Emily Kumler: I'm Emily Kumler and this is Empowered Health. Before we start this week's episode, I just want to remind everybody, we are taking donations via Patreon[1], which we are hoping people who listen to the show will consider donating. It's a great way to help us out and allow us to keep doing what we're doing. So if you find value in this and you can spare five bucks a month or something like that, that would be great. That will definitely make sure that this project stays alive and we can keep providing you with really great information about your body. So this week we're going to take a look at a topic that I've been interested in for a while. So back in March of 2019 we did two episodes on maternal mortality[2]. One was based off of the New York Times piece[3] that I wrote looking at C-section rates[4] and the increased rates of maternal death. Most of those deaths happen postpartum[5], but pregnancy complications are very serious and they come up for women throughout the course of the pregnancy. Part of that is that when you are pregnant and you are putting a huge amount of stress on your body. And so yes, it's wonderful and magical and I have said millions of times on this podcast that I think women are truly superheroes because we can regenerate our own species, which is pretty unbelievable. And we do it without thinking about it. So you just sort of grow this thing inside of you. But if you have any underlying health conditions, they will come out during pregnancy because of the fact that your blood volume is growing so much and there's so much more stress on your heart and all of these things are happening very quickly. So in a matter of 10 months you grow a human and then you have to get that human out of you. All of that is pretty complicated biology and even just the physics of how the baby comes out is tricky. So we weren't surprised when we heard from some maternal tech companies who are working hard to try and solve these problems. The first company that we're going to talk to is Bloomlife[6] and they are a patient facing device and they're already on the market so they've already got lots of women using their product and we're going to hear all about it.

Eric Dy: My name is Eric Dy[7]. I'm a co-founder and CEO of Bloomlife. I have a PhD in biomedical engineering from UCLA and ended up starting Bloomlife out of a Belgian company called IMEC[8].

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[1] https://www.patreon.com/join/EmpoweredHealth?
[2] https://empoweredhealthshow.com/the-u-s-maternal-mortality-crisis-part-i/
[3] https://www.nytimes.com/2019/03/05/well/family/reducing-maternal-mortality.html
[4] https://www.bostonmagazine.com/health/2019/04/25/hospital-c-section-rate/
[5] https://www.mhtf.org/topics/postnatal-care/
[6] https://bloomlife.com/
[7] https://www.linkedin.com/in/ericdy/
[8] https://www.imec-int.com/en/home

At the time I was working in business development there and got excited about maternal health space through personal experience and kind of struggles to start a family. And so Bloomlife is a maternal health company developing new prenatal care solutions.

Emily Kumler: One of the things that I was hoping you could just sort of explain is you guys are already out there, people can buy the product[9], and I've looked at it online, but I feel like you'll probably do a much better job describing what it is exactly. And you know, I sort of feel like if you want to elaborate a little bit on like what is the goal? Like why would somebody buy this?

Eric Dy: So, maybe we start on the problem and then we kind of dive into the goal. You know, in the US, which is where we currently offer the product, but actually some of the challenges we have in the US from a maternal health standpoint actually are global challenges. But in the US, we spend over a hundred billion dollars a year on pregnancy and childbirth[10] but get pretty terrible outcomes. High risk pregnancies and pregnancy complications have been on the rise for the past few decades. Access to care is increasingly becoming a problem. Over 50% of the US counties lack a single OB/GYN[11]. And so many women are having to travel well over an hour just to get basic prenatal care. You know, the biggest problems in pregnancy today, of which something like preterm birth is the biggest, are very poorly understood and managed. And so what we have been building at Bloomlife is a remote prenatal care platform that allows us to both increase access to care to women throughout the country, start to empower them with information that's previously kind of been stuck in the hospital or in doctor's heads and start to aggregate data through this remote care platform, start aggregating data longitudinally across thousands and thousands of pregnancies and see can we use that data to help doctors earlier identify risks, tailor care, and ultimately improve birth outcomes? And so for us, we have a small wearable device. It's a patch, it's one on the belly and it allows us to noninvasively track various health parameters of maternal and fetal health.

Emily Kumler: And so what are some examples of that?

Eric Dy: So today what we offer to women is contractions[12]. So we measure uterine activity, so tracking and timing of

[9] https://bloomlife.com/how-it-works/
[10] https://www.nytimes.com/2013/07/01/health/american-way-of-birth-costliest-in-the-world.html
[11] https://www.aamc.org/news-insights/labor-pains-ob-gyn-shortage
[12] https://www.marchofdimes.org/pregnancy/contractions-and-signs-of-labor.aspx

contractions. But beyond that, what we're able to measure, which again is not fully available to the users yet, are things such as fetal heart rate, fetal movement, maternal stress, maternal sleep, and these are parameters that are either used in clinical practice today as part of regular prenatal checkups or where there is a pretty strong body of medical literature linking these two birth outcomes[13].

Emily Kumler: Meaning that like if there is an increase or a drop in the fetal heart rate, the baby is at risk for something?

Eric Dy: Yeah, exactly. So for fetal heart rate, they do check fetal heart rate and contractions through what's called a nonstress test[14]. And typically what they're looking for is whether or not there are accelerations or decelerations of the fetal heart rate that they call reassuring or not.

Emily Kumler: But isn't that only done in like a high risk situation? I mean like I never had that.

Eric Dy: They are typically done for high risk pregnancies, indeed, since those are the moms that have the greatest risk. They are also done in the hospital, you know, when a woman's sort of going into labor, they'll also do a nonstress test.

Emily Kumler: Okay. So the reason to buy something like this right now though is that it does sort of help with, whether it's like Braxton Hicks[15] or contractions, once you really start getting into labor, is that right?

Eric Dy: That's right. So what we offer is a product available to moms to track and time contractions. And what we've seen is that for many women that knowing whether or not she's having contractions, timing these contractions can be confusing, creates a little bit of stress and anxiety. And so what we really provide is a validated second opinion to help a woman sort of better understand what's going on during this time of life. And as they're sort of entering third trimester and getting closer to the delivery date, use this information to more easily communicate with her care team either remotely or during her prenatal checkups. Just to have a little bit of a peace of mind over it, help her know whether or not it's, you know, it might be time to go or not.

