DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

WORKSHOP ON BEST PRACTICES

FOR REDUCING TRANSFUSION ERRORS

Volume II

Friday, February 15, 2002

8:30 a.m.

MILLER REPORTING CO., INC.
735 8th STREET, S.E.
WASHINGTON, D.C. 20003-2802
(202) 546-6666

Natcher Conference Center
Building 45
National Institutes of Health
Bethesda, Maryland

MILLER REPORTING CO., INC.
735 8th STREET, S.E.
WASHINGTON, D.C. 20003-2802
(202) 546-6666

C O N T E N T S

Panel Summary:

P R O C E E D I N G S

DR. LEWIS: Good morning. We had a full day yesterday and managed to keep to our schedule. So we set a standard for ourselves and we are going to try to keep that standard today.

Again, we have a very full schedule and less time to do it in, actually. So we are going to move right along. But there is still some time built into the schedule for people to ask questions. Everyone was rather shy yesterday, so I will encourage you to offer questions.

Mr. Wilzsck, who has been helping organize the conference, is standing over here. He is going to pass out cards so if you are a little intimidated to stand up and ask a question, you can write it down and someone will read it anonymously for you so that it can be addressed by the speakers.

We have no lunch break today. We are going to go right through and have a long morning in order to fit all the talks in.

Yesterday, we heard a lot about systems and how people can address their systems. Today, we are going to talk about some of the technology that might be applied to

improve those systems and to foolproof, if you would, some of the transfusion steps in both collection testing and transfusion.

We are fortunate to have Kay Gregory from the AABB as our moderator. She has offered to take the job of task master in keeping everyone on time. For those of you who don't know Kay, she is the Director of Regulatory for the American Association of Blood Banks.

Good morning.

MS. GREGORY: Thank you, Richard.

As Richard said, we do have a really full schedule so we will just go full steam ahead. Our first speaker is Pat Distler. Pat is the Vice President of Operations at the Blood Bank of San Bernardino and Riverside Counties. Pat is going to speak this morning about implementation of ISBT 128.

Pat is a very knowledgeable person on this subject. She has been involved with it almost from the very beginning and has been a member of the North American group that has put the specifics of how the bar code works together.

So, Pat,

Technology-Bar Coding

Implementation of ISBT 128

MS. DISTLER: Thank you, Kay.

[Slide.]

ISBT 128 is something I am really enthusiastic about, as you can probably tell as I go through this.

It is an internationally accepted standard for blood labeling. It has been accepted by the AABB and the FDA. It utilizes Code 128 bar code symbology. This is a bar code symbology that is used by many industries.

Certain data identifiers were set aside for blood banking, so that with those data identifiers, you can tell that this is indeed a blood product and they cannot be used by another industry. However, I will mention that ISBT 128 is actually symbology independent, which means if we move later into 2D bar codes, or into radio tags, the codes that have been developed can still be used.

It also replaces the current Codabar technology.

[Slide.]

This is what the labels look like. The one on the left is a Codabar label that you are pretty familiar with. The one on the right is an ISBT 128 label. They don't look

a lot different. The one on the right probably looks a little bit cleaner, there is a little less information on it.

One of the design features of the one on the right is that it is a 4 by 4 inch label, and it can be printed either as a 4 by 4 or it can be printed 2 by 2 in either direction, so that you can go crossways or up and down.

One of the other differences you will see is where the out date is. It used to be on the upper right. It is now in the middle right, and that is because out date is related to the product code, not to the ABO, and this could prevent one of the errors we are familiar with where perhaps we have irradiated a red cell product and not changed the out date.

You can set up your equipment, so that every time it prints out a new product code, it also prints out a new out date by doing the 2 by 2 across the bottom and picking up both, and by setting up your processes that way, you have got process control and you can ensure that that out date will always match the product code.

[Slide.]

One of the big differences in ISBT 128 is the unit number, the unit identification number. It is much longer, and it is much longer for a reason. Embedded in the unit number is the blood center that drew it anywhere in the world.

The first digit, the first character is a letter, in this case a W. W and K are for the United States. All of the W's will be for the U.S., about half the K's will be, a number set with the K's.

The next four digit is the center ID, so that worldwide, that center can be recognized as having drawn that unit of blood. The database for which numbers go with which centers is kept by ICCBBA and becomes your possession of you get a copy of it when you register.

Next, comes the year, which is represented 00 here, and this year would be 02. Then, a six-digit serial number, which is what we are familiar with; a flag character, which is at a right angle. Flag characters are for various process control reasons. Like this is the platelet bag, this is the primary bag, or this is the EDTA tube, this is the red top tube.

Finally, there is a manual keyboard entry check digit, which I will be talking about a little later, and that's inside the box.

[Slide.]

There were a variety of problems with Codabar. There is lack of ongoing support, so it is not really growing as the industry has grown. There are data security issues, traceability issues. There is limitations in the number of bar codes that can be assigned. There is an inability to encode data for autologous collections, and it has very weak process control capabilities when compare to ISBT 128.

[Slide.]

Because of these reasons, the ISBT, the International Society of Blood Transfusion, asked its Working Party on Automation and Data Processing to look into something new.

This committee consisted of people from Europe, North America, Australia, and Hong Kong, and together they selected Code 128 for blood labeling because of many of its data security features.

[Slide.]

The first thing to address was its ongoing support because any symbology, any codes that we used would have to be able to grow as new products came out and new processes were added.

The International Council for Commonality in Blood Bank Automation (ICCBBA) was created. This organization is based in the United States, but serves worldwide. It collects fees from the users and it uses these fees to maintain the databases, to support advisory groups who respond to changes in the industry, and it serves as a resource for blood and tissue organizations.

[Slide.]

Another of the problems with Codabar was data security. Substitution errors could occur, and there is no check digit for keyboard entry.

[Slide.]

By "substitution errors," I mean that on the tube it may read GS12345, where the equipment, the scanner reads GS12445, and sometimes this is even reproducible.

[Slide.]

We are about an average size blood center. We drew a little under 100,000 units last year. I calculated

to get one unit of red cells out of our blood bank, we scan a unit number 25 times through testing and processing release of the unit. That means 2 1/2 million scans a year if all goes well.

How often do errors occur? I don't label a lot, but after 9/11, like many of us, I got to do things I hadn't done in years. I labeled about 1,500 units of blood over a week's time. I saw twice where I scanned the unit number, looked at my computer screen, it was not a match. It gave me the wrong ABO type. Part of our SOP has our users looking up, but that is a manual process, and it has errors.

We also have built-in redundancies. That unit is actually scanned three times after the final label is applied to avoid this type of error, but other programs aren't quite as robust, such as fractionation, and we have had to build in manual check steps, workarounds, to verify that we haven't scanned and gotten the wrong unit number on our documentation. So that is a problem with Codabar.

[Slide.]

ISBT 128 avoids this. Each character, each number in that code has three separate self-checking features, and if something doesn't add up, an error message occurs.

Likewise, there is a built-in check character for the entire message, so the entire unit number has to read correctly or an error message occurs, and that is really what we want.

We know it is not going to scan perfectly every time. Maybe the label is a little bent or smeared, maybe the scanner is not set perfectly, but what we want to happen is an error message, not the wrong number being read.

[Slide.]

There is also a check digit for manual keyboard entry. Now, we would much prefer that everyone scanned our labels using a scanner, but sometimes that is not possible, there has to be a keyboard entry.

ISBT 128 offers a check digit, which is the one in the box at the end, and if all the numbers have been entered correctly, if there has been no transposition through an algorithm, it will add up to the final character, and when you enter in the S in this case, you will get an error message if there has been any error in data entry.

Now, right now this exists for the unit number, but in the next specification that is coming out, this is going to be optional for just about all the data fields.

[Slide.]

There are also traceability issues with Codabar, and these are related to the fact that unit identification numbers are not unique.

[Slide.]

Both we and the San Diego Blood Bank have a unit number E12346. We are neighbors, there are hospitals that are on our borders that receive blood from both of us. Likewise, a single lab does testing for both of us, and we both send our plasma to the same fractionator.

[Slide.]

There are obviously workarounds and what we are all familiar with on a blood label is a unit number in the middle, refers to the center that drew it, and if we want to renumber in order to avoid duplication, we can, and we have to put the name of our blood center on that extra label.

We had a short name that would work pretty well, but we have got this really long name that there is no way that we can get it onto a blood bag label in that little corner, so we have to abbreviate.

Now, all of the laboratories that we send our blood to, I am sure are quite familiar with our unit number, and they pick up on the way on the left very easily that

that is the local identification number, however, I can't be sure that nurses on the floor in the ER and the OR are always writing the right unit number down in their records.

[Slide.]

Likewise, we have had to do a workaround for our laboratory specimens going in, because we, in San Diego, send to the same laboratory and because we have duplicate numbers, we have to add what we call a region code. The 052 goes in front of the number on the tubes that are going out.

Then, they test actually under a different number than our records show. When those test records come back, we have a computer program that strips the 052 away, so that it can go in and be given to the right unit number.

The problem with this, or course, is we can't always get it right. Even though we have that cute little test tube icon, so that the collection staff can tell this is a sticker that goes onto the tube, the others go onto the bag, we get a certain number of errors where they pick the wrong sticker and put the unit number sticker on the bag or the bag on the unit, and we end up losing it if it's going onto the tube because the laboratory cannot test a specimen that is not properly labeled, and if it's on the bag, we

still lose it because we don't have a policy of relabeling our bags.

[Slide.]

Another problem is that in the 21 years, 22 years now that Codabar has been around, centers may use a number more than once, and this can create problems for the hospitals if they have systems that don't allow for duplication.

Further, some of us are about to run out of numbers. We have computer systems where we have brought over legacy data from old systems, we have already used that number, we are not allowed to use it again, and we are simply going to be running out of numbers.

So ISBT 128 addresses this. As I had mentioned before, the first four digits, the letter and the first four digits indicate which center drew it, so that means San Diego and we cannot have the same numbers. The next two, the 00 in small print is the year.

[Slide.]

Therefore, we have a unique number worldwide every 100 years. It eliminates the need to re-number units, it supports centralized testing, which is becoming more and

more a common thing, and it also supports international exchange of blood.

This is especially important in times of war. A lot of this came about because of the Gulf Storm War as the military received blood from all over Europe and the United States, Canada, and Australia, and had duplicate numbers.

[Slide.]

Another problem with Codabar is its limitation in product code assignments. It began life as a structured code and each of the five digits, each place had a special meaning. Well, that could not support all the products. When this was developed in the seventies, we never believed that we would be leukocyte reducing, irradiating, rejuvenating, freezing, deglissing, and aliquoting a unit of blood, and it is simply not set up to do everything that we do today.

Some of the problems is it doesn't generally distinguish between open and closed systems, so that if you have a red cell that has been created in an open system and has a 24-hour out date, it has the same bar code as something that has a 42-day out date.

It doesn't encode for volume, which is an issue with red cells when you have 500 ml collection and 450 ml collection, and it also aphoreses even more so where a 600 ml bag of plasma has the same unit number or same product code as a 200 ml bag of plasma.

[Slide.]

It also doesn't encode for an anticoagulant, so as one example here, we have a CPDA and a CPD plasma both with the same product codes.

[Slide.]

One of the problems with the limitation will be as we move on into progenitor cell products, Codabar may simply not be able to be versatile enough to have product codes for everything, where ISBT will have no problem with that.

[Slide.]

Another problem is the inability to encode autologous data. We are all pretty familiar with the way Codabar labels appear. On the left is a label that we are supposed to fill out for autologous units, handwritten for the name, the ABO, the hospital. I am sure all of us have seen mistakes made in our centers and misspelling a name.

When Codabar was developed, we might have seen two or three autologous units a year. Now, they represent 5 percent of our collections. Additionally, if we need to add a biohazard label because the unit is positive for surface antigen, and we are sending it out, that is a sticker that has no bar code, so we can't verify that it has actually been added.

Again, in the seventies, we never dreamed we would be sending out units that were positive for hepatitis.

[Slide.]

This is what the ISBT 128 label will look like. The ABO is computer generated. The biohazard, if it belongs there, will be generated by the computer, and the recipient information can also be printed by a computer.

[Slide.]

Now, obviously, in all of these things, the application software has to support it. ISBT has standardized it, it has made it available, but the software vendors will have to incorporate some of the process control issues into their software.

[Slide.]

Other control features are the encoding of the expiration time, concatenation, and encoding of special testing.

[Slide.]

Right now if you look at a Codabar label and you would see the eye readable, you may think that the time is there as in this example.

[Slide.]

However, if you read it on your computer, you will find out the time was not encoded, only the expiration date.

That is partly a real estate issue. In order to get all that information including the out date time onto a label, the label would probably wrap all the way around the bag and Codabar, and we can't do that because we have to be able to see if those red cells look hemolyzed or there are bubbles in them.

[Slide.]

What ISBT 128 offers is double density. On the left, the Subset C is a high density, a double density code versus Subset B. ISBT 128 has both, so if it gets to a point where there is not enough space for the information you want to encode, it switches to the double density, and

you can get twice as much information into the same space. That is what allows ISBT 128 to include an expiration time, as well as an expiration date.

[Slide.]

Concatenation is also available. This is the joining together of data from two bar code symbols and interpreting them as a single message, so that on the label, the unit number and the ABO are scanned, if your software allows, as a single bit of information, likewise, the out date and the product code.

Again, if you haven't chosen to print out a new expiration date every time you do a new product code, if you set up your computers to require that both be scanned together, it could eliminate any errors.

[Slide.]

The labels which can be concatenated are the donation ID number, the unit number, and the donor ID; the donation ID and the confidential unit exclusion on the donor history card; the donation ID number and the ABO; and the product code and the expiration date.

[Slide.]

Another feature that is going to be very nice and is just finishing with its development is some of the special testing information, CMV, red cell phenotype, and HLA can be bar coded.

[Slide.]

What we are used to seeing, many of us, is the CMV, which is just a sticker on the unit of blood.

[Slide.]

With ISBT 128, it is bar coded and it prints out if that information is in the computer.

[Slide.]

For antigen screening, again, a handwritten sticker that goes on.

[Slide.]

HLA, we happen to use the tie tag, and I am sure others are doing something similar. Once again, handwritten, no way for the computer to verify that the correct information is on the label.

[Slide.]

With ISBT 128, it is encoded.

[Slide.]

This is a genomic HLA type, which is why it is so long. It goes in the lower righthand corner. Again, it is being printed out by the computer with the proper software, so that there can be no error.

[Slide.]

There are a lot of reasons--and I have gone through just a few of them--why ISBT 128 seems to be the better system. It provides better data security, better traceability, better product identification, it allows for autologous or directed unit identification. It has many process control features.

[Slide.]

"Because the European Blood Alliance and the European Plasma Fractionation Association consider the use of the international ISBT 128 standard a definitive improvement in the quality of the operations of blood transfusion services and plasma fractionation organizations. It is recommended that all blood transfusion services and plasma fractionation organizations register with ICCBBA and start planning to implement ISBT 128 in their operations."

This statement came out in June of 2000.

[Slide.]

There are a lot of European countries that either partially or fully implement it, and by "partially," it means sometimes that some facilities in that country have done it and others have not, or it means they have done it in steps, such that they use the ISBT 128 unit numbers first and added product codes later.

[Slide.]

We have been using Codabar at least since 1980, and I don't want to put it down. It has been wonderful. From what was there before it, it was a tremendous improvement, but it's 2002, and life has gotten a lot more complicated.

We really need to be able to encode more information on that unit of blood in order to ensure accuracy.

[Slide.]

In conclusion, I think ISBT 128 is an extremely powerful tool that can help us with process control and help eliminate errors. It is just a matter of choosing to use it.

Thank you.

MS. GREGORY: The next speaker is Elizabeth Callaghan. She is from the Office of Blood Research and Review at CBER, and she is going to tell us a little bit about a view of ILET 128, what might be happening in the way of guidance and/or regulations.

Betsy.

FDA ISBT Guidance/Regulation

MS. CALLAGHAN: Good morning, everybody. I would like to thank Richard for inviting me to present at this very interesting and informative workshop. I think a lot of very important information is being shared, and I think we will gain a lot of insight.

[Slide.]

What I would like to present today is FDA's position on ISBT and bar coding. FDA published a labeling rule in October of 1980, which included a provision for requiring the use of bar codes.

The proposed rule required the container label for blood and blood components, the transfusion, to contain encoded information in the form of machine-readable symbols, approved for use by the Director and the Bureau of Biologics.

The bar code symbology that was approved by the Bureau was ABC Codabar which was chosen because it met rigid standards of readability and had a low error potential.

[Slide.]

The required bar code information that was considered critical in the proposed rule included the proper name of the product, the type of anticoagulant for whole blood and red blood cell products only, the collection center identifier, the unit number, and the ABO and Rh group of the donor.

[Slide.]

We received 11 comments to the docket regarding the bar coding requirement in the proposed rule. The majority of the comments indicated that the additional expense of encoded labels could not be justified by any potential benefits especially for establishments that were not computerized. Sound familiar?

[Slide.]

In August of 1985, FDA published a final labeling rule and responded to the comments received by changing the wording the bar code provision from "shall" to "may." This change allowed computerized establishments to voluntarily

adopt the use of the encoded labeling information along with the eye-readable information while not requiring establishments that were not computerized to endure the expense of installing a computer system.

However, included in the final regulation was he use of the document entitled, "Guideline for the Uniform Labeling of Blood and Blood Components." This guideline incorporated container labels with bar code symbology.

In addition, label manufacturers made obtaining bar-coded labels very easy, so essentially, all the units in the United States soon included ABC Codabar symbols. Over the years, as Pat just explained, blood banking has evolved into a complex entity with international ramifications.

As you have heard, ABC Codabar, although successful, can no longer keep up with the increased demand of our complex international blood banking community.

[Slide.]

A uniform system of labeling was designed to overcome the shortfalls of ABC Codabar, and it was developed by the International Council for Commonality and Blood Banking Automation.

A draft revision of the standard was submitted to FDA for review and acceptance. On November 21st of 1998, FDA made a copy of the draft standard available on its web site for public comment, and in a Federal Register notice of November 23rd, 1998, FDA published a Notice of Availability of the draft standard.

[Slide.]

Of the 16 comments we received, 11 of them strongly supported the implementation of ISBT. After reviewing the comments, FDA published in June of 2000, A Guidance to industry entitled, "Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components."

This Guidance stated that FDA recognized the ISBT Standard Version 1.2.0 as acceptable except where inconsistent with the regulations for labeling blood and blood components in the United States.

[Slide.]

At the publication of the guidance document, we had identified two regulations in 21 CFR 606.121 that were inconsistent with the ISBT standards. There was a third minor inconsistency which I will go into in a few minutes.

[Slide.]

The two regulations identified in the guidance document were: 21 CFR 606.121(d)(2), which requires that specific information on the container label be printed in solid red; and 21 CFR 606.121(e)(1)(ii), which requires the name of the anticoagulant to immediately precede and be in no less prominence than the proper name.

[Slide.]

Due to these inconsistencies with the regulations and the CFR, manufacturers who plan to implement the ISBT labeling standard have to request an approval under 21 CFR 641.20 from FDA for an exception or alternative to the labeling regulations.

[Slide.]

On January 10, 2001, FDA published a final rule entitled, "Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma," confirmation in part in the technical amendment.

I do want everybody to understand that we spend nights dreaming up these titles, just so you know.

This rule changed the requirements in 21 CFR 606.121(d)(2) by adding the words in solid black to the

statement. This change allowed for adherence to ISBT standard without the need of a 640.120 variance approval and made it easy to use the on-demand printers, which usually only print labels in black.

