[START 00:00]

(Music)

Mark Masselli: This is Conversations on Healthcare, I am Mark Masselli.

Margaret Flinter: And I am Margaret Flinter.

Mark Masselli: Well Margaret, I see the Department of Health and Human Services is taking an active interest in the world of medical research to create a clear path forward on ways to keep human subjects safe in the world of biomedical research.

Margaret Flinter: Well, this is rapidly expanding world mark in this era of big data computing and large scale participation through platforms like Apple Research Kit and patients like me and more motivated patients are becoming linked with researchers through these online portals.

Mark Masselli: Researchers are now able to tap into a much larger group of randomized trials, but there are ethical considerations that need to be reevaluated and redefined. HHS wants to ensure that those participants who are selected for clinical trials are given access to their data.

Margaret Flinter: And this is something that our guest today is very passionate about.

Mark Masselli: John Wilbanks has been an ardent advocate for opening up scientific research.

Margaret Flinter: I think this is a very important topic, Mark.

Mark Masselli: Really is and Lori Robertson, Managing Editor of FactCheck.org looks at misstatements spoken about health policy in the public domain, but no matter what the topic, you can hear all of our shows by going to chcradio.com.

Margaret Flinter: And as always if you have comments, please email us at chcradio@chc1.com or find us on Facebook or Twitter; because we'd love hearing from you. Now, we will get to our interview with John Wilbanks in just a moment.

Mark Masselli: But first, here is our producer Marianne O'Hare with this week's headline news.

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Marianne O'Hare: I am Marianne O'Hare with these healthcare headlines. The Commonwealth Fund has released a comprehensive report on the costs of employer

health coverage, which not surprisingly varies widely across the country. The report ranked States based on the average amount of the employee premium, the amount defrayed by the employer. Employees' contributions to their health insurance premiums rose more slowly between 2010 and 2015 in 30 States in Washington D.C. Still many families are spending on an average a bigger share of their income on healthcare than they were prior to 2010, that's because of median incomes despite their recent surge have not kept pace with healthcare costs. Southern areas are more likely to die from smoking related illness than in any other geographic region in the U.S. A report issued by the American Cancer Society revealed about 40% of cancer deaths in the South were smoking related compared to about 8% in other parts of the country, where smoking prevalence has declined in recent years. Smoking rates are noticeably higher in States that don't enact basic public policy interventions like higher excise tax on cigarette purchases, banning smoking in public places, and reducing nicotine cigarettes to non-addictive levels. The study estimates at least 28.6% of U.S. cancer deaths in 2014 were linked to smoking that translates to 167 thousand lives that could have been saved. The Veteran's administration may have stumbled on a scalable solution in their quest to reduce long wait times for patients. Vets regularly get next day and even same day appointments for primary care now. No longer waiting a month or more to see a doctor as many once did. Clinical pharmacists have special training that permits them to prescribe drugs, other lab tests, make referrals to specialists and are handling the chronic care needs of more and more patients. This frees physicians to concentrate on new patients and others with more complex needs. The VA underwent a major overhaul after a whistleblower revealed a couple of years ago, a culture of extremely long wait times that led to untimely deaths and many poor outcomes. The VA has made a pledge to Veterans seeking care. They shouldn't have to wait longer than 30 days for an appointment. I am Marianne O'Hare with these healthcare headlines.

(Music)

Mark Masselli: We are speaking today with John Wilbanks, Chief Commons Officer at Sage Bionetworks, dedicated to redefining how openly shared data will transform biomedical research. Mr. Wilbanks launched Consent to Research in 2011, a platform for people to donate their health data for scientific and medical research. He served at the Science Commons and created Commons, an open science effort aimed at freely shared scientific and medical data. He won numerous distinctions and was named a global game changer by the Utne Reader. He earned his undergraduate degree in philosophy at Tulane. Mr. Wilbanks, welcome to Conversations on Healthcare.

John Wilbanks: Thanks for having me.

