FTS-HHS FDA CDRH

Moderator: Margaret Gomez
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. Today's conference is being recorded, if anyone has any objections they may disconnect at this time. Now I would like to turn the meeting over Miss Stephanie Joseph; you may begin.

Stephanie Joseph: Good afternoon everyone. My name is Stephanie Joseph and I'm an engineer with the MedSun team. I'm happy to welcome you to today's Webcast, Human Factors: Tools and Tips for Clinical Engineers and Medical Device Users.

We have a great program lined up for you today. And before I introduce our speakers I'd like to say that the opinions and assertions presented during this Webcast are the private views of the presenters and are not to be construed as conveying either an official endorsement or criticism by the US Food and Drug Administration. Any discussion is not confidential.

The format of this Webcast will be as follows: We'll have each of our presenters give about a 20 minute talk during which they'll address questions that were emailed in by attendees during the registration process. There won't

be an open forum for Q&A, questions and answers, at the end of this presentation. But if you have any outstanding questions feel free to email them to us at medsun@s-3.com and that email address will appear on your screen.

You can also phone in questions to the MedSun toll free line and that number is 1-800-859-9821. This is the same number to call if you're having technical difficulty accessing the slides. I know we had some issues this morning so if you have any problems accessing the slides for today's Webcast please call us at 1-800-859-9821.

After this Webcast those of you who registered can go on to the registration site and fill out a short evaluation to receive a certificate of participation. Through this route you can also send us comments, questions as well.

I'd like to briefly introduce our speakers in the order that they'll be giving their talk. We have Dr. Melanie Wright from Duke University Medical Center and she'll be giving us an introduction to human factors and answering many of the questions that were posed by the registrations.

Following her we have Dr. Peter Doyle, who's a human factors engineer with Johns Hopkins Hospital and he'll share with us some specific examples of human factors problems with medical devices and also share with us some tips for establishing a hazard tracking system at your facility.

Our next speaker will be Dr. Joseph Cafazzo from the University Health Network who will be discussing design defects and use error and giving us an overview of the extensive human factors program at his facility and sharing tips for incorporating human factors at your own facility without a lot of resources.

Our last presenter will be FDA's own Ron Kaye who will share with us perspectives from the human factors program here at FDA.

I'm going to take a moment to share some background information about the MedSun program. The Medical Products Safety Network or MedSun for short, is an important patient safety initiative sponsored by the FDA. The Center for Devices and Radiological Health at the FDA learns about device problems through a variety of mechanisms and MedSun is one of them.

It's a network of 350 hospitals that the FDA uses to obtain knowledge about problems, experience with the use of medical devices in the clinical community. It's an Internet-based system that's designed to be easy and secure and a way to report adverse events involving medical devices.

Our hope is that by providing educational programs like this one today we can increase reporting about medical device problems and in particular we'd like to hear a lot more about human factors problems with devices.

Now I'd like to properly introduce our first speaker, Melanie Wright. Dr. Wright is the Director of Research at the Duke Human Simulation and Patient Safety Center and has been researching issues associated with the reduction of error in healthcare since 2003. She has a bachelor's degree in aerospace engineering from Virginia Tech and a master's degree in psychology and a PhD in industrial engineering from North Carolina State University.

She has 18 years experience in engineering and research in the areas of human performance, usability analysis and human machine systems design. With that I'd like to hand it over to Melanie Wright.

Melanie Wright: Thank you. Get my slides up here. Hello everyone. I'm Melanie Wright and I work at Duke University Human Simulation and Patient Safety Center. I'm one of several folks who are involved in these efforts. Just start with some acknowledgements and disclosures, some of my funding sources - most of my work is funded by the Agency for Healthcare Research and Quality and also I'm required to disclose that I have inventor rights in a potential commercial product called (3D eye team) which I will not talk about in any detail.

The missions of our Human Simulation and Patient Safety Center are, first of all, high quality interactive education so really looking at education beyond lecture based education, interactive education and simulation or virtual environments; really looking at teaching skills and behaviors and - as opposed to knowledge - simple knowledge.

Secondly, and which the piece that I am most involved in is the research in human factors in healthcare with a focus on reducing errors and increasing patient safety. And we also have a strong focus in research and how to improve education in healthcare. And then lastly we have a mission to translate these research findings into real clinical practice quality improvement efforts.

Just to - I'm going to do a little introduction to human factors engineering. To start with I'd like to start with the definition: Human factors engineers discover and apply information about human behavior, task, jobs and environments for productive, safe, comfortable and effective human use.

We're really interested in looking at the interface between the man and machine. I like to say that human factors work involves - or education really and work involves two things, one is really understanding the capabilities and

limitations of humans in their work environments or in the systems that they're working with if it's commercial products or work environment.

And then the second piece of this is really understanding and practicing methods for studying people in those work environments and for optimizing performance in those environments.

If you want to look at a history of human factors engineering it started sometime ago in the early 1900s with simple time and motion studies looking at personnel selection for specific jobs.

There was a big sort of boom in the - during World War II when we started to realize that pilots were responsible for many of the errors - loss of aircraft. One of the particular problems was when pilots instead of extending their landing gear were retracting their flaps and it was discovered that the controls were right next to each and with the same motion. And that was very much the beginning of human factors engineering.

Another thing that's interesting to note about the history of human factors engineering is that human factors becomes involved in industries as those industries begin to experience serious problems or accidents. We can see that in terms of the nuclear power industry and now starting in like '99, 2000 with the IOM reports in healthcare.

I - we could talk for an hour about the - about patient safety and errors in healthcare. I'm going to talk about 30 seconds on it just as an - by way of introduction. I think hopefully everybody on this call recognizes that errors in healthcare are a big problem, big contributor to sentinel events and even death.

And then secondly that patient safety is a systems problem that we need to really think about the work environment of our healthcare providers and not just focusing on the individual. And lastly that initial reaction fixes don't work; we can't solve these problems one at a time as the errors occur.

And hopefully everybody is also familiar with the Swiss cheese model of patient safety which basically says that accidents or errors occur when several problems line up. And, you know, at any point in the process if we have a slice of cheese with no holes or fewer holes we could stop those types of errors.

I put this slide in here from the Joint Commission Route Causes of Sentinel Events on Slide number 8 for those who are trying to follow along. Just to focus on the types of the way we're categorizing errors. So top in the list is communication and then we see training, we see patient assessment, we see things about education and leadership.

What we don't see in here is anything about the technologies we're using, the systems we're using, any type of focus on the tools that we're providing those individuals or the design as opposed to the education or training; both are important of course.

So how can human factors engineering help? One of the things that we can do is we can look at some of the theories of human performance and look at - and from those develop some guidelines as to how to design systems or processes or workflows to support what we know humans are good at.

And then we can also help by providing some methods for studying folks and for making improvements. And the other speakers, Dr. Doyle and Dr. Cafazzo are going to talk about some of those things in more detail.

I'm going to talk a little bit about some human factors theories - theoretical models just by way of introduction. There's four that I like to talk about. The first one is the idea of human information processing, so how do people process information? In that theoretical model we look at information coming into the human - their sensory perception of that information, perceptual processing, integration of that information with long-term memory - working memory and then decisions and actions.

But what some of the implications of those models that are important is, number one, that our attention is limited. You know, we can only do so many things at one time; number two, that our ability to process information, our working memory is limited; and number three, we can practice things. And as we practice we become more efficient and - or automated at processing information.

And when we do that it frees the attentional resources and we can use them for something - for other things and become much better at multitasking.

And then lastly there's the model of multiple resource theory which says that it matters what we're doing. So we may be able to walk and talk at the same time but we would have a hard time listening and reading at the same time because there would be a conflict between those - the types of processing that's going on.

