Medical Device Design for Consumer Health

Presenters:

Mark Schwartz, CEO, Product Development Technologies (PDT)

Tom KraMer, CEO, Kablooe Design

In collaboration with Joe Hage and the LinkedIn Medical Devices Group

---

Joe Hage: Hi, this is Joe Hage. I have the pleasure of leading your Medical Devices Group. As of this recording, we have over 270,000 members worldwide. I believe that one of the reasons that our group continues to grow is we have folks like Tom KraMer who is on the Medical Devices Group Advisory Board. He's pretty much my go-to for design and development questions.

And actually through Tom I'm meeting Mark Schwartz. He is the CEO of Product Development Technologies, the PDT Group. They have prepared a rich hour for us. I will hand it over to you Tom and I'm putting myself on mute. But I'll be around. And have a great webinar.

Tom KraMer: Okay thanks Joe, I appreciate it. Thank you for ... everyone for attending across the globe. Nice to have you all here. I'm Tom KraMer as Joe said. President and CEO of Kablooe Design. We're here in not-so-sunny Minneapolis where we're going to have for instance nice fluffy snow, which is *a propos* for this time of the year.

Just a quick word about who I am and where I'm from. I'm with Kablooe Design. Kablooe Design is a Minneapolis-based product development company. We invent, design and engineer all kinds of medical devices mostly as well as other things. Through everything from research to ideation, design, engineering, prototyping, and technology transfer, to production for all kinds of these devices.

We have fun in that sense of the word being design engineers that enjoy creating new things that help improve people's lives.

Mark if you want to chime in and give a little bit of your background that would be great.

Mark Schwartz: Sure thanks. I'm Mark Schwartz. I'm Founder of PDT. I was celebrating our 20th anniversary a couple of days ago, which was kind of exciting. We're a product development firm located in Chicago and we have some other offices around the world. We're about 100 a little better than 100 engineers and designers doing research engineering etc. We work in a number of industries including about 50% of our business is in medical devices.

Tom KraMer: Excellent! Thank you Mark. So to dive right in to what we're doing. Our webinar today is designing health for consumers and we're looking at some of the trends. And just to kick off one of the main points that we're looking at here is that vital tracking. Consumers are able to do a ton of vital tracking right now. This convergence of consumer vital tracking and clinical grade devices is coming.

The big questions for today's webinar is how do we approach that as design engineers, as developers, as medical device people? How are we going to approach that and what are the implications for us? We see people like Apple come out with devices like these that are focused on all kinds of sensing as well as Samsung's Simbands. The advancement in sensors has been huge. The ability to shrink things and have batteries that last longer is driving a lot of this. So it's an exciting and there's a lot of exciting devices that are being launched. Sometimes 00:03:31 devices just wondering what can be used? How should it be used? What kind of patient should be using what?

But right now home healthcare has been driving this trend. Home healthcare and patient empowerment. So we've got a rising number of patients being treated at home. And there's a lot of reason for this. Everything from the ageing of the Baby Boomers to legislation that's happening in different countries around the world including the US. That drives the different ways that we pay for healthcare. That is fastly increasing the amount of healthcare that's happening in the home instead of the clinic. That trend is definitely on the upswing.

The question is how do we do all this? How do we converge the vital tracking that we're seeing and the clinical or consumer-level devices? How do we converge it to meet the needs of our clinical world and communicate with our primary care physicians, caregivers, patients themselves? How do we do it? We'd love for it to all be a perfect communication line right now and have futuristic things like this happening. That's not happening now; it could be in the future. But in the meantime what do we do to develop our devices to get there and make it work so it's efficient, cost-effective and safe?

I wanted to share some issues to take a look at tackle first. I'm going to go through some issues that I think we should be aware of. Those of you out there that are developers, designers, engineers that are involved in technology thinking about how to make new devices. I just want to share things that we should be aware of, that we should think about, that we should use in our developing process.

And then Mark is going to attack some specific things about how we would things such as mobile apps. And how mobile apps play in and if you design something for a mobile app and what do you have to pay attention to when you're doing mobile apps.

Some issues to tackle here. First of all there's the health information and security issues, and I'm not going to spend a lot of time on those. Those are pretty obvious, being able to have security and confidentiality to health records. There's a lot going on there and it's a lot of secure transmission. And Mark can actually touch some of that a little bit later.

But what I want to focus on is a little bit more of the design engineering issues. One of the big ones is making the devices simplified for the patients but sophisticated enough for caregivers. This is a dichotomy that we really have to pay attention to as product developers. One of the things we have to realize while we're doing this type of development work, is that a huge part of our population is the elderly or the over-65 at home.

Obviously we've seen these kinds of devices, these sensing devices, these mobile devices in the fitness world up to this point. And that's because nobody was attacking the medical world with it. So in fitness it's a completely different demographic, but the fitness market I believe is dwarfed by the market that we're really trying to attach when we get to medical. And that's the elderly at home.

So we have to think about how can they interact with these devices and understand how to use the device and how to work it, and what are their ... What's their dexterity like? What are their hands like? What are their fingers like? What are their thinking like? And how can we make it workable for them? It's still have the technology in it that our caregivers and our clinicians and our clinics would need. It's a big issue to pay attention to.

Another issue is the idea of the manpower to screen data and who gets alerted when. So so many of these devices like we've seen with Fitbits and Fuelbands and Scannerdus and all kinds of other things. The sensor technology is wonderful and we're sensing all of this data. And the one thing that we have to be aware of is we can't be naive enough to think that there's going to be pings of receptionists or operators standing by in backrooms somewhere that are just going to be receiving all of this data and then filtering it to send it to the right people.

Right now there are not teams ... there are not rooms filled with teams of people just waiting to get massive amounts of data from individual people all over the world and then getting it to the right places. Those teams may be built in the future but right now it's not there; the money isn't there for it. We have to think about that as we're designing and developing these devices. What data are we going to capture? What's important to capture? Who are we sending it to? And how are we sending it to them? And I know Mark will address some of that as we get down the line here.

Another issue to really pay attention to as engineers and developers is the overwhelming of the physician. Kind of related to the last one. Studies have shown lately that physicians have on average they spend about eight to 12 minutes with each patient each day. They've got precious little time and it's not because they're necessarily eating bonbons or relaxing or reading books the rest of their time. Their day is packed full of patients. And they've got tons of paperwork they have to do and they've only got eight to 12 minutes to spend per patient.

