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Not Intelligent: Encoding Gender Bias

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The Ishango Bone, an artifact estimated to be 20,000 years old, is thought to be an ancient form of a 29-day calendar.[1] It may have been used to track the lunar cycle, or a woman's menstrual cycle.[2] Tens of thousands of years later, women still track their menstrual cycles, whether in digital or analog format. In 2014, Apple released HealthKit, a way to display health information for users.[3] The company was widely criticized for not including a period tracker in HealthKit.[4] The next year,

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1. *See* Claudia Zaslavsky, *Women as the First Mathematicians*, ISGEM NEWSLETTER (Int'l Stud. Group Ethnomathematics), Jan. 1992 ("Thus far the oldest such incised bone, discovered in southern Africa and having 29 incisions, goes back about 37,000 years. Now, who but a woman keeping track of her cycles would need a lunar calendar?").

2. *Id.*

3. *See* Chris Welch, *Apple HealthKit Announced: A Hub for All Your iOS Fitness Tracking Needs*, VERGE (June 2, 2014, 2:10 PM), https://www.theverge.com/2014/6/2/5772074/apple-healthkit-ios-8-announcement ("Apple just unveiled HealthKit, a new app bundled with iOS 8 that's designed to help users keep better track of their personal health and fitness data.").

4. *E.g.*, Arielle Duhaime-Ross, *Apple Promised an Expansive Health App, So Why Can't I Track Menstruation*?, VERGE (Sept. 25, 2014, 12:55

Apple added a period tracker.[5] Three years later, in 2018, the FDA granted the first marketing authorization to a software application to help monitor fertility.[6] Women's period tracking, a commonplace part of women's lives for hundreds of thousands of years, was not top-of-mind to a major technology company designing products for everyday use.

BACKGROUND

Although women are fifty-one percent of the United States population, women's health is still largely considered a specialty practice. Studies in health issues as wide-ranging as pain,[7] vulvodynia,[8] and cardiac disease[9] show the same thing—women's health issues are routinely underreported,

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PM),https://www.theverge.com/2014/9/25/6844021/apple-promised-an-expansive-health-app-so-why-cant-i-track (explaining Apple's HealthKit can track blood alcohol content, height, inhaler usage, but not menstruation).

5. Press Release, Apple, Apple Previews iOS 9 (June 8, 2015), https://www.apple.com/newsroom/2015/06/08Apple-Previews-iOS-9/ ("iOS 9 APIs and tools for developers include: . . . new HealthKit data points for reproductive health, UV exposure, water intake and sedentary state.").

6. U.S. FOOD & DRUG ADMIN., Sub. NO. DEN170052, DE NOVO CLASSIFICATION REQUEST FOR NATURAL CYCLES (2018).

7. *See, e.g.*, Laura Kiesel, *Women and Pain: Disparities in Experience and Treatment*, HARVARD HEALTH BLOG (Oct. 9, 2017, 10:30 AM), https://www.health.harvard.edu/blog/women-and-pain-disparities-in-experience-and-treatment-2017100912562 (describing studies that show women may suffer from chronic pain more than men); *see also* Diane Hoffman & Anita Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29 J. L., MED. & ETHICS13, 13–27 (2001) ("Women are more likely to seek treatment for chronic pain, but are also more likely to be inadequately treated by health-care providers, who, at least initially, discount women's verbal pain reports and attribute more import to biological pain contributors than emotional or psychological pain contributors.").

8. *E.g.*, Barbara Reed et al., *Prevalence and Demographic Characteristics of Vulvodynia in a Population-Based Sample*, 206 AM. J. OBSTETRICS GYNECOLOGY 170.e1, 170.e5 (2012) ("Vulvodynia causes substantial pain and suffering for millions of women in the United States, yet the disorder remains underdiagnosed and inadequately treated.").

