (top photo) are an urgent threat.

More than a quarter of a million children die each year due to poor quality and fake medicines, according to a study published in March in the *American Journal of Tropical Medicine and Hygiene*. The assessment by a team of experts from the public and private sector concludes that a “pandemic” of falsified and substandard drugs for treating malaria, pneumonia, hypertension and other diseases has become a “public health emergency,” especially in low- and middle-income countries. It cites evidence that up to 155,000 children die every year due to fake malaria drugs alone, and that a similar

number die from low-quality or counterfeit antimicrobial drugs prescribed to treat pneumonia. Other common fake drugs include prescription opioids and medicines for heart disease, erectile dysfunction and cancer.

Fogarty senior scientist emeritus Dr. Joel Breman, a co-author on the study, said that fake drugs are often peddled over the internet and sometimes linked to organized crime and terrorist groups. Poor quality drugs cost the global economy an estimated \$200 billion per year, Breman said, and contribute to the growing problem of antimicrobial resistance.

RESOURCE

Journal article: http://bit.ly/ASTMH_fakedrugs

Hepatitis C in Pregnant Women and Their Children

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Professor of Pediatrics
Sidney Kimmel Medical College at Thomas Jefferson University

ABSTRACT

Hepatitis C virus (HCV) infection presents unique challenges in the setting of pregnancy. HCV can contribute to pregnancy-related morbidity and pregnancy can influence the course of HCV infection. There is a significant risk of transmission to the fetus and newborn infant. Identification of HCV infection in women of childbearing potential and those who are currently pregnant offers important opportunities for the woman and for past, present and future children.

INTRODUCTION

Infection with hepatitis C virus (HCV) is common in women of childbearing potential, having doubled between 2006 and 2014. This increase is due in large part to the opioid epidemic and injection drug use (IDU). Currently, 1-2.5% of women in the peak childbearing age range have HCV, with wide geographical variation in the United States.¹ The State of Delaware has recently sought to identify infected pregnant women through use of the hepatitis C registry. Through 2014, about 29,000 infected women gave birth each year in the U.S., and that number is expected to increase.² Currently, it is estimated that 132,000 U.S. children and adolescents have HCV. In developed countries with hepatitis B virus (HBV) immunization programs, HCV has become the most common cause of chronic hepatitis in children.³

Caring for women of childbearing potential who are infected with HCV has challenges. They often are young, un- or under-insured, and currently or formerly addicted to opioids and other substances. Paradoxically, independent of access and linkage to care, this group is often considered “easy to treat,” in that most have been infected less than five years, have minimal hepatic fibrosis, and have fewer co-morbidities. Pregnancy is a time of potential opportunity for engaging women in HCV care, as they are usually seeking prenatal services and may be more likely to have insurance coverage.

Pregnancy has an effect on the course of HCV and vice versa. HCV RNA levels rise during the first and third trimesters and transaminase levels tend to fall at those times. Women with HCV also have higher rates of intrahepatic cholestasis of pregnancy. Currently, antiviral therapy during pregnancy is not recommended since the safety and efficacy of direct-acting antivirals (DAAs) in pregnancy have not been established (ribavirin is contraindicated due to risk of teratogenicity). There is an ongoing phase 1 study of HCV DAA treatment of pregnant women.⁴ It is evaluating the pharmacokinetics and safety of the fixed dose combination of ledipasvir/sofosbuvir and is expected to be completed by September 2019. Women who are on antiviral treatment and become pregnant should discuss the potential risks and benefits of continuing therapy with their physicians. Pregnant women with cirrhosis should be counselled about the risks of adverse maternal and fetal outcomes and should be co-managed with a maternal-fetal medicine specialist.

The risk of a pregnant woman transmitting HCV to her fetus or infant is 5.8% and with human immunodeficiency virus (HIV) co-infection, that risk almost doubles to 10.8%.⁵ Transmission may occur during pregnancy, as a result of transplacental passage of the virus, or during vaginal or cesarean delivery. Vertical transmission is generally confined to women who have detectable HCV RNA during pregnancy, but has been reported in women with undetectable HCV RNA as viremia can be intermittent. There is an increased risk of HCV transmission with higher viral loads. When HCV is acquired during pregnancy, the risk of transmission is higher due to higher RNA levels. Obstetric procedures and prolonged rupture of membranes (PROM) are additional risk factors for transmission. Mother-to-child-transmission (MTCT) is not associated with HCV genotype, mode of delivery or breastfeeding. However, women should be advised to abstain from breastfeeding if their nipples are cracked or bleeding.

The main strategy for reducing the risk of vertical HCV transmission is to identify and treat HCV-infected women prior to conception (Figure 1). Unfortunately, risk-based screening probably misses many HCV infected patients, including pregnant women.⁶ This was also the case in the early days of HBV screening, which is now universally recommended. Guidelines jointly published by the American Association for the Study of Liver Diseases and Infectious Diseases Society of American recommend screening for HCV infection during pregnancy.⁷ There are many advantages to this approach. Knowledge of HCV status allows for education and appropriate referrals for the pregnant woman. Obstetricians would be able to avoid performing invasive procedures which pose a risk for transmission to the fetus. The infant will be identified as perinatally exposed to HCV so that testing can be performed at the appropriate time. Moreover, children previously born to an HCV-infected woman can be tested for HCV. Women can be counselled about the availability and benefits of antiviral treatment at the conclusion of the current pregnancy, with obvious health benefits to the mother, but also to prevent perinatal transmission during future pregnancies. Finally, women who are identified as infected could facilitate the evaluation and treatment of their sexual and IDU partners and thereby increase the public health benefit of screening. A recent study concluded that universal screening for HCV, including for pregnant women and women of childbearing age, would be cost effective.⁸

Differing from the above, the American College of Obstetrics and Gynecology (ACOG) and the Society for Maternal-Fetal Medicine recommend targeted HCV screening during pregnancy with a focus on high risk groups including women who have used illicit drugs, women on long-term hemodialysis, women with percutaneous/parenteral exposures in an unregulated setting (e.g. unlicensed tattoo parlors), recipients of transfusion or organ transplantations before 1992, recipients of blood products from a donor who later tested positive for HCV, women with a history of incarceration, women being evaluated for sexually transmitted infections (STIs), and those with chronic liver disease.⁹ ACOG recommends testing high risk women for HCV at their first prenatal visit and later in pregnancy if there are new or persistent risk factors. Other recommendations include that HCV-infected women be screened for other STIs and should also be counselled to refrain from alcohol use. ACOG further recommends that women undergoing invasive prenatal diagnostic testing (e.g. amniocentesis) be counselled that data on vertical transmission, while limited, are reassuring. Obstetrical providers should avoid internal fetal monitoring and episiotomy, as well as PROM. Cesarean delivery has not been shown to reduce vertical transmission and ACOG recommends against this solely for the indication of HCV infection. Finally, providers should not discourage breastfeeding because of maternal HCV infection.

There is growing enthusiasm and support for universal screening. Kentucky, a state with a high incidence of HCV in the general population, has enacted legislation mandating HCV screening of all pregnant women.

Infants who acquire HCV perinatally are completely asymptomatic. Their liver function tests are usually normal and 20% spontaneously clear their HCV, like the adult population. The 80% who are chronically infected will eventually develop liver disease, usually taking years to decades, with the concomitant risk of hepatocellular carcinoma. Co-morbidities like HIV or HBV co-infection, alcohol dependence, and obesity can hasten the progression of liver disease.

Unfortunately, multiple studies demonstrate low rates of testing of perinatally HCV-exposed infants. In Philadelphia, only 16% of infants with perinatal HCV exposure underwent HCV testing.¹⁰ A report from Pittsburgh indicated that 30% of infants with perinatal HCV exposure were ever tested for HCV.¹¹ A recently published study from Boston demonstrated the enormity of the problem in women with opioid use, but also presented more favorable data in terms of infant testing.¹² Of 744 women with opioid use disorder who were tested for HCV infection, 510 (69%) were seropositive. Of the 404 infants born to seropositive women, 273 (78%) were tested at least once for HCV and 12 were diagnosed with chronic HCV infection. In Delaware, there are no current data concerning follow up of HCV-exposed infants.

Pediatric follow up of these infants is of paramount importance. Frequently, pediatric providers will see these infants due to neonatal abstinence syndrome (NAS). Women who deliver babies with NAS, if not already tested, should have their HCV status assessed. Newborns can be tested for antibody to HCV as well, but providers should realize that transplacentally transferred maternal IgG will cause a positive result until 18 months of age.

Current recommendations for the diagnosis of HCV infection in childhood are:

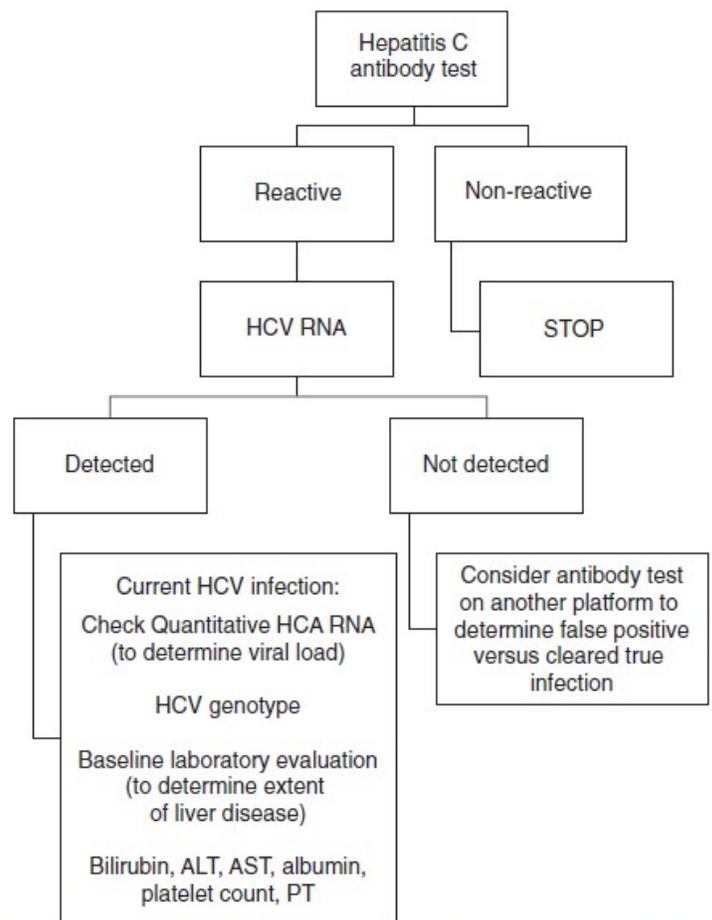
- Anti-HCV antibody at ≥ 18 months of age is the gold standard.
- HCV RNA between 1 and 2 months of age can be used if the 18 month antibody testing cannot be assured.
- Infants with negative HCV RNA results should still have the 18 month antibody test if possible.¹³

Treatment recommendations for children are limited. Ledipasvir/sofosbuvir and ribavirin/sofosbuvir are recommended for certain adolescents with HCV, but there is no current treatment available for children under 12 years of age. Other pediatric recommendations for DAAs are expected soon.

CONCLUSION

Women of childbearing potential and women who are pregnant comprise a very important population of HCV-infected persons. Identification of these women is critical, in order to link them to care and provide appropriate evaluation and treatment. Opportunities exist to improve HCV screening rates of these women and to test their children. Antiviral treatment during pregnancy and in early childhood are areas in urgent need of research.

Figure 1. Algorithm for diagnostic testing for HCV.



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DELAWARE
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DPHA
DELAWARE PUBLIC HEALTH ASSOCIATION

The *Delaware Journal of Public Health* is posting an open call for submissions. The DJPH publishes scientific articles, case reports, opinion pieces, editorials, and other articles relating to the public health sector.

Authors should refer to the Submission Information page:

<http://bit.ly/DJPHsubmission>

Submissions should be sent to ehealy@delamed.org



Inflatable lungs are traveling to Delaware's high-traffic events, hospitals, and schools to promote lung cancer screenings. Governor John Carney, center, stands with DPH Director Dr. Karyl Rattay, left, and Delaware Cancer Consortium Chair Kathleen Connolly. Photo by Donna Sharp.

Governor Carney signs Tobacco 21 legislation and promotes lung cancer screenings for high risk Delawareans

On April 17, Governor John Carney signed Senate Bill 25 that raises the legal age for sales of tobacco and vape products from 18 to 21. The law is effective 90 days from enactment.

A day earlier at the Delaware Cancer Consortium (DCC) Retreat, Governor Carney proclaimed April Lung Cancer Screening Awareness Month. The DCC recommends that eligible Delawareans – including those between the ages of 55 and 80 who have a smoking history equivalent to a pack a day for 30 years or longer, and who currently smoke or have quit within the past 15 years – receive a low-dose computed tomography (CT) scan. Low-dose CT scans can catch lung cancer early, when it is most treatable. The screenings are covered by insurance or by the Screening for Life program within the Division of Public Health (DPH). Determine eligibility at [HealthyDelaware.org/lung](https://www.healthylivingdelaware.org/lung).

Lung cancer is the most frequently diagnosed cancer in Delaware, with 3,965 cases (14 percent of all newly diagnosed cancer cases) and 2,839 deaths (30 percent of all cancer deaths) from 2010 to 2014. In the same period, Delaware (70.9 people per 100,000) had a statistically significantly higher lung cancer incidence rate compared to the U.S. (55.8 people per 100,000). Tobacco use is the number one risk factor for lung cancer.

To schedule a low-dose CT scan, visit www.healthylivingdelaware.org and call 302-744-1020 to speak to a nurse navigator.

Be prepared for tornadoes

Recent tornadic activity reported in Sussex County remind us to be prepared for emergencies. Advance preparations can reduce storm anxiety.

The National Weather Service issues these alerts:

- **Tornado Watch:** Weather conditions could form tornadoes or severe storms. Know your safe place and be prepared to act quickly.

- **Tornado Warning:** A tornado was spotted or weather radar indicated that it is occurring or will occur soon. There is imminent danger to life and property; immediately take shelter in a safe place.

Designate your household's safe room, such as a basement, storm cellar, or an interior room on the lowest floor with no windows. Clear the safe room of clutter. Store sleeping bags, blankets, pillows, and sports or motorcycle helmets there to protect heads from flying debris.

Best sheltering options recommended by the Federal Emergency Management Agency (FEMA) are in an above or below ground Tornado Storm Shelter (NSSA/ICC 500 compliant) or a specifically designed FEMA Safe Room. Less optimal shelter choices are gymnasiums and auditoriums, manufactured housing, mobile homes, and vehicles.

When driving, get off the road and seek shelter in a safe structure or lay in a ditch or ravine. Do not seek shelter under a tree or an overpass.