So we have to realize that if we're going to empower patients to capture a massive amount of data with sensors and body warn sensor devices, that we're not going to be sending all of that data right to their primary care physician. I mean they only have eight minutes per day to spend with them. So if we're going to ask them to send hours of data that has to be analyzed it's just not realistic. So again what data do we capture? Who do we send it to? And how do we send it there?

A related issue is again we're dealing with high-risk seniors. That's a big part of our market here as we're designing devices to go into the home, devices to be worn on the body or close to the body. A big part of this population is high-risk seniors. Currently in the US, and it may be similar in other countries, but right now the trend for spending time for nurses and caregivers to spend time with these patients is actually going down. So we have more and more patients that are in the home but nurses have less and less time to spend with them. A lot of our legislation here with the creation of accountable care organizations, has kind of led to this phenomenon where nurses aren't being paid by the hour to attend to these patients like they used to be. They're being paid per patients. So consequently they're having to spend less time with each patient and pack more patients into their day as they see them.

So as design engineers we have to understand what the competency level of our users are. It may not be a nurse anymore. It may be just a standard daily caregiver who is trained to a lower level, paid at a lower level. Or it may be the patient themselves.

Another issue that we have to really take a close look at is apps are cheap but devices can be expensive. Mark will be taking a look at different ways that we use smartphones with devices. And it's quick and easy to have an app. But what about when now we have complicated sensors and these sensors have to go into devices? And in the past many of these devices have been expensive and we haven't had access to some of the high quality sensors that we need to do the high-quality sensing that medical data would require.

So that's changing as these sensors are developed in higher and higher quantities down the road we'll have access to higher-quality sensors. But traditionally lower quality sensors give you lower quality results which might be fine for fitness but doesn't work so well when you're talking about medical world and potential life-saving situations and people's health. Again a dichotomy there that we really have to pay attention to as designers and developers.

And then another issue is what is the information format we're going to do? And Mark's going to really open this up and shed some light on what are some of the best ways to go about this. But we just have to be cognoscente upfront if we're going to choose what information format we're going to choose and who we're setting it to. And again if our recipients in our demographics is senior population, I know with my parents I can't they run on a Macintosh. And if they have something they run into this all the time and I get the phone call that, "This isn't working on my Mac. What's wrong?" And I have to show them how to download an attachment from an email because they don't understand it.

So we have to understand the level of information accessibility that our users will have and the ability for them to function well and actually manage their health to do it. It's just something that we really have to pay attention to.

And then the last issue that I wanted to share that we really have to be cognoscente enough and pay attention to is being able to make the device useable and well-understood by this senior population. So again I go to this population because I believe it is the biggest population coming up for what we're talking about here. Which is wearable devices, sensors, devices that are going to talk to smartphones.

And we have to pay attention to this inverse rule. And this inverse rule is more likely that you are to need a technology, the less likely you are to be savvy with it. So how do we make it, how do we use this technology but make it so my parents can use it and understand it. But especially without making mistakes, because if it's just for them seeing their heart rate when they're on the treadmill that's one thing. But if it's for some very important data that has to do with their health, it's a different story. So how do we do that? And that's something we have to think about going into it as designers.

So it really makes us think about changing the way we think about design. Instead of thinking about going into design with, "Hey, here's this great technology. How can we fit it into a device?" We have to sort of reverse that and say, "What is it that our users need? And what technologies out there are going to help our users meet their needs?" It's kind of a new way of thinking. It's a design thinking way of approaching the design and engineering process. But it's very important in this world of devices.

So here's a slide I want to share with you. I'm not going to go through all of this for the sake of time, but for those of you that are going to download the presentation this is a great slide that Deloitte University put together. Just some things to think about and focus on as you're leaping into the process of developing a wearable sensor technology. And the areas they work there I'm talking about 00:14:57. Your content, your communication, how you're influencing the patient, the interaction you expect that person to have with it. The intelligence behind it, the intention, how it enhances and what network you're going to use. These are just great rules of thumb I encourage you to print this out and just keep this with you in your design resource book.

So one of the interesting things and one of ... The importance of what we're talking about today is if we don't address this need with our design-innovative solutions, patients are going to use their consumer-level devices to track their vitals and do self-diagnosis. And we've seen this obviously over the last several decades of people being able to self-diagnose through things like WebMD and go online and do online self-diagnosis. Which has been great. But there's also some problems and issues we have to be aware when we see patients doing that.

Now that going online and diagnosing yourself is a symptom-based way of diagnosing, which is great. You go online and you look at your symptoms. But some of the problems with that are shown in this chart here. There's was a study that was done that shows that you go online. And what this is showing here is say you go online with a symptom a headache or muscle twitches or chest pain. If you're doing a web search and you're going online to do this, you are likely to feel like you have a 26% chance of having

a brain tumor because you have a headache. Or a 50% chance of having ALS if you have muscle twitches. Or almost one third chance of having a heart attack if you're experiencing chest pain. When in reality those diagnoses are miniscule compared to indigestion, or caffeine, or muscle strain.

But users don't necessarily understand the tool that they're using to diagnose themselves. So most users don't understand the mathematical models, the algorithms that are being used on a web search. And they could easily come up with a bad diagnosis.

Now the problem with this is large because for example people could go on here and assume that they have a brain tumor based on the fact that it looks like they've got a 26% chance of having that brain tumor. And that could it may lead someone to double or refusing different drugs. Or they can get into drug abuse in order to make the pain fade away because they're facing some sort of terminal illness. That may lead them to think they don't have long to live so they're not so concerned about an addiction and their quality of life. And they might feel like there's no reason to be sober so who cares about the addiction?

But if the pain really came through their allergies and they don't get that addressed, those allergic symptoms could increase and grow much more severe. Could change to asthma, and at some point they could have an addiction to drugs and have asthma and still have headaches.

So these are some issues that people face with self-diagnosis. And just understanding the technology that you're using to diagnose it, just the misunderstanding of that could be a huge issue for them.

One of the issues is, here's a study that was done that shows a large number of people are doing this this self-diagnosis but half of them never talked to a doctor about it afterwards. They've gone through the self-diagnosis. They believe they've got a really good diagnosis and they don't go to their doctor. So if they do fall into some of these issues where it's been diagnosed wrong, they're never getting a professional to take a look at it.

