Page 1

MR. CAULFIELD:

Q. I'm Tim Caulfield, I'm a law professor from the University of Alberta. And I am the Director of Research, I've had the opportunity to be the Director of Research for this Inquiry and really for this part of the Inquiry.

I know that this has been a very challenging issue for Newfoundland, an issue that has truly been a tragedy for many families and has touched the lives of people throughout Newfoundland and Labrador, and really, throughout Canada. So it is a challenge.

Over the next couple of days we are going to hear from legal and ethical, media, really, social policy experts and they really truly are a renowned group of individuals, so I see this as a really wonderful opportunity to talk about the issues that may allow us to look forward.

Now, I would like to emphasize that that is the goal of this event. We don't want to talk too much about the specifics of the Inquiry, the specifics that led us to create

Page 2

an inquiry, but rather to explore the norms, to explore the legal background, to explore the international trends that will hopefully allow us to look forward to inform the Inquiry's actions and allow Justice Cameron to have informed recommendations. So that's the goal, that's the goal of today.

We have, as I said, a truly remarkable faculty who have had the opportunity to write wonderful background papers which are on the web site. I hope some of you have had the opportunity to read them, at least some of them. And they really are an amazing team. And I'm not--this isn't hyperbole when I say that we have managed, we've managed to put together a group of individuals that have spent a good part of their career studying the issues around patient safety and it's a tremendous opportunity for us to pick their brains, to ask them questions about what may be relevant to recommendations for Justice Cameron. So I hope that what we can do today is set a tone of open discussion, I hope we can set a tone that allows us to scratch below the surface and hopefully really move, move

Page 3

things forward and look forward.

So let me give you some process and procedure. The presentations will be 25 minutes long. And I'm going to be strict, you guys. I'll give you guys a warning around 20 minutes. Then we'll have time for perhaps one or two quick questions for the first speaker. Then we'll have the next speaker, again, 20, 25 minutes. And then an opportunity for discussion. Now, we will, hopefully we'll have lots of discussion. As I said, I want this to be an open dialogue. And then at the end of next--end of tomorrow there will be about an hour and a half for a really open discussion where we'll bring all the panellists up and hopefully that'll allow us to get some closure on some of the issues that have come up throughout the day and a half.

I encourage our speakers to be--to speak freely, to speak their mind, hopefully to speak with passion and on really any topic. There are--given that this is an inquiry and there are some very delicate issues at play, the one thing we have to be careful about is issues that are direct to, perhaps, liability.

Page 4

But beyond that, beyond that I hope we can speak very freely.

I am going to have very, very short introductions for our speakers. Their long bios are on the web site if people want to explore a little bit about them, but I don't to take up precious time introducing them. Take my word for it, they are remarkable.

It has been a true pleasure to work with Justice Cameron and the entire Inquiry team. They really are a wonderful team and I know that they've been working very, very hard. I get e-mails at weird times, so that's always an indication that people are work strange hours and working very, very hard.

And but also before I begin I think it's important for me to disclose something. I have a magical ability over Newfoundland. I've been here over half dozen times, as my good friend, Daryl Pullman, knows and I've never seen precipitation. Now, I understand that it does snow here and it does rain here and it's not always blue skies, but it's apparently an ability--I have never seen it. So let's hope that this beautiful weather that

we're having, the sunny skies, will help to set the right tone and help us to look forward.

So, thanks very, very much and I look forward to introducing Justice Cameron, who is going to give us a few words about what brought us here. Justice Cameron.

THE COMMISSIONER:

Q. Thank you, Tim. Good morning and welcome. Tim has asked me to say a few words about the Commission and our task. I suspect most of you in the room know all too well what we're about, but for those few who are either not from the immediate area or perhaps are tuning in for the first time via the media, let me just say a few words about the task.

The Commission was established in July of last year. There are six terms of reference, four of those look to the past, one looks to the present and one looks to the future.

Essentially the Commission is to find out what happened to cause a high rate of conversion on retesting and whether those problems could have been determined earlier. I am directed as well to determine whether the

systems now in operation are reflective of best practice. Those terms can be said to deal with testing practices for estrogen and progesterone within the health care system. The Commission is also to examine communications about ER/PR, as we've come to know it, retesting with affected patients, with the public and with others within the health care system. As those of you who may have been following the Commission proceedings will know, we have chosen to begin with the issue of communications.

The final term of reference invites me to make recommendations. When considering how to go about doing this, I knew I needed the assistance of experts in the field of patient safety and in communications. I would not be making findings of fact which those in my profession are accustomed to doing dealing with the past in the context of making those recommendations. I would be trying to discover and articulate recommendations which will make a better system in future. Thus, the theme of the symposium is "Looking Forward." However, I also concluded that a

traditional hearing, the process which is already ongoing, as most of you would know, was perhaps not the most beneficial way to obtain the information I needed. I preferred a dialogue where perspectives of different disciplines would be expressed and different opinions could be discussed. That is where Tim Caulfield came in and joined our team.

I am most grateful for his assistance and encouragement in pulling together this group of presenters which, as he has noted, I think, is remarkable in the sense that we have been able to gather together so many on the one occasion who are in a position to give us so much information. Six of our presenters have prepared papers which you, as Tim has already noted, would find on our web site, and I recommend all of those papers to you.

Some of you will have observed that we have included some traditional legal analysis in the mix that includes principles relating to tort law. That is not to suggest that I or the presenters intend to engage in an analysis of civil or criminal liability as it relates to ER and PR retesting. That is outside the

Commission's mandate, as I have said often. For me, however, the legal obligations respecting communications are a part of the context which must be examined to enable me to make recommendations for the future.

I'm very much looking forward to the next day and a half and the discussion which will take place. A transcript of the presentations and the discussions will be available on our web site early next week for those of you who don't wish to take notes but sometime in the future have the thought that you might want to think again about something that was said here.

For those persons who do not have standing, that is, those of you who are beyond about the fifth or sixth row here, you are reminded that if you wish to do so, you may make written submissions to the Commission regarding matters such as communications with patients and how that should be handled in the future. We have set May 15th as the deadline for the submission of briefs by members of the public. I want to assure those members of the public who may be considering submissions of

Page 9

briefs that I very much welcome that and would look forward to seeing your perspective on the issues related to patient safety and communications to patients.

So without further ado, Tim.

MR. CAULFIELD:

Q. Thank you, very much, Justice Cameron. Well, we're already ahead of schedule, which is always a good sign when you're organizing a conference. I do have a few more details to say, important things like where the washrooms are. I did a little reconnaissance and they are to the left and then to the left again. So go through the double doors and then through another set of double doors. Also, please try to keep your cell phones on vibrate or perhaps even, best of all, turn them off. And other than that, as I said, I hope that we can have an open discussion.

Now, we're lucky, we're going to start now with our first speaker, who is going to lay the groundwork regarding patient safety generally, talk a little bit about the patient safety trends and things that the community have been talking about, the academic

Page 10

community in relation to patient safety. And we have Dr. Peter Norton. He--as I said, I'm going to keep these introductions very short. He is a professor at the University of Calgary. He is an expert in patient safety issues. I know he's spoken all over the world on these topics and he's written on these topics extensively and he's also a professor of family medicine. So, over to you, Peter.

DR. NORTON:

Q. I have to get this thing on because my wife tells me I wander all the time away from the podium, so. How is that? Have I got sound? Hello. Can you hear me now? Yeah, okay.

Well, thank you very much for having me come. I always enjoy coming to Newfoundland. It's one of my favourite parts the country right after the Rocky Mountains, and today it's even better because the Rocky Mountains are covered in snow and you can't move around. So it's really delightful to be here as spring comes to this province.

Tim asked me if I would talk a little bit about how things were going in patient safety. And as I prepared this, I realized it was a

Page 11

personal view, so I hope you'll enjoy it.

It is reasonable to say that modern patient safety began with the publication of what's called "The Harvard Medical Practice Study" which was published in 1991. This was a study undertaken in New York State to determine if no-fault insurance was a viable option for them, and so they were looking for potentially events which potentially would cost money to the insurance system. They looked at a lot of charts and in a retrospective way determined iatrogenic injury. They published this paper saying that probably 180,000 people a year were dying from iatrogenic injury. They cited this famous quote that this was the same as three jumbo jets crashing every two days and this was met in the United States and around the world with astounding silence, except in Australia where Ross Wilson and his colleagues read this and said, "We want to find out what's going in Australia."

They published their work in 1995. They studied 28 hospitals in two of the states of Australia and they looked at 14,000 admissions

Page 12

retrospectively, looking at the charts. They used the same methods that the Harvard Medical Practice Studies used, but they refined the definition of an adverse event to not just be things which had to do with the legal/medical interface, but also to deal with the quality interface. And redefining it was an important part of the patient safety movement. They shows 16.6 percent of Australians admitted to their hospitals, adult Australians, had an adverse event and 51 were considered highly preventable and that there was a huge burden on the system, as well, with extra hospital days being used. This happened, when the report was just ready to be released, hadn't yet finished its peer review, the minister of health in Australia stood up in the legislature and announced the number and caused a turmoil in Australia that took about five years to settle down. Nothing happened except fighting between the various players.

