

TOP BIOETHICS NEWS STORIES: DECEMBER—FEBRUARY, 2019

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“Ebola Detectives Race to Identify Hidden Sources of Infection as Outbreak Spreads” by Amy Maxmen, *Nature*, December 7, 2018

As the epicentre of the Ebola outbreak in the Democratic Republic of the Congo (DRC) shifts into the war-weary city of Butembo, public-health workers are trying to stamp out new infections from an inadvertent source: unregulated health centres. Decades of political instability in the northeastern DRC, the site of the epidemic, have fostered the growth of informal clinics that offer traditional and modern medicine. (<https://tinyurl.com/u9bhebq>)

The Ebola outbreak in the Democratic Republic of Congo continues to make headlines largely because of the many obstacles to getting people the proper care and quarantining those that are infected so the disease does not spread. There are several ethical issues surrounding the use of an experimental vaccine. Additionally, the political unrest and lack of trust of medical personnel has stymied containing the outbreak.

“The CRISPR Shocker: How Genome-Editing Scientist He Jiankui Rose from Obscurity to Stun the World” by Sharon Begley and Andrew Joseph, *STAT News*, December 17, 2018

In the three weeks since the remarkable announcement about Nana and Lulu, *STAT* has pieced together the story of the years leading up to that fateful Monday. With details reported for the first time, it

describes the many times He met with and spoke before some of the world’s leading genome-editing experts, the low opinion they had of his research, and the hints he dropped about his grandiose aspirations. (<https://tinyurl.com/yal5zo7c>)

“China Confirms He Jiankui Gene-Edited Babies, Says Scientists Involved Will Be ‘Dealt with Seriously’” by Hannah Osborne, *Newsweek*, January 21, 2019

An investigation by authorities in China has concluded that a scientist in the country did create the world’s first gene-edited babies. According to a report in China’s Xinhua news agency, He Jiankui performed human embryo gene-editing activities despite them being “officially banned in the country.” (<https://tinyurl.com/yagpnjbp>)

In November 2018, the world learned that a scientist in China, He Jiankui, had used CRISPR to genetically modify several embryos, implanted them, and that these twin girls had already been born. In the months that followed, He was placed under house arrest while Chinese authorities investigated his research. Academic institutions in the United States conducted their own investigations to see if collaborators were aware of the unethical research. *STAT News*’s special report clarified the timeline of events, the global backlash, and He Jiankui’s naive ambitions.

“Surgeon General Warns that Youth Vaping Is Now an ‘Epidemic’” by Rob

Stein, *NPR*, December 18, 2018

Vaping by U.S. teenagers has reached epidemic levels, threatening to hook a new generation of young people on nicotine. That’s according to an unusual advisory issued Tuesday by U.S. Surgeon General Jerome Adams about the the [*sic*] dangers of electronic cigarette use among U.S. teenagers. “I am officially declaring e-cigarette use among youth an epidemic in the United States,” Adams said at a news conference. (<https://tinyurl.com/yaext8t7>)

Statistics from the National Institute on Drug Abuse reported in December 2018 that 37.3% of U.S. high school seniors said they had vaped in the last month, a substantial increase from only a year ago. Vaping involves using an electronic nebulizer, called an e-cigarette, to vaporize liquids containing nicotine and/or THC. Juul, the largest seller of e-cigarettes and vaping liquids, has come under scrutiny for marketing products to teens, particularly their nicotine-containing flavored liquids.

“Study Links Opioid Epidemic to Painkiller Marketing” by Gene Emery, *Reuters*, January 18, 2019

Researchers are reporting a link between doctor-targeted marketing of opioid products and the increase in U.S. deaths from overdoses. In a county-by-county analysis, they found that when drug companies increased their opioid marketing budgets by just \$5.29 per 1,000 population, the

number of opioid prescriptions written by doctors went up by 82 percent and the opioid death rate was 9 percent higher a year later. (<https://tinyurl.com/u6eau3p>)

Every year, U.S. deaths due to overdose from opioids—either prescription painkillers or heroin—has been steadily increasing, and 2018 was no exception. Notably, overdose deaths increased more quickly in women than in men, although men still make up a larger number of overdose deaths.