9. *E.g.*, Laxmi S. Mehta et al., *Acute Myocardial Infarction in Women: A Scientific Statement from the American Heart Association,* 133 J. CIRCULATION 916, 916 (2016) ("Despite stunning improvements in cardiovascular mortality for women in the past 2 decades . . . , CHD [coronary heart disease] remains understudied, underdiagnosed, and undertreated in women.").

underdiagnosed, and undertreated.[10] This Paper highlights a few considerations related to digital health innovation, particularly artificial intelligence and machine learning, and women's health.

Historically women have been "othered"[11] in both medicine and technology.[12] When these two areas intersect, both perils and opportunities are heightened. One potential peril is that the biases inherent in the information used by programmers can be encoded, and magnified, by Artificial Intelligence (AI) systems.[13] Some scholars note that AI cannot easily recognize, mitigate, or

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10. *See*, *e.g.*, Ashley Fetters, *The Doctor Doesn't Listen to Her. But the Media Is Starting To.*, ATLANTIC (Aug. 10, 2018), https://www.theatlantic.com/family/archive/2018/08/womens-health-care-gaslighting/567149/ (providing examples of women's health and pain concerns being dismissed by doctors).

11. Joy L. Johnson et al., *Othering and Being Othered in the Context of Health Care Services*, 16 J. HEALTH COMMUN. 253, 253 (2004) ("Othering is a process that identifies those that are thought to be different from oneself or the mainstream, and it can reinforce and reproduce positions of domination and subordination.").

12. For example, it was reported that Amazon's artificial intelligence tool to help screen resumes for job candidates learned to be biased against women by using 10 years of hiring data — those data points came from mostly men. *See* Jeffrey Dastin, *Amazon Scraps Secret AI Recruiting Tool That Showed Bias Against Women*, REUTERS (2018), https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scraps-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G ("That is because Amazon's computer models were trained to vet applicants by observing patterns in resumes submitted to the company over a 10-year period. Most came from men, a reflection of male dominance across the tech industry. In effect, Amazon's system taught itself that male candidates were preferable. It penalized resumes that included the word 'women's,' as in 'women's chess club captain.' And it downgraded graduates of two all-women's colleges, according to people familiar with the matter. They did not specify the names of the schools. Amazon edited the programs to make them neutral to these particular terms. But that was no guarantee that the machines would not devise other ways of sorting candidates that could prove discriminatory, the people said.").

13. This suggests that women need to be, in the words of Aaron Burr in Lin Manuel-Miranda's *Hamilton: An American Musical*, "in the room where it happens." *The Room Where It Happens,* YOUTUBE (Apr. 20, 2017), *https://www.youtube.com/watch?v=WySzEXKUSZw*.

correct bias in its programming.[14] This could lead to poor health outcomes for women.[15]

Heart disease, which is the number one cause of death for women, can be used to demonstrate the potential problem.[16] Women's heart attack symptoms are different than men's: men tend to have chest pain or pressure, while women more often feel fatigue and indigestion.[17] If, for example, a cardiology diagnostic AI were coded with the "traditional" [read: male] heart attack symptoms, it might diagnose few, if any, women.

In oncology, IBM's Watson has been lauded as a potential breakthrough for cancer care.[18] Watson, a supercomputer, uses

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14. *See generally* Aylin Caliskan et al., *Semantics Derived Automatically from Language Corpora Contain Human-Like Biases*, 356 SCIENCE 183 (2017) (providing a study that demonstrates that "standard machine learning can acquire stereotyped biases from textual data that reflect everyday human culture"). *See also* Ian Johnston, *AI Robots Learning Racism, Sexism and Other Prejudices from Humans, Study Finds*, INDEPENDENT (Apr. 13, 2017, 5:30 PM), https://www.independent.co.uk/life-style/gadgets-and-tech/news/ai-robots-artificial-intelligence-racism-sexism-prejudice-bias-language-learn-from-humans-a7683161.html (summarizing the Caliskan study).