Oops, I'm sorry, I'm pushing the wrong button; there we go. So this slide here, on number 12, control versus automatic processing, what I want to show here is that controlled processing, when you're first learning a system or when something's new to you is deliberate and slow and effortful; you're thinking

very much about each step of the process and maybe knowledge-base - you have to make decisions based on knowledge.

Automatic processing on the other hand is fast and fluid. When you learn something to practice and practice and practice so you don't have to think about it; it becomes almost - you're not even conscious of the effort.

Another model that I like to think about when thinking about human performance and limitations is the idea of situation awareness. Situation awareness refers to our sort of dynamic knowledge; what our - a knowledge of the current situation and the current environment.

And this is important in healthcare to wise decisions; if you don't know what's happening with this patient, you know, what their history and physical is, what drugs they've been giving, how they've responded, what the current lab results are you're not going to make the right decisions in taking care of that patient.

What I find most interesting about models of situation awareness is that it very much places the focus outside of the individual - well in addition to factors of the individual; what are your backgrounds, what's your experience, etcetera.

There is a clear focus on things - the environment and the environment contribution to that situation awareness, the system design, if there's automation, how much complexity is in your work environment, how hard you're working. All of those factors affect our ability to really know what's going on right here right now.

And another theoretical model I like to think about when I think about human performance is the idea of naturalistic decision making. If we look at sort of more typical models of decision making we would say for example in trying to choose between two options what's the pros and cons of each option and then make a decision.

That's not actually what occurs in practice. In real practice people look at cues in their environment. It's really more like problem solving than decision making. And they use things like pattern recognition, something that might feel like intuition if you've gotten very good and skilled at interpreting the information in your environment; you may not even be aware of what cues are telling you, what types of steps you want to take next or how you would deal with the problem.

So naturalistic decision making is really very much a sort of a recognition-pronged model; we recognize a pattern and deal with it as we have had in the past. And we might use other tools like mental stimulation where we actually, in our minds, step through what will happen if we take certain actions.

So what are the types of errors that occur in naturalistic settings, so if we were to study people in the real world and not just in labs. And what we find is that errors occur when obviously people don't have the experience to recognize the patterns that they need to recognize or lack of information.

And this kind of brings us back to the idea of situation awareness. If we haven't presented the information that you need in a way that allows you to get to it when and where you need it we're going to have problems.

And a de minimis error is an error which occurs when we know it's a bad problem but we sort of try to find ways of - ways to explain it away. And then of course stress also limits our ability to - to problem solve.

Lastly I want to raise one more type of error that occurs. And I like to bring this one up especially for nurses, prospective memory error occurs when you have - intend to do something later. So you're working on a task and you have to defer it to a later point. And then there's some delay between when you thought about you had to do it and when you actually get around to do it.

And there's no cue for you to remember to do that. In this slide with the red Starbucks car - I think this was done on purpose but I think we've all left our coffee cups on the car at some time or another; that's a prospective memory error.

So we know that people and systems - incorporating people are predisposed to error; what do we do? We want to think about bad outcomes and how to prevent them. And we want to think about how do we change the environment to set up more slices of cheese.

So what are some of those system and design contributions to bad outcome? Number one is complexity; the more people who are involved, the more steps that are involved, a lack of knowledge of responsibility all lead to complexity which can lead us to bad outcomes.

Work load - so that's also staffing, if you don't have enough people to do the job. But it also can be the job is designed in a way that makes it inefficient and increases workload.

And lastly poor design; so it's a design that did not pay attention to how much our attentional limits are or our working capacity limits are or the types of resources we're using.

So there's many opportunities for improvement. And I think Dr. Doyle is going to show several examples so I'm not going to go into these in too much detail.

Here's one example from my work, this is a anesthesia information system. And I find that a lot of documentation systems are like this in healthcare where you have just simply - these long lists where you're expected to code what happened. And they're not particularly well organized. And in this case you can see we've developed our own system of number in order to sort them in the order we want them to be sorted.

So there is some customizability allowed in the system that's provided to us by the manufacturer but it's not customizable enough to allow us to provide the type of organization we need in our environment without resorting to using numeric code.

So some of the design and procedural solutions for error, I think Dr. Doyle is also going to talk a bit about some of these; if you can prevent error through design that's good. If you can't prevent it you try to reduce it or you make the errors easier to notice.

So if you think back on theories of human information processing and situation awareness, automated processing and prospective memory errors, all of those types of errors, you can come up with some design principles. And these are some of my favorites. The first one and sort of the most obvious to me is you optimize for human perceptual and working memory limitations.

And it's amazing to me how often I see systems where you can't even - basic, basic human factors like contrast. You know, it's easier to see black on white than, you know, red on green or something like that - where those basic principles are just lacking. And working memory as well; lists that are exceeding long, organizations of data in that way.

Secondly is the idea of designing systems around goals. So instead of being focused on designing systems to the task or the workflow we're doing now let's work on a process where we better understand the goals of the user; what the endpoint is and try to design systems to support that.

Thirdly is support skilled performance so that allows us to develop those automated capabilities. The one thing that we can do, the most important thing we can do there is consistency. So the more consistent we are in the process, in the location of the data on the display, in the action that you use, the colors, the coding we use, the names we label for use, the better we're going to be able to support people's learning and development of skilled performance.

And number four here is support recognition not recall. People are very good at recognizing what they need if they can see it on a list and particularly poor at trying to remember all of the things that they should be considering.

Distribute information across resources so to the extent that we can take advantage of all the different skills that people have using, for example, visual perception and auditory perception maybe even the tactile input mode considering both spatial ways of presenting information as well as verbal the better able people are going to be able to do more things at once.

And then lastly as we start to move into systems that are more automated and more intelligent, if we can focus those systems on improving the presentation of information so that it helps people to get to the relevant information quickly, makes more salient relevant information but doesn't try to do all the work for the human because ultimately humans in the work environment have much greater ability to understand the context; there are details in the context that are likely to be beyond what the automation system supports.

I'm just going to briefly introduce some methods, I think Dr. Cafazzo is going to talk quite a bit about usability testing which is quite interesting. This is a process of human center design - I'm on Slide 23. What I just want to lay out here is that the idea behind human center design is that you incorporate methods that involve users throughout the process, from the very beginning when you're evening starting thinking about what it is you're going to do.

And you use specific methods like task analysis or focus groups that try to understand the user requirements the user's goal. And then - so throughout the process, at the beginning, in the middle and at the end with the testing.

And then the other piece of this that I want to point out is the idea that the design process is iterative so at each step you incorporate methods involving users but then you also do some evaluation and you make some changes based on those evaluations and then you do reevaluation.

So one of the first things you need to do is gathering information and there's many different ways to do that; I'm not going to really go into detail in any of these. And then evaluation methods, and again I'm not going to go into these details.

So I'd like to wrap up with talking about some of the questions that you guys sent in. One question was: What technologies have reduced error? And my response to that is the technologies themselves don't reduce error, it's good design that does.

So there have been perhaps some technologies and some applications perhaps bar coding in certain applications where it fits well into the workflow might show, you know, good advances in reducing error. But bar coding in and of itself as a technology is not reducing error; it's the way that it's implemented in the workflow or in the system.

So secondly: How do we recognize a human factors problem? And I think it's - Dr. Doyle or Dr. Cafazzo are also going to talk about this. One of the things that is a good sign of human factors problem is work-arounds. When folks are trying to avoid a process or a system there's a good chance that there's a problem there.

You can also do observation, you can ask people. And there are specific methods for like there are specific procedures you should use in doing observations and focus groups and interviews. And there are books that talk about good ways to do that.