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[13] https://www.sciencedirect.com/science/article/abs/pii/S0002937811004807
[14] https://www.mayoclinic.org/tests-procedures/nonstress-test/about/pac-20384577
[15] https://americanpregnancy.org/labor-and-birth/braxton-hicks/

Emily Kumler: So it sounds to me like what you're sort of alluding to, and correct me if this is an incorrect inference, but like it sounds like you're basically saying people go in and they say they're having contractions and the doctors don't believe them or they're not sure that's what a contraction feels like. Is that what this is sort of supposed to be authoritative to doctors to say like, oh yes, Emily is definitely having contractions and here is the proof?

Eric Dy: We've heard from women that said that you're telling people, hey, I'm having a lot of contractions and then they say like, no, that can't be the case. And then they go in with the data and they go, oh wow, yeah, okay that is definitely happening. We should do something about that. You've probably studied this space too often, expecting women, what they think is happening and their views are not fully being appreciated and we give them objective data to be able to share. And so in many cases that is the case.

Emily Kumler: In terms of things that this would prevent, this is more of a way of communicating using technology. It's like another way of communicating with a physician about your feelings or conditions. I'm sort of confused I guess because I feel like, you know, it's interesting like you get Braxton Hicks like towards the end of your pregnancy, right? And not some people don't even really know that they have them, but then when you really start getting contractions, like you know what's happening, right? Like there's no question that you're in labor.

Eric Dy: I think it's good to parse out sort of where do we doing today versus sort of where are we heading? So what we do today is we provide a tool to track and time contractions. What we're doing behind the scenes is sort of looking at and collecting a very compelling data set, longitudinally across thousands of pregnancies, looking at physiological changes that occur in the third trimester. The thesis that we've had is that with having better data across sort of the end of pregnancy, that you could use that data to develop better screening and diagnostic tools that can help identify things such as an impending preterm birth.[16] And that's sort of where we're moving towards is moving not just from saying hey, okay you're having contractions. And yes of course at some point a when a woman goes into labor she will certainly self-identify at some point along the way that she is in labor. But by having a tool that is actually able to detect a labor onset with let's say the same accuracy as a clinical exam, what that does open up the possibility

[16] https://bloomlife.com/research/wish-project/

is certainly reducing incidents of false labor[17]. So these are women that sort of mistakenly think that they're in labor and they're really not. Maybe it's gas or some other sort of pains and helping them avoid those unnecessary trips. And on the flip side of that, if you do have a high risk mom that maybe is at risk for preterm birth[18], helping her identify as early as possible that she is going into preterm labor so she could seek care immediately.

Emily Kumler: So about how many women have used the device so far?

Eric Dy: We've had over 10,000 women throughout the US use the product.

Emily Kumler: I mean it's interesting because we just talked to another company, Nuvo,[19] which is you know, trying to get FDA approval and they're really going more of the physician route. So like the physicians will recommend their product. It sounds like mostly to women with high risk pregnancies and then they're hoping to expand it out. You guys are more of a consumer product that anybody can buy and then they can decide to share with the physician. But it's not a physician based platform, correct?

Eric Dy: So today it's not. Our intention has always been to enable better care models. What that implies is that the doctor will definitely be in the loop and at some point insurance companies should be paying for those things as opposed to Nuvo where they've said, hey, we're going to start by going directly to the doctors. We said we're going to start by going into the moms. And we did that for a few reasons, not the least of which is that we believe really the future prenatal care starts with women, doesn't start with the doctor, it starts with women. And it starts with understanding their needs and challenges and trying to serve those in making sure that they have access to information that they can use for themselves. The second reason is, as I mentioned, just extending care outside of hospitals by monitoring exactly what we're doing today. I think the business case around there is going to be challenging and so for us it's not a matter of can you monitor the same thing as you could do in hospitals? It's can you actually do something different? And to do something different you need better data and you need to be able to use that data to develop better screening and diagnostic tools and that's what

[17] https://my.clevelandclinic.org/health/articles/9686-true-vs-false-labor
[18] https://www.mayoclinic.org/diseases-conditions/premature-birth/symptoms-causes/syc-20376730
[19] https://www.nuvocares.com/

we've been able to do is essentially through this consumer, if you will, offering, you know, similar to a 23andMe[20] sort of is to aggregate by far the largest physiological data set on pregnancy and have successfully used that to develop better diagnostic tools, which we are taking through the FDA right now to get those launched within the clinical environment.

Emily Kumler: Yeah, because I mean I feel like one of the things that's interesting to me about all of this is that because nobody's really done this yet, there isn't really an awareness of what is healthy versus not. I mean like once you get into the realm of something really being dangerous, then of course it's clear, but hypothetically, let's say you're monitoring or they're monitoring or everybody in this space is looking at the high risk pregnancies because they're the most likely to face a dangerous situation. But then we take all that data and we aggregate it and we assume that like, oh, in these pregnancies, and this is totally hypothetical, right, but like the uterus contracts early or the baby's heart rate drops or the mom's blood pressure is X. Right? And then we sort of apply that to the general population. We don't know if the general population, maybe those are all normal things, right? But we don't have the information to know what the negative versus positive patterns are.

Eric Dy: That's exactly it. Pregnancy is probably the least studied condition of all medical conditions. And it's not, obviously pregnancy is not a disease, it's not a pathology. But, we do know that conception through the first, you know, two years of life are the most critical for lifelong health and development[21] of a child. And yet, we still don't know so much about this area. It's been traditionally, I mean women's health in general has been massively underfunded for decades[22] and there's been very little innovation in maternal health also in a very long period of time. And so it's only really through getting better data that you can start to decide and identify what is normal, what is abnormal, can you earlier identify potential risk factors and come up with better risk stratification models that can be used in clinical practice to tailor care to reduce these risk factors earlier before they turn into something that's, that's an acute complication. And that's where the longitudinal data in our approach, I think, becomes very powerful.

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[20] https://www.23andme.com/?new=true&vip=true
[21] http://www.urbanchildinstitute.org/why-0-3/baby-and-brain
[22] https://www.nap.edu/read/12908/chapter/2

Emily Kumler: Well, certainly, eventually it will be. But the question is how much data do you need before you have that impact?

