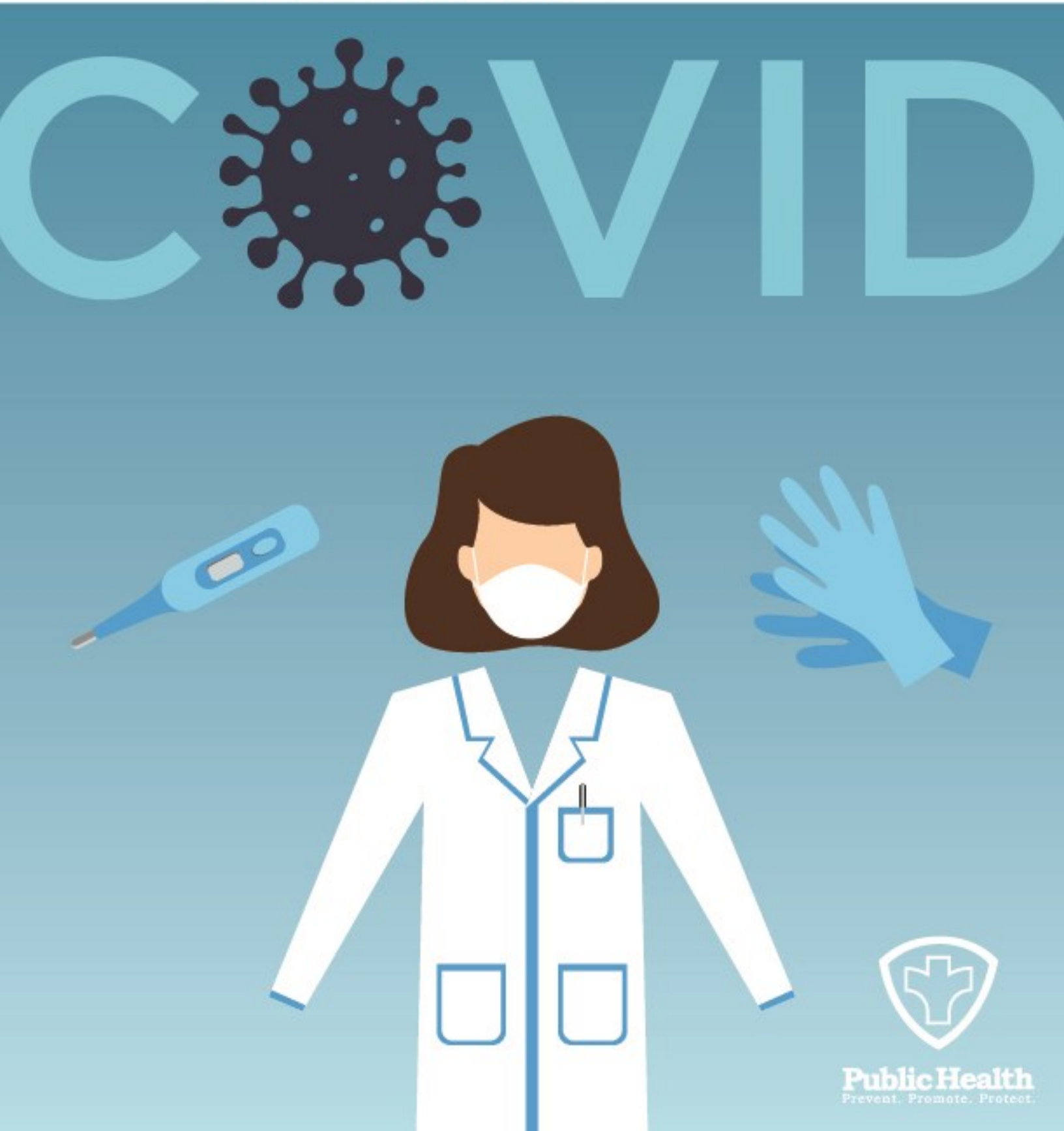
OJPH
Ohio Journal of Public Health
Ohio Public Health Association

Vol. 3, Issue 1
June 2020



OJPH
Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

TABLE OF CONTENTS

COVER CREDITS:
Kevin Murray, OSU BS Design 2019, Graphic Designer

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

EDITORIAL

Public Health in 2020

Amy Ferketich, PhD
The Ohio State University, College of Public Health, Columbus, OH

I would like to start as I usually do with a welcome to the latest issue of the *Ohio Journal of Public Health* (*OJPH*). Most papers in this issue were submitted to the Journal in December 2019, which seems like a lifetime ago. Can we remember December 2019? Back then, many of us had never heard of coronaviruses, much less the novel coronavirus that causes the coronavirus disease 2019 (COVID-19) ailment. The first reported cases in the United States were early in January 2020 and soon the disease became the focus of media attention. I taught *Introduction to Global Public Health* during spring semester and each week one of the students posted on a discussion board a public health news article to review in class. This activity started mid-January and *only* during the first week did a student chose an article *not* related to COVID-19. Back in January it was difficult to imagine that a few cases would lead to a worldwide pandemic. Yet here we are, 6 months later with no end in sight. Three op-ed pieces in this issue were submitted in response to COVID-19. Berman and colleagues wrote a highly informative piece that answers for a general audience many of the questions about what the government *can* do to regulate activity during a pandemic and about the balance between public health protections and individual rights. This excellent piece should be shared widely with our colleagues in schools and public health programs and with those working in public health practice. The second op-ed was written by current and former doctoral students at The Ohio State University (they make this teacher proud!). In this piece, Orellana and colleagues call for educators to use open access public health data produced in response to COVID-19 to teach students data analysis techniques, while reflecting on the ethics of collecting such data, and recognizing the limitations of open access data. Finally, in the third op-ed, Connell informs us of the vulnerable cancer patient population that was greatly affected in hospitals around Ohio. For numerous reasons, people with cancer were adversely impacted by COVID-19. Yet COVID-19 provides an incentive to strengthen infection-control measures in hospitals, which can hopefully help to prevent hospital-acquired infections in the future.

Two research articles in the current issue focus on breastfeeding among Ohio women. Knippen et al interviewed women who had gestational diabetes and examined breastfeeding duration and satisfaction. They report that mothers with gestational diabetes need more support to promote breastfeeding, support which could come in the form of education about the benefits and expectations of breastfeeding. In the second paper on breastfeeding, Furman et al reported results from the Ohio First Steps for Healthy Babies program administered by the Ohio Department of Health and the Ohio Hospital Association. They found that, overall, breastfeeding rates increased in Ohio between 2015 and 2018, with no difference between women who gave birth at hospitals that participated in the program and those that did not. However, when they examined data from the 17 hospitals that were the first to participate, greater engagement in the program was associated with significantly higher rates of breastfeeding. These promising results suggest that the program could have benefits for child health in the future.

The remaining 3 papers in this issue include a research brief by Vallabh et al about the dangers of e-cigarettes for children. Using national data, they found that most e-cigarette injuries that result in emergency department visits are due to ingestion of e-liquid or explosions. Tuiyott et al wrote a public

health practice paper that presents information about a web application designed to report overdose death data. Using the R Shiny package, a free statistical software environment, they created a data-visualization tool that presents Butler County overdose death data in various ways that are useful for public health practitioners. Finally, Kroustos and colleagues wrote a commentary about the benefits of horticulture therapy for adults with dementia. I encourage you to read the piece because they report that such therapy has benefits that can impact all of us through its ability to stimulate the senses, promote physical activity, and reduce stress. While we are physically distancing due to COVID-19, gardening is an activity that can be performed rather safely.

Most importantly, COVID-19 has underscored how intergenerational, structural racism is driving health inequities—including increased COVID-19 infections and deaths—among Black people in the United States.[1] Beyond COVID-19, the recent, brutal killings of Ahmaud Arbery, Rayshard Brooks, George Floyd, Tony McDade, Breonna Taylor, and too many others have sparked a national wave of outrage and calls for urgent action to address systematic racism as a driver of social and health inequities. Robert Jennings, President of the Ohio Public Health Association, stated: "The Ohio Public Health Association realizes there is plenty of work to do and asks all its partners to join forces in seeking equality and justice for all Ohioans. Let us together tear down the oppressive walls of institutional racism and begin building a better community where all have an equitable opportunity to freely breathe."[2] To this end, cities and counties across Ohio have declared racism a public health crisis. The autumn issue of the *Ohio Journal of Public Health* will present research, public health practice, educational efforts, and policy approaches that address racism as a public health crisis in Ohio (please see the call for submissions on our website: https://ohiopha.org/ojph/).

I once again thank the public health practitioners, researchers, and students who made important contributions in this latest issue of the Journal. I am also grateful to the members of the Editorial Board, which is comprised of public health leaders, scholars, educators, and students who are working tirelessly to make a difference in the lives of the millions of people who live in Ohio. Through this important work, we continue to promote the Ohio Public Health Association as the "voice" of public health in Ohio.

REFERENCES

1. Yearby R, Mohapatra S. Law, structural racism, and the COVID-19 pandemic. *Journal of Law and the Biosciences.* doi:10.1093/jlb/lsaa036

2. OPHA statement on the death of George Floyd. Accessed June 23, 2020. https://ohiopha.org/opha-statement-on-the-death-of-george-floyd/

Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

LETTER/OP-ED

Law and Ethics During a Public Health Crisis

Micah L. Berman, JD[1,2,3]; Patricia J. Zettler, JD[2,3]; Efthimios Parasidis, JD[1,2]
[1]College of Public Health, The Ohio State University, Columbus, OH
[2]Moritz College of Law, The Ohio State University, Columbus, OH
[3]OSU-James Comprehensive Cancer Center, The Ohio State University, Columbus, OH
Corresponding Author: Micah L. Berman, 1841 Neil Avenue, Columbus, OH 43210, (614) 688-1438, berman.31@osu.edu
Submitted June 5, 2020 Accepted June 16, 2020

Can the government do THAT? Can it shut down businesses, close schools, and limit travel? And what about our RIGHTS? Our rights to assembly, travel, religious freedom, and more?

As experts in public health law, we have been inundated with questions like these—from colleagues, students, public health practitioners, the press, and others—about the scope of the government's authority during the cornonavirus disease (COVID-19) pandemic. The pandemic, and the government's response to it, has upended all of our lives, albeit in different and unequal ways. The pandemic also has vividly highlighted the broad discretion the law grants to state governments to promote and protect the public health. This intersection of law and public health is far more nuanced than most people realize.

Beyond authorizing broad public health measures, laws at the local, state, federal, and even international level shape: (a) our nation's capacity to detect new disease outbreaks locally and around the world; (b) the size, resources, and structure of the thousands of local health departments around the country that are now at the forefront of the emergency response; (c) conditions in congregate settings (such as nursing homes, prisons, churches, schools, and workplaces) that contribute to COVID-19's spread; (d) the availability and quality of health care and health insurance; (e) the process by which new diagnostics, therapeutics, and vaccines are developed, authorized, and accessed; and so much more. This is not at all unique to COVID-19. Dig just below the surface of any public health topic and you will find a wide range of underlying legal and ethical issues.

Core to the field of public health law is balancing public health and individual rights. Even in emergency situations, individual rights must be respected, and restrictions must be based on the best available public health evidence. We have been troubled by governmental overreach during this pandemic, such as Ohio's effort to prohibit virtually all abortions within the state, using the need to preserve personal protective equipment (PPE) as the justification. To date, the courts have blocked this rule from taking effect, recognizing that delaying abortions until later in pregnancy is likely to result in procedures that are more dangerous and consume *more* PPE.[1]

At the same time, we have also been troubled by the use of "rights" language to express what are essentially policy objections to public health measures, not serious legal claims. Even our most cherished constitutional rights, including our freedoms of speech and religion, may face reasonable restrictions. For example, in refusing to block a California order limiting church attendance to prevent the spread of COVID-19, Chief Justice John Roberts recently explained that "[a]lthough California's guidelines place restrictions on places of worship, those restrictions appear consistent with the Free Exercise Clause of the First Amendment."[2] Claiming an unlimited "right" to refuse to wear a mask or to operate one's business or organization in ways that endanger others does nothing to advance the serious and nuanced discussions we need to be having about what restrictions are appropriate and necessary under the circumstances. It instead exacerbates societal and political divisions.

In the seminal case of *Jacobson v. Massachusetts* (1905), the Supreme Court said:

> There are manifold restraints to which every person is necessarily subject for the common good. On any other basis, organized society could not exist with safety to its members. . . . Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.[3]

In other words, as Ohio's pandemic-era slogan goes, we are all "In This Together." Public health law has long recognized that individual rights are exercised in the context of populations, and the "freedom" to be harmed by others is an illusory freedom.

To be clear, a government's exercise of its broad public health powers can infringe upon legally protected rights. But the application of constitutional and other legal constraints to particular cir-

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

cumstances is often subject to interpretation, and, especially in emergency contexts, this typically results in courts granting government decision makers a great deal of discretion. In the absence of clear legal guideposts, officials must exercise sound judgment to limit, as much as possible, untoward intrusions on individual liberties. The statement in the *Jacobson* case was used by the Supreme Court to permit forced sterilization and sanction eugenic policies during the first half of the 20th century, showing that courts have (and likely still do) uphold as legal that which is clearly unethical. Even today, the law does not specify what information officials must consider when enacting public health laws, either during a time of emergency or otherwise, leaving it to policymakers to exercise their own judiciousness.

Guidance on how best to balance benefits, burdens, and risks of specific activities may be found in fundamental tenets of public health ethics. These ethical principles include distributive justice (ensuring that burdens, risks, and benefits are distributed fairly amongst the population); necessity and least infringement (examining whether there are alternative ways to achieve the desired public health goals that infringe on the smallest possible number of people in the least possible way); proportionality (continuously monitoring restrictions to track whether the anticipated benefits are manifest and outweigh the infringed rights); and public justification (explaining to constituents in a transparent and clear fashion why infringements are necessary to achieve public health goals).[4] Taken together, although public health law allows for broad restrictions of individual liberties when disease poses an imminent threat to the public, the foundational principles of public health ethics help guide what restrictions are appropriate.

A contemporary synthesis of public health law and ethics must be mindful of public health's checkered history. For example, virtually every major infectious disease outbreak in our nation's history has been accompanied by racial, ethnic, or religious minorities being blamed for its introduction or spread. Public health officials have sanctioned research protocols that disproportionally impacted the poor, racial and ethnic minorities, and the disenfranchised. Groundbreaking vaccines—including vaccines to protect against polio, measles, and hepatitis—were tested on institutionalized children without obtaining informed consent. In far too many instances, the coercive power of the state has been used in punitive ways that did not advance—and often impeded—an effective public health response. These transgressions have caused long-lasting resentment and mistrust toward public health officials. Moreover, constitutionally permissible public health policies can stigmatize or otherwise harm certain populations—as was often seen, for example, in the government's response to the AIDS epidemic. For policymakers, the question must always be "not can we but should we."[5]

In our view, effectively advocating for public health requires meaningful training in public health law and ethics. Put simply, one's ability to advance population health outcomes will be limited without an understanding of the frameworks in which public health policy is made. The COVID-19 pandemic forced schools of public health across the country to quickly rework *how* they educate their students. We urge them to also take the opportunity to rethink *what* is being taught. We understand the difficulty in finding additional space in the curricula of undergraduate and graduate programs, but the overwhelming majority of public health practitioners whom we have talked to in recent months have remarked upon how they wish law and ethics had been a greater part of their education, because of its centrality to their work. Public health students do not need to be able to answer every legal or ethical question—they're training to be public health professionals, not lawyers and ethicists—but they need to know, in general terms, how law *can* be used to advance health, and how ethics and history inform the way that it *should* be used.

REFERENCES

1. Preterm-Cleveland v Attorney Gen. of Ohio, No. 1:19-CV-00360, 2020 WL 1957173 (SD Oh 2020).
2. South Bay United Pentecostal Church v Newsom, No. 19A1044, 590 US __ (2020).
3. Jacobson v Commonwealth of Massachusetts, 197 US 11 (1905).
4. Childress JF, Faden RR, Gaare RD, et al. Public health ethics: mapping the terrain. *J Law Med Ethics* 2002;30(2):170-178.
5. Bayer R. Stigma and the ethics of public health: not can we but should we. *Soc Sci Med* 2008;67(3):463-472.

Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

LETTER/OP-ED

An Opportunity for Future Public Health Professionals to Learn from Open Access COVID-19 Data

Robert C. Orellana, PhD, MPH[1]*; Angie Hetrick, MPH[2]; Shibani Chettri, MPH[2]; Zachary A. Weber, MS[2]; Sara Conroy, PhD[3]
[1]Bureau of Infectious Diseases, Ohio Department of Health, Columbus, OH
[2]College of Public Health, The Ohio State University, Columbus, OH
[3]Center for Biostatistics, Department of Biomedical Informatics, The Ohio State University, Columbus, OH
*Views of the author written here do not necessarily represent those of the employer.
Corresponding Author: Robert C. Orellana, 35 E. Chestnut, Columbus, OH 43215, (614) 477-6145, Robert.C.Orellana@gmail.com
Submitted June 13, 2020 Accepted June 23, 2020

In early 2020, the virus responsible for coronavirus disease 2019 (COVID-19), SARS-CoV-2, spread globally and was declared a pandemic by the World Health Organization (WHO).[1] During this time, Ohio has experienced widespread community transmission and, as of June 12, 2020, has reported 40 424 cases.[2] New partnerships quickly developed between health departments, schools, and programs of public health, medical, and research institutions, and the private sector, leading to increases in data collection and sharing.[3] Educators have an opportunity to use these data in the classroom to explore 3 critical skills for public health practice: (1) the appropriate use of open access, public health data, (2) the ethical considerations involved in balancing access with privacy and confidentiality, and (3) the recognition of data limitations.

Some health organizations have found ways to share their COVID-19 data publicly; for example, the Ohio Department of Health's COVID-19 dashboard has a de-identified data set updated daily.[2] These public data sets present opportunities to understand and interact with real data almost as quickly as it is collected.[4] Although the information provided is limited, it allows users to conduct descriptive epidemiologic analyses. Additionally, students could combine these data with other sources, like census bridged-race estimates, for more detailed analyses. Making public health data open access provides students the opportunity to apply their skills to real-world problems, potentially offering new and innovative insights.[4]

With increased availability of data comes the need to address privacy and confidentiality, which are essential to maintain the public's trust and protect citizen's rights.[4,5] For example, releasing data with more detailed information requires larger sample sizes so that individuals cannot be identified. Ethical considerations and legal implications are necessary to prevent breaches of personal identifiable information and ensure equitable use of data.[4] These should be taught alongside analytical approaches.

Public data limitations include changes in data collection processes and biases that are essential to understand when drawing conclusions from analyses. For example, incorporating changes of case definitions when describing incidence will help explain occasional increases in cases that might otherwise be attributed to increased disease prevalence. Restricting social factors protects identification of cases but inhibits evaluating how diseases exacerbate existing disparities, especially among vulnerable populations. The validity of interpretations and recommendations from limited publicly available data could be improved if students engage with subject matter experts from multiple areas, including health department staff.

The COVID-19 pandemic has emphasized the importance of public health while also addressing gaps in our field. The pandemic presents a unique opportunity for educators to prepare students for public health practice by teaching critical skills such as using publicly available data; understanding inherent ethical, confidentiality, and privacy issues; and identifying data limitations. Once students have been introduced to these skills, partnerships with health department experts can be used to better engage students for future careers including how to best communicate to the general public. It is our responsibility as public health professionals and advocates to inform the next generation of public health leaders of the best practices for using publicly available data.

REFERENCES

1. World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020. Published 2020. Accessed December 6, 2020. https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020
2. Ohio Department of Health. COVID-19 Dashboard. Accessed June 12, 2020. Published 2020. https://coronavirus.ohio.gov/wps/portal/gov/covid-19/dashboards
3. Infectious Diseases Institute at The Ohio State University. A Letter from the Director: The Infectious Diseases Institute partners with Ohio's Public Health Agencies to better understand and combat COVID-19. Accessed June 12, 2020. https://idi.osu.edu/news-articles/a-letter-from-the-director-on-covid-19

4. Edelstein M, Lee LM, Herten-Crabb A, Heymann DL, Harper DR. Strengthening global public health surveillance through data and benefit sharing. *Emerg Infect Dis*. 2018;24(7):1324-1330. doi:10.3201/eid2407.151830
5. Ienca M, Vayena E. On the responsible use of digital data to tackle the COVID-19 pandemic. *Nat Med*. 2020;26(4):463-464. doi:10.1038/s41591-020-0832-5

Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

LETTER/OP-ED

COVID-19 Impacts on Cancer Treatment—Nosocomial Infection, Therapy Disruption, and Research Application

Priscilla C. Connell, BS[1]
[1]Division of Environmental Health Sciences, College of Public Health, The Ohio State University, Columbus, OH
Corresponding Author: Priscilla C. Connell, 250 Cunz Hall, 1841 Neil Avenue, Columbus, OH 43210, (740) 277-8759, Connell.133@buckeyemail.osu.edu
Submitted May 16, 2020 Accepted June 28, 2020

One of the greatest ironies of health care is that the one place which ought to be a haven for the sick—the hospital—can also be one of the greatest threats to the sick. Sick patients with weakened immune systems walking into crowds is a recipe for a deadly threat: a nosocomial infection (also known as a health care-acquired infection). Nosocomial infection, caused by exposure to infectious agents in hospitals, has recently been brought into full play during the coronavirus disease 2019 (COVID-19) pandemic. The COVID-19 (SARS-Cov-2) has the potential for high rates of nosocomial infection; for example, an estimated 41% infection rate, including both health care workers and hospitalized patients, was observed before the virus and infection control was understood and implemented in the original Wuhan outbreak.[1] However, recent data indicate that adherence to infection control limits health care acquired infection. For example the health care workers most likely to be infected with COVID-19 were young (< 40 years of age) people who were not on the front line (with less stringent infection control), and the majority were infected during the first part of the epidemic, again before infection control was standardized.[2]

Nosocomial infection is an important issue in Ohio, as there are many large hospital systems that include treatment centers for cancer patients, who tend to be older and immunocompromised. Yu et al observed a higher rate of COVID-19 infection in patients with cancer in contrast to their observed cumulative incidence of COVID-19 (0.79% to 0.37%), and a higher risk of contracting COVID-19.[3] They theorized that this is because patients with hospital admissions and repeated hospital visits, such as cancer patients, are at a higher risk of COVID-19 infection, especially considering that less than half of the cancer patients were in active treatment. Further supporting the theory that cancer patients are at higher infection risk, a recent survey found that out of 85 cancer patients, 7 cancer patients had positive nasal swabs but were COVID-19 asymptomatic, and all eventually developed COVID-19 (5 were on active cancer therapy). The conclusion of this survey was that cancer patients should receive standard COVID-19 testing for infection control.[4]

Preventing COVID-19 infection for patients in cancer centers involves multiple prevention strategies. The National Comprehensive Cancer Network has a list of prevention strategies which include engineering controls intended to keep patients away from the COVID-19 virus. Their engineering controls include prescreening and screening patients for symptoms before in clinic visits, monitoring and limiting accompanying visitors/cohabitors, and ensuring that only essential visits are occurring. Their engineering controls also involve selecting cancer treatments which do not involve visits, maximizing televisits, and repeated testing of previously infected cancer patients before they come in for clinic visits.[5]

Infection control, although necessary, is causing a short-term disruption of cancer therapies due to the limitation of hospital visits necessary for therapy. Limiting hospital visits is halting the constant therapy cancer patients need to address their chronic condition.[6] Additionally, although the short-term effects of COVID-19 on cancer therapy are serious, the long-term impact of COVID-19 on cancer is another issue to monitor. For example, researchers at The Ohio State University are reviewing cancer screening and care within Ohio to see if COVID-19 decreased cancer screenings. Decreased cancer screenings threaten to leave cancers undiagnosed and thus increase the overall rate of cancer.[7] Another long-term impact of COVID-19 on cancer is the delayed development of novel cancer therapies in clinical trials. Infection control hampers the recruitment of new patients to trials, requires the suspension of current studies, and halts new studies, limiting the data available for cancer trials and delaying the development of drugs. Additionally, delayed hospital visits lead to a delay in recognizing cancer progression, adverse effects of the drug, and deaths which are related to COVID-19 infection, not cancer, which reduces the quality of the data in the studies. All of this occurs with staff and funding redirection to COVID-19, leading to a decrease in well researched new cancer therapies.[6]

The repercussions of the COVID-19 pandemic on cancer therapy and research are likely to continue even as stay at home orders lift and “normal life” resumes. It has been suggested that the hospitals which are the most successful at infection control do not have rigid

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

measures, but rather monitor, trace, and quarantine symptomatic employees, and enforce hand hygiene, limit patient visits, and use standard droplet control (gown, surgical mask, and gloves) when necessary.[8] Keeping this in mind, and the indications that the nosocomial spread of COVID-19 can be controlled, it is time to reevaluate the costs of short-term infection control strategies and ensure that they are not harming the long-term health of cancer patients. This will involve a balance of current infection control measures and innovative research methods to find the right measures to fully protect the health of this vulnerable population in Ohio. It is imperative that public health workers take what has been observed in COVID-19 and continue to apply prevention strategies as cancer research moves into a new era shaped by COVID-19.