Routinely check weather forecasts. Heed dark, greenish skies; hail without rain; funnel or wall clouds; and a loud roar.

Delawareans should have multiple ways to receive weather alerts and warnings, such as television, free phone apps, websites, and social media. A NOAA Weather Radio can alert sleeping families and is useful during power outages.

Set cell phone settings to receive free government text messages known as Wireless Emergency Alerts. They warn of severe weather and other emergencies, including Presidential Messages during national emergencies. When asleep, keep cell phones nearby to hear emergency alerts.

For more information, visit <https://www.weather.gov/>.



Delaware and Hepatitis C: Is it time for universal screening?

Navin Vij, M.D., M.S.H.P.

While training to become a physician caring for both children and adults, I relied upon evidence-based recommendations to guide nearly every decision I made: when should a pediatric patient be tested for lead exposure? How often should I screen for hypertension in an adolescent? In which patients should I screen for hepatitis C virus infection (HCV)? During this same time, I learned that I had been unknowingly living with HCV for nearly 26 years. My own experience led me to question this last guideline as I realized how many patients might fall through the gaps of current HCV screening recommendations.¹

I was in my first year of medical residency training when I was diagnosed with HCV. After an accidental needle stick while performing a procedure, I went to employee health services, only to learn days later that I had HCV – and that it did not originate from that needle stick. My life stopped. In a dimly lit hallway near the end of a long night shift, I stood in silence, feeling numb and scared of what lay ahead. In the weeks and months that followed, I met with a hepatologist, made decisions about treatment that would eventually cure me, and reflected on my medical history to learn how I contracted the infection.

In the summer of 1983, I was born a 27-week premature baby. Over several months in the neonatal intensive care unit (NICU), I had received – among other things – occasional blood transfusions. It was likely through those transfusions (which, until the early 1990s, were not routinely screened for HCV and HIV), that I contracted the virus.

HCV is an infectious disease of the liver. Transmitted through direct contact with blood, it is a silent disease, with most patients living asymptotically for years. Nearly 50% of patients living with HCV are unaware of their status and less than 10% of patients with known HCV have received successful HCV treatment.² The consequences are enormous. According to the Centers for Disease Control and Prevention (CDC), HCV now kills more people in the United States than 60 other infectious diseases combined.³ Economically, chronic HCV costs the U.S. healthcare system at least \$10 billion annually.⁴ And until recently, HCV was the leading cause of liver transplantations.⁵

I was ironically lucky to experience that needle stick. Without it, I could have lived for additional years or decades as the virus silently damaged my liver, potentially causing cirrhosis, hepatocellular carcinoma, and even liver failure.

Across exam rooms and hospital beds throughout Delaware and the country, young adults and babies may face a similar situation, but for an entirely different reason. Although blood is now routinely screened for HCV and other communicable diseases, the epidemic of opioid abuse has placed a new generation at risk for the disease. After over a decade's long decline both locally and nationally, the incidence of new cases of acute HCV began to dramatically increase after 2010, largely due to the explosion of intravenous drug use among young adults.⁶

In Delaware alone, nearly 2,600 HCV cases were reported in 2016, which is likely a significant underestimate. CDC research demonstrates nearly 13 unreported cases for every reported case of HCV annually.^{6,7} Delaware has a higher estimated prevalence of HCV than any of its neighboring states, placing it among the top ten nationally.⁸ Over half of these new cases are in Delawareans under the age of 40.⁷

Currently there are no national or state-based recommendations that endorse universal HCV screening for all adults. National guidelines from the CDC and United States Preventative Services Task Force (USPSTF) call for testing all patients born between 1945 and 1965 and others with identified risk factors for exposure.¹ Unfortunately, these guidelines result in a disjointed approach toward HCV screening, leaving providers to make decisions on a case-by-case basis. This ultimately contributes to delays in HCV diagnosis and increased potential for HCV transmission. Furthermore, with HCV increasingly affecting women of childbearing age, newborns are entering the world already infected and at risk for the long-term consequences of the virus, all because their mothers went undiagnosed during pregnancy.

Critics of universal HCV screening argue that it casts too wide a net or that the financial burden of universal screening outweighs the benefits. Recent studies provide evidence to the contrary, showing that universal 1-time screening either for an all adult cohort or as prenatal screening is both cost effective and improves health outcomes for women diagnosed with HCV infection.⁹⁻¹¹ With new pan-genotypic direct-acting antiviral (DAA) therapy with treatment courses as short as 8 to 12 weeks and cure rates upwards of 95%, including in children, guidelines regarding HCV testing need to change.

Delaware can lead the way by becoming the first state to endorse or mandate universal HCV screening. With recent changes in 2018 to its state Medicaid restrictions on HCV insurance coverage, Delaware has expanded patient access to HCV treatment. Furthermore, recent precedent exists within the state to conduct universal screening in adults – and in doing so, utilize primary care as an option for patients to concurrently seek HCV treatment.¹²

As I think back to my own journey with HCV and the patients I see every day affected by the opioid and heroin epidemics, I think of those 26 years that passed while I lived with this silent killer. I know I was lucky – lucky to have the needle stick, lucky to have access to curative treatment, and lucky to have the support of many friends, family, and physicians to help me through my experience. Others in this world should be just as lucky. Ask yourself – should another baby or young adult have to wait 26 years or an entire lifetime to know that they too can be cured? It is time for Delaware – and the country – to adopt universal screening for Hepatitis C.

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WHAT CAN YOU DO TO PREVENT OPIOID MISUSE?



TALK ABOUT IT.

Opioids can be addictive and dangerous. We all should have a conversation about preventing drug misuse and overdose.



BE SAFE.

Only take opioid medications as prescribed. Always store in a secure place. Dispose of unused medication properly.



UNDERSTAND PAIN.

Treatments other than opioids are effective in managing pain and may have less risk for harm. Talk with your healthcare provider about an individualized plan that is right for your pain.



KNOW ADDICTION.

Addiction is a chronic disease that changes the brain and alters decision-making. With the right treatment and supports, people do recover. There is hope.



BE PREPARED.

Many opioid overdose deaths occur at home. Having naloxone, an opioid overdose reversing drug, could mean saving a life. Know where to get it and how to use it.



For help, resources,
and information:

<https://www.hhs.gov/opioids/>

1-800-662-HELP (4357)



The Consequences of Medication Nonadherence are Stacking Up

125,000

PREMATURE DEATHS

in the U.S. each year result from NON-ADHERENCE



145 Million

Americans suffer from CHRONIC DISEASES



\$300

BILLION

In avoidable costs to the U.S. health care system ANNUALLY

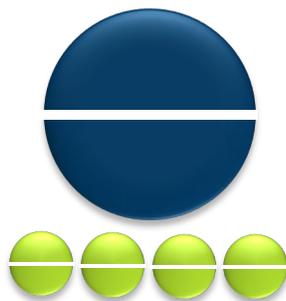
50%

of patients with chronic diseases DO NOT take medication as prescribed

APPROXIMATELY

1 IN 5

new prescriptions are NEVER FILLED in the U.S.



Sources:

<https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm>

<https://www.pillsy.com/articles/medication-adherence-stats>



Help your patients help themselves. Quality Insights can arm your practice with the strategies and resources to make an impact on medication adherence among your patients, especially those with chronic conditions, and improve their overall health.



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Help Your Patients Help Themselves

The Statistics Don't Lie

As you can see, the statistics surrounding medication non-adherence are frightening. Non-adherence is a complex and multidimensional health care problem that can lead to a huge amount of unnecessary physical and emotional suffering, financial loss, and premature deaths. Although it's incredibly important, there tends to be very little social support provided around this problem due to the personal nature of medications.

What Can Your Practice Do to Improve Medication Adherence?

Quality Insights, under a contract from the Delaware Division of Public Health, is leading a statewide initiative to prevent and control diabetes, heart disease, obesity and associated risk factors. Improving medication adherence among patients with these chronic conditions is one of the key focuses of this project. **We invite you to join us in this important work!**

Resources & Education

As a participant in this initiative, Delaware clinicians have access to a variety of practice and patient [tools & resources](#) to manage patient medication adherence at the point-of care, and most importantly, when the patients leave the medical office. Some examples of the resources we offer include a customizable office [Medication Adherence Protocol](#), a descriptive [list of FREE apps](#) to help patients better manage their medications, and the [Adherence Estimator](#) tool that can help you identify patients at risk for non-adherence. Your practice will also receive free jump drives containing the Adherence Estimator tool to share with your patients.

Contact Quality Insights

Quality Insights is here to support your practice's efforts to improve medication adherence among your patient population. Contact Quality Insights Practice Transformation Specialist [Ashley Biscardi](#) to sign-up or visit our [website](#) to learn more.



The healthcare improvement experts.

Statewide Antibiotic Stewardship: An eBrightHealth Choosing Wisely Initiative

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Abstract

Objective: To implement a collaborative statewide antibiotic stewardship initiative in both the ambulatory and inpatient settings.

Methods: Five participating Delaware health systems each convened internal team(s) to translate the vision set forth by the eBrightHealth LLC Choosing Wisely Work Group into clinical action through process improvement efforts at their institutions. The teams focused on implementing antibiotic time-outs, and on improving antibiotic prescribing for upper respiratory infections in ambulatory settings. The learning network utilized an “all teach, all learn” methodology via monthly conference calls and quarterly face-to-face meetings.

Results: All inpatient teams implemented antibiotic time-outs for at least 1 unit. Other interventions included commitment posters; submitting antibiotic utilization data nationally; provider/patient surveys; local stewardship champions; and provider prescribing data feedback. Barriers to implementation included competing priorities, lack of reliable utilization data, and suboptimal provider engagement. Overall antibiotic utilization decreased by 9%, compared to the pre-intervention period.

Conclusions: This initiative has demonstrated the value of multidisciplinary teams, from varying healthcare systems, coming together to work on a single project. While each team’s interventions and specific goals differed slightly, all teams implemented new initiatives to promote appropriate use of antibiotics.

Policy Implications: Antibiotic stewardship is a national priority. Acute care hospitals are required to have antibiotic stewardship programs; similar programs are proposed for ambulatory settings.

INTRODUCTION

In 2016, five Delaware hospital systems (Bayhealth, Beebe Healthcare, Christiana Care Health System, Nanticoke Health Services and Nemours/Alfred I. duPont Hospital for Children) developed a statewide strategic alliance named eBrightHealth LLC. The goals of eBrightHealth LLC are to increase access to health care services, to improve the quality and affordability of care, and to offer all Delawareans an even brighter health care future through collaboration and innovation. The alliance builds on the foundation and strengths of the statewide eBrightHealth Accountable Care Organization (ACO), which includes approximately 300 primary care and 900 specialist providers who are working together to deliver high quality care at a lower cost for traditional Medicare beneficiaries across the region. The network includes both employed and affiliated providers. The partners included in eBrightHealth LLC differ slightly from those of eBrightHealth ACO (*Figure 1*).

One of the early innovations eBrightHealth LLC (hereafter referred to as eBH) chose to focus on was to implement recommendations from the national Choosing Wisely campaign to avoid wasteful or unnecessary medical tests, treatments and

procedures, thus promoting better care and higher efficiencies. More than 80 professional societies and other partners have submitted lists with recommendations for tests and procedures “whose necessity should be questioned or discussed.”¹ The eBH Choosing Wisely Work Group decided to pursue antibiotic stewardship as its initial focus, given that antibiotic recommendations represented more than 30 items on the Choosing Wisely lists, across multiple primary care and specialty societies. Concurrently, the Work Group learned that others in the state were focusing on this topic and invited them to be collaborative partners in this state-wide effort. They included Quality Insights, the Quality Innovation Network-Quality Improvement Organization (QIN-QIO) for Delaware, New Jersey, Pennsylvania, West Virginia and Louisiana, who had been awarded a contract from the Centers for Medicare and Medicaid Services (CMS) to work on improving antibiotic stewardship best practices among all providers within the represented states; and the Delaware Division of Public Health (DPH), who had received grant funding to support antibiotic stewardship efforts in the state.

Antibiotic stewardship refers to programs, policies and actions designed to optimize treatment of infections while reducing

adverse events associated with antibiotic use.² More than half of all hospitalized patients receive at least one antibiotic during their stay,³ and enough antibiotics are dispensed from outpatient pharmacies in the U.S. each year for five out of every six people to receive one antibiotic prescription.⁴⁻⁶ While antibiotics have transformed the practice of medicine, approximately 30-50% of all antibiotics prescribed in the U.S. are either unnecessary or inappropriate.⁷ Based on available data, Delaware appears to have higher than average antibiotic prescribing practices. In 2016, 929 antibiotic prescriptions per 1000 population were dispensed by community and mail-order pharmacies in Delaware, above the national average of 836 per 1000 population.⁵ These represent prescriptions filled at the time of hospital discharge, as well as those prescribed in the context of outpatient visits or via telephone consultation. The Centers for Disease Control and Prevention (CDC) has published what they consider to be Core Elements of hospital antibiotic stewardship programs⁸ (*Table 1*); similar documents have also been published for long term care settings¹⁰ and ambulatory care.⁹ As of 2016, 75% of Delaware hospitals reported meeting all seven hospital core elements, greater than the national average of 64%.¹¹ However, the goal is to achieve 100% by 2020. Most hospital antibiotic stewardship programs, including all of those in Delaware prior to the eBH Choosing Wisely initiative, have focused primarily on inpatient utilization; however, more than 60% of all antibiotic expenditures in humans in the U.S. are related to care received in outpatient settings.¹²

Based upon this information, the Work Group's initial focus was to implement a collaborative statewide antibiotic stewardship initiative in both inpatient and ambulatory settings. To facilitate this effort, the Work Group decided to initially narrow the focus to treatment of upper respiratory infections (URI) in the ambulatory setting, and the implementation of an "antibiotic time-out" after 48-72 hours of antibiotics. The intention of an antibiotic time-out is to encourage data review, enhance documentation, and provide clarity amongst multiple caregivers. Improved documentation and clarity allows for increased knowledge about the patient and disease state, facilitating antibiotic de-escalation or discontinuation if appropriate, efficient and smooth transitions in care, and appropriate discharge planning. Upper respiratory conditions were chosen as the initial target because they are commonly caused by viruses (including the common cold, viral sore throats, and bronchitis) and thus do not require antibiotics, or do so only under specific circumstances (such as some sinus and ear infections).⁴

METHODS

THE COLLABORATIVE STATEWIDE ANTIBIOTIC LEARNING NETWORK

The eBH Choosing Wisely Work Group developed the infrastructure to lead and support a collaborative statewide learning network. They brought together both national and other statewide organizations with an interest in promoting antibiotic stewardship (e.g., American Board of Internal Medicine [ABIM] Foundation, the Delaware Health Information Network [DHIN], DPH, CareLink-CareNow, and Quality Insights); thereby enabling the coordination of efforts and messages to both the provider community and the broader communities in Delaware. In addition to the eBH organizations, other Delaware health systems

that are not members of eBH were invited to participate in this learning network.