Eric Dy: Well, I mean, listen, we have now, as I mentioned, over 10,000 people that have used this product. We have close to 750,000 hours of longitudinal data. And just with that data, we've been able to identify a digital biomarker to detect labor onset, let's say, to identify labor today, you know, clinically, requires a mom to go to the hospital, they hook her up to a cardiotachometer[23] to measure contraction frequency. And the doctor gives her a pelvic exam[24] to see if her cervix is dilated. And that's what we have today. And that's still not necessarily a super accurate way of determining it. Like, and there's studies out regarding how doctors accurately identify labor onset. And what we're saying is that labor is a physiological process. It happens kind of like a heart attack, if you will. And if you know what a non-labor state is and you should be able to determine what that physiological shift occurs and say, hey, labor started. And that's very powerful and we're showing that is possible with the data that we have. And I think that implications are, you could extend that to think about like fetal well being, right? You could start to look at that around looking at maternal mental health and elements of physiological stress as well. The theories have been proven and now we have to see how do you both take what we have today from a labor detection tool and turn it into an FDA cleared clinical tool that doctors can use? And how do you keep expanding out from there and looking at all the other conditions?

Emily Kumler: And as far as privacy goes, how do you guys handle the data? Are you like HIPAA compliant and all of that or is it more of the data could potentially be sold to a third party or do you work with third parties in any way?

Eric Dy: Because we have a part of our team is in Europe, we are GDPR compliant[25]. We believe women own the data. We've actually said that from the start. And so, because we are GDPR compliant, if the woman says, hey, drop my data, I don't want to be part of anything, then that's fine. We aren't currently pushing any information to doctors, so we aren't HIPAA compliant today. When we start pushing the data, the doctor, we will certainly be HIPAA compliant. We have end to end security and encryption protocols across all the data. Again, we believe that women own their data and so we would, you know, we would

[23] https://www.merriam-webster.com/medical/cardiotachometer
[24] https://www.mayoclinic.org/tests-procedures/pelvic-exam/about/pac-20385135
[25] https://eugdpr.org/

never start offering this data up to anyone without getting prior authorization.

Emily Kumler: And there isn't any built in prior authorization when somebody signs up? I feel like some of these consents are like nobody's reading them, right? They're like twenty pages long.

Eric Dy: Yeah. And we would love to be able to take the engineering time to make some sort of variable authorizations. But we're waiting for someone else to build the platform. And let us just build on that one. You know, we've been focusing on getting a product in the hands of moms, showing that it is valuable to her, showing that she can use it and showing what the meaning of that data is. We take the ownership side seriously. I mean, I think where there's some work we're doing to engineer this, to make it easier for women to kind of opt in and opt out, you know, early stage companies, not enough resources to go around for all the projects

Emily Kumler: And the product itself is rented, is that correct?

Eric Dy: Yeah, so we currently offer the products as a rental or lease. However you want to put it, it's available to women. And we actually landed on that model somewhat organically. When we started beta testing with this product a few years ago, we only had about 10 of them and I didn't want to sell them outright because, you know, at some point the woman delivers the baby and then we have to wait for the next batch of devices to arrive before we can start testing. And so we just started renting them and women organically in our interviews started commenting how they liked that because it lowers the cost and it doesn't feel as wasteful. And so we've kind of stuck with that since then.

Emily Kumler: Can you tell us a little bit about what the costs are?

Eric Dy: It's $20 per week.[26] And what we ship to a woman is a little box that has a reusable sensor in it and then these disposable patches. Each patch is good for about a week. She could take the product on and off as she wishes. Then, you know, she keeps product, if she wants to. After the third trimester, once she delivers a

[26] https://bloomlife.com/order/

baby, she just sticks the sensor back into the box, puts a prepaid postage stamp on it and then it comes back to us.

Emily Kumler: And is there any kind of like deposit that she has to make if the device breaks or something like that?

Eric Dy: So no deposit right now, you know, and the product is FSA and HSA qualified right now. And the goal as I mentioned, is to continue to demonstrate not just the value to women, which we've shown pretty clearly, but to really start showing what the clinical value is and how this product integrated into clinical workflow can improve doctor patient communication, could start to affect clinical decision making, and start to impact not just outcomes but costs. So we could start getting reimbursement around the product.

Emily Kumler: And is there any reason why a woman would keep it for postpartum? Because I know so much of the maternal mortality issues actually occur postpartum[27]. And I wonder if you guys are working on any of that.

Eric Dy: We definitely have an eye towards postpartum. I will say that there are definitive reasons why she would want to keep the product given some of what we can measure with it. I am not at liberty to disclose things just yet, but let's just say that some of the major causes for maternal death postpartum, we think we have an eye towards catching some of those things earlier.

Emily Kumler: I mean I even like Thinx[28], which is one of these period underpants companies just sent us a bunch of products and I'm like sort of obsessed with like all of these new ideas that are coming out. But it occurred to me the other day when I was giving some of these samples to somebody to try out that like, why don't they have some sort of tech underwear for postpartum women that measures how much blood you're hemorrhaging. Right? Cause everybody bleeds for like the first month at least if they deliver vaginally and so many women are dying from hemorrhages, right? And if you're home alone with a newborn baby and you're hemorrhaging, you know, you're exhausted so you're falling asleep or whatever you call your doctor. No one's paying attention. If there was like an alarm or like some, you know, way of measuring the volume of blood that could then say call for an ambulance. I mean like that sort of doesn't seem that far off.

[27] https://www.sciencedirect.com/science/article/abs/pii/0020729296026677
[28] https://www.shethinx.com/

Eric Dy: Yeah. My partner had severe postpartum hemorrhage[29] and almost bled out on the operating room when we had our first child. So that problem I'm acutely aware of, you know, what you communicate is similar light of like, well aren't people just going to know when they're bleeding badly? But the fact is is that people just don't know what to expect.

Emily Kumler: No, absolutely not. And this, especially after your first baby, you're like, my whole body is so fucked up. There's no way any of this is normal, but it's also not normal. Right?