REFERENCES

1. Wang D, Hu B, Hu C, et al. Clinical Characteristics of 138 hospitalized patients with 2019 novel coronavirus infected pneumonia in Wuhan, China. Preprint. Posted online February 7, 2020. *JAMA.* 2020;323 (11):1061-1069. doi:10.1001/jama.2020.1585
2. Lai X, Wang M, Qin C, et al. Coronavirus disease 2019 (COVID-2019) infection among health care workers and implications for prevention measures in a tertiary hospital in Wuhan, China. *JAMA Netw Open*. 2020;3(5):e209666. doi:10.1001/jamanetworkopen.2020.9666
3. Yu J, Ouyang W, Chua ML, Xie C. SARS-CoV-2 transmission in patients with cancer at a tertiary care hospital in Wuhan, China. Preprint. Posted online March 25, 2020. *JAMA Oncol.* 2020;e200980. doi:10.1001/jamaoncol.2020.0980
4. Al-Shamsi HO, Coomes EA, Alrawi S. Screening for COVID-19 in asymptomatic patients with cancer in a hospital in the United Arab Emirates. *JAMA Oncol*. Published online May 27, 2020. doi:10.1001/jamaoncol.2020.2548
5. Cinar P, Kubal T, Freifeld A, et al. Safety at the time of the COVID-19 pandemic: how to keep our oncology patients and healthcare workers safe. Preprint. Posted online April 15, 2020. *J Natl Compr Canc Netw.* 2020;1-6. doi:10.6004/jnccn.2020.7572
6. Saini KS, de Las Heras B, de Castro J, et al. Effect of the COVID-19 pandemic on cancer treatment and research. Preprint. Posted online April 24, 2020. *Lancet Haematol.* 2020;S2352-3026(20)30123-X. doi:10.1016/S2352-3026(20)30123-X
7. Ferenchik M. Coronavirus: Ohio State study to see if pandemic affected cancer treatment. *The Columbus Dispatch*. May 12, 2020. Accessed May 25, 2020. https://www.dispatch.com/news/20200512/coronavirus-ohio-state-study-to-see-if-pandemic-affected-cancer-treatment
8. Gauwande, A. News desk. Keeping the coronavirus from infecting health-care workers. NewYorker.com. March 21, 2020. Accessed June 13, 2020. https://www.newyorker.com/news/news-desk/keeping-the-coronavirus-from-infecting-health-care-workers

OJPH
Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

RESEARCH ARTICLE

Factors Associated with Breastfeeding Duration and Satisfaction after Gestational Diabetes among Women Living in Northwest Ohio

Kerri Lynn Knippen, PhD, RDN, LD, BC-ADM[1]; Natalie Walkup, MPAS, PA-C[2]; Cameron Burmeister, MD, MS[3]; Joseph Dake, PhD, MPH[4]; Kent Bishop, MD[2]
[1]Department of Public and Allied Health, Bowling Green State University, Bowling Green, OH
[2]ProMedica, Toledo, OH
[3]College of Medicine and Life Sciences, The University of Toledo, Toledo, OH
[4]School of Population Health, The University of Toledo, Toledo, OH
Corresponding Author: Kerri Lynn Knippen, 122 Health and Human Services Building, Bowling Green, OH 43403, (419) 372-8316, kknippe@bgsu.edu
Submitted November 13, 2019 Accepted May 8, 2020

ABSTRACT

Background: Given the potential for type 2 diabetes and the protective benefits of breastfeeding after gestational diabetes mellitus (GDM), there is a need to promote and support breastfeeding; however, delayed lactogenesis and postpartum experiences may challenge breastfeeding success. We aimed to describe factors that influence breastfeeding duration and satisfaction after GDM.

Methods: A cross-sectional survey, informed by an elicitation phase and subject matter expert review, was conducted to evaluate factors associated with breastfeeding satisfaction and duration after GDM. The study included women (n = 50) from Northwest Ohio who delivered a living child from a singleton pregnancy at greater than or equal to 34 weeks gestation, who intended to breastfeed after GDM. Spearman correlation and Mann-Whitney U test were calculated to evaluate factors associated with breastfeeding duration and satisfaction.

Results: Women described a lack of breastfeeding support, and there appeared to be a lack of awareness on the benefits of breastfeeding after GDM. Attitudes were associated with breastfeeding duration and satisfaction. Negative experiences in the child's first week of life were associated with shorter duration and lower level of satisfaction. Delayed lactogenesis, barriers after delivery, and negative normative influences were significantly associated with a lower level of breastfeeding satisfaction.

Conclusion: More work is needed to deliver breastfeeding education and support after GDM. Interventions tailored for GDM are recommended to promote positive breastfeeding beliefs and realistic breastfeeding expectations. Ongoing support to address early experiences and barriers after GDM is recommended. Further work should examine these factors in a larger, more diverse sample.

Keywords: Gestational diabetes mellitus; Lactation; Lactogenesis; Breastfeeding

INTRODUCTION

Approximately 7% to 12.5% of pregnancies in Ohio from 2009 through 2014 were impacted by gestational diabetes mellitus (GDM),[1] a condition characterized by high blood glucose in pregnancy that is not because of type 1 or type 2 diabetes.[2] Women with a history of GDM are at high risk for developing type 2 diabetes.[3] Taking this risk into consideration, there is a need to encourage modifiable health behavior that can reduce diabetes risk; one such behavior is breastfeeding.[4]

Breastfeeding can reduce maternal fat stores, improve weight loss, and lower the risk for diabetes after GDM.[5-8] The American Academy of Pediatrics recommends sustained breastfeeding for 6 months exclusively, with a total duration of at least 1 year.[9] Breastfeeding for a long-term duration (>10 months) can improve insulin sensitivity and glucose control after GDM;[6] however, even 1 month[8] to 3 months[4] of breastfeeding can reduce maternal diabetes risk. Data from the 2009-2010 Pregnancy Risk Assessment Monitoring System (PRAMS) illustrates that Ohio women with GDM were less likely to initiate breastfeeding compared to women without GDM (69.4% versus 74.2%), and a lower proportion of women with GDM were breastfeeding at 2 weeks post partum.[1] These differences require further attention, considering the benefits of breastfeeding after GDM.

There are many factors that may influence breastfeeding duration. Milk supply is a common reason for discontinued breastfeeding.[10,11] One concern that can compromise milk supply is delayed lactogenesis, defined as onset of milk production occurring beyond 72 hours post partum.[12,13] Existing work has demonstrated that breastfeeding self-efficacy is negatively influenced by delayed lactogenesis.[14] Without regard to GDM, women with delayed lactogenesis are more likely to discontinue breastfeeding.[15,16] For a variety of reasons, women with GDM are at risk for delayed lactogenesis.[17,18] While delayed lactogenesis has been cited qualitatively as a barrier to breastfeeding in the early postpartum period after GDM,[18] more work is needed to understand how lactogenesis influences long-term breastfeeding outcomes after GDM.

Although duration is an important outcome to consider, there is also a need to explore factors that influence maternal satisfaction.[19,20] In fact, breastfeeding duration and satisfaction, while related, are not the same[19] and both should be prioritized.[20] In studies not focused on GDM, early experiences (ie, skin-to-skin contact) are associated with duration of breastfeeding,[21] and the early use of mother's milk is correlated with maternal satisfaction.[22] Unfortunately, women with GDM have earlier initiation of pumping, opposed to feeding at the breast, and formula use.[23] It is unclear how these early experiences impact breastfeeding after GDM, especially with regard to duration and maternal satisfaction.

Theoretical frameworks are commonly used to evaluate volitional health behavior,[24] including breastfeeding.[25,26] An integrated behavioral model was selected for this study, as it incorporates constructs from a variety of theories, including the health belief model and the theory of planned behavior. These models have been used to understand breastfeeding duration[27,28] and satisfaction[29,30] in non-GDM studies. Integrated behavioral model describes the importance of reducing environmental constraints and barriers while addressing instrumental attitudes (beliefs about the behavior), experiential attitudes (feelings about the behavior and expectations), normative influences, and self-efficacy beliefs, as well as knowledge about the behavior, and prior experiences.[24,31]

Although knowledge,[27] positive beliefs,[28] self-efficacy beliefs,[29] and meeting breastfeeding expectations[30] have shown importance to understanding breastfeeding duration and satisfaction in non-GDM women, these factors are not well-described in women with GDM. A qualitative study of Vietnamese women with a history of GDM revealed a "fear of transmitting diabetes" to the infant from breastfeeding,[32] which represents a lack of knowledge. While it is not clear if women in the United States have similar beliefs, a qualitative study of low-income Ohio women with prior GDM identified gaps in knowledge related to breastfeeding after GDM.[33] Women were uncertain of the impact of glucose-lowering medications while breastfeeding.[33] Some women reported that had they known the benefits of breastfeeding after GDM, their decision to initiate or continue breastfeeding might have been different.[33] To that end, given the benefits of breastfeeding after GDM and the potential challenges identified, a better understanding of how breastfeeding duration and satisfaction are influenced is needed to inform future studies and breastfeeding interventions for GDM.

This study aimed to expand existing work on breastfeeding experience after GDM by exploring the impact of attitudes, self-efficacy beliefs, normative influences, early experiences, and barriers on breastfeeding satisfaction and duration. The study also aimed to determine whether breastfeeding satisfaction and duration are associated with delayed lactogenesis. We hypothesized that early experiences, delayed lactogenesis, and barriers to breastfeeding would be negatively associated with breastfeeding duration and satisfaction. We also hypothesized that attitudes would be positively associated with duration and satisfaction, while lower levels of self-efficacy, support, and knowledge would have a negative impact on breastfeeding duration and satisfaction.

METHODS

Setting and Design

A cross-sectional study was conducted to examine factors associated with breastfeeding duration and satisfaction after GDM among women who delivered in a Northwest Ohio urban hospital. The study included an elicitation phase to identify relevant themes that were used to inform a cross-sectional survey.

Participants

Women were eligible if they were 19 years of age or older, intended to breastfeed, and delivered a living child from a singleton pregnancy at greater than or equal to 34 weeks gestation. A partial waiver of authorization for use of protected health information was approved by the institutional review board to screen billing and medical record data to identify an eligible sampling frame. Written informed consent was obtained for the elicitation phase, and a consent information sheet was provided to those who participated in the cross-sectional survey.

Procedures

The study was approved by ProMedica Toledo Hospital's institutional review board. A summary of the procedures used in this study is provided in **Figure 1**. A retrospective query of the obstetrical unit's billing record was completed to identify a purposive sample of women who had a delivery admission (within the time period of September 1, 2015, to August 31, 2016) and a diagnosis of GDM using the appropriate International Classification of Diseases (ICD) diagnosis codes (ICD-9, 648.80, 648.83 or ICD-10, O24.410, O24.411, O24.414). Although the conversion to ICD-10 occurred in 2015, both ICD-9 and ICD-10 codes were used to reduce the potential for missing eligible women given this transitional period. We identified 468 medical records with diagnosis of GDM.

Screening of the medical records occurred in late spring of 2017. A primary screening identified records where all inclusion and ex-

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

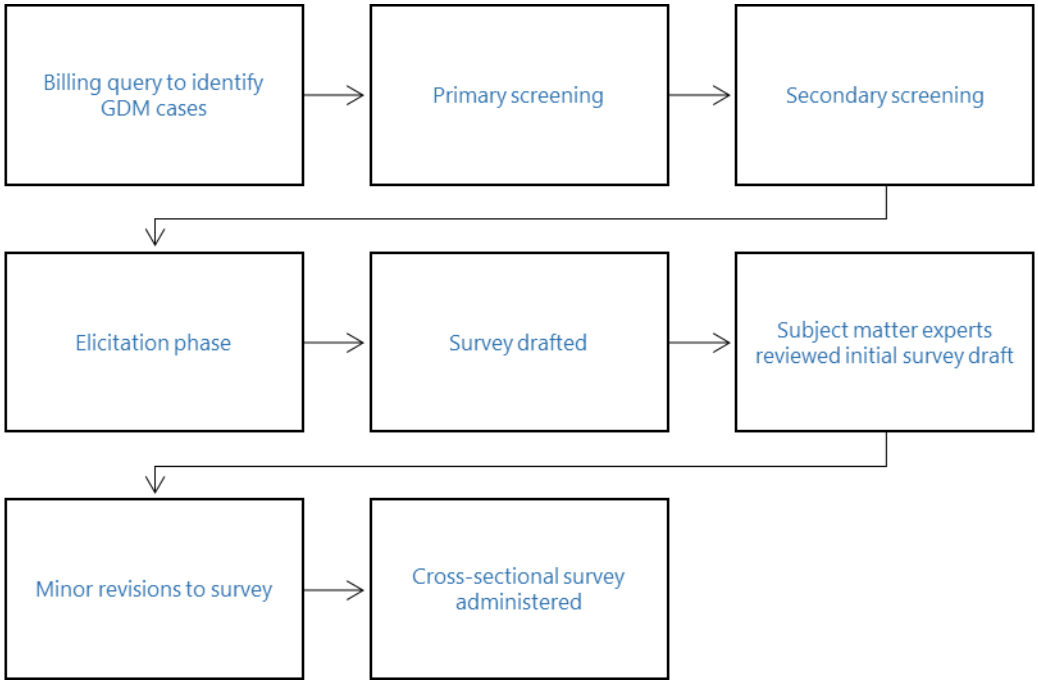


Figure 1. Overview of Study Procedures to Evaluate Breastfeeding Duration and Satisfaction among Northwest Ohio Women who Intended to Breastfeed after GDM

clusion criteria were documented, and the secondary screening identified records that met inclusion criteria. In the case of any discrepancy or uncertainty of medical notation, consensus was obtained from 2 members of the research team who conducted the screening.

The hospital system had transitioned to a new electronic system during the screening period. This presented challenges to locating eligibility criteria for cases within 2015. In addition, the initial billing query and access to the data screening system took longer than expected. As a result, a decision was made to exclude 206 records, retaining records after January 15, 2016. After the secondary screening, 160 eligible records remained. An additional 6 records were excluded due to undeliverable mail, email, or disconnected phone number.

To inform the questionnaire development, women were invited to participate in focus groups to elicit discussion about their experience. Elicitation, the use of open-ended questions to identify important issues that may facilitate or act as a barrier for a behavior, is a common practice to apply health behavioral theories in research.[24] A systematic random sampling approach was used to recruit 30 women, inviting every fifth eligible case. A standard phone script was used to invite women; 19 women were reached via telephone, 8 women indicated interest, and 2 focus groups were scheduled. Interested women were emailed additional details including a cover letter, consent information, and information on parking, time, and location. An email reminder was provided 48 hours in advance of the scheduled session. Women were given the opportunity to review the consent form and ask questions prior to deciding to participate. Written informed consent was obtained in person on the scheduled day. Light appetizers and refreshments were provided as an incentive for attending.

In total, 3 women consented to participate. The first session was limited to 1 participant, and she was interviewed individually. The second session was limited to 2 participants, and the women were interviewed together. Women were prompted to discuss their experience with breastfeeding using a theory-based elicitation interview guide (**Table 1**). A brief summary and debriefing were provided at the end of each session to clarify any questions or concerns identified in the discussion. A member of the research team recorded notes, and responses were audio recorded. The notes were compared to the audio record to ensure accuracy. A combination of inductive and deductive coding of the notes was completed by 2 members of the research team to identify themes relevant to breastfeeding satisfaction and duration.

Based on the information obtained from the elicitation phase and existing literature, an initial questionnaire, grounded by constructs from an integrated behavioral model, was drafted. We made minor revisions after obtaining feedback for content validity from subject matter experts (n = 4) with expertise in maternal health, gestational diabetes, breastfeeding, and questionnaire development. The final questionnaire included 47 items.

Table 1. List of Questions Used in the Elicitation Phase

1.	How many children do you have and what are their ages?
2.	Tell us about the interaction or experience you had feeding your baby during your first 72 hours (3 days) after delivery.
3.	How would you describe your breastfeeding experience in comparison to the expectations you had about breastfeeding during your pregnancy?
4.	What motivated you to try (or consider) breastfeeding?
5.	What did you find easy about breastfeeding? What did you find challenging?
6.	Describe your support system that you had prior to delivery? How about after delivery?
7.	How do you think breastfeeding did (or would have) impacted you? And your baby?
8.	What is one thing that would have, or did, help you be more successful with breastfeeding?

Excluding the subsample of women (n = 3) who participated in the elicitation phase, the remainder of eligible women (N = 151) were then invited to participate in the survey. Mixed-mode contact was used to optimize the response rate. Initial contact was made with email and postcard notification to inform women of the upcoming opportunity to participate in a survey about their breastfeeding experience after GDM. Following the initial contact, an online invitation was delivered via email. This invitation included a unique study identification code (ID) and a link to the online consent information and Qualtrics survey. Proceeding with the survey indicated consent to participate.

Nonresponders were emailed an initial reminder within 1 week of the study invitation which was followed by a mailed postcard reminder. The postcard contained the unique study ID, the URL for the survey, and a QR code for smartphone access. During the third week, nonresponders were emailed an additional time, and a study packet containing a hard copy of the cover letter, consent information sheet, survey, and a prepaid return envelope was mailed with a due date for return within 2 weeks.

Measures

The outcome variables assessed on the cross-sectional survey included breastfeeding duration and satisfaction. The questionnaire included items related to demographics, medical and reproductive histories, prior breastfeeding experiences, breastfeeding intentions after GDM diagnosis, experiences within the child's first week of life, maternal postpartum experiences (ie, feelings of worry, shame, postpartum blues), breastfeeding complications, knowledge about breastfeeding and GDM, initial cues to action, negative normative influences (pressure from others to breastfeed), and factors that encouraged or acted as a barrier to the achievement of breastfeeding goals since delivery. The remaining psychological items assessed instrumental attitudes (4 items related to beliefs about breastfeeding [ie. importance and health benefits]), experiential attitudes (7 items related to feelings about breastfeeding or their personal experience, i.e. ease of breastfeeding, expectations, and effort required), self-efficacy beliefs (2 items), and feelings about satisfaction with breastfeeding support and education (3 items).

Duration of breastfeeding was measured as a continuous variable (days, weeks, months of breastfeeding). Most other items included a close-ended response option, using either a dichotomous (yes/no) response option or a 4-point, balanced, bipolar, Likert scale (1 = strongly disagree to 4 = strongly agree); this method was selected to encourage a thoughtful response and avoid misinterpretation of a neutral midpoint. Reverse coding was used for negatively worded items (ie, "*Breastfeeding takes a lot of effort*"). Text entry was allowed for several responses.

Statistical Analysis

Survey data were reviewed and recoded to develop analysis variables. Lactogenesis was coded as normal (≤3 days post partum) or delayed (> 3 days post partum). An aggregate score was calculated for the number of cues to action, encouraging cues and barriers since delivery, and number of correct knowledge items. A dichotomous variable was created for negative normative influence, based on whether a woman indicated that she had felt pressure from family, friends, or a health care provider to breastfeed. A composite score was calculated for remaining psychological subscales and Cronbach α was used to assess internal reliability. Descriptive statistics and bivariate analyses were conducted using SPSS, Version 24.0.[34] Based on the Kolmogorov–Smirnov test ($P < .001$), Mann-Whitney U test (U) was used to assess the difference between breastfeeding duration and satisfaction based on whether a woman experienced delayed lactogenesis. Spearman correlation (r_s) was calculated to assess the impact of knowledge, cues, attitudes, early experiences, self-efficacy, satisfaction with support, normative influence, and barriers regarding breastfeeding duration and satisfaction.

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

RESULTS

Elicitation Results

Common themes about the breastfeeding experiences of women who participated in the elicitation phase are summarized in **Table 2**. Early experiences in the first week of life were particularly important. When comparing experience with expectations, a woman stated, *"GDM didn't make it more challenging, just a rough start."* Early use of formula, neonatal hypoglycemia, latching difficulty, and concern over milk supply was described as having an impact on their breastfeeding attitudes and perceptions. While we anticipated that early experiences would be important, women stressed their fears regarding the infant's blood glucose. Women also expressed concerns related to finding a "balance" after GDM and uncertainties about milk supply, blood glucose, and losing weight.

Barriers included transitioning to work, stigma, and family's influence. Women specifically highlighted excessive pressure from others and feelings of shame when milk production was not sufficient. Women also described the lack of support and resources in the hospital and after discharge. Women cited maternal and infant benefits of breastfeeding; however, there was a lack of awareness regarding the benefits of breastfeeding after GDM.

