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## PEER-REVIEWED CME ARTICLE: ETHICS CASE

### Should Physicians Consider the Environmental Effects of Prescribing Antibiotics?

Jeremy Balch, Julia H. Schoen, MS, and Payal K. Patel, MD, MPH

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#### Abstract

Pharmaceuticals are beginning to receive attention as a source of pollution in aquatic environments. Yet the impact of physician prescription patterns on water resources is not often discussed in clinical decision making. Here, we comment on a case in which empiric antibiotic treatment might benefit a patient while simultaneously being detrimental to the aquatic environment. We first highlight the potential harm caused by this prescription from its production to its disposal. We then suggest that Van Rensselaer Potter's original conceptualization of bioethics can be used to balance clinicians' obligations to protect individual, public, and environmental health.

#### Case

Dr. Turner, a hospitalist, is called to assess Mr. Johnson, an elderly patient with a history of urinary tract infections (UTIs), who presented to the ER with altered mental status. Urine cultures are pending but previous cultures have grown *Escherichia coli* (*E. coli*) with an extended-spectrum beta-lactamase (ESBL) gene. Although Mr. Johnson improves with intravenous fluids, Dr. Turner plans to treat Mr. Johnson with ciprofloxacin, a broad-spectrum fluoroquinolone-class antibiotic, to cover the *E. coli* that he has grown in the past. Dr. Turner recently read that this drug can persist, unaltered, in the hospital's wastewater collection system and in the municipal wastewater water treatment plant (WWTP). While much will be filtered, a quantifiable amount will end up in Mr. Johnson's local watershed. How should Dr. Turner, other physicians, and their institutions weigh the benefits that individual patients derive from pharmaceutical treatment with the contamination risk this treatment poses to freshwater resources used by entire communities and ecosystems?

## Commentary

Production and disposal of antibiotics, and their impact on water supplies, is often overlooked in health care. The AMA *Code of Medical Ethics* focuses primarily on a physician's responsibility to her patient, whose autonomy (or her surrogate's) can only be superseded in special circumstances for public health [1, 2] or when required by law [3]. In terms of public health, pharmaceuticals pose well-known threats to water quality, most famously documented in the feminization of fish in the United Kingdom [4], but also in the increasing spread of antibiotic resistance in surface waters [5]. In this paper, we trace the impact of ciprofloxacin from its production to its disposal to shed light on the ethical dilemmas posed by antibiotic contamination of aquatic environments. While a clinician's duty to meet the needs of her patients is undeniable, these needs must be balanced with a moral imperative to minimize the impact of antibiotics on the environment and on other community members, including future generations.

### Pollution of Aquatic Environments

The ciprofloxacin prescribed to Mr. Johnson is a synthetic fluoroquinolone antibiotic [6]. In the US, the Food and Drug Administration (FDA) places limits on the oxygen demand and solid sediment allowed in wastewater produced during pharmaceutical manufacturing [7]. However, these regulations do not prevent the release of pharmaceuticals into surface water. Trace amounts of at least 82 pharmaceuticals and other organic wastewater contaminants are present in streams across the US [8]. In India, where 39 percent of pharmaceutical plants that manufacture domestically consumed drugs are located, fluoroquinolone levels toxic to plants, algae, and bacteria have been found in wastewater discharged from drug manufacturers [9-11]. Antibiotic-resistant bacteria such as ESBL gram-negative bacteria and carbapenem-resistant Enterobacteriaceae have been found in surface waters and tap water in the same region [12]. Given the ease with which antibiotic-resistant genes can traverse continents, we must consider the global impacts of antibiotic production and effluent [13].

Locally, administration of Mr. Johnson's ciprofloxacin has a direct impact on his community. Classified as a nonhazardous waste, extra amounts of ciprofloxacin mixed by Mr. Johnson's (or any) pharmacist can be discarded down a common drain [14]. Once administered, up to 92 percent of the drug will be excreted unchanged in urine and feces [15]. It will join other ecotoxic contrast materials, antihypertensives, and synthetic hormones on their way to the WWTP [16].

### Harm to Human and Environmental Health

*Harm to human health.* While some antibiotics are removed during wastewater treatment, many are discharged into receiving surface waters or deposited on soils in the form of sludge [5, 17]. Multiple studies have found antibiotics and antibiotic-resistant bacteria such as ESBL *E. coli* downstream of hospitals and local WWTPs [18-23], likely contributing to the epidemiology of antibiotic resistance [20]. Current research has yet to

demonstrate a direct link between wastewater and human infections, but resistant bacteria in streams and soil can be taken up by crops, livestock, or humans [24]. Although the exact route of infection has not been established, there are several possible mechanisms. These microbes might be ingested through direct contact with streams or through the crops themselves, either causing immediate illness or colonizing a person's gastrointestinal tract [25]. If a person later becomes sick from this microbiota, he or she could already be resistant to antibiotic treatment.

*Harm to the environment.* Fluoroquinolones and sulfonamides have been shown to interfere with nitrogen processing in the environment, leading to buildup of harmful nitrogen and resultant toxicity to nonhuman species [26, 27]. The predicted aquatic concentrations of amoxicillin and oxytetracycline released from WWTP annually in England exceed limits that are toxic to aquatic ecosystems [28]. Although direct harm to vertebrates from environmental antibiotic exposure is challenging to measure, pharmaceuticals in the environment can be carcinogenic, sterilizing, or fatal to species ranging from microbiota to rainbow trout [29]. These changes also contribute to loss of biodiversity [30].

### **Ethical Dilemmas and the Origins of Bioethics**

Two ethical dilemmas are posed by prescribing empiric antibiotics to Mr. Johnson: (1) do the benefits that he derives as an individual outweigh the harm his prescription poses to the environment; and (2) do these benefits justify the consequences of antibiotic resistance and decreased water quality for other community members, including future generations?

To approach the dilemmas above, we can turn to the original conceptualization of bioethics as a tool for decision making. In 1970, Van Rensselaer Potter introduced the term *bioethics* [31]. He argued that human survival depended on adequate resource allocation and that ethics should prioritize our ecological support systems [32]. Potter's bioethics was not widely adopted and the term came to describe biomedical ethics [31, 33]. This form of ethics has traditionally been limited to individual patients and clinicians while environmental ethics focuses on the broader ecology and includes regard for sustainability as an ethical and not just a biological value [33]. Common ground exists in both fields to preserve resources and prevent the spread of disease [33].

*Individual benefit versus environmental harm.* If Mr. Johnson truly had a UTI, morbidity can include nephrolithiasis (kidney stone), pyelonephritis (kidney infection), and urosepsis (bloodstream infection). Moreover, delays in antibiotic therapy have been shown to increase mortality [34]. However, without observable signs or symptoms of these complications, the individual benefits could be small compared to the harms to the environment if all patients in Mr. Johnson's situation received antibiotics. In the US in 2014, about 21 million prescriptions were written for ciprofloxacin alone [35]. The CDC

estimates that up to 30 percent of outpatient [antibiotic prescriptions are unnecessary](#), including those which would have been prescribed for suspected UTI [36]. This magnitude of unnecessary antibiotic prescriptions demands intervention at the prescriber, institutional, and national level.

*Individual benefit versus community harm.* Clinicians and institutions can incorporate existing tools, such as the Treat Systems decision-support system (TREAT model) [37], to balance scientific and economic analysis and value-based judgements of generally acceptable risk in prescribing decisions. For a given course of antibiotics, the model balances the expected benefit (i.e., greater chance of survival) and the expected costs, including the dollar amount of a drug, its side effects, its contribution to future resistance, and even its effect on the mortality of other community members, including future generations [37]. Moral decisions about costs of reduced quality of life and the value of life for present and future patients underpin the TREAT model [37]. Without such models, the true cost of antibiotics will go unheeded. Antibiotics are not benign medications and their risks need to be fully accounted for and discussed with patients. Public and scientific discourse to determine who should receive treatment would be necessary to generate ethical guidelines for antibiotic use [38, 39].

In the meantime, antibiotic stewardship programs (ASPs) have already been successful at optimizing patient outcomes while minimizing toxicity, costs, and the potential for microbial resistance within hospitals [40, 41]. ASPs are coordinated programs led by an infectious disease physician and a pharmacist that promote appropriate antibiotic use, reduce microbial resistance, and improve patient outcomes. We traditionally think about stewardship in the context of antibiotics. However, as we develop a greater understanding of the ecotoxicity of other pharmaceuticals and their impacts on public health, the principles of stewardship applied to antibiotics might prove useful for other pharmaceuticals. The Choosing Wisely® campaign uses this stewardship framework [42]. Sponsored by the American Board of Internal Medicine and Consumer Reports, [Choosing Wisely](#) asks medical societies to publish five tests or interventions performed inappropriately [42]. The campaign also promotes conversations between patients and clinicians about these tests [42]. Sweden and the European Union have categorized drugs according to environmental risk to guide prescribers and institutions [43], and this data could be incorporated into existing prescribing models.

## Conclusion

Mr. Johnson's case highlights the tension between protecting an individual and minimizing harm to water sources and public health. While the environmental and public health consequences are clear, the ethical question of whether and how they should influence prescribing practices remains unresolved. Prescribers should cultivate greater environmental awareness of the fate of pharmaceuticals through medical education and through institutional and policy-level interventions such as the TREAT model, ASPs, and

the Choosing Wisely campaign. These programs would also help identify appropriate prescribing habits and which antibiotics have the most benign environmental profile. We need continued research to identify sites and quantities of pharmaceutical release in aquatic environments and their impact on human and environmental health. As the influence of environmental degradation on human health becomes increasingly clear, the health care community needs to examine its roles in current environmental contamination trends and work towards creating a healthier planet for all of us.

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**Related in the *AMA Journal of Ethics* and *Code of Medical Ethics***

[A Brief History of Environmental Bioethics](#), September 2014

[Caring for the Health of the Community Means Caring for the Health of the Environment](#), June 2009

[Choosing Wisely: Initiating Conversation and Culture Change around Overuse of Medical Tests and Treatments](#), November 2015

[Educating Patients as Medicine Goes Green](#), June 2009

[Hospitals and "Used Goods"](#), June 2009

[AMA Code of Medical Ethics' Opinion 11.1.2, Physician Stewardship of Health Care Resources](#), June 2016

[Unnecessary Antibiotics](#), June 2006

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## FROM THE EDITOR

### Clinicians' Roles in Ensuring Access to Safe Water

The Flint, Michigan, water town hall was overwhelmed with the discordant sound of crinkling plastic water bottles, as Flint community members protested the information being presented. It was January 2017, approximately one year since the Flint water crisis had been declared a federal emergency, and bottled water was still being used as the city residents' primary clean water source [1]. However, the timeline for the replacement of the city's water service lines had been vaguely presented. The distrust and tension in the room as the community members demanded answers was palpable. According to a flyer distributed to attendees, the town hall aimed to provide Flint residents with "the most recent and up-to-date information ... regarding the status of the Flint water system and to answer residents' questions regarding water quality, filters, [and] health and medical resources" [2]. It was reported that levels of lead as well as other toxins and microbiological growths that had contaminated the water flowing from Flint taps was continuing to improve, although representatives from city, state, and federal government agencies were unable to reach consensus about whether the water was safe to drink [1, 3].

As a medical student training in Flint, Michigan, during the water crisis, I have witnessed firsthand the intersection of medical practice, public health advocacy, and medical ethics. Key physicians who pledged to "first, do no harm" in taking the Hippocratic Oath aligned their pledge with their practice to protect and advocate for the community they served daily. However, I spoke to a few clinicians who felt largely unprepared for a public health crisis of this magnitude, and some asserted that environmental health, specifically knowledge of water quality, was outside the scope of medical practice. The wide spectrum of viewpoints I encountered raises questions about the nature and scope of clinicians' obligations to identify, assess, and respond to harmful microbial and chemical levels in drinking water.

Understanding the scope of clinician practice is essential, especially since safe water access is an issue of domestic and international proportions. According to the Centers for Disease Control and Prevention (CDC), although international organizations regard providing safe drinking water as a measure of progress in alleviating poverty, disease, and mortality, billions worldwide still lack access to this resource [4]. The World Health Organization projects that by 2025, half of the world's populations will be living in water-stressed areas [5]. The Columbia Water Center contends that the "aging pipes and urban water infrastructure lead to increasing rates of main breaks and the potential for

contamination of treated water supplies" [6]. To avoid these problems, rehabilitation and replacement of water service lines is necessary, but such endeavors are expensive. The American Water Works Association estimates that restoring and expanding US water systems "will cost at least \$1 trillion over the next 25 years, if we are to maintain current levels of water service" [7].

This issue of the *AMA Journal of Ethics* explores ethical issues that cloud the attainment of safe water and questions the extent of clinicians' roles in ensuring this basic health right for their patients and the communities they serve. The contributors explore four main themes: (1) clinicians' professional roles and the need for interdisciplinary collaboration, (2) the ethical conduct of research, (3) medical education and the preparation of water-quality conscious physicians, and (4) an update on the aftermath of the Flint water crisis and a call to action.

Four articles examine regulatory history and clinicians' professional roles in safe water access. Richard Weinmeyer, Annalise Norling, Margaret Kawarski, and Estelle Higgins examine the effectiveness of the [Safe Drinking Water Act](#) of 1974. Bruce Jennings and Leslie Lyons Duncan highlight the disconnect between the Lead and Copper Rule, which sets regulatory standards for contaminants in drinking water, and toxic lead effects on health; they argue that clinicians should [advocate for patients' health](#) and collaborate with environmental engineers, basic scientists, and policymakers. Two articles focus on clinical practice. John R. Stone responds to the case of a physician unwilling to believe a patient's claim that her symptoms are due to water contamination. Through the physician's conversation with a student, Stone explores how [humility in interactions](#) with patients can help bridge differences and facilitate patient agency. And Jeremy Balch, Julia H. Schoen, and Payal K. Patel examine how physicians can weigh individual benefit against environmental or community harm in their [antibiotic prescribing practices](#).

Three contributors address the ethical challenges of conducting research in areas of water insecurity. Both a physician and a public health expert respond to a case in which a medical student considers the ethical implications of participating in highly specialized [research in a resource-poor community](#). Although both authors agree that specialized cardiac research does not maximize community benefit and that water insecurity should be addressed, they differ in their views of how researchers can contribute to relieving a family's or community's water insecurity. While Anwar D. Jackson emphasizes the importance of treating host families with dignity in offering to help, Harold W. Neighbors emphasizes taking a medicine-public health perspective that embraces community-based participatory research. Analyzing a case in which Flint residents oppose participating in research on health effects of changes in water composition, Kent D. Key argues that engaging [community members as research partners](#) can establish trust, community-level protections, and mutual benefit.

Two articles address how to train clinicians to be water-quality conscious. Steven S. Coughlin and Osman Yousufzai argue that the medical school curriculum should be expanded to adequately prepare future clinicians to better help patients [interpret water quality data](#) and its potential impacts on health. And Laura A. Carravallah, Lawrence A. Reynolds, and Susan J. Woolford detail the challenges faced by Flint-area clinicians during the water crisis—especially the disconnect between medicine and public health—arguing that training in [environmental health](#) might have enabled clinicians to recognize the health problems caused by the Flint water crisis more quickly.