Each participating health system was asked to convene an internal team to translate the vision set forth by the Work Group into clinical action through process improvement efforts at their institutions. The benefit of participation for each team was the collaborative environment that enabled learning from one another, and teaching one another ("all teach, all learn"). This was accomplished primarily through monthly facilitated teleconference calls with all institutional team leads. Additionally, there were quarterly face-to-face meetings for all team members. These meetings were structured with a plenary speaker and breakout sessions where the attendees were taught process improvement skills, and had facilitated discussions on implementation tactics that included direct application of the day's learning to their individual projects. The project initially kicked off with a face-to-face meeting in August 2017, and concluded in August 2018; however, each institution has continued their internal work groups, and collaboration has continued via teleconference and in-person meetings, supported by the Healthcare-associated Infections Advisory Committee under DPH.

Throughout this initiative, Quality Insights distributed resources to all participating providers (including not only the eBH Choosing Wisely teams, but also urgent care centers, physician practices, and community pharmacies throughout Delaware) and met one-on-one with providers to review the CDC Core Elements and provide guidance on strategies to implement them. Additionally, Quality Insights created provider-specific antibiotic prescribing reports using Medicare claims data for participating providers. Lastly, they developed patient-focused educational videos and handouts supporting appropriate antibiotic use. In addition, the teams reviewed and selected resources from CDC's "Be Antibiotics Aware"¹³ and the ABIM Foundation's Choosing Wisely* campaigns.¹

STRUCTURE AND ACTIVITIES OF INDIVIDUAL TEAMS

The five participating hospitals convened six stewardship teams (Christiana Care created separate inpatient- and outpatient-focused teams). Of these six teams, most (n=4) included an infectious diseases (ID)-trained pharmacist, and three included ID-trained physicians. All teams comprised of both pharmacist and physician representatives, who included specialists such as hospital medicine and primary care. Infection Preventionists were also common members (n=4); other individuals included nurses and Quality/Safety representatives.

Prior to the initiation of the eBH Choosing Wisely project, all participating hospitals had inpatient stewardship teams already working on various initiatives (*Figure 2*). These initiatives included restricting certain antibiotics to specific providers, retrospective audit and feedback, requiring an indication for antibiotic prescriptions, making changes within the electronic medical record (EMR) to facilitate stewardship goals, guidelines development, and patient and provider education. One team had signed up to participate in the Agency for Healthcare Research and Quality (AHRQ) Safety Program for Improving Antibiotic Use.^{14,15} During the eBH Choosing Wisely project, many of these previous initiatives were either maintained or newly introduced at

other hospitals. Additionally, new stewardship interventions were initiated (Figure 2). All inpatient teams implemented an antibiotic time-out at 48-72 hours, a main goal of the project. Other interventions included developing and posting commitment posters, an evidence-based practice in which the provider(s) pledge to use antibiotics appropriately and these pledges are posted in exam rooms or other areas visible to patients;¹⁶ submitting antibiotic utilization data to CDC for benchmarking; surveying providers and/or patients; identifying stewardship champions at the clinic or unit level; and providing prescribing data feedback to providers.

It was well-recognized by all participants that patient education was an important part of this initiative, as real or perceived demand for antibiotics is considered a primary driver of inappropriate antibiotic prescriptions.¹⁷⁻¹⁹ Teams reported that prior to the project, patient education included handouts (n=2), posters in waiting rooms (n=3), and education embedded into the EMR that was available for nursing to distribute to patients (n=3). Additional methods that were utilized during the project included updating an external website (n=1), creating videos (n=2), and creating phone messages for patients while waiting on hold (n=1). In addition, more programs added handouts, posters and other signage, and EMR-based education.

INDIVIDUAL PROGRAM VIGNETTES

BAYHEALTH

Bayhealth's inpatient goal was to implement an antibiotic time-out to reduce antibiotic patient days by 10% in one year, and to improve patient outcomes including *Clostridium difficile*, readmission, and excess length of stay. This effort included participating in the AHRQ program in the intensive care unit (ICU). A dedicated pharmacist was assigned to complete the time-out for 10 patients per month, hoping that selecting a single pharmacist would increase rapport with the ICU intensivist team. The team also implemented a best practice alert in the EMR for a 72-hour antibiotic time-out for all inpatients receiving piperacillin/tazobactam or ceftriaxone. This time-out would alert only the attending hospitalist. The outpatient initiative's goal was to reduce the number of outpatient antibiotic prescriptions for the treatment of URI (sinusitis, acute bronchitis, otitis media, and pharyngitis) by 10% over one year. Efforts toward this goal included displaying patient education posters in the emergency department (ED) fast-track rooms and patient bathrooms. Provider education targeted internal medicine and other primary care physicians via letters and staff meetings about decreasing antibiotic use for URI.

BEEBE HEALTHCARE

The Beebe team's overarching goal was to develop and sustain a culture of optimal antimicrobial use throughout the health system. The team recruited ID and hospitalist provider champions, trained pharmacists via certification through the Society of Infectious Diseases Pharmacists (SIDP),²⁰ and identified the medical-surgical ICU – as the area with greatest opportunity – to participate in the AHRQ Safety Program for Improving Antibiotic Use. The team used adaptive training via TeamSTEPPS,²¹ clinical education via monthly webinars, and standardized real-time reviews of antibiotic use employing the

AHRQ four moments of antibiotic decision making.¹⁴ Quality Insights webinars were made available to hospital and outpatient providers, and Choosing Wisely commitment posters were placed strategically in both hospital and outpatient settings. The team implemented an EMR tool to submit antibiotic use and antibiotic resistance to the CDC, and conducted data analysis and timely feedback for specific antibiotics (e.g., mainly focusing on broad spectrum carbapenem usage, specifically ertapenem). The team conducted *C. difficile* deep dives for all hospital onset cases, as well as 1:1 meetings when opportunities for provider feedback and education were identified.

CHRISTIANA CARE HEALTH SYSTEM- AMBULATORY

The ambulatory team chose two key areas of focus: the health system's five urgent care centers, known as medical aid units (MAUs), and primary care practices. Within the MAUs, the lead physician served as a stewardship champion. After on-site education by the stewardship team to MAU providers, the lead physician performed manual chart audits in order to review antibiotic prescribing, and gave the MAU providers feedback via email or in-person meetings. Antibiotic utilization data became available in February 2018, and from this point forward emails were distributed monthly to all MAU providers with their antibiotic prescribing rates, allowing for peer-to-peer comparison.

For the system's 14 primary care practices, similar efforts were made to emphasize the importance of using antibiotics appropriately. Unfortunately antibiotic utilization data was not available for these practices, so efforts focused on provider engagement and education and patient education. The team distributed needs assessment surveys to all primary care providers, nurses, and medical assistants to gain a better understanding of the groups' baseline knowledge. The survey identified barriers to appropriate antibiotic prescribing that included lack of access to educational materials. Therefore, the team made educational resources more readily available within the practices. Posters and pamphlets that were developed by CDC and Choosing Wisely were made available in the practices' ordering system, and the task force developed a commitment letter that was posted in all exam rooms. Additional patient education efforts included developing a patient-focused external website, a phone recording that patients will hear when calling to request a sick visit appointment, in-person provider education at monthly clinic meetings at all sites, provider quizzes, creating a new sinusitis guideline, and identifying an office stewardship champion at each site.

CHRISTIANA CARE HEALTH SYSTEM - INPATIENT

The primary goal of the inpatient team was the incorporation of an antibiotic time-out into the rounding process with a focus on the 5D's of stewardship – discernment, drug, dose, de-escalation and duration of therapy. The team completed a pilot in the fall of 2017 with the help of medical residents, who completed a separate antibiotic time-out note for 29 patients over a period of two weeks. While the process was not overly time-consuming or difficult, the lack of ability to force this function created limitations. The team also had the opportunity to participate in the AHRQ Safety Program for Improving Antibiotic Use, choosing a geriatric medicine unit and surgical/trauma ICU to participate. The project started with engaging key stakeholders

including pharmacy, nursing, physician extenders, residents and physicians on each unit; sharing antibiotic utilization; and exploring opportunities for improvement. The geriatric unit focused on ceftriaxone use and the management of asymptomatic bacteriuria, while the surgical ICU focused on linezolid use.

NANTICOKE HEALTH SERVICES

Nanticoke formed outpatient and inpatient Antibiotic Stewardship Committees, which worked with their EMR to develop reports so that meaningful data could be collected. The team distributed education to all staff regarding antimicrobial stewardship, and provided face-to-face education to ED clinicians by pharmacy and physician leaders. The Infection Preventionist also provided face-to-face education at several community events. The team is currently testing a 72-hour antibiotic time-out for four frequently used antibiotics in the inpatient population.

NEMOURS/A.I. DUPONT HOSPITAL FOR CHILDREN

The Nemours team focused on two areas of antimicrobial stewardship: development and implementation of clinical pathways for ambulatory care practices including primary care, emergency department and urgent care; and development of an inpatient unit-specific antimicrobial stewardship initiative via the AHRQ Safety Program for Improving Antibiotic Use. For the clinical pathways, a multidisciplinary team was established and identified common diagnoses with the greatest potential for practice variation (i.e. acute respiratory tract infection). The team measured baseline data on antimicrobial prescribing and diagnostic test utilization for these diagnoses, and developed evidence-based clinical pathways. Ultimately the team developed and implemented 4 clinical pathways (streptococcus pharyngitis, URI, acute bacterial sinusitis and influenza) during the one-year period. The team leveraged the EMR to provide clinical support consistent with recommendations of the clinical pathways (best practice alerts, order sets, preference lists, express lanes), and engaged front line clinicians via in-person training and open communication regarding feedback or concerns about the pathway. Lastly, they developed individualized physician performance dashboards.

For the AHRQ program, the team identified the pediatric ICU (PICU) as the unit with the highest patient acuity and highest utilization of broad-spectrum antibiotics. The unit-specific initiative included identifying unit physician champions, with whom biweekly meetings were held to perform prospective review of patients' antimicrobial therapy and identify opportunities for improvement. With the champions, the team reviewed at least ten patients per month, after which they developed and implemented a formal process for antibiotic time-outs, in collaboration with the PICU attending physicians and PICU pharmacy clinical specialist. The pharmacist and clinical team assessed a standardized set of questions on antibiotic indications, route, and duration during patient rounds, and the pharmacist documented the assessment and decision in a progress note. All patients receiving antimicrobials for greater than 48 hours were included for assessment.

UTILIZATION DATA

Given the disparate EMRs utilized by the participating hospitals, we did not attempt to pool utilization data for this project.

However, Quality Insights, through a contract funded by CMS, provided pooled outpatient utilization data for Medicare beneficiaries, using Medicare Part D claims and national drug codes to calculate the total number of antibiotic prescriptions, divided by the total member months for beneficiaries with pharmacy benefits for the same time period. Available data included the first quarter of 2016 (2016Q1) through the second quarter of 2018 (2018Q2). We calculated overall utilization, as well as utilization of broad-spectrum (defined as agents effective against both Gram positive and Gram negative bacteria), and narrow-spectrum (defined as agents effective against specific families of bacteria) antibiotics. Because the initiative began in August 2017, we compared the pre-intervention one-year period (2016Q3-2017Q2) to the intervention period (2017Q3-2018Q2), and calculated rate ratios.

RESULTS

The teams reported many lessons learned as well as barriers to implementation of the project (*Table 2*). Examining the Medicare Part D fee for service antibiotic claims, 142,148 antibiotic prescriptions were filled during the baseline year (2016 Q3-2017 Q2), for an average of 1.19 prescriptions per member per year. This decreased slightly during the intervention year (2017 Q3-2018 Q2) to 132,736 prescriptions or 1.07 antibiotics per member per year. Clear seasonality was evident, with higher utilization during quarter 1 (January-March) of each year (*Figure 3*). Overall, outpatient antibiotic utilization decreased by 9% between the baseline and implementation years (*Figure 4*). In both years, broad-spectrum antibiotics made up approximately two-thirds of all antibiotics prescribed (69.7% during baseline; 69.4% during intervention). Utilization of broad-spectrum antibiotics decreased to a greater extent than did that of narrow-spectrum agents (*Figure 4*).

DISCUSSION

The eBH Choosing Wisely antibiotic stewardship initiative has demonstrated the value of multiple individuals and teams, with multidisciplinary backgrounds and from widely varying health care systems, coming together to work on a single project. While each team's interventions and specific goals differed slightly based on their unique clinical situation and patient populations, all teams were able to move forward toward their goal and implement new interventions to promote appropriate use of antibiotics. The "all teach, all learn" method of collaboration provides a framework for not only learning from others but also disseminating similar messaging to health care consumers. While many patients (and parents) are aware of the downsides of antibiotic use,^{22,23} hearing a similar message from providers across the health care continuum is essential for successful reduction of unnecessary antimicrobial use. Our results demonstrated a modest decline in outpatient antibiotic utilization among Medicare beneficiaries that was consistent with an overall downward trend. This is not unexpected given the relatively small number of providers impacted by this work over the one year duration of the project; the teams continue to work to further spread their interventions, and anticipate greater impact. Impact on other populations, including pediatrics and younger adults, is not known.

The importance of antibiotic stewardship cannot be overstated.

Antibiotics are unique among medications in that their use, appropriate or otherwise, affects not only the individual taking the medication, but also the community around them. While life-saving when needed, extensive research has demonstrated their overuse, which can include using antibiotics for diagnoses that are either not infectious in nature, or caused by viruses; using unnecessarily broad-spectrum agents; and prescribing unnecessarily long courses of antibiotics, when shorter courses are equally effective. Such overuse contributes to worsening antibiotic resistance, thereby making true infections increasingly difficult and expensive to treat. It is the primary driver of increasing rates of *C. difficile* infections, both within hospitals as well as the community, and is a major cause of significant allergic reactions and other adverse drug events.⁴

Antimicrobial stewardship programs have been recommended for all hospitals since 2014, and since 2016 have been required by CMS as a condition of participation for hospitals and nursing homes.²⁴ In early 2019 the Joint Commission proposed a new requirement for antimicrobial stewardship in ambulatory health care.²⁵ To support these efforts, the CDC has published a series of documents describing the Core Elements required for effective stewardship programs.^{8,9} Primary among these elements is the leadership commitment necessary not only to state that this work is a priority, but also to dedicate sufficient human and other resources necessary to complete this challenging task. The eBH Choosing Wisely framework was able to garner such leadership support from each health system, and foster accountability from all the teams via designating team leads and facilitating regular meetings. Additionally, eBH was able to convene other organizations to participate in these efforts, which not only served to facilitate the integration of their expertise and insight into team projects, but also to minimize the potential for redundant work being commissioned within our community.