This final rule also changed 21 CFR 606.121(e)(1)(ii) by removing the reference to the names of specific anticoagulants. This change would allow more flexibility to the acceptance of new anticoagulants or any name changes to existing anticoagulants, but it did not address the placement of the anticoagulant name as a modifier consistent with ISBT standards.

The rule continues to require the name of the anticoagulant should immediately precede the proper name of the product, so a variance to use ISBT must still be requested.

[Slide.]

The third minor inconsistency with FDA regulations as they are presently published in the CFR is the use of the phrase "Rx only" on the container label consistent with ISBT standards. 21 CFR 606.121(c)(8)(i) requires that the statement, "Caution, federal law prohibits dispensing

without a prescription" be on the label of transfusible products.

As the standard practice in the medical community and to be consistent with the FDA Modernization Act of 1997, the phrases "Rx only" and "Caution, federal law prohibits dispensing without a prescription" are considered equivalent. So the use of either statement on container labels have been approved by the Division of Blood Applications.

[Slide.]

So, where do we go from here? As part of the Blood Action Plan, we are presently working on a new proposed regulation that will revise the labeling requirements in the CFR.

Some of the changes will allow for the use of ISBT standards without having to request approval for a variance under 640.120. The three changes we are currently planning on putting in the proposed rule that specifically address ISBT are: 606.121(e)(i)(ii). We currently plan on proposing to remove the phrase immediately preceding and in a less prominence then, so that the regulation will only require that the name of the approved anticoagulant be on

the label, but will not specify the location or the size of the font.

606.121(c)(2). We currently plan on proposing to amend the regulations by replacing the word "registration number" with "unique facility identifier." This change will allow manufacturers who subscribe to ISBT to use their ISBT identification number on their container label while still allowing manufacturers who do not subscribe to ISBT to continue to use their FDA registration number or, if applicable, their license number.

21 CFR 606.121(c)(8)(i). We currently plan to change the phrase, "Caution, federal law prohibits dispensing without a prescription" to read "Rx only."

[Slide.]

This proposed regulation is in the final stages of preparation and should be out of CBER soon--she says hopefully. The rule, as it is being written now, will continue to say that bar codes may be used, not must be used, however, CDER and CBER are working on a proposed regulation that will require bar coded information to be printed on the labels of both drugs and biologics. That proposal will include blood and blood components.

Thank you.

MS. GREGORY: Since we are right on time, maybe a little bit ahead, I think if there are any questions on this particular topic right now, one of our speakers may need to leave a little bit early, so we would like to give you an opportunity to ask questions.

Richard.

DR. LEWIS: I want to ask Pat Distler if she had any information on use of the ISBT labels at the point of patient contact. We heard a lot of information yesterday about how administration of the units was a source of error, and how applicable is the ISBT 128 to that scenario?

MS. DISTLER: Right now, ICCBBA and NATAG are trying to work with NACCLS, that establishes the standards on how specimens for patients are labeled, so the two groups are working together, and this is the intent, is that there be patient identifiers and the two be linked.

DR. AuBUCHON: Jim AuBuchon, Dartmouth.

A question for an appropriate person from the agency, I don't know if you would like to take it or not. Since ISBT 128 has several recognized advantages over Codabar, and if the Agency is considering requiring bar

coding of all blood components anyway, would the Agency consider requiring ISBT 128 as the best system to deliver what is intended by bar coding?

MS. CALLAGHAN: Because the ISBT coding system is not FDA's, but belongs to a separate entity, our Office of Chief Counsel has said we can accept it, but we can't require it because if they make changes that we don't agree with, by requiring it, trying to change a reg where we don't agree with something anymore is, believe, very difficult.

So, we are allowed to accept it, but we are not allowed to require it because it is not ours.

MS. GREGORY: I have a written question here. 128 appears to be initially at least a blood center issue. The question is, when are ARC and the ABC blood centers going to convert to this?

MS. DISTLER: That is the big question. Blood centers are having to change their computer systems in order to make this happen. It is not enough to merely read the codes in order to take advantage of the process controls that are created through it, there is a lot of software programming that has to be done.

I think that is really what is holding it up, it is getting all that done. Each of the ABC centers, I think are each progressing at their own pace. The Red Cross will have to speak because I cannot speak for them at where they are in the process.

MS. GREGORY: Another question. How much will conversion to ISBT 128 cost for a transfusion service?

MS. DISTLER: That, I really can't answer. A lot of the vendors are already doing this. It is already being incorporated into the fees that we are paying annually for maintenance of our systems.

Certainly, with my blood center system that is the case. Because this was an AABB standards recommendation, that fell under a category that it is put into the annual fees. I know many of the transfusion service systems are also in the process or have already written the software, so some of that may have already been paid, but no, I don't know what each company is going to be charging their customers.

MS. GREGORY: I think maybe this one might be for Betsy. Will all drugs use ISBT 128?

MS. CALLAGHAN: The joint proposed rule that CDER and CBER are working on haven't made a final decision as to what symbology they intend to use on the drug labels. They are not even quite sure what they are going to require, whether it's just the NDC number or the expiration date, and the lot number or just the lot number and the NDC number.

There is a lot of decisionmaking going on right now, so I am not sure what drugs is going to use, but we will still accept ISBT 128 as the method to use.

MS. GREGORY: Has anyone mapped Codabar-labeled blood products to those that will use ISBT symbology? If so, is this work product one that can be shared with others, and how can we get it?

MS. DISTLER: No. The problem is there is not a 1 to 1 relationship between Codabar and ISBT 128. In Codabar, when you do an aliquot, it actually gets a different product code. In ISBT 128, there is three additional digits after a product code that allow for divisions.

In Codabar, it doesn't distinguish between CPD and CPDA1 for platelets and plasma, in ISBT 128 it does, so there is not a 1 to 1 conversion.

MS. GREGORY: I think this is going to be the last question. Transfusion services are trying to figure out where we fit into this. What do we have to do to convert or be able to use ISBT?

MS. DISTLER: Probably you need to be talking to your software vendor. They have the answers for your particular system.

I would like to have one more comment about the cost issue that was raised before. We are spending an awful lot of money right now on following up on errors on things like a CMV label that was applied to a unit that shouldn't have been in that type of thing, so there is going to be cost savings that are kind of soft and hard to calculate, but many of the errors that we saw yesterday in the transfusion service could be corrected by ISBT 128, and there is a lot of hours, labor hours, going into those errors.

MS. GREGORY: I would add just one more thing, and that is, that a couple of years ago, the AABB put together a task force to work on an implementation plan for ISBT 128. That implementation plan, I believe is still posted on the

AABB web site, and it weighs out all the steps that you need to consider in order to get ready to implement.

So you might take a look at that web site, and you can find some information there. If you can't, if you contact the AABB directly, we will see what we can do for you.

I would like to thank both of our speakers. I think they did a great job of telling us about ISBT 128.

Now, we are going to move on and talk about some technology trends. You remember yesterday we saw some examples of how to design things, so that they would fail when we wanted them to fail, et cetera, but they were generic examples.

I think this morning we are going to hear more about things that are more directly applicable to transfusion services.

Our first speaker is Dr. Jim Stewart. He is the Director of Core R&D at Abbott Diagnostics Division. He is going to talk to us about process control and how they design the PRISM system.

Technology Trends

Process Control by Design to Reduce Opportunities

DR. STEWART: Thank you. It is a pleasure to be here this morning and have an opportunity to talk a little bit about how advancements in technology can contribute to the ability to reduce errors.

Over the past few days we have heard about a number of different factors that are important to contributing or managing error reduction, things like human factors, system analysis, system engineering, failure modes, effect analysis, and the need for process controls and, where possible, multiple redundant types of process controls that can help be the failsafes for minimizing or eliminating types of errors.

[Slide.]

Today, I would like to share with you some of that type of thought. Many of these factors and approaches were utilized in the design and development of the PRISM system, which is a device for infectious disease testing within the transfusion laboratory.

[Slide.]

To just very quickly give you a sense of what the basic elements of this technology are, first of all, it

represents a fully automated system. Everything that is required for processing infectious disease testing on a blood sample from the sample pipetting to the process and delivery of the reagents in the assay, to the reading of the results and the determination of validity is contained within a single instrument.

It is based on new technology for the blood screening market, that is, being microparticle based and using chemiluminescent detection.

What I will highlight today is really some of the design features around process control as they contribute to reducing error, and contribute to a design which is tamper-resistant and enhances the ability of the laboratory to comply with good manufacturing practices.

[Slide.]

This is a cutaway cross-sectional view of the PRISM instrument. Just to give you a sense of how it operates, there are six independent immunoassay channels, represented by the red bar here, which are where the actual assay processing begins

Trays are loaded into this end of the instrument. As they progress through, the operator puts racks of bar

coded samples that are automatically read as the racks are entered into the instrument, and the pipetting is done directly into the trays.

This area right here is actually a blanketed heater channel, and the trays move down the channel in discrete 40-second instruments, so that elements of incubation time, incubation temperature are very carefully controlled by the instrument without the need for an operator to be moving trays and using multiple different pieces of equipment.

As different reagents are needed to be added, the fluidics are built on-board to deliver those at the appropriate steps. The reagents themselves are stored on-board the instrument in refrigerated storage, which eliminates the need for bringing reagents in and out every day.

Ultimately, in a chemiluminescent system, you are looking for optical light detection, and that is done here with computer control.

[Slide.]

Really focusing on how technology like this and automation can contribute to reducing errors, we really look

at a number of different factors that we have been talking about here the last day or two, and that is, system factors, what level of process control do you have, how much operator intervention of interaction is required in the processing of results, and in terms of the assays, which we will not talk about today, that being the overall sensitivity, specificity, or reproducibility of the assays.

[Slide.]

There are a number of ways in which technology like this can contribute to enhancing process control, first of all, be eliminating a significant number of the manual steps and instrument hands-on types of steps that are necessary today.

Secondly, by standardizing the methodology. Third, by incorporating into the process, electronic monitoring and multiple redundant controls in an effort to make sure the integrity of the testing process is maintained, and in capturing that information both as an electronic batch record of the test process itself, and providing the laboratory full documentation of the results.

[Slide.]

Let me expand on this a bit. In terms of the elimination of steps, PRISM does represent a walkaway technology. As I mentioned, everything is automated from the sample pipetting to the reading of results.

In practice, what that has shown is at least a two-thirds reduction in the number of steps, both operator- and instrument-related steps that are needed to process samples in the laboratory.

Being able to run up to six different assays within the instrument at one time, all off a common threshold, it eliminates some of the multiple different types of pieces of equipment and different procedures and SOPs that are required today for processing the same infectious disease assays.

[Slide.]

Standardizing the methodology in effect then gets rid of some of those. You have assays today, as you well know, that have different incubation times, different temperatures, some that require shaking of the incubation, some not, some with pre-dilutions of samples, others not, and it can be a very confusing setup to manage and having to

manage that through both the training of the operators and standard operating procedures within the lab.

The advantage of this type of technology is it takes a lot of that manual decisionmaking and operator judgment out of the equation.

[Slide.]

In terms of electronic monitoring of the testing process, this becomes important because if you don't have an operator who is physically overseeing every single step, you need to know that the instrument itself has been designed to be able to check and double-check that steps are done correctly.

The failure modes effects analysis comes in here, what could go wrong in particular steps when you have an instrument doing this, and how do you build in some of those elements. A handful are mentioned here including maintaining positive sample identification, being able to verify that sample dispensing has happened accurately, monitoring reagent additions, and tracking the validity of the run itself, and if errors are occurring, being able to identify them and record them.

[Slide.]

There is a lot of information that gets summarized as part of these test results, and this technology is able to capture that information automatically in tracking assays specifically, the operator, date, time, and instrument used, lot numbers that are utilized and the expiration dates of those lot numbers are automatically tracked, the control and calibrator data associated with the run is captured on a report automatically, along with the sample ID and the specific data and results.

Should there be an error code that influences whether a particular test result or the entire run is available, that is recorded. In addition, the instruments keeps an event log that basically enables the laboratory to track every event, every operator set that is being done to that instrument from the time an operator comes in, in the morning to set the instrument up, to any maintenance they may do is all recorded, and the ability of the laboratory to monitor that.

[Slide.]

If you look at the overall testing process and being able to have adequate process control, this schematic basically takes you through the different steps for doing

the infectious disease testing - managing the sample identification, getting it pipetted accurately into the reaction trays, managing the reagents that you will utilize in terms of having the right reagents, making sure there are a master-lotted set of reagents, and making sure they are in date, making sure they get dispense at the appropriate times and in the appropriate volumes, handling the actual reaction trays itself in terms of the incubation and the physical movement, as well as all of the data reduction parameters for reading the results and being able to determine validity and automatically determine whether a sample result can be reported versus having to have any type of operator judgment or intervention into the process.

Of course, this cycle is repeated thousands of times on the multiple tests including if retesting is necessary.

[Slide.]

I won't go through this in its entirety, but what this is meant to show is that for each of those steps that I just highlighted, there are a number of highlightable controls that have been built into this type of technology to ensure that the integrity of those steps is maintained,

for example, under Sample Identification, we heard quite a bit just now about bar code technology and what a powerful tool it is.

PRISM is compatible with the ISBT 128 symbology and uses the checksum type features that was reported to verify the bar code both on its entry into the instrument on any internal communications within the instrument and again, finally, when the sample information is sent to the laboratory's host computer system.

In terms of pipetting, the sample manager itself has sensors that are built into it to ensure that it is pipetting accurately from the right tubes and that on both the aspiration of the sample and the dispensing of the sample, pressure monitors are used to verify that the volume is accurately being delivered. Should you have clots, should you have bubbles, this technology has been demonstrated to be able to detect those without having to rely on an operator to somehow catch that, that there was a short dispense.

Reagent management itself, I will talk a little bit about again a slightly different use of bar coding

technology to help the laboratory managing reagents on a daily basis.

Reagent dispense and the multiple different ways, from monitoring the pumps themselves to actual direct dispense verification to ensure that reagents are dispensed properly.

The key really with reaction tray transport, as I showed you, is that in this technology, there really is no hands-on operator need to move trays from one place to another. Once the tray goes into the instrument, the operator does not touch it again until they empty the waste container at the end of the run.

As a result, timing, temperature do not need to be manually checked, manually written down. The instrument is capable within plus or minus 1 degree of know whether the temperature is in, and should it go outside that range, would shut the run down completely, and no sample results would be made available.

There are a number of data reduction checks as you look at the photomultiplier accounting that enable verification that the assays themselves have performed as expected.

[Slide.]

So there are a number of contrasts that one can draw for these different steps between this type of technology and what is currently available, having built in an automatic bar code reading versus manual. There are semi-automated procedures for bar coding reading today, and the verification of those bar codes at multiple points in the process.

Also, importantly, once the sample is in the instrument, not having access to inadvertently or purposely change the order of tubes or somehow get them mixed up.

Once the sample is in and the bar code has been read, the operator is restricted from being able to gain access to the samples or in any way inadvertently switch ID's and disrupt positive identification.

[Slide.]

Also, because of the standard test procedures themselves, there is no off-line pre-dilution of samples or things like that, that are required to introduce a manual aspect to the sample processing for the screening.

[Slide.]

The fluidics themselves are automatically primed. The instrument looks for that. We don't have to rely on an operator to make sure that they are making sure that fluidic lines are primed and preventing any air bubbles from being introduced, and I will talk a little bit about some of the automatic monitoring of those steps to ensure that reagent volume has been added.

[Slide.]

This is an illustration of one of the patented technologies that is in the device for directly verifying that a sample reagent has been added. What you have here is basically a light beam that is created from an LED to a photo transistor tube, and you are looking for the reagent stream as a particular reagent is being added and breaking that beam of light, so that you can measure both that the reagent has been added and how much reagent has been added.

What the instrument sees as part of this are a series of profiles. This would be a nominal dispense profile, whereas, the stream is introduced, it blocks the light path, and then resumes a normal condition.

But should you have, for example, a condition where you have air bubbles introduced into the line for some

reason, and that path were to be disrupted in some way, the instrument would detect that, an error code would be flagged, and that particular sample that was affected by that reagent dispense would be invalidated, and no test result would be reported, so there is no intervention needed to decide whether the result was a good one or not, the instrument would handle that.

[Slide.]

Similarly, as reagents are moved within the reaction tray, this is where a sample of microparticle incubate, they ultimately end up on a filter disk here, and there is also a mechanism, a sensor for looking directly at a light beam that is bounced off of that matrix.

When this mixture is transferred to the reading well, that light beam is disrupted until it has an opportunity to flow into the tray. That time of disruption of that light beam is measured to ensure that indeed the transfer has occurred successfully.

[Slide.]

These are some illustrations again of what the instrument records. This would be a nominal drain time as you see the solution moving through a blotter. If you were

to have some type of error where, for example, there was no blotter, you had a highly viscous sample, you would see the light beam never recover, and that would be flagged as an error condition automatically, or if you had some type of hole or perforation that caused it to drain too quickly, that also would be flagged. There is a specific time window characterized in which this needs to occur.

Today, as you know, in the laboratory, for these types of verifications of volume, it really relies very heavily on an operator being able to hold up a tray of some sort and look visually at whether there is solution in wells, and it is the type of process that screams for automation.

[Slide.]

When you look at the validity of assay results, another unique feature of this, because of the nature of the automation here, is the inclusion of an end-of-batch release control. This is a low level, multi-constituent control for each of the markers, infectious disease markers, that is on the instrument.

That control must test positive on each of the assays that are being run at the end of the run, or the

entire run is invalidated. This is an extra redundant system check that is put in to ensure that if something went wrong that was not detected by some of the mechanisms that I just showed you, that it could be captured as part of the end of the run.

In those situations, as I indicated, no results are reported.

[Slide.]

Another area for putting process controls in the area of retest management, what happens when you get an initially reactive result. Typically, assays require that result to be repeated in duplicate, which means a whole series of testing. That is an opportunity for error either by inadvertently retesting samples that had already tested negative, or by failing to retest in duplicate a sample what was initially reactive.

The PRISM monitors that automatically. If you have a sample that was initially reactive in a previous run, and you introduce it via the bar code to the system, it will automatically recognize which assay it had been reactive on, and automatically schedule it for the duplicate retest.

If, inadvertently, it were introduced and it had tested negative previously, it will flag that to the operator that this sample does not need to be tested, and even if the laboratory supervisor were to decide for some reason, based on the laboratory's needs, another test on that sample is required, it would be flagged on the sample report that there had been a manual override of that feature, giving the laboratory better control of retest management process.

[Slide.]

Reagent management is extremely important for the number of different assays that are in use in the laboratory today to move those reagents from morning to night, in and out of refrigerators, to make sure you have got the right combination of reagents that are part of a manufacturer's master lot, to verify that they are within dating, is an opportunity for automation.

The PRISM utilizes bar code technology that is built into the bottles of the reagents themselves and into the fluidics lines that are on the instrument for hooking the reagents together, so when an operator loads a test kit on the instrument, they bar code in the symbol that is on

the bottle, as well as on the fluidics line, and those two must match or the instrument will not allow the operator to proceed because it would be indicative that they had hooked up the wrong reagent in the wrong lines.

Likewise, using a set of master-lotted reagents, the operator bar codes in each of the reagents from that kit. If, for some reason, they are not the matched set of reagents, then, the instrument will not recognize it and will not allow the operator to continue until they have corrected that situation.

The instrument is also able to automatically monitor that reagent usage and try to prevent the situation where you are nearing the end of a particular set of reagents, you may only have enough to do a certain number of tests. It can flag to the operator what that number of tests are, so that the workload can be planned acceptably, and not be running short on reagents during the processing of a run.

[Slide.]

This is an example of a representative of what we call a "assay kit card," and this is the type of bar coding

that would be done for the master lot and for the individual components.

These same bar codes then are on the individual bottles for those components. If you bar coded this particular reagent in and then inadvertently when you went to load the reagent, bar coded a bottle from a different lot, again, the instrument will not allow you to proceed.