Finally, three contributors provide an update on the Flint water crisis and a call to action. Photographer and cinematographer Kwesi Reynolds visually documents ongoing impediments to safe water access in the aftermath of the Flint water crisis, which speak to both [environmental injustice](#) and attempts to remediate it. In the [podcast](#), Mona Hanna-Attisha discusses her continued advocacy role in the aftermath of the Flint water crisis and provides advice for physicians and medical students who may want to advocate for safe water in their own communities. In another segment of the podcast, Camara P. Jones discusses barriers to health equity in the US and suggests strategies for responding to racial and ethnic health disparities in the context of the Flint water crisis.

The contributors to this themed issue, “Safe Water Access and the Roles of Clinicians,” challenge clinicians to address safe water access by engaging in community-based research initiatives, expanding the medical school curriculum to prepare environmentally and water-quality conscious physicians, and seeking interdisciplinary collaborations among basic scientists, engineers, and public health experts. I hope that this work will contribute to the ongoing conversation by challenging conventional thinking, eliciting additional conversation, and inspiring positive action.

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## ETHICS CASE

### Cultivating Humility and Diagnostic Openness in Clinical Judgment

Commentary by John R. Stone, MD, PhD

#### Abstract

In this case, a physician rejects a patient's concerns that tainted water is harming the patient and her community. Stereotypes and biases regarding socioeconomic class and race/ethnicity, constraining diagnostic frameworks, and fixed first impressions could skew the physician's judgment. This paper narratively illustrates how cultivating humility could help the physician truly hear the patient's suggestions. The discussion builds on the multifaceted concept of cultural humility as a lifelong journey that addresses not only stereotypes and biases but also power inequalities and community inequities. Insurgent multiculturalism is a complementary concept. Through epistemic humility—which includes both intellectual and emotional components—and admitting uncertainty, physicians can enhance patients' and families' epistemic authority and health agency.

#### Case

Dr. K, a resident physician, informs medical student Mary that Mrs. J has returned yet again this week with a persistent rash. Mary is in the third week of a family medicine rotation. Dr. K. briefs Mary before they see Mrs. J. "I already told Mrs. J that it is highly unlikely that water contamination is causing her rash. She denies associated symptoms such as headache, fever, or chills. Physical examination shows no signs of malignant or infectious disease processes such as lymphadenopathy [swollen lymph nodes], hepatosplenomegaly [enlarged liver and spleen], nuchal rigidity [neck stiffness], or neurological dysfunction. Additionally, her complete blood count with differential and chemistry panel from her annual visit were within normal limits. I know she denies any exposure to food allergens, new soaps, or lotions, but it must be something like that. It just doesn't make sense that it's from her water."

Mary and Dr. K enter the patient's room. Mrs. J immediately reports that her rash remains. Also, she and neighbors notice reddish tap water. Mrs. J states that her son and neighbors developed similar rashes soon after noticing the reddish water and think the water is responsible. Although Dr. K nods his head, he repeats that her water is an unlikely cause.



Mrs. J replies, “Dr. K, you don’t seem to understand. We know it’s the water. Why can’t you believe our city’s water is harming and poisoning us? You don’t know what’s in my water. You go home to the suburbs with clean water and don’t have to worry about what’s in it. You don’t know our city and what our pipes produce. Our water’s hurting us. What will it take for you to see that?”

### **Commentary**

Dr. K discredits Mrs. J’s suggestion that tainted water is responsible for her rash, but he lacks a clear diagnosis or cause for her condition. Mrs. J says Dr. K excludes tainted water as the cause because he’s ignorant about Mrs. J’s community; rather, he lives in “suburbs with clean water.” Mrs. J asserts that Dr. K is deaf and blind to her concerns.

Is Dr. K prematurely excluding diagnostic possibilities? Lacking a specific diagnosis, why categorically reject her assertion about water if a water contaminant is a possible cause? Dr. K fails to offer plausible reasons. Mrs. J’s comments about the suburbs could mean that socioeconomic class and cultural, racial, or ethnic biases are skewing Dr. K’s professional judgment. Or perhaps Mrs. J thinks Dr. K isn’t invested in assessing the water problem simply because he lives elsewhere. What might indeed influence Dr. K’s judgment? What would help him better respond?

Employing a fictional narrative, the following remarks explain how cultivating humility and related virtues could help Dr. K (and physicians generally) more constructively respond to patients like Mrs. J. But first consider every clinician’s challenge to remain open to diagnostic alternatives.

### **Premature Diagnostic Closure and Epistemic Humility**

News reports reveal continued problems from lead-contaminated water in Flint, Michigan [1]. Our heightened public health awareness suggests Mrs. J could be correct. Thus, we should worry that Dr. K is making an egregious diagnostic error with potentially terrible outcomes for Mrs. J and her community. Perhaps he is committing “premature closure: the tendency to stop considering other possibilities after reaching a diagnosis” [2].

Of course, even the best clinicians can make diagnostic errors despite adhering to best evidence-based practice. One reason is that diverse diseases can present with similar symptoms and signs. Since mistaken diagnoses and related treatment can allow preventable suffering or avoidable death, clinicians should repeatedly consider alternative diagnoses, especially when a problem continues. What helps? A key strategy is for clinicians to cultivate the epistemic humility to accept that their conclusions are always fallible [3]: that what they think they know could be incorrect.

Suppose Dr. K is guilty of premature closure and that humility is an important preventive. The next section shows how humility involves much more than a disposition to appreciate diagnostic fallibility.

### **Cultural Humility, Insurgent Multiculturalism, and Diagnostic Frameworks**

*Cultural humility: basics.* After the above visit with Mrs. J, suppose Dr. K attended a retreat on “cultural humility” that drew on Melanie Tervalon and Jann Murray-García’s seminal account [4]. The authors’ 1998 essay railed against the idea that competency as an endpoint—a set of skills and knowledge—captured what health professionals need to provide satisfactory cross-cultural care for diverse populations. Quite the contrary, they argued that continuous learning about cultures is necessary to provide everyone quality, respectful, and equitable health care. Cultural variations are too complex for concrete endpoints. Consider differences related to race, ethnicity, national origin, sexual orientation, gender, gender identity, and socioeconomic classes. Thus nothing but a persistent [educational journey](#) will suffice for excellent health care for all. Tervalon and Murray-García explained that such education requires: (1) continual self-reflection based in humility, (2) addressing attitudinal barriers and ingrained stereotypes or biases, (3) recognizing and correcting power differentials, and (4) advocating for communities with disadvantages. And clinicians should continuously pursue growth in addressing these issues.

*Conceptual barriers to cultural humility.* After presentations and discussions, suppose retreat participants wrote self-reflections with self-critiques, as described by Tervalon and Murray-García [4]. Privately journaling about his attitudes, Dr. K worried that unconscious stereotypes and biases affected his clinical judgment, as reported in the literature [5]. Perhaps Mrs. J’s perceived race/ethnicity, cultural background, or social class biased his decision—what Dr. K suspected Mrs. J meant. Such possibilities assaulted his confidence. Did he wrongly dismiss her claims about the water? Did Dr. K even give Mrs. J a respectful hearing? Was Dr. K failing to ensure Mrs. J’s “epistemic authority” that involves perceiving her “knowledge claims are ... worthy of regard ... and ... responses” [6]?

*Insurgent multiculturalism and diagnostic frameworks.* Suppose the retreat also introduced Delese Wear’s analysis of “insurgent multiculturalism” [7], which includes critical reconsideration of biomedical paradigms and power dynamics, as does cultural humility [4, 5]. Regarding power, conferees learned that physicians gradually tend to become arrogant and more controlling in patient relationships [8]. Physicians are then likely to speak “to” rather than “with” the ill [9]. Not only does this approach maintain or enhance their power over patients, “speaking to” reduces opportunities for “listening to” patients and families. Furthermore, these power dynamics discourage the latter from voicing concerns. Thus Dr. K wrote in his personal journal that perhaps he was becoming

arrogant. He began to appreciate the need for cultivating and maintaining cultural humility.

Dr. K also started critically examining how ingrained communication and clinical diagnostic frameworks shaped his professional thinking. His training stressed assessing individual patients' problems. Hence perhaps he tended to discount patient or family suggestions about diagnoses with causes that operate at community levels. If his focus was on the individual and diagnostically he was "thinking from the person out" about etiologies, he might overlook broadly acting factors. In short, sometimes perhaps he needed to assess the forest to understand what was affecting the trees.

Dr. K wrote in his journal: "Am I *really* listening to Mrs. J? How *really* open am I to alternatives? Oh.... And am I humble enough to accept such potential defects in my work?" In short, Dr. K realized that Wear's analysis of resurgent multiculturalism could also correct restrictions in his clinical thinking. And having cultural humility meant rebelling against his own restrictive diagnostic paradigms.

*Empowering open and bilateral communication.* Cultural humility includes efforts to ensure that patients and families can speak and be heard—and to build their power. But conferees agreed with findings that physicians' much greater power and many health care environments discourage free discussion by and with those seeking help [4, 7]. Thus retreat participants explored how to foster "horizontal" and "dialogic" relationships [9] and epistemic humility. If the relationship is horizontal, the ill and loved ones feel able to speak freely on the same level with health professionals. Moreover, although physicians have specialized knowledge, Karen Lebacqz argues that epistemological (knowledge-related) humility includes respecting not only what health conditions mean for patients' lives but also people's wisdom about their medical diagnosis [3]. Expressing epistemic humility should help clinicians value and promote mutual respect and recognition between them and their patients and their patients' families. Then true back-and-forth exchange with clinicians is more likely—the dialogic component of relationships.

*Spatial arrangements and health agency.* Retreat discussants agreed that clinicians' humility motivates such enhanced communication. The consensus was that following Paulo Freire, humility includes a deep-seated sense of people's equality or nonsuperiority [9]. But discussants also concurred that clinicians' personal humility doesn't alter how health care settings discourage open dialogue with patients and families. Rather, institutional environments often undermine patients' and families' "health agency"—their capacity to express ideas and advocate for their concerns. Hence, retreat personnel concluded that ensuring health agency also requires quiet and private locations with sufficient seating and an atmosphere conducive to conversation. They built on Margaret Urban Walker's argument that adequate ethical consultations need

areas and arrangements conducive to critical discussions with stakeholders—what Walker calls a “moral space” [10].

### **Dr. K Reflects Further about Humility and Talks with Mary**

After the retreat, in free moments, Dr. K occasionally thought about his last interaction with Mrs. J. He realized that the clinic setting inhibited open exchange with Mrs. J and other patients. But yet she spoke assertively. Reflecting on all he learned from the retreat, Dr. J appreciated the challenges Mrs. J overcame when she spoke so firmly about her community’s water. Was he arrogantly dismissing Mrs. J’s suggestions?

*Humility’s scope.* With some trepidation, Dr. K spoke with Mary, the medical student, about humility and the retreat. Mary asked: “What should professional humility include? How can I learn and sustain it?”

Dr. K recalled Jack Coulehan’s influential thesis that “Humility in medicine manifests itself as unflinching self-awareness; empathic openness to others; and a keen appreciation of, and gratitude for, the privilege of caring for sick persons” [11]. None of these is easy. “I try to emulate Coulehan’s points,” Dr. K continued. “Tervalon and Murray-García’s account of cultural humility [4] supports what Coulehan asserts in its emphasis on cultivating ‘lifelong commitment to self-evaluation and self-critique’ [12]. And Coulehan’s ‘unflinching self-awareness’ obligates us to explore our unconscious biases and stereotypes. Also, Butler and colleagues advise that cultural humility involves continued efforts at ‘being receptive, empathetic, and compassionate to the various ideas, customs, and lifestyles of the patients’ [13]. So just as Tervalon and Murray-García explained in 1998, Mary, we must continue striving for humility in its many elements [4].”

“Okay, is it something like this?” Mary replied. “Without humility, we aren’t really open to everything the patient and family tell us. Cultural and other [stereotypes and biases](#) may obscure or slant what we should be hearing. And being closed to differences might block empathic connection to people’s emotional status and our compassionate responses.”

*Humility: internal and external focus.* Dr. K answered that Coulehan and Butler et al. [11, 13] should support Mary’s interpretation. “However, an internally-focused humility ignores structural features like inadequate physical surroundings for ‘moral spaces’ and overlooks problematic power inequalities. Tervalon and Murray-García’s broader schema of cultural humility includes addressing such inequities through advocacy and, as they write, ‘developing mutually beneficial and nonpaternalistic clinical and advocacy partnerships with communities on behalf of individuals and defined populations’ [12]. So, for physicians, humility as an inner-focused quality is important but radically incomplete. Cultural humility is also expressed through efforts to change external circumstances.”

Dr. K continued that, in Chochinov's words, "Physicians who lack humility talk *at* their patients; physicians who are sufficiently humble talk *with* their patients. Talking or partnering with patients can promote empathic connections" [14]. Dr. K added that "other factors also promote great professional communications and relationships. According to Chochinov, 'Acknowledging medical uncertainty invites dialogue, providing patients a greater voice in the decision-making process' [14]. And admitting uncertainty promotes moral space for two-way conversations."

*Uncertainty and epistemic humility.* Mary worried that displaying [uncertainty](#) might undermine patients' and families' confidence in their physician's expertise. Dr. K noted that admitting uncertainty or ignorance either to oneself or patients can require courage. However, he recalled Kelly and Panush's admonition that failure of epistemologic humility could encourage mistaken diagnoses [15]. As Marcum observed regarding "intellectual humility," openness to professional error can be crucial for accurate clinical judgment [16]. However, Dr. K added that "intellectual humility seems too narrow because clinicians should be emotionally receptive to and perceptive about people's mood or affect. Thus, Mary, rather than 'intellectual,' the broader concept of 'epistemic' or 'epistemological' humility is more apt—it includes all forms of knowing."

Dr. K continued that comfortably admitting uncertainty helps establish a safe climate for the patient and family to express diverse views [10]. "In Mrs. J's case, perhaps other facts are being withheld that bear on the water concerns. If I said I was wrong to exclude a waterborne cause, maybe other information will emerge. Also, Mary, most patients and families know we don't know everything! So comfortably admitting uncertainty can reinforce our professional legitimacy."

*Cultural humility and communities.* Dr. K and Mary further discussed Tervalon and Murray-García's arguments about cultural humility and communities [4]. Dr. K reflected on their call for physicians to address potential health inequities such as Mrs. J's community might be experiencing. Dr. K also reviewed an argument that physicians are obligated to address upstream social determinants that promote health inequalities [17]. "In short, Mary, we need to revisit Mrs. J's concerns about the water. We should test her blood for waterborne agents like lead and arrange a phone conversation with Mrs. J. Let's also seek her collaboration in working with public health colleagues. Other suggestions?"

Mary replied that she and some classmates might be interested in working with Mrs. J's community to address the issue. She and Dr. K then discussed possible next steps with student colleagues.

## **Conclusion**

This paper explains how practicing humility and cultivating related traits can help physicians better hear and respond to patient and community problems. Stereotypes

and biases related to economic, cultural, and racial/ethnic differences can unconsciously skew professional judgment. Physician-patient power imbalances and institutional arrangements can undermine patient and family capacities to self-advocate. Clinical diagnostic frameworks, adherence to initial impressions, and aversion to uncertainty limit physicians' openness to alternatives and patient and family knowledge. Cultural humility and insurgent multiculturalism have overlapping and complementary roles in eliminating personal stereotypes and biases, power imbalances, and community inequities. Epistemic humility helps physicians admit uncertainty, open themselves to new information and possibilities, bridge differences, establish safe moral spaces that foster patient and family epistemic authority and health agency, and expand clinical frameworks to consider influences at both individual and community levels.