There are some really good sites out there. Here's one, the Mayo Clinic has a great symptom checker site that's all geared towards getting to a healthcare professional at the end. So if you don't do that and you ... 53% of the people believe they're getting a completely accurate diagnosis, when in reality there might be things going on that lead them to the wrong diagnosis, that could be a problem.

So it's been a problem with web self-diagnosis. But what we're talking about here is different. We're talking about sensors and technology which is a data-driven diagnosis not a symptom-based diagnosis. But we face similar concerns, similar issues. Though there's pros and cons to doing this. And obviously one of the cons we talked about is over-diagnosis can use to a flooding of the system. And we've seen we can't be flooding. There just isn't the ability to flood your healthcare providers, your nurses with information.

The great thing about it though is self-diagnosing can be proactive and it can be preventative. And that's the whole purpose behind being able to use sensors yourself as the patient, and do some self-diagnosis.

We're trying to empower the patients to be preventative. And that's being preventative of course will save the healthcare system time and lots and lots of money.

So some of the issue with this. Now here's the Scanadu device, and most of you are probably familiar with this device. But this is a brand new device out there that's for self-scanning. And we see some of the chatter going on. I just captured some of the chatter that we have engineers out there saying these devices can be useful but only of course if the results are accurate. So accuracy was a big big thing with devices like this.

And then we see a quote from the CEO of Scanadu saying that they did have accuracy problems when they first got the device out there. And the initial tests had a persistent problem and they had to go back and go back. And for some of the reasons that we talked about, the cost of the proper sensors was a hindrance; it was an issue.

So again now going back to why is this important to us as engineers and designers and why do we have to think about this?

Well here's three big focal points for addressing these kinds of issues. And one of them is the accuracy of the sensors. And again we talked about that and Mark will talk about this a little bit too but sensors obviously get more and more expensive as they get more accurate. And time has to go by before that changes.

But the second thing is the difficulty of the sensor placements or for sensor placements. So where do we ... This speaks to where do we put the sensor on the device, but also how does the device enable the user to put the sensor in contact with the body. That's a huge huge issue. And of course user error too, does the user understand how to use it so the sensor is working?

A great example of this is in the 1990s. There was a company that had a patent on a device that used a pulse oxymeter to measure your oxygen saturation. And then connect that, they connected that to oxygen delivery for people who needed oxygen delivery in their home. This way they would get smart oxygen delivery.

Well the company went bankrupt for one, nobody wanted it at the time because nobody would pay for a more expensive oxygen delivery device. Now times have changed and hospitals are more interested in paying for devices that will keep patients from being readmitted. So the device got new legs again.

However, the little devices, the devices that we use currently to sensor your oxygen saturation, your pulse oxymeters, were designed for people to sit still and put on your fingertip. Unless you're going to sensing someone's oxygen as they're ambulatory and moving around, having something hanging from your fingertip is probably not in your list.

So we wanted to go to ear-placed oxygen-sensing devices. Well the sensors in the ear ones were of lower quality so that became a problem. If you can't get quality sensing, your device is not going to perform the way it needs to perform. So now those devices over the years have become more and more

accurate but they're still very expensive. And so we're running into this problem of how do we make it affordable and still as effective as we want it to be. That's just one of those issues.

As we go through we think about how we're planning on developing these devices, we have to also understand that it's a very complex situation. This dichotomy between clinicians, the clinics, the physicians, the technicians, the nurses, and the whole manufacturing side of the business, it's a complex issue. As we see manufactures we're developing more expensive, higher tech connective devices. And our hope is that hospitals will pay more for these devices to keep them from coming back in 30 days as we saw in the example that I just gave of the oxygen sensing device.

However, clinicians will be spending ... Well they will want to be spending less on devices because reimbursement is very difficult to get that to go up. So if we have a more expensive device, they may not be getting reimbursed for that. So they're going to want to be looking towards the cheaper devices just like in oxygen device. They were battling devices that already delivered oxygen but just did it poorly.

So the hospital has to take a look at, "Are we willing to spend money to make it a little bit better and what are the results?" And they need clinical data for results before they change their mind. But they're also getting paid less per patient with this population healthcare model. So as they're getting paid less per patient they have to decide, "Is this device going to make me spend more time with a patient or less?" And that's something that we as developers and designers and engineers have to make sure that when we design a device, it's designed for the healthcare worker to spend less time with the patient but still get the quality results that they need.

As a result, this is going to result in hospitals becoming the buyers of our new devices that are related ... Especially the ones that are related to ACO readmission, not necessarily the clinician, or the technicians or the physicians of the past. So in the past often times we have engineers who design a device knowing that the physician will like this better. Or this will make the procedure easier for the physician or it will cause less pain for the patient. These were some of our major concerns, and they will always be our major concerns.

But now we have to look at the hospital and say the hospital purchasing person is actually our buyer now. So how do we design this device to make sure that that hospital purchasing person will actually buy it. Because if they don't, no matter how wonderful we've made the device it's not going to do anybody any good.

So we really have to pay attention to that as our whole political landscape changes. And as this relationship between our clinicians and our manufacturers becomes very tenuous. As design engineers we have to bridge that gap between the two and make sure devices work for both sides of the equation.

Now I want to turn over to Mark. Mark's going to really dive in to some of the specifics with how some of these technologies work and why you would want to use them in certain situations and design them in a certain way.

Mark Schwartz: Thank a lot Tom and hello again everybody. I was fortunate enough to start my career in the 1980s at Motorola. So I had a front row seat of the maturation of the cellphone over the years. I also got to see the rise and fall of Motorola, Nokia, RIM 00:26:13. And now we've got Apple and Android leading the world. I genuinely believe that the reason that Apple and Android generally are so successful is because they're the ones; they were the pioneers of opening up the architecture of the phone.

Prior to that you think back about Nokia, RIM and Motorola, they were always very guarded about the architecture of the phone, and giving you access to some of the data that the phone was producing. Apple changed that paradigm, and lo and behold you've got apps everywhere, which is really a cool thing.

What I'm going to do in my portion is I'm going to touch on the four different levels as we see them, for leveraging a smartphone for medical applications. We're also going to show some other examples that are non-medical. These are in order of difficulty by the way.