These are the types of common errors that can happen in the laboratory, but where automation and technology are fully suited to try to minimize or prevent those.

[Slide.]

As part of our clinical trials in the U.S., we asked a number of the sites to look specifically at some of the types of errors that they had during their side-by-side comparisons of their current technology with the PRISM system.

What you see on this slide really is a summary of the types of errors that they experienced during the trial on their current semi-automated technologies. What I would like to highlight from this is really some of the process controls that I have described to you this morning are

capable of preventing all of the errors that are shown here, whether they be errors of adding the incorrect reagent or the wrong volume of the reagent, incorrectly calculating the layout of the trays or how many trays of reagents are required for a batch, somehow physically mishandling the tray or the reagents, placing them on a reader or dropping them or agitating them in such a way that reagents are spilling outside of the tray well.

Clerical errors, of course, you saw in one of the slides yesterday from Dr. Busch, the tens of thousands of manual entries and visual verifications that are required in a day, the opportunity for clerical errors clearly is there. All of that information is recorded automatically.

In at least two cases, even during the time frame of the clinical trial, it was observed by the laboratory that a wrong reagent had been utilized in their test of record, which could not have happened with the PRISM system.

[Slide.]

This just highlights what I mentioned a moment ago in terms of for these same sites that reported errors, how many manual entries per day, whether they are using current bead or microtiter technology. It is a large number of

manual events that someone has to mark down that they have put a tray into an incubator, they did it at a certain time, they sign and date perhaps, and all of those things need to be verified, as well as fluid level checks that are involved.

[Slide.]

This gives you an idea for the type of comparison for number of failed runs that are experienced as a result of this with the manual nature of today's technology. The overall number of failed runs during the clinical was about 4.5 percent for the current technologies and 1.8 percent for the automated.

The overall tests completed, when you put a test on the instrument, what percentage of the time do you get a valid result off was also higher on PRISM.

[Slide.]

This just shows in a different way what the typical, when you look at technician or operator type of error, that about 1 percent of the time in this site's experience, out of 2.7 percent lost results overall, about 1 percent of the time they could attribute that to preventable or operator-related issues.

As I showed on the previous slide, if a technology like PRISM can prevent even 90 percent of those, it is a significant improvement for the laboratory.

[Slide.]

So, to just very quickly summarize, going back to the three key factors of system, operator, and assay, the technologies like PRISM coming forward do have significant process controls that can help reduce and eliminate errors that occur today, and they are based on the incorporation of multiple redundant types of checks and electronic sensors where possible.

Having fewer interactions and fewer decision points for the operator helps in eliminating and reducing lab SOPs and minimizing the amount of time and, frankly, resources necessary for those types of record reviews and quality reviews, as well as the types of improvement that can be made from newer assays relative to technology and unnecessarily getting rid of donations that are falsely initially reactive in some cases today because of manual or variable inputs during the testing process.

Thank you very much.

MS. GREGORY: Our next paper fortunately needs no introduction because you heard of him several times yesterday. We are going to hear again from Jim Battles, and he is going to talk about consideration of applications of automation-a two-edged sword.

Consideration of Applications of Automation-

A Two-Edged Sword

DR. BATTLES: I do want to acknowledge co-authors on this effort of Hal Kaplan and Quay Mercer in the audience.

[Slide.]

The IOM Report, which is of course the basis of all things that we do now in patient safety, is the bible. We have to have a quote from the IOM. It talks about the use of automation in technology as a means of improving patient safety through automating repetitive and time-consuming, error-prone tasks.

You just saw a presentation of that kind of application and principle.

[Slide.]

But nothing is a perfect world, and so there are pluses and minuses of automation and technology. On the

plus side, we have lots of examples of high-risk industries have shown that automation has introduced an improved human performance and reduces the impact of skilled-based error, operator error, in certain features, and that applications of decision support help support rule-based, eliminate rule-based failures, as well.

[Slide.]

However, there are limits that we need to be quite aware of when we consider any kind of automation or technological solution. Charlie Billings has commented about the important human-centered aspects need to be considered and how individuals interact with the technology really is going to determine its success of failure.

Failures of automated systems really cannot be forecasted, ways in which they fail, and we have to be careful that we just didn't provide another layer of defense against human failure.

[Slide.]

We have to recognize that any new technology and automation really introduces new sets of new types of errors even when the goal is to prevent error. It may shift from

the type of error that happens to new sets. We just have to remember that that is going to be an inevitable aspect.

Therefore, the caution is that whenever you consider automation and move down this road, you should anticipate some trouble and be aware that things can go wrong and they will.

[Slide.]

One of the things that we looked at were what are some requirements for considering automation and technology. Well, Kukla has some design considerations. He said it has got to be technologically efficient. It has got to reduce cost, increase ease of operation, and increase the productivity of the process. If it can't do that, why automate or why do it.

It has got to be easy to use. People must be able to focus on their work, and not on the technology. The technology is to get work done, and that needs to be a focus. It has got to be a better way of doing business.

[Slide.]

It must be a better way for operators to do their jobs and be as least as good as the present method, and it also has to be adaptable. It must be adaptable to changing

constraints and other priorities of changing conditions in the environment to which it is being used. If it can't change as things change, it limits some aspects.

[Slide.]

Don Norman has looked at some design criteria. He said you have got to make things visible so user can determine what actions are possible in the process. It has got to be visible, so it can be monitored. You have got to simplify tasks to minimize use of working memory, and you need to have sort of a natural sense to communicate how the technology is being used. I think we saw some examples of that with some of the Poka-Yoke activities.

[Slide.]

Again, there are constraints. You need to have built-in aspects that make it hard to do things wrong. You can do that with forcing functions. You also have to assume that failure will occur and design for recovery. I think John Grout talked about the plan failure, kind of you want to fail soft.

If all else fails, Norman says standardize the actions, the outcomes, layouts, and displays.

[Slide.]

Jim Reason talks about some of the human-machine interface and the way you have to look at the allocation of functions between the humans and machines, and the configuration of the architecture of the system, looking at its control characteristics, its information characteristics, and the allocation of responsibility between the operators and the people who support the automated equipment.

[Slide.]

A big one is reliability, and reliability is obtained in a variety of ways, is a situational awareness, in an automated system, are you aware of what is going on, if something is about to fail, can you tell it, do you know. You have to define the optimum limits of automation because you can't totally take the human out of the loop.

The big thing is trust. One of the problems that we face when we automate is putting too much trust in the automation. You have to be a little skeptical, and the quote that you saw yesterday, "Nothing recedes like success." We have to be careful of that aspect.

[Slide.]

One of the things that is important to do when you are looking at new automated systems, we can do all kinds of nice laboratory tests and trials, but it is really when a system has been operating for a while in the real environment that we can begin to find out where are some of the issues surrounding that equipment.

So we have to study new systems in their early implementation stage once they have been rolled out for a while, to begin to find out where and when, what kinds of problems may exist.

[Slide.]

Hal, Quay, and I had the opportunity to look at the PRISM system in operation in the United Kingdom at three sites, which had been operating the PRISM system in blood testing laboratories for two years time, so we looked at PRISM operations in Carluke, Scotland, Manchester, England, and Cardiff, Wales.

We used our error classification system to begin to look at a framework for studying the implementation.

[Slide.]

We also said, okay, let's look at a kind of a model to plan our study in not only the automated system

itself being in the center of that diagram, what are the technical issues surrounding it, the human factors, and the organizational context built around the automated system, as well as looking at things upstream from the operation and downstream, because we needed to look at the context in which the testing equipment, in this case PRISM, operated, not just the equipment itself.

[Slide.]

So we conducted our study primarily by operational observation, watching what was going on, watching the process, looking at event record review, and then interviewing those people, operators, managers, decisionmakers about the system throughout the laboratory.

[Slide.]

Based on that observation and record review, interviewing, we then drew some conclusions, and we used the criteria then of design systems to say, well, how did it map up.

Well, first of all, for technical efficiency, PRISM meets those requirements very well. Clearly, the operators found the equipment relatively easy to use in a fairly short learning curve, so they were able to come up to

speed and feel comfortable on operating the equipment, and felt it was not too overwhelming and they could use it.

Clearly, everyone felt it was a better way to do business. They found that the PRISM system allowed them to process more product efficiently and effectively, so it was a better way. It also seemed to be adaptable to implementing changes in the UK.

One of the things that was going on about the time that the PRISM systems were implemented in these particular blood centers across the United Kingdom was a consolidation of testing throughout the country, so the blood centers were getting an increase of volume of testing because of that consolidation, and so this particular equipment was adaptable to those changing needs.

[Slide.]

There were significant changes in the operator roles. The automated system really changed the roles of the technicians to a much less hands-on role. This allowed some personnel mix because they could shift personnel around within the structure of the laboratories, and, in fact, because of some consolidation and other things, there were no net losses of personnel, but they could absorb when

people left, in attrition, they were able to maintain a fairly high volume, but it was a clear change of role of many of the operators.

Some of the laboratory technicians felt a degree of unease because they were not having as much hands-on, but it changed what they did, how they did it. Supervisors also needed to have increased skill and knowledge about the equipment and its operation and maintenance, and it was found that they needed additional training in how the system worked because the bioengineer support from the company, while it was readily available in some circumstances, there were things that supervisors needed to do, almost taking on a role of a bioengineer to a certain extent. So it clearly changed those roles.

[Slide.]

Everyone felt the equipment was extremely reliable. As one person said, they were able to sleep at night. I guess that's a good thing.

Internally, reliability was maintained by the use of a back-up channel, the different channels of operation, and so that was some internal redundancy, however, that

internal redundancy, if all the test channels are used, then, there isn't that back-up.

All sites did have major events that raised the consideration of how many units they needed. While the initial estimates of how many PRISM machines one needed through volume, did not necessarily account to the realistic aspect of what happens if the machine will fail and everyone had a period of time of which the machine failed.

It also had to do with issues of the reliability and the coupling between product flow. It also, everyone commented, that while there was the belief when they went into this that they could have their old system as a back-up, that was really unrealistic.

Once you made the decision to move down this automated chain, there was no going back, because the mix of personnel weren't available, their skill level. That old system back-up was an illusion, and they all realized that very quickly, which also gave to the consideration of the redundancy issue.

[Slide.]

Clearly, everyone reported a marked decrease in the number of human failures, the skill type based failures

to which the equipment was specifically designed. It met that requirement, major differences.

Within the laboratory, there was a significant drop in that, however, because the bar code system of, in this particular case PRISM, there was an increase in the skill-based errors downstream of how people put the labels on, because the previous system, there was a greater tolerance the way the label would fit. Now, you had to be a little more specific, so there was an increase of downstream errors that were caught, not that were tragic or anything, but it just shifted things that didn't matter before, now mattered a little bit that you caught.

There was the belief that the on-board computer system provided very good decision support in operating and monitoring activities along with the system. People felt comfortable that they could monitor what was going on with the decision support system of the computer operation. So, it helped with rule-based failures.

[Slide.]

There were a number of organizational issues surrounding the way the equipment was used, not the equipment itself, but the adjustment of the work flow

between the upstream and downstream was significantly changed in terms of the flow coming into the lab and particularly the way the results from testing were coming out as it affected labeling downstream activities. There were some shifts in terms of work flow balance that every organization noticed that they had to look at.

It required adjustments at staffing and procedures and policies obviously. It changed the whole flow of what was being done and probably required most adjustment in the conceptualization of the work flow than any of the laboratories initially had anticipated.

This was not necessarily a bad thing, but it was something that they encountered. It also highlighted the tight coupling between adjacent processes, so the impact of the consolidation of large batches through one system affected some of the flows again tight coupling.

[Slide.]

There were issues of the construction, the way the equipment was placed, and some minor design issues which were addressed.

[Slide.]

Some conclusions. PRISM provided an efficient and effective means compared to the characteristics of automated systems as noted in the literature.

Management at each of the laboratories felt justified in their decision to automate the testing process with PRISM. As anticipated by the manufacturer, it eliminated most of the common errors in testing, but everyone needed to consider careful planning of the personnel mix in that system and careful monitoring of the system over time is critical, and careful attention to maintenance is a critical element in any automated system. Again, that is where the changes in error, instead of operator error, now you have t worry about maintenance and other kinds of things downstream.

[Slide.]

I think one of the cautions that we always have to make in terms of automated systems, those who know me, I love the Titanic, you know, on April 12th, the world's most technologically superior piece of shipping equipment hit an iceberg and went down on its maiden voyage, and despite all the technological innovations, it sank.

[Slide.]

So, the take-home message is in any automation, automate with caution and have back-up and redundancy.

Thank you.

MS. GREGORY: Let me assure you that we didn't deliberately try to show the double-edged sword of technology in the delay before Jim was able to start.

Our next speaker is Dr. Jim AuBuchon. Jim is a Professor of Pathology and Medicine and the Acting Chair of the Department of Pathology at the Dartmouth-Hitchcock Medical Center, and Jim is going to talk to us about some practical considerations in the implementation of measures to reduce mistransfusions.

Practical Considerations in the Implementation of Measures to Reduce Mistransfusion

DR. AuBUCHON: I listened very carefully to Jim's talk, and I have my redundancy right here, but it appears that it is not necessary.

I appreciate the opportunity to share with you some of our experience at Dartmouth-Hitchcock in attempting to make transfusion events safer for patients.

[Slide.]

About a decade ago, we moved into a new facility. It was wonderful experience, but we realized that we were going to be facing some new problems. Chief among them is that the laboratory was not going to be close to the patients anymore. We used to be right underneath the operating room, and now we were two football fields away from the operating room and even further away from the patient wards.

We were no longer going to be collecting the samples, using our own staff at the laboratory. They would be non-laboratory phlebotomists. We would be receiving our orders for blood component issuance by telephone, and we would be delivering that blood by pneumatic tube, not by a transporter who was previously showing up in the blood bank with a card stamped with all the information regarding the patient.

Based on the work that Jeanne Linden and Kathleen Sazama have published, we knew we were setting ourselves up for a failure here because these are all issues that lead to greater possibility of errors in transfusion.

[Slide.]

So before talking to you in a little more detail about how we decided to approach that, I would like to tell you where I was coming from, what I had learned previous to this about quality and quality assurance.

Now, we would all like to think that what we are delivering in our hospitals is of high quality, we don't want a low quality medical system, but I don't think this is the best way to use that terminology. I don't think we should be talking about high quality or low quality.

[Slide.]

The one I understand it is the way Phil Crosby explained it, that quality has to be defined as conformance to requirements, not as goodness. In other words, quality is meeting requirements. Say that over to yourselves a couple times as a mantra, quality is meeting requirements.

[Slide.]

So, what is quality? If you understand what the requirements are for your system, and your system is set up to deliver those requirements, you will, by definition, be delivering what is expected, and you will have quality in the end.

[Slide.]

So, quality assurance then really becomes requirement assurance where you know that everything in your system, that you put into your system, is appropriate and that all the steps are appropriate, and therefore, the output must be what you expect, and you go home happy.

I think the PRISM is an excellent example of that where you make sure that the materials that go in are the correct ones, that personnel that need to be trained, obviously, would have to be trained. The process checks itself at every step, so there is no way you can't get the correct output at the end.

[Slide.]

Now, when we talk about a transfusion service system, as you saw by some of the diagrams yesterday looking at medication systems in hospitals, these get very complex. There are a lot of different inputs, there are a lot of outputs, some intermediate outputs in the system feed back into it, so there are lots of opportunities for error, and unfortunately, as you saw yesterday, documented by some of the FDA data and New York State data, we are very creative in finding ways to probe the system and demonstrate our ability to make errors in it.

[Slide.]

What we need to do instead, I believe, is put a circle around the system, understand every component in it, and then make sure that we are controlling each one of those components.

[Slide.]

So the quality assurance process should be then one where we have good process control in each step, we verify that all the key elements of every step are being performed, and that in the end, we satisfy all the intermediate requirements, so that we satisfy the overall requirements for the system.

[Slide.]

As far as transfusion goes, in my opinion, we need to do it right the first time and every time, because after you give a Group O patient a Group A unit of red cells, you may not have another opportunity to demonstrate that 99.99 percent of the time you do it right.

[Slide.]

My approach to this is one of process control. I think this is an excellent opportunity for us to use process controls. I am not an engineer by training although I

haven't necessarily been accused of having a personality, but the definition I learned of a process control is that it is a mechanism that ensures all previous steps in the process have been accomplished successfully and that the product or intermediate product meets the requirements.

So it means that everything that has been done to that car as it has been moving down to the assembly line so far is correct, and once you put the nameplate on it, the system will check that you did that correctly, and the next person down the assembly line doesn't have to worry about everything else, because everything has been done correctly up to that time.

Now, we have some examples of these process controls in blood banking. One that I am sure we are all familiar with is use of check cells when you are using an immunoglobulin reaction. The key measure there or the key step is you have to wash out all the plasma or serum before you add the Coombs' reagent. So after you add the Coombs' reagent and you fail to get a positive reaction, you check to make sure that your wash was complete by adding some check cells. We have been doing that for decades or maybe even longer.

There are many other systems where there are feedback loops in systems, and again the PRISM showed many examples of that, so that you can document that everything has been done correctly up to that step. That is a process control.

[Slide.]

Now, in the transfusion process, the public I think, and often we, think that the safety of the process relates to donor qualification and testing, and we all recognize that is important.

[Slide.]

But I think in the last two days now, we have been discussing a lot about the rest of the transfusion process that extends from the patient bedside, the patient's arm, the wristband and vein, through sample to the laboratory, and then back to the patient to make sure that we don't end up with a mistransfusion, that the right unit is going to the right patient each and every time.

[Slide.]

We have had now a decade of experience using a barrier system to prevent mistransfusion, an invention of Dr. Kaplan's actually, although I unfortunately don't

believe that he has yet become multimillionaire from it. My goal is to make him a multimillionaire because I think that this is an excellent idea.

Let show you how it works. It starts with every patient being given a hospital wristband, of course, but also having attached to that wristband a three-letter code. This comes on a little sticky label, randomly assigned, the sheets are randomly printed with lots of codes, with three-letter codes, and you merely peel one off and stick it on the patient wristband.

Now, when the phlebotomist comes to draw the pre-transfusion specimen, all the data is transferred from the patient wristband to the tube label, as you would normally do, but you add this three-letter code to that label, as well.

When the tube comes to the laboratory, we record that code. In our case, we record it in the laboratory computer system. That information is not available to the floor. When we release the unit of blood, we set a plastic lock, the so-called "blood lock," to this three-letter code on the tube. If you happen to be using a Fenwall bag, you can actually lock the lock over the outlet ports. If you

are using another company's bag, you can drop your blood bag into a plastic overwrap bag and close it up with the plastic lock.

Now, when the unit goes to the floor for transfusion, or to the operating room, the transfusionist needs to open this lock, and the only place the transfusionist can get the three-letter code is from the arm of the patient who gave the pre-transfusion specimen, so if the unit ends up at the wrong bedside, the lock won't open. If there has been a labeling error at the front end and the blood in the tube isn't really Mr. Smith's blood, it's Mr. Jones' blood, when the unit goes to the patient for whom the transfusion supposedly is intended, the lock won't open.

[Slide.]

When we began considering use of the system as we moved into our new facility, we considered where we should use it. We thought generally, we would use it for all red cell transfusions, but we probably wouldn't use it in some areas of the hospital.

For example, almost all of our neonates get transfused with Group O red cells. The only time they don't

is when they have a directed donor unit, which is not very common in our institution.

However, it is interesting that when we began talking to Nursing about this system, and the ICN nurses understood that they weren't going to be included, they got very upset, because they recognized that this was an improvement in the system, and they felt that they wanted to be included, as well, and their patients deserved the safety, as well, so we use it in the intensive care nursery.