The next major event occurred in 1999 when the institutes of medicine in the United States published this book called "To Err is Human, Building a Safer Health Care System."

Page 13

They really reviewed the Harvard Medical Practice Study and reflected on the quality of care in the United States. It was released on what has been called by many people as slow news day in the States and so made front-line headlines in the Tribune, the Chicago Tribune, the New York Times and so on. This produced an immense effect in the States, even though they were reporting on something that we knew for almost ten years.

And there was a ripple effect in Canada and one of the things that happened was Health Canada asked if someone would understand the state of safety in Canada, patient safety. And Ross Baker and I, Ross is a colleague who I've worked with for many years, received funding from Health Canada to undertake a study of the Canadian system to give an overall picture of where we were in Canada and whether we needed to be doing anything and what was actually going on. We used a complex set of methodologies, but the main one was to talk to key informants and then ask them who else we should talk to, what's called a snowball technique in most of the stakeholder

Page 14

groups. And we completed that report and listed it--and published it in, or sent it to Health Canada in 2002. It's posted on their web site still. And it really is-has, I think, had an effect in where we've gone in Canada.

We had made four major recommendations in this report: That there was a necessity to build awareness and set priorities in patient safety; that we needed better reporting systems so that we could learn from events; that we needed to create organizational and policy supports for patient safety efforts; and we had to build skills, disseminate knowledge and implement systems to improve safety.

What I want to do is reflect in just six brief years where we've gone with these recommendations.

The first was to build awareness and set priorities to improve safety. The first, I think, major event was the Canadian Adverse Events Study. This study was funded by the major federal funding agencies, the Canadian Institutes of Health Research and the Canadian

Page 15

Institute of Health Information. They put out a call for someone to do this research and Baker and I were lucky enough to receive the funding. You'll be hearing from two of the 40 folks that were involved in getting this report, study and report done today; Phil Hebert and Ed Etchells were both on the study team. This was an effort to replicate the Harvard and Australian studies in Canada and it was funded very generously at about $875,000. We also had about $200,000 to work on dissemination so that people were ready for the results.

It's important for me to just step back and tell you what an adverse event is according to the way we did it in this study. And this actually comes from Ross Wilson, the Australian I was telling you about. Thumb nailed is an adverse event is a bad outcome of care, but we have a very specific definition in this. So first of all, it's an unintended injury or complication. That's important because in our care we often injure people and we know the injuries are going to happen. You give--there are people down in the surgery

Page 16

suite at the hospital at the moment who are being injured, they're being cut open. That's, we're doing that because the risk of being cut open is small compared to the benefit of having surgery for the condition. So an unintended injury or complication. The second thing about this is it has to have an important result. Either--and this is focused now on the acute care setting, but either disability at the time of discharge or death or prolonged hospital stay. So you've got this unintended injury causing something and resulting in something and it has to be caused by health care management, not the patient's underlying illness.

It's a complex definition and hard to understand. And to make it a little clearer I thought I'd go through this diagram. So errors, we all understand errors. They're slips, misses, things we do wrong. People make them all the time and I think Ed'll talk a bit about people making errors. And then we have this adverse event, these things I just described. And here's three little stories about things that happen in hospitals and

Page 17

let's just go through them.

Looking up at the upper right-hand corner, a patient is admitted--no. Let's start with--yes. Let's start with the red one. Patients admitted is never--is asked by the admitting physician, "Are you allergic to Penicillin?" "No." The patient is admitted, Penicillin is the right drug, the drug is given, the patient has a severe allergic reaction with bad consequences. This is clearly an adverse event. There's an unintended injury caused by the medical treatment with a profound effect. However, there was no error in care here. So this sits in the adverse event box but not in the error box.

The second one is down at the bottom. Same patient is admitted, the Penicillin is ordered at 250 milligrams, four times a day and the patient actually gets, through many things that went wrong in the hospital, 500 milligrams. Now, Penicillin is a nice drug, that's why docs like it, because it doesn't hurt you much if you get 500 or 250. It's got what's called a large therapeutic range. So

Page 18

there's really no consequence here except for a few cents to buy another Penicillin tablet, instead of giving one, you give two. So this is clearly an error, things didn't work right, the system slipped, but it's not an adverse event because there was no injury. And so it sits in that box.

The one at the top talks about the patient is admitted, the medical student takes the history and writes down on the chart, "Patient allergic to Penicillin." The patient gets to the floor and somebody writes an order for Penicillin and then many things go wrong in the hospital, all the checks and balances we have in place to make sure this doesn't happen break. The pharmacist misses it, the nurse misses it, the physician misses it. The patient gets the Penicillin, they have a severe allergic reaction. It's clearly both an adverse event and probably a series of slips and misses. So it sits in this area.

Now, these areas are all important as we try to work to make a better system. First of all, the area at the top that the red box is in tells us about, sorry, tells us about the

Page 19

kind of things that happen that we have no control over, but we can do things about those. If that's happening all the time in my hospital, if I'm having a lot of people getting Penicillin and getting bad reactions, I can change the formulary and say "We're not going to give Penicillin in my hospital any more." or I can go to the basic scientists and say, "I need a better test for Penicillin allergy." That's a basic science question. So that's an important area for us to understand.

The area at the bottom, the errors that aren't adverse events are really important because they're what we might call near misses. The system didn't work but nobody got hurt. But next time the system doesn't work, we give a different kind of drug, a drug that you can't get away with doubling the dose on without causing harm, we're going to have harm to a patient. We don't want that. So this area is very good for us to study as we try to improve the quality of the system.

The intersection, the centre, is the really important thing. Those are preventable

Page 20

adverse events, those are the things we should be hoping in the future to get to zero. That's about the quality of the system.

So the Canadian Adverse Events Study was studying adverse events. We started it in 2002, we completed it in the fall of 2003. Some people have said this is the largest health service research project even undertaken in Canada. We used the methods, as I said before, of the Harvard Medical Practice Study and Australia and we were trying to find out how many adverse events occurred to patients and how many of them were preventable. We studied the--oh, the paper was published in 2004 in May. It really had quite an impact. It was downloaded 25,000 times in the first four days, an all-time record for the CMAJ still and Ross Baker and I within two months had 43 national and regional media contacts about the paper.

Here are the key numbers that we found: The overall Adverse Events Study in adults in Canada in fiscal year 2000 was 7.5 percent. 7.5 percent of adults admitted to our acute care hospitals had one or more adverse events,

Page 21

one in 13. The confidence intervals are small. And about three percent had a preventable adverse event. This is the number we want to push to zero, about half, a little under half.

These numbers are the same as the numbers that are in almost every study that's been done and is being done around the world. The number is around 10 percent of patients, plus or minus two percent everywhere. And I just listed a few of the places, the UK, New Zealand, Spain, Holland, Denmark, Australia, Brazil. More recently since I've got this I've seen the data from three of the Arab countries, they're coming in in the same range, and two Sub-Saharan countries. This number seems to be a pervasive number, which is an interesting fact. I told you this was -

So the second part, remember I'm talking about our 2002 report, and the second point I wanted to make was about setting priorities and improving safety was that the Canadian Patient Safety Institute was established in 2003. It's funded for $50 million for the first five years. It's to coordinate this

Page 22

effort across Canada. And putting a national organization in place, within funding, to move this ahead has been an important and, I think, foundational piece of work as we try to move to make a safer system in Canada. We just heard two weeks ago that their funding has been extended for another five years, which is very good news.

The second thing Baker and I asked--recommended in the report, asked for, that's a bit much, was to develop better reporting systems. There's something can CMIRPS, Canadian Medication Incident Reporting and Prevention System. This had been touted as the first really national reporting system for adverse events. It'll report adverse drug events, which are a big part of adverse events. This development has occurred much more slowly than we would have hoped, and it still is not in existence, although money continues to flow to it. We would hope it gets up. The Canadian Patient Safety Institute has taken a major lead with CIHI, Canadian Institutes of Health Information, in the next four or five years to try to get

Page 23

something going first in drugs and then across the country.

But provincially we've seen some amazing movement in this area. For example, Saskatchewan changed their regulations to allow all critical incidents to be reported to Sask Health where they're anonymized and then sent back out to all their regions. So if something bad happens in one place, they investigate it and they then, after sufficient confidentiality concerns, send it to every one of their health regions and say "All of you work on this." So I think that it--and there's some others here. This is occurring at the provincial level, we just haven't got the federal stuff in place yet.

Third point was to create organizational and policy supports for patient safety efforts. All the provinces have introduced some legislation concerning protection, legal protection around investigation of adverse events at this point and the legal experts will probably talk more about that.

Disclosure is moving ahead, it's either mandated or suggested or supported at various

Page 24

levels in each province, and I know there's going to be a lot of discussion with disclosure. And CPSI, Canadian Patient Safety Institute, has just recently released a national framework to help each institution, province, region accelerate their work in disclosure.

And finally, in 2005 our accreditation council for hospitals has began increasingly to demand organizational practices during accreditation directly related to improving safety. And their web site will show you a lot of stuff about that. So there's been a fair amount of work in this area.