The first one is the simple smart phone app. So we show an example here of a Weight Watchers app. Pretty simple to develop. User interface is extremely important, ease of use. But this allows you to write an app and access some of the sensors like geo-positioning or accelerometers within your phone for free. And then create algorithms to somewhat approximate exercise for example in calorie burn.

Is it going to be super-accurate? Probably not. It's not going to work if you're not wearing your phone etc. But then these apps also rely heavily on user input. So some of the pros are is they're really simple. The user interfaces are simple. They're on a device you're familiar with. They're relatively inexpensive and shortly times to develop them. And typically they're free for the most part.

But they are very limited as far as the accuracy of the data. And like I said they often rely on the honesty of the person putting inputs in. And if you're counting calories, putting in the right foods and etc. So I wouldn't say they're so much medical grade. But they're also very handy and quite frankly quite motivational. Generally speaking when you keep statistics you're motivated because most people are competitive and they want to outdo themselves. So it is very helpful from that perspective.

Two major players dominate the space. The Android devices and the iPhone devices makes up anywhere from 85-95% of the space. I personally had a Windows phone for a while and I absolutely loved it but I did give up on it because there's rarely any apps written for it because everyone's doing Android and iPhone for the most part.

One little tip to mention here is that in our experience we found it's better to develop one of the platforms first in its entirety and then do the second platform to follow. Because it goes much smoother it's much more efficiency ... efficient. In other words if you try to do them in parallel you're going to be debugging things twice and stuff. So generally speaking a tip would be to do them at the same ... one after the other.

The second slightly more complicated is linking a wireless device to a smartphone. The example here is the Nike Fuelband. So this is cool stuff. It's a wearable device, it's wirelessly attached to the phone. It can leverage the phone for things like setup but then compliments the phone by adding a whole new set of sensors that are strategically located on the body to perform various tasks, to feed data back wireless to the phone. Typically these are Bluetooth.

And something to note about that is by virtue of being wireless, one disadvantage is you're supporting two batteries, two devices; that can be kind of a hustle. And there are some limitations in bandwidth with things like Bluetooth.

There's another example of a device that's a very specific thing. This actually sniffs your skin to see if you've been drinking any alcohol. Lindsay Lohan actually made this famous. In fact she used to paint with nail polish to disguise it. Because it actually has a secure band on it so it's tamper-proof. So if you're lucky enough to get assigned one of these you're stuck with it.

What it does is it has a proprietary sensor in it. It actually runs a pump that constantly sniffs your skin and it can actually sense if you drink one single beer. If it does sense that it will send a report through your cellphone to the parole officer who then deems you that you're in violation.

Again these systems they raise the level of compliance to a whole other level. Think about asking Lindsay Lohan to be on her honor about things, as opposed to a device that actually tracks it and you really have no control over. It does mean that in this case it has to be rugged, you have to go take a shower with it.

It also the proprietary sensors if it's pump-based is a battery hog. So you do have to bring it in every month, have it taken off, cleaned and a new sensor and batteries put in it. There are several cons with this sort of technology.

There's also some developmental challenges. I'm going to say time and time again that architecture is key with any of these devices. Architecture meaning which wireless protocol do you pick, how much bandwidth do you need, how much battery space do you have, how small does it need to be, etc. All that stuff is critical when you're defining the requirements and specifications of devices like these.

I've included a handy chart that we won't go through here. But it does talk about the pros and cons of the various wireless protocols that you're given by default with your smartphone. And it also suggests what some of the best applications are. So Bluetooth and NFC and Wi-Fi. So please download the presentation and use that.

The third is actually where you hardwire or direct-connect the piece of hardware through the smartphone. We at PDT affectionally call those APPcessories. It means it combines an app with a physical accessory. This is not a medical device, it's a military device that we did but it's fully ruggedized and it uses an iPhone as the user interface and the screen and partially the brains. The cool thing about doing a direct connect is that it allows you to share battery power. So as long as this device is charged, it

can keep the phone charge. You don't have to worry about two devices of one wearing out before the other and shut you down.

The other cool thing about this is behind this door the iPhone becomes rugged for field use. But if you'd like to deploy it in a non-rugged situation, the soldier can deploy the iPhone and control this device remotely if you like, which is pretty cool.

Ultimately though, the best part of it all is it's an interface people are comfortable with. It's approachable, they understand it. And you can use it offline as well as standalone phone and look at your data anytime you wish.

Now we can see this really expanding in the healthcare relative to just cost-saving and things. But there are some downsides of course as well, particularly the fact that cellphones do change a lot, the hardware changes a lot. When you look at the myriad of different sizes and shapes of phones, you have to be very careful when you're using the shape of the phone to dock. There are clever ways around this. You also have to be careful of the life of the phone versus the life of the device. So that you always know that you can support your device.

Here's another issue too to be careful of. One of the reasons that Apple so well is they make you license through the MFI program or the Made For iPhone program they actually embed a chip in the lightning connector shown here. Which allows Apple to control the fact that you've paid a fee, you've basically overpaid for this chip in order to access the lightning connector.

We've actually seen lately iPhone 5 accessories that use the lightning connector are not working on a lot of iPhone 6 phones now because Apple actually clamped down on that protocol. So the result of that is I can tell you that this device that PDT developed for a juice pack for your phone, the workaround we have is a little adaptor, a micro-USB to Apple adapter. When the iPhone 6 came out, that little part went from $1-$3.60 because now they're policing it closer and making sure people are using MFI-approved connector.

Here's another chart that talks about the pros and cons again of the various ways that you can connect, hard-connect to the phones. And what those are ... Where the best applications are. There's also an interesting workaround here, using the headphone jack. There's a company called Square who has done very well. And their workaround was to plug into the audio jack. And they were able to because the data, the small packets of data that they needed to send for the credit cards were able to be passed through the audio jack. And there is a little bit of power that you can drop from the audio jack although it's very small. So that's an interesting option for the precisely for the right applications. Certainly not for all.

And then the last is the most exciting I think is the medical device full on ecosystem. Where the phone is kind of the central hub and you create an ecosystem of products. And I'll show you what I'm talking about.

So here's a great example of a very intelligent advanced glucose meter that has the ability to check your glucose with a disposable strip, as well as track your diet and some other things that its sensing. It has a Bluetooth connection to a smartphone, but it also has a Bluetooth connection to a ambulatory infusion pump.