[Slide.]

The other question was where would we assign these codes. The question really then boiled down to how do patients get into the hospital, where do they get admitted, what is the route that they come in, how many doors do we have. Well, we found we had a lot more doors to our hospital than we ever imagined.

There are a number of different ways that patients were getting admitted, and so we needed to make sure that we had a system in place, so that each one of those places where a wristband could get slapped on a patient's wrist, also ended up with that three-letter code being affixed to that wristband.

It really wasn't all that complicated once we figured out how patients were brought into the hospital.

[Slide.]

Well, does this work? We have been using it now since September of '92, and it has been responsible, by that I mean solely responsible, for detecting 35 mislabeled samples that we otherwise would have accepted as being correctly labeled and having the blood of the patient who we thought was in the tube.

That is an error rate of about 1 in 5,000 in phlebotomy, and that is very similar to the SHOT data and also to the data from Johns Hopkins that was presented yesterday.

This system has also been involved in averting three mistransfusions or that would amount to about 1 in 29,000 mistransfusion rate, similar to the data from New York State.

[Slide.]

Let me give you an example of one of these, a case study of a near miss. It was noon in the ICU. What happens? Half the nurses go to lunch, the other half take

care of two patients rather than one. It happens all across the country.

A pneumatic tube delivery occurred with the unit of blood. The nurse picked it up. She knew that her patient that she had been taking care of all day, Patient A, had had a transfusion ordered, and she assumed that this was his blood.

She went to the bedside of Patient A, was joined by another registered nurse, and the two of them verified all the information on the unit label that said it was really for Patient A, and the medical record number matched, and so forth, and so on.

Of course, it was not for Patient A, but often one finds, one reads what one expects to see. They then went to unlock the blood lock, and it wouldn't open because, of course, the unit wasn't for Patient A.

We got a call from a very grumpy nurse in the ICU telling us the blood lock won't open. We said, "Well, what patient are you trying to transfuse?" And she said, "Well, Patient A." We said, "Well, we haven't sent blood up yet on Patient A."

There was a moment of silence at the other end of the phone, and then the nurse was much more cooperative because she realized that we had not only saved her patient a problem, we had saved her a big problem, as well.

Now, this can happen anywhere. I think our hospital is actually very good at making sure all of our patients are identified, and our nursing staff is very diligent and well trained regarding transfusion procedures, however, this can happen anywhere to anyone.

[Slide.]

There are some residual problems or issues we have to keep in mind in using a system like this. Occasionally, these plastic locks won't open, and these are not wonderful intricate systems, they are wonderful intricate plastic locks, and occasionally, they don't work.

So, we have a protocol that is well known in the operating room and on the floors. It is in the Nursing Procedure Manual for what you do if the lock won't open. In some cases, we have workarounds, in other cases we say just send it back and we will try again depending on how urgent the transfusion is.

The OR is often worried about how much time it takes to open up a lock, and so the procedure we have set up there with the anesthesiologist is that, as they usually will do, they order blood a little ahead of their anticipated need, and then they open the blood lock as soon as the unit enters the room rather than waiting until that panic moment when they absolutely need to transfuse right now, and then the blood is seen as an impediment.

So, by working a few minutes ahead solves that problem.

Now, occasionally, our phlebotomists forget to put the code on the tube. That happens, that happens about 1 out of 250 samples. In that case, we call up the floor and say please try again. It doesn't happen very often, but this is something that needs to be considered.

[Slide.]

Now, those of you who know me know that I like to dabble in cost effectiveness analysis, and I couldn't resist in this situation either. So we did a cost effectiveness analysis of the use of a barrier system to prevent mistransfusion.

Shown here are all the things that can happen if you decide to use a barrier system or you decide not to use a barrier system because, of course, any system can have a failure rate, but if the patient is transfused, let's say, without a barrier system in place, they might get the wrong unit. There is a certain probability of that.

If they get a wrong unit, it might be incompatible. If it is incompatible, it might lead to morbidity, and it might also lead to mortality.

[Slide.]

One can work through all the probabilities here based on data from the literature and opportunities for things going right or going wrong, as your vantage point dictates.

The costs that we used are shown here. These locks cost between 3- and $4.00 per unit, per lock depending on many you are buying. So we just calculated out what the cost effectiveness was of using one of these plastic lock systems.

[Slide.]

It turned out that if you used the societal perspective, that is, we didn't figure in any liability

damage cost, didn't figure in any losses, just looked at the medical costs, the cost effectiveness of using the blood lock system was about $200,000 per quality-adjusted life year.

Now, most commonly accepted medical and surgical interventions have a cost effectiveness that is in the range of, or below, $50,000 per quality-adjusted life year. So this is not quite as cost effective as many other things we do in medicine.

However, if you look at the cost effectiveness of things we do in transfusion medicine, this is a bargain. NAT testing, for example, P24 testing, both in excess of $1 million per quality-adjusted life year. Solvent detergent plasma, 3 million per quality-adjusted life year. So, $200,000, that is a bargain.

I would also note that last week in JAMA, there was a Letter to the Editor on a non-medical issue, but the response mentioned that the FAA has concluded that an appropriate investment to save lives in the airline industry is $2.7 million per life saved.

I don't know where they came up with that number, but if you take $2.7 million per life saved for some

improvement on an airliner, and divide it, or consider that maybe the average age of a passenger on an airliner is 40 years, that works out to about $68,000 per year of life extended. So that is very similar actually to the $50,000 threshold. So maybe this isn't such a bad deal after all.

However, we took another run at this and took the hospital's perspective, because we all know that if something goes wrong in medicine, someone is like to sue, whether or not they should, but they still will.

Clearly, if you kill a patient who is getting a transfusion, their family and their family's lawyer will be in to visit you very soon, and even if you caused them some morbidity that they should not have experienced, they will probably sue.

It is a very legitimate aspect of these analyses to take into account the hospital's expense in defending itself, and in addition, if you move from a societal perspective to a hospital perspective, you would also be able to consider the damage award that would have to be paid.

[Slide.]

Well, if you do either one of those, all of a sudden, from the hospital's perspective, these various systems become cost savings. In other words, it is cheaper to buy this plastic lock and use it than it is to pay the lawyers afterwards when you have already damaged the patient.

[Slide.]

There is another approach, a more high-tech I guess you could say, modern electronic digital approach, and Dr. Sandler and Mr. Clark will be talking about these shortly.

Immucor has automated systems whereby you can read a wristband, a bar coded wristband at the bedside, label the tube using a small portable printer which accompanies your Palm Pilot with a bar code reader on it, so you actually label the tube at the bedside and then you generate a label that can be matched against the patient's label. I will let them give you all the details. A lot of advantages.

[Slide.]

A disadvantage that we ran into when we began using the system on a trial basis is that the system doesn't have to be used, and despite the fact that the company was

very cooperative in working with our anesthesiologist to make the system as appropriate as possible for use in the operating room, ultimately, our anesthesiologist said, you know, this is a really neat system, but I won't use it.

He said the blood lock, I have got to use it, I have got to do something, we have got to take it off, and that's the whole idea. It's a barrier. It prevents the transfusionist from getting to a unit of blood that they are not supposed to get to. So we have continued using that older system rather than the new fancy system.

[Slide.]

But either way, there are approaches available today to prevent mistransfusion, and my bottom line in this presentation is that there is something we can do to prevent these errors, right now, today.

Now, I am sure all of you are aware of the HIV transmission that occurred several months ago in San Antonio. It has been in the news lately. That is an unfortunate, tragic circumstance.

We all would like to avoid that, and we all are looking forward, I would anticipate, to a means of reducing the already rare occurrence of HIV transmission, but that is

one transmission in how many years, and how many patients do we kill every year by giving them the wrong unit of blood. Clearly, there is much more risk from an ABO error or a mistransfusion than there is from HIV.

[Slide.]

Now, we can certainly use education to make sure everyone is up to speed with the importance of checking everything they are supposed to check, but people don't always check everything.

Our hospital and other hospitals are considering transfusion safety officers who will work closely with those involved at the bedside end of transfusion to monitor what is being done, so we have an ongoing quality assurance system, watching the transfusionist and the phlebotomist, but that is not going to solve all the problems.

[Slide.]

But by using a process control, we can ensure that all the steps will have been conducted correctly, and in doing so, we can reduce mistransfusion fatalities at least by three-quarters. We will still have the laboratory-based errors to deal with.

We will probably save somewhere on the order of a dozen or 15 lives every year in this country. For some reason, the American public is scared to death of dying of AIDS or even getting HIV in a transfusion, but getting the wrong unit of blood and dying is somehow okay, or we have accepted that, and I am not sure that is entirely appropriate.

[Slide.]

So, the public is concerned about hepatitis and HIV, fine, let's make the blood supply as safe as we possibly can, but let's not forget to focus on where the biggest risk is, and make sure that that unit of blood that we hang on the patient is indeed the correct unit each and every time.

Thank you very much.

MS. GREGORY: Our next speaker is Laurie Rogenski. She is a nurse who serves as the transfusion safety officer at the Mississippi Valley Regional Blood Center. She is going to talk to us about what I think is an exciting new technology, the audio-video computer-assisted self-interview of blood donors.

Laurie.

Audio-Video Computer-Assisted Self-Interview

of Blood Donors

MS. ROGENSKI: Good morning. It is my job today to talk to you about talisman quality donor system that we began implementing in our center starting in May of last year. For those of you that know Dr. Lou Katz, you know this is a favorite subject of his. He apologizes for not being here, I am going to take his place, not an easy thing to do.

[Slide.]

Quality Donor System is the trademark for an audio-video computer-assisted self-interview program. So if I interchange the two, know that they are the same thing.

[Slide.]

Our assumptions in starting with this is that we knew that we would have consistently paced, automated screening and documentation and it would reduce screening errors.

For those of you who have ever screened donors very often, you know if it is very difficult with the monotony and the frequency and the time after time that you ask them to keep it consistently paced, pronounce half of

the words correctly when you get internationally Creutzfeldt-Jakob and veneceride, and those sort of things. We hope that it would help consistently pace those issues.

The disease transmission does result from window period infection missed by testing. Screening for behaviors associated with these infections should reduce the probability of donation during a window period, and more effective donor screening should reduce the risk of window donations.

[Slide.]

Also, with a QDS, it is a standalone, non-decisionmaking system at this time. It does have an on-screen text and pictures, a head set for audio privacy, touch screens that use the universal AABB donor history questions. Unacceptable responses by the donor or aberrant responses are highlighted by the system, and then are reviewed with a staff member.

The donor history card can't be printed until all aberrant answers are either corrected or addressed and documented.

There are two databases, one that is a static database, which is the actual donation for the day, and then

a Logs database that contains every key struck ever made on the system.

[Slide.]

This is a picture of one of our staff, who is also here, using the system. If you can see, it's just a touch screen computer, and at this point, this is where we enter the donor ID, so that we can identify the donor with the registered donor as the front end, and then you notice the headphones for the audio.

[Slide.]

This is an actual picture of one of the screens. You can see me. The question is stated in the middle. At the very beginning of the system, when a donor is signed onto the system, it will ask whether they are male or female, and then the system just asks only those male-related questions or female depending on which is chosen.

There is also a picture in a caption screen. You will see a back button, a yes button, question mark button, no, or next. In case a donor gets past one question and then remembers something, they can go back to the previous question and alter their answer.

The yes or no, of course, are self-explanatory. The question mark is if a donor would have a question, they are just not real clear on one of the questions, they can press that or not the next, and it will come upon the staff review screen as a skipped question.

[Slide.]

After the donor is finished with all of the questions, we have little boxes that they press the button and a light comes on, so the screener can come back in and review it with them, and the questions that are aberrant will be highlighted as you can see by this screen.

For instance, Question 4, they would click then on that question, it would bring up like the previous screen that we just saw, and the staff person then could review that question with the donor, find out what the reason for the aberrant answer is. Then, they would enter comments, if necessary, by a keyboard, and that would be recorded on the donor history form.

On 20A, you can see there is a stop sign. That means after review with the donor and the staff, that it is still an aberrant answer, so that means that it should alter

the staff person to remember they may want to defer that donor or to at least review that question.

[Slide.]

After the screener is completely finished reviewing the donor any aberrant answers, they scroll down and they get to this comment screen where it should show any comments that were recorded as they went through the process.

So, if they wanted to, if they looked at that and decided they didn't have enough documentation, they would go an Edit button. When they scroll down, there is an Edit button. They would go back in. They could make some changes or further comments to that section.

[Slide.]

When we are completely finished with a donor review, then, the staff scrolls down to a print box, and when our donor history card prints, it looks exactly like this. This is just the bottom section, but the entire question prints, the answers would be highlighted, as you can see, and then any comments that were made would be made at the bottom of the screen.

The Accepted or Deferred button, that is actually something at this point that is not on the current version we are using, but will be on the next, but that is still a staff decision. It is not the computer making that decision.

So if the staff decided that after they reviewed everything, that it was still an acceptable donor, it would just help them remember whether the donor is accepted or deferred at the end of the process.

[Slide.]

Now, we talked about the Logs database that collects every key stroke. From that, there is a lot of data that you can determine when you look back to see how you are doing with the system.

For instance, on this one, for all questions that the staff changes the answer on a donor, the donor's original answer, you can see that it was less than 5 percent of the time that that was even done, but that the top five questions that happened with were Received medications, Previous deferral, Donation within the past 8 weeks, Travel outside the United States or Canada, and History of heart disease, and those are pretty self-explanatory. If you

screen donors very often, that would not be a surprise to anyone.

We can also tell which questions the donor changes themselves more frequently, and it was interesting on that, which is no surprise to anyone either. The one that the donor would go back most frequently change was the question, "Do you understand that if you have the AIDS virus," and anybody that screen donors also understands that always catches the donor, and then they have to think twice, and then they would go back and change.

[Slide.]

In our system, we do 100 percent review of all donor history forms before the units are released to make sure that they are accurate and that the information allows us to release that unit of blood.

If there is anything that is at question, we will put the unit on hold for either discard or release after clarification.

[Slide.]

As you can see by this, that in the computer screened donors, we were able to reduce the errors by greater than 60 percent. The errors that were counted for

the purpose of this test were missed signatures and questions, vital signs not documented, documentation of responses or deferral codes, and also the one thing we didn't have written down there was no unit number.

[Slide.]

So you can see that out of the 85 percent of those residual errors that we had, with enhancements to this computer system, we could eliminate all of those except for the 15 percent that is insufficient or inaccurate documentation. Those are the things like we talked about yesterday. For instance, staff person may write the person went to Mexico, but there wasn't enough documentation as to where in Mexico they were.

[Slide.]

We did a survey of all of our staff, and you can see from this that the staff is very pleased with the system. The thing that is significant about that is we all want to make our staff happy. Staff do a lot better when they are happy.

[Slide.]

We could also from the Logs database, we can look at what time it takes from the time a donor signs onto the

system to when the system is actually finished and we print a donor history form.

You can see the average is somewhere between 7 and 13 minutes.

[Slide.]

On this screen, the differences between the two times we did time studies with our annual process, and with a computer-based system, it takes about 11.2 minutes. In the manual system, it's 7.4. That obviously looks like a big span of time difference, but for the staff it actually is much faster because the staff is not face to face the whole time, but for the donor, it is longer.

But when we surveyed our donors, we found that you can see that 86 percent, they were very satisfied with the time frame that it took. My only explanation of that is that the donor is engaged, they are actually busy during that process.

So they feel like the time is better used or it doesn't seem as long to them, and they were at least as likely or more likely to donate again with the system, that they were at least as likely or more likely to understand the system, and that they felt that they would be more

truthful. Sixty-seven percent felt that they would be more truthful with a computer-based system than the face to face.

[Slide.]

So, what would we do for the future with this system? Mobile blood drive implementation. From what I have shown you so far, the only place we have that is at all of our fixed sites. So we haven't done our mobiles yet, and basically that is a matter of equipment and what to carry and how to use it on mobiles.

The miniphysical, as I showed you, those were some of the missed issues. If we could put the results of the miniphysical on the screen, then, it would allow the card to be printed, then, we wouldn't have so many of those missed issues. Signature data input, "accept or defer" buttons, which you saw, would be on the next version.

We would also like to expand and enhance the current system with library functions. As we heard yesterday, malaria is the biggest postdonation recall information that happens. If we could have malaria maps that the staff could access or even a list of countries, that is very difficult. People are traveling to a lot of different places these days.

The donor acceptance criteria, drug lists, local area or wide area network. As I said, what we currently have is a standalone version.

Also, multiple language translations. Anyone who has gone through that process of translating all your information into other languages knows that is very difficult.

A paperless system. Like with the missing bar codes, if we could somehow be able to bar code, so that we can take that all the way from the donor and all the way to the patient, and not have to worry about the manual process of moving bar codes would be wonderful.

Then, a web quality donor system.

Most of these things, of course, would require FDA approval before going any further with these systems, so it would take some more work, but those things would all help us eliminate some of those issues.

[Slide.]

So, it is new technology. It is simple. We have had great success with it. We are in the Midwest. We thought maybe our donors would not like it, and as you can see, they have been very favorable to the process.

Thank you very much.

MS. GREGORY: Since we are running just a little bit behind, I think we are going to hold questions for the discussion period, because I think we have enough time for discussion at that point in time.

We are ready for our break, and if you would be back at five after 11:00, we should be able to stay on time.

Thank you.

[Break.]

MS. GREGORY: Ted Farrell is the Director of Systems Engineering at Ortho-Clinical Diagnostics. He is going to speak about automation for donor screening.

Automation for Donor Screening

MR. FARRELL: Thank you, Kay, and good morning.

[Slide.]

First of all, I would like to say you should pay attention to my personality because I am an engineer, as well, and I will let you make your own judgment call whether that is a good thing or a bad thing.

I have spent most of my career in the defense industry, and I really enjoyed some of the talks yesterday about fault trees and some of the things that we routinely

applied in that industry. As a matter of fact, at Ortho, we are spending a fair amount of time applying six sigma and process excellence processes to our product line specifically for future products.

We are doing things that are much more exciting than just the post-it notes that were mentioned yesterday.

For better or worse, I am not going to focus on those things right now. That, hopefully, will be a topic for a future talk if we have another one of these sessions.

[Slide.]

What I am going to focus on is what Ortho is actually doing today in the field to reduce errors in the environment. What I am primarily talking about is that we are the manufacturers of the Ortho Summit System. It does provide automation to the blood screening environment.

I am showing a schematic here, the components of that system. It is a very modular, extensible system, processors that automate the ELISA processing can be expandable in and amongst themselves to handle additional reagents and additional plate capacity.

In addition, laboratories can decide how many of those units they wish to have both to optimize throughput

and work flow, and to allow for redundancy, as you heard mentioned in several of the previous talks.

We tie all of the processing power together with what is called the Ortho Assay Software Network, and as I am going to explain in my talk, that has a lot of benefits for reducing errors because it is controlling all of the information technology on all the instruments that are on the network.

The system has been cleared for use in the United States since November 1998. It is also used worldwide in other countries, and we are currently running about 37 million tests per year in the United States. That is both in blood and in plasma.

So, the experience that we are talking about here is actually operational in the field.

[Slide.]

In general, you have heard a lot of talk about systems over the last couple of days. We also like to think that we provide a systems approach, and we are trying to provide comprehensive coverage of the things that might cause errors over the entire system.

For us, the context of the system is all of the things that go into producing a test result. It is much more than just the instrument.

The things that are on the instrument are, of course very important, and I will describe some of the things that we do in our automated processing, but we are also talking about things that are going to remain manual processes, that might even become more important with more complex instrumentation, things like installation, making sure that maintenance and reverification is done appropriately.

We are applying all sorts of technologies to solving these problems, information technology, assay technology, as well as sensors.