As a result of these findings, 2 items related to negative normative influence (pressure to breastfeed) were incorporated into the questionnaire. Items related to the infant's blood glucose and concerns about their own blood glucose were incorporated in the survey. In addition, we included items regarding a woman's support before delivery, in the hospital, and after the hospital, as well as a woman's satisfaction with the support she received for breastfeeding from her health care providers. As a result of the elicitation phase, we were interested in the self-efficacy of women to access breastfeeding support. Given the overall lack of awareness regarding breastfeeding after GDM, we included questions to assess whether women had received counseling on postpartum risk reduction, and if that included breastfeeding.

Survey Results

A total of 50 surveys were returned for a 33% response rate. Among nonresponders, the average time that had passed since delivery admission until survey invitation was 69 weeks, whereas 58 weeks (range 44-77 weeks) had passed for responders. These differences may correspond with nonresponders having a lack of interest, given the longer recall period. Most responders (**Table 3**) were non-Hispanic, white women, most were married or in a committed relationship, and the mean age was 33 years (SD = 5.20). Most had a prior viable pregnancy, prior breastfeeding attempt, yet no history of GDM. Women delivered on average at 38.5 weeks gestation, and the average birth weight was 3370 grams (SD = 394).

Regarding the outcome variables, 33% of women reported delayed lactogenesis, and 68% reported that they were satisfied with their breastfeeding experience after GDM. The duration of breastfeeding ranged from 1 week to 64 weeks (Median = 14 weeks). Collectively, 36% reported breastfeeding for 6 weeks or less, and 50% breastfed less than or equal to 12 weeks. Among those who set a duration goal, 59% did not meet their goal; 82% of those who did not meet their goal were dissatisfied with their experience. Delayed onset was not associated with duration of breastfeeding (U = -0.49, P = 0.64); however, it was associated with a lower level of breastfeeding satisfaction (U = -3.01, P = 0.007). Among women with delayed lactogenesis, 46% were dissatisfied with their breastfeeding experience.

Table 2. Themes and Sample Quotes from Women with Attempted Breastfeeding after GDM

Theme	Sample quotes
Early experiences, attitudes, and perceptions	"The first few days were rough time, I wanted to nurse, but baby could not latch, she was on me a lot because she was not getting enough milk." "Scariest thing, blood sugar test immediately was a blood sugar of 20, scared living day lights out of me…someone came in and brought 'Formula' right away." "Not knowing how much they are getting."
Normative influence and lack of support as barrier to breastfeeding	"Nurses seemed to not know I had GDM…never met with dietitian or maternal fetal medicine provider after delivery, had to advocate for self." "Family grabbed bottle because I was not around and disrupted cycle…done fighting everyone." "I did feel really pressured. 'Why aren't you still nursing?' "
Perceived benefits	"Breast is best, right…I nursed all my children, helps with immune system, reduce obesity, a lot of things." "Wanted the bond and feel closer to my daughter."

Table 3. Demographic and Health Characteristics of Northwest Ohio Women (n = 50) who Intended to Breastfeed after GDM

Variable	n (%)[a]
Ethnicity	
Hispanic	6 (12)
Non-Hispanic	44 (88)
Race	
Black or African American	1 (2)
White	48 (96)
Multiracial	1 (2)
Married/Committed relationship	47 (94)
Household income	
Less than $20 000	2 (4)
$20 000 – $49 999	7 (14)
$50 000 – $99 999	22 (44)
$100 000 or more	17 (34)
Not sure	2 (4)
WIC participation	7 (14)
Delivery type	
Vaginal delivery	31 (62)
Cesarean delivery, scheduled	11 (22)
Cesarean delivery, emergency	7 (15)
Parity (delivered where at least 5 months pregnant)	
0	2 (4)
1	15 (30)
2	26 (52)
3	5 (10)
4	2 (4)
Prior GDM	14 (28)
Prior breastfeeding attempt	36 (72)
Lactogenesis	
Normal (≤ 3 days post partum)	29 (67.4)
Delayed (> 3 days post partum)	14 (32.6)
Management of GDM	
Diet	50 (100)
Monitoring of glucose	50 (100)
Physical activity	39 (78)
Oral medications	18 (36)
Insulin	11 (22)

[a] % based on valid percentage

Internal reliability was calculated using Cronbach α for each psychosocial scale; results ranging from 0.69 to 0.88 were considered acceptable for continued analyses. The results of the bivariate analyses are summarized in **Table 4**. Experiential attitudes, the feelings about breastfeeding and a woman's experience, correlated with duration and satisfaction. Satisfaction with prior breastfeeding experience was positively associated with current breastfeeding duration and satisfaction. Instrumental attitudes, beliefs about the benefits and importance of breastfeeding, also correlated with duration and satisfaction.

A higher number of negative experiences in the child's first week of life (ie, introduction of formula, breathing problems, jaundice, neonatal intensive care unit (NICU) admission) was negatively associated with duration of breastfeeding and satisfaction (Table 4). Maternal postpartum experience (ie, postpartum blues, worry

and feelings of shame regarding milk supply) was also negatively associated with duration and satisfaction.

A higher level of encouraging cues after delivery was correlated with a higher level of satisfaction, while a higher number of barriers after delivery was negatively associated with duration and satisfaction (Table 4). Self-efficacy was positively associated with duration and satisfaction, whereas negative normative influence (pressure from others to breastfeed since delivery) was correlated with a lower level of satisfaction.

DISCUSSION

This study aimed to identify factors associated with breastfeeding duration and satisfaction. Attitudes were associated with breastfeeding duration and satisfaction, while early experiences correlated with a shorter duration and a lower level of satisfaction. The use of constructs from an integrated behavioral framework appears relevant in the context of understanding breastfeeding satisfaction and duration after GDM. Although the findings on positive beliefs are consistent with existing research,[28,35] this study highlights the impact of experiential attitudes and unavoidable challenges associated with breastfeeding after GDM. Proactive and ongoing support is needed to help women navigate the distinct challenges of breastfeeding after GDM, including delayed lactogenesis.

Consistent with past research on delayed lactogenesis after GDM,[17,18] one-third of women reported delayed lactogenesis, and 40% reported that milk supply was a barrier to reaching breastfeeding goals. While delayed lactogenesis was not related to duration of breastfeeding, it was associated with a lower level of breastfeeding satisfaction. There is currently a lack of best practices or interventions to address delayed lactogenesis; however, assessment of lactogenesis and proactive recognition of delayed lactogenesis may help coordinate a woman's postpartum breastfeeding plan after GDM.

Instrumental (beliefs about breastfeeding) and experiential attitudes (expectations and feelings about the experience) were correlated with satisfaction and duration. The finding related to experiential attitudes and satisfaction is an important contribution from this study. Forty-six percent of women reported that breastfeeding was uneasy or not easy at all compared to their expectations. It is possible that negative early experiences, including those in the child's first week of life challenged breastfeeding expectations. Women should be informed of the potential challenges related to breastfeeding after GDM (ie, delivery type, delayed lactogenesis, and infant complications). Although these challenges may not be always avoided, interventions may be enhanced by improving beliefs about the perceived benefits of breastfeeding after GDM while also addressing self-efficacy and expectations over the course of the breastfeeding experience.

Most survey respondents had prior experience with breastfeeding, and prior breastfeeding satisfaction was associated with current satisfaction and duration. Yet, among those with prior experience, 60% reported that breastfeeding after GDM was somewhat uneasy or not easy at all, and 32% of the overall sample did not feel confident to breastfeed future children. Given the relationships between prior experience and current satisfaction and duration, it

Table 4. Impact of Variables from an Integrated Behavioral Model on Breastfeeding Duration and Satisfaction among a Sample of Northwest Ohio Women with History GDM (n = 50) who Intended to Breastfeed

	Duration r_s	*P*	Satisfaction r_s	*P*
Prior breastfeeding satisfaction	.70	<.001	.72	<.001
Initial cues to action	-.09	.62	.27	.06
Knowledge	-.06	.72	.16	.26
Negative first week experiences	-.36	.03	-.32	.03
Maternal postpartum experience	-.42	.01	-.47	.001
Experiential attitudes	.67	<.001	.75	<.001
Instrumental attitudes	.35	.04	.43	.002
Negative normative influence	-.25	.14	-.43	.002
Self-efficacy beliefs	.37	.03	.52	<.001
Satisfaction with support	.05	.79	.41	.003
Encouraging cues after delivery	.35	.04	.59	<.001
Barriers after delivery	-.44	.008	-.69	<.001

may be important to investigate how challenging experiences after GDM may influence future breastfeeding intentions and expectations, especially for first-time mothers or those without prior breastfeeding experience. Health care providers should assess for prior negative experiences, as these women may benefit from additional support and counseling to encourage breastfeeding success.

Although the overall knowledge score was not significantly related to the outcome variables, 62% of the sample erroneously believed that *"If a mother's blood sugar is high, excess sugar could pass into the breastmilk."* Qualitative findings demonstrated that women were generally unaware of the benefits of breastfeeding specific to GDM. While most women (72%) reported some form of postpartum education to reduce risk for diabetes, this did not address breastfeeding after GDM for most women (74%). Early use of formula, lack of provider support, and mixed messages were cited in the qualitative interviews. Similarly, data from the Infant Feeding Practices Study II suggest that women with GDM were less likely to report that breastfeeding was ideal, and women with GDM were 3 times as likely to report that their health care provider preferred the use of formula.[36] There appears to be a need for consistent breastfeeding messaging that is tailored to address the specific benefits of breastfeeding after GDM. These efforts could be feasibly incorporated into postpartum care planning, starting in pregnancy.

Initial breastfeeding cues to action (before delivery) was not significantly related to breastfeeding duration or satisfaction. It is possible that cues to action may have contributed to breastfeeding attitudes; however, this was not a focus of this study. Encouraging cues after delivery were associated with breastfeeding duration and satisfaction. In contrast, negative maternal postpartum experiences and pressure from others to breastfeed correlated with a lower level of breastfeeding satisfaction. This suggests the importance of support that is positively framed. Efforts to educate family members and health care providers may be warranted to help women feel supported, rather than feeling ashamed about her breastfeeding experience or milk supply.

Most women (74%) were satisfied with breastfeeding education received during pregnancy; however, a higher proportion were dissatisfied with postdelivery education and support. Several women indicated no support, while others reported that social media and the internet were their primary sources of education and support after delivery. These findings are important, given the impact of barriers and self-efficacy. Women who participated in the elicitation phase cited an interest in having support from other women who have experienced GDM or low milk supply; this is in alignment with the US Preventive Services Task Force's recommendation for peer support.[37] Future programs should consider ways to assess a woman's self-efficacy and incorporate ongoing support, including the support of peers.

Identification of all eligible cases was not possible due to insufficient information in the screening record, and this may have led to sampling bias. It is also possible that nonresponders had a more challenging experience, which influenced their decision to not participate. The lack of diversity in the sample further limits the external validity. As a result, these factors limited the elicitation sample size, the potential for saturation, and the capture of a range of experiences to inform the survey. While common themes were identified and incorporated into the questionnaire, it is possible that other experiences not described in the elicitation phase have importance to breastfeeding after GDM. Phone interviews may be practical to use in future studies, given the challenges women are balancing in the first year post partum.

Some scales in the survey instrument were limited to a few items which may limit the understanding of the construct. This study is also limited by the potential for social desirability bias. Another significant limitation is that retrospective recall was required, which may increase reporting error. It is possible that women misreported the onset of lactogenesis. It is also conceivable that women who had a more challenging experience may have been able to recall a greater number of challenges or exaggerated their experience, whereas those who had a positive experience may have underestimated barriers or the positive impact of support.

Given that this was a small study with a limited sample size, descriptive statistics and bivariate tests were used to describe potential relationships of interest to breastfeeding satisfaction and breastfeeding duration. Future work including a larger, diverse sample and the use of multivariate analyses that control for confounders may improve understanding of these relationships. Despite these limitations, the exploratory study does provide insight into the possible facilitators and challenges to breastfeeding satisfaction and duration after GDM.

PUBLIC HEALTH IMPLICATIONS

From a public health standpoint, our study identified gaps in care, support, and the need to enhance early experiences with breastfeeding after GDM. While the findings are exploratory and have limited external validity, the information was shared with the hospital's women's services and maternal fetal medicine administration to initiate efforts to improve breastfeeding after GDM. Since this study, the hospital has explored opportunities to address postpartum health in general and efforts are continuing.

The findings suggest a need for health communication interventions that start in pregnancy to optimize attitudes about the importance of breastfeeding after GDM. Given that expectations will change over time with experience, it is important that interventions continue in the postpartum period to address negative experiential feelings. Community resources to provide ongoing support after GDM are recommended. While programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) are available in the community, not all women will

qualify for this program. Peer support programs focused on the woman with GDM should be explored by community breastfeeding programs and hospital outreach efforts.

Early experiences may also be influenced by improved hospital practices and postdelivery support. The Baby-Friendly Hospital Initiative (BFHI) encourages breastfeeding by improving hospital practices including, but not limited to, counseling mothers, providing mothers with support, and encouraging positive early experiences such as skin-to-skin contact and rooming in.[38] This initiative also ensures that staff have adequate knowledge and skills to support breastfeeding. The hospital where women were recruited is not BFHI-certified; however, it participates in Ohio's First Steps for Healthy Babies[39] program, which is modeled after BFHI.[40] While BFHI does not address GDM specifically, the broad clinical practice goals in combination with specific training and resources for GDM and breastfeeding could be explored. Collectively, this study provides a better understanding of the factors that have importance to breastfeeding outcomes after having GDM, but more work is needed.

ACKNOWLEDGMENTS

Thank you to the expert panel reviewers involved with this project including Dr. Kristin Castorino, Dr. Erica Gunderson, Dr. Reena Oza-Frank, and Dr. Rebecca Pobocik for their feedback on the quantitative survey instrument.

REFERENCES

1. Conrey EJ, Shellhaas C, Wapner A, Oza-Frank R, Michael D. Gestational diabetes in Ohio: 2009-2014. Ohio Department of Health. Published November 2016. Accessed October 16, 2019. https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/gestational-diabetes/collaborative/
2. American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2020. Diabetes Care. 2020; 43(Supplement 1): S14-S31. doi:10.2337/dc20-S002
3. American Diabetes Association. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes—2020. Diabetes Care. 2020; 43 (Supplement 1): S182-S192. doi:10.2337/dc20-S014
4. Ziegler AG, Wallner M, Kaiser I, et al. Long-term protective effect of lactation on the development of type 2 diabetes in women with recent gestational diabetes mellitus. *Diabetes*. 2012; 61(12):3167-3171. doi:10.2337/db12-0393
5. Gunderson, EP, Hurston, SR, Ning, X, et al. Lactation and progression to type 2 diabetes mellitus after gestational diabetes: a prospective cohort study. *Ann Intern Med*. 2015; 163(12):889-898. doi:10.7326/M15-0807
6. Chouinard-Castonguay S, Weisnagel SJ, Tchernof A, Robitaille J. Relationship between lactation duration and insulin and glucose response among women with prior gestational diabetes. *Eur J Endocrinol*. 2013; 168(4):515-523. doi:10.1530/EJE-12-0939
7. Dieterich CM, Felice JP, O'Sullivan E, Rasmussen KM. Breastfeeding and health outcomes for the mother-infant dyad. *Pediatr Clin North Am*. 2013 Feb; 60(1):31-48. doi:10.1016%2Fj.pcl.2012.09.010
8. Schwarz EB, Nothnagle M. The maternal health benefits of breastfeeding. *Am Fam Physician*. 2015 May; 91(9):602-604.
9. American Academy of Pediatrics Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatr*. 2012; 129(3):e827-e841. doi:10.1542/peds.2011-3552
10. Rozga MR, Kerver JM, Olson BH. Self-reported reasons for breastfeeding cessation among low-income women enrolled in a peer counseling breastfeeding support program. *J Hum Lact*. 2015; 31(1):129-137. doi:10.1177/0890334414548070
11. Hornsby PP, Gurka KK, Conaway MR, Kellams AL. Reasons for early cessation of breastfeeding among low income women. *Breastfeed Med.* 2019; 14(6):375-381. doi:10.1089/bfm.2018.0206
12. Dewey KG, Nommsen-Rivers LA, Heinig MJ, Cohen RJ. Risk factors for suboptimal infant breastfeeding behavior, delayed onset of lactation, and excess neonatal weight loss. *Pediatrics*. 2003 Sep; 112(3pt1):607-619. doi:10.1542/peds.112.3.607
13. Grajeda R, Pérez-Escamilla R. Stress during labor and delivery is associated with delayed onset of lactation among urban Guatemalan women. *J Nutr.* 2002 Oct; 132(30):3055-3060. doi:10.1093/jn/131.10.3055
14. Chertok IR, Sherby E. Breastfeeding self-efficacy of women with and without gestational diabetes. *Am J Matern Child Nurs*. 2016 May-Jun; 41(3): 173-180. doi:10.1097/NMC.0000000000000233
15. Nommsen-Rivers LA, Mastergeorge AM, Hansen RL, Cullum AS, Dewey KG. Doula care, early breastfeeding outcomes, and breastfeeding status at 6 weeks postpartum among low-income pimiparae. *J Obstet Gynecol Neonatal Nurs.* 2009 Mar-Apr; 38(2):157-173. doi:10.1111/j.1552-6909.2009.01005.x
16. Brownell E, Howard CR, Lawrence RA, Dozier AM. Delayed onset lactogenesis II predicts the cessation of any or exclusive breastfeeding. *J Pediatr.* 2012 Oct; 161(4):608-614. doi:10.1016/j.jpeds.2012.03.035
17. Matias SL, Dewey KG, Quesenberry CP Jr, Gunderson EP. Maternal prepregnancy obesity and insulin treatment during pregnancy are independently associated with delayed lactogenesis in women with recent gestational diabetes mellitus. *Am J Clin Nutr*. 2014 Jan; 99(1): 115-121. doi:10.3945/ajcn.113.073049
18. Jagiello KP, Azulay Chertok IRA. Women's experiences with early breastfeeding after gestational diabetes. *J Obstet Gynecol Neonatal Nurs*. 6459 Jul-Aug; 44(4):500-509. doi:10.1111/1552-6909
19. McBride-Henry K, White G, Benn C. Inherited understandings: The breast as object. *Nurs Inq*. 2009 Mar; 16(1):33-42. doi:10.1111/j.1440-1800.2009.00428.x
20. Edwards R. An exploration of maternal satisfaction with breastfeeding as a clinically relevant measure of breastfeeding success. *J Hum Lact*. 2018 Feb; 34(1):93-96. doi:10.1177/0890334417722509
21. Forster DA, Johns HM, McLachlan HL, Moorhead AM, McEgan KM, Amir LH. Feeding infants directly at the breast during the postpartum hospital stay is associated with increased breastfeeding at 6 months postpartum: a prospective cohort study. *BMJ Open*. 2015 May; 5(5):e007512. doi:10.1136%2Fbmjopen-2014-007512
22. Fischer-Fumeaux CJ, Denis A, Prudon MB, et al. Early use of mother's own raw milk, maternal satisfaction, and breastfeeding continuation in hospitalised neonates: a prospective cohort study. *Neonatology*. 2018; 113(2):131-139. doi:10.1159/000480535
23. Oza-Frank R, Moreland JJ, McNamara K, Geraghty SR, Keim SA. Early lactation and infant feeding practices differ by maternal gestational

diabetes history. *J Hum Lact*. 2016 Nov; 32(4):658-665. doi:10.1177/0890334416663196

24. Montano DE, Kasprzyk D. Theory of Reasoned Action, Theory of Planned Behavior, and the Integrated Behavioral Model. In: Glanz K, Rimer BK, Viswanath, eds. Health Behavior: Theory, Research, and Practice. 5th ed. San Francisco, CA: Jossey-Bass; 2015:168-222.
25. Park S, Lee JL, In Sun J, Kim Y. Knowledge and health beliefs about gestational diabetes and healthy pregnancy's breastfeeding intention. J *Clin Nurs*. 2018 Nov; 27(21-22):4058-4065. doi:10.1111/jocn.14539
26. Lau CYK, Lok KYW, Tarrant M. Breastfeeding duration and the theory of planned behavior and breastfeeding self-efficacy framework: a systematic review of observational studies. *Matern Child Health J*. 2018 Mar; 22(3):327-342. doi:10.1007/s10995-018-2453-x
27. Wallenborn JT, Ihongbe T, Rozario S, Masho SW. Knowledge of breastfeeding recommendations and breastfeeding duration: A survival analysis on Infant Feeding Practices II. *Breastfeed Med*. 2017 Apr; 12 (3):156-162. doi:10.1089/bfm.2016.0170
28. Schafer EJ, Campo S, Colaizy TT, Mulder PJ, Breheny P, Ashida S. First-time mothers' breastfeeding maintenance: role of experiences and changes in maternal perceptions. *Public Health Nutr*. 2017 Dec; 20 (17):3099-3108. doi:10.1017/S136898001700221X
29. Awaliyah SN, Rachmawati IN, Rahmah H. Breastfeeding self-efficacy as a dominant factor affecting maternal breastfeeding satisfaction. *BMC Nurs*. 2019 Aug 16; 18(1):30. doi:10.1186/s12912-019-0359-6
30. Gregory EF, Butz AM, Ghazarian SR, Gross SM, Johnson SB. Met expectations and satisfaction with duration: a patient-centered evaluation of breastfeeding outcomes in the infant feeding practices study II. *J Hum Lact*. 2015 Aug; 31(3):444-451. doi:10.1177/0890334415579655
31. Fishbein M, Yzer MC. Using theory to design effective health behavior interventions. *Commun Theory*. 2003 May; 13(2):164-183. doi:10.1111/j.1468-2885.2003.tb00287.x
32. Hirst JE, Tran TS, Do MA, Rowena F, Morris JM, Jeffery HE. Women with gestational diabetes in Vietnam: a qualitative study to determine attitudes and health behaviors. *BMC Pregnancy Childbirth*. 2012; 12:81-91. doi:10.1186/1471-2393-12-81
33. Oza-Frank R, Conrey E, Bouchard J, Shellhaas C, Weber MB. Healthcare experiences of low-income women with prior gestational diabetes. *MCHJ*. 2018 Jul; 22(7):1059-1066. doi:10.1007/s10995-018-2489-y
34. IBM Corp. Released 2016. IBM SPSS Statistics for Mac, Version 24.0. Armonk, NY: IBM Corp.
35. Wallenborn JT, Perera RA, Masho SW. Breastfeeding after gestational diabetes: does perceived benefits mediate the relationship? *J Pregnancy*. 2017 March 22. doi.org/10.1155/2017/9581796
36. Doughty KN, Ronnenberg AG, Reeves KW, Qian J, Sibeko L. Barriers to exclusive breastfeeding among women with gestational diabetes mellitus in the United States. *J Obstet Gynecol Neonatal Nurs*. 2018 May; 47 (3):301-315. doi:10.1016/j.jogn.2018.02.005
37. Bibbins-Domingo, K, Grossman, DC, Curry, SJ, et al. Primary care interventions to support breastfeeding: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2016 Oct 25; 316(16),1688–1693. doi:10.1001/jama.2016.14697
38. Baby-Friendly USA. *Guidelines and Evaluation Criteria for Facilities Seeking Baby-Friendly Designation*. Albany, NY: Baby-Friendly USA, 2016.
39. Ohio Hospital Association First Steps for Healthy Babies. Accessed March 1, 2020. https://ohiohospitals.org/Patient-Safety-Quality/Statewide-Initiatives/Infant-Mortality-Initiatives/First-Steps
40. Highlighting improvements in breastfeeding outcomes across Ohio. Ohio Hospital Association and the Ohio Department of Public Health. Accessed May, 2020. https://ohiohospitals.org/OHA/media/OHA-Media/Documents/News%20and%20Publications/Newsletters/First-Steps-BF-Month-flier-2019.pdf

Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

RESEARCH ARTICLE

Ohio First Steps for Healthy Babies: A Program Supporting Breastfeeding Practices in Ohio Birthing Hospitals

Lydia Furman, MD[1]; Andrea Arendt, RN, MPH[2]; Ryan Everett, MPH[3]; Breanne Haviland, MS, RD, LD[2]; Michael Monsour, PhD[4]; Reena Oza-Frank, PhD, RD[2]

[1]Department of Pediatrics, Case Western Reserve University School of Medicine and University Hospitals Rainbow Babies and Children's Hospital, Cleveland, OH

[2]Bureau of Maternal, Child and Family Health, Ohio Department of Health, Columbus, OH

[3]Institute for Health Innovation, Ohio Hospital Association, Columbus, OH

[4]Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Atlanta, GA

Corresponding Author: Lydia Furman, 11100 Euclid Avenue, Cleveland, OH 44106, (216) 844-8260, Lydia.Furman@uhhospitals.org

Submitted February 7, 2020 Accepted April 19, 2020

ABSTRACT

Background: Ohio First Steps for Healthy Babies (First Steps) is a free, voluntary statewide designation program coadministered by the Ohio Department of Health and the Ohio Hospital Association that promotes breastfeeding-supportive maternity practices aligned with the Baby-Friendly Hospital Initiative (BFHI).