So the cool the thing about this ecosystem, and again this becomes complicated. It becomes a Class II medical devices. It's making decisions about dosing. It's tracking clients to what you've been told to do for tests. So while this is complicated, it also takes everything to the next level from like I said a compliance standpoint.

And when you are tracking compliance so closely, it's really a win win win. It's a win for the provider of the device and the disposable because they get to sell what they're supposed to be selling. It's a win for the patient because they're going to feel better because they're doing what was prescribed and not blowing it off; it's being tracked. They're also going to feel a lot better because by using a device of this level of sophistication, it's constantly monitoring your readings and your health and your diet. So it's giving you shots of drug when you need it and in smaller doses so you don't have the ups and downs and crashes and things. And the device is discreet and wearable so you're just going to have a better quality of life frankly.

That also makes the healthcare provider or the insurance company much happier too because it allows them to control cost much better. Now you're more responsible for your own care and it's being tracked that you're doing it properly. It's also great for a family member too. So let's say that your older parent gets prescribed this device. Since it's using the smartphone to get to the cloud and run through a server, not only the practitioners and the physicians and everything have access to data.

I can also have the access to my 85-year-old mom and make sure that she's okay and things like that. And that her numbers are in the right zones and stuff. So this is really the future I think. I think that it creates that win win win I was talking about. I think it will help drive down the cost of care. It will give people better quality of life. I think it's really an important step.

But I can't stress enough that the full-on ecosystem-type level does require a fair amount of engineering and software. It requires good research to understand the needs of all the stakeholders. And it also is much more regulated obviously in this case like Class II.

So like I said there is ... can be a considerable lead time involved in these types of products. A fair amount of software, a lot of firmware. It also requires you to think about architecture much more thoroughly. So for example, does it make sense to put the cellular chip in this device or do you leave it in the cellphone. Most people like to keep the cellphone chip out of the device because it requires another SIM card. Which requires another bill, which requires a lot of battery drain, and bigger batteries and a bigger device. So we see it being popular to keep the cellular in the phone. But you also have to think about redundancies with servers. You also have to think about redundancies with the wireless protocols. If you say for example, grandma is in a extended care facility with big thick brick walls and cellular

doesn't work well. You may need to have another system where it picks up on Wi-Fi etc. So there are a lot of things to think about in this.

Continuing on that thought, I have mentioned generally high cost for development, long development cycle etc. And again this large diagramming and research and 00:42:10 because it really has to be studied correctly to come out with the right product and put the right technology and the right pieces of the ecosystem.

So there's a lot to consider. We think that a lot of it comes from good research and good development of requirements and specifications in order to do the best product. And to do that upfront really think this through before you embark on the larger scale-type device.

Tom and I will open it up for questions now if anybody has any questions. Thanks for your time.

Joe Hage: Thank you both. Actually yeah a few questions did come in. And I encourage you to use your chat box there to ask the question.

The first one comes from Massachusetts, it's for Mark and I think Tom. You mentioned research, would you expound on what you mean by research. What kinds of research are we talking about? Thank you.

Mark Schwartz: Joe I'll take a crack at that one Tom and then you can chime in if you like. But we think as the rest of stakeholders widens in this new healthcare arena, meaning that in the old days all we cared about was what the doctor thought. Did he like the product?

Nowadays it's much wider. There's the person who makes the buying decision. The person who actually purchases it. The person that maintains it, cleans it, sets it up. The person that uses it. The family member that wants to monitor it.

So we believe that it's really important when you're developing requirements for your new device that you do upfront stakeholder research. And that will also include voice of the customers, and voice of the stakeholders, and also voice of the business. So making sure you understand all those people's needs and you turn them into quality requirements so that you get the best product. And that when it does finally get to market, you've done your homework and it's what everyone wants because you've considered everyone's input.

Tom you want to talk about that too?

Tom KraMer: Excellent and very well put Mark. It really shows the importance of doing that research. And I think one thing that is always good to try to focus on is discovering, when you're doing that research trying to discover what is the weak link in the decision-making chain or purchasing this.

For instance, a patient may not like exactly how it's ... It's maybe too big and too clunky, but they might still use it and get comfortable with it. But as Mark was saying if this is being purchased by a hospital and that purchaser isn't going to pay more than seven cents more than the device they were previously

using and this is $20 more. It doesn't matter if the patient thinks it's too big or if you slim it down and the patient thinks it's really comfortable. That's the link in the chain that will when it breaks, nothing else matters after that.

That's one of the important things in research is identifying what are those links in the chain where if they break nothing else matters. I think that's one of the things you really try to sift out of that upfront research because it changes how you design and develop the product. And you don't want to be making those changes down the road after you've launched an alpha unit and a beta unit and you've got a unit in clinical ... You want to make those changes early on while you're still on paper.

Joe Hage: Thank you both. My friend Dave has a question. He says, "Is 510-K clearance mandatory for home healthcare personal care products?"

Tom KraMer: 510-K for a home healthcare personal care product. Well-

Joe Hage: I'll say it Dave if you want to add a little bit of context to your question. I think I can answer that it really is a function of what the product is. If your question is more about apps, I'm going to assume that do apps need 510-K clearance? Like Fitbit he writes. Does Fitbit need clearance?

Tom KraMer: Do they need clearance? Does an app need clearance? Well I'm not a regulatory expert. We should have one of our regulatory advisory board guys on here. Mark what do you think?

Mark Schwartz: Well there generally speaking the way we usually look at this is there's an FDA site that's really quite friendly. You have the ability to go on to that site and search around for similar or predicate devices. And what that will tell you is if you're a Class I, II or III. So for example, even a Band-Aid is a Class I medical device.

I don't believe apps are regulated now because they don't really drive any decisions per se. But certainly some of the stuff I was showing as it got further down the complexity chain, definitely are. And those depend then whether there's a predicate device and you do a standard 510-K, or if it's required that you do clinical trials and etc. So the whole regulatory thing is an important part of your early stage development and rendering an opinion and getting that verified relative to what your regulatory requirements are.

Tom KraMer: Yeah, and without knowing what the app does it's hard to say because if you're trying to prove that it's safe and effective, you're probably going to have to get FDA clearance. But if there's nothing about your app that has anything to do with patient safety. And if you don't have to prove that the app is making the treatment effective or non-effective, it may not even need FDA clearance. So it may not need a 510-K. So I think that's what you have to look at, and it just depends on what you're trying to do really.