Eric Dy: That's exactly right. But I think that idea though, I think you could extrapolate that back even into the pregnancy, right? It's like we just assume people are going to know. And listen, for a lot of people, they will know that some sort of instinct kicks in, but a lot of people that don't know, there's a lot of people are unsure about things and so yes, in the postpartum side of things, exact same thing. People just don't know, is this normal? Is this not normal? Is this something to worry about? And if you miss those signs, then things could go south pretty quickly. In terms of technology, I mean the fact is the technology exists, right? It's just a matter of is there a market for these things? Like are there enough people concerned about this that they would start paying for it and can you make a successful business given what price point you might need to charge for the cost of integrating these kinds of sensors into underwear, right? A lot of these things, it's not that you can't make them, it's just a matter of like is there someone interested in making that and can you actually make a business around it?

Emily Kumler: Well, and the other thing, I mean I wrote a story for the New York Times[30] that was all in maternal mortality and looking at the C-section rates and how other countries have dealt with this problem versus how the United States has, and one of the things that I didn't get to talk about in that story but has certainly been talked about in other stories is the undercurrent of sort of racial disparity[31], right? In terms of maternal mortality rates, you know, for $20 a week. I mean that's not an insignificant cost for a new mom who sort of like thinking about how to weigh her options. And I also wonder in terms of, I've also written about like sort of algorithms and how we program on bias because we can only program based on our past, right? Not on our future. Have you guys taken

[29] https://www.marchofdimes.org/pregnancy/postpartum-hemorrhage.aspx
[30] https://www.nytimes.com/2019/03/05/well/family/reducing-maternal-mortality.html
[31] https://www.sciencedirect.com/science/article/abs/pii/S000293780300067X

any sort of sample of either, you know, a larger sort of African American population or even just like socioeconomic disparities or differences?

Eric Dy: Yes. I'm actually really glad you asked that question because you can't talk about the maternal health crisis in this country without talking about that community of women. So there's a few things. We actually have been working with that community, not in the same volumes as we have with sort of the normal paying population, but we actually just did secure a Phase Two Award from the Maternal and Child Health Bureau[32] that was specifically a call for proposals for developing remote pregnancy monitoring technologies for underserved communities in both urban and rural areas. And so we actually spent some time earlier this year hosting focus groups, talking with these women, deploying the technologies into some of these communities throughout the country. And really the most interesting thing we found, because when we talk about access to care, you know, a lot of what people assume is that, okay, well there's physical barriers because they live far away or there is socioeconomic barriers because they have to work multiple jobs. You know, one of the barriers we identified within this community, specifically the black pregnant mom community, was that there is actually a barrier of trust[33]. We've talked with someone that lived literally lived across the street from their doctor and they would regularly skip appointments because they felt that their voice was not heard and that it was not respected. Part of what we've been digging into and what we're going to dig into even further in this at this Phase Two award is how does technology and the data you're able to get from these tools change the power dynamics in that relationship? And in a similar light to what we talked about before about women having access to information, to be able to advocate on the behalf. That idea I think is particularly crucial for these kinds of communities. And we're very interested to see can you actually help change the doctor patient dynamic in a positive way and a respectful way, in objective way that gives these women greater sort of agency in their pregnancies. And so it's something we're definitely very interested in digging into further. But we have been looking into that.

Emily Kumler: Yeah, I mean honestly I think there's such a need for that. Like in terms of sense of purpose. I feel like that would actually drive massive impact. After I did the New York Times piece, we did two episodes on maternal mortality[34] for this podcast and I went to a couple of events that were geared around maternal mortality and there

[32] https://mchbgrandchallenges.hrsa.gov/challenges/remote-pregnancy-monitoring/winners
[33] http://www.nationalpartnership.org/our-work/health/reports/black-womens-maternal-health.html
[34] https://empoweredhealthshow.com/the-u-s-maternal-mortality-crisis-part-i/

was incredible feedback from people talking in the medical community about the fact that so many African American women, we're feeling like they were, you know, the doula movement within the African American community is massive because of that trust[35]. Because people are like, don't go to the doctor because they'll cut you open and you'll end up dying. So just stay home and do the best you can. And that is somewhat terrifying. I mean, I think doulas serve a really important purpose and certainly midwives have been delivering babies longer than doctors, but I think the idea of making that choice because you don't feel comfortable or you don't feel safe going to the hospital is tragic.

Eric Dy: It is. And you know what we found as well, which I think you'll appreciate, is that because of the nature of pregnancy, this is probably the first time and maybe the time in a woman's life where she's going to have the most amount of interaction with the health care system. It's the first big inflection point and her experience with that medical system is going to influence how she views that interaction for not only the rest of her life, but it's going to influence how she cares for her children and their interaction with the healthcare system as well. And so we are institutionalizing this distrust, which as we saw through these interviews, is manifesting themselves in ways that are almost like certainly unintended but also massive. I mean, so to give you the perfect example, there was a number of women in these focus groups that had distrust of the medical system based upon their personal experience that they were not vaccinating their kids because I don't trust them and what they're trying to tell me.

Emily Kumler: Yes, of course. And it becomes, it's like a cascade effect or whatever you call it.

Eric Dy: It's a cascade effect. And then you can think about the postpartum phase. Like they had such a terrible experience in pregnancy that postpartum maybe when they do need care, they don't trust to go back again because they had such a traumatic experience and so it needs to change. I definitely think that technology will play a role. I don't think technology is a substitute for everything, but I think it can augment care. I think there's an opportunity, as we're exploring here, to see how does it change the power dynamics and actually improve communication and trust and understanding between everyone over what's actually happening. You know, there's still a lot more to explore

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35 https://www.washingtonpost.com/national/health-science/cities-turn-to-doulas-to-give-black-babies-a-better-chance-at-survival/2017/09/22/07420956-8363-11e7-ab27-1a21a8e006ab_story.html

here, but I mean, just to give you kind of a quick sort of stat, our users, of the folks that have actually been paying to use our products to date, over 30% had been high risk moms and over 45% are coming from rural communities. I mean that was a staggering stat. We were just not, we would just not think it was going to be that high, but over 45% of our users are in rural communities where access to care has become a problem.