Having teams comprised of multidisciplinary health care professionals allowed the efforts to benefit from the multifaceted expertise that contributed to all teams implementing multiple interventions. While education of both providers and patients regarding stewardship principles is necessary, it is also recognized that education alone is not sufficient to create lasting changes. Developing the ability to track and report reliable data is crucial for long-term improvement and sustainment of antimicrobial stewardship, but remains elusive and is probably the greatest barrier reported by all the teams; however, despite limited resources to make major changes in this arena during the one-year time span of this project, the teams were able to make progress in acquiring data. We are hopeful that additional data resources will be available in the near future.

The collaborative work described in this paper demonstrates the statewide progress that can be accomplished and the many efforts required to successfully implement such a multi-institution, multi-disciplinary project. The Choosing Wisely Work Group has since initiated similar collaborations around imaging for low back pain and end-of-life care. Creating a statewide group to focus, align and collaborate on issues such as these, which demonstrate wide practice variability, will improve the health of all Delawareans while promoting safety, efficiency, and access to quality care.

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Figure 1: Health system partners participating in eBrightHealth LLC Strategic Alliance, and eBright Health Accountable Care Organization (ACO).

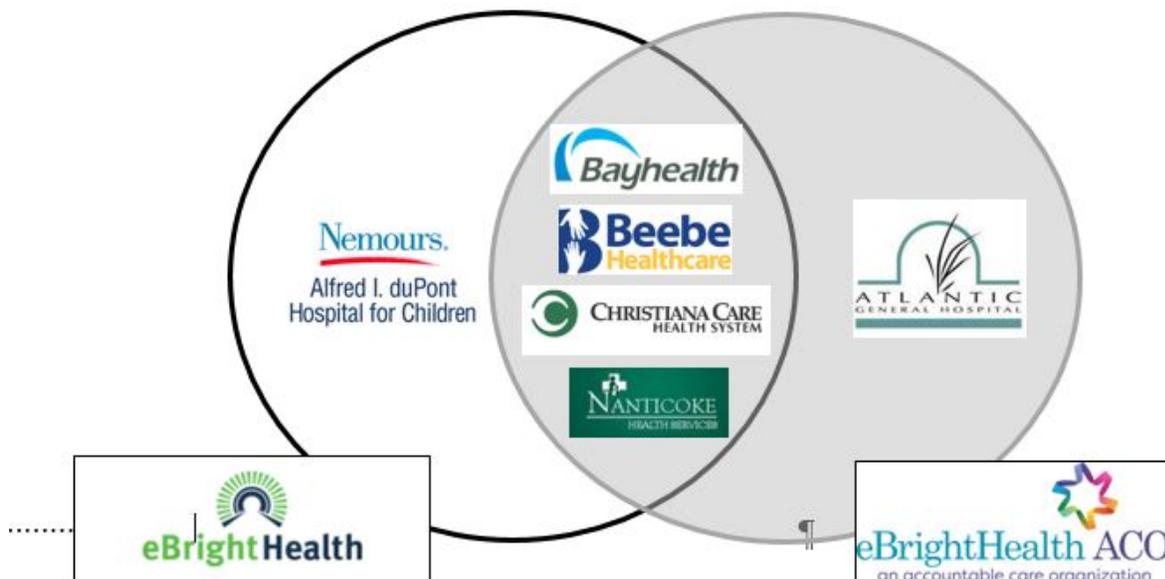
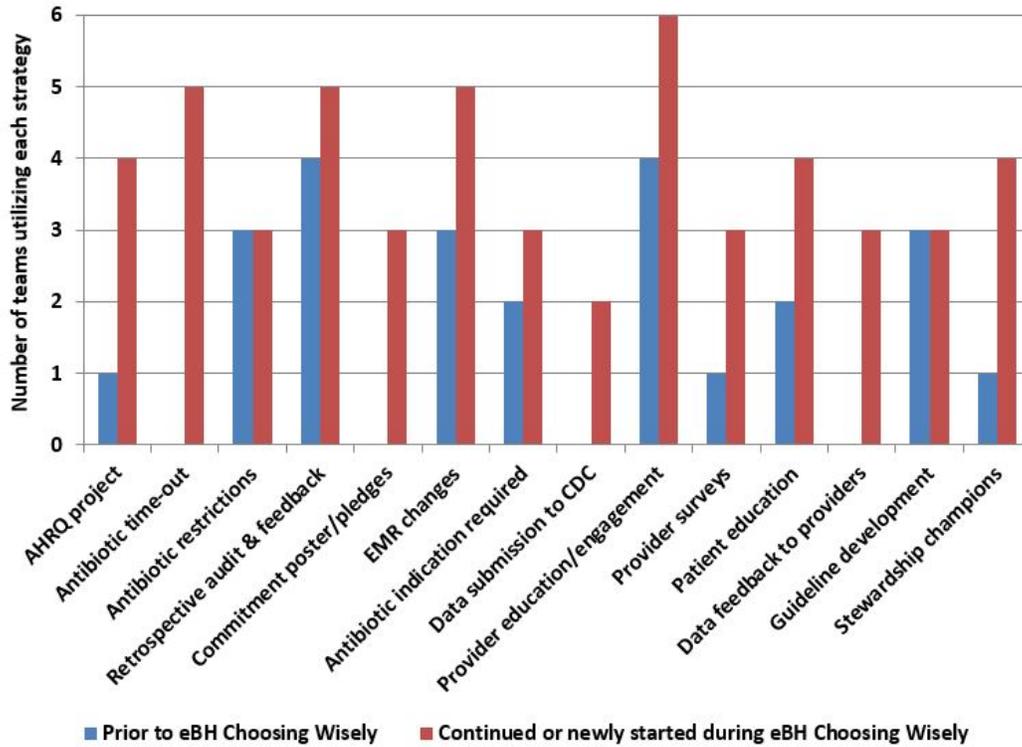
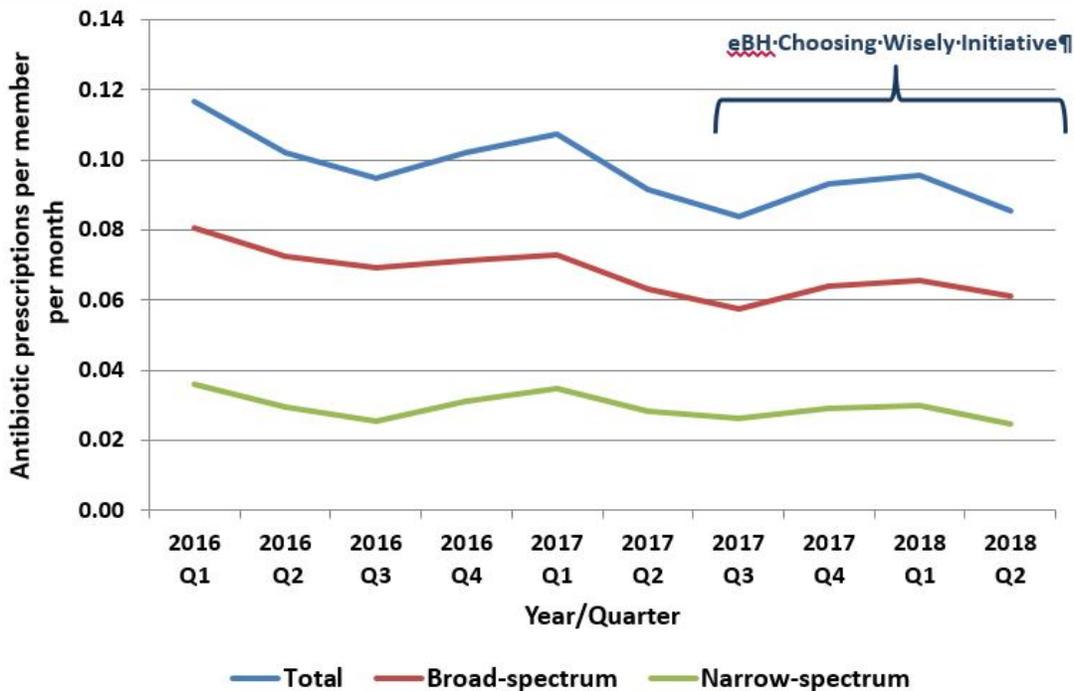


Figure 2. Antibiotic stewardship interventions in place prior to the eBrightHealth Choosing Wisely initiative (blue bars), and either continued or initiated during the project (red bars).



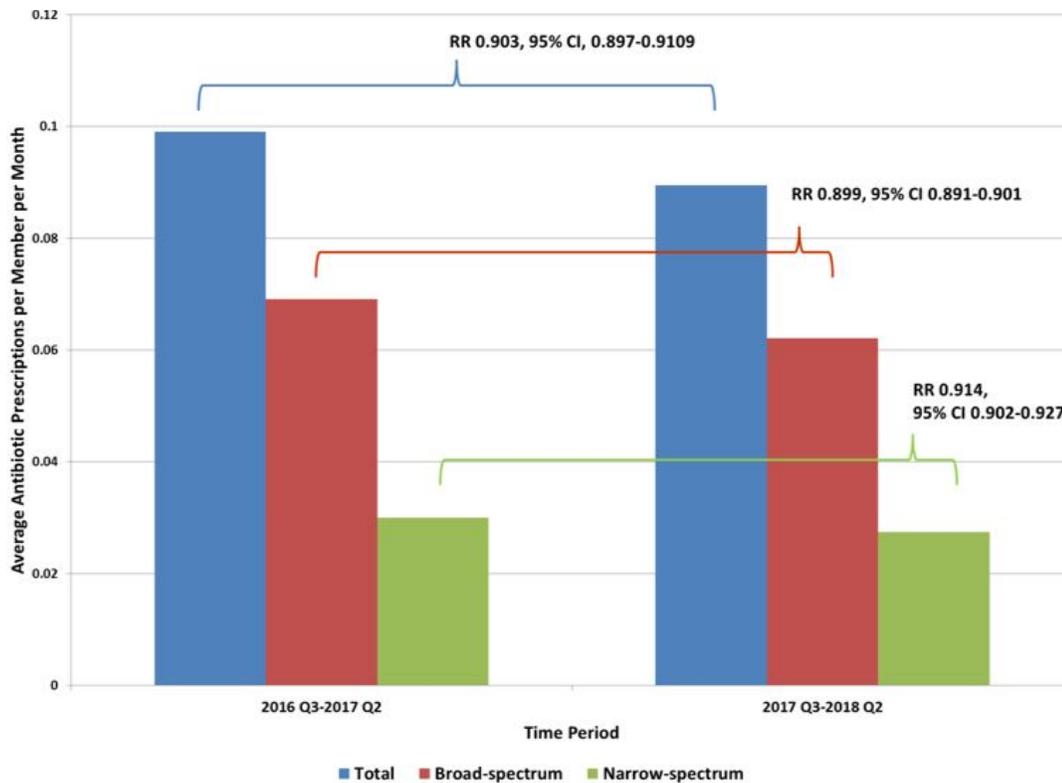
Legend: AHRQ, Agency for Healthcare Quality and Research; eBH, eBrightHealth LLC Strategic Alliance; CDC, Centers for Disease Control and Prevention; EMR, electronic medical record.

Figure 3. Outpatient antibiotic utilization among Delaware Medicare Part D beneficiaries, 2016 quarter 1 through 2018 quarter 2, based on claims data.



Legend: eBH, eBrightHealth LLC Strategic Alliance. Green bar demonstrates duration of eBH Choosing Wisely antibiotic stewardship project.

Figure 4. Outpatient antibiotic utilization among Delaware Medicare Part D beneficiaries, comparing eBH pre-intervention (2016 Q3-2017 Q2) to intervention (2017 Q3-2018 Q2) periods.



Legend: CI, confidence interval; eBH, eBrightHealth LLC Strategic Alliance; RR, rate ratio.

Table 1. Core Elements of Hospital and Outpatient Antibiotic Stewardship programs, proposed by the Centers for Disease Control and Prevention (CDC).

Core Elements of Hospital Antibiotic Stewardship Programs ⁸	Core Elements of Outpatient Antibiotic Stewardship ⁹
1. <u>Leadership</u> Commitment: Dedicating necessary human, financial and information technology resources.	<u>Commitment</u> : Demonstrate dedication to and accountability for optimizing antibiotic prescribing and patient safety.
2. <u>Accountability</u> : Appointing a single leader responsible for program outcomes.	<u>Action</u> : Implement at least one policy or practice to improve antibiotic prescribing, assess whether it is working, and modify as needed
3. <u>Drug Expertise</u> : Appointing a single pharmacist leader responsible for working to improve antibiotic use.	<u>Tracking and reporting</u> : Monitor antibiotic prescribing practices and offer regular feedback to clinicians, or have clinicians assess their own antibiotic prescribing practices themselves.
4. <u>Action</u> : Implementing at least one recommended action.	<u>Education and expertise</u> : Provide educational resources to clinicians and patients on antibiotic prescribing, and ensure access to needed expertise on optimizing antibiotic prescribing.
5. <u>Tracking</u> : Monitoring antibiotic prescribing and resistance patterns	
6. <u>Reporting</u> : Regular reporting information on antibiotic use and resistance to doctors, nurses and relevant staff.	
7. <u>Education</u> : Educating clinicians about resistance and optimal prescribing.	

Table 2. Lessons Learned and Barriers reported by the six Choosing Wisely Antibiotic Stewardship teams.

Lessons Learned	Barriers to Implementation
<ul style="list-style-type: none"> • Importance of multidisciplinary team approach, including providers, pharmacists and nurses • Critical to have clinical champions within each practice setting • Participating in national study (AHRQ project) provided additional momentum and interest • Important to identify one or two small efforts to focus on (e.g., specific drug and/or specific disease state) • Importance of communication with all necessary parties/people impacted by changes • Doing snowflake model at beginning with well thought out planning • Need to have dedicated time allocated for calls and face-to-face meetings for all members of the team • Need representation from different practice areas in pathway development as workflows vary by practice and by site • Need uniform way to disseminate information to the front-line clinicians • Need forum to obtain and respond to feedback • Leadership support key for driving improvement throughout multiple practice settings • Analytics don't have to be complex in order to be effective • Vary methods for engaging providers, nursing, pharmacy, patients and families - different approaches may work for each 	<ul style="list-style-type: none"> • Data issues: <ul style="list-style-type: none"> ◦ Access to all antibiotic prescribing data ◦ Development of accurate data dashboards ◦ Developing a consistent way to have oversight over development of EHR changes ◦ AHRQ data imperfect for specific units types/formularies ◦ Delays in implementing EHR changes • Engaging patients and other community members - population can be difficult to reach • Physician engagement • Competing priorities in primary care and among inpatient teams • Marketing delays • Insurance prior-authorization requirements vary between different states • Needs for discretionary time by team members - challenging to schedule meetings for a large team of busy clinicians

DISCLOSURES:

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TRAUMA-INFORMED DELAWARE EXECUTIVE ORDER 24

TRAUMA-INFORMED DELAWARE'S GOAL:

**Coordinate a sustainable,
community-based trauma awareness,
prevention, and early intervention system
that advances resilience through:**

Access to quality behavioral and intergrated health care
Strength-based services for youth and adults
Education for providers and the community

WHAT ARE ACEs?