15. *See generally* Erwin Loh, *Medicine and the Rise of the Robots: A Qualitative Review of Recent Advances of Artificial Intelligence in Health*, 2 BRITISH MED. J. LEADER 59, 61 (2018) (discussing the challenges of AI in health such as inherent bias in data and the open question of who is legally liable when a mistake in treatment is made when a physician uses AI-based methods).

16. *See Heart Attack Symptoms in Women*, AM. HEART ASS'N, http://www.heart.org/en/health-topics/heart-attack/warning-signs-of-a-heart-attack/heart-attack-symptoms-in-women (last visited Apr. 3, 2020) (explaining that women can experience a heart attack without any chest pain).

17. *See* Mehta et. al, *supra* note 9 at 922 ("Sex differences in clinical presentation among patients with ACS [acute coronary syndromes] are increasingly evident. Although most patients with AMI [acute myocardial infarction] present with typical chest pain or chest discomfort, women often present with atypical chest pain and angina-equivalent symptoms such as dyspnea, weakness, fatigue, and indigestion, as illustrated in Table 1. Sex differences in clinical presentation have consequences for timely identification of ischemic symptoms, appropriate triage, and judicious diagnostic testing and management. The detrimental consequences for women are misdiagnosis, delayed revascularization, and higher AMI mortality rates."); *see also* Matthaw Liakos & Puja B. Parikh, *Gender Disparities in Presentation, Management, and Outcomes of Acute Myocardial Infarction*, 20 CURRENT CARDIOLOGY REP. 64, 1 (2018) ("Delays in medical care and hence longer ischemic times exist in women, partly due to decreased awareness and lack of symptom recognition.").

18. *See* Casey Ross & Mike Swetlitz, *IBM Pitched Its Watson Supercomputer as a Revolution in Cancer Care. It's Nowhere Close*, STAT NEWS (Sept. 5, 2017), https://www.statnews.com/2017/09/05/watson-ibm-cancer/ ("Breathlessly promoting its signature brand — Watson — IBM sought to capture the world's imagination, and it quickly zeroed in on a high-profile target: cancer.").

machine learning to analyze thousands of data points, faster than any human. These cognitive systems learn from experience.[19] Taking people out of the equation, some would argue, takes out human biases.[20] The program relies on information from Memorial Sloan Kettering, the world-renowned cancer center, to train Watson. But that, in and of itself, can inject "bias into the system, because the treatment recommendations it puts into Watson don't always comport with the practices of doctors elsewhere in the world."[21] Not everyone thinks this is a bad thing. "'We are not at all hesitant about inserting our bias, because I think our bias is based on the next best thing to prospective randomized trials, which is having a vast amount of experience,' said Dr. Andrew Seidman, one of the hospital's lead trainers of Watson."[22] Others, however, disagree. Pilar Ossorio, a professor of law and bioethics at University of Wisconsin Law School put it bluntly, saying "What it's going to be learning is race, gender, and class bias.[23] We're baking those social stratifications in, and we're making the biases even less

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19. *See generally How to Get Started with Cognitive Technology*, IBM, https://www.ibm.com/watson/advantage-reports/getting-started-cognitive-technology.html (last visited Apr. 5, 2020) ("First, some background. The cognitive era is an ongoing movement of sweeping technological transformation. The impetus of this movement is the emerging field of cognitive technology, radically disruptive systems that *understand* unstructured data, *reason* to form hypotheses, *learn* from experience and *interact* with humans naturally. Success in the cognitive era will depend on the ability to derive intelligence from all forms of data with this technology. Cognitive computing is perhaps most unique in that it upends the established IT doctrine that a technology's value diminishes over time; because cognitive systems improve as they learn, they actually become *more* valuable. This quality among others makes cognitive technology highly desirable for business, and many early adopters are leveraging the competitive advantage it affords.").