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## ETHIC CASE

### Is Acute Care-Oriented Research Ethical in Resource-Limited Settings?

Commentaries by Anwar D. Jackson, MD, and Harold W. Neighbors, PhD

#### Abstract

In this case scenario, a medical student, Jenny, is conducting congenital heart disease research in a resource-limited setting faced with water insecurity. She has concerns about how ethical it is for her to conduct advanced clinical research in a region with more basic health needs. The first commentary argues that advanced clinical research in resource-limited settings follows the ethical principle of beneficence and interactional justice but violates the principle of distributive justice. The second commentary questions whether beneficence is enough, since the Belmont Report states that beneficence is the obligation to simultaneously reduce harm *and* increase benefit. It calls upon public health physician-scientists to think deeply about how to involve communities in their research—and how to insert themselves into health policy development processes.

#### Case

Medical student Jenny arrives in a developing country optimistic and eager to participate in congenital heart disease research under a world-renowned clinician and researcher. Jenny stays with a local family in a village. Each morning, she hears the eldest daughter of her host family rise before dawn on her way to the local river. Balancing a large, filled-to-the-brim basin on her head, she travels daily with other women from her village to bring water to her home for drinking, washing, cooking, and cleaning.

Jenny wonders whether it makes sense from an ethical point of view to focus research in this community on developing highly specialized interventions for congenital heart disease when the people here only have reliable access to clean drinking water because a woman from each home—like many women in the world—spends much of her day retrieving it. As a guest, Jenny is aware that members of her host family make do with less water so that she can have a share of it. Additionally, some of the women have expressed concern that their access to their current clean water source could be limited in the future, due to contamination threats from upstream farms and local petroleum extraction as well as potential privatization of a large tract of currently public land that the women traverse to get to the water source.



Jenny wonders whether she and other members of her research team should begin participating in the water retrieval journey with the neighboring women. She also wonders whether their research efforts might be better devoted to helping members of this community achieve more certain water security over the long term.

### **Commentary 1**

**by Anwar D. Jackson, MD**

Jenny's case represents what will undoubtedly become an increasingly common ethical dilemma in global health over the next 20 years. One of the major foundations supporting international development, the Bill and Melinda Gates Foundation, predicts that the economic gap between low-income and middle-income countries will disappear by 2035 [1]. This rapid economic development is expected to trigger and be accompanied by equally rapid developments in the health of their populations. Advancements in medical technology and health delivery systems in low-income countries can realistically reduce infectious, maternal, and child mortality to universally low levels within the next two decades [2-3]. However, achieving advances in medical technology does not always equate to the universal provision of basic public health needs. Even in high-income countries with fully developed and long-standing health systems, there are local populations suffering from persistent public health concerns such as food and water insecurity [4-5]. This dichotomy is more pronounced in nations that have not yet completed their economic transition and where many people reside in locations with limited resources. Researchers and health professionals working in these settings are thus faced with an ethical question of justice: How can they best allocate their talents and skills in order for the local population to receive maximum benefit [6]?

The complexity of this ethical conundrum's solution mirrors the complexity of the problem. Jenny is a member of a research team that specializes in congenital heart disease. Furthermore, the area where she is based might have an uncharacteristically high rate of congenital heart disease, which would make her research critical to the future well-being of her host village. Under these circumstances, Jenny's focus on congenital heart disease follows the principle of *beneficence*, which makes the welfare of research participants a primary concern, because she is using her knowledge and ingenuity to analyze and overcome a medical issue faced by her host village. Although Jenny exercises beneficence, she still falls short of upholding the principle of *distributive justice*. Distributive justice is the allocation of resources such that the community using the resources achieves the best outcome [7]. Under a utilitarian framework, the best outcome is synonymous with the maximization of benefit [7]. In settings where resource scarcity jeopardizes water security, it is unlikely that there are the additional resources needed to support specialized clinical research and thus to maximize benefit. Jenny and her team must choose between preserving local health resources while sacrificing quality research or diverting local health resources to uphold the standards of specialized

clinical research. While both options may yield good outcomes, neither yields the best possible outcome.

### **Balancing Clinical Research with Community Needs**

The amount of resources required to appropriately perform and act on Jenny's research might be extraordinary. Although people living in resource-limited settings are entitled to the same benefits of clinical research that are available to those in the developed world, these benefits are only possible if the clinical research from which they are derived is held to the same rigorous standards that govern clinical research in wealthier regions [8]. These standards include having adequate infrastructure in place for quality assurance and quality improvement of the study, having appropriate staff and resources necessary to execute the study, and being able to adequately educate and gradually assess the comfort and willingness of research participants in the study [9]. Given the potential drain on resources that could be required to achieve these standards, all measures should be taken to maximize the research's impact on the local population.

However, in a community where basic public health needs are difficult to achieve, advanced medical care may be a secondary concern. According to the renowned psychologist Abraham Maslow, people cannot address higher human needs until they have addressed basic necessities for survival such as food and water security [10]. In Jenny's host village, the principle of Maslow's hierarchy dictates that water security must be addressed before more advanced forms of health care can be successfully implemented. Otherwise, the people of the village would likely have difficulty in making the commitments necessary to ensure the quality of the study. These conditions could create an unfavorable risk-benefit ratio for the community if the risks of diverting resources away from water security outweigh the benefits that would be gained from a poorly executed study [8]. An unfavorable risk-benefit ratio would undermine Jenny and her team's ability to ethically perform their research [8]. Jenny and her team's research might meet other qualifications that govern clinical research ethics in resource-limited settings, but many of these components are tied to ensuring a favorable risk-benefit ratio, which would be difficult to do without first ensuring water security. Given these circumstances, Jenny and her team should first direct their attention to addressing water insecurity in the village. While addressing these concerns might be time consuming for Jenny and her team and would possibly require more than one trip to the village, Jenny and her team can ethically proceed with their research only after these concerns have been addressed.

Nevertheless, students and health professionals who perform advanced clinical research in resource-limited settings can be valuable assets to their host communities, and these communities often reciprocate the benefits researchers provide with generous hospitality. As the beneficiaries of their gratitude, researchers may find themselves facing a new dilemma. The purveyors of such generosity are usually the same individuals

who tend to a household's basic needs, such as food and water acquisition. In many resource-limited settings, this means the provision of hospitality becomes the primary responsibility of women and children [11].

While conducting specialized research in resource-limited settings might raise questions about distributive justice, the treatment researchers receive from their host communities might elicit concerns about *interactional justice*. Interactional justice is primarily concerned with how people are affected by decisions enacted by others and with treating the people affected by these decisions with [dignity and respect](#) [12]. Host families are subject to decisions made by their guests in several ways, with the provision of food and water being chief among them. Even if host families are compensated for accommodating visiting researchers, the household members responsible for providing and maintaining the accommodations must still expend additional time and effort that might have been used in other ways. For example, reductions in water collection times have been shown to allow women and children more opportunities for education, quality family time, and other proactive activities [13]. Jenny's desire to aid in water retrieval reflects her understanding of the ramifications of her presence for her host family. While it is appropriate and within the bounds of interactional justice for Jenny and other members of her research team to assist with water retrieval and other household tasks, they should offer their assistance while respecting the cultural and social practices of their hosts.

## Conclusion

In summary, Jenny's research and other research like hers can and should be ethically performed in resource-limited settings if the communities' basic needs have been fulfilled. Although her research exemplifies beneficence, it does not meet the qualifications for distributive justice, as it does not maximize benefit for the local population experiencing water insecurity. As such, Jenny and her research team should review the process through which their research is implemented in order for it to have the greatest impact on the local population and address water insecurity in the village. Jenny and others might also ease any burden caused by their presence by providing assistance with household tasks; however, they should do so in a manner that is culturally and socially acceptable to their host communities. If Jenny and her team are able to successfully implement distributive justice in their research and interactional justice in their host community, they can be the catalysts for both short-term and long-term positive change in that host community.

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## Commentary 2

by Harold W. Neighbors, PhD

In 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was convened to identify basic principles for the ethical conduct of research involving humans [1]. Five years later, the commission published the Belmont Report, which established three basic ethical guidelines for research: respect for autonomy, justice, and—the focus of this essay—*beneficence*. According to the Belmont Report, the principle of beneficence obligates researchers to minimize harm *and* “maximize possible benefits” to study participants and the community [1]. This essay addresses the challenge of what it means, on a practical basis, to embrace the notion that the ethically responsible public health physician-scientist should maximize community benefits within the context of research.

In this case, a medical student, Jenny, wonders if it is ethical for her to conduct research on congenital heart disease when those living in the community of study have such poor access to something as basic as drinking water. This case raises two important questions: (1) Should medical students pursue specialized research in resource-poor communities with water security concerns? (2) What is the researcher’s ethical obligation to community residents while conducting specialized research when residents do not have reliable access to clean drinking water?

I will address Jenny’s dilemma within the context of research on human health that seeks to provide the data, and the evidence, necessary to move the scientific process closer to providing a benefit. I write about Jenny’s case in the voice of an African American male and public health social scientist who is committed to health equity. I also write as one engaged in community-based participatory research (CBPR). CBPR is an especially appropriate research vehicle to use in exploration of beneficence because CBPR, perhaps more than other research approaches, is based heavily upon the ultimate goal of improving the social, political, and health conditions of the communities within which research is conducted. CBPR also requires researchers to ensure that the research provides benefits *equally* to the scientists, study participants, and community members [2, 3]; in fact, CBPR is ultimately a social change strategy [4]. However, conducting research that so clearly emphasizes community change to improve community health is a tall task.

If Jenny’s challenge sounds familiar, it is because it is hauntingly similar to the ongoing unnatural disaster in Flint, Michigan. Both communities are challenged by water insecurity and are under-resourced financially. Both communities have attracted the attention of researchers and, as a result, must confront the question of whether, and how, research actually benefits study participants and the broader community. While water insecurity has received the bulk of public attention in Flint, some research investigators are working on other health problems, such as heart disease, similar to

Jenny. It is also very apparent that those researchers in Flint must, in some way, address the issue of water insecurity, just as Jenny must.

Though similar to Flint, Jenny's situation is not exactly comparable. For example, Jenny's heart research is not *directly* related to water insecurity and does not seem to have any immediate or direct benefit to the community in which she is working. Nevertheless, by virtue of her living in the area, Jenny cannot avoid consideration of the impact that water insecurity has on her community responsibilities.

As mentioned, much, but certainly not all, of the research conducted in Flint bears directly on water insecurity, and, in some respects, Flint has benefitted from that research. It is clear that research played a vital role in drawing attention to the most recent episode of the ongoing water "crisis" [5]. In Flint, if it were not for the research showing high levels of lead in the water combined with the analysis showing an association between lead in the water and lead in children's blood [5], there may never have been the level of community outrage that mobilized the political action that has ensued. Research conducted in Flint has, to some extent, benefited city residents by providing scientific evidence consistent with community knowledge that the water was damaging to residents, especially children. Unlike the beginning of the crisis, when many doubted, refused to consider, or even denied that lead in the water was damaging the health of Flint residents, presently everyone believes this to be the case. However, this is an important but modest victory. The reality is that many Flint citizens do not fully trust researchers or governmental officials. Nor do they believe that their water is safe to drink [6]. In short, the research conducted in Flint has yet to deliver on the ethical obligation of maximizing community benefits for the residents of Flint [7]. Flint residents are still waiting for research to deliver a solution to the water crisis. This remains a work in progress.

Herein lies the difficulty with beneficence. It is an aspiration that can go unfulfilled. Research participants and the community residents they represent certainly deserve some benefits from research; and the Belmont Report clearly demands as much. The problem is that communities often have to wait to obtain those benefits. Even when there is benefit, it often takes decades before an intervention program is deemed effective enough to be widely disseminated [8, 9]. Offering *study participants* financial incentives is certainly a benefit. However, it must be made clear during the recruitment and consenting process that any potential community benefits are heavily dependent upon years of subsequent work, follow-up studies, and scientific debate.

Given this state of affairs, what is Jenny or, for that matter, any community-based research scientist to do regarding benefitting the community within which they are working? I offer three paths for consideration.

First, public health physician-scientists need not conduct research. Unlike most researchers, they have the option of patient care. Since, in my experience, most medical students are attracted to the profession because of a desire to help people by treating and healing their wounds, they need not engage this particular research ethics challenge. The treatment benefits are more obvious and immediate.

A second option is for the public health physician-scientist to remain primarily in the world of academia, conducting basic and applied research. It is not necessary for any research scientist, clinically trained or otherwise, to join the politically driven community activism characterized by CBPR. In fact, it might be the case that all research, no matter how far removed from local residents, may eventually provide community benefits, albeit *indirectly*. Some physician-scientists focus on the quest for knowledge and may not be especially concerned with the practical application of that knowledge or how their research affects community residents. As a result, they are less encumbered by the challenge of how to maximize benefits for marginalized and economically oppressed communities.

I am promoting a third option. Medical students, like Jenny, can forge a transdisciplinary research identity that places medicine more directly within the context of public health and CBPR. Medicine can be a natural ally with the CBPR public health approach to community change. It is true that public health is primarily involved in prevention and medicine primarily in treatment. However, public health and medicine overlap; they share much common ground.

I propose three recommendations regarding this case. First, both medical and public health approaches are equally necessary. As a medical student, Jenny must use her biomedical expertise to help build knowledge about congenital heart disease while also participating in the broader public health activities of water safety and retrieval. Periodically, Jenny must step away from the individual study participants in order to more clearly view the big picture of how both [medical healing and community research](#) exist within a larger ecological framework. By “stepping away,” I suggest that there is an advantage to periodically engaging a broader perspective that considers the role of economic, political, gendered, and racial factors in the production of chronic disease [10]. The limitations of patient care for improving population health demands that medical students like Jenny expand beyond individual patient care to obtain additional training, such as a certificate in public health or a second graduate-level degree (e.g., MPH, MS, PhD).

Second, there is a preferred sequence to helping. Helping the community to address, reduce, or eliminate water insecurity must be the first priority, although this need not be addressed within the context of research or patient care. Jenny, like all of us, has a civic responsibility to address such basic necessities before, or at least in conjunction with,

treating and/or conducting research on heart disease, diabetes, hypertension, depression, or cancer. Research and social activism are separate activities, although they are closely linked within CBPR. Jenny's study is not CBPR. That does not, however, release her from the responsibility of getting involved in such an important community problem. To be specific, Jenny should help the women in her community carry water.

Third, as research scientists, we must do more than reduce harm. Researchers should do as much as possible to maximize immediate and long-term benefits to the residents from the communities where studies are conducted. A good place to start is by asking community residents which problems need to be studied and why. Simply ask, "How can we help?" Researchers also need to share executive decision-making power with community residents. This means the research team, and especially the principal investigator, must include community representation *before* submitting research proposals. In this way, public health physician-scientists like Jenny can ensure that community residents are equal partners in the initial [research planning process](#). And in this way, community members can counsel, guide, and educate researchers about how best to identify and incorporate tangible community benefits, such as budget line items, appropriate respondent incentives, hiring local talent as research assistants, and the appropriate use and [dissemination of research findings](#).

In conclusion, rigorous research is the basis of evidence. Everyone deserves access to evidence-based treatment and intervention programs. For this to happen, public health physician-scientists must do at least two things: they must invite community members to help shape research proposals, and they must insert themselves into the health policy process. This is the path to community beneficence.