**Adverse Childhood Experiences (ACEs) are
stressfull events that can overwhelm a child's
ability to cope and have a lifelong negative
impact on health and wellbeing.**

MAY 2019

Low Incidence and High Profile: Tuberculosis Control in Delaware

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Abstract

Tuberculosis (TB) is an infectious disease of global burden. While Delaware has low incidence of active TB compared to other locales, because of its small size these few cases tend to garner widespread attention. In this article, a study of one such case of active TB is presented. This case serves as a didactic example of the public health response to the complexities of treatment, including institutional, transient settings, and patient refusal. This consequently led to ordered directly observed therapy of the individual. The article concludes with a discussion of the law and legal implications for such cases in Delaware.

INTRODUCTION

According to the CDC, one-fourth of the world's population is infected with Tuberculosis.¹ The vast majority of these cases are infected with latent tuberculosis. In 5-15% of cases, latent tuberculosis will become active. In 2017 alone, there were 10 million active Tuberculosis ("TB") cases and 1.3 million deaths.² However, TB cases in the United States have decreased in recent years thanks to the treatment of latent infections and a decrease in TB cases worldwide. In 2017, there were 9,105 cases of active TB in the U.S, a decrease of 2.3% from 2016.³

Tuberculosis infection is caused by bacteria (typically *Mycobacterium tuberculosis*). The bacteria can be anywhere in the body but 90% of TB infection occurs in the lungs.⁴ A person who has TB in the lungs (pulmonary TB), can spread the bacteria through coughing or speaking. Someone close to that person can breathe in the bacteria and become sick and contagious with active TB; alternatively, that person's immune system may be strong enough to contain the bacteria and it becomes dormant (latent TB infection). The person with the dormant bacteria is not contagious or sick, but if their immune system weakens through illness (e.g., from HIV/AIDS) or certain medications (e.g., immunosuppressive therapy), the dormant bacteria may become active and multiply causing the person to become sick with TB disease and, consequently, contagious. According to the CDC, HIV co-infection is the strong indicator that latent TB infection will progress to active TB.⁵ People with HIV are 20 times more likely to fall ill from TB than those who are not living with HIV.⁶

Because of the risk of infection, the Division of Public Health (DPH) encourages people with the latent TB infection to take antibiotics to kill the dormant form of TB to prevent disease in the future. Delaware had 15 active TB cases in 2017, a case rate of 1.5 cases for every 100,000 people, well below the national average of 2.8.6 For this reason, Delaware is considered a low incidence TB state.⁷ However, the limited cases of active tuberculosis in Delaware typically garner widespread media attention. In May 2018, the Delaware Division of Public Health notified the public that an active case in a long-term care facility may have exposed more than 600 individuals to TB.⁸ Months later, dozens of students and staff at a Sussex County elementary school were exposed to active TB.⁹ Neither exposure resulted in additional active cases beyond the index case but both made front-page news. In 2014, there were 22 cases of active TB state wide. One case in particular tested the limits of the law and the resources of the state of Delaware.

CASE STUDY: DANIEL

Daniel (a pseudonym) first became known to the Delaware Division of Public Health in early spring of 2014. He was born outside the United States and had been living in Delaware for more than five years. By the end of 2014, he would be hospitalized with cavitary pulmonary tuberculosis after exposing more than 700 people to this contagious disease. When Daniel came to the Division's attention, he had recently been incarcerated in Delaware. He had multiple prior felonies, a history of substance abuse and homelessness, and was HIV positive. During the course of his tuberculosis treatment in Delaware he would be incarcerated two more times.

Daniel was diagnosed with latent tuberculosis earlier in his life but failed to complete his treatment, only completing two months of the required nine months. In the spring of 2014, he had been incarcerated, released and later hospitalized with active pulmonary tuberculosis. Upon examination, cavities (holes) were found in both lungs and he was deemed "highly contagious." Daniel was hospitalized for over one month and was discharged to the community. At the time of his incarceration in early 2014, Daniel exposed a large prison population to tuberculosis. This exposure resulted in the need for 2,000 inmates, former inmates and staff to be tested for tuberculosis. A close contact in the prison subsequently developed active TB from this exposure.¹⁰

Daniel was placed on a nine-month regimen for treatment but was later transitioned to a 12-month regimen due to his immunocompromised status. The treatment consists of directly observed therapy ("DOT") which involves giving the antibiotics for treating TB (isoniazid, rifampin, ethambutol and pyrazinamide) under close observation, three days a week, by a public health nurse. The nurse meets the client for his DOT at a location most convenient for the client. Any doses the client misses are added into the time line, extending the amount of time the client must receive the medication to complete his treatment. However, missing an extensive amount of doses may cause the individual to "relapse", meaning the disease returns, and could become resistant to some of the medications previously used. A whole new regimen would be needed and the person would need to be re-treated.

Daniel was periodically housed in a motel financed by the state of Delaware, being provided with meals, groceries, hotel vouchers and was compliant with his treatment even though he was re-incarcerated for short periods during the summer of 2014.

Then he was released in the late summer of 2014. The Division of Public Health Division informed Daniel that they could no longer finance his motel, and he began missing doses. DPH nurses attempted to work with Daniel, bringing him food they paid for themselves, but he continued to resist treatment and often could not be located. Daniel's DPH case manager attempted to find a place for Daniel to stay, reaching out to shelters and programs but Daniel declined to follow through with offered appointments. Daniel traveled to other parts of the state but refused to meet with nurses from other counties. He traveled out of state and evaded attempts to be located.

In the fall of 2014, Daniel had missed so many doses that the Division of Public Health took the extraordinary step of issuing an emergency order requiring treatment of Daniel. The order included language that authorized local law enforcement to locate Daniel and bring him to a health care provider to receive his medication. Having also violated his parole, Daniel was picked up by local law enforcement and taken to a prison facility on an outstanding warrant. While in prison, he did not refuse medication. One week after the emergency order, the Division held a hearing to determine if the order for treatment should continue. Daniel was represented by a court-appointed lawyer and was given the opportunity to present evidence and question witnesses. Following the hearing, the Director of the Division of Public Health found that Daniel's noncompliance was a danger to himself and to the general public, that Daniel knew the risks of refusing treatment and that all less restrictive alternatives had been exhausted. The Director of the Division of Public Health ordered that Daniel undergo DOT until he completed his treatment.

INVOLUNTARY TREATMENT, QUARANTINE AND ISOLATION IN DELAWARE

Daniel's case is unique. He had a history of noncompliance and demonstrated a risk to the general public's health. While he was not contagious at the time of the forced treatment order, he had missed eight of twelve doses in a month and was at imminent risk of becoming contagious again. Isolation and forced treatment are not tools that the Delaware Division of Public Health uses often, and never without great cause. Quarantine and isolation laws are state specific and Delaware's laws are comprehensive. Before an individual can be subjected to testing, treatment, hospitalization or isolation against their will, they must be afforded due process.¹¹

In Delaware, those due process protections are codified in Delaware law.¹² Before any person can be involuntarily examined or treated, hospitalized or isolated in a community setting they must first have a hearing before the Director of the Division of Public Health. At the hearing, the person subject to the potential order has the "right to present evidence, cross-examine witnesses and to be represented by legal counsel." If the individual cannot obtain or afford legal counsel, the Division is required to petition the Superior Court to appoint an attorney for the individual. The individual shall also be "given at least five working days prior written notification of the time and place of hearing, a copy of documentary evidence to be presented, a list of the proposed actions to be taken and the reasons for each said action; and shall be given a verbatim transcript of the hearing on request for appeal purposes." In order for the Director to issue an order

of involuntary examination or treatment, hospitalization or isolation, they must find that: "(1) [t]hat there is a danger to the health of the person or that the public health and welfare are substantially endangered by the person; (2) [t]hat the person has been counseled about tuberculosis, the significant threat tuberculosis poses to the public and methods to minimize the risk to the public, and, despite said counseling, indicates an intent by words or action to endanger himself or herself and/or expose the public to infection from tuberculosis; and (3) [t]hat all other reasonable means of achieving voluntary compliance with the treatment have been exhausted and no less restrictive alternative exists." The Director must find that all three factors are met by clear and convincing evidence, meaning that is highly and substantially more likely to be true than untrue that the person has met all three factors.

The order will continue until "in the opinion of the attending physician or the County Public Health Administrator, the person is cured or said person is no longer a substantial threat to himself or herself or to the general public." The individual subject to the order may also petition the Director for "immediate release and termination of the order." The individual must demonstrate that they are no longer "an imminent and substantial threat to himself or herself or the public's health and welfare; and will voluntarily continue with prescribed medications and treatment, if medically necessary, to reduce the risk of infection to the public." An individual may also appeal an order directly to the Superior Court. The court reviews the hearing before the Division of Public Health but will also accept new evidence and makes a decision without deference to the Division's previous findings.

The Division of Public Health also has the authority to issue emergency orders, as they did in Daniel's case. An emergency order is issued when: "(1) [t]he person has tuberculosis or is reasonably suspected of having tuberculosis; (2) [t]he person poses an imminent and substantial threat to that person's own self or the public health and welfare" and the person has demonstrated that an order cannot wait for a hearing under section 526. These reasons could include threats to leave the jurisdiction, that the person will not appear for a hearing or the person "will act in such a way as to recklessly disregard the person's own health or the public's health." Before an order for emergency treatment can be entered, the Director of the Division of Public Health must find "the County Public Health Administrator presents clear and convincing evidence that a substantial threat to the person or the public's health and welfare exists unless the emergency treatment order is issued [and there are] no other reasonable alternative means of reducing the threat to the individual or public's health and welfare". The Division must also schedule a hearing under Section 526 when issuing an emergency order. The emergency order will contain a provision directing law enforcement to transport the individual for treatment or isolation. The emergency order cannot be in place for more than five business days.

RESPONSES TO COMMUNICABLE DISEASE CONTROL

How to isolate, or quarantine, a person in their home or a community setting is a question that many public health professionals struggle with; and when an individual is ordered to be isolated in the home or another community setting the logistics are daunting. States struggle with balancing the public's health with an appropriate response that protects individual liberties. Certainly, no public health lawyer will forget the image of nurse Kaci Hickox going for a bike ride while followed by

Maine state police after her return from treating Ebola patients in West Africa.¹³ Or her subsequent lawsuit against the state of New Jersey.¹⁴ Recently, a couple in Wisconsin were criminally charged after violating their measles quarantine orders.¹⁵ Both cases prompt discussion on how states should react to potential public hazards while also ensuring that individual liberties are protected to the greatest extent possible. All states should have plans in place on how to respond with quarantine, isolation and involuntary treatment. These plans should comply with applicable statutes but should also reflect best practices for the treatment and control of communicable diseases.

In the case of Daniel, the process went as smoothly as possible. Because of Daniels' outstanding criminal charges, he was treated while incarcerated. His hearing was conducted at the prison where he was incarcerated and he was given all the resources he and his attorney needed to prepare. While Daniel did not appeal the order, he had the right to do so. Daniel acknowledged the barriers to his compliance were social, informing the Division's responses for future patients with similar needs.

The last time the Division of Public Health forcibly examined, treated, hospitalized or isolated someone was in 2014. Involuntary treatment, examination or isolation is not something that any government agency takes lightly. The legal requirements placed upon the government when it seeks to limit someone's freedom are substantial, and for good reason. For weeks, the process can tie up staff, officials and resources. As in the case of New Jersey, lawsuits can last for years. To avoid the extraordinary step of involuntary treatment or isolation, the Division places emphasis on education and ease of treatment. In 2017, the Division initiated video directly observed therapy (VDOT) which allows individuals to virtually connect with their public health nurses to ensure treatment compliance. By using the method of VDOT, the individual acquires a confidential app for their phone and can video themselves taking their medications at a time and location which is convenient for them and it is sent to their nurse. VDOT participants demonstrate a higher median fraction of expected doses observed than traditional DOT participants and would recommend VDOT over DOT.¹⁶ A noncompliant patient is counseled by multiple individuals to encourage compliance with treatment. It is only when this counseling and education fails that the Division is forced to begin involuntary treatment, hospitalization or isolation proceedings. Thankfully, the Division has not needed to subject an individual to involuntary treatment, hospitalization or isolation in the past five years. As the incidence of TB cases in Delaware continues to decrease there is hope that the Division may never need to subject an individual to involuntary treatment, hospitalization or isolation again. However, if they do, the law and Daniel's case will guide the administration on how to proceed in a just and respectful manner.

Disclaimer: The views expressed herein do not necessarily reflect the views of the Delaware Department of Justice or the Delaware Division of Public Health.

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Four Decades of Epidemiologic Science on HIV Infection and Disease, and Its Impact on Public Health Practice and Policy for Sexual and Gender Minority Persons

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Abstract

Even at the cusp of the second decade of the new millennia, HIV continues to be a significant public health challenge for sexual and gender minorities (SGM). Men who have sex with men and transgender women, in particular, continue to report higher rates of HIV incidence compared to their heterosexual counterparts, while facing significant barriers to comprehensive sexual healthcare. In Delaware, HIV infection impacts a substantial number of individuals with approximately 14.5 incident cases per 100,000. This ranks Delaware as the 14th highest for HIV incidence among U.S. states. However, the largest healthcare provider in Delaware, Christiana Care Health System, has created many health initiatives to support the health needs of SGM and those living with HIV. The current sustained rate of HIV infection indicates the need for enhanced epidemiologic work to identify HIV cases in subgroups of diverse sexuality and gender identity, collaboration within and across research institution and community organizations, as well as engagement in creative solutions that target the multiple levels of factors contributing to HIV incidence. In addition, it is imperative that local agencies and health organizations continue to support these communities of SGM individuals during the current sociopolitical climate of the national U.S. government.