Materials and Methods: We examined Ohio birthing hospitals' participation in First Steps, and changes in breastfeeding rates at hospital discharge, over the first 12 quarters of the program (July 15, 2015, to July 14, 2018) for all 110 licensed Ohio birthing hospitals. The 81 (73.6%) that achieved at least 1 step over the study period (designated as First Steps hospitals) were compared to the 29 non-First Steps hospitals, and the 17 that began participation at First Steps startup (July 15, 2015) were identified for additional analysis. Changes in breastfeeding rates were examined using a mixed effects multivariate regression model.

Results: Breastfeeding increased significantly over the program period from 73.8% to 76.7% (mean 0.19% per quarter, p = .0002), but without a significant difference in breastfeeding rates between First Steps and non-First Steps hospitals. However, in a pre- and post-program analysis for the 17 hospitals that began participation at First Steps startup (excluding an additional 6 hospitals with BFHI designation), number of quarters in the program, number of steps completed, and number of births in 2015 were significantly associated with breastfeeding rates. Hospitals that completed at least 2 steps every 5 quarters in the First Steps program increased breastfeeding when compared to those not participating in the program.

Conclusion: These encouraging results provide a formal evaluation of a best practices BFHI-modelled statewide program.

Keywords: Birthing hospitals; Breastfeeding protection, promotion and support; Maternity practices; Perinatal care; Program evaluation; Baby-friendly hospital initiative

INTRODUCTION

Exclusive breastfeeding through 6 months of age, followed by addition of complementary feeds and continued breastfeeding as long as the breastfeeding dyad desires, is recommended by numerous professional organizations.[1-3] The multiple health benefits of breastfeeding for mothers, children, and society demonstrate a "dose-response," and benefits increase with greater duration and exclusivity of breastfeeding.[4,5] Optimal breastfeeding practices lead to lower risk of infection-related and all-cause mortality for infants, reduced risk of sudden infant death syndrome, and reduced maternal risk for breast and ovarian cancer, type 2 diabetes, and cardiovascular diseases.[4,5] The Department of Health and Human Services national health practices benchmarking goals (Healthy People 2020) include specific breastfeeding goals for initiation, and exclusivity at 3 and 6 months of 81.9%, 46.2%, and 25.5%, respectively.[6] Although Ohio's rates of 81.9%, 44.4%, and 23.7%, respectively, were encouraging,[7] Ohio's overarching goal is to go beyond Healthy People 2020 breastfeeding goals.

The Centers for Disease Control and Prevention (CDC) Guide to Strategies to Support Breastfeeding Mothers and Babies identifies breastfeeding-supportive maternity care practices as a key strategy.[8] These evidence-based practices align with the Ten Steps of the Baby-Friendly Hospital Initiative (BFHI), which are: 1) have a written breastfeeding policy that is routinely communicated to all health care staff; 2) train all health care staff in the skills necessary to implement this policy; 3) inform all pregnant women about the benefits and management of breastfeeding; 4) help mothers initiate breastfeeding within 1 hour of birth; 5) show mothers how to breastfeed and how to maintain lactation even if they are separated from their infants; 6) give infants no food or drink other than breast milk, unless medically indicated; 7) practice rooming-in (allow mothers and infants to remain together 24 hours a day); 8) encourage breastfeeding on demand; 9) give no pacifiers or artificial nipples to breastfeeding infants; and 10) foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.[9] Implementation of the Ten Steps, either individually or in any combination as a "bundle," is associated with improved breastfeeding outcomes, specifically increased rates of breastfeeding initiation, continuation, and exclusivity.[9-14] A systematic review similarly documented a "dose-response" improvement in breastfeeding initiation, exclusivity, and duration with implementation of the Ten Steps.[15] We acknowledge controversy regarding aspects of the BFHI designation process, with concern expressed by some for need for additional policies and procedures to promote infant safety and maternal choice in Baby-Friendly designated hospitals;[16,17] both point and counterpoint arguments are available.[15,18] We remain in full support of BFHI designation, but emphasize here that while Ohio First Steps is modelled on the BFHI Ten Steps, it differs meaningfully in requirements and implementation.

Public health efforts to increase the number of hospitals incorporating BFHI-aligned practices have included national initiatives, including "Best Fed Beginnings," Communities and Hospitals advancing Maternity Practices and the EMPower Breastfeeding Initiative,[19-21] that enroll individual hospitals in collaborative work to support BFHI designation; state-based quality improvement groups which include selected hospitals working together to improve breastfeeding-supportive maternity practices;[22,23] and initiatives modelled on the Carolina Global Breastfeeding Institute Program, in which state partners collaborate to improve maternity practices statewide.

Several national initiatives[19-22] and state-based quality improvement initiatives[23,24] have successfully implemented breastfeeding supportive maternity practices, but only 1 publication describes a statewide collaborative like First Steps.[25] The New Hampshire Ten Steps to Successful Breastfeeding Collaborative, led by 2 academic physicians, held workshops open to all 20 New Hampshire birthing hospitals, with a successful increase in step attainment.[25] The Ohio First Steps program differs from New Hampshire's in that Ohio's First Steps is led by the Ohio Department of Health (ODH) and the Ohio Hospital Association (OHA) in collaboration with multiple stakeholders, and Ohio is a more diverse and larger state with over 100 accredited birthing hospitals. We aim here to describe the program and evaluate its impact on statewide breastfeeding rates.

METHODS

Setting and Design

This work was conducted in the state of Ohio. In 2014, ODH led a 5-year CDC-funded "Ohio Chronic Disease Collaborative" strategic initiative which, relevant here, introduced a hospital "best practices" designation program. Partners included ODH, OHA, the Ohio Breastfeeding Alliance (an arm of United States Breastfeeding Committee), the Ohio Lactation Consultants Association, the American Academy of Pediatrics, and individual lactation providers. The ODH launched the program in 2015 modelled on the Carolina Global Breastfeeding Institute's program, "North Carolina Division of Public Health Maternity Center Breastfeeding-Friendly Designation," which offers recognition to North Carolina birthing hospitals for achieving practices that "protect, promote, and support breastfeeding" analogous to the Ten Steps of the Baby-Friendly Hospital Initiative.[26] The Carolina Institute provided coaching and technical support for Ohio's "First Steps for Healthy Babies," referred to below as Ohio First Steps.[27]

This research involved a retrospective case series conducted as a quasi-experimental program evaluation. We aimed to compare birthing hospitals participating versus those not participating in Ohio First Steps activities and designation.

Participants

All licensed birthing hospitals in Ohio were included in the evaluation. Hospitals were considered the unit of participation.

Procedures

The Ohio First Steps Program is run collaboratively. The ODH and OHA representatives share administrative duties for Ohio First Steps, and all Ohio birthing hospitals receive regular program communications.[27] Birthing hospitals can earn up to 5 stars, 1 for each 2 steps achieved, and can choose the order and number of steps they tackle. Hospitals can apply multiple times as they implement new steps. A designation team made up of stakeholders and ODH and OHA representatives meets monthly and reviews applications quarterly. Hospitals with BFHI designation at application are automatically awarded 5 stars. (Information on date of step implementation is not available, so it is possible that some non-BFHI designated hospitals had already implemented steps prior to the Ohio First Steps program.) Ohio First Steps is not intended to take the place of BFHI designation or provide designation coaching.

Ohio First Steps kicked off with a webinar and statewide training: ODH partnered with the University of Louisville Center for Women

and Infants (University of Louisville Hospital) to hold 21 "train the trainer" sessions for postdelivery skin-to-skin, attended by 92 Ohio hospitals. A program website was created in 2015, and posting of free additional resources available to all Ohio birthing hospitals is ongoing (**Figure 1**). In 2018, 19 "train the trainer" skills labs in support of step 2 (maternity staff training) were held with 80 Ohio hospitals participating; a free online step 2 staff training (with CEUs) was adapted and posted in 2018.[28] Ohio First Steps funding sources have included ODH, block grants to ODH, OHA and the Association of State and Territorial Health Officials grants.[29]

Measures and Outcomes

Birth certificate data from January 15, 2012, through July 14, 2018, were obtained from the ODH Bureau of Vital Statistics. This includes the program period (July 15, 2015, through July 14, 2018) and the baseline period, the quarter prior to the first applications (April 15, 2015, through July 14, 2015). Additionally, data from January 15, 2012, through April 14, 2014, (pre-program period) were used in analysis done on the first 17 hospitals that applied for recognition (see below). The birth certificate includes a unique identifier for birth facility and records whether the infant is being breastfed at hospital discharge. We utilized the "breastfed at discharge" variable as a proxy for breastfeeding initiation in order to calculate quarterly rates at the hospital level and better measure the effects of the Ohio First Steps program. "Breastfed at discharge" includes both exclusively breastfed infants and those receiving any breast milk at discharge, as per the relevant Joint Commission Perinatal Core Measure data collected at that time. Seven facilities exempt from licensing, such as freestanding birthing centers, were excluded from the analysis.

There were 438 896 live births at the 110 licensed birth facilities during the program period (April 15, 2015, through July 14, 2018). A total of 2818 births were excluded because "breastfed at discharge" was marked as unknown. Additionally, multiple gestation births, infants who died prior to discharge, infants who were transferred to neonatal intensive care unit or another facility, and mothers who were transferred were excluded (n = 32 679). These mother-infant dyads were excluded because breastfeeding at discharge could not have been reliably assessed. This left a sample size of 403 399 births.

A separate analysis of 17 hospitals that entered the program in the first quarter (explained in more detail below) was completed using data from January 15, 2012, through July 14, 2018. During that time period, there were a total of 146 693 live births at the 17 hospitals, of which 3951 were excluded due to missing information on breastfeeding at discharge. An additional 1078 births were excluded because they were multiple gestation, infants who died prior to discharge, infants who were transferred to neonatal intensive care unit or another facility, or mothers who were transferred. This left a sample size of 141 664 for this part of the study. For each included hospital, average maternal age, percent of mothers with a college education, percent of births covered by Medicaid, percent of births to non-Hispanic black mothers, and number of births (grouped into 5 categories, ≤249, 250-499, 500-999, 1000-1999 and ≥2000) were extracted from 2015 data.

Number of steps completed (0 to 10), number of quarters in program (0 to 12), obstetrical service level, BFHI designation status,[9] and micropolitan versus metropolitan location for each hospital were linked to the hospital level vital statistics variables described above. Participation was defined as making formal application for recognition through Ohio First Steps and achieving at least 1 step by April 2018. As noted above, date of step implementation was not available. Therefore, the assumption was made that steps were achieved in the quarter prior to the submitted application. Obstetrical level of service was defined per Ohio Administrative Code §3701-7: in summary, level 1 includes basic care, level 2 includes specialty care, and level 3 includes subspecialty care, with full cri-

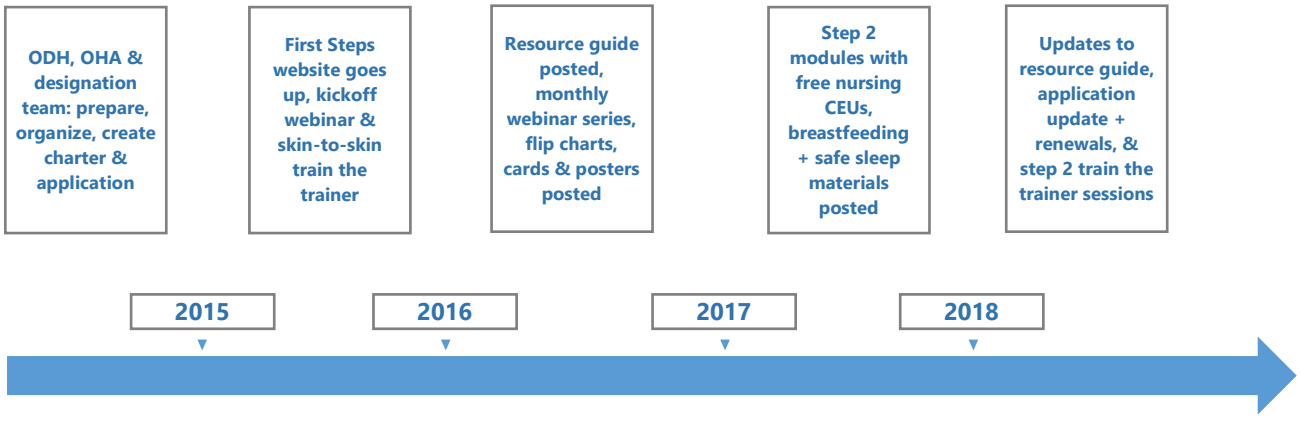


Figure 1. Timeline for First Steps Program: Startup Through First Three Years

teria as per the referenced code.[30] Micropolitan and metropolitan location were defined by the county they are located in as in section 3.1.1 of the Medicare Advantage Network Adequacy Criteria Guidance.[31] There were no licensed birthing hospitals in rural counties.

Statistical Analysis

For Ohio First Steps hospitals, defined as those Ohio birthing hospitals who applied for and achieved any steps, the number of steps achieved and number of quarters of participation during the program period were determined. The most and least frequently achieved steps were identified. Six hospitals closed during the program period. For these hospitals, number of steps and quarters of participation are as of the quarter they closed. Additionally, the total number of Ohio birthing hospitals (including both First Steps and non-First Steps hospitals) utilizing any Ohio First Steps trainings, resources, or educational offerings was summarized by count.

There were 3 separate analyses conducted. First, breastfeeding (BF) rates for all maternity hospitals in Ohio during the baseline and program periods were examined to determine if there was a significant increase in BF rates over time at the state level. The average rate for breastfeeding at discharge in Ohio was calculated using all live births (exclusions noted above) that took place at the 110 birthing hospitals included in the study. A Poisson regression was used to model the trend in numbers of infants breastfed at discharge over the program period (measured in quarters) with an offset term, the logarithm of the number of live births.

Second, a mixed effects multivariable regression model with hospitals as the random effect was used to compare changes in quarterly BF rates between First Steps hospitals and non-First Steps hospitals. The fixed effects considered in the regression model are detailed below.

Third, a cohort of First Steps hospitals that joined the program in the first quarter (July 15 to October 14, 2015) were identified for additional analysis to examine the effect of First Steps. This cohort included 17 hospitals. In the first quarter, there were 23 participating hospitals, but 6 of those had previously achieved BFHI designation and, thus, were excluded to prevent bias since they would have already been practicing the Ten Steps to Successful Breastfeeding prior to the Ohio First Steps program. For the 17 hospital cohort, BF rates in the program period were compared to BF rates in a pre-program period of 13 quarters (January 15, 2012, to April 14, 2015, with the first quarter January 15 to April 14, 2012, used as baseline for the pre-program period). A mixed effects multivariable regression model with hospitals as the random effect was used to determine if the program had an effect on quarterly breastfeeding rates in a pre- and post-program analysis above a baseline quarter (the first quarter of the pre-program period and the first quarter of the program period, etc.). A log transformation of standardized breastfeeding rates above the baseline quarter was modeled. Supplemental Material Table 1 defines the time period of each of the pre- and post-quarters.

The following fixed effects were considered in the multivariate regression model of breastfeeding rates: time measured in quarter of a year, a dichotomous variable designating the quarter as pre-program or post-program, obstetrical service level of the hospital (3 levels), the number of quarters the hospital has been in the program (for pre-program quarters this variable equals 0 and for post-program quarters it increases by 1 each quarter), the number of steps in the Ohio First Steps program that the hospital has completed (for pre-program quarters this variable equals 0 and for post-program quarters it equals cumulative number of steps achieved), average maternal age by hospital in 2015, percent of mothers at hospital with a college education in 2015, percent of mothers with Medicaid insurance at each hospital in 2015, percent of non-Hispanic black mothers at each hospital in 2015, number of births at each hospital in 2015, number of births by hospital in 2015 (by 5 levels described above), hospital location in a metropolitan or micropolitan area (as defined above). Quarter of application was used as a proxy for step implementation due to lack of information on specific dates. Therefore, all pre-program quarters were set to 0, SAS version 9.4 (SAS Institute) was used for all statistical analyses, and P values < 0.05 were considered statistically significant.

RESULTS

Hospital participation

At program initiation, Ohio had 110 licensed birthing hospitals. Of these, 103 (93.6%) attended an Ohio First Steps training or used Ohio First Steps materials. During the program period, 81 Ohio birthing hospitals (73.6%) achieved at least 1 step and were therefore defined as a First Steps hospital. First Steps hospitals achieved a mean of 6.0 steps per hospital. Of First Steps hospitals, step 2 ("train all health care staff…") and step 6 ("give infants no food or drink other than breast milk…") were least frequently achieved, respectively (39.5% and 40.7%). Step 10 ("foster the establishment of…support groups…") and step 8 ("encourage breastfeeding on demand") were most frequently achieved, respectively (87.7% and 90.1%). Characteristics of First Steps and non-First Steps hospitals (**Table 1**) and the number of hospitals achieving each step (**Table 2**) are presented. The number of stars, which is achievement of any 2 steps, and the number of quarters in the First Steps program for First Steps hospitals are presented in Supplemental Material Table 2.

Breastfeeding Rates at Discharge

For the first analysis, combining all birthing hospitals, there was a significant increase in the number of infants breastfed at hospital discharge by quarter over the program period (coefficient for quarter = 0.0025, P <0.0001). The increase in the proportion of infants breastfed at discharge by quarter in Ohio is shown graphically in **Figure 2**. However, for the second analysis, there was no

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

Table 1. Hospital Characteristics by Ohio First Steps Program Participation

	First Steps hospitals [a]	Non-First Steps hospitals
Hospital descriptors	(N = 81), n (%)	(N = 29), n (%)
Baby-friendly USA designation [b, c]	5 (6)	0 (0)
Level of obstetrical care [b, d, e]		
Level 1 - Basic care	37 (46)	20 (69)
Level 2 – Specialty care	24 (30)	4 (14)
Level 3 – Subspecialty care	18 (22)	5 (17)
Annual live deliveries (2015)		
≤ 249	5 (6)	7 (24)
250-499	15 (18)	7 (24)
500-999	33 (41)	9 (31)
1 000-1 999	13 (16)	3 (1)
≥ 2 000	15 (18)	3 (10)
County type		
Metropolitan county	69 (85)	21 (72)
Micropolitan county	12 (15)	8 (28)
Maternal descriptors	(N = 94,791), n (%)	(N = 24,952), n (%)
College education of mothers[f]	29 401 (31.0)	7373 (29.5)
Medicaid births[f]	37 298 (39.3)	10 316 (41.3)
Non-Hispanic black births[f]	15 908 (16.8)	3770 (15.1)
Maternal age, mean[f]	27.9 years	27.8 years

[a] First Steps hospitals are hospitals that have achieved at least 1 step by April 2018.
[b] Current as of July 2015
[c] Per Baby-Friendly USA https://www.babyfriendlyusa.org/about/
[d] Obstetrical levels of care are defined per Ohio Administrative Code §3701-7, summary descriptor provided here with full definition available in the Ohio Administrative Code as referenced.
[e] Level of obstetrical care was not available for 2 of the hospitals; 1 of which achieved First Steps recognition and 1 that did not.
[f] Among births that took place in 2015

Table 2. Participating Ohio First Steps Hospitals: Number of Hospitals Achieving Each Step

Specific steps achieved [a]	Hospitals achieving (N=81), n (%)
1. Written policy regarding breastfeeding	63 (77.8)
2. Train staff in breastfeeding policy elements	32 (39.5)
3. Inform pregnant women about breastfeeding	49 (60.5)
4. Help mothers initiate breastfeeding within 1 hour	63 (77.8)
5. Show mothers how to maintain breastfeeding even if separated from the infant	45 (55.6)
6. Give infants breast milk only unless medically indicated otherwise	33 (40.7)
7. Full rooming in	51 (63.0)
8. Encourage breastfeeding on demand	73 (90.1)
9. Avoid pacifiers for breastfeeding infants	45 (55.6)
10. Foster breastfeeding support groups for post-discharge and refer to these	71 (87.7)

[a] Step descriptions are truncated summaries for table purposes.

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

statistically significant difference in rates of breastfeeding at discharge between First Steps hospitals (81 hospitals) and non-First Steps hospitals (29 hospitals).

Multivariate Analysis with Respect to Breastfeeding and Program Participation at Startup

In analysis of the 17 hospital cohort that joined the Ohio First Steps program in the first quarter, the following fixed effects were found to be significantly associated with breastfeeding rates in a mixed effects multivariate regression model; time measured in quarter of a year (coefficient = 0.0026, *P* value = 0.0016), the number of quarters the hospital has been in the program (coefficient = -0.004, *P* value= 0.0067), the number of steps in the program that the hospital has completed (coefficient = 0.0104, *P* value < 0.0001), and the number of births at the hospital in 2015 (coefficient = 0.000025, *P* value = 0.046). The coefficients show that breastfeeding rates increased over time. All other fixed effects were not significantly associated with breastfeeding rates at discharge. *Specifically, hospitals that completed at least 2 steps every 5 quarters in the Ohio First Steps program increased* breastfeeding when compared to not participating in the Ohio First Steps program (pre-program quarters).