Are there limits to features and menus? Well of course there are. The more features and the longer the lists the more complexity you have and the more opportunity for error. Again there are guidelines - human interaction guidelines, documents and research papers that talk about what some of those limits are and how can do things to overcome those limits like, for example, chunking information.

So instead of having a single long list you - it's a single list of 24 items maybe it looks like groups of four or five - several groups of four or five items that are grouped in meaningful ways.

What are some sample screening questions for vendors? This one I like very much. And Dr. Cafazzo is going to take you to the extreme on this. But if you don't go far as doing your own usability testing when you're deciding to purchase a product you - I do think it's important that you can ask them. You can ask them, what is their design process? Did they mention human center design? Do they even know what it is? Do they do usability testing?

Again you look for the response. If it's obvious they know what you're talking about that's a good sign. If they do then you can ask questions like: What were the results? What types of changes did you make to the product in the process? It should be more than just a simple checking a box that we did usability testing. It should be we did the testing and it allowed us to identify these problems and we made these changes.

Have you considered the failure modes? Where do you think the places are where the most risk is in using your process? And then lastly I think this is quite important as well is that the system has some sort of usability when it's out of the box but it has a quite different usability when you implement it in your system and you add your data and you add your organization.

And so you might ask them do they have any support for usability on implementation? How customizable is their system? How willing are they to work with you as you move into using it in your environment to make sure that it's safe and usable.

What are the best risk mitigation techniques? Well to be honest I think this is a difficult question and I'm not sure we know that. We do know that performance measurement and feedback improves our - reduces error. We - failure modes of exit analysis is a method of trying to identify risk so that at least you're aware of where they can occur. And certainly clear responsibility of, you know, who does what job helps that as well.

We also got a question about how do you teach people to use equipment or technology? How do you get people to pay attention and read their - read the manuals? And one response to that is well if you find that the vendor training is inadequate you should do your own and simulation may be a way to do that, setting up the system is a, you know, simulated environment and making sure that people have opportunity to try it.

But ultimately good design will reduce the need for manuals and for training. So you should really talk to your vendors about that.

And then lastly somebody asked: Well how do we teach people to pay attention, to be vigilant, to be careful? And to be honest with you I don't think you can; this is something that we know is a human factor so we really should be looking at well do we have appropriate breaks? Do we have good design solutions?

And that's - kind of wraps up the part that I had and hopefully I haven't taken up too much of the other speakers' time. And I thank you very much for listening.

Stephanie Joseph: Thanks very much Melanie. Our next speaker is Peter Doyle. Dr. Doyle is a Human Factors Engineer with the Clinical Engineering Services Department of the Johns Hopkins Hospital. He has more than 25 years of experience

working in fields such as nuclear power generation, defense contracting, usability testing of communications equipment and most recently health and medicine. He has a doctorate in applied experimental psychology, this prepared him to analyze interface relationships between people and equipment. Peter, the floor is yours.

Coordinator: I'm sorry, Dr. Doyle and the other speakers if you could please remember to tell folks to advance their slides for those that are - that aren't on the Webcast but are looking at the slides.

Peter Doyle: Okay thank you. And thank you, Dr. Wright, for a very - a great overview of our field of human factors which I think by now the listeners can determine that it's not a new discipline, it's not something that was started recently but it's based on more than 60 years of research into issues - the many issues that Dr. Wright mentioned with the basic intention of improving - identifying and improving factors that are related to humans that ultimately will affect system performance or to improve system performance.

So along those lines of course, and to take a systems engineering kind of approach the human factors discipline is interested in both operation and the maintenance activities. And many of the bio-meds of course find themselves in the world of maintenance although you will also be doing many operational test kind of things. So you know both end of the spectrum and, you know, with many devices that you're using.

So, but in any case if you're a (b-ma), you're a diagnostician and you diagnose equipment problems and that's what you're good at. And those same skills can be used to examine medical devices in a manner that can improve patient safety. So let's go to our Slide number 2 here.

Dr. Wright discussed the analysis of design and test activities that we do. And it's all for the goals of easing use and maintenance of equipment, improving performance; to design tests that are easily learned, memorable and efficient and help us avoid from relying on procedures and training to ensure safety is a much better approach of course as to design equipment and systems and processes in the first place. So we don't have to rely on procedures and training which is one of the least effective means of doing so.

So this presentation shows some ways of how clinical engineering and bio-meds can help improve safety. Let's go to Slide number 3 which just is a title page that shows the beginning of some examples of human factors issues that you may encounter in the hospital. So on the next slide, number 4, we see an example of an equipment analysis.

And this is interesting; it was a case identified actually by a bio-med. This is part of a fast fluid warmer. And what is happening here is that this device had an air detector added on on the right hand side. A clamp comes down when an air bolus is identified by the air - the sensor. And the issue is that its power is removed when the clamp is in place; the clamp will release allowing the bubbles to pass.

So if we consider that the alarm - that the alarm is alarming there's only one way to turn the alarm off that's by removing power if the bolus was released or if any - would release - if any other condition that would result in loss of power again that clamp would release.

So there was one record of a patient dying in this country and we are presently holding these devices - sequestering these devices and working with the vendor to come up with solutions that would reduce risks. So you can see that sometimes it's the bio-meds who identify these issues first.

This is another case, a similar case in which a bio-med identified - and actually nurses by default found this one. We need to stick to our convention if we can to use the right equipment. In this case we have a keyboard that was used for the clinical information center, the physiological monitoring system on a unit.

And what happened is that with the factory unit the alarm silence key is in that position in the upper right. When that keyboard failed and was replaced with another keyboard that position was used for power. So when nurses went to silence the first alarm they shut the whole system down, couldn't get it up. So we had delayed monitoring for a number of cases which puts us on a risky position. So this is a case of poor conventions or being careful about using our stock.

You may have seen issues similar to this, we use (key ways) of course to make sure that we install equipment properly. This is a tram body and the (key way) happens to be right in the middle of the body so you can put it in either right side up or upside down.

Of course it doesn't work in the upside down mode. Not only that it's very difficult to get out; they have to call clinical engineering to come up and bring some tools to remove the tram. So once more another case of delayed - of monitoring.

As we remove and install components and assemblies during our maintenance activities we have to be very careful of course about reinstalling them in the correct fashion. This is the case of a valve and a ventricular (fit) device. And if you look at the picture on the left that's the correct installation. The picture

on the far right is incorrect. And you can turn the Ls at the top and bottom of that valve, left and right, there's only two little cues for that.

The one little lip on the right side you can see needs to be oriented correctly. And there's also a hose barb to be - looking in the left picture, there's a small hose barb. If you miss that and install that incorrectly which has been done the machine will provide pressure instead of vacuum and vice versa. So this being a very critical device which supports the heart during heart surgery it's a very critical kind of an error to make.

Okay another issue of course is proper installation during use. This shows an opportunity for putting in a hose in the wrong direction of the pump. So what can happen is that there's a lithotripter and it can end up pushing an air bolus into the kidney. So that's anther critical error that can happen best controlled by design rather than by procedures which might be rerouting hoses, marking hoses, making the hose too short to reach the wrong way, anything like that.

But you may very well be identifying some of the issues in your own shops like this that can happen and it's a good idea to bring - to identify those and track them. We'll talk a little later about how one might set up a system to track these issues so they can be identified and addressed in the best manner possible.

So in terms of installations it should be impossible or difficult to install components correctly - incorrectly, excuse me. And some of the means you can use to control that possibility is labeling, changing procedures, informing the manufacturers when we identify such cases and being - the best in the very beginning is to be selective about what you purchase and by evaluating equipment very thoroughly before you even bring it in.