[Slide.]

So I am going to try to organize this talk into three categories that cover our view of the system. The first is again installation and how the system gets validated when it is first up and running, process control and documentation that occurs during the operational automated assay processing, and then maintenance and

reverification that gets done as customers continue to use the system.

[Slide.]

The first thing is in terms of validation, and we follow the FDA's guidelines on general principles for process validation, and we provide test cases that guide our users through proper installation, quality, IQ, OQ, operational quality, and PQ.

These procedures provide independent verification of all of the critical parameters that are necessary for getting the proper assay results, things like incubation temperature and dispense volume, all those critical parameters.

[Slide.]

In terms of process control and documentation, we like to think of that as occurring really at two levels. One is at the overall Ortho Summit System level, which encompasses all of the different instruments that we showed along with the information technology that is linking those things together, and then the more detailed process control which is done for each automated step in the assay processing.

This slide, I am trying to summarize just a few of the things at the systems level that we consider to be important. One is the overall sample management where we are actually maintaining sample test and retest status across all of the instruments in the network, and it eliminates any inadvertent retesting of samples.

We also maintain control over the software configuration or everything on the network in a central location, and we have centralized security control for that, as well.

That becomes more and more important as you have more and more complexity in the software of any system, to have a centralized version control and configuration management of that.

We also, in addition to our own Ortho run controls, provide the capability to have external run controls on every plate. It is an independent monitor of the overall process integrity of the whole system, and we have the ability to set both an upper spec limit and lower spec limit for each assay. This is required in a number of states in the United States.

Any nonreactive test results are automatically invalidated and set up for a single retest.

[Slide.]

Now I am going to spend a little bit of time talking about the actual automation of the ELISA microtiter plate assays that we run and what process control steps are done at each of those assay steps.

Each processing step has multiple checks. You have heard a lot of talks about redundancy, and we do that today in the system.

[Slide.]

The first step in sample transfer, we have automated identification of the sample, calibrators, controls, and the plates using bar code scanner, and any no-scans or missed scans are automatically flagged to the user.

In addition, obviously we want to make sure that the right volume of sample gets transferred into the plate, and we used capacitor level detection in order to verify that we are aspirating correctly and that there are no clots or there are no leaks in the system.

We are also working in a development sense on pressure profile monitoring. We have been applying that

technology for well over five years operationally in our clinical chemistry and immunodiagnostic platforms, and we believe it should be pretty straightforward to implement that in this environment.

In addition, in Europe, several of our assays have color change technology where when a sample is added into the well, it trigger a color change, and that can be read and quantified with a photometer or, in labs that don't have automation, can be read and confirmed visually.

The first test in the United States that is slated is HBsAg System 3, and that is currently at the FDA pending approval.

[Slide.]

Our incubation steps. First of all, in the design, we make sure that each microplate is individually heated, that the slots that aren't meeting the temperature criteria are excluded from the schedule, and obviously, any plates that are outside the package insert for either the time that they spend in the incubator or the temperature are invalidated, and we measure that independently.

[Slide.]

In terms of the wash step, we have capacitance based, equal level detection, which checks both aspiration and dispense and the time, so that there are errors on time outs, as well.

[Slide.]

Reagent addition is obviously critical, and there is complexity involved in the automation that we have got, so there is a variety of steps here. First of all, we verify that the correct reagent is in the system via bar coded reservoirs.

There is a dedicated syringe and a container for each reagent to help eliminate the potential for contamination. Again, we are doing liquid level detection of the reagent reservoir for a couple of reasons.

First of all, we want to make sure that the reagent is actually present and in sufficient volume, and, second, we use that in order to help detect leaks in the syringe and monitor the inventory.

We check both pre- and post-dispense streams to make sure that syringe is full and free from error and leaks before and after delivery, and we also separately, a different physical mechanism, monitor the motor steps on the

plunger drive in order to verify that the full volume of reagent has been dispensed into each well.

You also have to be careful that you are dispensing into the right XY coordinator and the microplate, and we verify that by looking at the position of the syringe and the stepper motors of the XY motor control.

[Slide.]

Once the plate then is automatically moved over to the Read station, we do some checking in the optical density reading. There are eight measurement channels and one reference channel in our system.

The level of the reference channel is monitored. We have all the light sources brought up to 100 percent of reference at the beginning of the read, and then they are monitored. Their count levels are monitored to make sure that the light level is consistent with the original reading throughout the measurement.

Measurement channels, we oversample by quite a bit. There is 8,100 total measurements made for each plate. Then, we do some statistical quality assurance on those by looking for high and low values which are discarded, and

making sure that we are taking the best five measurements from the center of each well.

Just like I mentioned with the reagent metering system, we make sure the plates, automatic plate transport and the filter transport plates are monitored in terms of their motor steps to make sure that the read is being taken at the right location.

[Slide.]

Most of this information, in addition to the sample information, is automatically captured and generated in a report that summarizes all the information that is required for the batch record.

Now, I am sure you can all read every single piece of information that is up here, right? But if you look up in the corner, there is a section at the very top that says "Plate Validity Valid," and that is the systems automatic determination, that when you look at all these process control checks that are going on, that everything passed for this particular plate.

If there are errors, then those errors are reported up here. There are several different sections, one which keeps track of all kit lock components and their

expiration date. This section shows all the process data, and I will show that in more detail in a minute. This also shows the reagents, when they were prepared, and their expiration dates in and times, and information like the reader filters, which wavelengths were used, for which measurement channel.

Obviously, this automatic report generation helps reduce the errors in manual transcription.

[Slide.]

This is a blow-up of the process data section. I hope it is a little bit more readable. It goes through each step in the process, and the times are all automatically logged, as well as some of the critical process parameters, start temperatures and end temperatures. These are flagged if they are out of range.

It also includes information by who was performing it and which unit they were performing the tests on.

[Slide.]

This just quickly shows a blow-up of the kit lock section of that batch report. We make sure that all of the kit lock components match up with the master kit lock, and that the expiration dates are provided.

[Slide.]

Finally, I am going to jump back up to the system level and talk about, you know, once you have got our systems installed, and they are running, and you have got all this process control going automatically on each batch, we have processes that allow the users to independently verify all the critical parameters on that instrument.

By independent verification, I don't mean another sensor that is part of the instrument. As an example, for temperature of each incubator slot, we have a calibrated microplate looking device. It is blue with a little LED panel on it, and it is calibrated to a very tight spec.

That can be processed automatically through the system, and that has a separate, independent temperature measurement that verifies that the temperature precision of all the incubator slots are what they ought to be.

We have similar ways of independently verifying all the critical parameters that are listed here, the volume of sample delivered, the volume of the wash buffer that is delivered, the residual volume in the wells after aspiration, the volume of reagent, and the reader accuracy repeatability and reproducibility.

In addition, in terms of maintenance, our system automatically locks users out if the instrument verification fails or if it is not performed in a timely manner. In that way, we are preventing the use of instruments which are out of specification and it enforces the frequency of verification that we require.

[Slide.]

So, what does all this mean? I guess the message that I want to leave with you is that there is automation out on the market today, and we do have very extensive process control, and in addition, our process control extends beyond what is on the instrument itself into the broader system perspective.

We are running lots of tests in the United States and around the world, and we have had lots of feedback in customer testimonials telling us that we are reducing the impact of errors in the lab.

[Slide.]

You can read the one that I am putting up here. I didn't want to provide a whole lot of them, but this is real, it is out in the field, and we are having an impact with automation today.

I am going to try to keep us on schedule, I think.

Thank you very much.

MS. GREGORY: Our next speaker is Colin Clark. He is an I-TRAC Plus Product Specialist with Immucor. He is going to speak with us about blood transfusion bar coding: development of a model system.

Blood Transfusion Bar Coding:

Development of a Model System

MR. CLARK: Good morning.

[Slide.]

The main thrust of my talk is going to be more on the technical level as regards how one would go about trying to develop a system, a model system, to address and try and eliminate the clerical errors, and so forth related to blood transfusion errors. We have all heard a lot of statistics about those errors over yesterday and today.

[Slide.]

But before I get into that, we have heard a lot of statistics, but as you can tell from my accent, I am actually from the United Kingdom, and I keep up to date with the news over there.

This headline is from the BBC News about two years ago. It simply says, "Wrong Blood Kills Patient." In the news story, I believe it was a 72-year-old grandmother with two grandchildren. It was a typical situation, O-positive patient. A person goes to get the blood to transfuse. Two nurses cross-check the information and yet still A-positive blood is transfused to the O-positive recipient. Hence, dead grandmother.

I always like to start with this because we can all think about statistics, but we shouldn't get away from the fact that this is real human beings with real families.

[Slide.]

So, if one was going to design a system to address these errors, what would be some of the key things involved to try and prevent these errors? Well, there is a simple sentence up there. I am not going to read it all back to you, but there is a key word in there, is "portable."

If you are going to be using bar code technology, you need to have availability in your hand, a system of software/hardware combination, which you have the ability to use where and when needed at any time.

Now, technology has moved forward a lot in the last few years. Years ago, it seemed like the level of technology that we had was the desktop PC, and then we had developed the idea of Palm Pilots.

[Slide.]

The hardware platform available today or the technology available today from Symbol Technologies and many other companies is based on Palm Pilot technology is illustrated in this slide here.

The benefits of this, I don't know how many people in the room have their own Palm Pilot, but I am sure if you do, you use it to log in your family birthdays, appointments, and so forth, and telephone numbers.

Using the same support hardware system and the back-up software used on the Palm Pilots, you can actually install a designed piece of software to try and work with that and actually eliminate errors.

So the basis of good Palm Pilot technology is that it needs to be portable, hence, running around with it in your briefcase. It needs to have a graphical user interface, in other words, it needs to be easy to use. You need to be able to use a stylus to touch an icon and

immediately access the program that you need, like your telephone directory or whatever.

It needs to be user-friendly, ergonomically designed. It needs to sit very handily and easily in your hand. It is no good using a device that is 2 feet wide or you are just not simply going to use it.

So most Palm Pilots you have seen around in stores are basically, as described, are going to fit in your palm of your hand.

[Slide.]

Let's say now we take that hardware platform and we try and design a software system that is going to directly try, with the use of bar codes, directly try to address the problem of clerical errors at bedside as far as collecting specimens for cross-match, and also the back side of the system, which is the actual bag transfusion, so obviously, it is a two-part system, the specimen collection and the bag transfusion.

There are certain key pieces of information that can be bar coded, that should be bar coded. First of all, when anyone would pick up your system, it must be able to identify who did what and when. So, therefore, the internal

timing mechanisms of the Palm Pilot software system, and also the fact that your employee ID badges can be bar coded if they are not already done so today anyway because of payroll purposes, the nurse or employee or caregiver or phlebotomist, however you want to describe them, their ID badge should be bar coded.

Secondly, you need to positively identify the patient from the wristband, and the bar codes incorporated onto that wristband need to be compatible with the other parts of the system, and I will come to that in just a second.

Now, there are many different company vendors out there that actually are getting in the business of selling bar coded wristbands, and I will stress to you that Immucor ourselves are not one of them, but there are many out there, and the list seems to get longer by the month.

You go on the Internet and look for this kind of product, and the list gets longer mainly because the driving force, not just for transfusions, but for general hospital safety is the positive identification of the patient in all aspects of medical care, and bar codes are basically, today, the methodology and the way to go.

So, the third item, if we are not dealing specifically with the actual blood transfusion, is the donation center blood bag label. This is put on, for example, by the American Red Cross, and would include obviously the blood unit number, the unique number, which will include or can include ISBT 128. I will address that issue in just a second when I move on to one other slide.

Fourthly, lastly, but not least, is the transfusion service compatibility label. We all in every blood transfusion service in the U.S., produce some sort of piece of paper which is attached to your blood bag, and that then is checked before it leaves the blood bank, and then is sent off to the floor, and that has the patient demographic information on and lots of other information, too.

Now, today, I can probably say with certainty that 99 percent of blood banks in the U.S. simply have eye-readable information of them. Now, what we would do in trying to develop a model system like this, would be to incorporate key bar codes onto that same label.

Now, in terms of how you would achieve that, it is a philosophical concept that you really just need to think of your compatibility label that you generate out of your

LIS, as just another laboratory label, and if you can bar code your chemistry labels, you should therefore be able to bar code onto the compatibility labels.

So, those are the four sources of bar codes that you want to operate with: identify the caregiver, identify the patient, and then at the bag transfusion side, identify the bag and the compatibility label.

Now, looking at that, you can think, well, that's two or three or four or five bar codes there, how do you know that you have scanned the right bar code at the right time.

Well, the key to any system like this would be that you need to ensure that when the software on the Palm Pilot says scan the patient wristband medical record number, for example, that if you, by error, scan the medical record number bar code on the compatibility label, that the system should be able to jump up and tell you that you have scanned the wrong bar code.

So, how do you achieve that? Well, you embed into the bar codes that you can control, certain key security characters, simple characters like asterisks, slashes, and any combination of security character you choose to use.

So, when the software is asking you to scan that particular bar code, if you scan any other bar code into that field, it simply will reject it and say this is not the correct bar code.

So, I guess in the whole of my presentation here about developing a model system, the whole thing hinges or the whole talk hinges on that last sentence on the bottom of this slide, "You must incorporate security characters embedded in your bar codes to ensure that there it is correctly scanned at the correct time." That is at the core of everything.

[Slide.]

This here is a flash shot of what the Immucor product's main screen looks like with all the different menu items on it. The first four items relate to the actual bag transfusion, and fifth one relates to the specimen collection, utilizing commonly at any point in the system, first of all, identifying the caregiver, and secondly, identifying the patient from the patient wristband.

From that point, you then delve into whatever aspects that you want to do, do you want to begin the transfusion, and then there are many other things that you

can do if you wish, or if you don't wish to do them, can be switched off or configured off, for example, collecting vital signs.

Vital signs is kind of like when you enter your birth dates into your Palm Pilot, instead of entering numeric dates in this system, you would enter in, for example, the pulse of 65, and all of that data is saved.

The core of it is it needs to be easy to use and easily accessible and easily understood by the user with the knowledge that once they get into certain processes, that if they do scan the wrong bar code, it is going to jump up and tell you you scanned the wrong bar code.

[Slide.]

This is the sample screen, actually, it is the first screen that anybody would see, and it would be where you would scan or enter your ID from your ID badge. From then on, everything that that person would do within the system would be forever tied to their name with the time and the date, and would be archived and would be totally auditable.

[Slide.]

Another sample screen. Anywhere you would work in the system, you obviously want to positively identify the patient. This is what I was talking about before, scanning the patient wristband, and there is a field with the numbers in there that you see.

That is where that if you had scanned the medical record number off of the compatibility label, instead of the medical record number on the patient ID wristband, it would alert you and say the wrong bar code was scanned.

Effectively, what we are doing here, we are thinking about the critical points that we want to check in terms of where the errors occur. Let's occur on the bag transfusion for now.

What are the things that can commonly occur? Well, first of all, literally the wrong bag can be delivered to the wrong patient. Second of all, the wrong tag could be put on the wrong bag. So, the nature of the bar codes that are used in this system cross-check.

It is almost like a triangular check of the demographics off the wristband, the patient wristband versus the patient demographics on the compatibility label is the right bag to the right patient, however, you want to back

that up by also cross-checking the blood unit number on the compatibility label versus the blood unit number on the front of the blood bag to ensure that the right tag is on the right bag.

That is equally important because the whole integrity of the system relies on, number one, security characters; and number two, that almost if you think of it conceptually, almost like a triangular check.

From that point on, the system will alert you and say you are good to go, all of your information correctly matches, and therefore you can proceed.

Now, the key with this also is that the data has to completely match, and it will alert you, so you will want to design your system to look for any error. Say, for example, you have the patient name on the wristband, and there is a space between the first and last name, but then you go to the compatibility label and there is actually two spaces, two white spaces instead of one white space.

Now, if you are doing an eyeball check on that, that would seem like no big deal, but that space is embedded in the bar codes, so therefore, it would literally tell you the names do not match because you have a space missing.

There are ways to deal with that, which I won't be going into now because time is limited, but just stressing that it is looking for an exact match, there is no alternative, an exact match.

[Slide.]

So, in your model system, what you want to do, you have two goals, one primary, one secondary. Your primary goal is the transfusion safety, of course. Your secondary goal is why not use, for want of a better phrase, some additional bells and whistles in your system. You have the software available, why not use it.

Why not use your Palm Pilot technology to be able to allow the nurse to enter in data onto the face of the Palm Pilot and therefore into the system, for example, have a volume of blood transfused, was there a transfusion reaction, if so, what kind was it, things like that, did you check the patient's chart before you started.

All of these kind of things can be added onto the basic core safety side of the system. That is what I loosely like to call the bells and whistles. However, from a productivity side, it becomes very helpful, which will be shown in a slide in just a moment.

Audit trail, like any computer software system, it is auditable, tied to times and dates and identifications of people, and retrospectively, on your chart audits, you can go back and find out who did what, when, and how, and if necessary, interview that person to find out why they did or did not something that they should have done.

Now the way you would also write your software would be that you would want to make sure, you can't skip steps. You can't skip from A to D without going through B and C first, because otherwise, people can circumvent the software process.

Now, based on the SOPs of a given hospital, you can customize those steps, of course, but as long as it matches the SOP of the hospital, they have to go A, B, C, D. So, from a QA perspective, it helps to standardize your procedures.

[Slide.]

Now in terms of productivity on the Nursing side, historically, of course, two nurses cross-checking each other. Fundamentally, the productivity with the hand-held device would be that the hand-held device becomes the second nurse.

Therefore, you are now down to one nurse to administer the transfusion, and we all know nurses are so overworked these days, that from the productivity side alone, which is not the primary motivator, of course, safety is the primary motivator, but on the productivity side, that is an added bonus.

All of your steps on the screen are driven by screen prompts, and they are written such that it helps the user as much as possible to understand what they are supposed to do next, in other words, making the process as easy as possible, likewise, not directly applicable to this room today, but we have this system used in Italy and Spain. Naturally, the screens that they use in those countries are written in Italian and Spanish.

So, you write the actual visible prompts on the screen in fundamentally any language you want, but the background software remains the same.

[Slide.]

Now, we mentioned there is two parts to the process. There is a specimen collection and secondly, the actual bag transfusion. Basically, on the specimen collection, like again, it is a configurable system, you can

actually bar code certain pieces of information or not bar code pieces of information, totally the choice of the customization.

If you do bar code, why not bar code the medical record number? If you do that, you can then supply the specimen down to the blood bank, and then they can use that bar code on that label as a form of following through with positive ID on the sample versus positive ID on the patient.

So, again, I guess to use the term loosely, it is kind of trying to close a quality loop, and then once the information is downloaded from the device it is actually testing the blood sample into the LIS, then, the LIS can print your compatibility label with the bar codes on that the system use at bedside. So, it all becomes basically a very large loop.

[Slide.]

Once the transfusion is finished, again, a somewhat bells and whistles aspect, is most blood bankers will be interested in receiving back to the blood bank the transfusion data. So, how do you achieve that?

Well, again, with technology, you can actually do everything from the very simple to the very elegant. You

can simply reprint labels, not very sophisticated, not very elegant, but you could do it.

You can also print the information in two-dimensional bar codes. You can set interfaces as long you have an ethernet system throughout the hospital. You can download the information from the nursing floor where the activity is, back to the blood bank, or if you are really sophisticated, you can actually use a device made by Symbol, which has radiofrequency capability, which you, when you are finished, can download the information through radiofrequency network, back to your blood bank.

So, with any technology, you can go from the not very sophisticated to the very sophisticated.

[Slide.]

Once it is received in the blood bank, you can handle that information any which way you want. You can actually process it in some additional pieces of software, which are actually not critical to the use of the software at bedside, but certainly would be able to manage the data in the blood bank and present it in a manageable fashion.