“A Controversial Fertility Treatment Gets Its First Big Test” by Megan Molteni, *Wired*, January 20, 2019

She is now 28 weeks along with a baby boy, according to a Spanish company called Embryotools, which announced the pregnancy earlier this month. The fertility tech firm is collaborating with the Institute of Life to conduct the first known human trial of the procedure, called mitochondrial replacement therapy (MRT), for treating infertility. Their pilot study in Greece will eventually enroll 25 women under the age of 40 who've failed to conceive using conventional methods of IVF. It's the largest test yet of the controversial new method of procreation. (<https://tinyurl.com/rqznvn2>)

Mitochondrial replacement therapy, also called “mitochondrial donation,” “three-person IVF,” or “three parent embryos” in the media, involves having two different women contributing to the make-up of one egg. This technique is done in a couple of different ways, but it always involves the nuclear DNA of one woman and the mitochondria of another woman. Mitochondria have a small amount of DNA, but mutations in this DNA can cause debilitating diseases. There are several ethical issues with mitochondrial replacement therapy, but

the biggest problem is scientists just do not know the effects of having different nuclear and mitochondrial DNA. Every child born from these experiments is a test subject.

“Japan’s Approval of Stem-Cell Treatment for Spinal-Cord Injury Concerns Scientists” by David Cyranoski, *Nature*, January 24, 2019

Ten specialists in stem-cell science or spinal-cord injuries, who were approached for comment by *Nature* and were not involved in the work or its commercialization, say that evidence that the treatment works is insufficient. Many of them say that the approval for the therapy, which is injected intravenously, was based on a small, poorly designed clinical trial. (<https://tinyurl.com/yahjvk8o>)

“Macular Degeneration Trial Will Be First Human Test of Nobel-Winning Stem Cell Technique” by Sharon Begley, *STAT News*, January 16, 2019

The cause of AMD is well-known, the recipe for turning stem cells into retinal cells works like a charm, and the eye is “immunoprivileged,” meaning immune cells don’t attack foreigners such as, say, lab-made retinal cells. Yet more than a decade after animal studies showed promise, and nearly eight years since retinal cells created from embryonic stem cells were safely transplanted into nine patients in a clinical trial, no one outside of a research setting (or a rogue clinic) is getting stem cell therapy for macular degeneration. (<https://tinyurl.com/y7kvd9hx>)

The beginning of 2019 saw the announcement of several clinical trials involving induced pluripotent stem cells. Two trials, one in the United States and

one in Japan, gained some press. The U.S. trial for macular degeneration has been a long time in the making. Replacement of retinal pigment epithelial with ones created from induced pluripotent stem cells seemed straight-forward, but for technical reasons, the Phase 2 clinical trial was delayed. The Japanese trial is for spinal cord injuries, and several scientists are concerned that the preliminary trials were not sufficient to establish safety and efficacy.

“‘We Don’t Have Any Data:’ Experts Raise Questions about Facebook’s Suicide Prevention Tools” by Megan Thielking, *STAT News*, February 11, 2019

Over the past few years, Facebook (FB) has stepped up its efforts to prevent suicide, but its attempt to help people in need has opened the tech giant to a series of issues concerning medical ethics, informed consent, and privacy. It has also raised a critical question: Is the system working? (<https://tinyurl.com/yyksawm8>)

What is Facebook and what is its responsibility to its users? This is the on-going question for the social media company. In 2015 Facebook launched a feature called Facebook Live allowing a limited number of people to livestream video. It was opened to everyone in 2016, but in 2017, several people livestreamed suicides or violent acts. Facebook then announced that it would monitor people’s posts for potential suicidal behavior and contact authorities. Experts say Facebook is engaging in what amounts to medical research without consent. Additionally, Facebook announced that it would screen content promoting anti-vaccination, again placing the company in an ambiguous role of public health guardian.