DISCUSSION

Ohio First Steps for Healthy Babies is a statewide collaborative established in 2015 to protect and promote breastfeeding via maternity care practices modelled on the BFHI Ten Steps. Most licensed Ohio birthing hospitals (93.6%) have participated in Ohio First Steps trainings or used Ohio First Steps materials; 81 hospitals (73.6% of the 110 licensed maternity facilities) applied for and received Ohio First Steps designation as of July 14, 2018. Overall, Ohio breastfeeding rates increased significantly over the program period. Although there was not a significant overall difference in breastfeeding rates by Ohio First Steps participation over this period, there was an increase in breastfeeding rates in a subanalysis for the 17 hospitals (not already BFHI designated) that began Ohio First Steps participation when the program started (July 2015). Hospitals that complete at least 2 steps every 5 quarters in the program increased breastfeeding rates when compared to not participating in the program (pre-program quarters). We believe this is the first formal evaluation of a 10 step-modelled statewide public health supported breastfeeding program, which many states have begun.[29]

The only other statewide initiative to report on results of a BFHI Ten Steps-modelled program is The New Hampshire Ten Steps to Successful Breastfeeding Collaborative. This initiative was led by 2 academic physicians who conducted a statewide needs assessment, followed by 2 workshops open to all 20 New Hampshire birthing hospitals and focusing on 6 of the 10 steps found most in need of improvement. Follow-up analysis 3 years later documented increased step attainment among the 6 "intensive collaborating

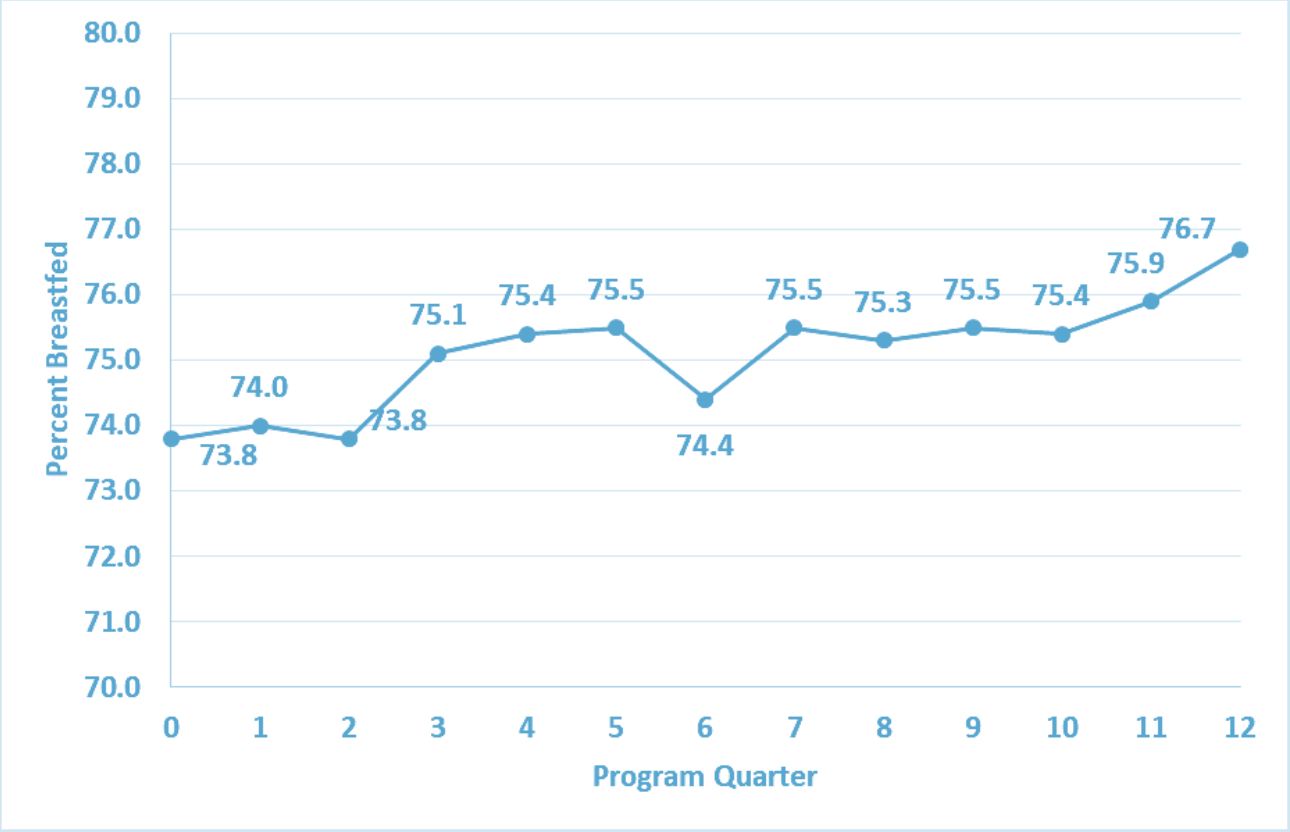


Figure 2. Percent of Infants Breastfed at Discharge by Quarter, Ohio 2015 – 2018

hospitals" and the 4 hospitals working toward BFHI designation.[25] Here we also provide a 3 year follow-up, and also note that a subgroup of birthing hospitals (the 17 with participation from program start up) had notable improvements in attainment of breastfeeding-supportive birthing hospital practices. However, Ohio First Steps differs in that it is a public health-led initiative that includes more than 100 birthing hospitals in a larger and more diverse state, focuses on surrogate achievements for all of the 10 steps, and is an ongoing program.

Evidence supports the positive impact on breastfeeding initiation, duration and exclusivity of the BFHI Ten Steps maternity practices.[13-15] Recent studies including a systematic review showed a dose response between the number of BFHI steps to which women are exposed and the likelihood of better breastfeeding outcomes.[13-15] In this study, we evaluated the influence of Ohio First Steps on breastfeeding initiation only, and utilized as a proxy the "breastfed at discharge" variable, which includes exclusive and any breastfeeding, because this was the most reliable measure of statewide breastfeeding outcomes available. Controversies related to BFHI designation, including calls for additional policies related to infant safety and maternal choice, appear to relate to the rigorous nature of the BFHI designation process. Ohio First Steps, and other state programs such as the Texas Ten Step Program, which similarly provide designation for breastfeeding-supportive birthing hospital practices, are modelled on the Ten Steps of the BFHI, but offer flexibility and less laborious verification. We emphasize that BFHI designation is an intensively monitored and highly specific process, and the work of Ohio First Steps, and any effects it has on Ohio's birthing hospitals, cannot be directly compared. Ohio First Steps does not conduct hospital visits and is not intended to substitute for the rigorous designation program of Baby-Friendly USA.

Although Ohio's rate of breastfeeding at hospital discharge increased significantly over the program period, we did not demonstrate a direct effect of the First Steps program on this outcome. Study limitations are several. First, the majority of other national and state proctored programs aimed at increasing breastfeeding-supportive maternity practices enrolled program-selected hospitals.[16,20,21] Hospitals willing to engage in facility-changing quality improvement work are appropriately self-selected for initiative, expertise, leadership, and hospital administration support. This approach differs from that of Ohio First Steps, which seeks to "lift" maternity practices of all Ohio hospitals by making tools, technical support, and trainings widely available and free, with designation recognition the main visible incentive. Second, the broad availability of First Steps resources, in use by 93.6% of all Ohio maternity hospitals, may have "diluted" the impact of First Steps. Demonstration of an effect among the first 17 First Steps hospitals is aligned with this "dilution" of impact over time, with increasing program visibility and exposure. Additionally, we did not collect information about breastfeeding-supportive maternity practices among nonparticipating hospitals, and therefore cannot measure any broader impact of Ohio First Steps to support this contention. Third, the Ohio First Steps program was not run as a controlled clinical trial with intervention arms for ethical and pragmatic reasons, and this makes program evaluation challenging. We lack information on initiation date of breastfeeding-supportive maternity practices ("steps") and, therefore, we had to assume steps were implemented in the quarter prior to applying for First Steps recognition. It is possible that non-BFHI designated hospitals had steps in place prior to the start of the Ohio First Steps program which could have influenced the results reported here. While all Ohio birthing hospitals had the opportunity to engage with Ohio First Steps at the beginning of the program, we can only assess participation of those that applied for and achieved steps. Therefore, given this analytic assumption, we cannot determine whether the significant positive change in Ohio breastfeeding rates is due to Ohio First Steps, or to other local and national initiatives. Fourth, for consistency within the analysis presented here, birth certificate breastfeeding was used. While a major statewide program to improve the quality and fidelity of retrieval and reporting of perinatal breastfeeding data to the electronic birth certificate (Integrated Perinatal Health Information System-IPHIS), preceded and ran concurrently with Ohio First Steps, we acknowledge data accuracy as a potential issue.

The main strength of this study is that it is the first comprehensive evaluation of a state-based public health-supported 10 step-modelled breastfeeding program for maternity hospitals. In contrast to the statewide initiative in New Hampshire, Ohio First Steps is supported by state resources (ODH and OHA) and includes multiple stakeholders beyond academic institutions, with ongoing outreach to all birthing hospitals, and continued development of new resources and trainings. The analysis used breastfeeding rates from the Ohio Department of Health, Bureau of Vital Statistics birth certificates and took a rigorous approach to examination of this data. Ohio is a large and demographically diverse state with over 100 maternity hospitals, and, thus, results may be generalizable to other similar programs and states.

Improvement is ongoing in the Ohio First Steps program. Hospitals now must resubmit their endorsement of continuing adherence to steps previously achieved after 3 years. While Ohio First Steps applications initially accepted estimates for step performance measures, with coaching and new data collection tools, measures now must include at least 15 chart reviews or 5 maternal interviews per question.

PUBLIC HEALTH IMPLICATIONS

The main policy implication of this work is that it supports continuation of the Ohio First Steps model, in which a statewide public health-administered 10 steps-based program disseminates best practices breastfeeding-supportive maternity care. Our results suggest consideration of several future initiatives. A "Next Steps"

initiative is being organized, with plans to enroll self-selected birthing hospitals in a data collaborative with monthly webinars, data and best practices sharing, specific step coaching, and availability of confidential benchmarking reports. Since step 2 ("train all health care staff…") and step 6 ("give infants no food or drink other than breast milk…") were least frequently achieved, Ohio First Steps created free training for step 2 (https://www.train.org/odh/welcome [courses 1079957 and 1087379]), which has already been used by over 1100 participants, and now has the opportunity to consider strategies to further support and promote breastfeeding exclusivity (step 6). The Ohio First Steps designation team is dedicated to ongoing quality improvement for the First Steps program.

The main aim of sharing the work of Ohio's First Steps for Healthy Babies is to inform advancements of national best practices. Although there was no overall difference in breastfeeding rates by Ohio First Steps participation over the program period, there was an increase in breastfeeding rates for the 17 hospitals (not already BFHI designated) that began First Steps participation when the program started. We believe this is the first formal evaluation of a 10 step-modelled statewide public health supported breastfeeding program.

ACKNOWLEDGMENTS

Thank you to the following individuals whose contributions to all aspects of the First Steps program during the program period were invaluable: Jennifer Foster, BSN, RN, IBCLC; Libby Svoboda, MED, BSN, RN IBCLC, FACCE; Laura Knisley, MSN, APRN, LD, FNP, IBCLC, CDE, RD; and Julie Ware, MD, MPH, IBCLC. Thank you to Connie Bish, PhD, MPH (Centers for Disease Control and Prevention) for her thoughtful review of the manuscript. No additional funding was received to support this work and none of the authors have a conflict of interest to report. Preliminary findings, not including the multivariable analyses and associated conclusions, were presented at the American Academy of Pediatrics National Conference and Exhibition meeting, November 2 to 5, 2018. The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

REFERENCES

1. American Academy of Pediatrics Section on Breastfeeding. Breastfeeding and the use of human milk [Policy Statement]. *Pediatr* 2012; 129 (3):e827–e841. doi:10.1542/peds.2011-3552
2. American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 756: Optimizing support for breastfeeding as part of obstetric practice. *Obstetr Gynecol* 2018; 132(4): e187-e196. doi:10.1097/AOG.0000000000002890
3. World Health Organization. Nutrition topics, breastfeeding, 2019. Accessed March 6, 2019. https://www.who.int/nutrition/topics/exclusive_breastfeeding/en/
4. Feltner C, Palmieri Weber R, Stuebe AM, Grodenski CA, Orr C, Viswanathan M. Breastfeeding programs and policies, breastfeeding uptake, and maternal health outcomes in developed countries. Rockville, MD: Agency for Healthcare Research and Quality, AHRQ Publication No. 18-EHC014-EF, 2018. Accessed April 27, 2020. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-210-breastfeeding-report_1.pdf
5. Sankar MJ, Sinha B, Chowdhury R, et al. Optimal breastfeeding practices and infant and child mortality: a systematic review and meta-analysis. *Acta Paediatr* 2015; 104(S467): 3-13. doi:10.1111/apa.13147
6. Maternal, infant and child health 2020 topics and objectives, healthypeople.gov website managed by the Department of Health and Human Services, last updated December 29, 2018. Accessed December 30, 2018. https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives
7. Centers for Disease Control and Prevention: Breastfeeding report card—United States, Breastfeeding, 2018. Accessed March 6, 2019. https://www.cdc.gov/breastfeeding/data/reportcard.htm
8. Centers for Disease Control and Prevention. Strategies to prevent obesity and other chronic diseases: the CDC guide to strategies to support breastfeeding mothers and babies, US Department of Health and Human Services. Accessed May 28, 2019. https://www.cdc.gov/breastfeeding/pdf/BF-Guide-508.pdf
9. Baby-Friendly USA, About Us. Accessed March 6, 2019. https://www.babyfriendlyusa.org/about/
10. Fairbank L, O'Meara S, Renfrew MJ, Woolridge M, Sowden AJ, Lister Sharp D. A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding. *Health Technol Assess* 2000; 4(25): 1-171. doi:10.3310/hta4250
11. Philipp BL, Merewood A, Miller LW, et al. Baby-friendly hospital initiative improves breastfeeding initiation rates in a US hospital setting. *Pediatr* 2001; 108(3): 677-681. doi:10.1542/peds.108.3.677
12. Kramer MS, Chalmers B, Hodnett ED, et al. and the PROBIT Study Group. Promotion of breastfeeding intervention trial (PROBIT): a randomized trial in the Republic of Belarus. *JAMA* 2001; 285(4): 413-420. doi:10.1001/jama.285.4.413
13. Patterson JA, Keuler NS, Olson BH. The effect of maternity practices on exclusive breastfeeding rates in US hospitals. *Matern Child Nutr.* 2019; Jan 4: e12670. doi:10.1111/mcn.12670
14. Nelson JM, Perrine CG, Freedman DS, et al. Infant feeding related maternity care practices and maternal report of breastfeeding outcomes. *Birth* 2018; 45(4): 424-431. doi:10.1111/birt.12337
15. Pérez-Escamilla R, Martinez JL, Segura-Pérez S. Impact of the Baby-friendly Hospital Initiative on breastfeeding and child health outcomes: a systematic review. *Matern Child Nutr.* 2016; 12(3): 402-417. doi:10.1111/mcn.12294
16. Bass JL, Gartley T, Kleinman R. Unintended consequences of current breastfeeding initiatives. *JAMA Pediatr*. 2016;170(10):923–924. doi:10.1001/jamapediatrics.2016.1529
17. Gomez-Pomar E, Blubaugh R. The Baby Friendly Hospital Initiative and the ten steps for successful breastfeeding. a critical review of the literature. *J Perinatol.* 2018;38(6):623–632. doi:10.1038/s41372-018-0068-0
18. Bartick M, Boisvert ME, Philipp BL, Feldman-Winter L. Trends in Breastfeeding Interventions, Skin-to-Skin Care, and Sudden Infant Death in the First 6 Days after Birth. *J Pediatr.* 2020;218:11–15. doi:10.1016/j.jpeds.2019.09.069
19. Feldman-Winter L, Ustianov J, Anastasio J, et al. Best Fed Beginnings: A Nationwide Quality Improvement Initiative to Increase Breastfeeding. *Pediatr*. 2017 July; 140(1): pii: e20163121. doi:10.1542/peds.2016-3121

20. Carolina Global Breastfeeding Initiative. Breastfeeding Exclusive September 2017 - EMPower Breastfeeding Initiative. Accessed March 6, 2019. https://sph.unc.edu/cgbi/empower-breastfeeding-initiative-update/
21. United States Breastfeeding Committee, Racial Equity Learning Community Blog. The community in CHAMPS. (2015) Accessed March 6, 2019. http://www.usbreastfeeding.org/p/bl/et/blogaid=385
22. Merewood A, Bugg K, Burnham L, et al. Addressing racial inequities in breastfeeding in the southern United States. *Pediatr*. 2019 Feb; 143 (2): pii: e20181897. doi:10.1542/peds.2018-1897
23. Hisgen S, Dennison BA, FitzPatrick E, Waniewski PA. Improving maternity care practices in New York: answering the surgeon general's call to action. *Breastfeed Med*. 2012 Oct; 7(5): 337-342. doi:10.1089/bfm.2012.0101
24. Ware JL, Schetzina KE, Morad A, et al. A statewide quality improvement collaborative to increase breastfeeding rates in Tennessee. *Breastfeed Med*. 2018 May; 13(4): 292-300. doi:10.1089/bfm.2017.0164
25. Whalen BL, Kelly J, Holmes AV. The New Hampshire ten steps to successful breastfeeding collaborative: a statewide QI Initiative. *Hosp Pediatr*. 2015 Jun; 5(6): 315-23. doi:10.1542/hpeds.2014-0104
26. North Carolina Division of Public Health. NC Maternity Center Breastfeeding-Friendly Designation Program. Updated April 16, 2020. Accessed April 27, 2020. https://www.nutritionnc.com/breastfeeding/bf-mat-center.htm
27. Ohio Hospital Association Ohio First Steps for Healthy Babies. Accessed April 27, 2020. https://ohiohospitals.org/Patient-Safety-Quality/Statewide-Initiatives/Infant-Mortality-Initiatives/First-Steps
28. Ohio First Steps for Healthy Babies Maternity Staff Training Program. OhioTRAIN (Course No. 1079957). Accessed April 27, 2020. https://www.train.org/odh/welcome
29. Association of State and Territorial Officials. In Brief - Promoting breastfeeding: state health departments and breastfeeding coalition partnerships in the ASTHO breastfeeding learning community. Published 2016. Accessed March 6, 2019. http://www.astho.org/Maternal-and-Child-Health/Issue-Brief/State-Health-Departments-and-Breastfeeding-Coalition-Partnerships/
30. Ohio Administrative Code, Chapter 3701-7 Maternity Units and Homes, 3701-7-01 Definitions. Effective January 1, 2012. Accessed July 12, 2019. http://codes.ohio.gov/oac/3701-7
31. Medicare Advantage Network Adequacy Criteria Guidance. Updated January 10, 2017. Accessed June 10, 2019. https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/MA_Network_Adequacy_Criteria_Guidance_Document_1-10-17.pdf

SUPPLEMENTAL MATERIAL

Supplemental Table 1. Ohio First Steps: Pre-Program and Post-Program Period Dates

Supplemental Table 2. Number of Steps Achieved and Number of Quarters of Participation Among Participating Ohio First Steps Hospitals

Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

RESEARCH BRIEF

Evaluating the e-Cigarette Epidemic in US Emergency Departments

Neil Vallabh[1]; Andrew F. Zheng, MD[2]; Hersh Varma, MD[1]; Ryan Reber, MD[3]; W. Walker Motley, MS, MD[1,4]
[1]Pediatric Ophthalmology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
[2]Family Medicine, Cleveland Clinic Akron General, Akron, OH
[3]Emergency Medicine, Cleveland Clinic Akron General, Akron, OH
[4]Ophthalmology, University of Cincinnati, Cincinnati, OH
Corresponding Author: Neil Vallabh, 3333 Burnet Avenue, Cincinnati, OH 45229-3026, (513) 636-7176, Neil.Vallabh@cchmc.org
Submitted December 15, 2019 Accepted April 19, 2020

ABSTRACT

Background: Electronic cigarettes (e-cigarettes) are often thought to be a healthier option to cigarette smoking. e-Cigarettes have been found to overheat and explode. e-Cigarette explosions have caused severe trauma and rendered patients in critical conditions. Inadvertent exposures to liquid nicotine products have caused systemic poisoning injuries. We sought to characterize e-cigarette injuries presenting to emergency departments (ED) in 2018.

Methods: We analyzed one year of data from the US Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS). Patients presenting with injuries associated with e-cigarette products were manually identified for inclusion. We performed descriptive analyses on demographic factors, affected bodily regions, dispositions, locations of occurrence, and mechanisms of injury. By applying sample weights, nationally representative estimates were calculated.

Results: A total of 361 667 injury cases were reported in NEISS (2018). We identified 50 e-cigarette injury cases, generating a national estimate of 1739 (95% CI [1333-2148]) patients presenting to US EDs with e-cigarette injuries in 2018. Approximately 1000 pediatric patients (age ≤17 years) and 700 adult patients (age ≥18 years) were included. The median age when presenting to the ED was 4 years (interquartile range [IQR], 1-25). Over 85% of injuries occurred at home. Ingestion (55.0%) was the most common mechanism of injury, followed by explosion (35.8%).

Conclusion: Children and adults are susceptible to injury from e-cigarette products. Changes in manufacturing standards may prevent injuries from these products.

Keywords: e-Cigarette; Vape; Liquid nicotine; Injury surveillance; Epidemiology

INTRODUCTION

Electronic cigarettes (e-cigarettes) reached the US market in 2007 and have since been perceived as a healthier option to cigarette smoking.[1] These battery-operated devices aerosolize liquid cartridges typically containing propylene glycol, nicotine, tetrahydrocannabinol (THC), or other chemical flavorants for personal use.[2,3] e-Cigarette users activate lithium-ion battery power sources to heat the cartridges and produce vapor for inhalation.[4] While e-cigarettes do avoid the use of matches and lighters associated with traditional cigarettes, e-cigarette use is not without its own immediate risks. e-Cigarettes have been found to overheat, ignite, and explode.[1-5] The process of thermal runaway associated with lithium-ion batteries appears to be at the crux of these failures in e-cigarettes. Given the lack of regulation on e-cigarette manufacturing practices, there could be great variability in the design, quality, and types of materials used by different manufacturers, potentially leaving consumers more susceptible to injury. Further, some consumers opt for personal modification of their devices such as changing coil resistance or battery voltage.[6] When these products are manufactured or modified poorly, they may be more susceptible to short-circuiting when contacting seemingly innocuous metal objects like keys and coins in users' pockets, further contributing to thermal runaway.[2,6]

e-Cigarette explosions have caused severe trauma and rendered patients in critical conditions. While lithium-ion battery malfunction is not a new phenomenon, e-cigarette-related events may hold the potential for more severe injury.[1] When used or stored, they are kept in close proximity to vital structures of the face or near the groin, respectively.[2,5] These patients often present for emergency treatment with third degree burns to the head, legs, groin, and hands.[2,5] Though e-cigarette explosions are not common, the US Fire Administration reported 195 e-cigarette explosions be-

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

tween 2009 and 2016 were due to explosions, the majority of which required hospitalization for management of burns around the head and neck.[5]

The increasing prevalence of e-cigarette use among US adolescents and young adults from 2017 to 2019 creates additional concerns for public health.[7,8] In addition to explosion of e-cigarette products, injuries have also occurred following inadvertent exposure to liquid nicotine, particularly among our youth.[9-13] Nicotine exposure in young children is highly concerning when considering the potential neurological insults that may result.[14] Nicotine has several effects on the human body. The binding of nicotinic cholinergic receptors primarily induces sympathetic nervous stimulation, though parasympathetic stimulation and neuromuscular blockade can occur with higher doses.[14] By efficiently penetrating the blood-brain barrier, nicotine can directly affect the brain, clinically manifesting as emesis, seizures, and coma.[14] We sought to explore the extent of e-cigarette injuries and better characterize the e-cigarette epidemic.