Emily Kumler: Yeah. No, and I think that access to care is a much bigger deal than people realize. Like, I think the idea that there are so few OB/GYNs in this country right now, in terms of all kinds of reproductive, like you know whether you're going to talk about abortion or whether you're going to talk about having a baby or access to cancer screenings. I mean all of this stuff is sort of wrapped up. It's kind of mind blowing. Is that like just because of liability issues that have made it so difficult to be an open, functioning, profitable OB/GYN?

Eric Dy: I think there's that. The OB space has moved under a bundle payment quicker than most other professions. So I think they have seen their payments perhaps get squished. And you know, when you take that and you combine that with the shortage and you're trying to see more patients, you have shorter period of time. Yeah, I think it's a combination of multiple things, but they definitely have been a profession that's had a lot of challenges. And again, if you look at all the areas of medicine, the obstetric spaces have probably seen the least amount of new technology[36] coming to try to support these doctors that are kind of doing the best they can with limited tools really. I mean the cardiotocogram, which is what they use to do these nonstress tests on, what they use in labor and delivery, that was developed in the fifties. I mean it fundamentally has not changed. I mean, I can't imagine any other area of medicine that is still working with the exact same technologies that it looked like in the fifties or sixties.

Emily Kumler: Nuvo[37] is another company that's doing something similar. Only it is not FDA approved and they are trying to get FDA approval because they will be a medical device used primarily physician facing. So, where Bloomlife was really for moms as we talked a little bit about, this device is going to be something that hopefully doctors will be able to prescribe. And I mentioned this in the interviews, but it's worth mentioning, I think pregnancy is a really stressful time of life. You know,

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36 https://www.washingtonpost.com/national/health-science/long-overlooked-by-science-pregnancy-is-finally-getting-attention-it-deserves/2019/03/06/a29ae9bc-3556-11e9-af5b-b51b7ff322e9_story.html

37 https://www.nuvocares.com/

my mom would say that she was able to just sort of relax and she rode a bicycle until we were all born and have this sort of idyllic experience. I didn't have that. I was worried a lot and I had two normal healthy pregnancies, healthy babies. So I consider myself lucky. But I also think that didn't alleviate the concern that something could go wrong. And I think the more information we have, sometimes the more we worry. And so as everybody on this podcast who listens regularly will know, I usually err on the side of saying more data is always better. But when it comes to these tech companies, you have to keep in mind that they don't necessarily know what the patterns of health are. So we talked a little bit about that in the last interview and I want you to keep that in mind when you listen to these other companies because it's true for all of them. This is a really new space for companies to be getting into and the data is just not available. So, when you're participating in these things, you are sharing your data, which will help. And so in 20 years, this will probably be something that we really understand very well, whereas at this stage of the game, I just don't think we do.

Debra Bass: So I'm Debra Bass[38], I'm the US president and global chief marketing officer for Nuvo. Nuvo is a maternal fetal connected health company. We have a bold ambition to re-invent pregnancy care for the 21st century with new technology tools and practices. So in short, it's a connected pregnancy platform, looking at creating a more empowering and distributed care delivery model between a mother and her care team.

Emily Kumler: So if somebody were pregnant and listening to this, how would they benefit from using the technology?

Debra Bass: So, today pregnancy is a black box. It is an episodic and fragmented care journey. So as a mother, and I've had three pregnancies and two children, you have no idea what is happening in between those episodic doctor visits. But mom wants to know, she wants reassurance in between visits and she wants more flexibility and monitoring throughout her journey. So, Nuvo enables two things. One, more mother centric medical grade care, we could start to deliver that medical grade monitoring through the home. The second thing that Nuvo enables is more equal footing between a mother and her doctor, because today it is more of a paternalistic care episode because mom doesn't have parallel information with the doctor. And we provide more data about what's happening in the womb environment, maternal heart rate, fetal

[38] https://www.linkedin.com/in/debra-j-bass-3775372/

heart rate, maternal uterine activity amongst other measures to really empower mother with more knowledge.

Emily Kumler: And so there is a band that people wear that is used to detect the various heart rates, correct?

Debra Bass: Yeah. So the platform has three different components. So one, a sensor band[39] that wraps the uterus in passive fixed location sensors and through a Bluetooth connection phone uploads your data to a cloud computing environment for digital signal processing, big data analytics, AI tools[40]. And then the third component is a visualization layer to create a dashboard[41] for the care team and a shallower view for mom of what's happening with her womb environment as well as other peripherals that we could tie into the platform, like blood pressure is one example. The other thing I want to be really clear on in this podcast is we are currently an investigational device in the regulatory pathway with a 510K[42] submitted and we expect to get our first FDA approval[43] later this year. We also have a pipeline of other indications to keep the innovation tunnel flowing and progressing.

Emily Kumler: And so about how many sort of test cases, I guess you could say, do you guys have of women having used this?

Debra Bass: So we have only been used per regulatory guidelines in our clinical trials to date. We are not yet commercially available. So the data we have with women using our platform are from our pivotal trials and those have been completed to support our FDA submission. So one pivotal trial shows agreement with legacy technology for fetal heart rate and maternal heart rate. A second shows self administration that mom could safely and effectively use our platform from home. That is our first submission. We'll have a second submission with more functionality of the platform but that one is pending.

Emily Kumler: Well, so I am just sort of curious from a data collection perspective, like obviously things like blood pressure, we have a standard, you know, metric by which we can measure if something is off, right? But for a lot of these things I would imagine the data collection you guys are doing is sort of the first of its kind and certainly on a global

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[39] The product is called Invu by Nuvo and is not FDA approved yet. https://www.nuvocares.com/solutions
[40] Artificial intelligence tools
[41] https://www.nuvocares.com/solutions
[42] https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances
[43] https://www.fda.gov/news-events/approvals-fda-regulated-products

level, right? Like we don't have a ton of information about like the day to day heart rate of the baby[44] growing in the mom the last trimester, right?