TOP BIOETHICS NEWS STORIES: MARCH—MAY 2019

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“China to Tighten Rules on Gene Editing in Humans” by David Cyranoski, *Nature*, March 6, 2019

China’s health ministry has issued draft regulations that will restrict the use of gene editing in humans, just three months after Chinese researcher He Jiankui announced that twin girls had been born with edited genomes. The proposal includes severe penalties for those who break the rules. If approved, scientists say the policy could have gains and drawbacks for research. (<https://tinyurl.com/y56t6zls>)

Chinese scientist He Jiankui violated both international and Chinese regulations by creating genetically-modified embryos that were then implanted in two women and grown to term. One set of twins was born in November 2018. Further investigations showed that he forged ethics documents to conduct the research. While China had rules against this kind of research, the country did not have penalties in place. The proposed regulations, which include fines, blacklisting from grant applications, as well as possible criminal prosecution, demonstrate that China is serious about adhering to international norms for research ethics.

“Uber Not Criminally Liable in Death of Woman Hit by Self-Driving Car, Prosecutors Say” by Laurel Wamsley, *NPR*, March 6, 2019

In the six seconds before impact, the self-driving system classified the pedestrian as an unknown object, then as a vehicle, and then as a bicycle,

a preliminary report from the National Transportation Safety Board explained. While the system identified that an emergency braking maneuver was needed to mitigate a collision, the system was set up to not activate emergency braking when under computer control. (<https://tinyurl.com/y4dulezd>)

“Tesla’s Autopilot Was Engaged When Model 3 Crashed into Truck, Report States” by Andrew J. Hawkins, *The Verge*, May 16, 2019

Tesla’s advanced driver assist system, Autopilot, was active when a Model 3 driven by a 50-year-old Florida man crashed into the side of a tractor-trailer truck on March 1st, the National Transportation Safety Board (NTSB) states in a report released on Thursday [May 16th]. (<https://tinyurl.com/y5u7mxsd>)

In both the case of the Uber self-driving car in Arizona and the Tesla semi-autonomous car in Florida, the distracted driver did not intervene in time to prevent a fatal crash. In the Uber case, the system did not recognize a pedestrian crossing the street because she was walking with a bicycle. The emergency braking system did not engage, and the driver was distracted from watching a video on his phone. In the Tesla case, the driver’s hands were not on the wheel and neither the driver nor the autopilot mechanism attempted to swerve around the trailer in front of the car. This is the fourth fatal crash involving Tesla’s autopilot.

“New York County, Declaring Emer-

gency over Measles, Seeks to Ban Unvaccinated from Public Places” by Helen Branswell, *STAT News*, March 26, 2019

Caught in the grips of a persistent and long-running measles outbreak, a New York county on Tuesday took the extraordinary step of announcing it would ban children who have not been vaccinated against the disease from enclosed public places as part of a 30-day state of emergency. (<https://tinyurl.com/r5s9hbd>)

Measles and vaccine information was consistently in the news. Rockland County, NY declared a 30-day state of emergency due to a measles outbreak and banned children who have not been vaccinated from public places. The measure is largely unenforceable, but authorities hoped it would work as a deterrent. Amazon, meanwhile, removed books that provide misinformation about vaccines and cures for autism (<https://tinyurl.com/woknahg>). Additionally, the media reported on a trial in Denmark that re-affirmed the lack of correlation between autism and the measles, mumps, and rubella vaccine (<https://tinyurl.com/y4ao84t2>).