[Slide.]

Specifically, after I am talking, Dr. Sandler is going to be talking about experiences at Georgetown University in the United States, but I-TRAC has been used in other parts of the world, and in Canada, we did some initial trials in the Toronto area.

The reason I just put this slide up, the figures won't necessarily mean a lot to you, but there were certain scenarios up there which were very useful. People will question is this applicable to a 24/7 scenario. Well, this was a 24/7 scenario, a full 24-hour, 7-day coverage on inpatient use in a hospital in Toronto.

Also, their bar code symbology was Codabar usage, which pretty astounding for here or anywhere.

[Slide.]

But then if we move to the United Kingdom, there were three trial sites set up there, which really got the ball rolling in the United Kingdom. The three different sites were specifically picked because Basildon is in London, Leeds is in the center of the UK, and Southampton is in the south of England, so geographically, there was a spread. Again, these were 24/7 sites.

Now, the interesting thing about the UK is, as we saw from a previous speaker, about ISBT 128, the UK has fully implemented ISBT 128, and all of the sidetrack activity in the UK was based on ISBT 128.

Now, one of the two main motivating reasons why there is a real driving force over there right now boils down to two things. Number one, because the health care system is basically socialized, the government has come down on the medical system over there, and said that you must use electronic verification of some description to cross-reference for medical errors in British hospitals, so that was number one.

Number two, getting back to ISBT 128, it was actually a British doctor who was at an I-TRAC presentation in the south of England, and he had concerns about his nursing staff. He was worried about errors, two nurses working together, cross-checking information.

Up to that point, they were using normal 7 eye-readable digits Codabar. He was totally blown away by the fact that he knew that in a few months time, he was going to have his nurses deal with an eye-readable 13-digit unit

number, and he was terribly concerned about the effect that that would have on his error rate.

He realize that scanning a bar code of 13 digits, or actually, in reality, in the bar code it is more than that number of digits, but in scanning a bar code of that length, the human perception is no different to scanning a bar code of 7 digits.

So, two big factors driving the UK are the British Government's enforcing compliance. Number two is the huge paranoia about how nurses will deal with reading back to each other ISBT 128 numbers. There is no faith in that at all in the UK. That is why they are going electronic.

[Slide.]

I will finish off by saying that there is a reference I encourage you to look at, published jointly in Milan, Italy, with the information from Georgetown, and fundamentally, this is a simple conclusion side that basically says that the system that we designed, based on the model that we started with, was attempting to address the two sides of the transfusion problem at the bedside.

That was the specimen collection and the bag transfusion side.

I apologize. Unfortunately, I am not going to be able to say for the open discussion time because of needing to leave, so I am going to open myself up for any questions that anyone may have at the moment.

MS. SHEEK: What type of paper is used by the I-TRAC, and does each piece have enough patient identification to be used as part of the permanent chart patient record?

MR. CLARK: Basically, the kind of paper that is used is inked paper, and ideally, though, if you work with a data management system, you can actually transfer the information from I-TRAC down to an MIS, basically, a medical information system. So, that would be the ideal goal.

There is no more questions? Thank you.

MS. GREGORY: The next speaker is Dr. Gerald Sandler, Professor of Medicine and Pathology, and Director of Transfusion Medicine at Georgetown University Hospital.

He is going to speak to us about a pilot program using the I-TRAC device.

I-TRAC Plus-Pilot Study

DR. SANDLER: Thank you, Kay.

[Slide.]

I am going to be describing a study that we conducted at Georgetown University Hospital. It was begun three years ago and is ongoing.

[Slide.]

We studied the decreasing risk of transfusion-related human error by bar code identification of patients, blood samples, and blood components. Very simply, we conducted transfusions from the time we collected the blood at the bedside, tested it in the blood bank, and then transfused the components in parallel, doing in one arm exactly what was our standard operating procedure, and in the other arm, using the test system, which was I-TRAC.

[Slide.]

The process that I will be describing is the I-TRAC arm. I think you are all familiar with the other arm. The process begins at the nursing unit where the nurses received an order from the physician.

[Slide.]

She goes to the computer and will enter into a special program three identifiers: the patient's first name, last name, and whole blood number.

[Slide.]

From the computer, there will be printed a special bar code at the nursing unit that will be affixed to the patient on the nursing unit, and that bar code has the hospital name, a readable first and second name, medical record number, and then the encoded bar code which can be, as Mr. Clark explained, Codabar, can be ISBT 128, can be Code 39, whatever you want.

[Slide.]

We are starting the transfusion, and as Mr. Clark said, the program says, "Start by bar coding the nurse," the person who is collecting the blood sample.

[Slide.]

So, this erroneous first slide that I have for you should have been after the other one, and the signal would have caused an audible alarm, and an inability for the program to go forward.

My first slide should have been the nurse, and this nurse is going to collect the sample. She is scanning with the I-TRAC her bar coded personnel identification tag, and then it will say, "Now, do the patient," which was

the first slide.

[Slide.]

The terminal, as you saw, is a combination scanner. It's a beamer, and it's a data terminal. What it is doing here is sending the signal of the information you just saw plus the time and the date to a portable battery-operated printer, and then this is a sticky label that is being printed, that will be attached to the tube, and then a second sticky label will be printed at this point, and that will be attached to the form.

We are going to get back to this as a big surprise in terms of what turned out to be one of the major benefits of the whole program.

[Slide.]

We are in the blood bank. The tube has arrived, and at this point, the tube can go straight off and be dropped into the fully automated blood testing system. The loop would be complete.

In our hospital, that optional piece of software that Mr. Clark described, that would link this information into our hospital's information system, we haven't purchased the optional software, which has got nothing to do with transfusion safety, but generation of records.

That link, we don't have, so we are just going to put that into our hospital information system, and put the tube straight into the ABS-2000. The ABS-2000 is a fully automated, that is, a walkaway blood typing system that, using microplate technology, conducts an ABO and a D typing using solid phase red call adherence technology, conducts an antibody detection test, and using a modified solid phase red cell adherence method, would do a cross-match.

This is FDA-approved. So, if you have someone who can load a tray and work a screen, then, you can end up with a cross-match ABO, rh, and an antibody detection test at the level of quality and proficiency required by the FDA.

[Slide.]

I love this machine. The ABS-2000 will log reagents and samples. It will prepare cell suspensions. It adds the reagent. We are in a microtiter plate now. It will incubate it, wash it, centrifuge it, agitate it, and it is going to read the results with a laser beam similar to the one that I am jiggling, and then you are going to get a pattern that is going to be interpreted by a neural network.

Now, the neural network was developed by having blood bank technologists look at the bottom of a microplate

with a whole variety of patterns, and say this is what I think it is, positive, negative, not interpretable, and so forth, and then the neural network is built up on that information.

So, when the plate goes through and the laser beams hit it, they look at that, and then they test that electronic reading against the results of a whole bunch of med techs who read that, and that is how the interpretation is generated. It prepares reports and then there is an electronic output.

[Slide.]

So, we have now completed the testing, and we have gotten to the point where a printer in the blood bank is now generating what Mr. Clark described as the cross-match label.

This cross-match label, as you can see, is bar coded and will go on the reverse side of the blood unit. It will have a copy that it has generated for the medical record number in its own symbology, the recipient's first, second name, and the bar code medical record number for the patient.

[Slide.]

We are now up at the bedside of the patient, and we are going to initiate the transfusion. We are going to bar code read the unit into the I-TRAC, checking the whole blood number, patient's name, and so forth.

[Slide.]

We are now checking the patient's wristband and we are going back and checking the operator's wristband, and if all of those steps are correct, there is no alarm, and the beamer can now be directed to a portable printer, the same one that we saw before, only this time--and this answers the question that was asked by the lady from the University of Virginia--this time it will print out a sticky label, and the sticky label says that nurse X, at such and such a time, and such and such a day, initiated the transfusion of such and such a type of component with such and such whole blood number to the name of the patient.

That sticky label then is attached to--this is the patient's chart, this is our transfusion administration record at our hospital, and here is the initiation of the transfusion with all of that information on it.

At the completion of the transfusion, you can generate another sticky label and place that in the chart.

There is an electronic signature from the bar coded personnel tag indicating the positive identification of who did what.

[Slide.]

This is a blank slide. On my way down, I ran by our administration and told them that I was going to present this information, and they said, "Well, let's see what you are doing." I showed them some hardcopies, and they said, You can't show them all that dirty laundry about the errors that we make here."

So the blank slide is the kind of thing that Dr. Battles showed you yesterday, that if you try real hard, and you look, you uncover clerical errors, and all of this. During the period that we did this study, we had the same number of re-draws up on the floor that you have, we had the same number of Johnny Smiths that we wouldn't accept if it was John Smith, and so forth, but the specifics, by a specific institution, is something that I am not going to give you.

You know what you get. What I can tell you is during the study that we conducted at Georgetown, we had 100

percent perfect label printing. Let me go over that because that is one of the very special benefits that turned up.

We send back nearly 1 in 10 of every request that comes down from certain floors - med students, new nurses, and other people not familiar with. We need a clear, legible signature. We want the time and the date. We want exact names, people not familiar with that send things down, we send them back up.

Nurses starting to talk about this process in our hospital realize that during the I-TRAC study, 100 percent of all of the labels were perfectly accurate, 100 percent of all the forms were perfectly accurate.

No one had to re-draw anything, and the other nurses on the other floor started to catch on to that, and one of the problems I am having now is the administration, realizing that this is not going to be given to us for free, is very concerned about how expensive is this going to be, because the nurses are really asking for it.

[Slide.]

So, the study at the time we concluded the first phase of it, we had transfused a wide variety of different

types of blood components, all of which are tracked by the software of the I-TRAC.

At that time, we had done 299 components to 148 patients. We are over 400 now. Specifically, the IRB umbrella for the study has expired because we have moved this technology into routine for the outpatient transfusion service which is operated by 10 certified nurses.

So, we have jumped in. We are now outside the study on a 10-nurse unit for outpatients with regard to the standard of identification--and I checked this with Kay Gregory just a few minutes ago to make sure--the AABB standard says there must be positive identification of the patient and the component by the transfusionist, in singular, at the bedside item by item.

So, the standard is that visual check made by the nurse. We use the I-TRAC instead of the double-check, instead of the second nurse, and that is how that fits into our SOP.

So, to summarize, combining bar code and automated microtiter plate technologies reduces human error when transfusing blood. Bar code readers improve nurses' efficiency because bar code readers can substitute for a

second nurse when checking the blood bag and the patient identification, and they love that.

They are busy, they don't want to have to go chasing after someone. They have got a Palm Pilot in their pocket, they scan it, they do it themselves, and this will record a lot of transfusions, you can download it later.

The bar code reader printer system eliminates labeling errors, which is a major cause of repeat blood sampling or redoing the forms.

Where are we going from here? There are two directions. One, we are going to do further research with this to try and determine what you might call the market penetration, what fraction of nurses, who are not transfusing multiple units every day as they are in the unit that we studied this on initially, what fraction of nurses like this, that they are given this and life and death depends on it. We say use this, and it is new, and it's electronic.

Most of the younger nurses who grew up with computers and Palm Pilots, they love it, but what, as we go in to people who didn't grow up that way? We don't know

that answer, and we are going to be studying that in the research mode.

The other is where do you get the money for this, and the only people that we can identify, who are going to save money, might be the insurance companies. When I get insurance for myself of my car, because I have antilock brakes, that is a safety device, I get a discount from the insurance company because they are going to have less business because I have got a safety device.

We are looking at the possibility that the insurer of a consortium of hospitals will save money and might consider an antilock brake type of discount that we would use to fund the operations or partially fund the operations of this.

For one individual hospital like mine, for me to sit with my risk manager and talk about 20 deaths that are going to occur next year, out of all the transfusions you have heard, and all of that, that doesn't get me to a point they say, okay, we will write out the check and we will buy you one of these.

So, to fund this, we are going to be looking at the insurance industry, and I don't know if any of you have

got any particularly bright ideas about that, but that is where we are headed.

Thank you for your time.

MS. GREGORY: Our next speaker is Steve McDermott, and he is the Director of Marketing, Biologics Products, Inc., in Salt Lake City. I think you can all appreciate that he was willing to leave the Olympics and come and speak to us today.

He is going to talk about Positive Patient Identification is More Than Just an Armband.

Positive Patient ID is More Than Just an Armband

MR. McDERMOTT: Good morning. It is an honor to be here. After the traffic we have had in Salt Lake City, 495 looks relatively empty, so I appreciate this opportunity.

A lot has been said about engineers this morning. I grew up in a family of engineers, and unfortunately, I went to business school. As I entered business school, my father pulled me aside and gave me one of those where-did-we-go-wrong talks. So, please bear with me, but I do understand.

[Slide.]

We have entitled the presentation, "Positive ID is More Than Just an Armband." The thrust of our company has been mainly the identification of both the patient and those samples collected from that particular patient.

[Slide.]

There are two basic types of errors that occur, and I am drawing from an article written by Dr. Henry Soloway.

A random error are those errors that occur when you collect or test, repeat the same test on different aliquots from the same sample. They are accounted for with their coefficients of variation and standards of deviation.

A gross error is an independent of any mathematical predictability except for the fact that we know that they will occur.

[Slide.]

I just defined what a random error was. A gross error, a good example of a gross error is when we draw a sample from Patient A, and identify that sample with a label with Patient B's identification.

[Slide.]

This is a classic example. It is a very popular ad that our company has used to illustrate what a gross error might be.

[Slide.]

One of our client hospitals, the University of North Carolina at Chapel Hill, a pathologist at the time that we implemented one of our patient identification systems, made this comment. She had experienced a transfusion reaction shortly out of her residency program, and was a big proponent of positive ID of both the patient and the sample.

In light of much of the sophisticated and very impressive technology we have witnessed this morning in laboratory instrumentation, it is interesting to note that her statement does still carry a great deal of validity.

"The substantial investment in sophisticated laboratory instrumentation is of little value unless the identity of the patient from whom the sample was collected can be assured."

[Slide.]

I am also drawing from a previous speaker, Dr. Sazama. I listened to Dr. Sazama about a year ago when I

was in Memphis at another meeting, and I am just taking excerpts. I checked with her at lunch yesterday if this would be okay, so that was kind of a Johnny-come-lately, is it all right, and she said it was.

But she indicated in her presentation that the basis of most lawsuits are negligence, and then she defined the elements of negligence. Obviously, there is a duty owed, responsibility, the responsible party failed to perform and it constituted a breach. Someone was injured or harmed. The breach caused the harm, and then damages can be determined.

The piece I want to focus on is the last piece. She indicated that there were some recent cases, negligence cases. They have defined negligence as, "An inability or a failure to adopt new technologies or techniques."

Patient misidentification results in basically bad, bad things, as everyone knows, and we don't have to go into those today. They have been reemphasized.

[Slide.]

A lot of people, however, have made the statement, "It won't happen in my facility because we have policies and procedures in place." A good example of these are never

asked, "Are you Mrs. Brown," but instead ask, "What is your name?" If there is no band, you don't draw from that patient. Always date, time, and initial the tube. The lab would reject all improperly or unlabeled tubes, and they never pre-label the tube at the patient's bedside.

[Slide.]

The reality is, according to Dr. Soloway, policies and rules can be broken and even forgotten.

[Slide.]

Dr. Howard Taswell conducted a study where they introduced clandestine errors into a hospital laboratory just to see if, in fact, in light of the practices they had in place, if these could be detected. Thirty-eight percent went undetected.

[Slide.]

Another study conducted by Dr. Stephen Renner where he surveyed what he classified as "wristband errors," in 712 North American hospitals. The phlebotomists were used as the monitoring group, and they checked ID bands during rounds over a four-week period. Almost 2 1/2 million ID bands were checked during that period of time.

[Slide.]

The result of that survey was obviously significant. Of the over 67,000 errors they encountered, almost half were that ID bands were missing entirely.

They found some interesting things out. They found that most of the errors occurred, this type of error occurred where the patient was admitted, the band was sent with the patient's chart to the nurses station, and then the nurse became responsible for attaching the band at the nurses station.

They had a much lower incidence of errors where the bands were actually attached at the point of admission, be it outpatient emergency, inpatient admissions. They also found that a lower error rate resulted when phlebotomists were used to help monitor both the presence and legibility of the ID bands, and refused phlebotomy when the bands did not meet that criteria.

Also, that interdepartmental communication was crucial as a means of maintaining some semblance of effective and a safe system.

[Slide.]

This graphic just shows basically the survey results, and again, just to reemphasize the fact that the

number one problem seemed to be the fact that the patient's ID bands were missing.

He went back and also discovered that all of these patients did receive a band in Admitting. Now, whether the band was attached and subsequently cut off or just was neglected to be attached in the first place was not clear.

However, that continues to be a major problem today.

[Slide.]

Who causes these errors? Well, obviously, everyone causes these errors, and including the patients. We have mad cases in some of our hospitals where we have heard stories of patient's parents that have removed the band because it looked uncomfortable, of patients that have taken the band off.

For example, when a nurse needs to move or start an IV, she will cut a band free, and instead of replacing the band, she will tape it to the bedside, tape it to the chart, or just throw the band away completely.

One of the biggest factors is the decentralized environment that has become so common in today's health care environment where shared responsibilities don't always carry

with them an appreciation for the severity of the responsibilities or the safety factors in place as part of those duties.

[Slide.]

Again, who gets hurt? We have more or less gone through that in the last day and a half. I will share with you one story with respect to the community image of a hospital.

In a western part of the valley, in Salt Lake City, there was hospital by the name of Valley West. Valley West was in an area that has continued to grow and develop. A few years back, Valley West had a number of problems, one relating to transfusion and a surgical misadventure.

Unfortunately, that got a lot of ink in the local newspapers, and the community around that hospital nicknamed the hospital "Valley Death." They subsequent to that found that they had people that would live within a few blocks of the hospital that required medical attention, and they would request the ambulance take them to the University of Utah, LDS Hospital, clear across town because of the concern for the image at Valley West.

It took two hospital corporations and a couple of name changes and a lot of other public relations moves to clean that image up, and today it is a thriving and very successful hospital, but that community image did take some time to reverse.

[Slide.]

Again, primary causes for patient identifications or gaps in patient ID, the patients' bands are missing. Another very common mistake or a common gap is that multiple systems are in use.

I don't know how many people here have worked in facilities where the patient receives one type of a band when they are admitted to the hospital. They receive a second type for blood banking, and then they receive a band by the nursing people to indicate that they have a drug allergy. Perhaps they came in through the emergency department, they received a name and number down there, so that band stays on.

If it's a maternity patient, they wear a band to identify themselves to their newborn children or child, heaven forbid, children, at least in my family, we have three.

Then, one very interesting aspect is that there was a lack of standardization in processes between the various departments. The policies were difficult to enforce, and if I could, I would like to give you an example.

Some of the policies that we have found as we have gone in and worked with our client hospitals are more tradition or historic based. I don't know, and if you have, and if a lot of people have heard this, raise your hand and I will move on.

But a few years back, one of the subcontractors for the F-16 fighter jets received the specifications for the seats, the pilot seats in the planes, and if specified a specific type of leather. The leather had been treated with a certain type of chemical, whereupon, on further investigation, they found that the chemical was actually camel urine.

They could not understand why this was an essential part of a very sophisticated, high-tech aircraft, and they began to investigate and backtrack. It turned out that this spec had been carried forward from almost the beginning of the aviation arm of our armed forces, and it

turns out that this camel urine treated leather was actually essential.

In the days of the cavalry, they would treat their saddles with camel urine, and that would eliminate the smell that would potentially spook the horses, and yet this particular specification had been carried forward to the F-16's.

As you go through your policies and practices, take a look at some of the things that you might have, and you will find that there is no rhyme or reason.