20. *See*, *e.g.*, Bernard Marr, *The Rise of Thinking Machines: How IBM's Watson Takes on the World*, FORBES (Jan. 26, 2016, 2:28 AM), https://www.forbes.com/sites/bernardmarr/2016/01/06/the-rise-of-thinking-machines-how-ibms-watson-takes-on-the-world/#68d6f2031e43 ("The word 'cognitive' of course implies that the system is thinking – and in a way, scary as that may seem at first, it is! Its processes mirror those of our own brain – accessing relevant data in order to come to a conclusion based on experience of what is likely to work. It will, however, work through this process in a far faster, more accurate and repeatable fashion, unhindered by emotion, fallibility of logic, or ego.").

21. Ross & Swetlitz, *supra* note 18.

22. *Id.*

apparent and even less easy for people to recognize."[24] Watson has been in development since 2010 and has been programmed for diagnosing patients since 2012.[25] In 2019, IBM announced bias monitors in OpenScale—a system for developers to monitor their AI products—as a way to help "detect and mitigate bias against protected attributes like sex and ethnicity . . . ."[26]

Existing and developing AI systems seek to pull data from numerous sources, analyze it, and help provide medical information or recommendations.[27] These require large computing resources, interoperable systems, and smart regulation. Social media is just one medium from which large data sets can be pulled; it already provides access to adverse

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24. *Id.*

25. *See The History and Future of IBM Innovation,* IBM BUS. PARTNER NETWORK, https://www.ibmbpnetwork.com/ibm-innovation-timeline (last visited Apr. 5, 2020) (depicting an interactive timeline of IBM innovation over time starting in 1891).

26. Susannah Shattuck, *Making Monitoring AI Bias a Little Easier*, IBM THINK BLOG (June 17, 2019), https://www.ibm.com/blogs/think/2019/06/making-monitoring-ai-bias-a-little-easier/.

27. The FDA has granted marketing authorization to two AI-based devices for detection of medical conditions. One to detect greater than mild level of diabetic retinopathy (2018) and one to detect wrist fractures in adult patients (2018). Additionally, the FDA granted marketing authorization to an AI-based clinical decision support software to analyze CT results to notify providers of a potential stroke in their patients (2018). *See FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems*, U.S. FOOD & DRUG ADMIN (Apr. 11, 2018), https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye ("The U.S. Food and Drug Administration today permitted marketing of the first medical device to use artificial intelligence to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes."); s*ee also* Jennifer Bresnick, *FDA Clears Marketing for AI Algorithm to Detect Wrist Fractures*, HEALTH IT ANALYTICS (May 25, 2018), https://healthitanalytics.com/news/fda-clears-marketing-for-ai-algorithm-to-detect-wrist-fractures ("The FDA will allow marketing of an artificial intelligence algorithm that can help to detect wrist fractures in x-ray images."); *FDA Permits Marketing of Clinical Decision Support Software for Alerting Providers of a Potential Stroke in Patients*, U.S. FOOD & DRUG ADMIN (Feb. 13, 2018), https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-clinical-decision-support-software-alerting-providers-potential-stroke ("Today, the U.S. Food and Drug Administration permitted marketing of the Viz.AI Contact application, a type of clinical decision support software designed to analyze computed tomography (CT) results that may notify providers of a potential stroke in their patients.").

event information,[28] epidemiological trends,[29] and direct access to subsets of patients.[30] Many consumers and patients are voluntarily publishing their data by tweeting it, posting it, and joining research networks.[31] Other potential data sets include coordinated registry networks and insurance claims data.

At the same time, the average person has direct access to more health-related data than ever before: published articles, peer-reviewed scientific papers, and personalized direct-to-consumer advertising.[32] Conversely, false, misleading, and incomplete information abounds, and can be easily spread through social media.[33] This direct access to health information,

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28. *See* Abeed Sarker et al., *Utilizing Social Media Data for Pharmacovigilance: A Review*, 54 J. BIOMEDICAL INFORMATICS 202, 203 (2015) (discussing the FDA's Adverse Event Reporting System).