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## ETHICS CASE

### Expanding Ethics Review Processes to Include Community-Level Protections: A Case Study from Flint, Michigan

Commentary by Kent D. Key, MPH, PhD

#### Abstract

As the Flint community endeavors to recover and move forward in the aftermath of the Flint water crisis, distrust of scientific and governmental authorities must be overcome. Future community engagement in research will require community-level protections ensuring that no further harm is done to the community. A community ethics review explores risks and benefits and complements institutional review board (IRB) review. Using the case of Flint, I describe how community-level ethical protections can reestablish a community's trust. All IRBs reviewing protocols that include risk to communities and not merely individual participants should consider how community members are engaged in the proposed research and identify and respond to questions and domains of concern from community members.

#### Case

All researchers who use federal funding to do their work, including those interested in investigating effects of lead water contamination on health in the aftermath of the Flint water crisis, are required to have their protocols reviewed by an institutional review board (IRB) to motivate compliance with federal human subject research regulations. A team of researchers from University X has proposed a protocol that involves investigating acute changes in kidney function, new onset of high blood pressure and gout, and each of these conditions' relationship with changes in Flint water composition. They hope to arrange for community members' blood tests, urine tests, blood pressure measurements, and joint aspiration and fluid analysis. Furthermore, they hope to enter community members' homes to sample and test their tap water for lead, phosphates, and trihalomethanes. The protocol is being reviewed by an IRB from University X. Some members of the Flint community have raised strong opposition to this research, citing no reasonable basis for trusting the researchers or their institutions to do the research ethically or to justly share the risks and benefits of their work with the community.

#### Commentary

The community of Flint, Michigan, suffered a manmade public health crisis based on the decision of a governor-appointed emergency manager (EM) to change Flint's water

source from Lake Huron to the Flint River, which began in April 2014 [1]. However, the root of the Flint water crisis (FWC) began in March 2011, when the Michigan state government passed the Local Government and School District Fiscal Accountability Act [2]. This law allowed state-appointed EMs to replace community-elected representatives in executive and legislative branches of city government. EMs were charged with protecting the health, safety, and welfare of citizens with a focus on fiscal “belt-tightening” [3]. Community members in Flint and other parts of Michigan organized and protested this law, which resulted in the law being overturned in November 2012 [4]. Months later, the state government passed a very similar law, the Local Financial Stability and Choice Act [5]. Two critical components of the law were met with opposition from the Flint community: (1) the implementation of the EM, which undermined the local community’s democratic processes [6]; and (2) the switch to the Flint River as an intermediate water source, which was made from a fiscal perspective with no consideration of health risks to residents. Although required by law in water systems serving more than 50,000 residents [7], anticorrosive chemicals were not added to the water supply due to cost (less than \$150 a day) [8]. These decisions resulted in damage to public health from elevated lead levels and *Legionella* in Flint’s water as well as over \$100 million in Flint water infrastructure damage [9]. Because the government, at all levels, failed to protect the Flint community [1], the residents were harmed [1], and their trust in government and other institutions eroded [10].

### **Purpose and Ethical Principles of Institutional Review Boards**

The 1979 Belmont Report, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established three ethical principles to protect research subjects and provide a framework of accountability and responsibility for researchers: (1) respect for autonomy, (2) beneficence and nonmaleficence, and (3) justice [11–14]. These principles provided new levels of protection for research participants following the outrage of the Tuskegee syphilis study [11]. This was a first step in the evolution of ethical protections in human subject research.

The [institutional review board](#) (IRB) process was established to protect research participants [14]. IRBs typically deliberate about whether risks are reasonable and whether participants, especially those from vulnerable populations, are adequately informed to consent to participate and are aware of the benefits and risks of participating [12, 14]. IRBs are often housed within academic institutions or community institutions, such as hospitals [15], but some IRBs are corporate entities. In either case, community considerations are often missing from IRB deliberations [16, 17], although IRBs are federally required to have community members and consider community concerns, according to Title 21 of the Code of Federal Regulations (CFR) [18]. Some IRBs do not fully assess community protections, consent, risks, or benefits, restricting their

main focus to individual protections [16], and thus failing to incorporate another important ethical principle, respect for communities [19].

To understand why Flint residents in the case scenario did not trust researchers, it is worth examining how the ethical principles guiding IRBs and the Belmont Report were violated in the Flint water crisis.

- *Respect for autonomy.* Community members' autonomy and the democratic processes in place to support it were undermined by the governor-appointed EM and the EM's decision to switch the water source [10] and the state's decision not to add anticorrosion chemicals [8].
- *Beneficence.* The EM model was designed to maximize fiscal savings in selected communities experiencing financial hardship, but it provided no consideration for maximizing the health of the community residents.
- *Nonmaleficence.* The harm experienced by the Flint community manifested in various forms: biological, psychological, environmental, financial, social, and cultural.
- *Justice.* Undercurrents of racism and socioeconomic classism led to the FWC. Results of the Michigan Civil Rights Commission's report highlighted environmental racism as a contributor to the FWC [10], legitimizing some Flint residents' claims that the crisis occurred because Flint was a predominantly black city and inciting the "Flint Lives Matter" movement, derived from the ongoing Black Lives Matter movement.

[Community engagement](#) would allow members of the community to take on the responsibility of distributing risks and benefits that they identify. This process could address, and possibly alleviate, distrust and restore key relationships between the community and research institutions by giving the community a sense of co-ownership and co-leadership.

### **Evolution of Community Ethics Reviews**

The First Community Consultation on the Responsible Collection and Use of Samples for Genetic Research of the National Institute of General Medical Sciences took place in 2000. This consultation yielded ten recommendations, three of which included: (1) defining community in appropriate meaningful ways, (2) obtaining broad community input in all phases of the research, and (3) establishing appropriate review mechanisms and procedures [20]. Although these recommendations helped move the needle in a positive direction for community-engaged research, other problems remained. Over the past decade, there have been a growing number of concerns regarding the inconsistency of community representation on IRBs [21, 22]. Community-based researchers have expressed deep concerns about the ethics of community partnership and engagement processes, social justice, and the need to expand the boundaries of ethical reviews to include community-level considerations [21]. In addition, some university IRBs have struggled to recognize the role of community partners since it was not customary to

view community partners as equals with academic researchers, which has created challenges in obtaining IRB approval [23]. Community-based research shifts the traditional power dynamic, raising questions of equity, co-ownership of data, and mutual benefit. Shore et al.'s [16] study of community-engaged researchers' experiences with IRBs revealed that there is a need to expand the ethical analysis to include community-level considerations, which they posit is often missing in the IRB process.

[Community-based participatory research](#) (CBPR) practitioners have argued that the Belmont principles must be reconceptualized in order to address community-level considerations in ethical reviews [13, 19, 20, 24]. The community-level ethical principles (see table 1) of veracity, sustainability, nonmaleficence, and justice are meant to expand the frame and ethical lens of the traditional Belmont principles. As community engaged research has evolved, it has become evident that efforts to incorporate diverse community stakeholders in the research process have progressed from "subject"-focused-only engagement to include a "community-partnered" focus.

**Table 1.** Comparison of internal review boards and community ethics review boards [14]

Internal review board	Community ethics review board
<b>Ethical principles</b>	
Respect for autonomy	Veracity
<ul style="list-style-type: none"> <li>• Right to know, informed consent</li> </ul>	<ul style="list-style-type: none"> <li>• Respect for dignity and recognition of worth within community frame</li> <li>• “Right to know” expanded to “right to know and understand,” transparency</li> </ul>
Beneficence	Sustainability
<ul style="list-style-type: none"> <li>• Maximize benefit</li> </ul>	<ul style="list-style-type: none"> <li>• Maximize benefit not only for the group but also for the individual and over time, for generations to come</li> <li>• Research efforts sustain the broader ecologic and local community to which individuals are connected</li> </ul>
Nonmaleficence	Nonmaleficence
<ul style="list-style-type: none"> <li>• Do not harm the subject</li> </ul>	<ul style="list-style-type: none"> <li>• Do not harm the community</li> </ul>
Justice for study subjects	Justice for the community
<ul style="list-style-type: none"> <li>• Fair distribution of costs and benefits to research subjects</li> </ul>	<ul style="list-style-type: none"> <li>• Fair distribution of costs and benefits to the community</li> </ul>
<b>Other key differences</b>	
Narrow focus on individual research subjects	Broader focus on the community regardless of participation in research
Institutional lens	Community lens
Individual autonomy	Community autonomy
Individual benefit	Community benefit

### Expanding the Boundaries of Ethical Reviews in Flint

In 2009, the author, who is the executive deputy director of the Community Based Organization Partners (CBOP), founded the CBOP Community Ethics Review Board (CERB) in Flint to establish a community-level ethical protection entity led by local residents [25]. Members of the CERB are community members with years of experience in research and in serving on regional and national ethics review committees. They

review proposed studies and work with researchers to ensure compliance with human research protections outlined in the CFR and to ensure community protections and mutual benefit. The CERB partners with two local universities to continue ongoing research ethics training for its members, who are required to obtain CFR human subjects protections training certificates from one of the two universities. In a community experiencing psychological stress and mistrust from failures of government at all levels [26], in spring 2016 the CERB also partnered with the Healthy Flint Research Coordinating Center as the vetting arm for research in Flint. The CERB process is a win-win for both the community and researchers. CERB services include: (1) community ethics reviews and critiques of proposals; (2) identifying and assisting in developing a community advisory board for research projects, if needed; (3) identifying community partners, research participants, and community research sites; (4) suggesting strategies for community engagement; (5) vetting research ideas; and (6) issuing letters of support for particular projects.

### **Case Analysis**

As illustrated by the case scenario that opened this essay, an overarching concern for researchers is residents' lack of trust in research and government institutions. The proposed research in this case includes blood draws and other biospecimen extractions, in addition to physical space intrusion through home visits. To an already overburdened, stressed, and distressed community, community-specific questions need to be addressed, including: What are the community-level protections? What are the community-level benefits and risks? What are best methods of community engagement to obtain community-level buy-in? It is critical to approach this study with the aforementioned considerations in order to respond to distrust and to reach a level of effective community participation. Given that in this case the research protocol has been reviewed only by a university IRB and has had some opposition from the community, it will be necessary for a respected community entity to review and possibly endorse this research project to ensure the protocol's compliance with community interests, priorities, and ethical standards. Hence researchers in this ethics case should engage with the CERB. Upon completing the CERB's review process, a letter of support or endorsement could be granted confirming that the research has been reviewed and deemed appropriate by community members. Considering the current climate of mistrust and the historical mistrust of communities of color toward research [27], the local IRB in this case study should recognize and respond to ethical concerns, such as community protections, and partner with the CERB. This approach would expand the lens of the ethics review that researchers would receive.

### **National Implications**

Nationally, the ethics review process should not protect institutional power at the expense of community [23], but instead reconstruct its review domains to include questions that assess community-level protections, risks, benefits, and issues of social



justice. This reorientation would ensure that IRB research protocols explicitly address community-level considerations. Specific questions to assess studies' risk of community-level harms—biological, psychological, environmental, and socio-cultural—are ideal. Questions could include, but are not limited to: Are the risks and benefits from this study different for the individual participant than the collective community? If so, how are they different? Is there a fair distribution of these risks and benefits on a community level? Additional questions should focus on the consent process. IRBs should ask researchers how they are verifying that participants understand all the risks and benefits before giving consent. The concept of the "right to know" should be expanded to include the "right to understand." Is there a level of "community understanding" regarding the study? Is there acceptable or sufficient transparency with community members? Will this study protect the dignity of the community?

There are three recommended strategies to assist IRBs in including community-level ethical protections: (1) IRBs should partner with local CERBs to conduct a joint-review process; (2) IRBs should include community members from local CERBs; and (3) IRBs should reroute researchers to local CERBs for protocol review prior to the IRB review and consider the results of the CERB review in their deliberations. Furthermore, risks and benefits of research should be justly distributed by engaging the community in the process of identifying and assessing those risks and benefits.

## Conclusion

In conclusion, research is a critical component in the growth and evolution of knowledge aimed at making the lives of people healthier and better. Research institutions are working to develop more effective approaches to engage communities in their studies, which require a reconstructed frame for assessing ethical protections. IRB review processes would be enhanced by incorporating community ethics reviews to ensure community-level protections and to maximize the impact of engaging communities in research across the disciplines. Flint is an excellent example of how city residents came together to develop and set in place a mechanism for the community to access proposed research to ensure protection of the community.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

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## THE CODE SAYS

### **The AMA *Code of Medical Ethics*' Opinions Related to Physicians' Roles in Safe Drinking Water Access**

Annalise Norling

The Flint, Michigan, drinking water crisis highlights ethical issues concerning clinicians' roles in public health, specifically in helping at-risk populations secure safe drinking water. American Medical Association policy ("Lead Contamination in Municipal Water Systems as Exemplified by Flint, Michigan," H-60.918) addresses the need for specialized care that children exposed to water contamination require. The policy states that the American Medical Association will "advocate for biologic (including hematological) and neurodevelopmental monitoring at established intervals for children exposed to lead contaminated water with resulting elevated blood lead levels (EBLL) so that they do not suffer delay in diagnosis of adverse consequences of their lead exposure" [1]. While the *Code of Medical Ethics* does not explicitly address clinicians' roles in preventing water contamination and treating patients who have been harmed by contaminated water consumption, it addresses clinicians' roles in preventive care and community health promotion, including their obligations not only to individuals but also to at-risk populations.

Opinion 8.11, "Health Promotion and Preventive Care" [2], urges physicians to "consider the health of the community when treating their own patients and identify and notify public health authorities if and when they notice patterns in patient health that may indicate a health risk for others" [3]. Recognizing that effective communication is necessary in order for the physician to help patients understand environmental factors that might be influencing their health, opinion 8.11 urges that physicians "encourage an open dialogue regarding circumstances that may make it difficult to manage chronic conditions or maintain a healthy lifestyle, such as transportation, work and home environments, and social support systems" [3]. Furthermore, this opinion outlines actions physicians should take to improve public and community health, including [advocating](#) for "healthier schools, workplaces and communities" and encouraging "community resources designed to promote health and provide access to preventive services" [4].

The *Code* also has an opinion (8.5, "Disparities in Health Care" [5]) that acknowledges disparities in health care among demographic groups, which is an important element of the water crisis in Flint [6]. This opinion states that the medical profession has an ethical responsibility to "help increase awareness of health care disparities" and "support research that examines health care disparities" [7]. It is consistent with the guidance in

this opinion and opinion 8.11 that physicians advocate for vulnerable populations' [access to safe drinking water](#) and to quality health care in the case that contaminated water has been consumed.

Critical to addressing the needs of the population experiencing contaminated water is the active engagement of clinicians. This not only includes treating patients who show symptoms of water contamination but also advocating for communities at risk, developing patient-physician relationships that nurture conversations about the best information and resources available, and informing authorities when necessary.

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## Related in the *AMA Journal of Ethics*

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## MEDICAL EDUCATION

### Lessons for Physicians from Flint's Water Crisis

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#### Abstract

Physicians form a vital front in recognizing unusual clinical presentations that could herald a health threat. In the Flint water crisis, physicians can be credited with playing critical roles in both uncovering the crisis and providing leadership when government failed to respond effectively. Yet most physicians in Flint were not formally trained in advocacy or leadership and might have recognized the health implications of the crisis more quickly had they received formal environmental health training. Furthermore, connections to other professional disciplines—and to the community—are vital for effective responses to environmental health threats. We explore some lessons learned in Flint that might help expedite resolution of future environmental health crises, particularly those involving aging infrastructure and diminished or dysfunctional regulation or oversight.