Joe Hage: We have a comment. You'll have to forgive me if I mispronounce this Yahonatan 00:48:44. I probably messed that up. But he/she, pardon me, offers that wellbeing devices do not require FDA

approval. However, if it presents HR or any other medical info, heart rate that is, FDA approval is required. So thank you for that.

Our next question comes from Tim who asks, "With so many devices all needing to work together, there seems to be a lack of collaboration between companies resulting in the lack of cohesion inside the hospitals. Hospitals get frustrated as a result. How can we do better to develop solutions to this growing issue?"

Tom KraMer: That's an excellent observation, I mean that is so true. And we see that in the hospitals that you're going into a hospital and we're developing a new device and we're doing some research. You can see people in the hospital roll their eyes and say, "Oh, not another screen that I have to look at and pay attention to that just is by itself 00:49:56."

The answer would be a complex one; the question is a complex one. But there are groups out there that are trying to unify all this data collection. And Mark maybe you will know some too, but I know of a group right here in Minneapolis that is trying to put together a platform that will link all sensing devices, or any sensing device that's putting out information in its signal. The health records that hospitals will be using. And data for the reimbursement people and what reimbursement needs.

And they're trying to put together a hub a portal with a software platform that sort of brings all this together. We may see a kind of a race to find out who is going to end up with the system or the hub that works just like VHS and beta and Windows and Apple. I mean there may be one system that wins out that just people use for all this to come together. But I think it's going to take something like that because everything is desperate and disparate and separate right now.

Mark Schwartz: It is true that a very popular term these days is the internet of things. And as we see so many devices getting internet-enabled. It actually does have the benefit of harmonizing a platform in a sense that devices that may have their own idiosyncrasies and user interfaces and stuff. If they're going to the internet they quickly then go into the nurse's iPad that she's carrying around. So in a way that those consolidate a lot of data and a person can monitor several devices in a common platform that's friendly. So there is some good things going on in that area too to get it a little better consolidated. We see that across lot of industries not just healthcare.

Joe Hage: Thank you both, more questions coming in. And just a note, I've shared with everyone on the call the link to the slides. And Mark and Tom up to you but you can send a note to the audience perhaps if you want to give your email address if people want to contact you after the presentation.

Pamela asks, "What do you think about the amount of information a patient can get from those devices? For sure people feel comfortable staying at home but what about the interaction between the doctor and the patient?

Tom KraMer: Well that's an issue that we were discussing as we went through. How much information can you get and how much do you want to gather? How much do you want to give to your physician?

How much is the for the patient? And it's tough if you can't get an accurate result, or if your patient has trouble using it and the sensor staying in good contact with the skin and you're not getting a good reading. You don't want that patient becoming distraught and sharing that information with the physician when he just maybe wasn't wearing it correctly. I mean that's something that the caregiver or the nurse should be addressing, so that information should go to them.

So I don't know, it's hard to answer that. What was the nature of the question Joe? Were they asking how to share that information?

Joe Hage: I think it was more of an observation about there may be plenty of information but at what point do patient and doctor come back together to talk about a plan.

Tom KraMer: Yeah, that goes back to the eight minutes that the doctor has to spend with a patient. So if you went to the clinic and saw your doctor yesterday and he spent eight minutes with you, and then tomorrow you were wearing one of your devices and you saw something that alarmed you, that's a good question. Do you set up another appointment? Do you send them a text? Do you expect them to read every patient's text all day long? I mean this is really a problem that needs to be addressed. I don't know if there's a good answer. It's just for now we know that we just have to be aware that we certainly can't expect every patient to be texting their doctor five times a day. There's no way the doctor can sift through that much information.

Joe Hage: It's actually the subject of today's Medical Device Group discussion about chronic care. Tom you were with me last year at 10x you recall when IBM Steven Pierce talked about this. So in a moment's time I'll 00:54:42 that link and share it with the group.

Gary asks the next question, "Do you have any thoughts on product development based on platforms for use and consumer devices such as self-administration self-injection devices?"

Tom KraMer: Self-administration self-injection and which platform Android or Apple would be more useful? Is that what he's asking?

Joe Hage: Gary you can type in for clarification. Let's tingle back for just a moment and John asks, "Which organizations do you work with to test the efficacy of your products? Do you work with hospitals, universities?"

Tom KraMer: Oh.

Joe Hage: How do you, you both, make sure that the products that you're designing are efficacious?

Tom KraMer: Well the efficacy culminates in the clinical trial. So in the clinical trial you're in ... Well it depends on what your device is, but if it's a hospital device you're in a hospital. If it's a clinical device you're in clinics. It's a home device you may be working with a homecare agency to bring your device into homes and to use it there and test it. So that ultimate efficacy from that testing is done in those places.

Prior to that we're doing your more informative-type studies. The level of efficacy you're getting gets simpler and simpler groups the earlier you get in the development process. So early on we're doing bench tests in the lab and we're finding out how efficacious it is. And we're trying it out on ourselves, and things like that to a degree.

And then we move into having volunteers come into our lab. It's things like that. So it moves down the line until you get volunteers that you can show it to and get feedback from and you can test it and see if they understand the results and they know what to do with it. And those can happen through little research informative studies that we have along the way.

So the answer is all of those places obviously depending on what it is. But the universities here in our local area in Minnesota we are able to do some of that with the University of Minnesota and some other local universities that we work with.

I don't Mark, is it different for you there?

Mark Schwartz: I would just chime in that as much as we sometimes curse the FDA I suppose when they're in our shorts I suppose. You have to appreciate that the process works and the fact that you go through various ... You establish a V&V plan, you go through a feasibility stage which is then under design control. You create proof of concepts, you test them. You switch over to the next stage where you get into formal design and you're under design control. And you have to do Verification and Validation against the initial requirements. And you're keeping 00:58:01 history file. You're tracking hazards and risks.

I think the process that the FDA has for us and forces us to use is a healthy one. And I think it works really well. It's different from a case-on-case basis, but I really think it works very well.

Joe Hage: Thank you. We are at the top of the hour and if you're okay staying on a little bit longer I am. You have a few more questions here. For those of you who need to drop off, we thank you for joining us. We are going to continue recording. I will send out a link later today with the replay, and I've already shared the slides link.