29. *See* Lauren E. Charles-Smith et al., *Using Social Media for Actionable Disease Surveillance and Outbreak Management: A Systematic Literature Review*, 10 J. PLOS ONE 1, 1 (2015) ("Research studies show that social media may be valuable tools in the disease surveillance toolkit used for improving public health professionals' ability to detect disease outbreaks faster than traditional methods and to enhance outbreak response.").

30. *E.g.*, Allison M. Burton-Chase et al., *The Use of Social Media to Recruit Participants with Rare Conditions: Lynch Syndrome as an Example*, 6 J. MED. INTERNET RES. RES. PROTOCOLS (2017) (providing an example of a study that uses social media to recruit patients with Lynch Syndrome); Christopher-Paul Milne & Wendi Ni, *The Use of Social Media in Orphan Drug Development*, 39 J. CLINICAL THERAPEUTICS 2173, 2177 (2017) ("Besides site selection, companies can utilize social media to efficiently reach potential patients to accelerate patient recruitment.").

31. PatientsLikeMe, a for-profit research network, has more than 600,000 patients, with more than 2,800 conditions, has amassed more than 43 million data points and published more than 100 studies. *See PatientsLikeMe Homepage*, PATIENTSLIKEME https://www.patientslikeme.com/_(last visited Apr. 5, 2020).

32. Caitlin Dewey, *98 Personal Data Points that Facebook Uses to Target Ads to You*, WASHINGTON POST (Aug. 19, 2016, 10:13 AM), https://www.washingtonpost.com/news/the-intersect/wp/2016/08/19/98-personal-data-points-that-facebook-uses-to-target-ads-to-you/?utm_term=.f410525d5f65 (explaining that Facebook advertisers target consumers based on location, age, gender, education level, and many other indicators).

33. *See generally* Luigi Lavorgna et al., *Fake News, Influencers and Health-Related Professional Participation on the Web: A Pilot Study on a Social-Network of People with Multiple Sclerosis*, 25 J. MULTIPLE SCLEROSIS & RELATED DISORDERS 175, 175–178 (2018) (speculating that the presence of "neurologists and psychologists supervising the information flow might have contributed to reduce the risk of fake news spreading"); Questioning Reliability Assessments of Health Information on Social Media, 105 J. MED. LIBR. ASS'N 61, 61 (2017) (examining "assessments of the reliability of online health information retrieved through social media to ascertain whether health information accessed

called disintermediation, arguably takes the healthcare provider out of the role of learned intermediary to help guide a patient. However, disintermediation can work the other way, where patients can directly report adverse events, symptoms, diagnoses, or other relevant health care information.[34] Disintermediation may reduce some types of bias by allowing the data systems to directly collect information from patients; however, satisfied patients often have little reason to provide feedback, leading reporting to be overwhelmingly negative.[35] This patient-generated health data, or patient-reported outcomes, might help lead to a healthcare system that better listens to women. Women who are told, for example, they have not had a heart attack, may be able to advocate for themselves with data gathered from a wearable device. However, if this disintermediation does not overcome bias, but rather reaffirms it, it will continue on to *other* women, leaving them under-diagnosed and under-treated.

REGULATION

The federal government's role in regulating medical products has a long history, focused on consumer protection. The FDA seeks to ensure not only that medical products are likely to be safe and effective, but that new products have a predictable

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or disseminated through social media should be evaluated differently than other online health information"); Przemyslaw M. Waszak et al., *The Spread of Medical Fake News in Social Media— The Pilot Quantitative Study*, 7 J. HEALTH POL'Y & TECH. 115, 117 (2018) ("40% of the most frequently shared links contained text we classified as fake news.").