Mark Masselli: You have been a strong advocate for the past two decades for people interested in accessing and sharing their medical data and we've had a sort of a number of European friends and colleagues on, all advocating for similar version of open access to patient data and there is this growing course, people demanding that scientific studies, especially those supported by the Government should be made readily available for people to access.

John Wilbanks: Science has been for a very long time, at least since the 1940s in the United States, the way that we do biomedical research and biomedical science has been one in which the Government gives money to academic institutions, studies that take long times, those papers get published, and the expectation is that the market will find ways to translate the things that are published in the journals and get those back out to the citizens. What it's created is a system that is quite glacially slow to change and there is bureaucratic inertia that runs through the system in the way that we review grants and give money away. You see it when you look at the ethical review processes that happen before clinical studies, where the often the forms that are being used are forms that develop 10 to 15 to20 years ago and then we haven't had a lot of systems designed thinking about, well how would we redo this. In many cases, we tinker around the edges, we try to change the way that we access the articles. We try to use mobile phones to do mobile clinical studies. We have to start designing systems that are as self reinforcing and in many ways intersectional with themselves as the current system or we won't be able to replace with one that's sort of more modern.

Margaret Flinter: Well, John, you have been tackling this problem from a number of angles and your works at the Scientific Commons and Creative Commons and these entities have been advocating for open sharing of data for a couple of decades now and how would you characterize the progress that you have made so far, what do we say?

John Wilbanks: I was very fortunate to be around some of the ideas of that Larry Lessig had and so I got exposed to a lot of the ideas of the Commons and while I was there, I sort of became fascinated with how these things attach to science. A lot of these concepts of the way that we build knowledge products like software or encyclopedias could be applied to the way that we build knowledge products in science, because that's really what science is about, because when you get down onto the weeds, you run into a very messy reality that science is not nearly as methodologically clean as it thinks it is, working at Creative Commons, we are exploring how would you share data, given that copyright doesn't attach today, you can't use the same licensing methods that you use in software or for Wikipedia, how do you share things like biological materials. About six or seven years ago, I started to get obsessed with informed consent, because it looked increasingly like one of those leverage points, where individual citizens actually had

some leverage that could un-stick some pieces of the system and if we could put that into context, with people doing data collection, with people doing data analysis, we might have a chance to start building a system that works a little better than the existing.

Mark Masselli: Well, let me pick up a concept of informed consent. Walk our listeners through sort of the historical context of informed consent and how it's evolved?

John Wilbanks: Historically speaking, informed consent has been around for a while or you can trace it back, you know, at least to the early 1900s to some of the Yellow fever work done in Caribbean, but what we found and we did some of our research at Sage, everyone we talked to, loved informed consent. They loved the idea, the loved the ethics behind it, but a lot of people despaired for the way that it actually happened in reality. No one had time to explain the documents to the people that were signing them. The documents were written in a format that made them very hard to understand. They were often written by attorneys. You know, they don't write the cleanest English necessarily for people who are in a stressful situation and they seemed like an opportunity that if you took some of the concepts that were sort of initiated back at Berkman and Creative Commons about human readable contract, there was an opportunity to start creating lay person readable summaries of these very complex documents and that gave us an opportunity to translate some of those to the screen. Unfortunately, when you do that, you also run into two extra issues, one is that we are sort to used to clicking okay to get to things that we want and the other is even if we do read it, the evidences available indicates that physiologically we don't read the same way on screens that we do on paper and so we built a series of essentially interface tools that allow us to create visual summaries of consent documents and we put all that in front of the signing of a document, because we don't expect people to actually read the long form, because the evidence just shows that they won't and even if they do, they probably won't process it.

Margaret Flinter: Well, you've said that creating a massive open database of health and genomic information doesn't have to be particularly complex and in your TED talk, you note that such open platforms require four simple elements, so I am going to ask you to tell us what they are, tell us how does the explosion of personal health data mining devices fit into your thoughts about how these open platforms for health information sharing can function?