So back to Gary's question, he wasn't talking about Apple or Android. He was talking about for self-administration, self-injection devices; he was talking about electromechanical design. Have you thought about platforms can be developed and used in this context?

Mark Schwartz: Yeah so I think for drug delivery systems, right, they're a excellent candidate for this notion of a ecosystem. So if you're infusing some sort of a drug through an electromechanical process of whatever. That's the perfect kind of device where you probably want to keep it small, you're focused on pain, ease of use, compliance. So it's very similar to what I had shown where you keep that device as small as possible with smaller batteries with the simple wireless protocol. That then uses your cellphone strategically for user setup and monitoring and that being a hub to the cloud or whatever.

So I think that's exactly where you want to lay out an intelligent architecture as opposed to for example saying, "Wow! I'm going to put Wi-Fi in this device and then it's only going to upload stuff when it happens to be on a valid Wi-Fi wireless connection. Or you know what; I'm going to assume that the user always has a smartphone next to him when they're using this. So yes I'm just going to simply use Bluetooth and I'm going to use the phone for these things. And move that technology to this appropriate place and not do it over again."

So as I stressed architecture throughout my whole thing, I think that's exactly what I was talking about.

Tom KraMer: I would agree too. I think the ecosystem where it's the smart device is incorporated into the electromechanical platform and they're all working together. For something as critical as continuous drug delivery, something like that, you can't have the reliability issues of a wireless or something and something going wrong.

Joe Hage: The next question comes from Jan. "For medical grade devices, what do you think about the necessary infrastructure configuring and delivering the devices, monitoring their integrity, reacting to generate the logs, etc. In my opinion setting the organizational structure is a major hurdle."

Tom KraMer: The organizational, it sounds like, if I'm interpreting that correctly, it sounds like she's talking about the occurrence of events of what happens. Some sensing occurs that generates some information, that information is interpreted. Does that sound like what she's asking there?

Joe Hage: Yes, I believe she's talking about the way to take the data and make it insightful so that it helps the patients. There are a lot of obstacles. And what if anything from a produce design standpoint can you or Mark talk about to help alleviate that strain?

Tom KraMer: Well one of the things that I've seen in some studies that have come out lately is one of the big benefits of using these kinds of things for patient healthcare is just the idea of getting them to adhere to a regiment. So for some of these devices, we may not want to be focusing on having a sensor show them every time their oxygen drops below this, or every time their heartbeat has a little tiny ... That might not be the important thing.

The important thing might be just giving them a way of continually being aware of what's happening to their body, what's happening to their health. And giving them a way to interact with it. It's kind of the accountability factor that they're talking about is if you make patients accountable and you give them a means to be accountable by seeing things that were otherwise invisible to them. That can just help them stay on top of the regiment.

So you might want to set it up in a way where we're giving them just enough information to make sure they're knowing what's going on. But the important thing if they have a heart condition and they hit a certain level, and that's the real important thing. Then you give them that information.

So developing a smart algorithm to deliver the information that they need based on the disease state that they have, I think that's an important design consideration. But I think that can be done, because I

think the point Jan's making and it's a very good one, is we don't want to just be giving them tons of this data and expecting the patient to even know or want to know what to do with all that. But we can give-

Joe Hage: Let me interject.

Tom KraMer: ... them enough to be effective in energy per care.

Joe Hage: Jan adds, "My question is who is configuring the device? A nurse, a computer guy, the patient, who?"

Mark Schwartz: Yeah that's ... So I think that's how I read the question. I believe that if you take the analogy of a ... You find out you're diabetic and you're being given a glucose meter for the first time, there is a nurse that trains you for the first time. Helps you set up the device. Teaches you how to use it. And then when you go away and you start using it and get confused and things, then there's hotlines and stuff that you call.

I think with these types of devices, it'll be a lot easier for when the device is connected and when the device is going to the cloud. Instead of it just being a 01:05:16 autonomous device like I just explained, once it's connected that nurse that trained is going to be able to see that they're doing it correctly remotely. You're going to be able to do ... have more ... be able to push more tutorials and things like that when people forgot because they were nervous, they just found out they have this diabetes. And they were given this glucose meter and they weren't paying close enough attention because they're upset and things like that.

So I believe that what we all see with our smartphones now, I mean back in my travels there was huge user manuals for cellphones. And you actually had to use them. And nowadays nobody looks up anything anymore. You can just figure it out. So I think the user interfaces have gotten so good, the screens have gotten so good. As long as you can make the user interface that common thing that you're using every day anyway, I think the chances of success and ease of use, and user satisfaction are just much higher.

Tom KraMer: I agree [crosstalk] 01:06:22-

Joe Hage: Dipanka 01:06:22 makes this ... Go ahead. Well I thought you had concluded, I was reading the next question.

Tom KraMer: Oh, I was just going to add to what Mark was saying. Jan was asking who configures and so on. On one level configuring the interface I agree with Mark 100%, it's easier to ... The device can sense maybe you did something wrong because it wasn't configured correctly. And it could send a message saying, "Oops! You didn't have this turned on," and send that to you. And that's one of the wonderful things.

Configuring even a little bit deeper like when the device is developed and engineered and we have to configure how information is being presented. That has to happen with the collaboration of all the

people in that research phase that we were alluding to earlier. You have to talk to the nurse, the technician, the clinician, the patient, the dietician, the physician. And you have to find out what is important to all of those stakeholders. So when you configure it then we're making sure that the right information is coming up and getting used.

Joe Hage: Just a few comments from Dipanka, he ... This is a few moments ago. That he is letting us know that the FDA is welcoming the dialogue about the development phase of how to overcome the obstructions to fluid information coming from these devices. And as that apps or devices that pass through data without rendering diagnosis will not require a 510-K. So thank you for sharing that.

David asks, "The development cycle for the devices can be 24 months or longer. Have you managed the evolution of the interface, the smartphone, while you are developing the device and trying to validate your application?"

Great question David.

Tom KraMer: Well what we've done in the past, and Mark maybe you've done similar things. We go with the barebones interface as we're getting through it just enough to work and to give us the data that we need through testing. And then there's we get ... But all the time knowing what we need and discovering what it needs to be. And then as we get closer to the end, finalize it at the end. So we've designed that user interface with the most up-to-date latest technology and look and feel that we can.