And finally, build skills, disseminate knowledge and implement systems to improve safety. So the first three, if you like, are the framework to make us somewhere and this one says now let's do something.

One of the places where, in my estimation, we haven't done enough is in the educational form for new health professionals. The penetration of the safety information into the curriculums has really been quite slow and I think is accelerating but not as much as we

Page 25

should have done. However, we have lots of professional development opportunities available, we've funded a lot of demonstration projects, there's been significant, 5 and a half million dollars worth of funding from the federal government toward doing research. And the involvement of the public has-- understanding the public have to be part of the solution, posing the questions, moving us to a safer system. We're seeing some of the health regions in the country, Winnipeg is the one I picked here, take a real leadership role in engaging the public in a new way to make the system safer.

However, now we get very personal because I'm part of this story I'm going to tell you. We're doing another major thing to improve the system, and this is called "Safer Health Care Now." And I wanted to spend a little time telling you about this national initiative because I think it's a hopeful thing that we can actually do something. So here's the story.

December 14th, 2004 Jack Davis, who you see on the left, who's the CEO of the Calgary

Page 26

Health Region where I work, was at a meeting in Florida where Don Berwick, who is international, "the" international leader in patient safety said he was impatient, nothing was changing, safety wasn't getting better. He, as was announced in the paper, threw down the gantlet and said the Americans were launching a campaign to save 100,000 lives in the next 18 months. Well, Jack, being an Alberta, said, "Well, that's good. If they can do it, we can do it, right." And Ward Flemons, who I couldn't find a picture of, who is the vice president of safety was sitting beside him, so Jack leans over to Ward and he says, "Ward, I think we'll do this in Calgary." Ward comes back and phones me and says, "Peter, Jack wants to do this in Calgary." I said, "Well, I'm not doing it in Calgary, Ward, I'm only going to do it if we do it in Canada." And so that lead me to get Ross involved and we established Safer Health Care Now.

Now, we didn't call it 100,000 lives campaign. We had some feelings that it was more Canadian to say Safer Health Care Now,

Page 27

let's get on with it, let's do it. But we've certainly borrowed much from the Americans. They've helped us with this, they've been our allies. We've taught them things and we've learned things. And I want to tell you what we've done.

Remember, this is now Christmas of 2004. So we decided we had to Canadianize the American approach, you know, you couldn't possibly follow it directly, and we would align Canadian experts in quality improvement and clinical areas as faculties to assist front-line teams, the doctors, nurses, pharmacists and therapists who are actually taking care of patients to improve their care. That was the idea. And we would do it in six targeted low-tech areas where we had good evidence that there was a gap, we weren't providing as good care as we could, and we're going to give them the tools to make them able to provide the care they wanted. We assumed anyone could come at any level, you didn't have to be, you know, a teaching hospital in downtown Toronto, you could be a small hospital in Baie Comeau, you could be up in

Page 28

Nunuvik, you could be on the rock. And we were going to do this together, we were going to form communities of practice across the country and all work and learn from each other. Those were the fundamental principles we set down. There were six key interventions, these are directly from the Americans. I'm not going to go through them. You can read them on the Safer Health Care Now web site. But none of them are really high tech.

And I'll come and discuss just one, the prevention of surgical site infections as an example. So what would happen is a team from a hospital would pick one of these and work on it and we would support them with quality improvement and clinical knowledge.

How did we get the funding? We scraped it together, CPSI gave us some, the provinces put some money in, the provincial quality and safety organizations did, we had a variety of sources and we launched it, notice, in four months with four regional nodes. Now that was a good idea, you know, because Canada just loves to compete and if I can say, you know,

Page 29

Ontario is ahead of the west, the west gets a lot of excitement going, so part of it was that, because it's a Canadian thing to do. We had a national coordinating group, we had the faculties which are both clinical experts and quality experts and we produced what are called "Getting Started" kits which were, they're all posted on the web, but they're explicit details about both the evidence for improving practice, the ways to measure where your practice is at and improvement techniques. We had a goal to enrol 100 front-like teams by December, 2006, that was our goal.

The western node, just so you understand the depth of staff, for dealing with the four western provinces I have a secretary, two quality staff advisors, the team director and me. The first four get paid and I don't. Lot of people doing unpaid work here. This campaign is probably costing Canada about 2.3 or 4 million dollars a year, plus contributions in kind from the hospitals and regions who send teams and support teams so they can do the work. And there's a national

Page 30

measurement team and we have learning meetings, national learning meetings and teleconferences and web conferences and use all the modern educational techniques that we can.

Well, here's the enrolment starting from September, 2005 and you'll notice by October we had done a little better than 100 teams, 789 teams working across the country in those six initiatives. It's now over 850 teams. That in itself is impressive, there are that many doctors, nurses and pharmacists who actually say we're going to work together on this and we're going to work together close to the patients at the bedside.

So I thought I'd just explain surgical site infection and show you their results. Surgical site infections were the most frequent adverse event in the Canadian adverse--were among the most, it says were the most, were among the most. Surgical site infections were very prevalent in the Canadian Adverse Events Study. A recent Quebec study showed about two percent surgical patients have a surgical site infection. These are not

Page 31

just little things on the surface, these are bad infections, deep inside you that require either re-operation or--and complicated antibiotics. You're sick. And there's timely--there's very strong evidence, 20-year evidence that if we give antibiotics within 60 minutes of surgery starting, the cut, we can substantially reduce these, substantially reduce them. You want a lot of antibiotic around so when you go through the skin, bacteria die if they try to go into the surgical site. Get the idea?

When we--and so there were four things that the teams were going to try do. The first is easy. Don't shave the skin, clip the hair, because when you shave, you make little cuts and the bacteria can get inside the skin before the operation, and now they're not, they're closer to the site. You think that sounds easy, you think that all you have to do is not buy more razors, well, that costs more money, so you have to convince the chief financial officer not to do that, but in addition you got to go and find all the razors that are hidden all over the hospital. True.

Page 32

The second is to make sure that antibiotics are given and stopped on time, these prophylactic antibiotics, you got a 60 minute window. Now, that sounds like it's easy, right? The trouble is the patient's down in the ward, and it says on the list, "Surgery will start at 10:30" so at 9:30 the antibiotic is given, but of course, the OR is not running on schedule, never is, and the floor doesn't know the time, so you've got to change the system to make it work differently. And then you've got to control blood sugar during cardiac surgery and body temperature during abdominal surgery. Very simple.

We've known these things should happen for 20 years. Every surgeon, every anaesthesiologist, every OR nurse wants these to happen all of the time. Yet, when we began, for example, with hair removal, across Canada, that's the baseline measure, the teams were averaging around 66 percent. Two thirds of the time they were clipping the hair, but one third of the time they were shaving it. However, working together as teams across the country by 11 months out, 100 percent and

Page 33

holding. So you can actually change something.

Receiving the antibiotics, the right antibiotic by the right room at the time, when we started across the country the surgeons and anaesthesia guys were shocked when they actually measured it, because the system doesn't give us these kind of measurements. Forty-five (45) percent of the time we were getting it. The goal here is not quite 100 percent because some people are very allergic, sometimes you have to do crash surgery, there's some reasons not to get to 100 percent clinically. But look at the gain, look at the gain. We have the teams 90 percent of the time, and that's holding, as well. So this is a demonstration that we can do something, we don't have to spend a lot of money, but we have to enable people to change the system they work in and reflect on it.

Here's some comments about, I just picked a couple, about participating in Safer Health Care Now from hospital leaders. These are a couple from other provinces. "To not participate is not an option." "Finally

Page 34

someone is giving us the tools to change things." "Safer Health Care Now has provided us with leadership and coordination in all the intervention."

We've just launched new initiatives in Safer Health Care Now. In the last month in addition to the first six, preventing falls in long-term care, preventing harm from these terrible antibiotic-resistant organisms, preventing clots in your legs, in your tummy during surgery and after surgery, high-risk medications in paediatrics and getting the medications right in home care when people are admitted.

We're sort of nibbling away at the edges and sometimes you might want to get discouraged about this. But, you know, I sort of have to think about this and I just put up a couple of very old quotes, "The journey of 1000 miles begins with one step" said Lao. He was a contemporary of Confucius. I think we've actually done more than one step, but it's a long journey and we're not going to get there.

Where's Tim? Can I go--can I do five

Page 35

more? Okay.

So why is this journey so hard? And I just want reflect on this, this one last point. I want to talk about hospitalization. And one of the things people keep saying is, "Well, if we can get airlines right, how come we can't get hospitals right?" "If we can get the oil rigs right, how come we can't get the hospitals right?" I think that's really unfair. Hospitals are complex places that deal with a product line, if you like to talk about business, the patients are all different, they're vulnerable, they're sick. We make big risks in taking care of them. It's a very complex system.