“Death by a Thousand Clicks: Where Electronic Health Records Went Wrong” by Fred Schulte and Erika Fry, *Fortune* and *Kaiser Health News*, March 18, 2019

The interviews reveal a tragic missed opportunity: Rather than an electronic ecosystem of information, the nation’s thousands of EHRs largely remain a sprawling, disconnected patch-

work. Moreover, the effort has handcuffed health providers to technology they mostly can't stand and has enriched and empowered the \$13-billion-a-year industry that sells it. (<https://tinyurl.com/y4chldt>)

Electronic health records (EHRs) were meant to make the medical world run more smoothly. Instead, EHRs have led to thousands of mistakes due to miscommunication, user error, or malfunctioning software. Kaiser Health and Fortune interviewed over one hundred experts and administrators, patients, health policy experts, attorneys, top government officials, and representatives at more than six EHR vendors. They found mistakes, including fatal mistakes, are often not reported because of lawsuit settlements and confidentiality agreements.

“Chinese Scientists Have Put Human Brain Genes in Monkeys—And Yes, They May Be Smarter” by Antonio Regalado, *MIT Technology Review*, April 10, 2019

According to their findings, the modified monkeys did better on a memory test involving colors and block pictures, and their brains also took longer to develop—as those of human children do. There wasn't a difference in brain size. The experiments, described on March 27 in a Beijing journal, *National Science Review*, and first reported by Chinese media, remain far from pinpointing the secrets of the human mind or leading to an uprising of brainy primates. (<https://tinyurl.com/y57f56ya>)

A Chinese scientist created transgenic monkeys by incorporating a gene found in humans, thought to be associated with intelligence, into a monkey embryo. Of the eleven embryos tested, five survived. While the transgenic monkey's brains were not larger than normal

monkeys, they did perform better on short-term memory tests. Ethicists and scientists raised several concerns with this experiment. Some scientists, including one involved in the study, said the research is sloppy and unhelpful for studying human brain development. Others have said it is unethical to treat animals in this way.

“A Baby Was Born with DNA from 3 People. Here's How That's Possible” by Alice Park, *TIME*, April 11, 2019

Researchers at the Institute of Life in Athens, Greece announced that a healthy baby boy was born on Tuesday morning to a 32-year-old woman who had experienced several failed cycles of IVF. The six-pound boy, who the doctors say in a statement is healthy, was born using a technique called maternal spindle transfer. (<https://tinyurl.com/tocrjj>)

For the first time, a form of mitochondrial donation (also referred to as mitochondrial replacement therapy and referred to as three-parent IVF in the media) was used for a woman who did not have mitochondrial disease. The technique involves using the genetic material of the mother's egg and a donor egg of another woman. The genetic material (i.e., the spindle) is transferred to the donor egg whose nuclear genetic material has been removed. Among the bioethical considerations is the reality that no one knows the long-term effects of a person having two different sources of nuclear and mitochondrial DNA.

“Lost Fertility Clinic Embryos Weren't Living Persons, Ohio Appellate Court Rules” by Jessica Ravitz, *CNN*, May 3, 2019

Frozen embryos are not living persons, an appellate court in Ohio affirmed Thursday. The ruling is the latest development in a case brought by a couple

who lost three embryos in a fertility clinic storage tank malfunction last year. (<https://tinyurl.com/y3n6s9eu>)

“Judge Rules Parents of Deceased West Point Cadet Can Decide What Happens with His Sperm” by Andrew Joseph, *STAT News*, May 20, 2019

The parents of a West Point cadet who died after a skiing accident earlier this year can take control of his sperm and, if they wish, use it to pursue a pregnancy using an egg donor and surrogate, a New York judge has ruled. The judge, state Supreme Court Justice John Colangelo, in March ordered that a hospital retrieve the sperm from 21-year-old Peter Zhu before he was taken off life support, following a request from his parents. (<https://tinyurl.com/y3arj6lj>)

Two court cases highlight the complex problems surrounding the largely unregulated reproductive industry in the United States. Both cases are the result of an accident. In the first, a malfunctioning refrigeration unit resulted in the loss of over 4,000 embryos that were intended for IVF. One couple sued claiming life begins at conception, allowing them to sue for wrongful death rather than loss of property. The court ruled against the couple. In the second case, a West Point cadet died in a skiing accident. The court ruled that the parents could obtain his sperm for future use before his ventilator was shut off.

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