#### Introduction

The Flint water crisis, in which the municipal drinking water of Flint, Michigan, was contaminated with lead, microorganisms, and other toxins, has been extensively covered in the media. This event was described by Michigan's Governor Rick Snyder as "a failure of government at all levels" [1] and resulted in the potential exposure of roughly 100,000 people to these harmful substances. Besides a variety of substances, *Legionella* was found in the water, which was associated with a more than fourfold increased case incidence in Genesee County in 2014 and 2015 as compared to the years immediately preceding the water switch in April 2014 [2-5]. In fact, to date, the director of the state health department and four other government officials have been charged with involuntary manslaughter, and at least 15 other officials (including Michigan's medical executive chief, who is a physician) were also charged with felony and misdemeanor counts [6, 7].

In view of these administrative failures, the alleged cover-up [8], and the conflicts of interest for governmental leaders involved in the ongoing criminal investigation, it is not surprising that there has been a lack of coherent official leadership in the response to the crisis. The authors are part of a small group of physicians who, along with other health

and nonhealth professionals—and in the face of obfuscation by government officials [9]—continue to provide health recommendations and advocacy for the citizens and agencies of Flint [10–12]. In the remainder of this article, we focus on the roles and the additional training of physicians that will be required to deal with similar current and future challenges to patients' health. But first we ask, How could such a disaster happen in modern America? We believe a fundamental contributor to the crisis was the failure to recognize and value connections, particularly those that nurture clinicians' curiosity and caring, such as personal connections and professional connections among cross-disciplinary clinicians.

### **Geographic and Professional Divides**

Persistent racial and class segregation have increasingly isolated older cities like Flint from centers of power and capital resources. From the 1960s to the present, the City of Flint was pushed into bankruptcy by the loss of more than 72,000 General Motors Company jobs, a 50 percent decrease in its peak population of almost 200,000 due to wealthy (generally white) residents moving to the suburbs, and cuts in funding from the state for municipalities [13, 14]. In the shadow of the historical and pervasive institutional racism that helped to bring us to this state, the city was placed under an emergency financial manager in 2011 [15]. All decision-making power was removed from locally elected officials, including the emergency manager's decision in June 2013 to switch the city's water source from Lake Huron to the Flint River, putatively to save \$5 million in under two years [16, 17].

In addition to geopolitical divides, there is also the problem of physicians' feeling disconnected from members of the communities they serve. Particularly in relation to underserved populations, there is a significant difference in average income and education between physicians and their patients [18], and many physicians do not live in the communities where they work. The effects of systemic poverty and stigma can also create a distance that makes it hard to recognize our connection to each other.

Another divide exists between medicine and public health. When medicine had little to offer for specific disease treatment, sanitation and population-wide hygiene measures accounted for most progress in mortality reduction. This changed when antibiotics were developed and it became possible to effectively treat individual patients, contributing to specialization and decreased cross-disciplinary knowledge [19]. Additionally, the success of public health has resulted in its absorption into normal governmental function, with the unintended consequence of giving a rationale for physician inattention to the health of the population as a whole. Unfortunately, this tunnel vision risks narrowing the area of physician concern to a point at which we no longer recognize a public health problem that needs our attention. While no one person or profession can do everything, if we physicians are unaware of when interdisciplinary effort is required, we will not be able to



perform our essential duty of keeping our patients healthy. In fact, the Flint water crisis would not have been revealed without interdisciplinary knowledge.

### **The Necessity of Interdisciplinary Collaboration in the Flint Water Crisis**

The medical community did not recognize a number of events that occurred after the switch from Lake Huron to Flint River water as the warning signs of an impending health crisis. While many long-time Flint citizens were skeptical about drinking water from the industrially polluted Flint River, we saw the mayor and other governmental officials drink it at the water treatment plant [20], and most physicians accepted the official, but inaccurate, narrative. When the General Motors Company declared that the water was too corrosive for auto parts [21], most physicians didn't seem to understand that corrosion of the machinery could also mean corrosion of metal pipes, including lead service lines and fixtures, and none spoke up. When a more than fourfold increase in cases of Legionnaires' disease occurred in 2014-2015 [5], most physicians seemed not to understand that such outbreaks are almost always related to the municipal water until the complete information was disclosed by public health agencies almost a year and a half after the initial outbreak in 2014 [22, 23].

This lack of recognition of connections between drinking water and health started to change when Flint residents were notified by county public health officials of increased levels of total trihalomethanes—byproducts of disinfection—in the municipal water [24]. The knowledge that some of these derivatives are actually carcinogenic led some physicians living in Flint, who were dealing with their own rusty-colored, foul-smelling water, to finally realize that we needed to learn more about [drinking water and health](#) if we were to instruct our patients appropriately [25].

A chance congruence finally occurred: an area pediatrician with both a public health and an environmental health background had a social discussion with a water engineering friend who told her that there was no corrosion control in the Flint municipal water and that the water might be leaching lead from the older pipes into the drinking water. Her friend suggested that she look into pediatric blood lead levels [26], and she and her team did this with the help of a local public health geographer. This interdisciplinary collaboration was ultimately able to connect elevated blood lead levels to the areas that were showing the highest levels of lead in the water (as discovered by other water engineers and citizen scientists), ending months of squabbling over testing protocols [27] and misleading practices and communications by city and state agencies [28]. Local physicians and a coalition of health providers and purchasers were able to issue a clear warning to residents and local officials in both governmental and nongovernmental agencies. Finally, almost a year and a half after Flint's water supply was switched, a local health emergency was officially declared by the county health department in October 2015 [29]. It would be another three months before the state government, and subsequently the federal government, declared an emergency [30]. It was only through

this serendipitous cross-education and interdisciplinary collaboration that the contamination of Flint's water was brought to light.

The Flint water crisis has illuminated crucial roles for physicians in environmental health and in public health, in general. We must be involved in [surveillance](#) of unusual presentations of illness; we must provide culturally competent medical care to all of our patients, especially those in communities that bear a disproportionate share of risk and poor health outcomes; we must recognize the sociocultural and environmental underpinnings of health and illness; and we must be able to assist disaster response teams in times of emergency. Perhaps most importantly, we must use our position to forge alliances to advocate with our patients at both an individual and a policy level. These functions can only be adequately accomplished with knowledge of public health and environmental health in particular.

### **The Need for Physicians to Receive Both Public Health and Environmental Health Training**

There is a strong consensus that we should educate trainees in public health. The Centers for Disease Control and Prevention in collaboration with the Association of American Medical Colleges (AAMC) and other organizations have signed on to a collaborative set of population health competencies for medical students, including elements of environmental health [31]. Graduate medical education organizations have also embraced this need [32, 33]. Short of adding a year for a master's degree in public health (MPH), many educational institutions have attempted to implement enhanced training in environmental health via its integration into other learning activities, electives, summer internships [34], and certificate programs [35], but medical curricular time is scarce. Despite a clear call from many medical organizations to teach environmental health [36], the 2013 AAMC graduate survey still shows more than one-third of graduates reporting inadequate exposure to the topic [37].

We certainly must better train our future colleagues, but in this time of increasing environmental health challenges [38, 39], this endeavor will not suffice for immediate problems. Practicing physicians must also be willing to learn about specific problems when they arise locally and to collaborate with experts in fields outside of medicine to effectively address these problems. While established physicians can obtain a degree in public health, this is often impractical. In Flint, we did not have time for such formal training, and as we recognized each new health problem related to the Flint water crisis, we needed to actively pursue information gleaned through individual reading and by reaching out to experts. A key component of this endeavor was collegiality and a shared sense of purpose. Numerous health responders in the community have reported to us that there was a point at which they might have given up pursuing this learning if it hadn't been for encouragement from, and also for fear of disappointing, their colleagues. For Flint physicians, our Genesee County Medical Society has played a key role in

maintaining connections and the fabric of this endeavor. This role is important to ponder in view of the declining membership in organized medicine [40], as it would have been difficult to maintain our connection without this existing infrastructure.

Finally, there is the issue of physicians' attitudes about their responsibility beyond the clinic walls. While concerns about a cover-up and inadequate response by government officials remain, physicians must consider the following questions: Why did the *Legionellosis* outbreaks not raise more concern? Why were we not curious about General Motors needing noncorrosive water for its machinery and the city *not* needing noncorrosive water for its people? Why is it acceptable for anyone, anywhere, to drink brown, smelly water?

### **The Way Forward**

Knowledge and skill in public health, and environmental health in particular, are crucial, but not sufficient. Physicians have a duty—and also significant power and prestige—to effectively [advocate](#) for the health of our patients and, by extension, for the health of the broader community. Undergraduate, graduate, and continuing medical education also needs to inform medical personnel of the necessity of their engagement and of the relationships and attitudes needed to effectively advocate for the public's health. We must expand our perimeter of concern and look for the connections between disciplines, and even more so between people. The Flint water crisis would not have been exposed when it was without these connections, and in this time of decaying infrastructure, increasing socioeconomic disparities, climate change, and other environmental health threats, we need the analytical tools, the intellectual curiosity, an expanded network of other content experts, and—most of all—the ability to listen to, and advocate for, the communities we serve.

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**STATE OF THE ART AND SCIENCE**

**The Importance of Clinicians and Community Members Receiving Timely and Accurate Information about Waterborne Hazards**

Steven S. Coughlin, PhD, and Osman Yousufzai

**Abstract**

It is important for clinicians and community members to receive up-to-date information about the microbiological and elemental composition of local water supplies. Clinicians play an important role in helping their patients to interpret water quality data and understand the potential impact of water quality on their health. Expanding the medical school curriculum to include environmental health, public health, and health disparities—including disparities related to environmental quality and waterborne hazards—is key to clinicians' fulfilling this role.

**Introduction**

Physicians often use information from public health agencies to optimize care for their patients. For example, data about the prevalence of pathogenic and environmental exposures can influence a clinician's index of suspicion and inform decisions about which laboratory tests should be ordered to screen patients for a hazardous exposure or illness.

Although the US has one of the [safest](#) public drinking water supplies in the world, sources of drinking water can still become contaminated and lead to adverse health effects [1]. Water contamination can occur as a result of industrial effluents (e.g., from pulp and paper mills, steel plants, and food processing plants), municipal sewage treatment plant overflows, storm-water and sewage overflows, and agricultural runoff (e.g., pesticides, fertilizers, and pathogens) [2]. For example, in 2014, an industrial solvent contaminated West Virginia's Elk River and 15 percent of the state population's tap water [3]. Along the coast, toxic algae blooms (cyanobacteria) and bacterial contamination in shellfish occur each year in warmer months [4]. Moreover, water supplies and water distribution systems are potential targets for terrorist activity [2].

Ensuring water quality and safety in the US requires the participation of the medical community. However, the majority of health care professionals have received limited training in the recognition and evaluation of waterborne disease from intentional contamination of water [5] and in the adverse health effects of water pollution [1]. In this article, we consider the importance of clinicians and community members receiving up-to-date information about the microbiological and elemental composition of local

water supplies. We argue that clinicians have an important role to play in helping their patients to interpret water quality data and to understand the potential impact of water quality on their health.

### **Timely and Accurate Information about Waterborne Hazards and Why Physicians Need It**

The Centers for Disease Control and Prevention (CDC) provides health alerts, health advisories, and updates through the Health Alert Network [6], which is designed for use by members of the public health and medical communities. Outbreak investigation reports appear in the *Morbidity and Mortality Weekly Report*, which is designed for the same communities and published with a rapid turnaround time, enabling tracking of new disease outbreaks [7]. Public health officials in the 50 states, the District of Columbia, and US territories voluntarily report outbreaks of recreational water-associated illnesses to the CDC. During the period 2011–2012, for example, 90 recreational water-associated outbreaks—resulting in at least 1,788 patients, 95 hospitalizations, and one death—were reported in the CDC’s Waterborne Disease and Outbreak Surveillance System [8]. *Cryptosporidium* caused 52 percent of the outbreaks associated with treated recreational water venues (e.g., pools, hot tubs). *Escherichia coli* O157:H7 and O111 caused 33 percent of outbreaks associated with untreated recreational water (e.g., lakes, ocean beaches) [8]. During the period 2011–2012, 32 drinking water-associated outbreaks accounting for at least 431 cases of illness, 102 hospitalizations, and 14 deaths were reported to CDC, with *Legionella* being responsible for 66 percent of outbreaks and 26 percent of illnesses [9].

The medical and public health professions play important roles in helping community members to interpret information about water quality and to understand the data’s potential impact on their health. Factors such as the time of year, chronological progression of cases, and constellation of symptoms and whether an occurrence is isolated or clustered with other cases can influence clinicians’ index of suspicion. This information helps clinicians determine which laboratory tests and imaging studies should be ordered to rule in or out potential causes for a clinical presentation.

### **Ethical Implications of Clinicians and Community Members Not Receiving Timely and Accurate Information about Waterborne Hazards**

According to the American Medical Association’s Principles of Medical Ethics, physicians “shall ... apply ... scientific knowledge ... [and] make relevant information available to patients ... and the public” [10]. These professional obligations are hindered when clinicians and community members do not receive timely and accurate information about [waterborne hazards](#). The ethical implications of physicians not receiving timely information about waterborne hazards and of government officials deliberately withholding such information are illustrated by the Flint, Michigan, water crisis. In 2014 Flint switched its municipal water supply from Lake Huron to highly corrosive Flint River

water and did not treat the water with an anticorrosive agent, causing lead from the pipes to leach into the water [11]. For 18 months, the people of Flint were drinking water contaminated with lead while government officials were downplaying the seriousness of the problem [12]. Lead exposure, especially in young children, can cause irreversible harm including brain and nervous system damage, slowed growth and development, and learning, behavioral, and speech problems [13]. Finally, after research revealed a significant incidence of elevated pediatric blood levels, Genesee County declared a public health emergency in Flint [13]. Taylor et al. [13] described urgent efforts to provide continuing professional education at Hurley Medical Center in Flint to ensure that clinicians were equipped to address the environmental health crisis. In such situations, the professional role of physicians includes ordering appropriate tests and interpreting information about waterborne environmental hazards for patients so that they can take steps to protect themselves. These professional obligations relate to the ethical obligation of physicians to minimize risks and potential harm to their patients. Thus serious ethical problems arise when physicians do not receive timely and accurate information about waterborne hazards because of the actions or inaction of government officials or when they do not have sufficient training to interpret information about waterborne environmental hazards.

Delays in receipt of timely and accurate information also raised ethical concerns in the Freedom Industries chemical spill in West Virginia. In January 2014, coal-cleaning chemicals, such as 4-methylcyclohexane methanol (MCHM) leaked from Freedom Industries in Charleston, West Virginia, and flowed into West Virginia American Water's intake in the Elk River [14]. Shortly before noon on January 9th, state Department of Environmental Protection inspectors alerted West Virginia American about the spill. But the information flow was confusing and contradictory, according to a US Chemical Safety Board report [15]. Initially, the water company was told the material that spilled was a flocculant, or a coagulant, and that only 1,000 gallons, a relatively small amount, had been released into the river. West Virginia American thought its plant could easily treat the chemical it was told Freedom had spilled [15]. The water company soon learned that the leak was of a "frothing agent," something that Freedom sold to the coal industry to help it separate coal from rock. Shortly after, the water company began receiving revised estimates of the size of the spill and later noted its impact.