And if you're going to say "Are hospitals good or bad?" you should say, "Well, what happens if we close all the hospitals tomorrow?" That's really the comparison. What are hospitals doing for us? And let me tell you, if we close all the hospitals in Newfoundland tomorrow and your nephew goes out and plays hockey and gets boarded badly and ruptures his spleen, he will die. If the hospitals are open, he won't die. Or if your

Page 36

niece gets a red rash and a bit of a stiff neck and the hospitals are open, she has a 70 percent chance of living through her meningitis and if there were no hospitals, she wouldn't. So let me tell you, I am absolutely convinced that hospitals make a huge gain overall on the quality of Canadian life.

However, having said that, I will now compare hospitals to other industries in Canada. And I have to thank Phil Hebert for this work. This diagram is an important diagram, it's a safety diagram. The first thing I'd point out is these scales are both logarithmic, they get big very fast, so they go 1, 10, 100. Up that side is how many lives are lost a year in Canada by various activities and this is the number of encounters needed for one person to die at that activity. And the lines are important. The safety scientists break us into three kinds of activities; dangerous activities, regulated activities and ultra-safe activities based on those lines. And the important thing here is from the safety sign is to cross one of those lines you have to fundamentally

Page 37

change the system. You don't get that--you can move inside an area by little things, moving across is a big thing, and I'll show you that.

So here's commercial airlines in Canada, they're very safe. They're ultra-safe, we never worry much about getting on an airplane in Canada. There's, this is an Alberta thing. You can fire guns a lot of times before you kill anybody in this country. And we're pretty interested in that in Alberta, as you can imagine, anyway. I won't say more about that. Here's some of our sports activities. Phil has a funny sense of humour, you'll see later on today. That's the scuba diving. And of course, the bungee jumping here, this is Canadian bungee jumping which is done at places like the national exhibitions. We don't jump into canyons like the New Zealanders and Australians. Their bungee jumping might be a bit later--lower. And the rock climbing, 25 hours of rock climbing is pretty dangerous activity, but we let people do that in Canada. And my colleagues who work in the emergencies close to the foothills see

Page 38

these people all the time.

Here's some of our industries, primary industries. And I want to just talk about coal mining for a second. 100 years ago coal mining was down in the dangerous area and it got up into the regulated area. And how did they do that? They fundamentally changed the way we coal mine in Canada. Back then they were mining underground, now they're above ground. That's a fundamental change. And that's how you move. There's driving, we all do it every day. And if you average all that, that's about where we are. That's what Canadian acceptable risk is. And that's where hospitalization is. That's where hospitalization is in Canada, based on the Canadian Adverse Events Study.

So my goal when I talk to people like yourselves or anyone else is to say, "Well, we want to go across the line. It's going to take a lot of change and it's going to take a generation or two, but you got to start, you got to make the first part of the journey." Churchill said, "Every day you make some progress, every step will be fruitful, yet

Page 39

there are stretches before you, an ever lengthening, ever ascending, ever improving path. You know you'll never get to the end of the journey, but this is not discouraging. It adds to the joy and glory of the climb." And that's the climb we're on. Thank you.

MR. CAULFIELD:

Q. We have, now have some time for a discussion, obviously. I have many questions myself. It would be great if we could concentrate some of our discussion on the general topic of patient safety and perhaps some of the framework issues. So I have some questions myself, I'd be happy to start, but let's open it up to the group first. Does anyone have some questions they'd like to dive in on? Yes.

UNKNOWN SPEAKER:

Q. I'd like to ask Dr. Norton whether he knows offhand how many participants there are from the Province of Newfoundland and Labrador in these Safer Health Care Now initiative?

DR. NORTON:

Q. I believe that we have teams from every region of the province. I don't know the exact number. I'm sorry, I should have looked that

Page 40

up, I do have it. It's posted on the web site. If you Google "Safer Health Care SHN!" you'll fin the web site and we have all the enrolment figures. But the campaign in the Atlantic Provinces, the Atlantic Provinces form a node, just like the west. So the nodes are Ontario which, of course, assumes its the biggest node; and then the west, which knows its the biggest node; and then the Maritimes, which is doing an excellent job and has the highest penetration; and Quebec, which came on late because it took them longer to join. So that's a very Canadian thing. Alberta is--I mean, Alberta, here we are, the western node is responsible for the Arctic. It's really very exciting to go to the meetings. I can't tell you how exciting it is to see that many clinicians. Like, we had a meeting in Winnipeg, of all places, three weeks ago, and we had 400 clinicians and quality improvement people come to talk about getting better.

MR. CAULFIELD:

Q. Daryl?

DR. PULLMAN:

Q. Thank you for your very interesting talk. I

Page 41

am curious, most of the data that was presented and so forth has to do with errors in treatment, and I'm curious whether there--whether there are statistics kept on diagnostic issues because many of the issues that we're dealing with here have to do with diagnosis and errors in diagnosis, which seem to be slightly different. And I wondered if there's work being done in that area and recommendations in that respect, as well?

DR. NORTON:

Q. Let me say two things. First of all, we did, there were 255 patients out of 4000 charts who had one or more adverse events in the study. And when one of these errors was found, these--not these errors, these adverse events was found. The doctors and nurses who were reviewing the charts wrote quite extensive notes. These were quite painful for the reviewers to look at, many because you can see yourself doing these things, being involved. And we've done an extensive analysis, what's called a qualitative analysis trying to understand those stories and put them together. Seventy percent of them sit in

Page 42

three categories.

The first category is misdiagnosis, but this is not misdiagnosis exactly in a way you say. Here's a typical example of that. First it's either missing another illness. The patient has two illnesses which are contributing to their condition, both are active. It's not what's called a co-morbidity. So the patient might have pneumonia and congestive heart failure but the clinicians only understand the pneumonia and they treat the pneumonia but after a few days they realize they've got to treat congestive heart failure, which is water in the lungs, as well, and so there's a prolonged hospital stay. The other thing is just plain having the wrong diagnosis, so you think it's pneumonia, but it's just congestive heart failure. So that's the most common thing we saw. Those are not quite lab diagnostic errors, those are different. I'll come back to that.

The second most common thing are errors in drug and fluid management. So having two drugs together that shouldn't be together,

Page 43

having a drug present when the patient is intolerant, having a drug present which doesn't deal with the condition, the condition of the patient.

And the third is the fact that organ failure is occurring and it's not recognized. Typically treating a person with congestive heart failure, the pump failing, we push their kidneys pretty hard and sometimes the kidneys start to fail and the clinicians may not see that happening early enough and the patient gets into trouble because of renal failure as well as their underlying condition. And those account for 70 percent, one or more of those is present in 70 percent of cases.

I use that with my residents, I tell them, you know, when you walk around and someone's not behaving the way you'd expect them to on the ward, sit down and say, "Let's do a quick review, let's--the whole team, let's review this. Let's say, have we got the diagnosis right, are the drugs and fluid okay, but if we aren't sure let's get a pharmacist here to help us. Let's not assume doctors and nurses can do that. And, you know, have we

Page 44

checked all the vital organs, are they all functioning okay. If not, let's get the tests done."

In terms--I'm not an expert at all in quality at the lab end. There are lots of people in Canada who are. I've been much more interested in the sharp end where the clinicians meet the patients. I know that, I mean, you're hearing a lot about that here at this Inquiry both from--but there is a lot of work that's been done, I know, in the biochemistry about quality assurance, but I'm not really an expert, so I did have to tell you about the other part of diagnosis, though.

MR. BROWNE:

Q. Yes. (Inaudible - not at microphone) is there any tracking of what type of resources, the amount of resources is necessary (inaudible) implement these roles in the end.

DR. NORTON:

Q. The Safer Health Care Now stuff? Well, -

MR. BROWNE:

Q. (Inaudible) always an issue in health care.

DR. NORTON:

Q. Yeah, yeah. No, I want to be honest about

this. I beat myself up about this because I should have, if we weren't--excuse me. If we weren't in such a rush to get it started, we would have put a better evaluation in place, and so we're cobbling together an evaluation at the moment. It is pretty easy for us to get the direct costs, the costs of hiring those people and moving them around the country. What is hard to get is how much is being put in by the health regions, because those teams are not supported by the campaign. If your hospital here has a team working on surgical site infection, we know that for that team to be successful they've got to release maybe about a half a day of staff time to do some of the team meetings and things and then you've got to get people to come to meetings, so there's a real cost for them and we have no good way of capturing that. We have some surrogates for it, so--because we are in discussions with health care, with Health Canada right now about sustaining this program and how it should be sustained and where it should be put. And I don't have the data I should have had. So that's sort of a long

answer to say I didn't do a good job.

MR. CAULFIELD:

Q. I want to jump in with a question, if you don't mind, and then we'll go directly with you. I'd like to open this one up to the entire panel. You spoke about the 1999 report, the IOM Report and of course we've known about these issues for so long, and you kind of touched on this at the end of your presentation. Could you give some specifics why you think change is just--we've known about this. Why has it taken so long, what are the actual kind of barriers? Maybe you can give a couple of examples. We've know a change is required and it just has taken so long to happen. I know it's a complex system, but I wonder if you could just push--and that's--I'm curious what Ed thinks about that, also. Ed, sorry.