And later on Dr. Cafazzo will give some good guidance on how we can conduct better trials in evaluating our equipment so that we don't get stuck with equipment that we have to try to compensate for by - once more by procedures and training.

We'll go to the next slide which would be Slide number 10. When we are coding components and assemblies for installation we have to remember that 7% of males have a red/green color blindness issue. And this shows an example of when you see the first two indications there of Google.

In the second case the O and the E are green and that's how a person with a red/green color blindness sees red so red and green labels need to be supported by labeling - yeah, by text in the labeling, excuse me.

There's also a number of software interfaces, you know, more and more everyone is seeing more menus and more complexity in equipment, more features. And how the software is implemented is an issue of course. This shows an example of an infusion pump and how they use the cursor to indicate what field we're putting data in and it's not conventional use.

In some cases where the cursor is under the 6 in our first little panel there, if you go to change the 6 to a 7 what happens, the second panel you see that the number is added to the end. In other cases when you - with the same device - when you go to change something with the cursor under it that very digit will change.

So because this is an infusion pump someone could put in the wrong value. If the value exceeded the value that was allowed by your (scope) in software controls for drug overdose you could get a prompt there as you can see in the last panel, dose exceeds guardrails limit of so much.

But what happens is on this last page there's no indication of what the value is, how much am I exceeding by. So once you make the mistake you don't have an opportunity to review it when you're given the prompt to make the corrections. And I'm sure once more that you have opportunities to see a lot of similar kinds of issues with software but it's good to try to identify these and track them using the methods again that we'll discuss in a little bit.

We all know that visual cues are very helpful but they're insufficient in many cases. And using design or forcing functions is ultimately sometimes what's required or preferred. This is a case of a bed cable and though we have a - this is a DB cable shown in the upper left it's really a Centronix cable. But in any case what happened was nurses were jamming the two connectors together 180 degrees out which it rounds out the receiver.

And we went through several changes with the manufacturer first putting little triangles on to show which sides should match and we did several iterations and eventually had to come up with this shape coding which you see the littler arrow in the middle which almost 100% successful in averting the misconnections and rounding out the connectors.

So this is an example of a case where we were able to work successfully with the vendor to get some changes which is always helpful and motivating.

In the next case, which is Slide 13, this shows a pacemaker which has an error upon startup. If you're holding the power button down and it happened to touch any of the other buttons on the lower part of the device there you'll get an error 004 message which the nurses don't know what it means, there's no indication of what to do. And your startup is locked out.

You have to know the secret to disconnect the battery and to restart without holding the two buttons down at once. So we've discussed this with the vendor and the best solution we could come up with in the short term is to use warning as a means to prevent this from happening.

And it's not the preferred method as this is seen in Slide number 14. We just put a little message in; it was a challenge to get something as small as we could in there and to get something which can withstand all the washing types of activities they have to (unintelligible). We're still trying to work on developing the right label that will withstand multiple washings.

Slide 15 is directly involved with the maintenance activities. We have to be careful in how we handle our devices. In this case a screw can affect the air in line components and it's a reminder that we can change things but we always need to do an operational test of equipment after we have handled it and it should be the last test before it goes out - the last step before it goes out of the shop.

Similarly in number 16 here's a procedural step that seemed to be overlooked in the procedures that we added and that is to clean the air in line sensor; it wasn't included in the inspection procedure and if you get a little bit of foreign matter in there we found that it can render the air in line detector useless. So we've added our own procedures.

So the next slide, 17, asks the question: How can bio-meds use human factors to assure safety? You have these analytical skills. And you know how to do both repair and operation of devices. So along the way what maintenance errors can you identify that affects safety. Can you share them across your shop? What kind of procedures need modification?

What we did here at Hopkins was to do a human factors review of all of our life support equipment, a review of all the preventative maintenance, OPM activities by going back with a human factors engineer to go through the maintenance procedures with each of those devices with the bio-med and look for different kinds of issues both procedures and the design, you know, that might result in some kind of error in the shop.

And at the end of this presentation I've put an Appendix on there which if you can get copies of this, which I'm sure you can, have some guidance for developing a checklist or evaluating procedures for doing that kind of activity to, once more, to make sure we're putting everything back together correctly, taking the right steps to make sure the proper warnings and cautions are included in the procedures, that the procedures are in the right sequence and steps etcetera.

So what aspects of unsafe use can you uncover? Errors of omission, what can be overlooked, what, in terms of sequence of use, what information is missing that - is needed to support your decisions, what kind of faulty control inputs; all these are issues that you can keep in mind and identify during your working day.

And then to identify those corrective measures for anything you do institutionalize the practice so that everyone in the institution is thinking along those same lines and you have a means of relaying this kind of information to your management.

And in order to do that in an efficient manner, as we move to Slide number 18, we can look at a method of assessing risk which was developed by the military and is also used in the AIME literature or standards for risk assessment. It's very similar - once we identify some kind of a potential

accident or hazard we can rate it according to severity where it's catastrophic meaning a person could die from it, critical, a person could be severely injured or it could be negligible.

Similarly what's the possibility of this hazard really happening? Could it be frequent? Could it be improbable? And if we look at those two factors we can come up - use a table like this that gives us guidance on which things need to be attended to, which would be in this case the items in the red or the yellow and which things are really kind of negligible that we don't have the full resources to address everything we do.

So if you were to come up with a scheme like this of identifying hazards you would know which ones to track using a form something like that on Page 19 which is our next slide. This is what we use here, a little different format, but all the same information is in there. We identify the hazard by a number, status is when you fist identify it, monitor is when it's under consideration until you agree on what the recommendation is.

And once that recommendation is implemented it can become a closed item. You can note here the severity and probability, what action needs to be taken, the originators, etcetera. So this is very helpful for you so that once you identify these kinds of issues they don't fall between the cracks.

And if you spread the word with the other bio-meds it can become a practice within your institution and working with your management you can, once more, institutionalize that so you can track the things that are important and avert the kinds of accidents that often get reported in the form of PSNs or hazards in the units.

And it's also a good idea as we're told by Stephanie, to report the significant problems to the FDA because they have the capability to help resolve them at higher levels and hopefully to get things addressed at a design - from a design standpoint so again we're not always just relying on training and procedures.

As we go to our next slide, which would be number 20, this is my attempt to answer the question about what can we do to - about staff knowledge of operation and troubleshooting. So I see this as an ongoing challenge and there are many factors that address it: workload, attitude, many others.

And what we're beginning to undertake here to do this in working with - we have of course our physicians and clinical personnel, we have our equipment specialists who set up the equipment in the rooms and we have our clinical engineering folks. And sometimes, you know, across those three sets of people it's difficult to tell who has what responsibilities, for instance in checking out an anesthesia machine.

So we're starting to do analysis to allocate who's responsible for using and troubleshooting what equipment, what parts of the equipment. And if varies across the hospital so let's get our responsibilities aligned first so there's no confusion, something isn't overlooked.

Then we'll be analyzing operation and troubleshooting tasks to identify the learning requirements; what needs to be learned. And establish a certification program of sorts using those training requirements. Then once the training program is in place we have to update the user and maintain our knowledge and skills with the new learned tasks as we go along and learn about new hazards.

So naturally this requires buy-in from management. But it's more of an organized approach, we think, to try to identify who's responsible, do assignments and get the proper training in place and then follow through by verifying and validating this whole system and entering new training as needed.

Another question was what are the limits for device features and menus? And I think very similarly to Dr. Wright on this is the best defense against getting lost is to use good - limited features and have a good information architecture at least in the case of the menu-driven types of devices. So the user needs to be able to find what they want and you have to be able to provide the user with a good mental model of all the offerings.