METHODS

Setting and Design

The National Electronic Injury Surveillance System (NEISS) is a national injury database maintained by the US Consumer Product Safety Commission (CPSC). The CPSC uses NEISS data to aid in surveillance of injuries associated with consumer products and in regulating manufacturing practices and sale of most consumer products in the United States.[15] The CPSC analyzes these data for evidence of the need for product recalls, public awareness campaigns, or product safety standards.[15]

The NEISS collects emergency department (ED) injury data from approximately 100 US hospitals providing continuous emergency care, yielding a statistically valid probability sample of the over 5000 hospital EDs across the nation.[15] Professional NEISS coders review medical records from each participating hospital and collect from patients presenting to EDs with injuries associated with consumer product use. The data collected include patient demographic information, affected bodily regions, diagnoses, dispositions from ED, locations where injury occurred, associated product codes, and text fields for clinical narratives.[16]

We examined e-cigarette product injury incidence and trends across the United States. Per the Code of Federal Regulations and US Department of Health and Human Services, research involving the study of existing records is exempt from human subjects research review if the source is publicly available or if information is recorded in such a manner that subjects cannot be readily identified, directly or through linked identifiers.[17] The NEISS is a publicly available, anonymized database; thus, this research is exempt from institutional review board approval.

Participants

We analyzed data from all patients with injuries reported by NEISS from January 1, 2018, through December 31, 2018. We did not restrict inclusion by age, affected bodily region, diagnosis, or specific product codes. Since tobacco products are not within the CPSC's regulatory jurisdiction, NEISS data are not coded specifically for e-cigarette products.[18] The investigators analyzed case narratives to determine if e-cigarette products were involved with injuries. All patients experiencing injury secondary to e-cigarette products were included for analysis.

Procedures

We identified injuries associated with e-cigarette products by searching clinical narratives for mention of the following terms: "vape," "vapor," "vaping," "cig," "hookah," "e-liquid," "eliquid," "nicotine." We extracted all cases in which the clinical narrative contained at least one of these terms. Two investigators independently reviewed all extracted cases and determined whether e-cigarettes were associated with each case. A third investigator compared the independent reviews and determined if there were any discrepancies in the determination of e-cigarette association. For cases on which the two investigators were not found to agree, a fourth investigator made the final decision independently. The fourth investigator was blinded to prior reviews. The cases found to be associated with e-cigarette products were extracted and included for analysis in this study. Data were cleaned using Microsoft Excel (Microsoft Corporation, 2013).

Measures

The primary study objective was to characterize the annual incidence of injuries associated with e-cigarette products presenting to EDs across the United States in 2018. Secondary objectives were identifying differences in injury incidence among pediatric and adult patients, mechanisms of injury, affected bodily regions, and dispositions. The CPSC considers NEISS estimates unstable if the estimate is less than 1200, the number of cases is less than 20, or the coefficient of variation exceeds 33%.[16]

Statistical Analysis

We performed descriptive analyses and applied adjusted sample weights, yielding nationally representative estimates of e-cigarette injuries presenting to US EDs. We analyzed the weighted distribution to determine proportions of e-cigarette injury by age, sex, race, disposition, location of occurrence, bodily region affected, and mechanism of injury.

We assessed normality with both Shapiro-Wilk tests and Q-Q plots. We reported measures of central tendency for nonnormal metrics as medians (interquartile ranges [IQR]). Statistical analyses were performed using jamovi[19] and R (R Core Team, 2019).

RESULTS

A total of 361 667 injury cases were reported in the NEISS database in 2018, including 50 e-cigarette injury cases. This resulted in a national estimate of 1739 (95% CI [1333-2148]) patients presenting to US EDs with e-cigarette injuries in 2018 (**Table 1**). The

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

median age of patients when presenting to the ED was 4 years (IQR, 1-25 years). e-Cigarette injuries most frequently occurred among females (55.1%; n=958) and whites (80.0%; 877 of 1097 reporting race) and at home (86.1%; 1248 of 1449 reporting location). Most injuries were systemic and affected all parts of the body. All injuries found to affect all parts of the body were caused by ingestion (n=901, 51.8%). The cases reported as affecting an unknown bodily region were also caused by ingestion (n=56, 3.2%). Explosions and burns typically involved the upper leg (n=317, 18.2%), lower trunk (n=168, 9.7%), pubic region (n=18, 1.0%), and head (n=6, 0.3%).

Among all cases presenting with e-cigarette injuries, 1022 were pediatric patients (age ≤17 years) and 717 were adult patients (age ≥18 years) (**Table 2**). The median age of pediatric patients was 1 year (IQR, 1-2 years), and the median age of adult patients was 30 years (IQR, 19-45 years). Ingestion occurred among 93.5% (n=956) of pediatric patients. Explosion occurred among 79.1% (n=567) of adult patients. Pediatric patients experienced 100% of ingestion injuries (n=956), whereas adult patients experienced 91.0% of explosion injuries (n=623). Most e-cigarette injury patients were treated and released (n=1299, 74.7%), though the severity of injuries sustained by 347 (20.0%) patients necessitated further care or hospital admission.

DISCUSSION

The United States currently lacks robust injury surveillance systems to monitor explosions, burns, and poisonings caused by e-cigarettes. We analyzed nationally representative data to estimate the incidence of e-cigarette injuries in a 1-year period and found over 1700 patients presented to EDs in 2018 with e-cigarette injuries. Approximately half of these injuries were due to ingestion, and one-third were due to explosion of e-cigarette products. These findings parallel trends noted in similar studies regarding e-cigarette explosions and may raise concerns regarding the safety of our youth and e-cigarette product ingestion.

Dohnalek and Harley[1] found a relative decrease in e-cigarette burn and explosion injury incidence from 944 patients in 2016 to 726 patients in 2017. They also found most explosion injuries damaged the upper leg and lower abdomen. Chang and colleagues[9] found the annual incidence of e-cigarette poisoning event in children from 2014 to 2017 to be 1000, 1736, 1416, and 411 injuries, respectively. Nearly all were caused by ingestion.

We used the NEISS to estimate the public health burden of emergency e-cigarette injuries among youth and adults in the United States. Our study is not without limitations. Our study only examined injuries presenting to US EDs; our estimates may be conservative with regard to capturing all e-cigarette injuries since patients experiencing less severe injuries may not have sought emergency care, individuals experiencing injury may not have been able to overcome health care access barriers, and fatal injuries may not have presented to EDs. Additionally, since NEISS currently does not use product codes specific for e-cigarette products, we may have underestimated the value of e-cigarette injuries presenting to EDs. Further, caution should be taken when interpreting the generalizability of these results, as some reported measures do not meet all the CPSC's stability criteria and may potentially be unreliable.

Other studies[11-13] have utilized data from the National Poison Data System (NPDS) in attempts to characterize the extent of liquid nicotine ingestion and poisoning in children. It was found that most e-cigarette poisonings tracked by poison control centers (PCCs) had minor health effects, with less than 3% of cases having moderate, prolonged, or life-threatening symptoms.[11-13] However, analysis of NPDS data does have limitations. The NPDS findings cannot be used for deriving population estimates, as NPDS is not nationally representative. Further, NPDS data is collected from telephone calls made to PCCs, but not all individuals poisoned by these products call PCCs. It can be reasonably theorized that patients and families experiencing more serious injuries would be inclined to directly seek emergency care rather than waiting to consult a PCC before proceeding.

PUBLIC HEALTH IMPLICATIONS

The US Food and Drug Administration commissioner and US surgeon general declared youth e-cigarette use an epidemic in 2018.[20,21] e-Cigarette products continue to harm youth and adults across the nation, including in Ohio, though some longer-term health effects are still unknown. The Ohio Department of Health has reported 102 cases, including 96 hospitalizations, of vaping-related lung illnesses across 38 counties, with a median patient age of 25 years (range, 15-65 years).[22] Chronic vaping-related injury surveillance and the recent implementation of Tobacco 21 legislation in Ohio could prove beneficial to the health of our adolescents and adults. Additional state-wide surveillance of acute incidents, like burns and poisonings, may be beneficial for characterizing the immediate harms of e-cigarette products in Ohio. Evidence-based population-level interventions are paramount for addressing public health concerns of this magnitude.

Our findings are likely consistent with the downward trend in e-cigarette explosion and burn incidence from 2016[1] but may be inconsistent with the downward trend in e-cigarette product ingestion and poisoning incidence from 2015. The increase in ingestion injuries from approximately 400 in 2017[9] to 950 in 2018 may raise concerns regarding manufacturing standards and product accessibility. Children may be susceptible to inadvertent nicotine exposure from leakage in open systems and from pods lacking tamper-proof mechanisms in closed systems. Haphazard storage of liquid nicotine and pod refills could also contribute to unintentional exposures. We encourage manufacturers, legislators, and regulatory bodies to reevaluate the efficacy of e-cigarette product manufacturing standards.

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

Table 1. e-Cigarette Injuries Presenting to US Emergency Departments in 2018

Characteristics	Unweighted N	Weighted N (%)
All [95% CI]	50	1739 [1333, 2148]
Age, median (IQR), years	14.5 (1-29)	4 (1-25)
Sex		
Male	34	781 (44.9)
Female	16	958 (55.1)
Unknown	-	-
Race		
White	22	877 (50.4)
Black	7	107 (6.2)
Other	2	97 (5.6)
Asian	1	16 (0.9)
Unknown	18	642 (36.9)
Bodily region affected		
Elbow	1	75 (4.3)
Knee	1	5 (0.3)
Pubic region	1	18 (1.0)
Head	1	6 (0.3)
Face	1	87 (5.0)
Lower trunk	4	168 (9.7)
Upper leg	14	317 (18.2)
Hand	2	91 (5.2)
Foot	1	75 (4.3)
All parts of body	23	901 (51.8)
Unknown	1	56 (3.2)
Disposition		
Treated and released	35	1299 (74.7)
Treated and transferred	1	87 (5.0)
Admitted and hospitalized	9	194 (11.2)
Held for observation	3	66 (3.8)
Left without being seen	1	79 (4.5)
Unknown	1	17 (1.0)
Location of occurrence		
Home	30	1248 (71.8)
Public	4	145 (8.3)
School	1	56 (3.2)
Unknown	15	292 (16.8)
Mechanism of injury		
Ingestion	24	956 (55.0)
Explosion	22	622 (35.8)
Other	4	161 (9.3)

Unweighted N: raw counts from database
Weighted N: national frequency estimate, statistically weighted
The CPSC considers a national estimate unstable and potentially unreliable when the weighted estimate is less than 1200 or fewer than 20 cases are present.
Counts and percentages adjusted for rounding; may differ from reported total.

Table 2. e-Cigarette Injuries Among Pediatric and Adult Patients

Characteristics	Pediatric	Adult
All	1022	717
Age, median (IQR), years	1 (1-2)	30 (19-45)
Mechanism of injury		
Ingestion	956 (93.5)	-
Explosion	56 (5.5)	567 (79.1)
Other	11 (1.1)	150 (20.9)

Pediatric: Patients age ≤17 years when presenting to the ED
Adult: Patients age ≥18 years when presenting to the ED
The CPSC considers a national estimate unstable and potentially unreliable when the weighted estimate is less than 1200.

REFERENCES

1. Dohnalek HM, Harley EH. Analysis of electronic cigarette-related Injury presenting to US emergency departments, 2008-2017. *J Emerg Med.* 2019 Sep;57(3):399-404. doi:10.1016/j.jemermed.2019.05.037
2. Rossheim ME, Livingston MD, Soule EK, Zeraye HA, Thombs DL. Electronic cigarette explosion and burn injuries, US emergency departments 2015-2017. *Tob Control.* 2019;28(4):472-474. doi:10.1136/tobaccocontrol-2018-054518
3. Breland A, Soule E, Lopez A, et al. Electronic cigarettes: what are they and what do they do? *Ann N Y Acad Sci.* 2017 Apr;1394(1):5-30. doi:10.1111/nyas.12977
4. Rudy SF, Durmowicz EL. Electronic nicotine delivery systems: overheating, fires, and explosions. [Epub ahead of print March 9, 2016] *Tob Control.* pii: tobaccocontrol-2015-052626. doi:10.1136/tobaccocontrol-2015-052626
5. McKenna, LA Jr. US Fire Administration. Research Group National Fire Data Center. Electronic cigarette fires and explosions in the United States 2009-2016. Published July 2017. Accessed December 11, 2019.
6. Mulder HA, Patterson JL, Halquist MS, et al. The effect of electronic cigarette user modifications and e-liquid adulteration on the particle size profile of an aerosolized product. *Sci Rep*. 2019;9(1). doi:10.1038/s41598-019-46387-2
7. Gentzke AS, Creamer M, Cullen KA, et al. Vital signs: tobacco product use among middle and high school students — United States, 2011–2018. *MMWR Morb Mortal Wkly Rep*. 2019;68(6):157-164. doi:10.15585%2Fmmwr.mm6806e1
8. Dai H, Leventhal AM. Prevalence of e-cigarette use among adults in the United States, 2014-2018. *JAMA.* 2019;322(18):1824-1827. doi:10.1001/jama.2019.15331
9. Chang JT, Wang B, Chang CM, Ambrose BK. National estimates of poisoning events related to liquid nicotine in young children treated in US hospital emergency departments, 2013-2017. *Inj Epidemiol*. 2019;6(10). doi:10.1186/s40621-019-0188-9
10. Wang TW, Gentzke AS, Creamer MR, et al. Tobacco product use and associated factors among middle and high school students — United States, 2019. *MMWR Morb Mortal Wkly Rep.* 2019;68(12):1-22. doi:10.15585/mmwr.ss6812a1
11. Chatham-Stephens K, Law R, Taylor E, et al. Exposure calls to US poison centers involving electronic cigarettes and conventional cigarettes-September 2010-December 2014. *J Med Toxicol*. 2016 Dec; 12(4):350–357. doi:10.1007/s13181-016-0563-7
12. Kamboj A, Spiller HA, Casavant MJ, Chounthirath T, Smith GA. Pediatric exposure to e-cigarettes, nicotine, and tobacco products in the United States. *Pediatrics*. 2016 June; 137(6) e20160041. doi:10.1542/peds.2016-0041
13. Wang B, Rostron B. Tobacco-related poison events involving young children in the US, 2001-2016. *Tob Reg Sci*. 2017 Oct; 3(4):525-35. doi:10.18001/TRS.3.4.12
14. Akhavan AR, Burns R, Stone K, Reid J, Mazor S. Pediatric Toxidrome Simulation curriculum: liquid nicotine overdose. MedEdPORTAL. 2018;14. Accessed March 12, 2020. doi:10.15766/mep_2374-8265.10735
15. US Consumer Product Safety Commission. The National Electronic Injury Surveillance System, Frequently asked questions. Accessed November 2, 2020. https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data/Neiss-Frequently-Asked-Questions
16. Schroeder T, Ault K. The NEISS sample (design and implementation) 1997 to present. Published June, 2001. Accessed November 2, 2020. https://www.cpsc.gov/s3fs-public/pdfs/blk_media_2001d011-6b6.pdf
17. 45 CFR 46. Code of Federal Regulations. Dept of Health and Human Services, Office of Human Subjects Research Protections. Published October 1, 2019. Accessed November 2, 2020. https://www.govinfo.gov/content/pkg/CFR-2019-title45-vol1/pdf/CFR-2019-title45-vol1-chapA.pdf
18. NEISS Coding manual. 2019. Published January 2019. Accessed November 2, 2020. https://www.cpsc.gov/s3fs-public/2019_NEISS_Coding_Manual.pdf
19. The jamovi project. jamovi (Version 1.1.7) [Computer Software]. Accessed November 7, 2020. Published 2019. Retrieved from https://www.jamovi.org
20. US Department of Health and Human Services. Surgeon General's Advisory on e-Cigarette Use Among Youth. 2018. Published 2018. Accessed December 14, 2019. https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf
21. Statement from FDA Commissioner Scott Gottlieb, MD, on new steps to address epidemic of youth e-cigarette use. Silver Spring, MD: US Food and Drug Administration. Published September 11, 2018. Accessed December 14, 2019. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use
22. Ohio Department of Public Health. Ohio Vaping Investigation Update. Updated March 5, 2020. Accessed March 12, 2020. https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/tobacco-use-prevention-and-cessation/news-and-events/

OJPH
Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

PUBLIC HEALTH PRACTICE

Web Application to Investigate Butler County Overdose Death Data

Alison C. Tuiyott[1]; Bri Clements[1,2]; A. John Bailer, PhD[1]; Lisa K. Mannix, MD[3]; Jennifer F. Bailer, RN, MS[4]
[1]Department of Statistics, Miami University, Oxford, OH
[2]Covail, Columbus, OH
[3]Butler County Coroner's Office, Hamilton, OH
[4]Butler County General Health District, Hamilton, OH
Corresponding Author: Alison C. Tuiyott, Miami University, Oxford, OH 45056, (513) 265-7079, tuiyotac@miamioh.edu
Submitted November 19, 2019 Accepted May 17, 2020

ABSTRACT

Background: Drug overdose deaths, specifically opioid-related deaths, are a public health crisis in the United States with high incidence observed in many Midwestern states, including Ohio. Butler County, Ohio, has the third highest opioid-related death rate in the state. Information on overdose deaths, collected by the county coroner, can serve as a data source for analysis of this public health concern. Given this access, stakeholders can investigate trends in their community for their idiosyncratic interest.

Methods: A web application was developed, using the R Shiny package, to visualize and explore the characteristics of all overdose deaths in Butler County between 2013 and 2018. Demographics of the decedents, drugs found in the decedents' postmortem toxicology analyses, annual trends in overdose deaths, and the location of these cases can be examined.

Results: The web application provides a graphical user interface that allows a user to request specific analyses and summaries. "Who is dying from opioid overdoses?," "What drugs, including opioids, are found in people dying from drug overdoses?," and "Has the number of opioid involved deaths increased in a specific community over time?" are examples of questions that can be explored using this application.

Conclusion: This application empowers both the public and local policymakers to investigate the impact of overdose deaths on their communities. Understanding characteristics of the epidemic is an important first step to addressing this problem. The expansion of this application to include other counties in Ohio could be truly beneficial to communities that need it.

Keywords: Epidemic; Ohio; Opioid; Overdose death; R Shiny application

INTRODUCTION

In the United States, more than 46 000 people died from an opioid-involved overdose, including prescription and illicit opioids, in 2018.[1] Opioids include heroin, fentanyl, and prescription drugs such as oxycodone.[1] To put that number into perspective, roughly 36 000 people died of a fatal motor vehicle crash that same year.[2] Ohio had the fourth highest rate of opioid-related drug overdose deaths in the United States in 2018; 29.6 deaths per 100 000 people in Ohio versus 14.6 deaths per 100 000 people in the United States.[3] Ohio also had the fifth highest rate of drug overdose deaths in general in 2018 in the United States; 35.9 deaths per 100 000 people in Ohio versus 20.7 deaths per 100 000 people in the United States.[4] Butler County, Ohio, has the second highest overdose death rate in the state with 43 deaths per 100 000 people.[5]

A web application displaying various interactive data visualizations regarding overdose deaths was created to spread awareness of the issue and to educate the community of Butler County. Stakeholder access to these data and to summaries of these data can be provided on the internet. Given this access, stakeholders can investigate patterns in trends in their community and for their idiosyncratic interest. This article describes that web application with hopes of empowering the public to use it to query and explore a critical public health issue in their community.

The interactive application provides an accessible way to see and understand trends, outliers, and patterns in the Butler County overdose death data through various views. Users can explore the demographics (gender/sex, race/ethnicity, and age) of the decedents and specific drugs (eg, heroin, fentanyl, carfentanil) detected by postmortem toxicology analyses. For the purposes of this appli-

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

cation, gender was used synonymously with sex. Likewise, race was also used synonymously with ethnicity in this application. Users can also analyze annual trends of categories of drugs (eg, opioids, fentanyl analogs, stimulants) found in decedents. The application also provides insight on location information including a map of Butler County displaying the locations of each overdose incident, annual trends of overdose incidents by city/township, and the types of places the overdose incidents and deaths occurred (eg, home, motel).

The goal of the application is to provide a framework to answer basic questions about the opioid epidemic at a local level. Questions such as "Who is dying from opioid overdoses?," "What drugs, including opioids, are found in people dying from drug overdoses?," and "Has the number of opioid involved deaths increased in a certain community over time?" are examples of questions that can be explored. This article delves into the process of using such an application to answer these kinds of questions.

METHODS

Data Source

Overdose mortality data was collected by the Butler County Coroner's Office. According to the Ohio Revised Code Title III Chapter 313, all records in the coroner's office that are public records are open to inspection by the public, and any person may receive a copy of any such record or part of it upon demand in writing.[6] Similar to the disclaimer on the Ohio Department of Health (ODH) website,[7] the data in this web application are to support ongoing activities such as public awareness, surveillance, investigation, assessment, and evaluation. The developers of this application specifically disclaim responsibility for any analyses, interpretations, or conclusions.

Setting

Butler County is in the southwest corner of Ohio, with Indiana on its western border. The major cities in the county include Middletown and Hamilton. According to the United States Census Bureau, almost a third of the population of Butler County residents live in either Hamilton or Middletown. The cities of Hamilton and Middletown have lower median household incomes than Butler County and the entire state of Ohio. These cities also have twice the percentage of people in poverty compared to the county and statewide percentages. The race/ethnicity compositions of the cities are similar to Butler County and Ohio, in general. The percentage of people with a bachelor's degree or higher in Hamilton and Middletown is lower than the county and state percentages. Supplemental Material Table 1 provides a more detailed comparison of the demographics of Middletown, Hamilton, Butler County, and Ohio.[8]

The coroner's office investigates when any person dies as a result of criminal or other violent means such as by casualty, by suicide, or in any suspicious or unusual manner.[9] This includes all suspected overdose deaths that occur in the county. Deaths investigated by the coroner's office that had drug toxicity listed as a cause of death and manner was ruled accidental were identified as overdose deaths and used in this analysis. The term "toxicity" is used consistently by this coroner to identify cause of death in these cases. The Ohio Department of Health (ODH) would classify the cause of death as "poisoning" and apply an International Classification of Diseases (ICD) diagnosis code, ICD-10. Suicide and undetermined manners of death were not included in these data. Data used in this application were provided by the coroner's office and already classified as overdose deaths according to the criteria defined above. These data contain information on opioid and nonopioid drugs detected in postmortem toxicology analyses. Data from 2013 to 2018 were included in the application.