DR. ETCHELLS:

Q. Well, I think you have to put it in context. I think the best context is aviation, so the aviation safety movement really came to the forefront during and just after World War II and it took that many decades to reduce

accidents and errors in aviation to its incredibly safe level now. For example, in the '40s and early '50s pilots complained that you shouldn't standardize cockpits because it takes away the art of being a pilot. And this is just the sort of thing that you start to hear in health care now is that we don't want to over standardize health care because it takes away from the art of clinic medicine. So I think it just takes a long time to do these sorts of things.

What are some of the barriers? I think that if I could pick the biggest barrier for me as an internal medicine, hospital-based specialist, it's lack of coordinated information flow. So it is virtually impossible for me at two in the morning on a Sunday to figure out what a patient has had done to them in the past, what medications they might be taking, what doctors who saw them on Friday might have been thinking. That lack of coordinated information really makes it very difficult to provide safe continuous care, which, so I've started to get more interest in that particular area. There are

many others, but that's the first one that jumps in my mind. I don't know if -

DR. NORTON:

Q. I just happen to have a slide, Tim.

MR. CAULFIELD:

Q. This wasn't planned.

DR. NORTON:

Q. It's about the history of medicine, at least part of it. Modern medicine emerged, I think this is very easy to argue, somewhere between 1860 and 1910. During that period we developed new standards for clinical education, the Flexner Report is the big one. Strict requirements for professional licensing in Canada back in 1850. Anyone could say they were a doctor. There were no rules, there weren't a regulatory system. The beginning of clinical practice being founded on scientific research. And we organized the hospitals. We essentially haven't changed the hospitals since then. This is a very interesting quote from a noted medical historian saying "In 1912 was the first time that a random patient attending a random physician had a better than 50/50 chance of getting a benefit." But,

Page 49

after that it started accelerating. When I think about my own clinical practice, I take care of frail elderly people with pneumonia in the community because I have in my armamentarium powerful antibiotics. Before those existed, if you go back to 1940, if those people weren't admitted, they died. So I think that the system is based--we haven't taken the structural part of our system and moved it along as quickly as the care has. And it's very hard for us to catch up now because we can't just shut the hospitals down and redesign them.

MR. CAULFIELD:

Q. Gerald, did you want to get in on that question?

ROBERTSON, Q.C.:

Q. No.

MR. CAULFIELD:

Q. No. You're good. I'm sorry, sir, you had a question.

CROSBIE, Q.C.:

Q. It sounds like if you could start with a blank sheet of paper and a very fat budget, you could do much better?

Page 50

MR. CAULFIELD:

Q. Good question.

DR. NORTON:

Q. Maybe. If you look carefully at the effect of the hospital sector, which is what I talked about mostly, on the health of Canadians, sometime around 1970 you see an accelerated in major public health indicators, an acceleration which you can--an improvement that can be attributed to hospital care. It's around the time when we started doing cardiac surgery and then accelerated into more other highly technical procedures. And you'd have to--it would be, I think, complex to redesign the system on a blank sheet of paper. And I think that's one of the reasons that some of the efforts in the '80s and '90s where we were talking about some of the industry things, the radical redesign kind of stuff, sort of didn't take off was because we weren't sure we knew what to do. People that work in organization theory talk about this being the most complex system that they see, much more complex than flying airplanes and building cars and stuff. So I don't know, it would be an interesting

Page 51

exercise. I wouldn't want to sacrifice the health of Canadians for it, though. So that's the balance. I don't know, Ed, do you -

DR. ETCHELLS:

Q. Yeah, I don't think it would be any easier to start on a blank sheet. I think the other, one other barrier that we run into in the hospital setting is the lack of measurement of value of our care. So in the hospital we have a very good knowledge of how much money is being spent year to year, that's very accurate. We have very little sense of the value that we get from spending those dollars, what adverse events are occurring not in 2002 in chart reviews, but this week, last week, last month, where the inefficiencies were, the good things, we don't have a sense of that so it's very hard to make wise decisions about what's working and what isn't. I think that's an investment that has to be made. Good businesses know what value they're getting out of their work. We need to get a better sense of that.

MR. CAULFIELD:

Page 52

Q. Can we make sure we speak into the microphone so everyone can hear?

DR. ETCHELLS:

Q. Yeah. Sorry.

MR. CAULFIELD:

Q. No, that wasn't you.

DR. NORTON:

Q. When I was saying that the surgeons couldn't believe those 40 percent figures, they really couldn't, but no one had measured it for them in a systematic way. So this evaluation component of the system is--and it gets worse as you move away from hospitals. For example, if you're working in community-based mental health, you have very little feedback available about the efficacy of your treatment, except on a case-by-case basis, which is not good enough to understand. I mean, I understand--and so when we talk to clinicians, they say things like, "Well, of course I gave good care to every patient." But it's the sum, right, and is there an opportunity to move the mean and narrow the standard deviation along. I don't think that--Ed said communication is the--I mean, I

Page 53

would--is necessary and communication is a thing that can really help. Moving the information with the patient through the system is really important. But feedback to clinicians and to hospitals and to regional health authorities of real data about the care they provide will allow them--I mean, it isn't that people don't want to get better, it's that they don't know they have to get better, I think, I think a lot of the time.

MR. CAULFIELD:

Q. That's a really interesting point because--and you touched on this in your talk, also, of the difficulty of measuring outcomes, and I think we're going to touch on this throughout the day. Is there any evidence that things are getting better? I mean, again, 1999, IOM, we've instituted some kind of framework changes. What's the data tell us about how we're doing, are some areas getting better?

DR. NORTON:

Q. Do you want me to say something? Okay. I'll tell you two anecdotes where things really have gotten better. One of the interventions on there is called Central Line Infections.

Page 54

Central lines are lines that we put in through the major arteries and veins into the body to get access, very quick, big access into the vascular system. So when you go into an ICU, you see people with lines in here and here and in their legs and all over the places. I don't know that kind of--I'm a family doc, you know, but they put these lines in. And of course, because you've--the skin is a wonderful protection against infection, I was sort of talking a bit about that, but once you put a hole through it, infection can creep in. And the central line infection is a bunch of very simple things that you can do to reduce the risk of infection in these lines. So you can imagine if the bacteria crawled down one of these lines and they're into your heart or something, you're in big trouble, right. You don't want bacteria in your heart or lungs or any of those places. And the--I won't go into the protocol but it's proper cleaning and proper changing of the lines, things we've known about for a long time. The 16 paediatric hospitals in Canada, we have 16 specialized paediatric hospitals, took that

Page 55

on, they were part of the teams to do that. And we knew, we know from other work that every time a child in a paediatric intensive care unit in one of those hospitals gets a central line infection, the mortality rate is 30 percent and the cost is around $30,000. It's easy to remember because they're both 30s. I like the number. We have--and they were averaging about two central line infections per 100 patient days. This is a complex measure, but, and six of them--seven of them had six months without one, as of December last year. That's a real gain. I mean, we saved a lot of money, we saved a lot of kids' lives.

A second example is about another one of those called ventilator-acquired pneumonia. Ventilator-acquire pneumonia means when you're in a ventilator in the ICU again, you can get, the bugs can creep down the tube into your lungs and you get a ventilator-acquired pneumonia, because we've breached the system, all the nature defences. And the intervention is quite simple, you sit people up at an angle so that the bugs have--it's harder for them to

Page 56

go down and you put them--you don't let the stomach acid come up and things like that. We've been running contests across Canada to see who can get the one-year reward. Don't have one for a year. I would have said five years ago it was impossible for an ICU anywhere in this country to make a one-year award. We've had about ten of them. Furthermore, we now are able to show that people that institute this protocol 100 percent of the time have lower mortality, adjusted for all the other factors, in their ICUs.

So the answer is, yes, you can change things but they're small and I just have to go back and say Lao said you got to start by walking. I mean, that's where we are.

CROSBIE, Q.C.:

Q. Okay. That was a valuable discussion, but it wasn't actually the question I got on my feet to ask.

DR. NORTON:

Q. I'm sorry.

CROSBIE, Q.C.:

Q. The overall theme of today and tomorrow is, of

Page 57

course, disclosure. And I wonder if you could relate your remarks about the state of safety, you didn't put it this way, but I guess you could say, or what I took out of what you said is that hospital safety is in a relatively primitive stage of development, relative to where we are in other industries such as aeronautics or even driving our car to work. And you used the analogy of coal mining 100 years ago, which is kind of a vivid analogy. Can you relate all that to the role of disclosure of adverse events, errors, whatever, the taste these days I think is to call it adverse events, and make it a little more concrete? So, for example, in the case at hand that sparked this symposium and the Commission of Inquiry, we've learned that there was an outside reviewer report or reports into ER/PR pathology testing and there was a court argument about whether they should be disclosed to the Commission and the public and the judge ordered that they should be. I won't go into the complexities of that. We've also learned that they were held very closely, when they were prepared, by the hospital

Page 58

authorities and I think there were only four copies given to the hospital. And it's not clear to my mind, but it may be that there were only four copies ever, ever made. So, I know it's a broad topic, but we've just been told by Sir Winston up there that you can turn exquisite complexities into exquisite simplicities. Could I ask you to comment on disclosure of adverse event and what role that has and relationship does that have to the patient safety movement generally and achieving greater safety?