34. *See* Marlene Beggelman, *Why Do We Doctors So Often Fail to See Symptoms are Drug Side Effects?*, *WBUR* (Dec. 30, 2016), http://www.wbur.org/commonhealth/2016/12/30/doctors-side-effects-medication (recognizing physicians are unable to attribute symptoms to medication side effects and, therefore, suggesting that patient stories about reported side effects deserve consideration); *see also* Northwestern University, *Why Women Quit Breast Cancer Drugs Early: Side Effects are So Bad Women End Treatment and Risk Return of Cancer, Study Finds*, SCIENCEDAILY (Dec. 12, 2011), https://www.sciencedaily.com/releases/2011/12/111209171936.htm (describing a study that shows that doctors underestimated the side-effects of a breast cancer therapy at least in part because women often did not want to share their side effects with their doctors).

35. *See, e.g.*, Giuseppe Verlento et al., Asthmatics and Ex-Smokers Respond Early, Heavy Smokers Respond Late to Mailed Surveys in Italy, 104 Respiratory Medicine 172 (2010) (detailing a study in which self-reporting lead to a statistical biasing effect because the response rate was significantly higher for respondents with certain chronic respiratory diseases).

pathway to market.[36] This, in fact, encourages innovation, which furthers patient health.[37] Federal and state regulations exist to protect patient health as well as privacy. Additionally, regulation that addresses the need for data system interoperability and correction for bias in clinical studies have been enforced for years. Regulation can help, in part, to control or mitigate some biases—like gender—in the development of medical evidence.

Legislative mandates and regulatory requirements have increased the representation of women in clinical trials. After a 1992 GAO report on women and prescription drugs,[38] the FDA published a guidance titled "Guideline for Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs", which included the "FDA's expectations on inclusion of women in drug development."[39] Congress passed a law that required NIH to ensure that women and minorities were appropriately included in NIH-funded trials.[40] In 2014, the FDA issued a final guidance on the Evaluation of Sex Specific Data in Medical Device Clinical Studies, the purpose of which was to encourage "appropriate enrollment by sex in clinical studies of devices, and

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36. *See* A HISTORY OF MEDICAL DEVICE REGULATION & OVERSIGHT IN THE UNITED STATES, U. S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states

37. *See* Scott Gottlieb, COMM'R OF FOOD AND DRUGS, U.S. FOOD AND DRUG ADMIN., MEDICAL DEVICE INNOVATION CONSORTIUM 2018 ANNUAL PUBLIC FORUM: ADVANCING OUR PARTNERSHIP FOR PATIENT SAFETY AND MED TECH INNOVATION (Sept. 5, 2018) ("We're focused on ensuring efficient, timely access to new technologies; but also to making sure that the same policies that promote these goals also make our regulatory programs more rigorous, more science based, and more effective. Promoting product safety is a touchstone for all of our new policy efforts.").

38. *See generally* U.S. GEN. ACCOUNTING OFFICE, FDA NEEDS TO ENSURE MORE STUDY OF GENDER DIFFERENCES IN PRESCRIPTION DRUGS TESTING (Oct. 1992) (emphasizing the need to study how women respond differently than men when approving prescription drugs).

39. Guideline for the Study and Evaluation of Gender Differences in Clinical Evaluation of Drugs, 58 Fed. Reg. 39,406 (July 22, 1993).

40. *See* National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 492B, 107 Stat. 122 (1993) ("SEC. 492B. (a) REQUIREMENT OF INCLUSION. -(1) IN GENERAL.- In conducting or supporting clinical research for purposes of this title, the Director of NIH shall, subject to subsection (b), ensure that- (A) women are included as subjects in each project of such research; and (B) members of minority groups are included as subjects in such research.").

that data from such studies is appropriately analyzed by sex."[41] In 2012, Congress required that the FDA address the inclusion of demographic subgroups in clinical trials.[42] The law required the FDA to publish a report and action plan regarding the availability of data on demographic subgroup analysis.[43] These legislative and regulatory requirements started to address potential bias in the health research. These requirements could similarly apply, as appropriate, to digital health and AI health systems to mitigate the coding of bias.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[44] is a key medical privacy law. HIPAA security and privacy protections apply only to covered entities—health plans, health care providers, health care clearinghouses—and business associates of covered entities.[45] However, health data not subject to HIPPA may not be held to federal legal protections of privacy,[46] laws can also differ by state.[47] When apps interface

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41. U.S. FOOD AND DRUG ADMIN., EVALUATION OF SEX-SPECIFIC DATA IN MEDICAL DEVICE CLINICAL STUDIES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, 1 (Aug. 2014).