John Wilbanks: What I tend to be biased towards the system is that are, what I say are simple, weak, open, and together and so weak doesn't mean weakness, simple doesn't mean simplistic, and open doesn't mean, you know, unpaid necessarily. A weak system for example would like HTML, as a language for formatting and displaying content, HTML is a relatively weak one and that means that you don't break future

things that might add power to it, so because it was weak, it was extensible and so the idea is that if you are going to build, you know, a system like this, we should build it in a way that it can be extended by other people. One of the rules inside the web consortium is what's called the Rule of Least Power, which is when in doubt, use the least powerful tool that solves the job and I think that that's a concept that we can really bring forward from the web design world into the legal design world and then the idea that things need to be open, you know, it doesn't mean that they are free or unpaid, it means that they are nondiscriminatory. The rules are clear and can be taken forward. Open might be something like open source software, but in many ways something like water or like electricity are things that are utility functions. Those things that were available to anyone that was a participant in the system and then the together part is more to indicate that if we are going to do this without consuming a massive amount of resources and then charging a lot of rent, we have to build it ourselves. If we wait for the Encyclopedia Britannica, it's going to be quite expensive and they are going to sell it back to us, whereas if we build it together, it will be more like Wikipedia, it will be something that we own together, something that we can change together, something that we can use together.

Mark Masselli: We are speaking today with John Wilbanks, Chief Commons Officer at Sage Bionetworks, a collaborative of network partners dedicated to redefining how openly shared data will transform biomedical research. John, you know, we've got stage 2 of meaningful use that allows an individual to get access to their data, to download it, to transmit data, you've got Sync for Science working hard. You all, at your company are also working on the same, walk the consumer through all of these changes that are coming on, grab my information, and do everything I want to do with it.

John Wilbanks: You know, in many ways, all of these things that you've mentioned come together to the context of empowering the individual to get a copy of what's known about them, whether it's our medical records, whether it's our ability to order our genomes, it's the capacity to profile in ways that haven't been possible and then the right to get a copy of it and no one really knows what it's going to be like when all of these things really gel. They are, I don't think, they have quite gelled yet, you know, I can't sort of just log on, put in my provider ID and get my EHR yet. I have to send an email to my provider. They send it back as a PDF, right, and you what it means is that, you know, first of all we are going to have more power that's the point of empowerment, but we are also going to have a lot more obligations and a lot more opportunities to make mistakes. You know, I am more savvy than most folks in this area and I don't know what do with my genome, you know. I wouldn't know what to do with my EHR and so as the system gels and lets us get access to this and send this data around, we are going to need to have a marketplace, an ecosystem that merge of interpretation tools that help us understand what these things mean for our daily life, what choice should I make while I get insurance next time, but also, you know, who is the trustable recipient. Who should I actually send my EHR to through Sync for Science and you know, what I would like to see is, is some kind of member owned collective or coop or credit union style organizational structure emerge or even something like alliance trust,

where you know, if you and I share common goals, may be we both have the same disease, we can pool our data with a bunch of like minded people and manage it together, because in the end I do not keep my money in my mattress. I keep it in a bank and my expectation is that that's where we are going to wind up as consumers and so I just, I tend to think that there's going to be an ecosystem that springs up to meet the function, when the function is there and my hope is that we can shape that ecosystem in a way that it's not venture back companies who want to make ten X returns or hundred X returns that some of this is about member ownership and governance mechanisms that are appropriate to you and me because we share the same goals.

Margaret Flinter: So, John, I would like to ask you about a project that we are all hearing a lot about and engaged within that is the National Institute of Health Precision Medicine Initiative spearheaded by Dr. Francis Collins, the man who oversaw the Human Genome Project. Dr. Collins has called for a million citizen scientists to participate in this very bold venture to accelerate the pace of research and to make sure that it is inclusive of everybody, we'd love to hear your comments on the kind of infrastructure that's going to be required to pull this off. How can efforts like Blue Button help us move towards the goals of precision medicine and what do you think is going to be done to build a more robust infrastructure that allows for this kind of data sharing?