DR. NORTON:

Q. Yes, I can't speak specifically to the Newfoundland situation. But many of us believe that an important--that the journey to the safer system requires three components. It requires first leadership and the leadership must exist at multiple levels from the leadership at the provincial ministry to the leadership at a nursing unit. So leadership is an important component. The second important component is the one we've reflected on, evaluation, the ability for us to understand how our performance is and get

Page 59

feedback and have mechanisms to act on that feedback and improve our processes of care. And the third important component is culture. And without the three components being aligned and aligned toward a safer system we probably won't make the changes we need. And the culture one is the one that I think is so critical, and I think that things like disclosure and--are part of the cultural dimension that we must move along and improve. So I look at, from my perspective, the legal people will have a different cut on this to some extent, but to my perspective adopting and implementing and facilitating a disclosure policy is an important step in developing a culture of safety which is one of those three components that goes together to allow us to accelerate the changes toward a safer system.

MR. CAULFIELD:

Q. Other questions? I see a couple.

MS. NEWBURY:

Q. Just two questions. You had a danger graph and hospitalization was shown to be in the dangerous part of that graph. Does that take into account, you know, the underlying disease

Page 60

or illness that brought the person to the hospital?

DR. NORTON:

Q. The underlying illness?

MS. NEWBURY:

Q. Yeah, obviously if someone is going to hospital, then they have some -

DR. NORTON:

Q. No, I mean, that was my whole point about it, it was really unfair because I think that I was comparing hospitals to organizations that don't deal with things like complex ill patients. And so it--I do that slide more to pin to your mind the fact that it will require a fundamental change to really produce the next level of safety. And we know to make those kind of changes it's generational, it won't happen tomorrow, so we've got to be on this journey. So that's really what it's about. And as I said, I think it's unfair to put hospitals in those comparisons, but people tend to do it. And I think that we must reflect as a balance that most of the people who enter a hospital today, if we didn't have hospitals, would have very much worse outcomes

Page 61

than they do with hospitals. Having said that, there's lots of things we can do better. We can reduce infection rates, acquired infection rates, you know. We can make sure that the clinicians know what their practice is. There's lots things we can do.

MS. NEWBURY:

Q. A second question that I had, is there any room for including the patient in the patient safety movement by, you know, explaining to them the benefits of having hand washing or maybe patients if they're not, you know, unconscious or too ill could help to monitor drugs, for example, especially when they return home after hospitalization?

DR. NORTON:

Q. I think that the--it's not going to happen until we engage patients as active partners. So my answer, my big answer is yes. And but there are complex cultural issues involved with that. And if I could tell a brief story, I don't know, Tim, can I tell? So we thought that we--let me talk about NICUS, neonatal intensive care units. Many of you have had, been to one of those. The little wee babies

Page 62

with lots of tubes in them, pretty scary places. And they're not very safe places. And one of the places where they have a lot of trouble and they work really hard on this is getting the drug doses right for those little kids because they're very small and they don't have much tolerance to not having exactly right, and making sure they're given at the right time when--because the child has to clear the drug before the next drug is given. And it seems to me, it seems to me in my naivety that putting an extra check in the drug system would be a useful thing. And so we, as a pilot, devoted a bunch of clinical pharmacology time, clinical pharmacists time to educating the family members to be able to help the nurses and pharmacists make sure that the right drug was given to the baby in the right dose at the right time. And we were doing this as a pilot, which was one of our good things we did. And so you can educate people and they can understand the drugs. And then we found out that nobody liked it after they tried it for awhile. And so we did what good researchers do, we did qualitative

Page 63

analysis, how come you didn't like this. So, from the nurses there was--when you could get them away so they could talk about it, they felt they were losing some of their professional--professionality was being questioned. And so I would reflect that back and we've got to train our next generation of health professionals differently. I mean, those are embedded cultural beliefs they have. But for the families the reason they didn't like it was they weren't sure that there wouldn't be a bad consequence if they questioned the nurse or the pharmacist when they weren't there. Will my child get the same care when I'm not there. And so it just struck me that if we naively say we could do it without talking about the cultural dimensions and how we fit together the patients and the system and don't pay attention to that, we're not going to make that part of the journey. We have to pay attention to that. But we have to have the patients there. The only thing I can think to make the NICUS safer is have the families as active partners. One of the things about

Page 64

being an active partner, to me, is that the accountability has to change. If you have more--if you're more active, you have to have more accountability for what happens. And, you know, we've lied--well, maybe I should say I've lied in terms of we'll take care of you, the health care system, instead of let's work on your care together. So we've produced a culture that sort of says to you you don't have to be part of it, we'll just take care of it. And that's going to be, that's going to be a bit of a journey for us. And that's a long answer, I hope it was okay.

MS. NEWBURY:

Q. Thank you, very much.

MR. CAULFIELD:

Q. Sir?

MR. RITTER:

Q. I have a question about the issue of human factors. It's something that we've been struggling with for a very long time and it's very much, I think, at the core of some of the issues we're dealing with here in our province. You were saying that it's not always appropriate to compare industries, but

Page 65

in the aviation industry I think there are some lessons to be learned and I think there's a reason why we don't have two 747s crashing every day. And I think one of the reasons is that there are standards that recognize the frailties of human error and the risks of human error. And the standard that I'm thinking about is the standard where they establish certain set time frames for how many consecutive hours you can work, what your cycle ought to be, you know, what's the maximum hours you ought to be working within a given time frame, and I believe that that has a lot to do with why their risk is so diminished. I was wondering, of course, in the health care world it's a difficult challenge given, you know, the supply and demand issues and so on and the cost implications. Do you have any advice or thoughts about what can be done in the health care sector in terms of managing the human or engineering the human error situation with respect to those kinds of standards?

DR. NORTON:

Q. Yeah, I think Ed's going to speak more to

Page 66

that. But let me just say that we've seen some very promising stuff about the fatigue issue which you raised. The residents and interns across Canada now do not subject themselves to what my generation did and they're not going to go into practice expecting to have to work that way. And that was really lead by the anaesthesiologists in '80s when they said, "Well, if you worked overnight, you had to go home the next day." And so we're making progress.

There are other areas where we've made progress. It is increasingly common in Canada for surgeons to do time outs prior to surgery and that's right out of aviation. So what they do is the team stands there, and depending how you run it, you say, "Okay, let's review the operation, let's make sure the kit's right." This is just like the pilot walking around the airplane before you start the flight, I mean, this is common sense. And they usually say "What can go wrong today?" The good teams say, "What can go wrong today? Let's think of all the things that can go wrong and are we ready for them."

Page 67

We're using similar sort of checklist technology in many of the ICUs in Canada where during the rounds, I mean, it's complex, lots of stuff going on, much like--and rapid, needing rapid response. And so ICU guys are doing that thing about saying, "Okay, we've just reviewed Mrs. Smith. What can go wrong with Mrs. Smith today?" Let's anticipate it because we know whether it's human or her biology and physiology something can go wrong and let's be prepared as far as we can for it." So we're taking -

And the third thing I should talk about is the communication. A guy called Mike Leonard in the States has looked at communication in the airline industry where they have special rules about how you talk in the cockpit and stuff. And we're taking those down to some of the areas in the hospital. It's called ESPAR (phonetic), and it's very interesting. But it's a structured communication that helps us convey information quickly when there's a need to get it quickly conveyed. So structure it more, make it work better so that we really understand what is

Page 68

needed at that moment. It isn't probably the way we should deal with the whole person medicine when--but if the person's failing and we need to do something, we need to get the information around the team quickly, and that's what that does.

So I think while I say we shouldn't compare them in a sense, we can learn from every one of those other industries and we should.

Don Berwick, who I mentioned briefly, says "Steal, steal shamelessly and don't let anybody who owns something that'll make care safer hold onto it or patent it. Get it out there, spread it across the country." That's what we're trying to do with Safer Health Care Now. The teams talk about things, they share their forums, they share their ideas.

MR. RITTER:

Q. I guess one of the concerns I have is that you don't always have the luxury of a time out. If you've got a team of people that let's say is inadequate for supply and demand reasons but the workload is there, are you better off taking the time out or seeing more patients

Page 69

than you ought to because, you know, someone's got to see them and you don't want the wait times to get any longer than they already are. So those are the kinds of dilemmas I think we all face, but they're certainly very much at play here in our province these days, and I think we're going to have to wrestle with those issues.

DR. NORTON:

Q. Yeah, I think a lot of those really aren't issues for the health professionals, they're issues for society, at least we need society involved telling us or the citizens telling us. But there are things we can do. Ed and I were talking this morning about how the system rewards failure, almost. So if make something not work too well, then you have to see the patient again, so you get another fee. What other industry would tolerate that? Think about that for awhile.