A classic example I like to use is I have a fairly regular exercise program, and I have a story. Every morning I would go for a run, and I would pass a home. There would be a woman on the front steps with a loaf of French bread. As I would pass this home, she would be hitting this small boy over the head with this French bread.

It happened day after day after day, and I didn't understand. One morning as I am passing, she is striking the small boy, but this time she has got a cake. My curiosity got the best of me, and I stopped, and I said, "Please explain something to me. Every morning I run by and

you are beating this child over the head with a loaf of bread, and today it's a cake. What's the story?"

She said, "Well, it's his birthday."

[Slide.]

There are some mistaken assumptions within patient identification. ID bands are not souvenirs of a hospital stay. Another common phrase is patient ID is not part of my job, someone else is re-band the patient.

A crucial element is that the patient is not always capable of being an informed consumer. I had an operation a few years back. I had a skiing injury, and had to have my shoulder rebuilt.

My wife was in the room when they came in to prep me for surgery, and she was amazed at how very docile I was. After they left, she said, "They could have taken you to Labor and Delivery, and you would have gone willingly." And I believe that is true.

Most patients, from the lay person's standpoint will not object to or argue with those people who were there to help them. As a result, we can't always depend on that person being a willing participant or active participant in their individual care.

A study conducted a few years back showed that when you enter a patient's room, and on purpose call out the wrong name, almost 85 percent of the time, the patient will respond affirmatively, not because that is who they think they are, but, golly, we are just trying to help.

[Slide.]

This is a classic example. I don't know if you can read the caption, but I fit into this category, so it is important.

[Slide.]

Very quickly, how do our product lines prevent these errors? We specialize in patient identification systems, and they range from a very simple John Doe/Jane Doe type system up through a full hospitalwide bar coded system, with a lot of step in between. They are both mechanical and electronic.

They complement both plastic card and label admitting systems, and let me define what that means. In your hospital, if when the patient is admitted, a sheet of labels is printed, as well as an armband, that is considered a label system. If a plastic card is embossed, that is a plastic card system.

But we have patient ID systems for both. They are very flexible, and, in fact, if I walked people through 300 of our accounts, you would see 300 variations of the various products that we offer.

[Slide.]

Now, they are not dependent on visual verification. Because of their design, they physically force the use of the ID band. They provide physical evidence of policy compliance, and the very basic systems provide a mechanical means of generating a label directly from the patient's ID bracelet. That label becomes physical evidence of the fact that I used that ID band to print that sample.

Our bar code system, the label itself is evidence of the fact that the complete verification loop was completed. A label can't be obtained unless the various steps in reading the caregiver's badge, in reading the ID band, and scanning in the information from the worksheet all match. And it does work in all areas.

One of the challenges we face with our bar coding products is there are certain areas where it is difficult to adapt electronic devices, in particular in infectious

isolation areas, in some emergency areas, in our helicopters, in ambulances, where because of the circumstances, because of the type of patient, it is difficult to carry in an electronic device, and because right now most of us are afraid to try to sterilize one of our scanners for fear it just be an expensive lesson, and it shouldn't have been done to begin with.

So, we do provide mechanical label printers that are fully sterilizable and can be used in these areas, and they provide a fallback or mechanical back-up position for these systems.

[Slide.]

Very quickly, these are just a couple of the product lines. Identi-Match is just a blood recipient or an emergency system. Again, you can see the small blue label printer is a means of generating data that has been pre-embossed and a plastic tag.

[Slide.]

This system can be upgraded to become an admitting band and a blood bank band, and it's the Identi-Match II.

[Slide.]

Identi-Match III, I don't know if you can see by these pictures, but in the center picture there are some alert labels that can be inserted into the band, and that becomes a nursing alert band, as well, so instead of just having an admitting and a blood bank band, it is also a band to provide Nursing with various alerts.

The advantage to having all of your information in a single bracelet is as follows. First of all, Nursing has some investment in that band. They are less likely to try to remove that band if it has data that they will need.

On top of that, because all of the information is in a single location, they are not searching for additional ID bracelets, but it is all contained in a single location, and thereby standardizes your information transmittal.

[Slide.]

This is a plastic card system. The basic system, as you can see, and again we are putting a label directly to the patient's bracelet.

[Slide.]

This has the Nursing alert labels.

[Slide.]

This is an Identi-Clinic card that adapts again to the same systems.

[Slide.]

This is our Identi-Scanner, our bar code data collection. At the present time, we have three modules. We have a laboratory module, a pharmacy module, and a piece called Neolink, which attaches mothers and babies, and provides an activity report, so that it complements current security systems in labor and delivery areas.

[Slide.]

This is an important aspect of our particular approach to patient identification. We don't believe that upgrades should be mutually exclusive of benefits that were enjoyed up to that point. So, these are the building blocks of what we consider a very complete patient identification system.

First of all, if not all your patients are wearing bands, no matter how sophisticated your downstream equipment and processes and instruments are, they are of no use because you cannot link anything back to that patient.

Our bands, as you noticed with those bands, because all the information is attached with a plastic tag,

can more easily be, if the band does have to be removed, can be cut free of the old vinyl strap and reattached.

Again, all of the data is located in a single bracelet. The policies are standardized. There is a mechanical back-up for areas where the electronic devices aren't able to enter or aren't as effectively used. And then, of course, the bar code is kind of the icing on the cake where we provide the automatic data entry aspect, as well.

[Slide.]

Standardization is an important aspect. In a recent article--well, I shouldn't say recent--but about two years ago in the Journal of the American Medical Association, they indicated that standardization is one of the key factors in enhancing quality in health care today.

Our lab labels are identified regardless of where the sample is drawn, and they are all done the same way, and all the alerts are contained in the same bracelet.

We participate in every step of the process, in helping the hospital design their policy.

[Slide.]

Very quickly, I just had a quick report. We helped with Intermountain Health Care. They are a 24-bed, I believe, hospital chain in the Intermountain West.

[Slide.]

Our customers range from 20 to 1,300, but they range from 20 to 650 beds. It was an 18-month project, and they brought in representatives from all major hospital departments.

[Slide.]

What they wanted to do was find the best means to identify their patients and enhance their quality.

[Slide.]

These are the steps they went through. I spent 18 months on a committee working with them, and this is just one of the graphics they used in a presentation I made with Ann Merkley, one of the quality improvement coordinator, just to show wristband compliance before and after.

What is important about this is that although the process was a few years old, in business school we learned the story of a factory where a light salesman came in, and he indicated that by increasing wattage, productivity would increase.

They increased wattage in a certain area, and sure enough, productivity increased. They increased wattage again, they increased again. The cost accountant came in and he decreased the wattage, and the productivity still went up.

So, this was about four or five years after the fact, and as you can see, these numbers continued to be as effective.

I thank you very much for this opportunity, and just again to reiterate the fact that patient identification is more than just a product, it is a process.

Thanks.

Open Discussion

MS. GREGORY: We have time for a few questions and answers from our speakers so far this morning. If anybody has a question they would like to ask from the floor, if you will go to the microphone. If you have a question written down, we will take those, too.

Ira.

DR. SHULMAN: Hi. Ira Shulman from Los Angeles.

At our facility, which is a Level I trauma center, we see about 10 or 11 trauma registry qualified patients

daily, and many of them need to go up into surgery, and many of those cases are banded before they go up to surgery, but there is a tremendous temptation for bands to be cut off, especially off of wrists in trauma surgery.

So, we do redundant banding, both wrists and ankles. My question is, in the banding strategy from Biologics, I am assuming that there is a strategy for both wrist and ankle or other body part banding?

MR. McDERMOTT: Yes, there are. We have bands that will accommodate, not only different sizes, but every type of patient, and the redundancy in banding is not an uncommon practice in a lot of facilities.

DR. SAZAMA: Hi. I am Kathleen Sazama.

I have a question actually prompted by Jerry's presentation, so I will ask him that part first, but then may also relate to Biologics.

It seems to me that there are three opportunities that still need to be addressed with the systems that you have tried. The one is that there seems to be a gap that doesn't incorporate the issuance and transport step, which is a very highly vulnerable step once the blood is issued until it actually gets to the patient's side, and there is

an opportunity to capture the identification and the timing of those steps, so that from the moment the blood bank issues the unit until it actually begins to be identified and transfused, so I think that is an area for improvement.

The second is, what if you need a second tube, which is a recommendation that some facilities are following if you don't have a medical history and you want reverify the ABO, is there a way to capture the fact that a second has been drawn? It may not be necessary because you have a high degree of confidence in the identification that is going on.

Then, the third, and this is directed to both of you, how do you know the band is actually on the patient?

DR. SANDLER: Let me take questions 2 and 3 first. With regard to a second tube, first, if you are using the system, and if you are using the ABS which goes with it, you don't need much blood at all.

We operate on 3-milliliter tubes, and from a 3-milliliter tube, we are able to take the sample that has a positive antibody screen, do a panel screen, do an elution, and do the whole workup on a 3-milliliter tube.

DR. SAZAMA: I am not talking about how much volume you have. I am talking about the fact that if you have no medical history to verify the ABO type of that patient, there are some facilities that will then draw a second independent specimen to assure that you have got the ABO type and that patient correctly identified.

DR. SANDLER: Yes, and we have basically the same system, and your question is if a new patient shows up, brand-new to the institution--

DR. SAZAMA: Correct, never seen before.

DR. SANDLER: Never seen before --then, whatever your SOP is, the system can adapt to it. If you would like to have a second sample drawn by a different person or whatever, that is adaptable.

Your third question began with B, and I can't read my writing. What was the third question?

DR. SAZAMA: How do you know the band is actually on the patient?

DR. SANDLER: How do you know the band is on the patient, that is a very interesting question because if you put the band on the person, because it comes on that person,

then, whoever that person is, even if everything else goes wrong, the wrong blood can't go into the wrong person.

DR. SAZAMA: Unless the band is the wrong person.

DR. SANDLER: Even if the band is on Mary Smith, and it says John Jones, the wrong blood can't go in because you bar code when you draw the sample, and then when you are coming back, you are going to bar code that person.

DR. SAZAMA: The band. But if the band is on the wrong person, you are still going to do the wrong, right. I mean--

DR. SANDLER: You will transfuse blood to the person that it was matched to.

DR. SAZAMA: Misidentified person, right. So you won't kill the person, but you still don't know that the band is actually on the right patient.

DR. SANDLER: Yes, that's a fact.

DR. SAZAMA: And you don't even know that the band is on the patient. You can still have the band taped to the bedside record. You can have it on the chart somewhere. I mean everything that you have described presumes that it is physically attached to the person, and that has not been

solved, that part of it. I am not trying to be argumentative.

DR. SANDLER: No, no, I understand. Everything I have described depends on a professional person at the bedside.

DR. SAZAMA: Which is where are today.

DR. SANDLER: To do a certain minimal behavior, but if that minimal behavior isn't followed, then, yes, things will go awry.

DR. SAZAMA: We are still limited by the fact that you have got to physically attach something to the person in order to start the whole process.

DR. SANDLER: I wanted to go back to question 1 because it wasn't quite clear to me why it is so important, if we have the label on the back of the bag, and from a safety point of view, from the safety point of view, the label is on the back of the bag, and however that unit gets up, whether it's--we use pneumatic tubes--what the concern would be in terms of safety when it gets up there, and it is bar coded, why does that link--

DR. SAZAMA: Well, first of all, not every institution has pneumatic tubes, and they create their own

separate set of policies that you have to follow. Those of us who don't use pneumatic tubes have a person who comes physically, collects the unit, and takes it somewhere.

I don't know about you, but I can share a story about another institution I used to be with where the transporter decided it was lunchtime and took the bag of blood right through the cafeteria line, and we do know that timing is of concern, particularly for red cells.

So, one opportunity you can capture is at the time that it physically leaves the blood bank, you can capture both who or how, and the time that it left that facility, and the time at which someone at the other end acknowledged that they had received it and were ready to use it.

It's a controlled step that electronically, you have the potential for capturing, so I was just going to raise that as a question. Why not capture the data, so that then you have a complete record?

DR. SANDLER: I think Mr. Clark pointed out that there are--I think he used the term "bells and whistles--there are a variety of bells and whistles that could be added on to the basic system.

I could easily imagine that the machine would beep, beep, beep, beep four hours after the unit was transfused--I am sorry--four hours after the unit was issued.

DR. SAZAMA: No, I am concerned about the 30 minutes before, when it is returned to the blood bank. I don't know if you have many of those, but in systems where you have red cell units coming back untransfused, the time I am worried about is the 30-minute time, and what that delay is.

DR. SANDLER: Sure, and I think all sorts of additional things could be built into the system that aren't there now.

MS. BLADEN: Hi. Barb Bladen from Montgomery General Hospital. We are actually looking at some of these systems.

My question for Steve is, it seems like we have got the patient identification piece okay when you are making labels at the bedside. I guess my concern is the created other source of error once the specimen gets back in the laboratory, and you are popping these specimens on

either the ABS or the Vitros, how are you interfacing that label, testing label, to the results?

MR. McDERMOTT: If you are just using the mechanical label printers, is that the system you are looking at?

MS. BLADEN: That is the one we are looking at.

MR. McDERMOTT: If you are just looking at the mechanical system, what the majority of our facilities do is they actually attach that label to the tube first, the label generated from the ID band tag, and then they overlap with the computer, the ILS label, which has your request data.

MS. BLADEN: Which is my other concern, because that is like another source of error, so someone in the laboratory is going to have to identify that before it goes on a machine.

MR. McDERMOTT: That's correct. What it does give you, is does give you an audit trail, and the advantage to that is, if I am just using a single label, carrying that to bedside, and I draw the wrong patient, I have no traceability of that error.

With this particular method, I have the copy of the ID band of the patient from whom I collected the sample,

and then the label requesting a sample from a different patient. Side-by-side, you can at least pick up that error before you do the chemistry analysis and testing and diagnosis based on that sample.

MS. BLADEN: I guess my question is interfacing the two, because then you still have the other source of error of someone overwrapping the wrong label, the wrong testing label onto assessment.

MR. McDERMOTT: You mean overlapping the first tube?

MS. BLADEN: The first tube is named Joe Smith, and your testing label is named Mary Smith, and you have to put the testing label on before you put it on the machine, so are you interfacing the two?

MR. McDERMOTT: That is done at bedside. In fact, probably the best thing to do is--I don't know who are working with--but we could give you a list of customers, and they could tell you how they have resolved that.

That is by far the most common approach, and people have their concerns about double-labeling, but by putting the first tag on that is made from the patient's ID bracelet, then, overlapping it with the request label, they

seem to find that that is very effective as a means of at least catching errors before they take any work with that sample any further.

MS. SPRINGER: Teresa Springer, VA Medical Center, Washington, D.C.

I was in a discussion about looking at some of these automated bar code scanning items that you can use at the bedside, and it was alluded to in the last talk to some degree, but I am still curious. What do you do with these Palm Pilots when you are taking them from room to room to room? Some of these rooms are underneath Isolation, and how are you going about making sure that these little Palm Pilots, which you just can't dip in clorox, as we have already talked about, how are you making sure that they are being decontaminated?

MR. McDERMOTT: I can take the Palm Pilot in and seal it inside a plastic bag, and scan through the bag and read the data, and collect the data. The problem comes when I have to print a label. If I have my printer inside the bag, inside some kind of a sealed area, as soon as I open the bag, I have contaminated the printer, and that is what our concern has been.

So, as an alternative in those particular areas, they just use the little mechanical label printers. Those printers can be detached, sent down to Sterile Processing, and gas-sterilized, and they are very durable, but it is a step back, but nevertheless, at least you are using the ID band to identify something, so it provides you with some method of utilizing the band to identify the sample.

DR. SANDLER: We haven't encountered that, and it is a very interesting question. It happens with stethoscopes and otoscopes, and a whole variety of other things, and it has been solved in that way.

As I indicated, the direction that we are going now is research into what we call the penetration of the market, and I can give you a whole bunch of scenarios--I don't think anything is going to really, really work except the old way, because there are so many.

I think that your scenario, and incidentally, the scenario that Dr. Ira Shulman raised also about people snipping things off, I think are going to be outside the electronic box. I don't think that there is one system that is going to work for all, and I think that the situation that you described, 10 real bad emergencies where limbs are

involved, and a lot of blood is splashing around, and someone is in a room with a white count of 100, and you can't bring anything in, you really have to be very careful about bringing stuff out and going somewhere, those are going to be, in my opinion, outside the box.

So, I think it is a matter of what degree of 100 percent is going to be suitable for the failsafe electronic bar code reading. I think it is going to be very high, but it is not going to be 100 percent.

MS. GREGORY: I have a couple of questions for some of our earlier speakers. First, for Ms. Rogenski.

They would like to know, have you noticed any change in post-donation information as a result of using your Cassie? They were likely to be more truthful, have you been able to demonstrate that?

MS. ROGENSKI: We do believe that we will see an increase, however, at this time, we are only at our fixes sites where it is a lot more controlled environment, donors are pre-screened by our Telerecruitment Department. There are more regular donors. We really do expect, though, that we will see an increase initially when we take it out on mobiles. At this date, we haven't seen that yet.

MS. GREGORY: Dr. AuBuchon, the blood works only if a three-letter code is only on the patient's wristband. How do you keep staff from recording the code on the chart, the nurses station, the addressograph, or all kinds of other places?

DR. AuBUCHON: It certainly could be transcribed elsewhere. It is not a formal part of the medical record. I would say that the primary reason that we don't see it being written elsewhere is that the nursing staff recognizes that this is an important safety advantage for the patients.

The nursing staff is the strongest proponents of the blood lock system in our hospital. I never hear a complaint about the blood lock system from nurses. I will occasionally, not very often, but I will occasionally hear one from a physician, usually, a physician who doesn't have to deal with the system or deal with a transfusion problem.

The other feature probably that keeps the codes from being written where they are not supposed to be written is the fact that I do spend a fair amount of my time wandering around the wards, people know me, and they know that if I were to see something written somewhere, would take some action.

We did find several years ago that the ICU was using the blood lock codes for an unintended purpose. Our intensive care unit, as probably many of yours, have difficulty identifying who is really a family member and who should have access to information about critically ill patients, and they began handing out the blood lock code to the family member authorized to receive information. That is how they would identify the authorized receiver of information.

That led to a blood lock list appearing next to the telephone, the main telephone in the ICU, because when a family member would call and want to know how their father was doing, the person answering the phone would have to quickly be able to identify whether or not that was the appropriate person, and they didn't want to have to run to the arm of the patient to do that.

I saw that, and we had some discussions with the head nurse at the ICU, and they went to another system.

MS. GREGORY: The next question is for Dr. Battles. What is the back-up for PRISM when it fails since a manual system could not be instituted?

DR. BATTLES: In most cases, there was sufficient time within the equipment. In some cases, they shipped the units out to be tested in another facility.

MS. GREGORY: The second question sort of along the same line. If you have two different PRISMs in operation, does it matter when you use PRISM I or PRISM II when you have an initial reactive, and then you are doing repeat reactives, when you are repeating the test?

DR. BATTLES: I can't answer that question.

MS. GREGORY: You can answer that.

DR. STEWART: I will just briefly address that. There is a feature called the PRISM retest server, which links multiple PRISMs together. So the retest management functionality that I talked about, you could test an initial reactive on one instrument, and retest it, do the duplicate retest on a different instrument, and it will still recognize the positive sample ID.

MS. GREGORY: I have a couple more questions for Dr. Stewart. Does the PRISM use disposable tips or a fixed probe, and is carryover a problem?

DR. STEWART: Yes, each sample is tested with separate tips. A new tip is put on for each sample.

MS. GREGORY: When PRISM is determining validity of a run, does it take into consideration the results of external controls?