If the person can't conceptually grasp how the device is used, what the options are they may forever be wandering through decision trees to find out what they want to do which as Dr. Cafazzo I'm sure has experienced many times in his usability testing after some period of time the user gets frustrated or is liable to make errors.

So you have to be able to - it has to be simple enough that a person can have a good mental model, a limited number of ways to get to the same need of the tree. And you have to enable people to get back to the starting points. And the achievement of those goals is best verified in usability testing where you can bring in typical users to exercise these devices while they're being observed by the people who designed and by human factors engineers for performing evaluations.

So with respect to menus a really good resource for usability is the www.usability.gov site. It has the many different aspects of design; it was kind of geared toward Web site design however it has a lot of good standards

which is based on the research. They're used for human/computer interface. And I would encourage you to go to there, spend a little time if you're interested in menu design, how things might be improved where you have some trouble.

Okay our next slide, number 22, addresses how do we prioritize correction actions. And something that, again, was borrowed from the military system safety approach is this order of precedence to control hazards and to promote safety.

And from top down we have the most to the least successful means of addressing hazards. And naturally the first type to address hazards is to design devices with forcing functions that prevent errors. So it's not even possible to commit certain types of errors.

If we can't do that we would incorporate safety devices as necessary or where we're able. The next best approach is to have warning devices, alarms that will alert you to conditions that can result in harm or hazard. And after that is special procedures and training so we see that training and warnings and cautions are among the bottom here. And as practitioners we find that we often are not in control of the first steps, we don't design; we don't incorporate safety devices often.

We can put stickers on; we can change our procedures and training. But this points out the need to be in touch wit the FDA when we identify critical hazards because they can be effective in communicating these issues to a broader audience and getting effects to make changes which are more successful in controlling the critical hazards.

And it's important after any changes are made to validate these performance improvements by testing and less sometimes by introducing new technologies and making changes we can eliminate certain errors and introduce new errors of course.

So this is one approach we've taken here to helping to control some hazards and that is to develop some equipment safety bulletins. In this case this is a case which a hose was flexed too often. The technicians thought the hose could be taken off its valve to clean it. And eventually it led to a crack in the hose and it's used as a jet ventilator so it was important. There was some losses in oxygen to the patient when the hose was used.

So something as simple as this, a one pager that can be printed out and distributed to the users of specific devices may be helpful to alerting them to new issues.

So we do have to be careful when we make work-arounds. This happens to be two of the most important controls in a nuclear power plant. They're used to control the fuel rods to increase and decrease the fission activity. And the operators are looking up at a very complex (menu) on the wall so they can't look down. But there's two round knobs that used to be here that would get confused and activate the fast knobs - the slow knob which would - could get into runaway fission activity.

So they took it upon themselves to change the knobs this way. With the shape coding they don't have to look down. It's a good memory aid. There are no apparent problems with this work-around but we do have to be careful when we do work-arounds to consider what some of the unintended consequences might be.

So that brings us to the Appendix which I'll just show you on Page 26 is just the start of a number of issues or guidelines you can use to address procedures if you wish to use these to review your own procedures, develop a format which provides a guidance.

As you know the variability in the procedures you get from different manufacturers is very high and in some cases you might be writing your own procedures but in any case these are some steps in these following pages here you may use to get better control of the activities in your shop.

So that's the end of my presentation and I'll turn it back to Stephanie Joseph. Thank you very much.

Stephanie Joseph: Thank you, Peter. Our next speaker is Joseph Cafazzo. Dr. Cafazzo is Center Lead and Director of Medical Device Informatics and Health Care Human Factors at the University Health Network. He's also an assistant professor at the University of Toronto's Institute of Biomaterials and Biomedical Engineering.

He holds degrees in electrical engineering and clinical engineering from the University of Toronto and is a professional engineer. He completed his PhD in health informatics from the same institution. With that I'd like to hand it over Joseph Cafazzo. Joe, are you on the line with us?

Joseph Cafazzo: Hi, thanks. Thanks Stephanie. So today I'd like to talk about how you might use human factors methods in your own institution and apply it to a procurement process. And let's get into how the healthcare human factors group came to be.

We actually started out of a biomedical department, 50 staff over three sites. Our routes are in clinical engineering and biomedical engineering technology. What we identified in the late 90s is that we started seeing the signs of human factors problems.

And some of the signs we saw typically were things like an increase in the incidents of things like no problem found. So for a lot of you bio-meds you maybe familiar with this problem is where a system is brought down to you, you check it and you cannot find any functional defect in that product. So the staff is reporting problems that were - where there's seemingly none.

So I'm on Slide 4 at this point. So seemingly there is a defect in the product but you can't find the problem and after looking at it and investigating it further you just conclude that it is no problem found and it's due to user error.

So what do we typically do? Sorry, I'm losing my slides.

Stephanie Joseph: Sorry, what slide were you on Joe?

Joseph Cafazzo: I was on Slide 4.

Stephanie Joseph: Okay. There you go.

Joseph Cafazzo: Thank you. So what do we typically do with these situations? Well we try to remediate through training. And that has - may or may not be effective. And unfortunately we rarely notify the vendor of these problems because, you know, functionally there is no defect.

What we want to get at though with human factors principles is that, you know, looking at the total number of adverse events device failures actually

constitute a very small percentage of the total causes of adverse events and that even when a device is involved it's usually attributable to this notion of a user error.

And what we'd like to focus you on is this distinction between a functional and design defect. And so this issue of - this frequency of having no trouble found quite frequently is that, you know, although the device is functioning as it's designed we contend that this device actually has a design defect as a result of this that hopefully won't eventually occur in an adverse event.

So design defects may facilitate use errors which could lead to these adverse events and they can be just as serious as a functional failure and perhaps more because they're not as obvious.

So we're suggesting then, on Slide 8 is that devices that cause these use errors are as flawed as those that fail functionally. And what we'd like to talk about today is how we could prevent these systems from getting into our hospital system, into the healthcare system, and having a higher standard in terms of the evaluation we do during our procurement process.

So on Slide 9 is a typical procurement process which, you know, constitutes of vendor demos, trials facilitated by the vendor, somewhat unstructured. And typically we use surveys to indicate what the users' preference are. And so bio-med is typically involved in heavily in Stages 3 and 4 as indicated here.

Unfortunately as many of you may have experienced and as we have here in Toronto is that occasionally we pick products that don't work out and we have this buyers' remorse. There may be adoption problems which are actually quite prevalent, not so much perhaps in medical devices but in the information

technology areas, systems like CPOE have all kinds of problems related to adoption.

But generally, you know, with all technology we may be experiencing complaints. We see this occurrence of no problem found in the bio-med shop. And what this requires is more training and hopefully it doesn't lead to adverse events attributable to user error.

So how do we prevent error? Now this is not evidence-based but it is the prevailing wisdom of the risk management/patient safety community is that there is actually a hierarchy to the types of interventions that you can have to prevent these errors.

And if you look at the top of the list, computerization and automation is very high. But look at what's dead last, is training. And that's typically what we do to remediate on problems that we find with products after we've procured them.

So human factors at UHN started about seven years ago as a result of our interest in this area as well as looking at how we could evaluate our products that would eventually get into our system and having a higher level of scrutiny during procurement.

So we were fortunate to get some federal funding to build a usability facility. And this is absolutely not necessary in order to do this and I'll get to how you might do usability testing without a facility. But, you know, fortunate enough we were able to get a jump on this and have this facility.

And over the years we've slowly built up a team of 12 human factors specialists and it's a mix of individuals who have a background in human

factors engineering, cognitive psychology or clinical engineers such as myself.