Mark Schwartz: Yeah I think from a ... Be aware when you do the hard-connect to the phone, the APPcessory that we talked about. That's really tricky. But I think on the software side, I think maintaining upgrades of software from say a Apple 5 to an Apple 6 etc. or Samsung, that's relatively clean and relatively easy. We don't see ... The devices these days are quite stable. And we don't see functionality going away, we just see additional functionality.

So normally you're going to get good upwards compatibility while you still need to do some upgrades and account for new screen sizes and resolutions and things. Generally speaking that's relatively smooth to support I think.

So having said that you have to move your development along with the greatest, latest and greatest thing you have is. A lot of these have evaluation tips or things that you can leverage. And Android's being pretty ... Even though it's free, license-free there's not a lot of support necessarily but they've been very consistent with the releases. And there's a lot of support blogs out there and stuff if you do get into issues when a new 01:10:29 comes out. You can get good support.

Joe Hage: Nicholas asks, "Are there any fully integrated fully diagnostic platforms that are consumer-focused, eliminating the need for individual separate disease conditions?"

Tom KraMer: Boy! Not that I know of. I know there's handfuls of them being developed right now that are for several sensing or actual diagnostic devices that can take a sample, whether it bladder, saliva or urine. And you can do an Assay and test for several different things. I know that's out there. But I

haven't seen anything that's kind of the holistic thing that Nicholas is describing. Have you seen anything out there Mark?

Mark Schwartz: No, I mean the place to roam around is the AACC Conference for that question. Which is coming up here in June in Atlanta I believe. But that's where stuff like that is launched. But what we are seeing is we are seeing much more point of care testing being done, so you don't have to send out to a lab necessarily. A lot of the stuff may not make it into the home necessarily but it is at least in the doctor's office now. So you do get quick feedback on tests, which I think is the next step. I don't think it's going all the way yet but.

Joe Hage: It seems as though you guys have hit on a couple of cords here for questions to still be coming in 75 minutes into the presentation.

Scott writes, "From what I've understood, the specialization gained from a unique standalone device provides the greatest data from centers of diseases or conditions tracked."

His question is, "How does the user deal with the overload of having multiple devices?"

Mark Schwartz: Yeah that's definitely an issue. And in the case of the glucose meter that I showed, the one unit that the user really didn't have to worry about was the pump. So there can be ... when they're designed very well, the user can only be exposed to just need-to-know basis stuff and not have to be an expert in all these different complicated stuff. It all boils down to the user interface and great design honestly.

Tom KraMer: Yeah and then I think-

Mark Schwartz: When you're managing care like that and you happen to get some sort of a condition, I think most people feel blocked that they've been given an opportunity to manage it themselves and not have to 01:13:36 all the time. So I think they're sort of like, "I'm okay with it because I'm controlling it and I can manage it myself and I have freedom." So while it does think they have a pile of pieces of electronics perhaps, I think the benefits far outweigh the downside of it.

Tom KraMer: Yeah, and it's getting there. It's similar to the same problem of all of the drugs that one single patient might be on. There's patients who are on many many drugs for many different things at the same time. When it comes to devices, the only solution is the silver jumpsuit that we'll all wear in the future that we saw in our sci-fi movies years ago. Because you'll need the sense, breath, and oxygen saturation, and sweat all at the same time.

To have one device sensing everything is impossible right now. But as sensor technology gets better in the future those things will continue to become one. At one point we all had to have a separate digital camera and a separate phone and pagers and all of these things and a PDA. And now they've all converged into one. Over time as sensor technology increases I think we'll see some of that convergence.

Mark Schwartz: We just saw two of the latest Samsung phone has a heart monitor on it now. So 01:15:13 functionality to the cellphones. And now these watches are going to come out. And they're going to start, since they're body-worn now, they're going to enhance and take on more measurements for us. So it will, exactly what Tom said boy, you think about all the stuff you used to have to carry around. Think about your CD players with 01:15:37 batteries and carrying all that stuff around. It's all gone so.

Joe Hage: I'm going to squeeze in two more questions.

Pamela asks, "Are 3D-printed personalized devices ready to be incorporated in the medical device ecosystem?

Tom KraMer: Oh yeah on some levels yes for sure. We see some out there right now. We're dealing with one here that is just simply a pediatric device for these children that are born with this inability to move their arms. And they're 3D-printing these little exoskeleton things that work on rubber bands for these children and that's a simple medical device. Now it's not electronic in nature but it very well could have an interface electronic component put in.

I think right now there's plenty of applications right at this moment for 3D-printed personalized devices to be utilized that way.

Joe Hage: And let's wrap up with Dipanka who writes, "Can you suggest some online focus groups to get feedback on a product we're trying to develop as a startup?

Mark Schwartz: Well I'd say one of the ultimate online opinion getters is either Kickstarter or Indiegogo. I mean if you do a Kickstarter campaign and you get funded, people like it. That's for sure.

Tom KraMer: I might have missed the nature of the question. Was he looking for funding online or was he looking for feedback?

Joe Hage: Feedback, focus groups.

Tom KraMer: Feedback, well you're right then, and those are great ways to get feedback.

Mark Schwartz: And I can tell you that we mentioned research earlier. These days more people do qualitative research not quantitative. So there's a lot less focus groups going on these days as there's a lot more of the qualitative kind where you're talking to the stakeholders and stuff.

Tom KraMer: Right, and I think-

Mark Schwartz: I three out there Kickstarter and Indiegogo too because it's a great way to validate a product. It really is. And we've seen a lot of medical device-oriented things get launched there. And some of them go wild. There was a Generation II watch that just came out, raised $9 million in the first day.

Tom KraMer: And I would say too there's another group out there called Medstartr, which is just a smaller and overate version of Kickstarter for medical devices.

And then I'd suggest using leveraging the power of the LinkedIn network. And utilizing this group and/or other groups depending on what this device is. We've done that before too. Reached out to a group that a device was specific for. And in that group asked if there was people who would be interested in giving feedback on it. Then you reach out to that group of people and you get some really really good feedback.

Joe Hage: Well let's leave it there. I will thank our presenters Tom KraMer from Kablooe and Mark Schwartz from PDT. Great presentation, I've already got a few emails telling me so, so I know it's true. And I will have the video slides and transcript available online shortly.