Procedures and Program Description

The application was developed to allow the exploration of drug overdose death data in Butler County by community members and decision makers. The application, using the Shiny package[10] in the R[11] software system, was developed in the RStudio IDE.[12] The RStudio IDE, R software, and the packages utilized for data cleaning and visualization are free open source technologies.[10-12] The Shiny server (dataviz.miamioh.edu) hosting this application uses a paid license on a virtual server that is provided by the Department of Statistics at Miami University. This Shiny server also hosts other applications that can be accessed through a main gallery page. Google Analytics was installed on the main gallery page; however, these were not installed on the individual application. If the process were restarted, it would include analytics to track the demand of this application. In addition to the obvious benefit of cost, an advantage to open source software is the abundance of online tutorials.[13-17] Links to a few online tutorials for the software used in the creation of this application are provided in the Supplemental Material. Also included in the Supplemental Material is a flow diagram to clarify the procedure to create the application.

The application originated as a client project for the coroner in a data visualization course. Later, one student continued to enhance this web application and launched the application on a Shiny server hosted at Miami University on April 25, 2018. Finally, the application was enhanced, updated, and relaunched on May 1, 2019.

To illustrate the features and controls of this application, we demonstrate how questions such as "Who is dying from opioid overdoses?," "What drugs, including opioids, are found in people dying from drug overdoses?," and "Has the number of opioid involved deaths increased in a specific community over time?" would be addressed by a user of this application.

Measures and Outcomes

Demographic data available in the database included date of birth, date of death, age, gender/sex, and race/ethnicity. Location information, such as place (eg, home, motel), city/township, and ad-

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

dress of an overdose incident, as well as the place, city/township, and address of the actual death were provided. Postmortem analysis of blood and urine were performed to determine drugs present in the decedent at the time of death. Data from 2013 to 2018 included up to 3 or 4 drugs detected in each decedent. For deaths occurring between June 2016 and August 2018, information was also collected on fentanyl analogs, a new and potentially more dangerous category of opioids.

Statistical Analysis

Bar graphs and segmented bar graphs were used to represent the number of times a specific drug was traced in a decedent. As more than 1 drug could be detected during testing, decedents could be counted in multiple bars within the 'number of times drug traced' graph. Bar graphs were also used to represent the number of overdose deaths in a specific city and a specific place, such as a home or motel. Line graphs were used to visualize the number of drugs or categories of drugs traced over time, along with the frequency of overdose deaths in cities and townships. Maps were used to illustrate the specific locations of overdose deaths.

RESULTS

The web application can be accessed at dataviz.miamioh.edu/Butler_County_Overdose_Deaths/. The landing page describes the contributors to the application and the years of data included in the application.

The left sidebar contains 4 options. The landing page is **Home**. The **How to Use the App** tab provides instructions to use and explore the application with notes of a few details specific to these data. The **Drugs Found in Overdose Decedent** tab is a drop-down menu with 3 options, **Demographics**, **Annual Trends,** and **Annual Category Trends**.

By selecting the **Demographics** tab, the application displays a bar graph of the most frequent number of times a drug was traced in a decedent. **Figure 1** shows a screenshot of this bar graph. The 3 boxes above the segmented bar graph are used to specify gender/sex, age, and race/ethnicity of the decedent to be displayed.

Figure 1 can be used to explore the demographics of who is dying (restricted here to ages 31-60 years and white decedents) in the opioid epidemic in Butler County during 2013 through 2018 and from what drugs. Fentanyl and heroin were the 2 most common drugs traced in drug overdose deaths in this age-race group during this time. In addition, of the top 12 drugs traced in decedents, more were traced in males than females.

The second tab, **Annual Trends**, shows a line graph that describes the patterns and trends of the number of times a drug was found

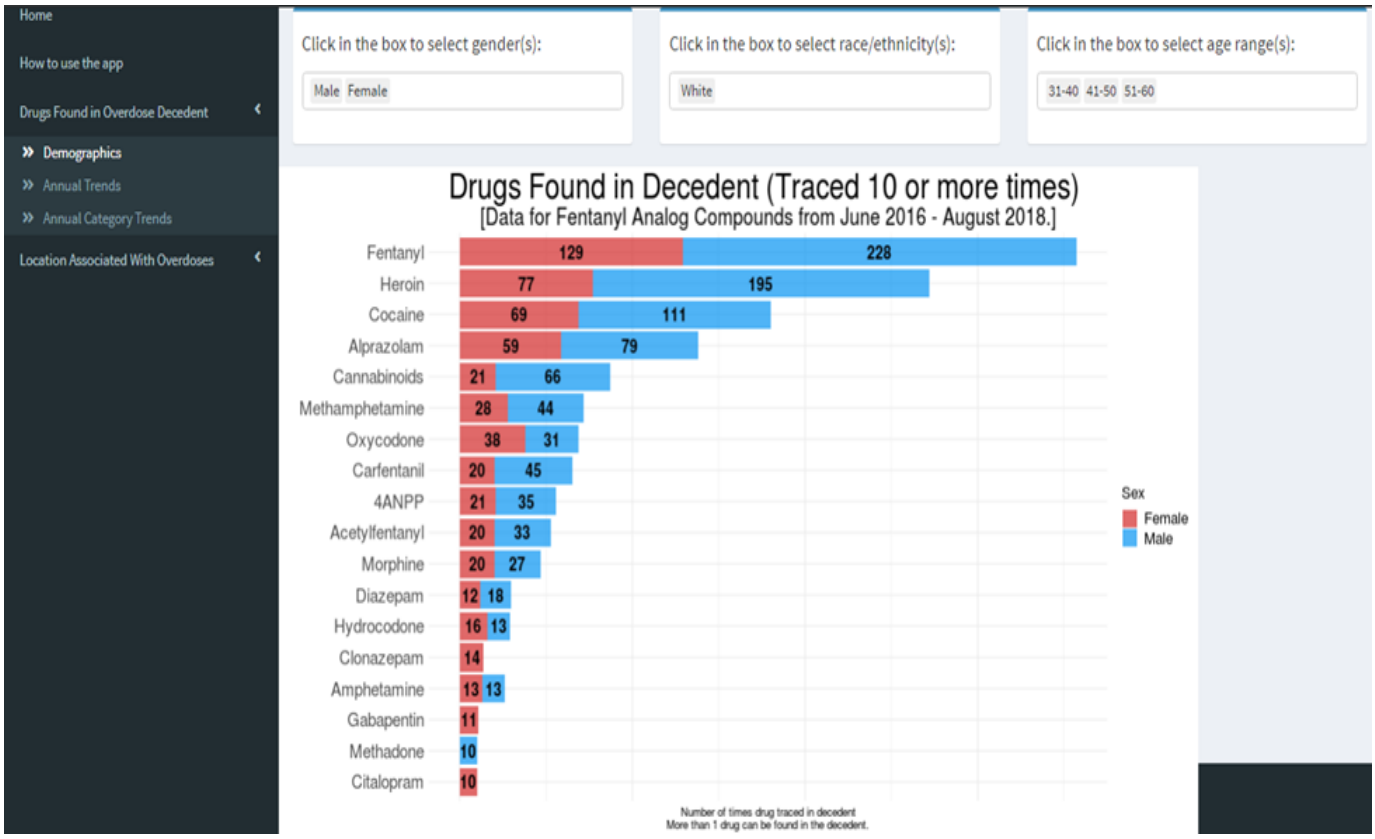


Figure 1. Segmented Bar Graph Illustrating Number of Times Drug Detected in White Male and Female Decedents Between Ages 31 and 60 years from 2013 to 2018

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

in a decedent over time. **Figure 2** shows a screenshot of this line graph. The selection box above the graph can be used to specify the drugs to be highlighted.

Figure 2 also displays the trends in which drugs, including opioids, are found in overdose deaths. Fentanyl and methamphetamine have increased rapidly since 2014 and remain some of the most common drugs traced in decedents. Other drugs such as heroin have had rapid declines in the number of times traced since 2015. Other drugs are displayed as light gray connected segments but will change color once the drug associated with that segment is selected.

The third tab, **Annual Category Trends**, produces a line graph that describes the number of times a drug category was found in a decedent over time. This value was calculated by utilizing the individual drug data used in Figure 2 and sums the 'number of times drug traced' for each drug category. This display is similar to Figure 2; however, Figure 2 displays individual drugs. Drug categories combine similar drugs into a category to provide ease and clarity on the type of drugs playing large roles in this epidemic. This line graph helps to easily identify patterns and trends in the categories of drugs in the epidemic.

The **Location Associated with Overdoses** tab is a drop-down menu with 3 options, **Address of Overdose Incidents**, **Trends by Cities Townships**, and **Location of Incident vs Death**. By selecting the **Address of Overdose Incidents** tab, the application displays a map of the address where the presumed overdose incident happened (eg, drug was used at this location) with an animation to show the addresses' change over time.

The last tab, **Location of Incident vs Death**, contains 2 different bar graphs controlled by a drop-down menu that can be changed to view the overdose incident or death data. The location of the presumed incident is the location of overdose, which may not be the same as the location of death. The first bar graph on the left side illustrates the number of overdoses in each location of incidents/deaths within each city or township. The second bar graph illustrates the number of overdoses within each place of overdose incidents/deaths faceted by city or township selected. Examples of place of death include home, vehicle, or motel. **Figure 3** contains a screenshot of this visualization. The input boxes above the graphical displays allow for the selection of the location of the incident and the city/township where the incident occurred.

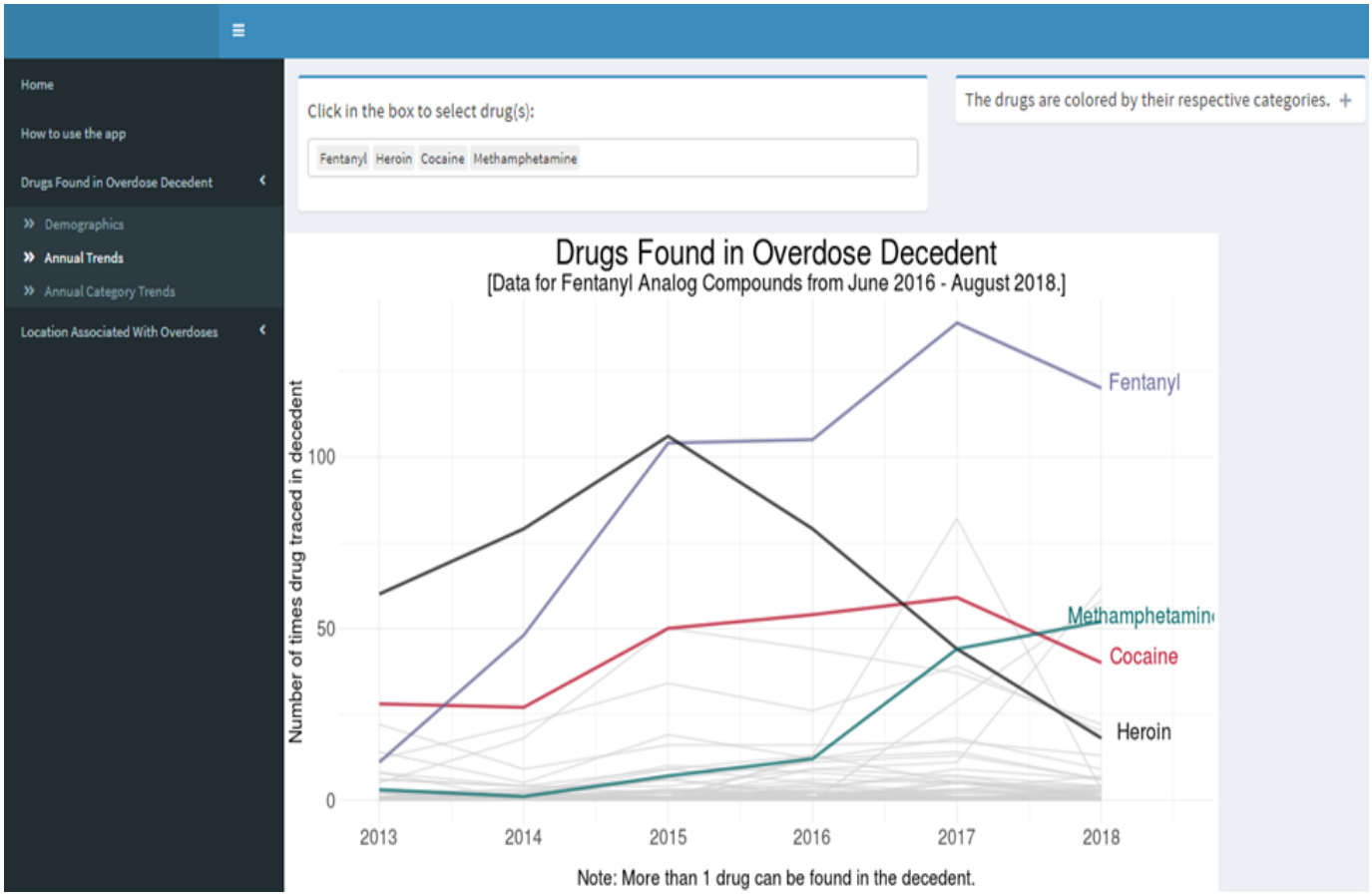


Figure 2. Line Graph Illustrating Number of Times Each Drug Found in Overdose Decedents 2013 to 2018

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

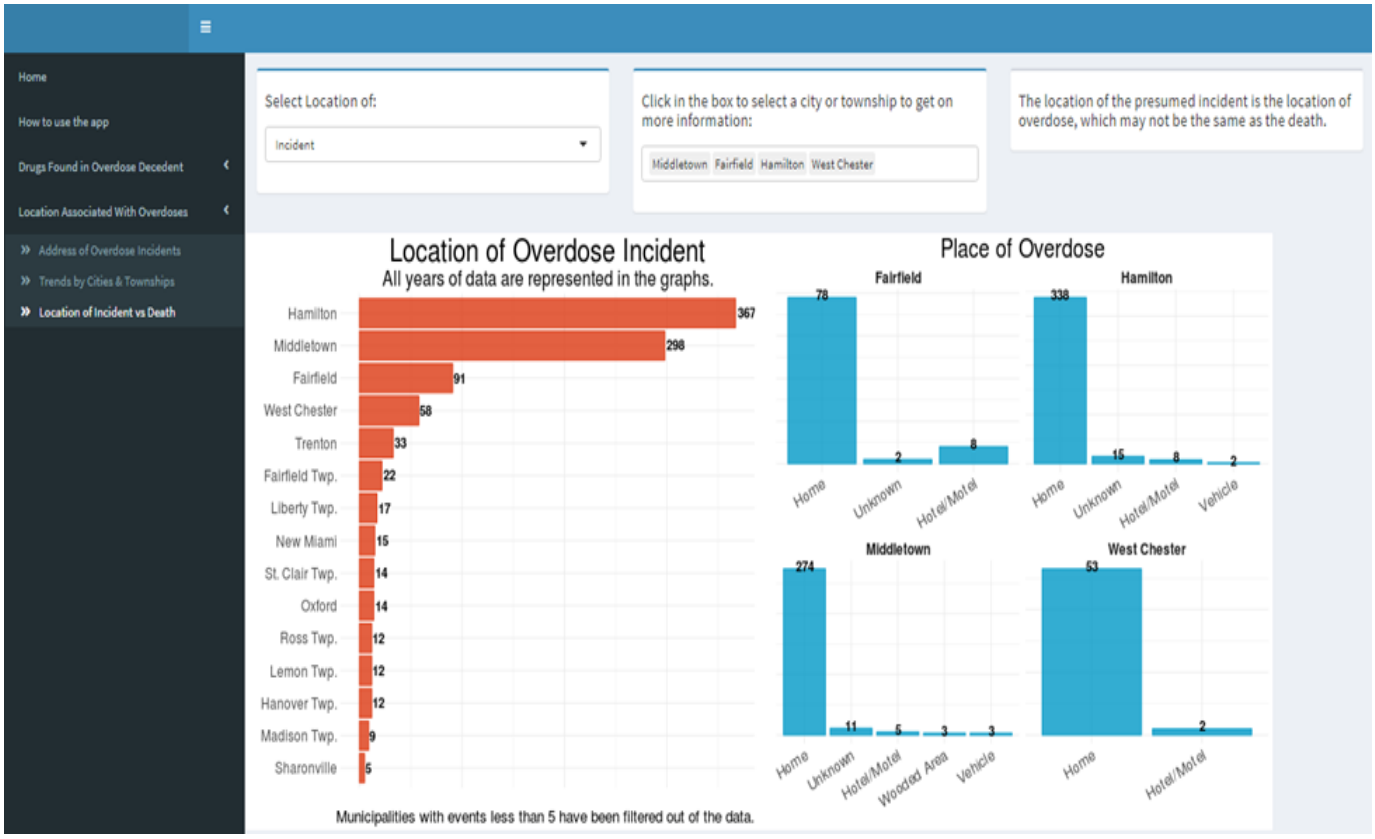


Figure 3. Bar Graph Illustrating Number of Overdoses 2013 to 2018 by Location of Incident/Death and Place of Overdoses by City/ Township

Using Figure 3, we can see that most of the overdose incidents in the top 4 cities or townships–Hamilton, Middletown, Fairfield and West Chester—occurred in homes.

DISCUSSION

This application was developed with the intent of providing public access to information regarding drug overdose deaths in Butler County. More specifically, the purpose of this application was to provide the ability to look at specific drugs or drug categories over time and explore community locations of interest. For example, as stated above, drugs such as heroin have had rapid declines in the number of times detected in decedents since 2015. What could this mean? Policy changes might have contributed to this decline, but the number of times fentanyl has been traced has not decreased over time. Why is that? Also, why are more males dying from the opioid epidemic? Although we may not have answers to these questions, we realize the benefits of collaborative efforts from the public health subject matter experts and the data gathering and developing experts to gather necessary insights.

Although all drugs detected in overdose victims are presented, communities are most interested in the impact of opioid-related deaths. This information is available as public record from the coroner's office. However, this tool allows the public to access that information to answer specific questions. One of the challenges in developing and updating this application is the data cleaning process. The raw data from the coroner required custom data processing for use in this application. This mandates that every update to the application be manual. This would be especially challenging if this application were expanded to other counties in Ohio since there is no standard reporting format among all coroners.

The data set used in this application was provided by the coroner's office. This data set was initially intended for internal use only, but then later developed into the public application it is now. Ideally, data can be structured and formatted for ease of use in an application and for ease of updating in an application. For example, future data sets could use ICD-10 codes. However, this would require adjusting the data set from previous years to be able to connect them.

Limitations of this data set are that it only contains reported overdose deaths in a single county and that the decedent had to have their postmortem specimens available for toxicology analysis. The data set used in this tool from the toxicology report only includes 3 to 4 substances with the largest quantities found in the decedent. It is important to note that the data set only includes over-

dose deaths while excluding nonfatal drug overdoses. In addition, the presumed location of the incident cannot always be verified if there is no evidence of drug use or eyewitness reports of the use. Another limitation is the lack of historical context. If data were available for years prior to 2013, the application would provide more historic context to these epidemic concerns. The application can be expanded as more recent data become available, although data processing and reformatting is required.

There are many ways to improve the application in the future. First, by creating a standardized data collection system both within counties and across counties, the data cleaning and preprocessing could be automated leading to a simple updating procedure of the application when new data become available. This could lead to real time displays of the data set within the application, rather than seeing data from the previous year. This could lead to different views as well such as displaying these data by months rather than over an entire year. It would also allow for offices such as the coroner to make decisions sooner when there are unusual trends observed in the data set. There is also room to enrich this application with external data, such as data regarding nonfatal drug overdoses, if data could be found at the city/township or zip code level. An additional major improvement would be expanding outside Butler County. By standardizing how every coroner collects their data, we could potentially expand to the entire state and address the epidemic directly. Also, adding to the tool when certain interventions were put in place would allow for stakeholders to directly see how policy and regulations are affecting the trends. We note that the Ohio Department of Health (ODH) provides a dashboard for "Emergency Department Visits for Suspected Drug Overdose Among Ohio Residents Ages 11 Years and Older" (odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/suspected-od-dashboard2). This site provides some demographic information for overdose cases encountered in emergency department visits; however, this does not capture the granularity of detail about drugs found in overdose decedents nor the detail of locations of cases in a county.

Other counties can implement similar applications such as this. The key to success when developing this application was close collaboration on a team that included the coroner, county health officials, and data scientists. Rapid prototyping of the application was needed to get feedback to improve the presentation of these data and the functioning of the application.

PUBLIC HEALTH IMPLICATIONS

The application developed and the results reported above have implications for public health practice and policymakers in Ohio. In addition to raising awareness about overdose deaths, this application allows the public to explore pertinent questions regarding this crucial matter. The policymakers in Ohio can use this information to make data driven decisions when passing new policy and addressing issues. For example, the amount of the opioid reversing drug, naloxone (Narcan), available to first responders in a community can be increased or decreased based on the presence of opioids in that specific community. Once a community is aware of the number and type of overdoses, implemented policies or interventions may be able to reduce the number of overdose deaths over time. Knowing the place that most overdoses occur could identify areas where treatment resources could be made readily available. This application provides a way to understand the problem so subsequent actions can be taken to begin alleviating the problem.

ACKNOWLEDGMENTS

The Butler County Overdose Deaths application was initially created as a part of a data visualization class, enhanced in a senior independent study, and finally updated in a senior capstone class. We particularly acknowledge the contributions of Katherine Shockey, Rachel Lewis, Lulu Liu, and Martin Schneider. We also thank Brad Koby for his support in maintaining the server and software packages and licenses. Finally, we would like to thank the anonymous reviewers and editor for suggestions that improved this manuscript.