INTRODUCTION

Disparities of HIV infection within and across populations in the United States have been evident since the earliest days of the HIV epidemic. Sociodemographic determinants of infection, including age, gender, race, ethnicity, and exposure to poverty, as well as sexuality, injection drug use and commercial sex work and other proxies for individual risk factors have modulated the risk of HIV infection, morbidity, and mortality.¹⁻⁵ Additionally, disclosure of HIV risk, and willingness to access HIV testing and counseling, and treatment and/or clinical care have been impacted by sociopolitical conservative ideologies that have stigmatized and marginalized sexual and gender minorities (SGM) and other high-risk populations, including persons who inject drugs (PWID). These high-risk populations continue to be at greatest risk for infection due to individual-level (e.g., condomless anal intercourse or sharing of syringes and other injecting paraphernalia) and population-level (e.g., limited access to prevention services and structural stigma related to same-sex orientation or injection drug use) risks.¹⁻⁴

Since the early 1980s, epidemiologic research has informed our understanding of HIV prevention strategies and treatment. Epidemiologists have been pivotal in the development of surveillance systems that have tracked HIV infection in high-risk subpopulations,⁶ established national standards for HIV diagnosis, treatment, and prevention,⁷ visualized geographic distributions of infection using various mapping techniques,⁸ and employed molecular epidemiologic techniques to elucidate HIV transmission in sexual networks.⁹ All of these approaches strategically inform the use of limited HIV prevention resources.

Finally, demonstration of the efficacy of antiretroviral treatment as prevention, and more recently, pre-exposure antiretroviral prophylaxis has emerged a critical tool for HIV prevention.^{10,11}

In the present commentary, not only do we discuss how epidemiology as a scientific discipline has informed public health practices and policies targeting SGM, but we suggest potential epidemiologic approaches to address unmet prevention challenges that could reduce the HIV infection disparities among highly stigmatized and marginalized communities.

EPIDEMIOLOGY OF HIV IN THE UNITED STATES WITH A FOCUS ON DELAWARE

INITIAL DESCRIPTION OF FIRST CASE SERIES OF COMMUNITY-ACQUIRED IMMUNE SUPPRESSION

HIV was first recognized in the United States during the early 1980s when five cases of *Pneumocystis carinii* pneumonia¹² were reported to the Center for Disease Control and Prevention (CDC). The initial report raised concerns because all five cases were previously healthy, gay men in Los Angeles that developed a rare opportunistic infection. Shortly after the initial report, additional cases of an unknown disease occurring in gay men from New York described the development of Kaposi sarcoma as well as *Pneumocystis pneumonia*.¹³ Researchers had posited the potential pathology and one of the earliest case series documented reductions of T-4 cells and suggested potential cell mediated immune dysfunction as a mechanism.¹⁴ In addition to early recognition the pathogenesis, investigators hypothesized that HIV transmission may have been related to the "homosexual lifestyle."¹³ This potentially stigmatizing inference that these

opportunistic infections were due to “homosexual lifestyle”, leading to the initial labeling of Gay-Related Immune Deficiency (GRID) to designate HIV-associated immune dysfunction, has remained prevalent in social discourse—even as we are on the cusp of the second decade of the new millennium. Not surprisingly, researchers have reported many adverse consequences due to HIV-related stigma, including lower access to and engagement in antiretroviral therapy.^{15,16}

RECENT ESTIMATES OF HIV INFECTION PREVALENCE

Since the initial case findings, there are approximately 1.1 million people (ages 13 or older) living with HIV in the United States, including an estimated amount of 162,549 (14%) people that were unaware of their infection in 2015.^{17,18} The prevalence of those living with HIV has substantially increased due to increased surveillance of new infections, as well as the development of highly active antiretroviral therapy (HAART). Although the magnitude of the United States epidemic is less severe than other regions of the world such as Sub-Saharan Africa, there remains subpopulations of individuals that are disproportionately affected by HIV infection. These critical health disparities have been well documented in previous studies: Black and Latino individuals comprise only 13% and 17% of the United States population,¹⁹ yet account for 44% and 26% of persons living with HIV, respectively.¹⁷ Similarly, gay, bisexual, and men who have sex with men (MSM) represent a very small percentage of the population (~2%), yet continue to be the most affected group, representing approximately 56% of prevalent HIV cases.^{17,20} In 2016, the CDC estimated that one in two black MSM and one in four Latino MSM will be diagnosed with HIV over their lifetime.²¹

In Delaware, surveillance data demonstrates a similar trend to the United States. The estimated number of people living with HIV in 2015 was 3,449 (365 per 100,000 population), with black individuals accounting for 60% (n = 2,075) of those with HIV.²² Racial disparities in HIV infection also persist in Delaware as the prevalence of black men and women living with HIV are approximately 1.5 times and 3 times the rates observed for white men and women in 2015, respectively.²² As is observed nationally, MSM remain one of the groups most impacted by HIV: of total HIV infections, 33% were as attributed to MSM high-risk behavior despite comprising about 1% (n = 13,049) of the population in Delaware (prevalence: 14.7%).^{20,22} Moreover, black MSM accounted for the largest proportion of those with HIV infection from 2011 to 2014. Since 2015, surveillance data suggest among HIV infections attributable to MSM, 46% were among white and 42% were among black men.²²

NEW INFECTIONS: INCIDENCE

HIV incidence estimates are critical as they provide insights concerning HIV transmission trends from which public health professionals can appropriately target prevention efforts and resources. Through the CDC’s HIV Surveillance system, 2016 HIV incidence was estimated to be as approximately 40,000 new infections annually in the United States.^{17,18} Populations with the highest proportion of incident cases included adolescents 13–24 (n = 8,593; 22%) and young adults 25–35 (n = 13,592; 34%) years of age, black adults or adolescents (n = 17,269; 43%), and MSM (n = 26,844; 67%). The highest number of new infections among

MSM was observed among young Black MSM 13–24 years old (n = 3,994; 15%).¹⁷ Among states, Delaware was ranked 14th highest for HIV incidence with a rate of 14.5 per 100,000.¹⁷ Accordingly, the lifetime risk for HIV diagnosis among an individual living in Delaware was estimated to be 1 in 96.²¹ Epidemiologic data also suggest that female sex workers and incarcerated individuals have a heightened risk for HIV; factors associated with increased infection among these risk groups may include alcohol and drug use, lower healthcare access, stigma, and poverty.^{23,24} One of the most critical challenges in providing resources for these groups is the denigration of sex work and incarceration, which potentially limits population-based studies to estimate counts of HIV among sex workers and those in the criminal justice system.^{23,24} Without sufficient data, it is difficult to ascertain the burden of HIV and factors associated with infection as well as develop tailored programs for HIV prevention.

While HIV incidence continues to increase in virtually all of these high-risk populations, new infections among persons who inject drugs have declined in recent years, most likely due to the implementation of harm reduction and syringe exchange programs.¹⁷ Despite this, high numbers of new HIV infections have unfortunately remained stable without evidence of decrease, highlighting the need for enhanced epidemiologic works to understand potential causes of sustained infection (including the characteristics and impact of HIV transmission networks)—all of which can guide the development of strategies to interrupt potential new infections.

TRANSMISSION ROUTES

Routes of HIV transmission include condomless intercourse, injection drug use, blood transfusion, and mother-to-child transmission during pregnancy, birth, or post-partum breastfeeding. In the United States, HIV transmission due to condomless anal intercourse is the primary mode of infection,²⁵ with risk of HIV infection highest for those engaging in receptive anal intercourse due to microtears in rectal epithelium that can facilitate transmission.²⁶ Compared to earlier stages of the epidemic, blood transfusion is longer a substantial risk factor for HIV due to rigorous testing of the blood supply in the United States.²⁵ In addition, surveillance data indicate that perinatal acquired infections have decreased annually in the United States, with approximately 100 new HIV infections in 2016¹⁷ despite challenges in data collection for vertical transmission.^{27,28} However, evidence suggests that avoidance of breastfeeding and elective cesarean section among HIV positive women may be effective in reducing the risk of vertical transmission, with recommendations suggesting complete avoidance of breastfeeding even if the HIV infected mother is adherent to antiretrovirals.^{29,30}

HIV-RELATED MORBIDITY AND MORTALITY

The advent of HAART has greatly improved the survival among persons living with HIV. Current estimates suggest that expected life expectancy for a 20-year-old HIV-infected individual receiving antiretrovirals is approximately 70 years.³¹ With current guidelines recommending antiretrovirals for all HIV-infected persons regardless of CD4 count,³² chronic diseases will most likely become a growing concern as more patients are engaged in care and consequently living longer. In

addition, other bio-medical innovations such as treatment as prevention (TasP: taking antiretrovirals to reduce HIV viral load to an undetectable level) and pre-exposure prophylaxis (PrEP, i.e., taking antiretrovirals to prevent HIV infection) will likely beneficially impact HIV transmission. However, prevention of infection by PrEP use may be reduced by increased rates of high-risk behaviors (risk-compensatory behaviors) resulting from perceived lower risk for infection due to pre-exposure prophylaxis.³³ Additionally, questions remain concerning the long-term side effects of pre-exposure prophylaxis, including bone fragility, kidney disease, and gastrointestinal disorders.³⁴

HIV INFECTION AMONG SEXUAL AND GENDER MINORITIES

DEFINING SEXUAL AND GENDER MINORITY POPULATIONS

It is important to understand that sexual orientation and gender identity are distinctive entities: sexual orientation denotes to whom a person feels romantic or sexual attraction towards^{35,36} whereas gender identity is a person's innermost sense of self, which may not correspond to that their assigned sex at birth.³⁷ The term "sexual minorities" typically refers to individuals who identify as gay, lesbian, bisexual, or any other non-heterosexual orientation, whereas the term "gender minorities" refers to individuals who have gender identities that are not associated with their birth sex. Increasingly, there is recognition that self-identification of gender can be non-binary, with some individuals experiencing a gender identity that is outside the categories of man or woman.³⁸ Taken together, sexual and gender minorities may include lesbian, gay, bisexual, queer, transgender, gender non-binary or non-conforming, gender fluid, intersex, and asexual individuals. However, HIV transmission does not occur as a result of one's sexual orientation; rather, risk is conferred by sexual behaviors that facilitates infection. For the purpose of our commentary, we will focus on homosexually-active men and male-to-female transgender persons, since these individuals are more likely to engage in higher-risk sexual behaviors.

MEN WHO HAVE SEX WITH MEN AND TRANSGENDER WOMEN FACE UNIQUE CHALLENGES AND BARRIERS TO MEDICAL/HIV TREATMENT

MSM and transgender women (TGW) traditionally have faced significant barriers to health care, resulting in decreased access and utilization of services, and particularly preventative care services that may have downstream effects on HIV infection.^{39,40} One method of conceptualizing this cascade is through the HIV care continuum—a model for measuring HIV care engagement, including screening and diagnosis, linkage to care, retention in care, prescription of antiretrovirals, and viral suppression (Figure 1).⁴¹ Overall, estimates suggest a high proportion of those HIV infected are diagnosed, however, only 50% of those diagnosed are retained in care.⁴¹ Of those initially diagnosed, younger individuals, women, as well as racial/ethnic minorities tend to

have lower HIV care engagement.⁴² In addition, HIV infected individuals that are unaware of their infection status represent a great challenge to slowing the epidemic as the risk of transmission is greatest among untreated individuals who may have higher viral loads. Since MSM and TGW have the highest prevalence and risk for HIV among all risk groups, identifying gaps in their HIV care continuum is vital for resource allocation and targeted intervention strategies.

Lack of health insurance has been a major barrier for HIV care engagement among MSM and TGW, particularly those infected with HIV. One major resource for providing HIV care among low-income or uninsured persons living with HIV is the Ryan White HIV/AIDS program, which allocates funding to state and local governments, as well as community-based organizations to deliver essential primary care and HIV treatment. Moreover, the enactment of the Affordable Care Act and expansion of marriage rights have served to expand health care insurance coverage; many MSM and TGW now qualify for coverage through employers or spousal insurance policies, Medicaid, Medicare, or the Office of Veterans Affairs.⁴³ Despite these recent healthcare access advances, MSM and TGW continue to report more cost-related barriers to care and unmet needs than heterosexual peers^{40,44} in particular, transgender individuals have specific challenges in accessing appropriate healthcare for sexual health and gender reassignment. In 2016, attempts to expand Medicare and Medicaid coverage to include gender transition-related costs were met with opposition, and current regulations concerning transition-related care and issues are deferred to states' discretion.⁴⁵ In Delaware, costs related to gender transition are not covered under Medicare or Medicaid; however, private insurance are prohibited from discriminating against transgender individuals.⁴⁵

Beyond insurance obstacles, MSM and TGW often struggle with finding medical providers who have training and experience working with SGM populations and often face discrimination from health care providers.^{40,46,47} In Delaware, numerous healthcare and community-based organizations have made concerted efforts to provide culturally competent healthcare for MSM and TGW. For example, the largest healthcare provider in Delaware, Christiana Care Health System, has established comprehensive health initiatives specifically for MSM and TGW as well as those living with HIV.⁴⁸ As gender identity is increasingly understood to exist along a spectrum, with some individuals not identifying exclusively as man or women—the lack of data about non-binary gender minorities presents another obstacle to evidence-based care.⁴⁹ Creating an inclusive, culturally responsive, and welcoming clinical environment is an important first step in providing optimal clinical care services for MSM and TGW and for reducing HIV acquisition and transmission risk within these communities. This process can involve training in cultural awareness and diversity, along with educating clinical staff about the unique health needs of SGM populations. A prime example of culturally responsive care is Christiana Care's provider

Figure 1. HIV care continuum in the United States. Abbreviation: ART, antiretroviral therapy



referral listing for MSM and TGW, which includes both primary care providers and specialists that are trained to handle healthcare issues related to same-sex and transgender health.⁴⁸

HOW DOES EPIDEMIOLOGY ADDRESS THE HIV EPIDEMIC AMONG MSM AND TGW

The epidemiology of HIV among MSM and TGW in the United States has evolved over the past four decades. Assessments of infection patterns traditionally relied on HIV surveillance data to document the burden of the epidemic. The United States National HIV Surveillance system has characterized the epidemic since the initial cases in 1981.^{12,13} Initially used to count and describe cases of HIV/AIDS, the surveillance system has grown as the evidence and our understanding of the disease unfolded. In addition, syndromic surveillance (i.e., methods that rely on patterns of behavior and symptoms to detect HIV infection prior to a confirmed diagnosis) played a critical role in capturing information about “hidden populations” such as MSM and TGW who are at a greater risk for infection. For example, the National HIV Behavioral Surveillance system collects data of individuals who were marginalized and had the highest HIV incidence (e.g., MSM and PWID).⁵⁰ These surveillance systems allowed for the identification of high-risk groups, which can inform targeted interventions and resource allocation. As persons infected with HIV began to live longer due to earlier diagnoses and linkage to antiretroviral therapy, these national surveillance programs have evolved to capture a more complete spectrum of HIV-related exposures and outcomes; including behavioral, molecular (e.g., genetic data that is used to monitor HIV trends and drug resistance), and HIV-related morbidity data.⁵¹

Other traditional epidemiologic methods such as case-control and longitudinal cohort studies have been useful in understanding the underlying behavioral mechanism of HIV transmission among MSM and TGW. Thus, our understanding of HIV infection traditionally revolves around behavioral risk factors such as condomless anal intercourse.^{52,53} However, there is a growing body of evidence examining how sexual networks and the social determinants of health impact HIV infection among MSM and TGW.^{54–57} For example, TGW face higher levels of social marginalization, resulting from the underlying transphobia, which contribute to their vulnerability for infection. Stigma related to sexuality has also been reported to lower healthcare access, increased levels physical and sexual trauma, as well as higher rates of other sexually transmitted infections (i.e., chlamydia, gonorrhea, and syphilis).^{15,39,58,59} Therefore, engaging in rigorous epidemiologic methods allows a thorough assessment of the potential gaps in healthcare and HIV prevention services for MSM and TGW and determine appropriate points in the HIV continuum to intervene.