The DEP [state Department of Environmental Protection] provided a new estimate that showed the leak could have been of more than 5,000 gallons. Still later, that estimate would grow to 10,000 gallons—and the public would learn that chemicals other than MCHM were involved.... "Shortly before 4 p.m., the water company determined that the filters did not fully remove the chemical," the CSB [Chemical Safety Board] reported. The water company told the state Bureau for Public Health and Gov. Earl Ray Tomblin's office that the chemical "was detected in the

water beyond the filters and that the water distribution system might be contaminated." At about 6 p.m., residents were advised to not drink their tap water or use it for cooking or bathing [15].

Tap water use was banned for days across nine counties. The ensuing state of emergency closed schools and businesses. Hundreds of people went to emergency rooms for nausea, vomiting, rashes, and similar issues after breathing near, bathing in, or drinking contaminated water [16], illustrating the importance of physicians being trained in how best to respond to public health emergencies related to environmental disasters and waterborne hazards.

In the Freedom Industries chemical spill as in the Flint water crisis, a lack of accurate and timely information about health hazards during an environmental disaster impaired the ability of physicians to minimize risks and potential harm to their patients. Such problems can lead to the erosion of community member trust in company representatives, physicians, and government officials.

### **Improving Public Health and Health Disparities Education in Medical School Curricula**

Although physicians can play an important role in interpreting water quality data and helping their patients understand the potential impact of water quality on their health, many physicians do not have sufficient public training to enable them to respond to illnesses related to water contamination. One solution is expanding the medical school curriculum to include training in how best to respond to [public health emergencies](#) and about the root causes of health disparities, including disparities related to environmental quality and waterborne hazards [17, 18]. Such training could provide physicians with an improved understanding of social and environmental causes of diseases and with strategies for identifying and ameliorating waterborne hazards. For physicians, the link between the public health community and the medical community should be forged during medical school [17]. However, epidemiology and population health only comprise 1-5 percent of the United States Medical Licensing Examination® (USMLE®) Step 2 Clinical Knowledge exam [19]. Instead, much of the focus of the medical school curriculum is on disease pathophysiology, diagnosis, and treatment [17]. This emphasis is also reflected in the first and second parts of the USMLE, which focus on organ systems, normal and abnormal processes, and therapies. Yet, as exemplified by the case studies included in this article, the causes of health disparities extend beyond disease pathophysiology to include social determinants of disease at multiple levels (e.g., individual, neighborhood, community, health care system, public policy). Thus a greater emphasis is needed on social determinants of disease in medical education as well as on epidemiologic and public health knowledge and insights pertaining to emergency response to environmental disasters and waterborne hazards. As noted by Finkel, "Disparities based on race/ethnicity, socioeconomic status, geography, and other factors continue at unacceptably high levels" [20]. Disparities based on environmental quality, such as

waterborne hazards, have a great impact on health. Indeed, poor environmental quality has the greatest impact on the health of those who are already at risk [21].

Medical schools have begun to address disparities based on environmental quality in several ways. Incorporation of screening techniques, receiving basic public health training, and partnership with accredited programs have all been suggested [18]. In the case of waterborne hazards, physicians with public health knowledge would be better equipped to look for timely and accurate information and to adjust their practice based on the most recent evidence.

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## HEALTH LAW

### The Safe Drinking Water Act of 1974 and Its Role in Providing Access to Safe Drinking Water in the United States

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#### Abstract

In 1974, President Gerald Ford signed into law the Safe Drinking Water Act, the first piece of legislation of its kind to provide a comprehensive regulatory framework for overseeing the nation's drinking water supply. The law has proven instrumental in setting standards for ensuring that the US population can access drinking water that is safe. However, the law delegates much of its monitoring requirements to states, creating, at times, a confusing and complicated system of standards that must be adhered to and enforced. Although it has proven valuable in the safety standards it specifies, the law's administration and enforcement poses tremendous challenges.

Many people in the United States consume tap water without giving it a second thought. When you add a cup of tap water to a recipe, gulp it down during an intense workout, or bathe an anxious dog in the bathtub, you rarely consider the water's source and what is undertaken to ensure it is accessible and safe. Yet up until the latter half of the twentieth century, there was no federal regulation protecting drinking water. Instead, what existed was a patchwork of state- and local-level water regulations created to deal with providing adequate *quantities* of drinking water to growing communities, with little thought given to the *safety* of the water itself [1].

Following the establishment of the Environmental Protection Agency (EPA) in 1970 [2], and in the midst of the environmentalism movement gripping the United States during the 1960s and 1970s [3], Congress enacted a vital federal law for protecting much of the nation's public water supplies from harmful agents: the Safe Drinking Water Act (SDWA). Signed into law in 1974, the SDWA grants the EPA the power to set national health standards for drinking water "to protect against both naturally-occurring and man-made contaminants that may be found in drinking water" [4]. At its outset, the law served as an invaluable regulatory framework for adding uniformity to safe drinking water standards and provided many mechanisms to update the law and enhance its oversight. But in the years since its passage, serious questions and concerns have been raised about its enforcement and the government's inability, at both the federal and the state



level, to implement monitoring and adopt methods for measuring known contaminants and to identify new contaminants that threaten the health and well-being of millions of Americans.

This article examines the history, operation, and evolution of the SDWA as a novel vehicle for increasing the citizenry's access to safe drinking water. We argue that though the SDWA is noble in its intent, it is faulty in its implementation.

### **History of Safe Drinking Water in the United States before 1974**

The United States' first steps in drinking water governance began in the earliest years of the twentieth century. Since the Republic's founding, water management had been largely treatment focused and locally enforced [5]. Things began to change after the passage of the 1912 US Public Health Service Act [1], whereby Congress sought to prevent communicable diseases from being introduced into and transmitted via water by, for example, eradicating waterborne typhoid through chlorination treatment [6]. Additional federal oversight of interstate transportation waters would be launched in the following decades to limit microbes and chemical, organic, and radioactive materials in water and to monitor and test water supply systems [1, 7, 8]. Despite this work, widespread alarm over the nation's drinking water would not capture the American public's collective attention for some time.

Mounting concern during the 1960s over the environmental harms posed by industrial runoff and [synthetic chemicals](#) leaching into the water supply triggered several federal studies of the country's water sources [5, 9]. One such study conducted by the US Public Health Service in 1969 found that only 60 percent of surveyed water systems providing drinking water to interstate carriers met current federal guidelines, with more than half exhibiting deficiencies in disinfection, clarification, and water pressure [5]. Between 1961 and 1970, officials documented over 46,000 cases of waterborne hepatitis, salmonellosis, and gastroenteritis—diseases caused by chlorine-resistant pathogens [10]. Furthermore, the "Community Water Supply Study," published in 1970, concluded that 90 percent of surveyed drinking water systems exceeded permissible microbe levels [7], while a 1974 Environmental Defense Fund report attributed cancer deaths in New Orleans to consumption of contaminated drinking water from the lower Mississippi River that had been exposed to sewage and industrial waste [1, 11].

### **The Safe Drinking Water Act of 1974**

Amid growing concerns over the impact that human activity could have on the environment, President Richard Nixon oversaw the consolidation of the federal government's environmental responsibilities through the creation of the EPA as well as the pursuit of signature legislation to protect the environment. This would include the SDWA.

*Legislative process.* Tension ran high throughout the legislative process to pass the SDWA, however. Although there was broad national support and widespread recognition that current water oversight had been lacking, it took nearly four years to pass legislation for the federal regulation of public drinking water systems [10]. As public pressure mounted, water industry associations vied for strong federal standards while resistance from some congressmen and oil company lobbyists impeded the act's progress [7]. Hostility towards the SDWA centered on scientific uncertainties and administrative and enforcement responsibilities, and many criticized the EPA for excessive spending, inexperience, and insufficient coordination [10]. In particular, scientific uncertainties remained as to which substances were to be legislated and with what methods they were to be measured, while administration and enforcement questions led some to maintain that state and local governments should retain primary responsibility for safe drinking water [10].

Political turmoil notwithstanding, in 1973 the Senate passed its bill calling for the federal supervision and control of drinking water, and in 1974 the bill was further revised with amendments from both the House and the Senate [12, 13]. Once the bill passed both the House and the Senate, the SDWA was signed into law by President Gerald Ford on December 16, 1974 [1].

*Legal power.* Under the SDWA, the EPA has been granted the federal power to regulate drinking water, which includes water that is used for bathing, cooking, dishwashing, and maintenance of oral hygiene, to protect public health [1, 14]. These national drinking water regulations apply to privately- and publicly-owned "public water systems" that have at least 15 service connections or regularly serve at minimum 25 people [15].

Responsibility to implement the SDWA lies at both the federal and the state level [9]. The EPA sets the national drinking water standards by imposing regulations on contaminants that are detrimental to public health [4]. The administrator of the EPA is then responsible for oversight and enforcement of these standards [16]. In accordance with the SDWA, the EPA regulates contaminants if the following three criteria are met: (1) the contaminant might have adverse health effects; (2) there is substantial likelihood that the contaminant will occur in public water systems at levels of public health concern; and (3) its regulation will reduce public health risk [15]. To ensure adequate contaminant regulation, every five years the EPA must announce unregulated contaminants to be monitored by public water systems and make regulatory determination regarding at least five of the contaminants that were on the list [15]. Once this benchmark is set, states are responsible for primary implementation and enforcement of the drinking water program [15].

At present, 49 states have assumed primary authority over the Public Water Supply Supervision (PWSS) Program. This program requires that the states and territories do the

following: adopt regulations as stringent as the national requirements; develop procedures to purify water and monitor its contaminant levels; assume authority for administrative penalties; conduct inventories of the purification and monitoring systems; maintain records and compliance data; provide the EPA with any required reports; and construct a plan for safe drinking water during emergencies [15]. To ensure compliance, public water systems must report monitoring results to the states, which review the results and conduct their own monitoring, with the EPA monitoring compliance chiefly by reviewing reports of violations submitted by states [15]. If it is found that a public water system does not comply with regulations, the EPA must assist the system in order to bring it into compliance [15]. Furthermore, in the event of a violation that poses a threat to public health, such as an exceedance of the [lead action level](#), water systems must notify the public of a violation within 24 hours [15]. And should there be an imminent and substantial endangerment, with no action from state or local authorities, the EPA has authority to act [17]. In order to support state costs in administering the PWSS program, Congress distributes approximately \$100 million annually to the EPA for grants, although the EPA requested a smaller amount for fiscal year 2018 [15, 18]. When appropriating these funds among states, the EPA considers a number of factors such as state population, geographic area, and number of public water systems [15].

There are several legal avenues for holding the EPA and individual states accountable under the SDWA. Through the enforcement powers granted to the EPA by the SDWA, if the EPA brings a civil suit against a negligent water system, courts may make judgments to protect public health and impose civil penalties based on the seriousness of the violation, the population at risk, and other appropriate factors [1]. Moreover, the EPA can obtain injunctive relief to stop the actions of noncompliant water systems, although courts have noted that they have discretion in SDWA cases and do not necessarily have to order the requested remedies for violations. In addition to civil suits, criminal violations may be sought against individual employees of federal agencies [17]. To ensure accountability, the SDWA contains a citizen suit provision that allows citizens to take civil action against any federal agency or the EPA administrator if they are alleged to be violating the SDWA [4]. There is an exception, however: citizens may not file a suit if the EPA, the attorney general, or a state has already filed and is prosecuting a civil action against a water system that is not in compliance with the law [17].

### **Effectiveness of the SDWA**

In large part, thanks to the SDWA and other regulatory actions by the EPA, the quality of drinking water in the United States has improved steadily throughout the last 40 years. Before the passage of the SDWA, many parts of the country did not have safe drinking water whereas now Americans enjoy some of the safest drinking water in the world, and, according to a former EPA administrator, “more than 90 percent of water customers enjoy drinking water that meets all standards all the time” [19]. In March 2010, the EPA completed a six-year-long review of the National Primary Drinking Water Regulations

(NPDWRs) in order to identify NPDWRs for which current health effects assessments, changes in technology, and other factors provide a health or technical basis for supporting revisions that would support and strengthen public health systems [1].

The SDWA's effectiveness is also attested by recent research, additional regulated contaminants, and transparency requirements. The EPA is currently evaluating risks of specific health concerns associated with drinking water, including microbial contaminants (e.g., *Cryptosporidium*), byproducts of drinking water disinfection, radon, arsenic, and water from likely vulnerable groundwater sources [3]. Amendments made to the SDWA have sought to reduce risks from numerous naturally occurring chemicals including arsenic and radionuclides, from manmade chemicals and pesticides, and from pathogens including *Giardia lamblia* and *Escherichia coli* [20]. The result has been a threefold increase in the number of contaminants regulated under the SDWA since its introduction in 1974 [5]. Additionally, the SDWA mandates public notification, which provides information about the suppliers of drinking water, the level of pollution in particular drinking water sources, and potential sources of pollution near drinking water sources [1]. Since 1971, the EPA and the Centers for Disease Control and Prevention (CDC) have collaborated to gather information and minimize waterborne disease outbreaks across the country. According to this data, the highest incidence of outbreaks since 1974 occurred in the early 1980s and the incidence of outbreaks has generally declined since then [5]. Even with the persistent challenge of waterborne disease outbreaks, US drinking water quality has gradually but consistently improved, in part due to the SDWA and other regulatory actions of the EPA, including the Total Coliform Rule (1989) and the Surface Water Treatment Rule (1989) [5].

### **Challenges Facing the SDWA**

Despite its effectiveness in reducing water contaminants to safe levels and protecting the public's health, the SDWA still faces obstacles to more effective implementation. Up to half of the US population drinks unregulated water from small systems that have fallen through the cracks of the regulatory protections imposed by the SDWA and other laws [21]. In California, for example, small service providers and private well owners are not regulated by the SDWA, resulting in consumption of contaminated water in schools and homes [22].

Another challenge comes in the form of inadequate funding, which continues to hamper the supply of safe drinking water especially in cases involving expensive treatment techniques [9]. As seen in the example of California, the water crisis is exacerbated by the water systems' lack of funding for maintenance and regulation [22]. Current estimates indicate that nearly one trillion dollars' worth of upgrades and maintenance is needed to update the drinking water infrastructure in the United States [23]. As reported by the National Resources Defense Council:

Under the SDWA, the Drinking Water State Revolving Fund (DWSRF) allocates congressional funds for utilities to use to achieve or maintain SDWA compliance.... From 1998 to 2016, the federal government invested about \$19 billion in the DWSRF, which has translated to more than \$32.5 billion in total allocations to water system projects across the United States [24].

But even with efforts to provide states with greater financial assistance to maintain safe drinking water standards, grants continue to fall short of states and cities' needs [9].

Moreover, local governments have accused the EPA of not always acting effectively and efficiently, particularly in situations in which compliance can be achieved through less costly alternatives [9]. In the early 1990s, a city in Maine was told by the EPA to install a filtration system that would cost \$20 million even though there was a more cost-efficient solution: a pipe replacement system that cost half that amount [9]. And as a result of smaller water systems being unable to shoulder the financial burdens that come from SDWA regulatory requirements, states have delayed implementing new monitoring schedules, installing new treatment devices, and making improvements to their existing systems [5]. Water systems' limited "breathing room" in implementing the SDWA is compounded by consequent compliance violations [5].