John Wilbanks: Yeah, we at Sage were very fortunate, we are a subawardee in the Precision Medicine Initiative, PMI, and so I have been fortunate to be participant in a lot of the last several month's worth of work on it and it's both the recruitment cohort of a million or more residents of the United States of America, but it is also the technology infrastructure to do the measuring and the dissemination of that data back off to science, so it is really interesting to watch how these pieces are coming together and things like Blue Button and Sync for Science really piece into this, because the concept of this study is kind of unique, it's not simply that we are going to measure people through their phones, which is great and I've done a bunch of those through Sage. It's not simply that we are going to do a physical exam and get a sample, which is you know what the UK Biobank has done and we are not simply going to call through EHRs like many studies have done. The idea is we are going to bring all those things together, so that we have the ability to track the interactions of the medical system through health record synchronization and we have the ability to do some longitudinal monitoring out in the environment with people's phones or variables; the real promise is that the tech platform that supports all of this will be re-purposable in many ways to use for lots of follow on and knock on studies. It will have a large enough cohort that's diverse and inclusive enough to actually let us look at rare disease under study populations and then we will be able to run these sub-studies, you know, relatively cheaply and relatively profusely because the technical infrastructure is there and I don't really know what's going to come out of it, that's probably the most exciting thing. You know, what bores me about traditional clinical studies a lot of time is that we know what's going to happen and what I find fascinating about the Internet, the Web, mobile devices as platforms is that the vast majority of the really valuable things that happen on them are things that nobody predicted and so by building this sort of generic massive detailed resource and

not predicting exactly what's going to come out of it, we have a chance to bring some of that same, you know, Jonathan Zittrain calls it generativity, we can finally start having that in clinical studying.

Mark Masselli: You know, Margaret did mention that we were fortunate to be selected as one of the 10 health organizations that is part of that NIH initiative and I want to really give a shout out to Dr. Collins, who really thinking about it from our vantage point for people who live in poverty, who is the sort of main cohort of the folks that we care for and obviously racial and ethnic diversity amongst the population and I was fascinated when you started talking about interpreting tools, because I think that's really going to be something that's going to be important for all the different groups, who are going to receive information back, because you also, at Sage, are out on a million lives' quest. Talk to us a little bit about the work that Sage is doing.

John Wilbanks: Sure, so it's a nice clean round number that I would get to help rally support, but it's also probably close enough to start doing some really interesting work. You know, I discovered pretty quickly that it was very hard to make informed consent portable so that you just carry it around with you and so that the PMI is a good example of study that's going to go right at that million number frontally. What we've been doing at Sage is a little bit different, which is, you know, we've over the last couple of years started running our own clinical studies. We started hosting clinical studies for others and use Apple's Research Kit Framework 10 roll through iPhones. We've just gotten into Android in the past month or two with research stack as our first foray there and will be adding more there as well and we are in all phases of clinical study; at this point, we are working with academics and disease foundations and we are also working with the pharmaceutical industry and the biotech industry and what we do is we say within any given study, we want to make sure that individuals have the right to donate a copy of their data to science and so it's more that we want to offer people the choice to do a donation inside a study that they are motivated by, so something like our Parkinson's mPower Study. We've even rolled more than 20 thousand people in 18 months. We ask them, would you like to have the data stay with us at Sage or would you like to force us to share it with qualified researchers world wide and what we are seeing is, you know, generally somewhere between 70% and 75% of participants across all of the studies that we are involved in, so I think that for us, that's where that million person number is going to come from, is from that percentage of people, who decide to prevent whoever is running a study from siloing it off and keeping it as a trade secret. We are a 42% nonprofit and that's only four more employees than total awardees in the PMI, so that's why it is so much fun to be a part of it is that we can take what we learn at Sage and feed it over to PMI and we can take the learning from PMI and feed it over to Sage, that's a pretty nice way to work.