Debra Bass: So Nuvo is very novel in what we call womb transparency. So, providing the physiologic measures from the womb or collecting data from the womb is another way to say it. So it is novel in being able to collect high fidelity data location agnostically, right? So our platform of the sensor band, the cloud computing environment, the visualization layers/dashboards could be administered at home in the employer clinic, in your doctor's office, even on the hospital floor. So it is very novel both in terms of the proprietary data we collect and the ability to do location agnostic monitoring in a medical grade fashion.

Emily Kumler: But so from the consumer perspective, when this goes live, will women be able to have an idea of what's like "normal" or not? I mean I sort of seems like you need to have a lot of that data collected before you can conclusively say something's irregular. Right? I guess I'm sort of thinking in the back of my mind about the fetal heart rate monitor being introduced in the 70s[45] to reduce the rates of cerebral palsy[46] and that a lot of people are actually saying that that has a negative impact because it sets off an alarm that then sort of escalates the care environment.

Debra Bass: So there are two things that I want to be really clear on just as backgrounds and then I'll answer your specific question. So the first is that Nuvo's in view platform will be available by prescription only. So I as a patient would get access to the platform through my doctor. And my doctor would write a script, one to enable me to engage in the platform. And two, my sessions will be scheduled according to doctor protocol of how often he or she wants me to wear the device, for how long, when my data will be read, and when I'll be notified. So the doctor is really in the driver's seat in terms of dictating the protocol. What Nuvo enables through 21st century technology is that flexibility to do medical grade monitoring from home, as an example, and also through this hive data fidelity way as a patient, there will be guidelines in our app so you have a sense of what's normative, but know that your doctor would have a much deeper diagnostic dashboard for decision support versus what we provide to the patient. It's more of a shallower reassurance view.

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[44] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3678114/
[45] The first fetal heart rate monitor was introduced in 1968. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6427711/
[46] https://www.mayoclinic.org/diseases-conditions/cerebral-palsy/symptoms-causes/syc-20353999

Emily Kumler: From the patient's perspective, what are the kinds of things that you, and I understand this is like you know, too soon to say anything conclusive, but just from your perspective, what are the kinds of things that you hope this technology will allow moms in terms of whether it's like a preventative kind of situation or a regular problem that comes up in pregnancy that this could potentially catch early?

Debra Bass: So I want to say there's two aspirations in how Nuvo will empower moms. First, for more flexibility in her care journey. Because monitoring today, particularly for high risk pregnancies, is burdensome to mothers. In your third trimester, if you're high risk, many women have to have nonstress tests[47] multiple times per week. And that means leaving a job and/or leaving your family to go travel to a doctor's appointment to sit in a waiting room for 45 minutes to then sit plugged into a wall for 40 minutes. So one, we aspire to make the journey more mom centric and enable greater compliance. The second is we are building our big data AI machine to ultimately enable personalized predictive pathways for pregnancy management and be able to catch things early like preterm birth[48] risk, like fetal arrhythmia[49], like mood disorders[50]. So the real hope is to get to personalized predictive pathways and enable tailored earlier interventions, which is where all of healthcare is shifting to be more preventive versus reactive.

Emily Kumler: Well, I mean I feel like it sounds so exciting, right? In so many ways, I feel like anybody who has had a high risk pregnancy or even, I have two kids, and they were both, you know, pretty normal I would say like healthy pregnancies, but I was nervous, right? I mean I think there's this sort of unbelievable feeling of like how is my body making a baby without my having to think about it so much. And the more data that you get, the more you sort of feel, maybe, I don't know if it's in control, but I think being pregnant is one of the moments where you feel the most out of control in your body and also the most vulnerable in the sense that you really hope things are going well. In that regard, I feel like the more data we can get, the better. Now my mom would have the opposite idea. She would say to me like Emily, you know I had one ultrasound with four kids and with my sister and I, our pregnancies, she felt like we were, you know, sort of neurotic because we would go from one appointment to the next hoping everything was okay. So I sort of wonder in terms of stress management, like have you guys thought at all

[47] https://www.mayoclinic.org/tests-procedures/nonstress-test/about/pac-20384577
[48] https://www.mayoclinic.org/diseases-conditions/premature-birth/symptoms-causes/syc-20376730
[49] https://americanpregnancy.org/pregnancy-complications/fetal-arrhythmia/
[50] https://focus.psychiatryonline.org/doi/abs/10.1176/appi.focus.10.1.51

about how having more information, I mean I feel like no one's ever going to say like don't give me information about my own body, right? But the idea of maybe like false alarms or how to counterbalance the onset of so much information in a changing body. Is that something that you guys are looking at or is it that sort of more of the doctor or the physician interface with the patient?

Debra Bass: No, I mean if you look at millennial mom and parent, because I include partner dad in this as well, behavior, they want to know more, right? Pregnancy should not be a black box in 2019. Moms already have behaviors of quantifying themselves, including their wombs, by buying gadgets off the internet because they want to know more. Nuvo is fulfilling this need for mom to know in what we believe is the most responsible approach, which is through a medical grade platform that is going through the FDA pathway that is clinically validated and is a connected care experience between a mother and her doctor. So she wants to know, she deserves to know. Let's help her know responsibly is point one. Point two, the premise of your series around evidence based interventions, pregnancy today and OB is still more of an art than a science and we need to get to evidence based protocols to really get more consistency and higher quality care and this arsenal of data and what's possible today with machine learning and AI tools is what's needed to get to data-driven pregnancy and evidence based protocols for empowerment, better outcomes, better system effects.

Emily Kumler: So is the goal to start with high risk pregnancies[51] and then spread to the general population?

Debra Bass: We see utility both for low risk pregnancies and high risk pregnancies. So in low risk pregnancies, we see virtual visits where a portion of the wellness visits are moved to the home with heart rate, blood pressure, and weight. And we can enable some of the low risks visits to be moved to the home is one use case. The other use case that is more of a pain point for the system is high risk pregnancies because again, more complications, higher burden of monitoring for mother and doctor and a much higher cost to the system, particularly through the complexities and bad outcomes that still happen too frequently today. So I would say it's for both, but high risk pregnancy is more of an acute pain point that we could uniquely lean into given the sophistication and what's possible with our in view platform.