And it was very deliberate to put this facility and this team right in the middle of University Avenue in Toronto which is situated amongst some very large teaching hospitals, Toronto General, Princess Margaret Hospital for sick children, Mt. Sinai. So there's, you know, we have access to 10,000 nurses, 1500 physicians, just steps away from our facility.

And the facility has the capability of recreating these clinical environments, some acute as the two on the top, some in the home environment such as this mock up of a home hemodialysis environment. And even some work that we did for the US military on the interior of a medical helicopter where we were testing a portable ICU system with ventilation and physiological monitoring.

So using human factors in procurement is that what we're looking at is actually doing a comparative evaluation of let's say a short list group of products of maybe two or three individual products. And what we'd like to do is conduct actual usability experiments in these labs. And so we design experimental tasks with the actual users be it nursing, physicians, pharmacists and so on.

And we typically test 8-10 users measuring things like task times, errors and classifying the severity of the error that occurs. And we try to have a lot more objective measure than what the typical preference - survey preference is that we typically use.

So here's a shot of - on page - on Slide 15 - of our usability labs with our human factors specialists behind one-way glass observing actual clinicians using the technology in a simulated environment.

Moving on to Slide 17 now. So specifically what we're looking at in these usability studies is some quantitative and qualitative measures. So we are measuring task completion time. We're looking at the task accuracy and the frequency of errors, the number of requests for help, number of attempts to correct these errors.

We have to rate the severity of these and assess whether or not this is actually an impact on patient safety. And we're looking at the workload difficulty because are very cognizant of the fact that this is making - this product may or may not be making more work for the individual. And obviously we still take into consideration this user feedback and preferences.

So some of examples from our lab on Slide 18 is an anesthesia information system. And we had actually great participation from about 17 anesthesiologists which was probably more than we needed in order to do the evaluation but there was a lot of interest in what we were doing here.

And we compared three products. And it was actually a very frustrating process because clearly our anesthesiologists were having a great deal of difficulty doing documentation on these commercial systems. And it was a very complex decision but in the end it was viewed that it was not going to be very beneficial to our anesthesia department to proceed. And so in the end of the procurement process we opted not to have any product use so they went back to paper.

We do a lot of work on infusion pumps. On Slide 19 we see here an infusion pump that has some advanced features including a drug library. I don't want to pick on any single vendor in this presentation. We've - every single product that we see through our labs has usability problems and it's just a question of

severity. But this particular device, the nurses were having difficulty actually find the drug libraries in the menu system.

On Slide 20 we see another infusion pump that has an integrated bar code scanner that was too difficult for the nurses to use; they ended up bypassing that process and doing everything manually just because they were frustrated with the use of the device. Also with this device there was some tasks that a couple of nurses had a lot of difficulty with and ended up accidentally infusing a bolus of the drug inadvertently.

On slide - I think I'm on Slide 21 now on the automatic external defibrillators. So you may have seen these devices in various places including your facility as well, they're becoming very population within hospitals as well. And the notion of testing these devices came to us but we were actually told that these are very simple devices; that they were designed for lay people and we were wasting our time doing usability testing on such a simple device.

And we were actually surprised to see what we came up with. These are our own nurses in our usability facilities doing a task of a simple resuscitation of the - a very straightforward what was asked of them. And we were quite surprised that nurses were actually having difficulty even opening the case creating delays in the resuscitation process.

Even before the device is turned on at this point, even the pads placement the nurses were having difficulty based on the instructions that were on the back of the pads, a lot of confusion in terms of the pad placement again, further delaying the resuscitation.

Here's a shot of that - the instructions on that pad showing the two sets of instructions that caused confusion in the heat of the moment. And finally this

last example on the AD is that this particular device had an audible cadence response that you used to time your chest compressions with. The one nurse under test she interpreted that cadence incorrectly and she thought it was an alarm system going off; she wanted to mute the alarm and she inadvertently turned the device off completely in the midst of the resuscitation.

We actually are in the midst of a very detailed evaluation of smart pumps. And I know that the audience submitting questions had a great deal of interest in smart pumps and pumps in general. And we are doing a very comprehensive study on behalf of the ministry of health here in Ontario. We're doing experiments with smart pumps, surveys, field reports and the results of our study will be published in the summer.

And some of our preliminary results on the usability of smart pumps is that what we found that these systems are really only effective when they're completely and properly planned including a lot of time spent on the design of those drug libraries, getting your pharmacist involved, having the ability of - and the infrastructure - the wireless infrastructure to update those drug libraries on a regular basis.

The use of soft limits seems to be only marginally effective in preventing adverse events. Certainly hard limits with prevent the person from bypassing the limits of the pump are effective but soft limits are easily bypassed and we don't see that as a great enforcement of those limits. And it's certainly, perhaps, just a design issue on how soft limits can be implemented. Also integration with (positation) ID and CPOE systems we think is eventually quite critical to fully realize the benefit of smart pumps.

As well is that we were quite surprised to see that, you know, smart pumps are meant to be safer in that you're programming the system as a dose rather than

a rate however nurses are still conditioned and - with their, you know, years of training are conditioned to program in rate. And they had a lot of difficulty moving away from programming pumps as a rate rather than a dose so this is an issue that needs to be addressed.

So when do we us HS in procurement? And we can't use it for everything obviously or we would be totally overwhelmed in a major teaching hospital. So we identify products that have a high risk of adoption such as CPOE systems and other IT systems. There's a financial implication, purchases of millions and tens of millions of dollars. And most importantly one - systems that we feel that have a clinical risk in particular, ones that have been implicated in the past for adverse events and certainly infusion pumps are one.

On Slide 28 I'd like to show you another slide here of sort of an updated version of what a procurement process looks like if it's user-centered. So a couple of additional steps in here which hopefully don't take a lot of extra time in the procurement process. But we've added a heuristic-based expert review which I won't get into too much detail.

But I really want to emphasize that inserting a usability test can be really helpful in the decision making process during procurement. So how do you do HF in your hospital if you don't have the labs and the staff? And just so you know that, again, back when we started this group we didn't have the facility and we didn't have the staff and this has happened over time.

But it is, you know, if you started the same way we did this is, you know, you do something as simple as engaging the users. And bio-med departments have great relationships with their clinical counterparts. And you need to really engage with the user in order to help design the experiments during your

usability testing and identify the common tasks and the tasks that are probably - have a high likelihood of use error.

And on Slide 31 is how you might seek out some expertise in your local area in order to get some help in doing this. Usually procurement processes are, again, financially high risk and if there is some funding in order to fund a graduate student as we did back when we first started - our first procurement process was started simply as hiring a graduate student in industrial engineering.

And if you, again, any urban centers should have an engineering school. And if you look in the industrial engineering department you certainly find human factors expertise there. There's also the computer science schools that also have people with HCI backgrounds. Psychology also - especially in the applied psychology usually have people who have these skill sets.

And even in the industrial design schools you'll find people who have this skill set in order to conduct usability testing. And so it's a great way of getting you off the ground.

After you complete this process and you have all this data and you've made the decision and, you know, it's very important that you share the data. And in particular we find that it was - it's been very beneficial to share it with the vendor. Sometimes the reaction is very positive and they appreciate the feedback despite the fact they may or may not have won the procurement. Sometimes it's somewhat hostile and questioning our methods in terms of making this determination.

But we find that this is raising the bar for most of the vendors in terms of having them - forcing them to consider these usability issues and their

products. And what we find also interesting is that most vendors already know of these problems; they're already starting to get field reports of these issues. And it's sometimes not new to them.

And it's very persuasive to have these video tapes and the audio recordings of actual users using their products in context because it's actually very persuasive. And unfortunately typically what we do is just anecdotal feedback to these vendors and it's not as compelling.