Margaret Flinter: We've been speaking today with John Wilbanks, Chief Commons Officer at Sage Bionetworks. You can learn more about their work by going to Sage.base.org or follow him on Twitter@wilbanks or sagebio. John, thank you so much for joining us on Conversations on Healthcare today and for the fascinating contributions you are making to knowledge.

John Wilbanks: My pleasure.

(Music)

Mark Masselli: At Conversations on Healthcare, we want our audience to be truly in the know when it comes to the facts about healthcare reform and policy. Lori Robertson is an award-winning journalist and managing editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in US politics. Lori what have you got for us this week?

Lori Robertson: In the final Presidential debate, each candidate misrepresented the others position on abortion. Let's start with Donald Trump. He claimed that based on what Hilary Clinton was saying, "you can take the baby and rip the baby out of the womb in the ninth month on the final day." First, late term abortions are rare, just 1.2% of all the abortions in the United States occur after 20 weeks gestation. Second, medical experts say there's no such thing as an abortion on the final day or the due date as Trump describes. Daniel Grossman, a Professor of Obstetrics and Gynecology at the University of California, San Francisco, told our fact checking colleague that as a matter of fact that if the mother's life was in danger, the treatment would be delivery. The New York Times similarly quoted the chairman of obstetrics and gynecology at Oregon Health and Science University as saying the scenario Trump described "is not happening in the United States. As for Clinton's position, she has been a staunch defender of abortion rights, but she has said, she is open to restrictions on late term abortions provided exceptions would be given when the health and life of the mother are an issue, but Clinton also misrepresented Trump's current position. She claims that Trump said, "there should be some form of punishment for women who obtain abortion." He did say that, but he also walked back that statement only hours later. On March 30th, Trump pulled MSNBCs Chris Matthews that women who get abortion should receive "some form of punishment" if the procedure is banned in the United States. He also added that the man who impregnates the women should not be responsible under the law for the abortion, but on the same day, he put out a statement recanting the punishment claim. He said that if abortion were outlawed, the doctor or any person performing this illegal act upon a woman would be held legally responsible and that's my fact check for this week. I am Lori Robertson, managing editor of FactCheck.org,

Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact, that you would like checked, email us at www.chcradio.com. We will have FactCheck.org's Lori Robertson check it out for you here on Conversations on Healthcare.

(Music)

Mark Masselli: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. No parent wants to hear their young child's chronic health issues requiring complex and risky surgery, but that was exactly the case for 3-year-old Mia Gonzalez; plagued for years with severe life-threatening respiratory issues, her doctors discovered the cause was a severe aortic abnormality that would eventually kill her without intervention. Dr. Redmond Burke, Head of the Pediatric Cardiovascular Surgery at Nicklaus Children's Hospital in Miami would once have deemed her condition inoperable. So we chose a new tactic, created 3D printed model of her actual heart to offer surgeons a chance to map out an approach to the complex surgery.

Dr. Redmond Burke: This was printed out because she was thought to be inoperable and by having this type of model, we were able to conceive of an operation that hadn't been done before.

Mark Masselli: Dr. Burke said he carried the heart around with him for weeks analyzing the problem from every conceivable angle, the surgery ended up being a resounding success.

Dr. Redmond Burke: Her operation was extremely successful and she is recovering very well. Now, her life instead of being measured in terms of days and weeks is going to be measured in terms of years and decades.

Mark Masselli: This method of deploying 3D technology could help surgeons everywhere create workable solutions to complex surgical problems. A 3D printed model of a patient's organ offering surgeons a visual tool to help tackle complex surgical dilemmas, leading to better surgical outcomes. Now, that's a bright idea.

(Music)

Margaret Flinter: This is Conversations on Healthcare, I am Margaret Flinter.

Mark Masselli: And I am Mark Masselli, peace and health.

Conversations on Healthcare, broadcast from the campus of WESU at Wesleyan University, streaming live at www.wesufm.org and brought to you by the Community Health Center.

[END 25:00]