[51] https://www.nichd.nih.gov/health/topics/pregnancy/conditioninfo/high-risk

Emily Kumler: Well, and so it's interesting because I feel like from the AI perspective, if the rollout is going to be based on physicians recommending this to patients who are at risk for something, right, where they're deciding that this is something that's going to be a helpful tool, then you're going to be training your AI devices on those high risk people, right? And so that won't be as applicable to low risk people, I would imagine. Where it's going to have different implications.

Debra Bass: We're going to be getting data on everyone, just through some of the partnerships, which I can't talk about publicly yet. Again, we're pre-commercial, but we will collect data on both low risk and high risk. So we'll have a broad arsenal. Data is the new oil, right? I know it's a cliche phrase, but it is, to really enable what's possible with modern technology and pregnancy desperately needs that.

Emily Kumler: And so I think one of my last questions would just be around privacy. Do you guys follow the HIPAA privacy compliance of medical treatment[52] for this or do you retain any rights to people's private data when they use the device?

Debra Bass: So we have built the platform to be HIPAA compliant, GDRP compliant[53] to the highest level of privacy standards because trust is the currency of reputable brand building today. And what's nice about creating a platform from the bottom up is we can do it to today's standards, not try to retrofit old technology. So yes, we've developed this to the highest standards of privacy and we go through risk assessments with any health system or OB practice that we would partner with to ensure it meets their standards.

Emily Kumler: That's excellent. I'm so happy to hear that because I feel like so often it seems women especially are put into these situations where they sign up for something and they don't realize the third party potential for their data to be used in other ways. So, while Bloomlife and Nuvo are doing really interesting things with pregnancy, the next company we're going to look at is really focused on the postpartum period. And I would say in some ways they seem to be already making the biggest impact. Mahmee[54] is a company that is integrating both the care provider and the moms sort of care and treatment through a lot of different angles. So you're going to hear a really compelling story of a mom who signed up for the device because she needed help

[52] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html
[53] https://eugdpr.org/
[54] https://www.mahmee.com/

breastfeeding. And it ended up potentially saving her life. It's worth mentioning that since we spoke to Mahmee, they have raised a significant amount of money and one of their big funders is Serena Williams[55], who most of us are familiar with, had a terrible postpartum experience and almost died herself[56].

Melissa Hanna: Hi, I'm Melissa Hanna[57], co-founder and CEO of Mahmee. My background is in law and business. I am a JD[58] MBA[59]. I've been working in tech for the last 10 years.

Linda Hanna: My name is Linda Hanna[60]. I am the director of care here at Mahmee. I'm a registered nurse. I am a board certified lactation consultant. My career spans about four decades now and I've had an amazing career taking care of mothers and babies. I'm an OB nurse and I specialize in breastfeeding support and guidance through pregnancy and after the delivery.

Emily Kumler: I feel like it would be great to have you start by just sort of explaining what Mahmee is.

Melissa Hanna: Mahmee is a comprehensive maternity care management platform. We connect patients, moms, and babies, to their care teams, who are professionals, and care providers who are often in different locations or in different practices or different health systems, but are all technically on the mom's same care team. We make it possible to have all of those folks digitally connected to each other and set up around the patient that's at the center. So those professionals would be the OB/GYN, the pediatricians, the lactation consultants, nutritionists, therapists, doulas[61], midwives, childbirth educators, anyone who's a licensed and trained professional that's providing maternity care support either during pregnancy or in the postpartum period[62] and even infant care through the baby's first year of life.

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55 https://www.forbes.com/sites/estrellajaramillo/2019/07/15/mahmee-raises-3m-serena-williams-mark-cuban-to-disrupt-prenatal-and-postpartum-care/#604b6d7a5d1a

56 https://www.cnn.com/2018/02/20/opinions/protect-mother-pregnancy-williams-opinion/index.html

57 https://www.linkedin.com/in/melissachanna/

58 Juris Doctor (law degree)

59 Master's in Business Administration

60 https://www.linkedin.com/in/linda-hanna-ab691013/

61 https://www.dona.org/what-is-a-doula/

62 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3279173/

Emily Kumler: And this is a user interface that Mahmee uses, correct?

Melissa Hanna: Yes. There is a portal for the mom to sync up her care team, to invite her care team members in, and to really get everyone on the same page about her care and her birth history and her baby's health and well-being. There's also a provider side and we make that available to all of the independent providers and practitioners that are supporting that mom. We, as a company, not only provide the digital tools to make this possible, but also provide ongoing support, educational guidance, and community experiences like virtual support groups, classes, and mommy and me sessions for all of the moms in the community across the country. And so in that regard, we're providing this layer of ongoing support and guidance throughout the pregnancy and postpartum period. And that allows us to keep track of how everyone's doing across the population and identify moms or babies that are rising in risk and need additional physician attention. And we can then flag and escalate a concern directly to that doctor's office and say, hey, we noticed that one of your patients needs a little extra attention right now. And in that way we're able to provide additional support to the physicians as well as the parents.

Emily Kumler: Can you walk me through that process a little bit?

Melissa Hanna: There are a number of ways that Mahmee participates in the maternal health care ecosystem. One of those is in this role as a first responder that is often the first to catch something that might be going wrong with mom or baby. And we do that through a combination of live and automated support and we're able to aggregate data on how everyone's doing from across the care team. So we're looking at the mother and baby's health record as it's being compiled by the doctor's office, by the lactation consultant, by the nurse midwife, or by a nutritionist, and so on, and by the mom herself. So getting that composite of information allows us to assess whether or not that mother/baby dyad is rising or lowering in risk over time. And if we see something, it becomes our responsibility to say something. For example, we're often the first to catch early signs of postpartum depression[63], of postpartum complications from childbirth, whether those are hemorrhages [64], infections, other concerns related to mom and baby's health and

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63 https://www.mayoclinic.org/diseases-conditions/postpartum-depression/symptoms-causes/syc-20376617

64 https://www.marchofdimes.org/pregnancy/postpartum-hemorrhage.aspx

recovery from childbirth. We also identify patients that are struggling with breastfeeding, struggling with nutritional issues, and so we're able to provide sort of this dynamic of being the eyes and ears across the population by bringing everyone together into one digital ecosystem.