UNMET NEEDS AND CHALLENGES RELATED TO THE CURRENT EPIDEMIC

Recent work has pointed the major gaps in the response to the epidemic in relation to sexual diversity⁶⁰; however, translation of such work into programming have been slow. In addition, various key methodological issues remain a major concern for association studies.^{60,61} We, therefore, highlight current challenges in studies assessing HIV risk among SGM and future directions in which epidemiologic methods can be used to address these issues.

One of the major methodological challenges relates to the changing context and needs of SGM individuals such as accurately capturing the diversity of gender identity and sexual orientation among SGM across cultures and lifespan.⁶⁰ Current studies rely on data collection instruments that may have inappropriate use of language or reporting intervals for capturing low- and high-risk behaviors. In various subpopulations of racial, ethnic, and religious SGM, sexual activity among men is not commonly discussed and referred to indirectly.⁶⁰ The term “sex” may be reserved to describe activities that potentially lead to reproduction, and “sex with other men” may not elicit responses that include sex with transgender individuals.⁶⁰ This could lead to misclassification of the exposure and potentially bias HIV risk estimates. Current analytical techniques such as sensitivity analysis or Bayesian analysis are quite robust in assessing and adjusting for such biases; however, such methods remain underutilized in studies estimating HIV risk among MSM and other SGM populations.⁶¹ In addition, bias in sampling is often a problem because samples are often small and derived using non-probability sampling methods.⁶² SGM samples are rarely ever representative of the population and more prone to selection bias.^{62–64} Incorporating various advancements in epidemiologic techniques for sampling hard-to-reach populations will be vital to produce accurate HIV risk estimates and determine mechanisms in which prevention strategies can intervene.^{65,66}

There are also several limitations with the use of surveillance data when assessing the magnitude of the HIV epidemic, particularly for SGM who are racial/ethnic minorities. Individuals captured through surveillance only include those that have been diagnosed and reported to a surveillance system. For example, CDC estimates that NHSS data are representative of 80% of all HIV cases in the United States.⁶⁷ Establishing cohorts that follow high risk groups such as young, Black MSM may allow researchers to better characterize risk behaviors, social and sexual networks, as well as allow for more rapid diagnosis of incident infections and thus preventing ongoing transmission.⁶⁸

Overall, there is a need to develop data collection instruments with increased sensitivity and specificity. One potential avenue is for national surveys to use language that can accurately assess sexual orientation and behaviors, as well as be familiar and inclusive of transgender individuals. In addition, better strategies to engage hard-to-reach SGM such as those geographically isolated, non-gay identified men, and racial/ethnic minorities are needed to enumerate HIV cases as well as provide targeted and appropriate interventions. Part of this work will require the development of methods in the context of the prison system as well as clients and sex partners of sex workers. Therefore, epidemiologic methods are crucial in accurately informing responses to the HIV epidemic.

CONCLUSION

In conclusion, an epidemiologic perspective on public health practice and policy can be effective for identifying gaps in HIV medical care and social services among SGM. In addition to determining prevalence and factors associated to disease end-points, epidemiologic methods can be used to determine components associated with intermediate outcomes, for example medical care retention in the HIV care continuum. Results from these assessments can be used to direct future directions

for research and inform intervention strategies and policies. However, entities engaging in HIV research and practice often take place in their respective silos. Without collaboration across disciplines, HIV control and prevention for SGM will not be feasible. From an epidemiologic viewpoint, there is a need for providers and policy makers to: 1) improve their understanding of the factors that contribute to HIV infection among sexually and racially diverse communities, 2) recognize the existence of non-binary individuals and provide culturally sensitive and tailored healthcare, 3) collaborate across disciplines and organizations to improve delivery of medical services, and 4) engage in creative solutions that tackle the multiple levels of factors (individual, interpersonal, and structural) that influence HIV transmission and retention in HIV care. In Delaware, various healthcare and community-based organization have begun their efforts to improve medical and prevention services for SGM, such as Christiana Care's SGM health initiatives. Maintenance of prevention strategies will require capable leadership and long-term investment from key stakeholders throughout Delaware to ensure the health equity of individuals that long been marginalized.

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Highlights from the 89th Annual Meeting & Awards Ceremony

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Access to HIV Medication in the Community Versus a Nursing Home for the Medicare Eligible HIV population

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Abstract

Access to appropriate antiretroviral therapy (ART) is key to people living with HIV/AIDS (PLWH) living a near normal life time, which has resulted in increasing numbers of PLWH requiring nursing home care for age-related reasons. However, one study found that 21% of Medicare eligible PLWH in US nursing homes between 2011 and 2013 were not dispensed ART through the nursing home pharmacy. Cost-sharing assistance programs exist to facilitate access to medications for low-income community dwelling older adults, but these programs do not necessarily extend to people admitted to a nursing home, which may cause interruptions in access to ART for PLWH in this setting. Policies may need to be updated to reduce drug-related financial burden to PLWH and nursing homes in order to maintain continued access to ART in the nursing home setting.

Access to appropriate antiretroviral therapy (ART) is key to people living with HIV/AIDS (PLWH) living a near normal life time, which has resulted in increasing numbers of PLWH requiring nursing home care for age-related reasons. However, one study found that 21% of Medicare eligible PLWH in US nursing homes between 2011 and 2013 were not dispensed ART through the nursing home pharmacy¹. Admission to a nursing home may interrupt already existing coverage for ART and/or present medication-related financial burden to Medicare eligible PLWH or the nursing home to which they are admitted.

This article explores current statistics regarding Medicare eligibility for PLWH – including Medicare Part D drug coverage – followed by a review of assistance programs PLWH may be accessing to help cover out-of-pocket drug costs in the community. A discussion of a lack of similar programs in the nursing home setting highlights that there may be a need for new policies to mitigate cost sharing in the nursing home settings. Finally, suggestions of policies that could augment access to ART in the nursing home setting are presented. It is the aim of this article to inform consumers and nursing home stakeholders of the potential challenges related to ART access and associated financial repercussions that may take place as older, Medicare-eligible PLWH transition from community to nursing home residences.

PLWH ON MEDICARE

Medicare is a federally administered health insurance program, and the largest source of federal money for HIV health care.² There are three ways to become eligible for Medicare: age 65 or older, qualifying for disability status, and having end stage renal disease or Amyotrophic Lateral Sclerosis (ALS). A diagnosis of advanced HIV disease or AIDS is considered a disability. Disability status plus 24 months of Social Security Disability Insurance (SSDI) or Social Security Income (SSI) qualifies people less than 65 years old for Medicare, including PLWH. Currently, more than half of PLWH (56%) are insured by Medicare, of whom approximately 80% are disability-eligible; the rest are either Medicare eligible by age or end stage renal disease/ALS diagnosis.² Furthermore, 69% of Medicare eligible PLWH are dually eligible for Medicaid, a government insurance program for qualified low-income individuals, which is independently administered by each state.^{2,3}

Eligibility for Medicare is evolving for PLWH because longer life expectancy due to advances in treatment means PLWH are transitioning from being strictly disability-eligible for Medicare, to being age-eligible. One study showed that 15% of California's Medicare population of PLWH transitioned from disability to

age-eligibility between 2007 and 2010.⁴ It has also been reported that the number of PLWH age-eligible for Medicare doubled between 2000 and 2013; that number is expected to continue to grow as treatment advances and the population of PLWH continues to reach older ages.⁵ Additionally, 17% of incident HIV occurs among people aged 50 or older. Assuming ideal HIV care post diagnosis, this group will most likely age into Medicare eligibility rather than transition through disability eligibility.⁶ The CDC estimates that 70% of PLWH will be over age 50 by 2020.⁶

PRESCRIPTIONS FOR PLWH

One of the biggest financial challenges in caring for the Medicare population of PLWH is covering costs for HIV medications vital to survival. Medicare Part D is the primary source of coverage for HIV medications. However, HIV medications often have high cost-sharing and PLWH disproportionately lack financial supports.^{7,8} Cost-sharing relief programs exist for community dwelling older adults, some of which are specifically for PLWH. These programs are of particular interest to long-term survivors (PLWH diagnosed prior to the 1996 introduction of HAART⁹), who have often been exposed to several ART regimens over time, become treatment resistant and are forced to use newer more expensive drugs.¹⁰

PART D FOR PLWH

Medicare Part D was introduced in 2006 and is part of Medicare. This means that, unlike Medicaid, the requirements for the program are the same regardless of an individual's state of residence. Medicare beneficiaries must sign up for a Part D plan administered by a third party insurer, prove they have equivalent drug coverage and are eligible to decline Part D, or face penalties for late enrollment in the event they do not sign up during open enrollment. Part D plans differ in what drugs are covered and how much of the cost of that medication is covered making, it imperative that PLWH choose a Part D plan carefully to minimize out-of-pocket costs. Dual eligible individuals – eligible for Medicare and Medicaid – are automatically enrolled in baseline low-cost Part D plans, but can change their Part D plan during open enrollment.

Part D is mandated to cover at least 2 drugs in each of 6 protected drug classes, including antiretrovirals and HIV related pharmacotherapies. The amount of coverage for each antiretroviral can vary by Part D provider. In turn, medications may be covered, but as tier 3 or 4 or specialty drugs with high cost-sharing. It is also possible that certain drugs have restricted access through utilization management processes. Utilization management is a way of limiting access to certain medications to control costs and may include, but is not limited to, step therapy and prior authorization. Though HIV medications are not currently subject to prior authorization, there is legislation proposed in the Bipartisan Budget Act of 2018 to give Part D insurers more ability in fiscal year 2019 to implement such processes for drugs in protected classes, including antiretrovirals.¹¹

Clearly there are several variables governing the cost assumed by PLWH related to their HIV medications: the regimen prescribed, insurance coverage, or eligibility for cost-sharing assistance programs, to name a few. Increases in out-of-pocket costs may be a barrier to accessing ART. However, when out-of-pocket ART costs increased with the introduction of Part D in 2006, HIV medication adherence among Medicare eligible PLWH did not seem to be impacted.³ One likely explanation is that PLWH were taking advantage of medication cost-sharing assistance programs. Assistance programs ensure continued access to ART despite cost-sharing that PLWH may not otherwise be able to afford.

EXAMPLES OF PRESCRIPTION COST-SHARING AND COVERAGE ASSISTANCE

MEDICAID AND EXTRA HELP DRUG COVERAGE

Where Medicare is the source of the greatest federal funding for PLWH, Medicaid – the joint state and federal low-income insurance – is the largest source of health coverage for PLWH. All states voluntarily offer Medicaid outpatient drug coverage.¹² Drug coverage is provided through Medicare Part D and pricing determined by each state's unique Medicaid formulary.¹³ Regardless of state of residence, Medicaid eligible people are automatically qualified for an additional federal program, Extra Help, also known as the Part D Low-income Subsidy. This program can provide full or partial cost-sharing assistance, depending on income.

Extra Help offers alternative copayments (full program) and/or a 15% coinsurance (partial program). In addition to reducing prescription costs, this program can also pay for Part D premiums up to an amount determined by each state (\$29.98 in Delaware) and remove Part D late enrollment penalties.¹⁴ Extra Help enrollees are still responsible for prescription copayments, however will pay the lower of the two copayments/coinsurance between Extra Help or Part D, until they reach the Part D coverage gap. Once in the coverage gap, individuals are responsible for full drug costs according to Part D coverage. Once the out-of-pocket maximum has been reached, full Extra Help coverage eliminates drug costs, and partial coverage reduces copayments to equal those offered to full Extra Help enrollees prior to the coverage gap.¹⁵

If a person does not qualify for Medicaid based on income, but has healthcare costs including prescriptions which deplete their monthly income to the point where they would otherwise qualify, there exist Medicaid Medically Needy Programs in select states. Delaware does not have a Medically Needy Program.¹⁶ Many of the people in this program are living in nursing homes, and by depleting assets through cost of medical care become eligible for Medicaid and subsequently Extra Help.¹⁶ Other programs, including Programs of All-Inclusive Care for the Elderly (PACE), Medicare Advantage Special Needs Plans, and Medicare Savings Plans provide varying degrees of healthcare cost-sharing assistance, specifically for Medicare Part A and B premiums. However, all rely on Part D and Extra Help eligibility to determine drug coverage and copayment amounts as outlined above. Qualifying for Extra Help in 2019 requires an individual's income to be at or below 114% of the federal poverty level, or \$14,390 annually.¹⁷ Additionally, enrollment in either Extra Help or Medicaid requires annual re-application.