So what I'm encouraging everyone to do is consider like raising the bar on these vendors and have higher standards and creating a market force. So meeting these functional requirements is not enough. That user friendly, which is used quite frequently in marketing materials, needs to be demonstrable. And though usability testing this is an opportunity for vendors to actually show how user friendly their systems are.

And just as the other speakers have mentioned is that, you know, you should try to ask these vendors for their testing data. This is all required by FDA when - as they went through the FDA process they had to report on their human factors process in the testing that they did so it should be available to you as well.

So in the end what if you can't do this? Well there's still methods that you can use if you can't pull off a usability testing. There's a heuristic evaluation which I can't get into now but it is just using someone who's familiar with human factors principle and applying a general set of rules against the design of the device in order to make a quick determination of how user friendly a device is.

Also direct observation is good. And again before we had our usability lab is this is how we would actually conduct our evaluations is through direct observation. Now it's long hours in the operating room or wherever the technology might reside but we actually watched the system being used in context.

And obviously if we can't actually record it it's difficult to provide evidence but it's a good start just the same.

So on Slide 39, one of our first evaluations was field observations of usability testing. Not a full usability test but just a field observation of the - of using three different popular electro-surgical units. And we made a determination based on our observations in the operating room on the difficulty that the nursing staff had operating the device.

And, you know, what we found is that what we tried to do is make sure the vendors don't intervene when the nurse or the physician is trying - the surgeon is trying to problem solve with the device.

Another example of field observations in our pharmacy area is we had reported cases of severe repetitive strain injuries with the pharmacy systems. And we were quite surprised the extent that some of the pharmacists had to compensate for the system. And you can see this is a major work-around of trying to use, you know, sort of a foot method of operating the pharmacy system.

So I want to just close with a, you know, with a summary just reiterating how humans are fallible; we will always make mistakes, it's inevitable. And we need to demand of the technology that devices need to be designed to accommodate normal human behavior and the limits of human performance.

And so I'm trying to strongly encourage you to look at using human factors methods in your procurement process to raise these standards. Why we do it is to ultimately improve the user experience which will hopefully improve the adoption of the technology, improve the efficiency of the workplace, actually decrease training and ultimately improve patient safety.

So I'd like to sort of reiterate this notion of this market force in getting greater accountability for usability problems, demand greater than the mediocrity that we seem to see in a lot of medical devices and help creating this market force.

So thank you for your time.

Stephanie Joseph: Thank you very much Joe. Our next speaker will be Ron Kaye. Ron is a human factors expert with the FDA's Center for Devices and Radiological Health. He has a bachelor's degree in general biology and a master's in applied psychology and has worked in applied psychology of human factors for 25 years.

Prior to coming to FDA he worked on human factors and human performance issues of safety critical systems such as nuclear power plant control rooms, military, weapons and control systems, aircraft cockpit systems, air traffic control instrumentation as well as medical devices. And he's been with the FDA for 11 years.

So with that I'd like to hand it over to Ron.

Ron Kaye: Thank you Stephanie. Okay well we've had some good talks and some of the topics here I'm going to present have been discussed to some degree in various ways. I'm going to kind of give an overview of the fact that we at the

FDA understand human factors; we're doing something about it, a little bit about some of the main issues that bear on that program and what we can do with it in a very general sense and some definitions of some key concepts.

And in the limited time I have I'm going to try to get through some of that right here. And Dr. Wright gave a good definition of human factors engineering. This is very similar. It's a science, of course, that applies data on human capabilities and characteristics to the design and evaluation of systems and devices.

And it's about making products efficient, safe and easy to learn. And it relies heavily on methods of the behavioral sciences. And interestingly here perhaps for some of you is the synonyms, you've probably heard of ergonomics, feasibility engineering, user experience, design, user center design etcetera.

These terms come up in the context of doing what we can call human factors engineering in various ways and various parts of the process. They're essentially synonymous without getting into split hairs. But it's all, you know, about a similar thing which is what we can call human factors engineering; making good device designs.

And here at the FDA of course we're primarily interested in safety and effectiveness of those designs in terms of limiting or eliminating use related errors.

On the next slide there is a graphic with a dark blue top and a gray bottom. This is just a depiction of what we mean by the user interface or what in the military used to be called in various sexist terms the man/machine interface. But the interface is the dividing line between those and you can see at the top

the user. You can start to cycle on the left, perceives information from the device through visual and auditory displays, sometimes tactile even.

Next is the information process, what they do cognitively in their head making decisions about what needs to be done next and what the device is telling them. And then they control actions that input back in the device through that part of the interface. And the device receives that and decodes input electronically typically sometimes mechanically.

And may go - often goes through some processing perhaps software-based etcetera, controls the device, adjusts the device as necessary. And this cycle is what goes on while users are using a device. And to the extent that this cycle works well and that everybody's happy on both sides, the user and the device, we expect the outcome to be good. And when things aren't designed quite right, you know, at the point of the interface things can not go well for a wide variety of reasons.

But I'd like to add here that when we're talking about interface that, you know, really the interface of the device is, you know, often considered to be the displays, might be a display screen, individual displays, alarms, auditory feedback, etcetera. It's really often the user manual instructions for use, etcetera, basically anything about the device that communicates to the user about okay this is how you use me.

And that really is the interface, what the user detects about the device, using the device either generally and overall or on a minute to minute basis while they're using the device.

On the next slide a little carton with ants figures on it. This has been discussed, you know, Dr. Cafazzo mentioned this in terms of no problem

found. It's kind of a larger issue that permeates human factors and the recognition of use problems. And that is the tendency for - it's almost a philosophical outlook that people have or sometimes it's convenient to blame problems on the device.

Traditionally devices, you know, were not as numerous; they were good when you could get them, good to have. And it really was your responsibility to, you know, if you could use them and make them work that was good. If you couldn't for some reason, well, you know, things just didn't get done.

Now that devices have developed and become much more complex and often much more capable and much more demanding on the capabilities of human users the design - the way the interface is designed has a lot to do with what's going to happen whether the device is going to end up rolling away with the patient in it or overdosing somebody with radiation or drugs or what have you.

But so this is - this cartoon depicts kind of an overall and overarching issue that pervades human factors not just in medical equipment but in all areas of technology. I've seen it consistently.

And again Dr. Cafazzo mentioned the no problem found. And, you know, that's what we're talking about here. You know, there's a device that is reportedly malfunctioning. And then it gets tested by a bio-med department. It might get sent back to a manufacturer. They test it on the bench and it works perfectly there.

And the idea here is that often what's happening is that people are having problems using the device and may really operate as it should except that they unknowingly are making some kind of errors when they're using it. But of course, you know, that doesn't help the well being of the patient on the other

end of the device. So that would indicate some kind of difficulty with the design or some kind of flaw with the design. It's often a foot when you see things like this.

Getting into a specific definition of use error, this is from the AIME standard, (HE74) which came out in 2001. There are other definitions but they, you know, it's fairly similar. Use errors in act or an omission of an act that results in different outcome than intended by the manufacturer or expected by the user which may result from mismatched situations between user, man/machine interface - they use the old term man/machine interface here I see - task and/or environment.

The term user error and human error are no longer used officially. And in fact that's true, we do like to use use error rather than user error which tends to blame users. And human error which is looked upon by many people as just an inevitability. Use error is a phenomenon that we can deal with if we go about it in the right ways.

Next slide, human factors at the FDA; the way we see human factors here, first and foremost is the harmful errors especially with medical device use most often results from well intended use of a device. So we're talking about we're concerned with people who want to help their patients or home users who want to help themselves, they're not trying to sabotage anything or commit euthanasia with, you know, somebody or that sort of thing.