Emily Kumler: And that's because the moms are sort of self-reporting on how they're feeling or how the breastfeeding is going and then it's alerting the health care team, is that correct?

Melissa Hanna: Well, that's one way that we find out about things. We're also engaging in a proactive manner with the parents to be able to find out what's going on and ask very specific questions that will reveal whether or not certain symptoms are normal parts of the recovery process or are actually the beginnings of a more serious medical concern. And not only are moms reporting this information, but we've created tools for the practitioners to engage with us as well and chart and document those observations. The challenge is that right now, when something does go wrong, whether it is a concern with the mom or a concern with the baby, either way, when something goes wrong, it's going to cost everyone in the health care supply chain and especially the payer or health system responsible for that mother baby dyad a ton of money. Most of the time, what went wrong was preventable and really shouldn't have happened. Let me give you an example of this. We had a mother who was onboarded by her pediatrician for assistance with breastfeeding. The pediatrician said, you know, you're doing well, but it'd be good if you had a little bit more education and guidance and I'd love for you to get into a breastfeeding support group and we can do that for you on Mahmee. And so the pediatrician onboarded her and linked her to his practice. And so there was a double opt in there. Her record was created in Mahmee. It was shared with that pediatrician's office and we were able to then provide ongoing education and guidance to her when she onboarded. Now, she had a 14 day old. When she joined Mahmee, we also, in addition to providing breastfeeding education that she was requesting, sent her some other educational content and a survey on postpartum mental health. And so we asked her, hey, how are you feeling today? Can you answer a few quick questions for us? We want to just take a snapshot of your mental health right now. And she answered those questions and she scored the highest score for postpartum depression and postpartum psychosis[65] that we'd ever seen in the platform. And she had no idea that she was this serious of a case. She was actually demonstrating suicidal tendencies, so in an automated way, it immediately flagged in the platform that this patient needed help. Her pediatrician was notified

[65] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3109493/

because her pediatrician was already in the platform. Our team was notified. The Mahmee care management team was notified immediately of this patient. And the patient was notified that there was a concern with her responses and that someone was going to be in touch with her. We called her within 30 minutes of this happening. We were able to get on the phone with her. Someone from our team spoke with her, verified the symptoms. She expressed over the phone that she didn't realize it was that bad. She'd been told by her friends, you're going to feel a little weird after you have a baby. She thought maybe this was what it meant to feel a little weird. She said, you know, I had a crazy thought the other day that maybe I should leave the baby with my husband and walk into oncoming traffic and I don't know why I thought that. This is beyond postpartum depression. This is now manifesting the beginning of postpartum psychosis and the ability to harm oneself for one's baby. Because a pediatrician onboarded this mom, they were notified. Now, she had also noted who her OB/GYN was as part of her care record, but the pediatrician wasn't necessarily in Mahmee. So we picked up the phone and we called that doctor's office and said, hey, we have critical information for you. You need to know that this is what's going on. Now mind you, this whole story began because this mom was getting help with breastfeeding for her baby. So the point is that when you look in maternity health care and you look at women's health holistically, you realize that there's a lot of other players who need to be notified of what's going on. And sometimes information gets manifested on one part of the record that doesn't necessarily transfer to the other unless everyone is synced up and on the same page. And the reality is that this cannot all be done at this point in time through the magic of technology. Sometimes you just need to pick up the phone and call people and that's something that our company isn't afraid to do and that's really why we're both health care and health tech company. We do what we can with automation and proactive engagement with parents and with practitioners, but when there's a critical health crisis going on, someone needs to pick up the phone and call that patient's doctor, which we are legally able to do on her behalf. She was able to see her doctor the next morning. She was put on Lexapro right away for antidepressants and she was referred to a psychologist immediately. All of that happened in less than 24 hours. That's care management.

Emily Kumler: We have a real shortage of OB/GYNs in this country, which we've talked a little bit about in the abortion episode[66], but this really comes down to birth, too. And that both pregnancy and postpartum care

[66] https://empoweredhealthshow.com/abortion-access-united-states/

is really critical care for women. And if you have to drive two hours and miss a day of work, you may not go in to get your blood pressure checked, especially when you have a new baby and the new baby is going to the doctor once a week or more. Prioritizing the woman's health by using technology that allows her to have easier access, I completely can get behind and I think that's really great and I think in the next 20 years it'll become way more common and women will have a lot more options. So I applaud these companies that are sort of on the forefront of this kind of innovation because certainly there is a need for better care and better access to care in maternal health. So I hope you guys have enjoyed the episode and had it be thought provoking while also remembering like you have to be your own guide and if you get stressed out about stuff you should probably consider whether you really want to incorporate more data into your life or not. Which I feel crazy saying because I feel like I always am the one that errs on the side of data. But anecdotally, there was a mattress pad[67] that a bunch of friends of mine had when they had newborns and it basically set off an alarm if the baby didn't move. And the first year of a baby's life is when you're really worried about SIDS[68] and sudden infant death is something that's sort of terrifying because people don't really know why it happens. And so people would put this mattress pad under their kids, you know, mattress cover or whatever so that they would know if the kid didn't move for a while. And I remember thinking to myself like I'm already so nervous, if I use this new technology, which seems really cool because it sets off this alarm and and lets you know the baby's in distress, but like what are the chances that my baby's going to be in distress? Probably pretty little. And certainly when my kids were little they slept right next to me in a sort of co-sleeper bed and I decided not to do it. So in that case I decided it was going to be way too stressful to be waiting for an alarm to go off. And I think that's probably like a good reference point for anybody who's thinking about incorporating this kind of stuff.

Emily Kumler: I'm Emily Kumler and that was Empowered Health. Thanks for joining us. Don't forget to check out our website at empoweredhealthshow.com[69] for all the show notes, links to everything that was mentioned in the episode, as well as a chance to sign up for our newsletter and get some extra fun tidbits. See you next week.

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[67] https://angelcarebaby.com/us_en/blog/post/wireless-breathing-movement-sensor-pad/

[68] https://www.mayoclinic.org/diseases-conditions/sudden-infant-death-syndrome/symptoms-causes/syc-20352800

[69] https://empoweredhealthshow.com/