DR. STEWART: That capability does exist. I mentioned specifically the independent release control that is provided by Abbott, but you can run external controls as designated by the laboratory, and you can set specification limits on those either for tracking purposes or, if you want them to invalidate the run, set it appropriately to do that.

MS. GREGORY: The last one is in your clinical data or international data, do you have any results on processing the required six assays in the U.S. in regards to reliability, failed runs, or initial reactive, repeat reactive rates?

DR. STEWART: In terms of six assay system, we do not. Right now, for PRISM outside the United States, there are five assays in use, and the sixth channel serves as a back-up channel, so in partial answer to the earlier question, as Dr. Battles said, that is one of the redundancies.

The sixth assay, P24 antigen, that is utilized in the United States is under development, but there is no real

field data with all six channels. The reliability of the five-channel system has been very good.

MS. GREGORY: I have a question for Dr. Ted Farrell. How does the Summit assure that each well in each tray receives exactly the same incubation temperature and time?

DR. FARRELL: Can you repeat the question, please?

MS. GREGORY: Yes. How does the Summit assure that each well in each tray gets exactly the same incubation temperature and incubation time?

DR. FARRELL: They are all incubated simultaneously in essentially an incubation hotel, and those incubation times are all tracked by the central processor.

MS. GREGORY: Thank you. I think in the interests of time we need to move on to our next speaker. We are going to move into the realm of the future, what is in the future in the way of technologies.

We are going to hear from Catherine Tilton, who is the Director of Special Projects at SAFLINK Corporation. She is going to talk about Biometrics for Positive Identification.

Future Technological Possibilities

Biometrics for Positive Identification

MS. TILTON: It is always a dubious honor to go right before lunch.

I will start off by telling you that I know very little about your profession and your area. My hope is to introduce you to a technology known as biometrics, and speculate on some ways that that might be able to be used to help you with reducing the errors.

[Slide.]

I am going to an introduction to biometrics, talk a little about identification applications, some considerations also.

[Slide.]

What are biometrics? They are measurements of certain physical or biological characteristics of an individual that can be captured, stored, and compared electronically, so that you can verify the identity of that individual.

Some examples of biometrics are fingerprints, facial recognition, speaker verification also known as a voice print, dynamic signature verification, your iris

pattern, your retinal pattern, and the others that you see there.

The level of uniqueness associated with the various different types of biometrics varies by the type and also by the particular algorithm that are used.

[Slide.]

How do these work? Well, the first step is the enrollment process where you need to capture that individual's biometric, and register it into some sort of database. So, the person presents their biometric--I will use the fingerprint as an example--places that on a fingerprint scanner. It is usually an optical or a silicon chip scanner.

Then, that information is processed. What we mean by that is you are taking from that fingerprint image, you are extracting the useful, unique features or characteristics out of that fingerprint, and basically, turning it into a long binary stream of information.

Then, that information is stored somewhere. It could be stored in a central database, it could be stored on a local PC, or in a device, or even on a Smart Card.

Later, when you need to verify the identity of that individual, again, that biometric is presented to the sensor device, it is captured, processed, but this time it is compared against that previously stored biometric characteristic, known as a biometric template.

Then, a decision is made as a result of that comparison on whether that is a match or a no-match, a match being you have a high confidence that that sample came from the same individual as was registered.

[Slide.]

We talked about enrollment, and I told you a little bit about verification. Verification is called One-to-One Matching. In this case, you are matching against a single record, against a claimed identity.

So, you are answering the question is this person who they claim to be or who I think they are. In this case, again, you need a claimed identity, something like a patient ID number or something like that, so that when you pull that record out of the database, you know which one you are pulling.

The other type of matching is called One-to-Many Matching or Identification, in which case you are matching

an unknown sample against all of the records that you have in the database, and trying to answer the question who is this person, is this person registered, previously registered with us. Obviously, the second is much more difficult than the first.

[Slide.]

So, what do you need to make a system like this work? Well, first of all, you need that capture device, a sensor, depending on the type of biometric, it might be a fingerprint scanner; for a voice print, it could be a simple sound card-microphone combination. Facial recognition, you could use the video camera. Iris recognition, there are special cameras available for that.

Once you have that information captured, that raw biometric data, there are algorithms that are used both for processing the biometric information. That is sometimes called feature extraction. Then, another algorithm to perform the matching operation. Of course, you also need a repository or a database, somewhere to store those biometric templates that have been enrolled.

For privacy and other reasons, security reasons, it is highly recommended that that information be protected using some sort of technology, such an encryption.

[Slide.]

These are some samples of some biometric devices that are out there. Just so you will get a feel for this, in this case, you have a keyboard where you have a biometric fingerprint scanner built it. It also happens to have a Smart Card reader in that example.

This is an iris recognition camera that is typically used for physical access into secure areas. This is a facial recognition system. This is just a typical video teleconferencing type camera. This is a hand geometry unit, again typically used for physical access, time and attendance, those types of applications.

You see something very similar to that for the annual passholders at Disney. They use a two-finger unit. These are some of the types of microphones that you might use for speaker recognition. This is a fingerprint scanner that is built into a combo device with a Smart Card read in it. You have a fingerprint read built into a mouse.

This is a chip, a fingerprint chip that is actually embedded in the Smart Card itself. Those are just now starting to come into the market. You can have them built into peripheral devices. It this case, there are PDAs that have got now fingerprint readers and other types of biometric devices built into them.

This is an iris camera for the desktop, and this is just a signature pad. So, those are just a very brief sampling of some of the devices that are available today.

[Slide.]

What are some of the benefits of using biometrics? Well, they are very convenient, because there is nothing that someone has to carry around or remember. They are very accurate in terms of being able to positively identify a person. They are becoming much more socially acceptable.

It can prevent impersonation, identity theft. It is considered a strong method of authentication as opposed to something you know, like a password. That frequently comes into play when you are using the biometrics for things like computer network access.

They can be used to protect privacy, for example. One of the applications for biometrics that is moving pretty

quickly is the use of biometrics for HIPAA compliance in making sure that access to clinical applications and medical records is limited to only those authorized to use those applications.

You also can provide an audit trial. The devices are becoming much more expensive. Of course, the main thing is that biometrics links an event or an action to a particular individual, not just something that they know, like a password or something that they carry around that can be shared or misplaced.

[Slide.]

Here are some of the applications where biometrics are being used today. I mentioned the medical records. There are actually a couple of patient ID applications out there also in the pharmacy, various other applications in financial, for network and computer security, many applications in the government that you can see there.

I think that biometrics has got a reputation. It came from a law enforcement background, and some people feel that biometrics are this star wars, James Bond kind of technology, and that it is outrageously expensive and you

would only use such a thing if you were protecting a nuclear facility or top secret information.

But the case is that the technology is here today, and it is only limited at this point by your creativity and the integration with various different solutions.

[Slide.]

So, how can they help you? As I was listening to the last speaker--and I am glad that the Metro got me here in time to hear that, so I have a better feel for where you guys are coming from--but when you are looking at having to identify an individual, biometrics, that is what they are good for, that is what they do.

Some of the things you have to consider, though, is that that patient needs to be enrolled initially, so at what point would you enroll that person, when they are admitted, at the bedside, at some previous visit to the hospital. There is an enrollment process in order to get that person's characteristics into your system to start with.

It could also be used in conjunction with a patient ID card. Frequently, you will see biometrics. The biometric template, not for all technologies, but for some,

is small enough to be included in, for example, a 2D bar code, that could be included on a label, it could be included on a card.

We are also seeing biometrics being used with Smart Cards where the biometric template is stored on the card.

In many cases, the One-to-One Matching might be what you are looking for, and the accuracy is certainly higher, the response time is certainly higher for a One-to-One system. However, if you do have a patient that is unconscious or for some other reason you are unable to identify them, then, One-to-Many Matching may be appropriate in some cases.

Again, this is considered personal information in most cases, so you do have to consider the person's privacy, and so the protection of that data, especially if it's located in a computer system, so you want to make sure that the system is protecting that in terms of encrypting and signing the information, and having access controls on the ability to access that information.

[Slide.]

At some point, you can use this, as this slide illustrates, there is a point where you have to enroll or perhaps this person is already enrolled and now he is about to have a procedure, so you have a device at the bedside.

I am showing a laptop with the fingerprint scanner attached. This could be a PDA with a fingerprint scanner in it. So, that fingerprint then goes back, and the matching is performed in a central server. Then, the identity, it comes back so that you can make sure that you know who the person is that you are dealing with. That is just one hypothetical example of how that might be used.

[Slide.]

Another hospital application I already mentioned is the data protection. Through the clinic, if you need to make sure that the information that you are using throughout your process remains unchanged or unmodified or uncorrupted, controlling access to that system would be important, and biometrics can also be done for that reason. Those solutions are deployed today.

[Slide.]

So, some of the considerations I mentioned, the enrollment process and the logistics associated with that,

and there is also the selection of the biometric technology type. There is quite a few out there, and you might have to think about which one might be most suitable for your environment.

Also, the case where some people are not good candidates for a particular biometric technology. For example, very elderly patients with very dry skin, sometimes you can have difficulty with a fingerprint system with those individuals, so you might also have to consider alternate biometrics.

You also might have people with certain disabilities that are unable to use a particular type of system, and you might want to have maybe even two different biometrics that you have the ability to use.

The device and architecture selection, taking into consideration the environment that you are working in and the space limitations that you may have would drive some of your decisions in this area.

I know one hospital we worked with really wanted the device in the keyboard, so that they didn't have one more thing at their nurses station that they had to have, taking up the area. But also as was mentioned earlier, the

cleaning of the device. I know that we have a fingerprint scanner installed at St. Vincent's Hospital in Indianapolis, Indiana, and that was one of their concerns is that we need to pour disinfectant over this thing, it's a silicon chip scanner, how is that going to react.

In that case, actually, the device was modified with a seal to make sure that there was no damage done to the device by the cleaning regimen and the specific disinfectants that would be used.

Of course, the other thing is how is this integrated within your existing network system. When I say "client platforms," I am talking about your workstation, your PC's and your applications.

So, there is system integration. In the future, there might be an enterprising vendor out there, that comes up with up a product very specific for this environment. I am not aware of any right now.

I mentioned the database integrity and confidentiality. There are always cost-performance tradeoffs that you would want to look at also, and standards compliance. There are a number of technical standards out there with regards to biometrics, and I would suggest that

you would want to choose something that complies with those standards, so that you don't have a proprietary point solution, that as the technology evolves, you get locked into as specific product or a specific vendor.

You want to be able to substitute and upgrade your technologies over time.

Lastly is vendor selection. As you are working with the various vendors, the trade association for the biometrics industry is the IBIA, the International Biometric Industry Association, which has member standards associated with it in terms of ethics, in terms of privacy, and truth in advertising, all those kind of things that you would expect.

So, if you are looking for a vendor, you would probably want to consider someone that is a member of the IBIA.

I mentioned the synergy of technologies. Biometrics work very well in combination with other technologies, such as PKI, such as Smart Cards. So, in the system that you are developing or using, those are some possibilities on how they can be used together.

[Slide.]

I have a conclusion slide, but I also made a couple of other notes, so I am going to mention that.

When we talk about accuracy of biometrics, again, I said it is dependent on the particular type of technology, but just as an example, fingerprint technology, you can expect to get about 1 times 10 to the 6th accuracy out of those. Iris recognition, you will get a higher accuracy. I think they claim an error rate of 1 times 10 to the minus 78th power, or something like that.

Some of the other biometrics are not as accurate as those, so that is one of the considerations that you will want to take.

[Slide.]

In conclusion, biometrics provide positive identification of a human being. They can be integrated into new or existing systems, and basically, can be used at any point where you need to know or verify the identity of that person.

There are other uses beyond patient identification, but I think that is probably of most interest to you. It can be integrated with other

technologies, and the costs have come down to where they are very cost effective.

My company, SAFLINK, doesn't specialize in patient ID. If anyone is interested, I would be glad to refer you to other companies that would be more suitable for that. I mentioned the other medical applications where you are interested in computer and network security, application security, and that is actually the area where my company works.

Thank you very much.

MS. GREGORY: Go ahead.

DR. LINDEN: Could you elaborate a little bit more on the limitations of this type of technology in the patient setting, such as pediatric patients, babies, patients who are unconscious, may not be able to cooperate? Which types of methods might work and which would not be applicable in that setting?

MS. TILTON: That is a very good question, because certain other technologies do lend themselves to different sets of user populations, environments, and applications.

Fingerprints can be used, we have used them on children down to about five years old, but when you start

looking at infants and very young people, my guess is that there might be a special sensor that may be required for that, because the finger is so small, and the ridge structure. You know, we are looking at those friction ridges on your finger, and they are very, very fine for children below that age.

There may be, for example, iris recognition might be something you would use there. One issue with that would be that if your patient is unconscious, generally, they have to be able to look in the direction of the camera, and if they are not able to focus, that could be an issue with that technology.

The one thing with fingerprints on 5 and above, that is something that they can be assisted with, where you can actually pick up their hand and place their finger on the sensor, so assistance with some of these in certain cases may be required.

MS. GREGORY: Are there any other questions? If not, please help me thank our speakers for this morning.

[Applause.]

MS. GREGORY: We are now ready for our panel discussion, and I am going to introduce Marilyn Bogner, who you met yesterday, and she is going to take it from here.

Panel Summary

DR. BOGNER: This will be a very brief discussion. I had mentioned to Richard Lewis, is there any kind of summary for the workshop, and in the best of traditions, he said, yes, why don't you do it.

In turn, then we have a couple of people I am going to call on to give their impressions of the workshop, just to kind of pull it together, to give us a sense of closure for what is going on.

First, I going to talk to Dr. AuBuchon, if he would give a few words.

DR. AuBUCHON: It is really striking when you look at how complex the blood banking and transfusion medicine systems are that we currently have, that we succeed in delivering a safe, fully tested, appropriately qualified unit of blood, from a qualified donor, to the correct patient as frequently as we do.

I didn't attempt to add them up, but there are almost innumerable opportunities to mess this system up, and yet we usually don't. So that is the good news.

However, with whatever frequency we are failing to achieve that goal, we are failing to meet the public's expectation. The public expects to receive the safe unit of blood and the right unit of blood every time. That may be an impossible task for us to achieve, but we can probably do better than we are doing. I think we can do far better than we are doing.

I think it is important that we take advantage of very innovative approaches, such as Mike Busch showed yesterday, of using some of the redundancies in our system to identify where the system may not be functioning properly.

By doing that, they are able to document that we are usually performing our testing entirely correctly, but other systems are showing us that we are not doing everything that we might do, and I think we should turn our attention to those areas.

So, as I have stated earlier, I think we do need to make the blood supply safer, but we need to make the

transfusion process safer, as well, and take advantage of the steps that are available. You know, biometrics sounds wonderful, it sounds very interesting. We aren't going to go home and use those things tomorrow, but we should go home and look at our systems, to start with, to see if the systems are set up so that our humans in the system have the greatest opportunity to be successful, and then take another look at the system to see where they can be bolstered, to make sure the system, make sure the human is doing the right thing at each step, so that we can indeed deliver the safe transfusion that we all want to.

Thank you.

DR. BOGNER: Also, Dr. Hilborne is going to give his summary, words to take away from the workshop.

DR. HILBORNE: When I found out I was going to do this, I jotted down a couple of notes from what I heard in the last day and a half.

The first message I heard actually yesterday was that if our government can work together, probably we should be able to, too, so I think that is a challenge. As Dr. AuBuchon said, by medical standards, we are actually pretty good in terms of laboratory and transfusion medicine, and we

ought to be moving our clinical colleagues along while we are striving to the next level.

Basically, I heard from Dr. Sazama and others, as we went all the way up until the last presentation, how important patient identification really is, something where we really need to focus our efforts, and that the majority of errors occur outside of the blood bank, but yet 25 percent still occur in the blood bank.

So, if we are really going to be high-reliability organizations, it is going to be very important for us to actually respond and learn from that.

I learned it wasn't good to be Type O, but I am aware there is nothing I can do about that, that we are human. You know, if the presumption is guilt, we will make sure that that happens. Usually, faulty systems are behind human issues, however, and usually, there is convergence of multiple factors.

I learned also that sometimes cheap fixes result in big buck benefits, that basically, we take risks all the time, but we should actually work to minimize some of the more high-risk situations, and strive for healthy behavior and remove some of the incentives for at-risk behavior, so I

guess I wonder why it was that the croissants were next to the fruit this morning.

We learned a lot about a just culture that will create a learning environment, that will yield a responsive culture, that we need to admit our mistakes, we need to speak up when we see problems, and that will reduce behavior, but as we identify problems, it is very important for us to be feeding them back.

We heard a lot today about technology and automation can help us out, but we shouldn't be accepting it blindly, because as we implement new technology, we will need to be vigilant that new errors, the kinds that we hadn't ever seen or expected before in health care will start to emerge, and we have heard that some of the vendors are really very interested in working with us to make sure that that happens.

From my point of view, I think it is important to give the message that blood safety really is a component of patient safety, so that as we are developing systems to deliver safe health care, things like patient identification, we need to be cognizant that we need to put that together with other forums and other activities where

patient identification is important, particularly medication administration, because it is a big one, so we need to do that together.

I guess I learned in the last hour that if Disneyland can tell who I am, and FedEx can use a bar with my fingerprint, FedEx can tell me, or my retinal scan or whatever they are using, and FedEx can tell me with a bar code where a package is anywhere in the world, I wonder why it is that we can't tell these kinds of things in the hospital.

So, I think that we should look to Disney, we should look to other industries, and it's a small world, and if we are really smart, we will be moving to something a lot more complacent than health care, which right now looks like Mr. Toad's Wild Ride.

DR. BOGNER: It must have been Disneyland right out in his territory.

Although redundancy is very good in transfusion medicine, I am not going to be redundant with any comments that we have had before, but just a comment, an observation, too, about the meeting here.

I think it is wonderful, the number of people who not only stayed throughout the day yesterday, but who came the second day, often people drop off, and who are here, even now, knowing that people have planes to catch, and other temptations to do, as well as get something to eat.

The interaction I think is very valuable at the breaks, and I wonder again what the message was, not only in the placement of the croissants next to the fruit, but also the obesity display that was down at the end of the hall considering the good things we have had, I am going to not eat I think for the next month.

There is a great big thank you that I want to pass on to Richard Lewis and to the organizing committee, the people who worked together to make this happen, and Jim Battles, Kay Gregory, Harold Kaplan, and Jeanne Linden.

I would like to ask Jeanne Linden if she would like to say a few words just to tie us all together as a person who has been very much involved with the whole blood program and this meeting.

DR. LINDEN: I won't keep you, but just briefly, my impressions of the meeting are that I am very pleased at how everything was able to come together. I think we

learned a lot. We clearly documented the problems that are out there, and we have also been fortunate to be able to draw from other industries to learn some of the principles of approaches that we can try to solve some of the problems.

We have heard about some of the technology that is presently available, may be available in the future, and maybe we can all put our thinking caps on and think about how some of these can be applied to our particular application.

I am very pleased with the number of people who came here to listen. I am concerned a little bit, though, that we are preaching to the choir. When you look at the most significant transfusion errors, those that involve a patient actually getting the wrong blood, three-quarters of those occur outside the blood bank, and I think our challenge is to spread the word to other parts of the hospital about some of these things that we have learned and how some of these innovations may be able to be applied outside the blood bank, as well as the challenges that we face inside the blood bank.

I hope that we can all apply what we have learned here and go out and spread the word to others.

DR. BOGNER: Just one last comment. Does anybody else have anything they want to say, comments about the workshop, anything in general? I don't want to cut you off without an opportunity.

No? Okay. Well, thank you very much for attending. Let's thank our organizing group.

[Applause.]

[Whereupon, at 1:15 p.m., the workshop was concluded.]