MR. CAULFIELD:

Q. One more question, perhaps? Yes, please.

DR. KEARNEY:

Q. Just a comment. Just we are at the university here and there's 20 projects across Canada

Page 70

promoting interprofessional collaborative patient-centred practice, so that is happening at the education level. And there is evidence emerging that when there are professionals working in teams that not only know about each other's scope of practice but really respect that and allow all members of the team to practice the full scope that there is better quality care, less risk, less liability concerns. The Conference Board of Canada just said that. The Canadian Protective Medical Society just came out and said that, as well. But, and this is not a reflection on the speakers this morning, but when we continue to say medical care and the doctor who admitted the patient and the resident who took the history, then we're still falling back on the old way that we used to practice or that we are still practising but we need to move forward to talk about full scope of practice so that other members of the team can have equal, as appropriate, care for the patient and role in the system.

DR. NORTON:

Q. Yeah, I agree with you. But the reality of

Page 71

2000 when the study occurred was that it wasn't that way. I would point out that David Bates, who is at Harvard Brigham and Women's, has shown that the single cheapest intervention to produce improved quality and safety in an internal medical ward is to put a clinical pharmacist on as a full-time team member and to empower that person to essentially manage the drugs. So there's an example of moving away from the physician who, you know, gets 20 hours of training on drugs to someone who gets four years of training. I mean, it just makes sense, right. And it isn't like we don't--we have enough docs or enough nurses or enough anything. We don't have enough anything, so let's put the right people in the right jobs and make the team work as a team. I agree.

MR. CAULFIELD:

Q. Okay. I can see we have lots to talk about today and I see that you guys aren't shy for asking questions, which is wonderful. After our break we'll be moving into focus more on disclosure, a point that was made by one of our--one of the questions. And that really

Page 72

will be much of the focus.

I want to make sure, can everyone hear? I know there's some problems with people who are--any problems hearing, everyone? No, okay. So all the speakers please speak clearly into the microphones so everyone at the back can hear clearly.

I said at the beginning that we had a wonderful faculty and I think you can see already the tremendous knowledge base that we have in the room. So let's exploit it over the next day and a half and let's thank again our panel.

So let's meet back at quarter to. Thanks.

(RECESS)

MR. CAULFIELD:

Q. We'll now begin the next session and we'll have two speakers. And this one is called "Medical errors and the providers disclosure obligation." Now, we're going to start with Ed Etchells. You've already heard him speak a little bit. He is an internist from the Sunnybrook Health Science Centre in Toronto. So he's a clinician, he does have a practice,

Page 73

but he's also been extremely involved in patient safety. He's published, again, published in the area. And as I understand it, he also do a lot with information management, which obviously is very relevant to the discussions that we are having here today and tomorrow. So Ed, I turn things over to you.

DR. ETCHELLS:

Q. Thank you and good morning. I was honoured when Tim asked me to speak with you today, but I felt that he had made perhaps an error in sending the e-mail because I felt I probably wasn't qualified to speak with you. I'm an internist at Sunnybrook. All of my work is related to the in-patient care of mostly elderly patients with medical problems and really my expertise is in medication error. But Tim reassured me that I was a reasonable choice for the job, so I spent the last few months convincing myself that he was correct.

And I think I want to start by saying that although I'm going to be talking about medication errors, what I hope to leave you with is a way to improve the system beyond

Page 74

just medications. I want you to know that, you know, myself and my family, we've all experienced illnesses, we know how important it is to feel trust in the health care system. We know that when there are errors, that they cause wounds that take a long time to heal. So with that introduction, I'm going to start.

I'm going to talk about two cases. These are real cases. The first is a patient who got too much Morphine. Morphine, as you know, is a narcotic. If you get too much, it slows your breathing down or stops your breathing and is quite a dangerous medication if given in excess. And in the second case a patient who is in the midst of a medical emergency, the intern was giving the patient medications through the intravenous line but the medications kept leaking all over the bed leading to some delays in the patient getting their medication.

What I'm going to do is try and give you an approach to improving safety and I'm going to bring that approach back to how we've looked at these two cases and made what I think were useful improvements.

Page 75

So whenever there's an error that either caused harm or may cause harm to a patient, there are really four steps in the management. The first is you have to take care of the patient and do whatever you can to make them better immediately. I'm not going to get into those details today. Second, which is part of my job, is to figure out what happened. And third, reduce chances of it happening again. I'm going to spend much more time on item three and less time on item two, although I'd be happy to get into that in the discussion. And the fourth point is telling the patient and the family what happened and what you're doing. Also extremely important, part of what we're here about, here to talk about today. I'm not going to talk about in any deal in this specific presentation, but three other speakers today and one other speaker tomorrow are going to be talking about those details. And again, I'll be happy to discuss it in the discussion.

So I'm going to focus on what can we do to prevent these sorts of things from happening again. That is the core activity of

Page 76

the patient safety movement learned from the past to improve the future.

So in my presentation I'm going to try and accomplish three things. First, I'm going to outline the three steps to improving patient safety. That will take me a couple of slides. Next I'm going to explain the systems approach to patient safety, which is really the philosophic and scientific cornerstone to the patient safety movement. And finally, I'm going to demonstrate a few safety change principles. These are things that are proven concepts from other industries that can reliably improve safety.

So I'm going to start by telling you what the three steps to safety are. So the first step is really a philosophic one, which is you have to believe in what I'm going to call the Swiss cheese model, and I'm going to explain what that means and I'm going to refer to it many times in this presentation. And I hope at the end that you too will believe it in. I believe in it. And if you don't believe in it, it's very hard to make patient safety improvements.

Page 77

If you believe in the Swiss Cheese model, obviously the analogy is that there are holes in the system, so then the next step is to study those holes. You have to understand why they're there before you can fill them. And that's step three.

So I'm going to just step to the side here. You can read at the back? All right.

Okay, so this is the Swiss cheese model. The concept here is that in health care, in other industries, there are layers of defences and each layer is imperfect and has holes in it. For example, in the context of the patient who got too much Morphine, we would often conceptualize that the last safety layer in a patient in the hospital in getting a medicine would be the nurse because the nurse is generally who administers medications. So we might conceptualize this last layer of the Swiss cheese model as the nurse, and nurses are imperfect and may make errors. We might consider this to be a pharmacist, we might consider this to be a doctor, we might consider this to be a ward manager and so on and so forth. The number of layers of cheese

Page 78

in health care is countless. This is just a simplified model.

Now in the discussion we heard last time prior to the break, you might actually re-conceptualize this and say the last layer is the patient. A well-informed patient who feels empowered to speak up and ask questions might be a very effective safety mechanism but still might be imperfect and might not ask the right questions or might be unable to defend themselves.

So the concept here is that each layer has weaknesses. Most of the time the weaknesses or the holes don't cause any trouble. So here is an arrow, that represents an error that just didn't cause any trouble. We know from very good studies of medication errors that there have to be 100 medication errors in hospitalized patients before one of those errors causes harm. So we get away with it 99 times out of 100, which is why individuals tend not to react to errors, because they tend not to cause harm. In one's personal experience, you don't see it as a big problem until it happens to you or one of your

Page 79

patients.

The concept here, this arrow is awful close to the patient but a vigilant nurse who happened to double check something caught it just before it got to the patient. That's what we call a near miss, and that's something that Peter alluded to in his talk. So we know again from very good medication literature that there are seven near misses and these are situations where patients were very close to being harmed, but they weren't harmed just because of good luck or random vigilance, someone just happened to catch it today, but tomorrow could well have been a different story. There are seven of those for every one preventable harm caused by drugs.

That's the Swiss cheese model. The concept is that there are many errors in the system. We only pay attention when they all line up. We have to start paying attention to the situations where they don't line up. We have to start filling these holes so that patients can't be harmed. If we only focus our attention at the last layer of cheese, that mistake that the nurse might have made or

Page 80

that the pharmacist might have made or that the doctor may have made, we're not going to improve the system. We have to systematically look at every hole, pick the biggest ones, pick the most dangerous ones, and hammer away at those.

Oh, I don't have to walk over there, okay. All right. So now I've outlined the three steps to safety and I've told you what the systems approach is--the Swiss cheese model is. I'm going to extend the Swiss cheese approach to the systems approach.

So this is the key philosophic slide in my presentation and I'm going to back it up with one study that's referenced because I think it's really important to show you that this isn't just philosophic. So the systems approach is as follows: Preventable adverse events. That means harms caused to patients by errors. Whoops, I didn't do that. Are caused by interactions between two things: unavoidably imperfect humans and flaws in the working environment or the working system. So in the Swiss cheese model the unavoidably imperfect humans are represented by certain

Page 81

layers of cheese with holes in them, but the imperfectly designed system represents many other layers with many other holes. If we focus only on the unavoidably imperfect humans, we're not going to get very far.

I think I just said that, so I'm not going to say it again. To make patients safer, to reduce adverse events we have to build a system that does one of two things, either reduces error, so even though humans are unavoidably imperfect, there are things we can do to reduce human error. For example, we know that interns who work 85 hours a week are six times more likely to make serious diagnostic errors than interns who work 64 hours a week, therefore I would rather be taken care of by a 64 hour per week intern and so would you. We need to fix that.