An especially salient problem facing the SDWA has been the ever-increasing scientific knowledge about novel contaminants found in water as well as growing evidence that smaller amounts of chemical exposure can have serious health consequences. While more than 60,000 chemicals are in use in the United States, thousands of which have been studied by government and independent scientists, only 97 chemicals or chemical groups and 12 microbial contaminants are currently regulated by the SDWA [25, 26]. And government scientists generally agree that many chemicals commonly found in drinking water pose health risks at lower concentrations than previously thought, whereby "millions of Americans become sick each year from drinking contaminated water, with maladies from upset stomachs to cancer and birth defects" [25]. Even with these revelations, the SDWA has proven rather limited in that nothing in the law addresses the cumulative risks of multiple pollutants in a single glass of water [25].

Enforcement of the act has also been heavily criticized. In 2015, close to 77 million Americans lived in parts of the country covered by the SDWA where their water systems were in violation of the SDWA's safety regulations [27]. But because of a lack of reporting by states and local water systems about such violations, many of these people remained in the dark as to whether their drinking water was or was not contaminated [23]. Approximately nine out of ten violations of the SDWA are not subject to disciplinary or corrective action, often, according to public health and safety officials, because drinking water infrastructure is considered a problem that is "out of sight, out of mind"

and part of a complicated regulatory system wherein adherence to federal law rests largely on the monitoring actions of states [27].

## Conclusion

There is no doubt that the availability and accessibility of safe drinking water in the United States is in large part due to the Safe Drinking Water Act of 1974. The SDWA established a uniform set of regulations that continues to provide a baseline level of safe water. Its existence is complicated, however. Scientific, bureaucratic, and enforcement problems have hampered its ability to protect far too many people in the United States, and its inefficiencies raise serious doubts about its resiliency in an environmental health landscape marked by political recalcitrance when it comes to regulatory change.

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## POLICY FORUM

### Water Safety and Lead Regulation: Physicians' Community Health Responsibilities

Bruce Jennings, MA, and Leslie Lyons Duncan, PhD

#### Abstract

This article reviews the regulation of lead in drinking water, highlighting its epidemiological, engineering, and ethical aspects with a focus on the Flint water crisis. We first discuss water quality policy and its implementation with a focus on lead contamination of water, primarily from pipe systems between a water treatment facility and a tap. We then discuss physicians' roles and ethical responsibilities regarding safe drinking water using a human rights framework. We argue that physicians can play an important role in safeguarding drinking water in their communities by being vigilant, honoring the community's trust in them, and warning, educating, and empowering patients and broader communities so as to protect tap water safety and public health.

#### Introduction

Safe drinking water is a key factor in health and well-being. Children are particularly vulnerable to the health effects of unsafe drinking water, which include not only diarrheal disease but also diseases linked to inorganic pollutants such as arsenic, copper, fluoride, lead, and nitrate [1]. Fetal and early childhood exposure to such contaminants can cause neurological damage and developmental impairments with lifelong consequences [2, 3]. Recent cases involving lead contamination in municipal water systems, such as occurred in Washington, DC, in 2003-2004 [4] and in Flint, Michigan, in 2014 [5] illuminate significant health risks and failures of existing public health and governmental systems to respond robustly to contamination risks. This article reviews the regulation of lead in drinking water, highlighting its epidemiological, engineering, and ethical aspects with a focus on the Flint water crisis.

#### Regulation of Lead Levels in Water, but Not Blood

It was not until the Clean Water Act of 1972 [6] and the [Safe Drinking Water Act](#) (SDWA) of 1974 [7] that systematic water safety regulation began in the US. The SDWA was significantly strengthened and expanded in 1986, when the Environmental Protection Agency (EPA) was authorized to set regulatory standards, one of which was the Lead and Copper Rule (LCR) issued in 1991 [8]. The LCR sets an "action level" for lead—a point at which regulators must take steps to reduce risk—of 15 parts per billion (ppb) in 1 liter of

tap water standing in pipes for at least 6 hours [9]. Lead, the toxicity of which has been known since ancient times, is a particular concern in environmental health today. Beginning in the early 1970s, the EPA gradually reduced the amount of tetraethyl lead permitted for use in on-road vehicles, which culminated in a complete ban in 1996 [10]. Since then, the legislative and regulatory focus on environmental lead exposures has been on physical particulates, such as house paint containing lead, and lead contamination of drinking water. In 1991, the EPA estimated that between 14 and 20 percent of total lead exposure was from drinking water [11]. Further changes to the SDWA in 1992 and 1996 strengthened protections of drinking water, but the LCR action level has remained unchanged [12].

While the LCR addresses lead concentration in tap water, no toxic threshold has been identified in human blood levels of lead (BLLs) because research suggests that no blood lead level is a “safe” level, for either adults or children [3, 13–15]. Young children, infants, and developing fetuses have been the most susceptible to [lead exposures](#) [16, 17]. In children, BLLs as low as 10 µg/dL (100 ppb) or even 5 µg/dL (50 ppb) are a causal risk factor for developmental impairments and neurobehavioral disorders such as hyperactivity and attention deficit disorder [2, 3]. From 2007 to 2010, approximately 535,000 US children aged 1–5 years had BLLs of at least 50 ppb [2]. To the extent practically feasible, the various sources of lead exposure, including but not limited to tap water, should be identified and mitigated. The situation of “practical feasibility” is complex and includes technological possibility, cost effectiveness, and value priorities set by political forces and the influence of past regulatory objectives. As Brown and Margolis point out, “Current water sampling protocols were designed to assess the adequacy of water treatment, not the level of human exposure to lead. Important fluctuations in water lead levels might be missed because of limitations inherent in sampling protocols developed for regulatory purposes” [18].

### **Water Regulation, Monitoring, and Management**

Water withdrawn directly from rivers, lakes, reservoirs, and underground aquifers is rarely safe enough for human consumption if not subjected to some degree of treatment. In the case of lead, the contamination usually comes from the distribution system rather than the treated source. Older homes were often built with lead plumbing and fixtures, and those built more recently might contain lead solder [19]. Drinking fountains in schools have lead in their storage tanks [19]. Millions of American homes and buildings receive water from service lines that are at least partially lead [20, 21].

The goals of the SDWA and the LCR are difficult to meet for several reasons. One is the diffuse nature of the water management system in the US. As public health historian David Rosner observes, “In the United States there are 155,000 separate water systems serving communities and institutions, which leads to a haphazard system of enforcement” [22]. These systems may be publicly or privately owned. Many households

are not subject to regulation because they draw untreated water from private wells that are not regulated by the EPA. The responsibility for ensuring that public drinking water systems actually meet the SDWA standards is divided among the EPA, state governments, tribal governments, and private water systems acting as public utilities [12, 22].

This regulatory system is based upon regular monitoring and reporting by local officials. In 1986, amendments to the SDWA required that new or revised drinking water standards be developed for 83 specific contaminants and called for the addition of contaminant standards thereafter [12]. Water sampling frequency requirements vary for each contaminant group. The primary contaminant group that contains lead is inorganic chemicals. Other contaminants within this group are arsenic, asbestos, chromium, copper, fluoride, mercury, and nitrate [23]. Radionuclides comprise a separate contaminant group, as do organic chemicals, microorganisms, and turbidity [23]. Water sampling requirements also vary with the size of the water distribution system. Some small systems collect as few as five samples per year, and some large systems only collect 50 to 100 [24]. Detection of a contaminant above a certain level sometimes triggers increased sampling requirements. The EPA and the states primarily monitor public water system compliance with the SDWA and the LCR standards through review and evaluation of water quality test results and reports, usually done by certified laboratories [25]. Under the LCR, water systems serving more than 50,000 residents must have “optimal corrosion control treatment” regardless of the tested lead level [26]. In water systems serving fewer than 50,000 residents, when results indicate that more than 10 percent of sampled homes have a lead level that exceeds the action level, “the utility must identify and install optimal corrosion control treatment” [26]. The EPA requires, by law, that water systems control the corrosivity of their water so that lead in the pipes does not enter the water as it passes through [8]. The current lead action level of the LCR, developed in 1991, was based on the feasibility of reducing lead with the corrosion control technologies available at that time. Ideally, as remediation technologies improve, regulation will adjust as well by incorporating the most effective control methods. Timely public notification is required to advise consumers of potential health hazards and to identify steps people should take to protect their health regardless of the size of the water system’s population [9].

This regulatory system, however, is imperfect. The LCR permits up to 10 percent of homes to exceed the action level of 15 ppb. Moreover, the LCR requires public water systems to test tap water in a comparatively small number of homes with lead pipes—50 to 100 homes for large systems—and intervals between testing can extend from six months to three years, depending on the levels of lead [24]. Although water systems use various procedures for tap water tests that specify how long tap water must be run before a test sample is drawn and other protocols that lead to accurate test results, they can easily be compromised by inattention or lack of proper training. Nevertheless,

regulations allow homeowners to conduct these tests unsupervised, and hence the data reported might not always be reliable [19, 20, 27].

### **Complex Regulatory and Value Choices**

No matter how sophisticated the quality control and monitoring methods, health and safety will not be well served if prevailing financial and ideological considerations compromise their use, if regulations are interpreted in an overly permissive way, or if regulations are flouted by officials. It has become clear that this happened in Flint, where a new water supply system (the Flint River) was adopted to save money in the fiscally stressed city in 2014. Chemicals required to treat the Flint River water were known to have corrosive properties that released lead inside the pipes of the city's water system and contaminated drinking water [28]. Yet other corrosion-inhibiting chemicals that would have formed a protective layer on interior pipe surfaces, reducing dissolution of lead into water, were not also used [28, 29]. The irony of Flint was that the city and state could have treated the water with these anticorrosive chemicals for a cost of about \$100 per day. Now it faces the cost of repairing the entire system for \$1.5 billion [29]. The cost of lead remediation for the entire country is estimated at \$1.3 trillion [29]. These are the costs of fixing pipes; the cost of providing medical care for those who have already been—or will be—affected by lead exposure if better protective measures are not taken has yet to be calculated [1, 2, 12].

Even when large water systems are managed or replaced to deliver noncontaminated drinking water, lead contamination can still occur as water travels through or sits for long periods in internal plumbing of commercial or residential buildings. If interior plumbing presents a risk, one effective way to reduce metal concentrations in household drinking water is to flush the plumbing system by running water for up to two minutes before drinking the water [30]. At the community and personal level, physicians can play a particularly important role in public health outreach to and education of residents of high-risk sites.

### **Physicians and Communities Working Together**

In Flint, after the concerns and complaints of residents and parents were dismissed and ignored by local and state officials for many months, the voices of Marc Edwards, an engineer whose team members documented water lead levels, and Mona Hanna-Attisha, a pediatrician whose team documented blood lead levels, were essential in getting government officials to publicly acknowledge that lead in the water was causing lead poisoning in children [22]. Yet documenting objective risk and harm is only one of several activities that help enable access to safe, uncontaminated drinking water, which physicians should consider to be within the purview of their professional ethical responsibilities.

The foundation for this set of responsibilities pertains to physicians as professionals and as ethical persons; it is that equitable access to safe drinking water is a [human right](#) [31]. This right is recognized in virtue of the essential biological role that fresh water plays in human life. As a principle of justice and a human right, access to this necessary substance cannot be limited in arbitrary or discriminatory ways; and in fulfilling this right, societies are obligated to make resources available and to prohibit conduct that violates this right, even if lower priority must be given to other social interests and preferences. In turn, the specific ethical responsibilities incumbent on physicians *qua* physicians stem from at least three factors:

1. *Physicians' scientific training and knowledge.* This should include health risks associated with water contaminants, such as lead. Arguably, physicians, such as pediatricians, who serve some of communities' most vulnerable patients, should be prepared to identify those community members' risks from such contaminants.
2. *Physicians' social authority and community trust.* Physicians are obligated to fulfill public trust by drawing upon their knowledge and credibility regarding environmental health and safety. Many health and environmental regulations, such as the LCR, call for standards and conditions that are "optimal," which is a complex notion that is subject to dispute when it is operationalized by particular engineering requirements. For example, from an engineering standpoint, drinking water systems ought to take into consideration cost, feasibility, potential for scaling, ease of handling chemicals, and potential to increase other undesirable water quality characteristics such as turbidity, the acidity of the water, and the like. From a medical and health perspective, however, "optimal"—at least when it comes to BLLs and the multiple pathological effects of lead—is a value-laden notion. It does not entirely embrace the calculus of costs and benefits calibrated in monetary terms, and it suggests a preventative and precautionary priority. Physicians are well positioned to keep a community's focus on what is morally right and obligatory.
3. *Physicians' strategic position as brokers and mediators between public officials and corporate leaders, on the one hand, and community members, on the other.* In virtually every community there are some who are socially and economically disadvantaged and vulnerable to environmental health injustices and risks associated with poorly managed drinking water systems. These persons need physicians to exercise the duty to warn of the risks and to advocate for the health interests of those who cannot protect themselves. Government, corporate, and civic leaders, who themselves have a duty and a public trust, also need physicians to remind them about the importance of safe drinking water to public health.

Physicians should carefully monitor and recognize not only blood levels but also developmental and behavioral signs of toxic exposure. They can also learn about concerns from their patients' reports of changes in the quality of water they use. Physicians' insights into possible health effects of poor water quality can also come from their broader engagement in civic affairs, such as attending community meetings, being in touch with local college and university faculty, and being active in local health professional societies and service organizations. Required water testing, as has been noted, is episodic and does not always result in symptom identification or early warning of contamination problems. Communication between physicians and patients is a supplemental facet of [public health surveillance](#) that can be vital for protecting patients from exposure or further exposure to lead-contaminated water.

Physician communication with patients and community members can help inform and warn. Physicians can educate their patients and families about precautionary measures and about the availability of testing and remediation support for older plumbing and fixtures, just as they have been attentive in the past to the hazards of peeling lead-based paint and leaded gasoline [13].

Finally, lead contamination is not a problem that can be solved within clinical encounters, so physicians are obliged as citizens and professionals to play more active civic roles as advocates. Physicians' reliance on their medical expertise and their reputation for general respect and trustworthiness can have significant impact on local affairs in several ways. Physicians can serve on local government panels. They can become active in local not-for-profit environmental and health organizations. They can work with professionals from other disciplines, such as environmental engineers and chemists, while serving as pro bono advisors to neighborhood and civic groups.

When it comes to safe drinking water, the voice of physicians can be a voice for the ethical values of equity and social justice, a voice for the futures of children, and a voice for transparency and accountability. Physician leadership can make a difference to water policy and regulation, and it is sorely needed [28].

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**IMAGES OF HEALING AND LEARNING**

**Waterborne**

Images and captions by Kwesi Reynolds

**Abstract**

These photos capture the Flint water crisis from the perspective of a photographer and cinematographer who is a resident of Flint. They represent citizens' struggles, town hall meetings, and some of the city's repair efforts. They also illuminate environmental injustice as a violation of human rights.



**Figure 1.** *Corrosion of Trust.* Photo: Kwesi Reynolds.

**Caption**

After talking with a Flint resident and learning he had just completed some home renovations, I was invited to take a look at some of his home's plumbing.