42. *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No 112-144, § 907, 126 Stat. 993, 1092 (July 9, 2012) (" . . . the Secretary shall . . . shall publish . . . a report . . . addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups . . . is included in applications submitted to the Food and Drug Administration.").

43. *See Id.* at § 907(b) (explaining that the FDA must put together an action plan "to improve the completeness and quality analyses on demographic subgroups in summaries of product safety").

44. Health Insurance Portability and Accountability Act, Pub. L. 104–191, 110 Stat. 1936 (Aug. 21, 1996).

45. *See Are You a Covered Entity?*, CTRS FOR MEDICARE AND MEDICAID SERV., https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AreYouaCoveredEntity.html.

46. *See The Disruptor Series: Health Care Apps: Hearing Before the Subcomm. On Commerce, Manufacturing, and Trade of the H. Comm. on Energy and Commerce*, 114th Cong. (2016) (opening remarks for H. Energy and Commerce Subcomm. Hearing on Health Care Apps) ("However, the most disruptive health apps are those that are patient-facing. These create a direct app-patient "relationship" that lacks professional intermediation and, as a result, traditional regulation of safety, quality, and confidentiality . . . . Most mobile health apps (particularly the more disruptive patient-facing examples) are not subject to HIPAA privacy and security rules leaving patient wellness and health data woefully unprotected.").

47. *See* DEP'T OF HEALTH AND HUMAN SERV., NAT'L COMM. ON VITAL HEALTH AND STATISTICS: MEETING OF PRIVACY, CONFIDENTIALITY AND SECURITY SUBCOMM. (Nov. 28, 2017) ("So, here are some of the primary entities of concern that I think you ought to be looking at. There are still a few providers

directly with health data rather than an electronic health record or doctor, the app developer may offer no privacy protections at all.[48]

The data gathered through electronic records, registries, and other media could have more value if they are in a format that allows them to be aggregated and analyzed.[49] This standardization and ensuing interoperability might be mandated by law,[50] agreed upon by participating bodies, or incentivized in other ways. For example, the FDA published a rule in 2013 requiring the use of the Unique Device Identifier (UDI) on medical devices.[51] The use of UDI can help track

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who aren't HIPAA covered. There is all of the social media, as Frank described. There is web search history, such as somebody visiting websites like WebMD. There are wearables. There are the remnants of the personal health record industry outside of the tethered ones. There is a whole range of ones of storage that either may or may not be social media that people can import their data into, like all of those calorie counters and MapMyRun app available online. There is all of the recreational genetics. Some of the data from some of these goes into registries and then there are registries all over the place. So, why are non-HIPAA covered entities a problem? Well, they might have, in fact, health information that is as detailed and as sensitive as what HIPAA-covered entities have. They may be getting their PHI actually from HIPAA-covered entities, when patients don't realize that their PHI has been transferred and is no longer HIPAA-protected. The protections that do exist, as Frank outlined, primarily the FTC, there also are some state laws relevant here, are uneven. The privacy policies and the terms of conditions that these entities have are all over the map. They are very hard to find. Critical pieces of information may be buried in the terms and conditions. The downstream uses of these data, once they get into some of these entities, particularly if they are deidentified, but even in some cases when they are identified, may be very difficult to trace.").

48. *See generally* Sarah. R. Blenner et al., *Privacy Policies of Android Diabetes Apps and Sharing of Health Information,* 351 J. AM. MED. ASS'N 1051 (2016).

49. For example, ACOG embarked on a multi-year, multi-stakeholder effort to standardize obstetric definitions for the purposes of its registries. See current definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions.