People who aren't often being neglectful and they're certainly not trying to be harmful. They're trying to do the right thing but because of the way the device is designed that does not come about. And again second point is really what I just covered, the flaws in the design with the medical device user interface permit and/or induce use errors, you know, permitting likely errors is one

problem area and in fact a arguably worse situation is when the nature of the device use interface actually compels the user to make an error and there are some examples of that. A little short on time so I'll continue here.

Systematic application of human factors can eliminate dangerous use interface design before new medical products come to market. And here at the Office of Device Evaluation I do review human factors components of new device submissions. And because we believe this we are looking for good work to have been done there for the purpose of making sure the devices are safe and effective for the intended users.

We also see human factors that - we also see that human factors can be applied to devices that are recalled because of use problems. And this comes up repeatedly and a device is out in the field, people are having problems with it, people are perhaps dying or becoming injured because of a design flaw. We have a recall, we coordinate a recall and the device manufacturer comes up with a strategy for fixing that user interface.

Well, okay, we've figured out the problem we're going to X, Y, Z and I'm always there to be sure to say - and make sure you test that to make sure that that's effective. But then when they do that the problem goes away. So, you know, if there's any - if there's any doubters about the effectiveness of human factors in fixing use related problems and preventing dangerous errors, I mean, it's well exemplified in these cases when they happen.

And finally it can't be overemphasized that warnings and instructions in user manuals can help but don't necessarily overcome flawed design problems and I'll discuss that again in a later slide.

The next slide with the ven diagram - this is from our guidance on human factors. Basically what it says - and this was also mentioned by the other speakers I think again Dr. Cafazzo particularly, that use related problems or hazards particularly for some devices are more frequent and they're more - and they should be more of a concern for all than the more traditional device failure hazards.

Oftentimes, again, when there's a problem with a device and somebody, you know, ends up getting overdosed or something horrible like that it's because of the way the device was used and the user did not want to do that and the device didn't have a piece fall off or a valve that didn't - ended up failed to operate, it was because of the use.

So the focus at the FDA over the past decade or somewhat more - well actually the last 30 years but it has been fairly slow until more recently but the focus for ensuring safety is shifting from device reliability to include use safety for medical devices.

We're also looking harder at the - and are more concerned with the necessity to validate device use for new devices and new device submissions particularly where there's a heavy interaction component and tasks that are critical.

We want to see evidence that users can use these devices under simulated conditions without committing - or particularly without making patterns of use errors that could indicate that the device could be very dangerous when it is out in general use.

And as far as the post-market or the Office of Surveillance and Biometrics where the MedSun program is the human factors program can help them. We

have worked with them in the past and intend to in the future to reduce or eliminate problems when users report them in various ways including MedSun constituents reporting problems. And once we're aware of the problem, you know, and understand it we can start taking steps to do something about it and hopefully fix that.

Often I'm asked for examples. It's difficult for me to provide them as much as - as many examples as I have. But sort of an anonymous situation that has come up and fairly recently is this, it's sort of a classic and very straightforward example of a design problem. And this has to do with the display of the time setting on a medical device.

And in this case you use the actual values that are displayed, the numerical values, you know, the one, two, three, indicating, you know, 1 hour and 23 minutes supposedly, of course that can change that would be some kind of an LED type of display on the device. With the label corresponding to that, hours, (pull) in minutes, abbreviations which is on the casing of the device.

And human factors testing which was done by, you know, a very competent contractor for this company after we had discussions about the previous testing that the company had done which seemed to be insufficient to me in terms of its methodology, it didn't go into much depth in terms of critical aspects of use.

So I suggested to them that for us to process their new device application that they would need to do some better human factor testing, they did. That testing came up with 3 out of 15 users misinterpreting this. They thought that was saying 23 hours which and of course that can be clinically significant depending on the device as you might imagine.

So there's - and so that's in the process of being fixed now. They have to change the design of the device because this is a bad design flaw that could cause problems. And, you know, we don't want to clear the device that has that - such a problem.

Here's our - kind of jumping to a different concept but, you know, in terms of hazard control hierarchy you've heard several speakers as well as myself saying that labeling is not often the answer. Here's a hierarchy in terms of desirability. The most desirable thing to do when there's a use related hazard is to eliminate that hazard through design.

And we go on down through the various levels of desirability next being protect or guard against that error, third being one, fourth train and instruct and finally modify use. And of course those are in order. This is not just for human factors, this is, you know, this hierarchy is used and has been used by safety engineers, you know, throughout that specialty area for, you know, mines and process control, environment. But it applies to medical devices as well.

Next slide, this cartoon - again this is another concept. And this is again something that's changing but like blaming the user the perspective of device manufacturers is too often as stated here; not always but still too often. And that is that they design, test and build high quality medical products and it's the responsibility of the users to avoid making errors with them.

And this is rapidly - well this is constantly diminishing and sort of the new enlightened view of, you know, the responsibility to make designs that support users and help them prevent errors, you know, being a desirable goal is replacing this. But still we run into this and perhaps I know better than anybody because I talk to these people and they say these things to me. And,

you know, it's always surprising how much of this residual viewpoint remains.

From the post-market perspective on the next slide, as far as use error goes, yes, there's quite a bit of it happening. You know, I have the picture of an iceberg to indicate that on the next slide I believe. It can - use error can be detected and if so it can guide effective corrective actions. Again it can be minimized or eliminated by design modification but the first step is to understand - and this is difficult - what actually is happening. And that's a big area of confusion.

Next slide shows the iceberg. Perhaps what we see in terms of use error and what comes to our ears and eyes at the center is maybe the tip of that iceberg; we all know that there's a lot more of it going on and that's just kind of a difficult aspect of reality.

The next slide of course, you know, the idea here is that use problems are subtle and they're complex and when you're trying to figure out what's going on you really need a lot of information often you need to know the context of use, you need to really almost know what was going on in the mind of the user as they were interacting with the device.

And so putting that puzzle together is quite challenging especially when you have on the next slide - this is a summary that was done a couple of years ago - the top 10 IV pump or infusion pump manufacturer reported use error codes. Number 10, no device failure; okay, there's a problem but no device failure so there we go; what do we do with that, you know, again that's like no problem found.

And we're into that deal but we don't really have much information if that's all they're going to report. Nine, unusual events, another, you know, perhaps limited in its helpfulness for figuring out what's going on. Device failure related to user handling. Use error contributed to the event. Device evaluated cause unknown. Use error caused the event. No conclusion can be, you know, a lot of vagary here with use error mentioned in this top 10 reported codes.

But you can see and, you know, considering what I've talked about and the other speakers is that use error is prevalent here and very - its' very compelling case that design and users is probably interacting often and a negative result comes out of that. And hopefully, you know, and sometimes we do figure that out when we can get the information to do it but of course it's very difficult and challenging to do that.

So reporting US MedSun constituents reporting use error problems to us identifying them and telling us about them is a big help. We can get valuable insights from you folks that we really can't get a well from - in - from other sources.

And following that we can work directly with manufacturers and we have and it's very good when we have a case and when we have information that we can say look this is what's happening; this is what they're telling us; this is the problem they're having, you know. And they're not kidding around; they're really having this problem. And that helps us talk to manufacturers and gets them to listen and then we can raise the priority of that and get something done; it's very important.

So that concludes my talk and I don't know where we are in time, probably a little over but I'll let Stephanie continue from here.

Stephanie Joseph: Thank you very much Ron. That's going to conclude our program. I'd like to thank you all for attending. Again if you have any questions about the program or you have questions outstanding from the program that weren't answered give us a call on the 800 number, that's 800-859-9821, once again 800-859-9821. And thank you all again for attending and that will end our program.

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