**Figure 2.** *Portentous Vote.* Photo: Kwesi Reynolds.

**Caption**

At this Flint City Council meeting on March 25, 2013, the council heard comments from the public and voted to change its water source from the Detroit Water and Sewerage Department to the Karegnondi Water Authority.



**Figure 3.** *Signs of Change.* Photo: Kwesi Reynolds.

**Caption**

"Water Line Replacement Work Area" signs are scattered all throughout the city. Work crews dig up old pipes and replace them with new ones, which began in March 2016.





**Figure 4.** *Can Do: Water for Washing.* Photo: Kwesi Reynolds.

**Caption**

"Please Use This Water" sign found in a local public restroom instructing people to use canned water to wash their hands.



**Figure 5.** *Greetings from Flint.* Photo: Kwesi Reynolds

**Caption**

This "Greetings from Flint" mural is found on Saginaw Street. Inside the letters are images that resonate with many people in the city following the water crisis. The artwork is part of a mural project by unspecified artists.



**Figure 6.** *Watered Down Rights.* Photo: Kwesi Reynolds.

**Caption**

This use of image and words highlights the overarching issue of environmental injustice and citizens' right to safe water.



**Figure 7.** *Waterborne*. Photo: Kwesi Reynolds.

**Caption**

The words “human rights” on a pregnant woman’s stomach represent unborn Flint residents with no voice, whose human rights are being neglected.

**Kwesi Reynolds** was born in Detroit and raised in Flint, Michigan, where he attended Flint Central High School. After graduating from high school and spending four years in the US Navy, he moved back to Michigan to pursue his education. He graduated with honors from Mott Community College and received a bachelor’s degree in film from Wayne State University. He now lives and works in both Flint and Detroit and looks forward to bringing a major motion picture to the city of Flint.

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## CORRESPONDENCE

### Elder Self-Neglect: Another Ethical Dilemma for Physicians

Nancy Lutwak, MD

*This correspondence responds to Joshua M. Baruth and Maria I. Lapid's "[Influence of Psychiatric Symptoms on Decisional Capacity in Treatment Refusal](#)," which appeared in the May 2017 issue, 19(5), of the AMA Journal of Ethics.*

I read the recent article, "Influence of Psychiatric Symptoms on Decisional Capacity in Treatment Refusal," with great interest and applaud the clarity of the authors' analysis of the difficulties physicians face when patients refuse treatment. Baruth and Lapid effectively lay out principles to follow in that circumstance [1]. They indicate that the majority of psychiatric patients have decision-making capacity, that the impact of patients' refusal of treatment should be considered, and that physicians must avoid being paternalistic. In addition, the authors emphasize that the assessment of capacity should consider a patient's needs and express respect for a patient's autonomy and that physicians' beliefs should not unduly influence the process.

I recently took care of a 91-year-old man who had history of nonadherence in taking his antihypertensive medications and eye drops to reduce intraocular pressure. He lived alone and frequently missed appointments with his primary care physician and in the eye clinic. He had a long-standing history of glaucoma and had lost total vision in his right eye because of his self-neglect. This man consistently refused help at home, stating he was "fine," and had no close relatives or friends that could provide assistance. He was mobile and able to travel without difficulty to the hospital. He answered questions appropriately but clearly lacked the ability to care for his health responsibly.

The patient required immediate treatment in the emergency department on several occasions in the past after he missed multiple prescheduled primary care or eye clinic appointments. His medical history demonstrated an inability to adhere to prescribed medications and routine visits. He sought acute care when one of his chronic conditions worsened precipitously. On this occasion, he arrived in the emergency department complaining of four days of right eye pain, redness of the lower eyelid, and yellow discharge emanating from the corner. He stated he had not come in sooner because "I thought I would get better." The workup demonstrated right orbital abscess, necessitating his admission to the hospital for intravenous antibiotics. If the patient had been treated earlier in the walk-in clinic when the problem was less serious, oral antibiotics would have sufficed, thereby obviating the necessity for admission.

This case illustrates a growing problem among elderly patients, as lifespan is increasing and certain cognitive skills become more impaired with age [2]. Elder self-neglect is an adult's inability, due to physical or mental impairment or diminished capacity, to perform essential self-care [3]. Self-neglect is associated with an increased risk for all-cause mortality [3, 4] and, as the population ages, will become more common. More specifically, it is associated with an increased risk for cancer-related mortality and an increased increase in mortality resulting from endocrine or nutritional deficiencies [5]. The number of Americans over age 65 is expected to increase the burden of dementia [2].

Yet elder self-neglect is often unrecognized by clinicians [4]. If older patients suffer from self-neglect but understand the consequences of refusing aid at home or changing their living conditions, physicians face a moral dilemma. On the one hand, geriatricians or primary care clinicians might feel their patient would be better served by obtaining help from a caregiver to increase medication compliance, arrange adequate nutrition, improve hygiene, or enable activity with assistance. On the other hand, the patient-physician relationship requires respect for the patient's dignity, independence, and autonomy.

Unlike physical or psychological [mistreatment](#) by caregivers, which is a problem with a clear-cut solution since it involves responsible adults whose irresponsible actions have negative consequences for dependent persons in their care [6], self-neglect is more complex, presenting shades of gray and an ethical challenge for health care professionals. Health care professionals take on some of the responsibility of the caregiver by trying to do their best for the dependent elder, balancing the elder's wish for independence and the risks of poor self-care [6, 7]. They try to determine the extent of the patient's cognitive decline and its consequences over time, barring intervening medical illness or accidents.

Many patients with mild [cognitive impairment](#) are unable to take adequate care of themselves but, because they do not have moderate or severe dementia, maintain their legal right to make health care decisions [8]. As mentioned earlier, this situation creates a dilemma for physicians: many seem to favor patients' rights and autonomy but might be concerned about safety if the patient wishes to live independently. Geriatricians or primary care clinicians might feel their patient would be better served obtaining help from a caregiver, but overriding a competent patient's informed choices is unethical and violates the trust that has evolved over time [8]. This complex situation presents difficult legal and ethical questions for physicians concerned about both the patient's health and the patient's wish to remain independent [6-9].

Self-neglect is a chronic problem of geriatric patients, but it was not a feature of the case discussed by Baruth and Lapid, which involved a 55-year-old woman with depressive

symptomatology who refused specific aggressive treatment for stage II breast carcinoma though she had a clear understanding of the risks and benefits [1]. The authors adroitly argue that a prior or current psychiatric diagnosis should not determine judgments of decisional capacity. By contrast, this correspondence describes an older man who lives alone, has not been diagnosed with depression, and who might have worsening dementia that has not severely limited his daily functional capacity. He is not refusing a specific treatment or procedure. The dilemma for health care professionals is at what point to question the patient's right to be autonomous as his functional capacity slowly declines. At what point is he considered a "danger" to himself? The problem is made more complex when it is not possible to view a patient's living conditions or when consultation with relatives or close friends is not an option. I would like to invite Baruth and Lapid to offer advice or comments on this type of dilemma, which seems less straightforward than their interesting and informative case.

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## Related in the *AMA Journal of Ethics*

[Differentiating among Depression, Delirium, and Dementia in Elderly Patients](#), June 2008

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## CORRESPONDENCE

### Capacity Determinations and Elder Self-Neglect

Joshua M. Baruth, MD, PhD, and Maria I. Lapid, MD

*This correspondence responds to Nancy Lutwak's "[Elder Self-Neglect: Another Ethical Dilemma for Physicians](#)," which appears in the October 2017 issue, 19(10), of the AMA Journal of Ethics.*

We recently published an article in this journal on the determination of decision-making capacity in the case of a 55-year-old patient suffering from complicated grief who refuses treatment for stage II breast carcinoma that reviews the principal literature and discusses approaches clinicians can use in assessing capacity [1]. Here, we respond to reader correspondence and expand further on the determination of decision-making capacity by considering the often ethically challenging issue of elder self-neglect.

Self-neglect is a critical issue in a rapidly aging society in which people live alone and lack psychosocial support. Elder self-neglect is the impairment of an elder adult's ability to perform essential self-care according to the culturally accepted standard due to a physical or mental impairment or diminished capacity [2]. Self-neglecting behavior can be either intentional or unintentional and poses risks to one's health and well-being [3]. When elderly patients retain medical decision-making capacity in the absence of advanced dementia or psychiatric disease but cannot sufficiently care for themselves, physicians are often faced with ethically challenging decisions. Specifically, physicians are asked to balance the ethical principles of beneficence (acting in the best interest of the patient) and nonmaleficence (avoiding harm) while respecting a patient's right to self-determination or autonomy. Additionally, physicians must remain mindful of their own biases and avoid paternalism—that is, overreliance on their own authority in directing care.

There are no specific guidelines for clinicians about how best to respond to self-neglecting elderly patients who retain medical [decision-making capacity](#) but who are unable to adequately care for themselves. For a severely depressed patient actively intent on suicide who demands to leave the hospital, any reasonable clinician would probably prioritize patient safety and well-being over respect for autonomy. But in cases of elder self-neglect, how should a clinician balance beneficence, respect for autonomy, and nonmaleficence? At which stage should a clinician privilege the principle of nonmaleficence over the principle of respect for autonomy, or when does elder self-neglect become self-abuse? When should a patient's decisions be regarded as expressing a lack of insight or lack of appreciation for his or her current situation and

thus as indicative of a lack of capacity? Allowing self-neglect of elderly patients with multiple risk factors when their behavior and symptoms suggest poor insight and a lack of capacity has been considered elder mistreatment and a form of elder abuse [4], which would be a clear violation of the principle of nonmaleficence, for example. However, it does not have to be the case that one ethical principle is more important than another. Rather, clinicians should use ethical principles, such as those discussed here, to guide clinical decision making.

Additionally, for comprehensive evaluations, a tool that has been shown to be both reliable and valid is the Elder Self-Neglect Assessment (ESNA), which is also available in a shortened version [5]. The ESNA measures both environmental and behavioral aspects of elder self-neglect including ratings of living conditions, physical and mental health, social connectedness, and financial issues [5]. Evidence suggests that elder self-neglect is associated with greater cognitive impairment, executive dysfunction, depressive symptoms, missed medical appointments, medication nonadherence, deteriorating health status, poor personal hygiene, and nutritional deficiencies [2, 6-10]; it is also associated with increased risk of nursing home placement and all-cause mortality [11, 12]. Recognizing these indicators of self-neglect is especially important for primary care physicians, who can often first detect self-neglect.

Smith et al. [13] and Torke and Sachs [14] provide some useful approaches for clinicians of elder patients who express self-neglect. It is important to determine first if the patient has capacity and then what interventions are needed in the patient's best interest [14]. If there is an underlying condition (e.g., depression, delirium) contributing to the patient's impaired capacity, it should be treated [14]. The patient's past decisions and behavior can also be reviewed in order to assess whether the self-neglecting behavior is consistent with his or her prior decision making [14]. In dealing with self-neglect, clinicians can align themselves with their patients and work toward common goals. For example, patients could be encouraged to accept interventions that would allow them to stay in their home; or physicians could go into patients' homes for regular follow-up to help them achieve their goal of aging at home [13]. A shift could also be made from maintaining exceptionally high safety thresholds to focusing specifically on greater harm reduction. For example, physicians could work with the health care team to recommend interventions or modifications at home that might significantly improve patients' health and safety [13]. Furthermore, any potential worst-case scenarios and advanced care plans should be discussed to assist in future decisions regarding home hospice, for example [13]. Of course, if it is determined that a given patient lacks medical decision-making capacity, a surrogate decision maker would be assigned who would be expected to make decisions on behalf of the patient in his or her best interest [4, 13].

With the growth in the aging population, elder self-neglect and [abuse](#) will remain important issues. As physicians continue to be faced with the ethical challenges of elder

self-neglect, validated clinical guidelines and assessment tools are needed to assist clinicians with these difficult cases. Additionally, interventions allowing elders to remain safely in their homes for longer periods might improve patient quality of life throughout the aging process and potentially decrease the overall number of hospital readmissions with a reduction of associated costs.

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## CORRESPONDENCE

### Response to “What Should Physicians Do When They Disagree, Clinically and Ethically, with a Surrogate’s Wishes?”

Petros Ioannou, MD, MSc, PhD

*This correspondence responds to Terri Traudt and Joan Liaschenko’s “[What Should Physicians Do When They Disagree, Clinically and Ethically, with a Surrogate’s Wishes?](#),” which appeared in the June 2017 issue, 19(6), of the AMA Journal of Ethics.*

In their recent article, “What Should Physicians Do When They Disagree, Clinically and Ethically, with a Surrogate’s Wishes?” Terri Traudt and Joan Liaschenko present a didactic case of a patient admitted to the ICU with a worsening medical condition whose surrogate’s wish for continued intensive medical care is in obvious disagreement with the ICU resident’s impulse to stop care based on the patient’s prognosis and the course of his hospitalization [1]. The authors offer detailed commentary on several aspects of the case; this correspondence seeks to augment their analysis.

The first comment has to do with the differences between the reasoning of the ICU resident and the patient’s surrogate (his wife) in terms of faith and religion. It is obvious that the surrogate mostly relies on religious faith that allows space for the impossible to happen, and because of that the patient required aggressive medical interventions. On the other hand, the ICU resident’s reasoning relies on empirically based predictions of an unfavorable outcome concerning the patient’s prognosis, and because of that he felt that further aggressive medical interventions would be more harmful than beneficial. There is literature showing that religious faith can affect the way a patient and his surrogates perceive the end of life and how they make decisions when faced with important questions concerning [resuscitation](#) and use of medical care [2-5]. Although one could argue in this case that the surrogate’s wishes might sound irrational to some and that the results of the surrogate’s wishes, if acted on, might even be harmful for the patient, still, this is not the way the surrogate feels since, according to her beliefs, these choices sound quite reasonable [5]. Thus, understanding the religious background of the patient and his surrogate are of critical importance in order to establish trust and allow for common understanding and the planning of the patient’s medical care. Arguably, medical practitioners, especially young ones, cannot be expected to be competent in [communicating with patients](#) of every religion, but attempts could be made during postgraduate medical training to expose residents to these kinds of discussions, allowing for a deeper understanding of the different religious faiths that patients represent. Indeed, one could also think about the need to better educate health personnel more

generally in understanding surrogates' reasoning according to their religious views. Finally, one could suggest involvement of the clergy in these kinds of discussions, especially if the patients and their surrogates refuse involvement of the palliative care team, as in this case. However, involvement of the clergy can have an ambiguous result, since it could either enhance or decrease conversations about futile medical interventions [6-8].

The second comment has to do with [medical paternalism](#). The ICU resident's impulse to withdraw or withhold medical care from the patient might derive from an inner belief doctors have that they know best. Although this belief derives from years of exhaustive studies and medical training, it could still be a sign of misunderstanding about who should have the last word on how patients should be treated from a medical perspective [9, 10]. An attempt should be made, therefore, to reduce medical paternalism in current medical practice in order to ensure that patients receive the medical care they wish and deserve.

In conclusion, this case highlights several aspects that do not have to do with the actual practice of medicine per se (like examining a patient, making a diagnosis, or prescribing a potentially life-saving medication) that still pose some of the greatest challenges that physicians frequently encounter. In these cases, physicians should control their impulse to be paternalistic and give some space to dialogue. Understanding of religious differences, for example—which must be taught or learned through experience—makes a health practitioner competent to better serve his patients, no matter what their beliefs and faiths are.

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