50. *See* 21st Century Cures Act, Pub. L. 114-255, § 4003, 130 Stat. 1033 (Dec. 13, 2016) ("The term 'interoperability', with respect to health information technology, means such health information technology that— (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law . . . ").

51. *See* Unique Device Identification System, 78 Fed. Reg. 58,786 (Sept. 24, 2013) (to be codified at 21 C.F.R. pt. 16).

products and allow a more reliable adverse event report.[52] In this way, large data sets can report the same information—via the UDI—allowing researchers and regulatory bodies to track emerging health events.

Registries, mentioned above, can be a wonderful way to gather data. However, they are expensive and can take time and effort to gather longitudinal data.[53] Additionally, many registries are established by disease state or device-type, meaning that a large amount of data are not captured. And there may not be any standard way to capture gender/sex data.[54]

In late 2019, the FDA announced it would launch a program to study the sex and gender differences in reactions to medical devices—both for safety and effectiveness.[55] The first step of the plan as released in 2019 was to review and standardize sex and gender specific data collection for medical devices.[56] While this is a reasonable first step, it is long overdue. As far back as 2014, the FDA announced that it would enhance its systems for collecting and analyzing "diverse clinical information."[57] This is not to lay blame at the feet of the FDA—the industry and

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52. *See Are You Ready for UDI?: Unique Device Identification for Medical Devices,* GS1 (2015) https://www.gs1.org/sites/default/files/docs/healthcare/a3-ready_for_udi-bd.pdf ("The implementation of UDI can enhance patient safety and improve efficiency in the healthcare supply chain. The system is expected to unambiguously identify medical devices throughout the global supply chain by providing precise information for healthcare professionals, thereby providing a secure global supply chain allowing for more accurate reports of adverse events, more effective management of medical device recalls and reduction of medical errors.").

53. *See, e.g.*, REGISTRIES FOR EVALUATING PATIENT OUTCOMES: A USER'S GUIDE (Richard E. Gliklich & Nancy A. Dreyer eds., 3rd ed. 2014) https://www.ncbi.nlm.nih.gov/books/NBK208643/.

54. *See, e.g.,* Madeline B. Deutsch & David Buchholz, *Electronic Health Records and Transgender Patients—Practical Recommendations for the Collection of Gender Identity Data*, 30 J. GEN. INTERN. MED. 843 (2015) ("Barriers to standardization may include lack of specific functionality in a given product, limited understanding of gender identity. . . issues among EHR implementation teams, competing institutional priorities, or a lack of institutional will to address a new and confusing issue.").

55. *See* U.S. FOOD AND DRUG ADMIN. FDA-2019-N-3804, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH: HEALTH OF WOMEN PROGRAM STRATEGIC PLAN (Sept. 2019).

56. *See Id.* at 13.

57. U.S. FOOD AND DRUG ADMIN., FDA ACTION PLAN TO ENHANCE THE COLLECTION AND AVAILABILITY OF DEMOGRAPHIC SUBGROUP DATA (Aug. 2014).

researchers doing these studies do not consistently gather and report sex and gender differences.

CONCLUSION

Much progress has been made in the past twenty years when it comes to women's health, but issues of inclusion have not disappeared. Numerous government agencies continue to work on issues of gender bias and subsequent biased reporting. Relevant regulatory requirements may apply to some digital health tools, including AI, to help protect patients. Disclosure of information that can help screen for or provide transparency about potential issues of bias, as well as other patient protections, may also help patients and providers choose the appropriate tools.

Patients, regulators, providers, and industry must all play a role in ensuring that bias is not incorporated, and reinforced, in the burgeoning field of digital health and artificial intelligence. Legislation and regulations are necessary, but not sufficient, to overcome biases. There are growing technological solutions that provide an outside check on AI, to ensure that it is not biased. A growing reliance on AI is in the cards for healthcare—it is imperative that the technology take us beyond the Bronze Age.

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