REFERENCES

1. National Institute on Drug Abuse. National Institute on Drug Abuse: Opioid Overdose Crisis. Published January 22, 2019. Accessed May 27, 2020. https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis
2. Insurance Institute for Highway Safety. Fatality Facts 2017: State by state. Published December 2018. Accessed May 27, 2020. https://www.iihs.org/topics/fatality-statistics/detail/state-by-state#fatal-crash-totals
3. National Institute on Drug Abuse. National Institute on Drug Abuse: Ohio Opioid Summary. Published March 30, 2019. Accessed May 27, 2020. https://www.drugabuse.gov/opioid-summaries-by-state/ohio-opioid-summary
4. Centers for Disease Control and Prevention. Opioid Overdose. Published June 27, 2019. Accessed May 27, 2020. https://www.cdc.gov/drugoverdose/data/statedeaths.html
5. University of Wisconsin Population Health Institute. County Health Rankings and Roadmaps. Drug overdose deaths. Published 2019. Accessed May 27, 2020. https://www.countyhealthrankings.org/app/ohio/2017/measure/factors/138/data?sort=desc-3
6. LAW Writer® Ohio Laws and Rules. Chapter 313: Coroner. Published January 30, 2004. Accessed May 27, 2020. http://codes.ohio.gov/orc/313
7. Ohio Department of Health. Ohio Public Health Information Warehouse-Public: Disclaimer. Accessed May 27, 2020. http://publicapps.odh.ohio.gov/EDW/Site/Disclaimer
8. US Census Bureau. QuickFacts: Middletown city, Ohio; Hamilton city, Ohio; Butler County, Ohio; Ohio. Published September 10, 2019. Accessed May 27, 2020. https://www.census.gov/quickfacts/fact/table/middletowncityohio,hamiltoncityohio,butlercountyohio,OH/PST045218

9. LAW Writer® Ohio Laws and Rules. 313.12 Notice to coroner of violent, suspicious, unusual or sudden death. Published January 30, 2004. Accessed May 27, 2020. http://codes.ohio.gov/orc/313.12
10. Chang W, Borges Ribeiro B. shinydashboard: Create Dashboards with 'Shiny'. R package version 0.7.1. Published October 17, 2018. Accessed May 27, 2020. https://CRAN.R-project.org/package=shinydashboard
11. R Core Team. The R Project. R: The R-Project for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria. Published 2018. Accessed May 27, 2020. https://www.R-project.org/
12. RStudio Team. RStudio. RStudio: Integrated Development for R. RStudio, Inc., Boston, MA Published 2015. Accessed May 27, 2020. http://www.rstudio.com/
13. Grolemund G, Wickham H. Dates and times made easy with lubridate. *J Stat Software*. 2011;40(3): 1-25. doi:10.18637/jss.v040.i03
14. Kahle D, Wickham H. ggmap: Spatial Visualization with ggplot2. R J. June 2013;5(1):144-161. http://journal.r-project.org/archive/2013-1/kahle-wickham.pdf
15. Auguie B. gridExtra: Miscellaneous Functions for "Grid" Graphics. R package version 2.3. Published September 9, 2017. Accessed May 27, 2020. https://CRAN.R-project.org/package=gridExtra
16. Wickham H, François R, Henry L, Müller K. dplyr: A Grammar of Data Manipulation. R package version 0.8.5. Published March 7, 2020. Accessed May 27, 2020. https://CRAN.R-project.org/package=dplyr
17. Wickham H. ggplot2: Elegant Graphics for Data Analysis. New York: Springer-Verlag New York. doi:10.1007/978-0-387—98141-3_3

SUPPLEMENTAL MATERIAL

Supplemental File. Data Cleaning Files, Application Code and Creation Resources and Tutorials.

Supplemental Table 1. Demographic Characteristics of Residents in Ohio

Ohio Journal of Public Health
Ohio Public Health Association
Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

COMMENTARY

Remembering Your Roots: The Role of Horticulture Therapy in People Living with Dementia

Kelly Reilly Kroustos, PharmD, CDP[1]; Gretchen Horning, PharmD[1]; Jennifer Gurevich, PharmD[1]; Anna Gurevich, (PharmD candidate 2021)[1]; Kristen Finley Sobota, PharmD, BCPS, BGCP[1]
[1]Raabe College of Pharmacy, Ohio Northern University, Ada, OH
Corresponding Author: Kelly Reilly Kroustos, 525 South Main Street, Ada, OH 45810, (419) 772-3955, k-reilly@onu.edu
Submitted September 13, 2019 Accepted May 10, 2020

ABSTRACT

Introduction: Dementia is a debilitating disease affecting over 50 million people. Major challenges facing patients with dementia lie in the impact of the behavioral and psychological symptoms of dementia (BPSD). The American Geriatrics Society and Dementia Action Alliance recommend against the use of antipsychotics as first-line treatment. Antipsychotics often fail to treat BPSD whereas nonmedication practices such as horticulture therapy may lessen BPSD. Guideline evidence has provided a unique opportunity for public health officials to assist in filling this vital role in the approach to BPSD management.

Methods: Several studies and meta-analyses were reviewed to determine the effectiveness of horticulture therapy in managing BPSD, and evidence supports horticulture therapy as an effective method of addressing BPSD.

Results: The benefits of horticulture therapy extend beyond addressing only BPSD; through multisensory stimulation, patients have increased physical activity, reduced stress, and improved sleep. Horticulture therapy has been shown to decrease the sense of loss and reestablish the patient in a familiar nurturing role, providing the patient with a sense of purpose.

Conclusion: Stakeholders within the public health sector are strategically positioned to implement evidence-based interventions that address the unmet needs for the care of dementia within the community.

Keywords: Dementia; BPSD; Horticulture; Gardening therapy; Nonmedication

Current Perspectives on Dementia

Dementia is a debilitating and progressive disease affecting over 50 million people globally, with an estimated US financial impact of $818 billion in 2015 health care costs.[1] In alignment with Healthy People 2020 and the topic area of dementia, the overarching goal is to reduce morbidity, improve the quality of life, and address cost-related barriers to care in people living with dementia and Alzheimer's disease.[2] Within the state of Ohio, Alzheimer's dementia is the sixth leading cause of death, impacting 220 000 seniors (> 65 years of age) with a projected 30 000 senior increase in the next 5 years.[3] A reported 600 000 family caregivers bear the responsibility for direct care and/or health decisions for their loved ones.[3] The Ohio Medicaid program pays approximately $2.5 billion per year in caring for people with Alzheimer's dementia.[3] "These numbers show that a public health approach is necessary to lessen the burden and enhance the quality of life for those living with cognitive impairment and their families."[3]

The American Academy of Neurology dementia guidelines classify dementia-related decline into various overlapping realms of impairment that include cognitive, behavioral, and functional.[4] The cognitive domain of dementia includes language and social skill, memory, learning, attention, and perception.[5] Individuals exhibiting deficits within the social domain of dementia often have stark changes in personality and behavior.[5] These are collectively referred to as behavioral and psychological symptoms of dementia (BPSD) and include agitation, aggression, depression, delusions ,and hallucinations due to frustration, pain, and the inability to communicate unmet needs.[5-7] Changes in functional capacity should be assessed using validated methods during medical visits as guidelines support the use of rehabilitation and therapy ser-

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

vices.[8] Due to the detrimental effects of dementia, people often require medical, emotional, and socially supportive interventions.

Approach to Care

Dementia management goals are to preserve independence, stabilize and delay further loss of cognitive and functional ability, and improve quality of life.[9,10] First-line medication management for mild to moderate dementia is monotherapy with an acetylcholinesterase inhibitor: donepezil, rivastigmine, or galantamine. For moderate to severe dementia, memantine may be used in combination with the acetylcholinesterase inhibitor.[4,11]

Management strategies for BPSD often include unlabeled use of antipsychotics; however, research indicates that antipsychotics fail to show benefits when compared with placebo, leading to more adverse events.[7,12,13] Both the American Geriatrics Society and the Dementia Action Alliance indicate that nonmedication therapies are first-line interventions for individuals with BPSD. The Food and Drug Administration issued a black box warning for the use of antipsychotics in people with dementia due to heightened risk of mortality and adverse events.[13] Further restrictions on the utilization of antipsychotics within the dementia population were implemented through the Centers for Medicare and Medicaid Services (CMS) with the National Partnership to Improve Dementia Care. While antipsychotic utilization nationally has decreased to 23.9% in 2011, CMS announced an additional reduction of 15% by the end of 2019.[14] These benchmarks directly relate to the Five-Star Quality Rating System and highlight the partnership's larger mission of enhancing the use of nonmedication strategies in person-centered dementia care practices.[15]

Implementation of person-centered strategies has been recognized by the Alzheimer's Association as the "single most important determinant of quality dementia care across all care settings is direct care staff." Increasing numbers of people with dementia will necessitate the need for both family caregivers as well as long-term care providers. The need for paid care providers will continue to increase from 3.27 million in 2014 to 4.56 million in 2024.[16] Guideline evidence and subsequent CMS mandates have provided a unique opportunity for public health officials to engage local aging sectors to assist in filling this vital role in the approach to BPSD management. Creating a network within area agencies on aging, councils on aging, senior centers and senior housing developments can help to support the resources needed for family caregivers in home and community-based settings. While institutional care settings are charged to meet current CMS regulations, implementation of individualized nonmedication strategies may be challenging because of current staffing responsibilities. Collaboration with the previously mentioned aging sectors as well as external community stakeholders (church groups, philanthropic groups, and students from high school and/or college programs) would provide an opportunity for volunteers to contribute to the management of BPSD.

Nonmedication strategies provide a targeted approach to addressing BPSD and potentially lighten caregiver burden.[9] Current nonmedication approaches include cognitive, reminiscent, multisensory, and stimulation therapies.[11] Cognitive therapy encompasses activities like reading books and doing puzzles to help maintain cognitive function.[17] Options for effective therapy include aromatherapy, massage, touch therapy, music therapy, pet therapy, and multisensory stimulation (MSS).[18] Multisensory stimulation uses everyday objects to engage or arouse 4 of the 5 senses (acoustic, tactile, olfactory, visual) with the goal of evoking positive feelings.[18] Lastly, there are stimulation therapies like cooking and social robots that provide people with a sense of purpose and recollections of the past.[19,20] Newly emergent is horticulture therapy which combines sensory, reminiscent, and stimulation therapy,[9] and allows individuals to partake in gardening which, among other benefits, provides a sense of purpose and improves quality of life.[10]

Health care providers within the public health sector are uniquely positioned to assist in the care of people with dementia and address caregiver burdens through evidence-based intervention. Various health-centered professionals or caregivers can implement first-line therapies for BPSD including nonmedication practices such as horticulture therapy. The versatility of who may deliver these nonmedication practices is proved by the fact that they are not limited to those within the health care setting.

Horticulture Therapy

Horticulture therapy is used to describe the health benefits of therapeutic gardening, including reduction in BPSD, improvement in circadian rhythm, and an increasing muscle strength.[10,21,22] Recently, horticulture therapy has been identified in literature and practice as beneficial for people with dementia. Therapeutic gardens are primarily described as wander or sensory gardens. Wander gardens allow individuals to walk uninhibited to alleviate restlessness, a common symptom associated with dementia. Thus, individuals who suffer from restlessness wander in a safe, secure, and enclosed environment. Sensory gardens cater to all 5 senses and allow people to enjoy fresh air and nature. The gardens are designed with safety in mind, often including high walls and simple arrangements.[10]

There are 2 main uses of sensory gardens, active and passive. Active use includes purposeful activities of gardening, including watering, planting, and weeding. Passive use refers to the sensory experience of seeing, touching, and smelling the garden as well as being in the fresh air and sunshine of outdoors.Both types of gardens have shown benefit in people living with dementia.[10]

Health Benefits

Horticulture therapy has been noted to improve cognitive symptoms in individuals with moderate dementia.[21,22] D'Andrea et al implemented horticulture therapy in study participants with

Alzheimer's disease at a long-term care facility. Twenty out of 40 participants with dementia attended 45-minute horticulture therapy sessions twice weekly for 12 weeks. The remaining 20 participants served as the control group, partaking in all other recreational events except horticulture. With the assistance of a therapeutic recreation specialist, participants planted seeds and later tended and watered the plants. Using observation, medical records, and 2 scoring systems, Minimum Data Set Plus (MDS+) and Test for Severe Impairment (TSI), researchers assessed psychosocial and cognitive changes from baseline. The MDS+ is a comprehensive quarterly assessment that is used to evaluate all areas of a residents' physical, social, and emotional well-being and was used to identify problem areas and document behavior changes. The TSI is an objective and valid means of assessing the cognitive and psychosocial functioning of persons and is divided into 6 sections valued at a maximum of 4 points per section with a maximum TSI score of 24 reflecting high cognition. The 6 sections cover 1) well-learned motor performance, 2) language comprehension, 3) language production, 4) immediate/delayed memory, 5) general knowledge, and 6) conceptualization. D'Andrea et al concluded horticulture is associated with reduction in feelings of helplessness, enhanced decision making, stimulated interest in socialization, and alleviation of lack of concentration and memory loss. Study findings also reflect positive outcomes for the MDS+ assessments within the intervention group as compared to the control group. Statistically significant differences ($P < 0.0005$) were identified between the control and the intervention group TSI difference scores (mean difference scores = 2.8 points) regarding cognitive functioning.[23]

Lee et al studied the effect of indoor gardening on sleep, agitation, and cognition in 23 institutionalized study participants presenting with BPSD.[21] Edible dropwort and bean sprouts were chosen for the garden as they were familiar plants, grew quickly, and were edible. Every morning and afternoon during the 4-week study, participants tended to their plants with the assistance of nurses. Along with gardening, participants were encouraged to touch or look at their plants outside of the cultivating sessions. Once plants reached full height, they were harvested and were used as a side dish in their meals. As a result, participants not only shared in the gardening process, but also tasted the fruits of their efforts. The findings of Lee et al suggest improvements in sleep measured by wake time after sleep onset (WASO), time during naps, nocturnal sleep time (NST), and nocturnal sleep efficacy percent (NSE%=NST/WASO x 100). Pre-horticulture intervention WASO duration was 75.2 (± 34.9) minutes while post-horticulture intervention resulted in WASO duration of 54.75 (± 26.6) minutes ($P < 0.05$). Time spent napping decreased from 158.43 (± 63.64) minutes pre-horticulture therapy to 85.87 (± 43.97) minutes ($P < 0.05$) post-horticulture therapy. Once horticulture therapy was implemented, NST went from 440.5 (± 59.2) minutes to 483.5 (± 56.6) minutes ($P < 0.05$) and NSE showed an increase from 85.09%(± 6.98) to 89.62% (± 5.27) ($P < 0.05$), respectively. A decrease in WASO and duration of naps, with an increase in NSE and NST indicates less fragmented sleep which may lead to a decrease in agitation. Further study is required to conclude that gardening improves cognition; however, the results suggest that providing sensory stimulation through gardening leads to a decrease in agitation and aggression.[10,21,22]

An observational study conducted by Murphy et al collected baseline data for 12 months on 34 veterans residing in a memory unit.[22] The facility opened an outdoor wander garden for residents and observed the impact on agitation. Twenty-one participants were able to walk unassisted, and the others used merry walkers or wheelchairs. Outcomes observed included the change in the Cohen-Mansfield Agitation Inventory (CMAI) short form, which is an established validated tool for measuring agitation in institutionalized patients and consists of 14 items with a 5-point rating scale with a maximum score of 70 points (1= patient never engages in the behavior to 5 = behavior occurs several times per hour). The CMAI short form used in the current study includes a variety of dementia-related behaviors. For the first 2 months, the average CMAI score decreased (21.38-18.85) then plateaued (18.9) for 2 months, then increased (18.97-19.67) during the winter months when the wander garden was unavailable and by the end of the study period decreased (18.9) once again. Even with the CMAI increases during the winter months, the increase in score never equaled the original CMAI score. These findings suggest wander gardens promote a decline in agitation and mirror the findings from the meta-analysis of Gonzalez et al (see **Table 1**).[10,22]

Conclusion

Statistics from the Ohio Alzheimer's Associations clearly demonstrate future needs surrounding the care of people with dementia.[3] A unified public health approach is necessary to maintain person-centered care, lessen caregiver burden, and support the needs of the community. Recent evidence recognizes horticulture therapy and outdoor wander gardens as an alternative method of addressing BPSD with health benefits. Behavioral and psychological symptoms of dementia include agitation, aggression, and depression due to the inability to communicate unmet needs.[5-7] Horticulture therapy is associated with a reduction in feelings of helplessness and agitation, while promoting sleep, decision making, socialization, and concentration.[10,23] Public health advocates in collaboration with aging sectors have an integral role in introducing the concept of horticulture therapy to caregivers and long-term care providers as an option for BPSD management. By harnessing the healing and restorative effects of nature, improving quality of life, and instilling a community-like environment, horticulture therapy promises a bright future for people living with dementia.

The authors deny any conflicts of interest.

ACKNOWLEDGMENTS

Ohio Northern University American Society of Consultant Pharmacists Student Chapter, Vancrest of Ada, Martha Mazak, RPh

Ohio Journal of Public Health, June 2020, Vol. 3, Issue 1 ISSN: 2578-6180

Table 1. Summary of Selected Studies on Horticulture Therapy in Individuals with Dementia

Authors	Subjects and study design	Population studied	Implementation of therapy	Trial length	Outcome measures	Results
Lee et al[21]	One group repeated measures study n=23	Dementia	Indoor garden: each individual planted a pot with dropwort and bean sprouts to care for daily	5 weeks	Sleep patterns, agitation and cognition evaluated using the modified CMAI and revised HDS	Sleep, agitation, and cognition improved (P <0.05)
D'Andrea et al[23]	RCT n=40	AD	Participants randomized into the treatment group attended biweekly horticulture	12 weeks	MDS+, TSI used to evaluate cognitive levels and functioning	Overall functional levels improved (P <0.0005)
Gonzalez et al[10]	Meta-analysis 16 studies n=549; interventions with pre- and post-tests, RCT	Dementia and AD	Sensory garden benefits, therapeutic horticulture benefits	Trials varied in length	Measures of behavioral and psychological therapy, including well-being and sleep patterns	Improved well-being, sleep, behavioral problems; decreased falls and use of antipsychotics
Murphy et al[22]	Observational study n= 34	Veterans in secure memory unit	Wander garden	12 months	CMAI score	CMAI decreased during the first 2 months (P <0.001)

Abbreviations: CMAI = Cohen-Mansfield Agitation Inventory, used to measure frequency and severity of aggressive behaviors; HDS= Hasegawa Dementia Scale; MDS+= Minimum Data Set Plus; TSI= Test for Severe Impairment; AD= Alzheimer's disease; RCT= Randomized controlled trial

REFERENCES

1. World Health Organization. Dementia. Published December 2017. Accessed March 6, 2018. https://www.who.int/news-room/fact-sheets/detail/dementia
2. Healthy People 2020. Office of Disease Prevention and Health Promotion. Dementia, Including Alzheimer's Disease. Updated September 6, 2019.Accessed March 6, 2018. https://www.healthypeople.gov/2020/topics-objectives/topic/dementias-including-alzheimers-disease
3. Alzheimer's Association-Ohio. Alzheimer's Impact Association. Updated February 28, 2020. Accessed March 6, 2018. https://www.alz.org/professionals/public-health/state-overview
4. McKhann GM, Knopman DS, Chertkow H, et al. The diagnosis of dementia due to Alzheimer's disease: Recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. *Alzheimers Dement*. 2011;7: 263-69.
5. Hugo J, Ganguli M. Dementia and cognitive impairment: epidemiology, diagnosis, and treatment. *Clin Geriatr Med.* 2014 Aug; 30(3):421-442. doi:10.1016/j.cger.2014.04.001
6. Cerejeira J, Lagarto L, Mukaetova-Ladinska EB. Behavioral and psychological symptoms of dementia. *Front Neurol.* 2012 May 7; 3:73. doi:10.3389/fneur.2012.00073
7. Kroustos KR, Trautwein H, Kerns R, Sobota KF. Fidget Blankets: A Sensory Stimulation Outreach Program. *Consult Pharm*. 2016; 31(6):320-324. doi:10.4140/TCP.n.2016.320
8. Dementia assessment: management and support for people living with dementia and their careers. *NICE*. 2018; 97. Accessed March 6, 2018. https://www.nice.org.uk/guidance/ng97
9. InformedHealth.org. Cologne, Germany: Institute for Quality and Efficiency in Health Care (IQWiG); 2006-. Non-drug interventions for Alzheimer's disease. 2013. Updated June 29, 2017. Accessed March 6, 2018. https://www.ncbi.nlm.nih.gov/books/NBK279355/
10. Gonzalez MT, Kirkevold M. Benefits of sensory garden and horticultural activities in dementia care: a modified scoping review. *J Clin Nurs*. 2014 Oct; 23:2698–2715. doi:10.1111/jocn.12388
11. American Psychiatric Association. Practice Guidelines for the Treatment of Patients with Alzheimer's Disease and Other Dementias. Accessed January 31, 2019. http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/alzheimers.pdf
12. Gitlin LN, Kales HC, Lyketsos CG. Managing Behavioral Symptoms in Dementia Using Nonpharmacologic Approaches: An Overview. *JAMA.* 2012;308(19):2020-2029. doi:10.1001/jama.2012.36918
13. Steinberg M, Lyketsos CG. Atypical antipsychotic use in patients with dementia: managing safety concerns. *Am J Psychiatry*. 2012;169 (9):900–906. doi:10.1176/appi.ajp.2012.12030342
14. National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report. Centers for Medicare & Medicaid Services. Accessed: May 23, 2020. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes

15. Larrick AK. Request Comments: Enhancements to the 2017 Star Ratings and Beyond. 2015 Nov. Accessed March 3, 2019. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf
16. Gilster SD, Boltz M, Dalessandro JL. Long-Term Care Workforce Issues: Practice Principles for Quality Dementia Care. *Gerontologist*. 2018;58 (suppl_1):S103-S113. doi:10.1093/geront/gnx174
17. Carrion C, Folkvord F, Anastasiadou D, Aymerich M. Cognitive Therapy for Dementia Patients: A Systematic Review. *Dement Geriatr Cogn Disord.* 2018; 46(1-2):1–26. doi:10.1159/000490851
18. Witucki JM, Twibell RS. The effect of sensory stimulation activities on the psychological well-being patients with advanced Alzheimer's disease. *Am J Alzheimers Dis Other Demen.* 1997;12:10-5.
19. Valentí Soler M, Agüera-Ortiz L, Olazarán Rodríguez J, et al. Social robots in advanced dementia. *Front Aging Neurosci.* 2015;7:133. doi:10.3389/fnagi.2015.00133
20. Fitzsimmons S, Buettner L. A therapeutic cooking program for older adults with dementia: Effects on agitation and apathy. *Am J Recreat Ther.* 2003;23-33.
21. Lee Y, Kim S. Effects of Indoor Gardening on Sleep, Agitation, and Cognition in Dementia Patients – A Pilot Study. *Int J Geriatr Psychiatry*. 2008;23(5):485–489. doi:10.1002/gps.1920
22. Murphy PF, Miyazaki Y, Detweiler MB, Kim KY. Longitudinal analysis of differential effects on agitation of a therapeutic wander garden for dementia patients based on ambulation ability. *Dementia*. 2010; 9 (3):355-373. doi:10.1177/1471301210375336
23. D'Andrea SJ, Batavia, M, Sasson N. Effect of horticultural therapy on preventing the decline of mental abilities of patients with Alzheimer's type dementia. *J Ther Hortic*. 2007;18:8-17.

OJPH
Ohio Journal of Public Health
Ohio Public Health Association