AIDS DRUG ASSISTANCE PROGRAM (ADAP)

Specific to PLWH, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 has several parts that, combined, provide access to HIV/AIDS related primary medical care and support services across the United States and related territories. Part B of the Ryan White CARE Act includes funding for the AIDS Drug Assistance Program (ADAP), which is provided to all states and territories based on a calculation weighted by reported cases of PLWH/AIDS in the designated area.¹⁸ Though ADAP funds can be used to purchase health insurance and provide services for improved access and adherence to HIV medications, it is most known for acting as a payer of last resort, helping to provide FDA approved HIV medications to low-income PLWH lacking adequate drug coverage. Each ADAP is independently operated by the state or territory. More than 500,000 PLWH are served by ADAPs and the majority have some insurance, but need ADAP funds to off-set out-of-pocket costs such as copayments.¹⁹ Specific eligibility criteria are determined by each state or territory and must be only for those that prove, every 6 months, both residency in the designated catchment area and financial and medical need. Financial need is often defined as a percent of the Federal Poverty Level and medical need is based on the presence of a HIV diagnosis. Each ADAP covers at least one drug from each category of HIV medications and independently governs distribution of the covered medications to community dwelling PLWH.²⁰

340B DRUG PRICING PROGRAM

One of the reasons ADAPs are able to provide low cost medications is due to their eligibility for the 340B Drug Pricing Program.¹⁹ This program was initiated in 1992 to bolster hospitals and clinics serving low income clients. Pharmaceutical manufacturers that participate in Medicaid must offer 340B eligible clinical sites prescription drugs at a cost lower than the Medicaid reimbursement rate. Cost of acquiring medications for the facility is thus much lower than it would be if the facility was not 340B eligible. The money that the clinical sites save was meant to be returned to the healthcare system in order to alleviate some of the debt incurred by serving low-income clients that otherwise could not afford healthcare. The discounted medications are reserved for outpatients that are regular clients of the eligible facility.^{19,21} Notably, ADAPs only provide medications and not healthcare, but are exempt from this requirement. Unfortunately, the unintended consequence of 340B drug pricing is that the money the facility saves on the cost of acquiring drugs does not always translate into reduced copayments for people seeking care at a 340B clinical site.²¹

MANUFACTURER COST-SHARING AND PATIENT ASSISTANCE PROGRAMS

Many drug manufacturers offer cost-sharing assistance or patient assistance programs to under insured or uninsured individuals for their HIV medications. Cost-sharing assistance programs offer financial assistance with copayments, coinsurance, and deductibles. Eligible individuals have commercial insurance, but are unable to cover the cost-sharing for HIV medications. These programs are not available to anyone receiving medication coverage through government programs such as Part D, which would often serve the population aged 65 and older. Each cost-sharing assistance program is unique to the company and provides cost-sharing assistance up to specified monthly or annual amounts.^{22,23}

Patient assistance programs are also offered through drug manufacturers and are targeted at helping the uninsured, people who do not qualify for insurance such as Medicaid, Medicare, or ADAP or are eligible, but on an ADAP waiting list. There is a universal application for these types of drug cost assistance programs that can be submitted to each individual program of interest. There are also several resources available to navigate the wide variety of patient assistance programs, such as RxAssist²² or HarborPath, which specifically operates the ADAP waitlist patient assistance program.²³ Like cost-sharing assistance programs, patient assistance programs are unique to the companies offering them and may not apply to people with Part D drug coverage.^{22,24}

PRESCRIPTIONS IN THE NURSING HOME SETTING

Between 2011 and 2013 there were approximately 7,500 Medicare eligible PLWH residing in nearly half of US nursing homes, 93% of whom were dually eligible for Medicaid.¹ During the first 90 days of a nursing home stay after a qualified hospital stay, healthcare, including prescriptions, are covered by Medicare Part A. When the Part A covered care is for a person with an AIDS diagnosis, facilities are eligible for an AIDS adjustment, a 128% add-on to their usual reimbursement, to better cover

the costs associated with caring for a PLWH.²⁵ After the 90 days expire, prescription coverage for most Medicare eligible PLWH in US nursing homes is through Medicare Part D or equivalent coverage (e.g. Retiree Drug Subsidy related plan, henceforth collectively referred to as Part D), and depends on the nursing home pharmacy contracting with the residents' specific Part D plan. If the pharmacy does not contract with the Part D provider, the individual has the opportunity to change Part D providers. Changing Part D providers is allowable upon admission to the nursing home, once a month while in residence, and once within two months after discharge from the nursing home. Copayments, deductibles and premiums remain the responsibility of the nursing home resident unless they are also eligible for Medicaid (dual eligibility).

Cost-sharing for Part D covered drugs for qualified dual eligible individuals residing in a nursing home for 30 or more days should be fully subsidized. For other medications, the Extra Help program still applies while residing in a nursing home, however other cost-sharing assistance programs do not.²⁶ The manufacturer cost-sharing assistance and patient assistance programs are only available for community dwelling individuals and Ryan White legislation views residence in a nursing home as inpatient status. Inpatient status precludes use of ADAP funds. If the Part D provider does not cover a drug or the out-of-pocket for the drug is beyond the ability of an individual to pay, there is also an exceptions process where individuals can petition the Part D plan to cover or lower the cost of the drug needed. During this process a Part D plan is required to provide an emergency 31 day supply of the medication.²⁷ In the event that a nursing home resident can not get drugs covered by their plan provider, nursing homes should still provide the needed medication, but are allowed to bill residents separately for dispensing the prescription.²⁶ In each of these instances the patient becomes responsible for higher out-of-pocket costs than they would have incurred outside the nursing home due to a lack of available cost-sharing assistance programs.

PLWH are often mitigating out-of-pocket drug costs through programs like those mentioned above. This ensures their continued access to ART and viral suppression. In the event of admission to a nursing home, there is potential for interrupted access to these necessary medications due to reduced availability of assistance programs. For example, if a person relies on ADAP for access to ART medications and is then admitted to a nursing home, they must find new means by which to cover HIV medications. Additionally, CMS has acknowledged and attempted to address the issue of dual eligible individuals admitted to a nursing home incorrectly being billed with copays that they otherwise would not have to pay in the community setting.²⁸ If PLWH are accessing assistance programs to cover out-of-pocket costs related to HIV medications prior to admission to a nursing home, there is no reason to believe the financial need would change upon admission.

With less cost-sharing assistance available to nursing home inpatients, nursing homes may be at risk for incurring debt related to unpaid medication costs. In the event that nursing homes provide HIV medications in a timely manner after someone is admitted, avoiding gaps in medication, they may dispense the drug before checking if the drug is covered by a residents' Part D coverage. If PLWH are unable to afford the subsequent bills,

the facility must absorb the costs related to the medications. Evidence suggests there may also be instances of Part D plans do not cover an emergency drug supply and placing a cost burden on the nursing home. One report mentioned this type of debt represents one percent of a long-term care pharmacy's revenue.²⁹ This is particularly a problem given the high cost of acquiring and dispensing HIV drugs.²⁹ The risk of high cost burden related to HIV medication dispensing may incentivize nursing homes to refuse admission to PLWH. A relative dearth of information regarding costs incurred by nursing homes related to unpaid HIV medication cost-sharing by residents presents an opportunity for future research.

OPTIONS FOR REDUCING HIV DRUG COSTS TO NURSING HOMES AND RESIDENTS

If it is, in fact, the case that nursing homes are at undue risk for HIV medication related debt, one solution may be to extend the 340B Drug Pricing Program to include nursing homes and their respective pharmacies. Currently nursing homes do not qualify for this program, despite their disproportionately low-income patient population, for two reasons: (1) nursing home residents are considered inpatients and (2) the majority of nursing homes are for-profit institutions.³⁰ Exceptions to the rule have been made in the past, such as allowing ADAPs to acquire drugs through 340B, despite the fact that they do not provide healthcare services.

ADAPs assist in drug coverage by design and nursing homes do not. Nursing homes dispense drugs by design and their for-profit status makes them averse to financial risk, including that related to acquiring and dispensing drugs. To that end, one hesitation to expand the 340B program to include nursing homes may stem from their often for-profit status: money saved on medications may be perceived as revenue rather than as a means for low-cost or fully subsidized ART dispensing in this setting. Another concern may be that expanding 340B eligibility could encourage drug manufacturers to increase drug prices more quickly, in an effort to save profits, particularly in the case of HIV medications which are generally high cost and rising.^{10,21} Monitoring how 340B savings are returned to the healthcare system could squelch some of these concerns, but there are currently no agencies responsible for monitoring what 340B eligible facilities do with saved money.²¹ Nursing homes are unique in that there already exists a mandated system of reporting nursing home quality to the government. Including 340B revenue assessments in the existing quality evaluation structure may be one option to address the lack of oversight and assuage anxieties related to expanding the legislation to such for-profit institutions.

Another option to diffuse medication-related costs incurred by a nursing home is to expand ADAP. Allowing similar coverage of copayments and cost-sharing for individuals residing in nursing homes as are offered to outpatients would minimize potential interruptions in care for the more than half a million individuals that currently rely on ADAPs for HIV medications.

CONSIDERATIONS FOR DELAWARE

As of 2015, Delaware has a population of 944,076, of which 3,230 are living with HIV and 18.1% are aged 65 or older.^{31,32}

As of 2013, Delaware contains less than 7% of the population of PLWH residing in nursing homes, but still has more PLWH in nursing homes than 19 states and the District of Columbia.¹ Most PLWH reside in the south, the census region in which Delaware is included.³³ Southern nursing homes care for more PLWH than nursing homes in any other census region, making it particularly imperative for southern states to assess policies related to ART access in nursing homes.¹

PLWH in Delaware currently utilize many of those cost-sharing assistance programs described above, as well as the Delaware Prescription Assistance Program (DPAP).³⁴ Specifically, DPAP is funded by a tobacco settlement and reduces copays to \$5 or 25% of a drug's cost for people ineligible for Medicaid or lacking health insurance. Also, Delaware received \$6.1 million dollars in Ryan White funds in fiscal year 2016.³¹ The primary payer for nursing home care, Medicaid, is called Diamond State Health Plan in the state of Delaware. It paid for 61.2% of nursing home care in 2017 and an individual's income can be no more than \$1,927.50 per month in order to qualify.³⁵ Furthermore, it can be inferred that if 84.9% of admissions to any nursing home in Delaware in 2017 were 65 years or older and Medicaid paid for more than half of nursing home care, many people in Delaware nursing homes were dual eligible for Medicare and Medicaid.³⁶ Medicaid eligibility is an automatic qualifier for the federal Extra Help program, which, along with ADAP and pharmaceutical company cost assistance programs, can help PLWH access ART. However, as described earlier, many of these programs no longer apply once admitted to one of the 46 Delaware nursing homes that were at nearly 90% occupancy in 2017.³⁶

CONCLUSION

Cost-sharing assistance programs exist to facilitate access to medications for low-income community dwelling older adults, some of which are specific to PLWH. However, these programs do not extend to people admitted to a nursing home, which may cause interruptions in access to ART for PLWH in this setting. Utilizing existing infrastructure to expand or amend drug cost reduction programs might provide one solution to this issue. Otherwise, current policies may be incentivizing nursing homes to refuse PLWH admission on the grounds of high drug-related financial risk. It is an ideal time, while the population of PLWH in nursing homes is still relatively small, to proactively consider how we maintain seamless access to ART without undue financial burden to PLWH or nursing homes.

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COMMUNICABLE DISEASE – LEXICON OF TERMS

Antimicrobial stewardship

A system-wide effort to educate prescribers of antimicrobials (antibiotics) to follow evidence-based prescribing, in order to stem overuse of antibiotics (which can lead to antibiotic resistance).

Antiretroviral

A medication that works against retroviruses (i.e. HIV)

Bayesian Analysis

a statistical procedure which tries to estimate an underlying distribution based on the observed distribution (e.g. based on a study population's observed incidence, what would the incidence in the entire population be?)

Broad Spectrum Antibiotics

Agents effective against both Gram positive and Gram negative bacteria.

Cavitary Pulmonary Tuberculosis

When the disease is advanced enough to carve out necrotic areas (cavities) in the lung.

Hepatology

The study of the liver, biliary tree, the gall bladder, and the pancreas.

Herd Immunity

The resistance to the spread of a contagious disease within a population that results if a sufficiently high proportion of individuals are immune to the disease, especially through vaccination.

Immunization

The process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine.

Narrow Spectrum Antibiotics

Agents effective against specific families of bacteria.

Necroinflammatory

A process which results in both necrosis (dead tissue) and inflammation, especially in the liver.

Oncogenic

Cancer causing.

Oropharyngeal

Relating to the mouth and top of the throat.

Pathology

The study of the causes and effects of diseases, especially the branch of medicine that deals with the laboratory examination of body tissue for diagnostic or forensic purposes.

Pathogenesis

How a disease develops.

Recidivate

To go back to bad behavior. The recidivism rate is the tendency of a convicted criminal to re-offend.

Respiratory Papillomatosis

A rare condition in which benign (non-cancerous) tumors form along the air passageways (mouth, throat, trachea, etc).

Retrovirus

Any of a group of RNA viruses which insert a DNA copy of their genome into the host cell in order to replicate, e.g. HIV.

Seroprevalence

The level of a pathogen in a population (usually measured by blood tests)

Sustained Virologic Response (SVR)

No hepatitis C virus (HCV) can be found in blood in the 24 weeks after completing a course of hepatitis C treatment. SVR very likely means that a patient has been cured.

Tuberculosis

An infectious bacterial disease characterized by the growth of nodules (tubercles) in the tissues, especially the lungs.

Vertical Transmission

The passage of a disease causing agent from mother to baby, in the period immediately before and after birth.

COMMUNICABLE DISEASE – RESOURCES

Communicable Disease Statistics

This spreadsheet, from the County Health Rankings website, provides state and county level communicable disease data.

<http://www.countyhealthrankings.org/using-the-rankings-data/finding-more-data/delaware>

Immunization Action Coalition

The Immunization Action Coalition (IAC) works to increase immunization rates and prevent disease by creating and distributing educational materials for healthcare professionals and the public that enhance the delivery of safe and effective immunization services.

<http://www.immunize.org>

Immunization Coalition of Delaware

This website provides information to the public and health care providers about vaccine-preventable diseases and immunizations.

<http://www.immunizedelaware.org/>

National Centers for Infectious Disease (CDC)

Includes the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), and the National Center for Immunization and Respiratory Diseases (NCIRD).

<https://www.cdc.gov/ddid/centers.html>

Office of Infectious Disease Epidemiology

All Delaware physicians, laboratories, and other health care providers are required by law to report certain communicable diseases. Both lab-confirmed and clinical diagnoses are reportable.

<https://dhss.delaware.gov/dhss/dph/dpc/rptdisease.html>

Vaccines and Immunizations (CDC)

The Centers for Disease Control and Prevention main website for information about vaccines and immunization.

<https://www.cdc.gov/vaccines/index.html>

Index of Advertisers

APHA's 2019 Annual Meeting and Expo	5
American Public Health Association	
The DPH Bulletin Special Issue May 2019	11
Division of Public Health, Department of Health and Social Services	
AAHD Call To Action	28
American Association on Health and Disability	
DJPH Submission Information	44
Delaware Journal of Public Health	
The DPH Bulletin May 2019	45
Division of Public Health, Department of Health and Social Services	
The Consequences of Medication Nonadherence are Stacking Up	48
Quality Insights	
Help Your Patients Help Themselves	49
Quality Insights	
Trauma Informed Delaware	59
Trauma Delaware	
The Nation's Health - May 2019	63
American Public Health Association	
Highlights of The 89th Annual Meeting	71
Delaware Journal of Public Health	
Save the Date - John Scholz Stroke Education Conference	79
John H. Ammon Medical Education Center Christiana Hospital	



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The Delaware Academy of Medicine is a private, nonprofit organization founded in 1930. Our mission is to enhance the well being of our community through medical education and the promotion of public health. Our educational initiatives span the spectrum from consumer health education to continuing medical education conferences and symposia.

The Delaware Public Health Association was officially reborn at the 141st Annual Meeting of the American Public Health Association (APHA) held in Boston, MA in November, 2013. At this meeting, affiliation of the DPHA was transferred to the Delaware Academy of Medicine officially on November 5, 2013 by action of the APHA Governing Council. The Delaware Academy of Medicine, who's mission statement is "to promote the well-being of our community through education and the promotion of public health," is honored to take on this responsibility in the First State.