Second, we can never eliminate error because humans, the very things that make us creative people who can make brilliant diagnoses, come up with brilliant treatments, be very caring at the bedside are the same things that make us prone to random slips and lapses. So we will never eliminate error,

Page 82

rather we need to build a system that prevents those errors from causing harm.

I actually don't mind making medication errors. I only mind if they hurt my patients. Which is why it's much nicer to be a doctor than it is to be a nurse or a pharmacist because there are very good studies to show that doctors make just as many mistakes as nurses, the only difference is that our mistakes get caught by nurses and pharmacists, whereas nurses mistakes don't because there's no systematic double check in place for nurses like there is for doctors. So let's build the systematic double checks in so that any errors that are left over can't hurt patients.

Now, if we just focus on the unavoidably imperfect humans using the name, blame and shame approach, that means Etchells, you made a mistake, you gave too much Morphine, you need to be either educated, disciplined or punished, depending on whether we like you or not, that will not make things better for patients. All it will change is that next week we'll have the same set of holes, same layers of Swiss cheese that are imperfect and

Page 83

the same events will happen again, there'll just be different patients and different health care personnel involved next time.

Now, this isn't just random musing, so I think it's very important to present this study to you. This is a study that was published about 13 years ago in the Journal of the American Medical Association. This is a prospective study of 264 preventable adverse drug events or close calls, near misses, situations where the patient experienced a medication error that could easily have caused harm even though in that particular case harm was avoided. So what they did in this study is systematically looked at those events and looked for the errors that lead to those events. They identified 334 obvious human errors and then tried to pin it on a person or a team and they were unable to do it. These were 334 random cognitive human failures that lead to harm to patients. We need to build a system that traps those errors rather than just focusing on the 334 people who made those mistakes. If we just focused on the people, we would have 334 people either in classes or

Page 84

undergoing discipline. We'd have to get another 334 people in to work and they'd experience exactly the same problems.

Now the doctor--I don't know why this keeps advancing, but okay. That's a systematic error, which I can't fix right now, although it has happened before.

The doctor who did this work repeated this work in the paediatric setting and found exactly the same result.

And I think it's important to say that there was an exception where there was a physician who had notoriously bad handwriting and this did lead to several errors related to dosing in paediatrics and so the appropriate response in that case was to focus on that physician's individual performance. So I'm not saying that it's a mindless blinkered approach where personal accountability is completely thrown to the window, but rather, the most important thing is to focus on systematic improvements rather than individual errors.

And I think I just said that, but I'm going to say it again. I want to reemphasize

Page 85

that this is not a message that is saying let us throw personal responsibility out the window, but it is rather saying let us reemphasize the focus away from individual performance, because we know it is flawed, and rather shift our focus to system. We're really only interested in making sure patients get highly reliable safe care. That's the goal, that's what we want to do and the way to do it is to embrace the systems approach. There are certain situations where the best response is to focus on individuals, but that's only right probably one to five percent of the time.

So what I'm going to do now is talk to you a little--I'm going to go back to the Swiss cheese model, I'm going to go back to the two case that I presented at the beginning and show you some of the holes in this Swiss cheese that we found and then how we tried to fill them.

So just to remind you, the first case was a patient who got too much Morphine. And again, we wanted to go to the staff, and they need to believe that when you come and say,

Page 86

"What happened"?" that they're not going to get in trouble for an honest mistake. It's a key cultural issue which by the systems approach is not just a scientific issue, it's a philosophic and cultural issue. If people don't believe that you're coming to ask them what happened in order to make improvements, they're not going to want to talk to you. So, you know, we try and send this message at Sunnybrook, the system focus is what we're interested in so that people are more willing to talk to us about preventing future similar events.

So the patient got too much Morphine. Obviously the nurse--actually, what happened was the nurse took the wrong drug out of the carton and brought it to the doctor, the doctor was treating the patient at the bedside in a medical emergency, didn't double check the dose, and the patient got the wrong dose. So it would be easy to just focus on those two holes. We wanted to look a little bit further.

And this is what we found when we looked in the narcotic drawer. So just so you know,

Page 87

narcotics have to be kept in a special cabinet on units in locked drawers because narcotics are controlled substances. So nurses carry the lock--sorry, the key to the lock. When you open the drawer, this is what you see, a whole bunch of different narcotics stored in there. Now, there are many problems with this drawer, which I won't bore you with, but you can see that it's rather full and it would be very hard to know what you were selecting if you tried to get anything from this side.

In this case they were looking for Morphine ten or Morphine two. Those are actually pretty good labels, but unfortunately the nurse picked this one which had been torn. And this is what she got out. And I'm just going to ask you--I'm just going to tell you that one of these is a two milligram per millilitre dose and the other is a ten milligram per millilitre dose and they are virtually identical. They're not identical, but they are virtually identical. And the nurse believed that she had pulled out a two and once you've made that substitution error, you're doomed, you're never going to catch it.

Page 88

And this was not enough of a signal to catch it. I don't think I brought pictures of the vials, but they're, you can see, you can't even see what the dose is. You'd have to be very astute to see a two there and a ten right there, which I can't see, so you probably can't, either. So that's a hole that we thought needed to be fixed. It was systematic. If we let that go, then next week it's going to be a different nurse, different doctor, same problem.

Now, I would also add that if I had to have ten milligrams of Morphine or two milligrams of Morphine be given to me, I would want that nurse to give it to me because that nurse is going to be the most expert nurse on the choosing between two and ten milligrams of Morphine in the hospital. So there's no point in punishing her, we need to punish the drawer. All right.

Now, so I'll get back to how we fix that in a second. But I just--the purpose of that is to show you why you need to look beyond the human holes, into the system holes.

Okay, now the next case as a patient who

Page 89

was getting medications and they leaked all over the bed as they were trying to squirt the medicines into the intravenous port.

So what happened here is the intern told me that he thought that the syringes were not working properly. And so, and the nurse also had concerns. Without boring you with the details, as they were going to attend the patient, they went to pick up some syringes to give the patient the medications. So this is the--where the syringes are stored. And the intern told me that he didn't know which ones to pick, so he just grabbed a whole bunch and kind of threw them on the table to see what he had. If you read them carefully, there are bar codes there and there are some labels there. I can tell you they're virtually--they provide no useful information about what you're getting. So this is what the intern picked up. They don't really--they don't give a useful signal. And what the intern then did is he just turned it over and he said, "You know what, I need to give this patient some medicine. I need to draw the medicine up with a needle first and then take the needle off

Page 90

and hook it up to the intravenous and inject it into the patient, so I'm going to pick this one because this is a syringe with a needle already attached." Perfectly logical. Probably what I would have done, too. Unfortunately, it was the wrong thing to do because if you read, this is the same product, if you read it very carefully it says, "BD integra syringe with retractable precision-glide needle" and in the small print it's for subcutaneous and intramuscular injection only. It actually isn't compatible with the intravenous ports. All the other ones are, that one isn't. So that was the hole there, all right.

So what I'm trying to take you through is we believe the Swiss cheese model. We talked to these people. We allowed them to give us information which helped us understand what the holes really were.

And again, that intern is now an expert in syringes and needles at the hospital. He could probably teach a course on it. There's no point in getting mad at him.

All right. So the next issue is filling

Page 91

holes. And I think one of the questions in the--before the break was related to human factors. Human factors to me means something slightly different. There's a whole discipline of reliable design of work environments, sometimes called ergonomics, sometimes called human factor science. Part of human factor science is the frailties of the human mind, like fatigue, lack of caffeine, something I'm suffering from right now, but also many other disciplines as well. And really, in my opinion human factors science is really the way to fill holes smartly. So the idea is to work smarter, not to work harder. Don't create new holes as you fill old ones. I call that moving cheese. So it doesn't make sense to tell someone to work harder in one area, because it means by definition they are not working harder in some other area. You've now created a different hole, you're going to have a different adverse event next time. The other analogy is that's swatting mosquitos instead of draining the swamp, okay.

So the game here is to fill holes without

Page 92

creating new ones. Obviously more resources would be nice. And I'm not against more resources, but you still need to use those resources wisely and efficiently whether you have a small amount of resources or a larger amount and human factor science is the way to do that.

So let's go back to the cases again. What did we do? So, human factors design concept number one is hazard removal. You can't pick something up that isn't there. So the real question is not why did the nurse pick up the ten milligram instead of the two, the question is why is the ten milligram there to be picked up at all. Now, on some units there's actually a very good reason to do that. If I worked on C-3, which is our oncology unit where patients are getting very high doses of narcotics, they use this dose regularly and that needs to be there. On our unit, which is mostly frail patients, the average age is over 80, they're not used to getting these sorts of drugs, they rarely would get that dose. And in fact, we looked at the use of that dose over the preceding two

Page 93

months and found that it had only been used once. So we said the best way to prevent this from happening again is to get rid of it, so we took it out. It is impossible for a nurse to pick up ten milligrams by mistake on our unit any more because it's not there. Now, if you really need it, you have to ask for it. That doesn't happen very often.

We also did some work redesigning the drawers. This all basic human factors concepts. We've grouped them into logical areas. So these are all intravenous, these are all short-acting pills, these pink labels tell you that they're long-acting drugs, you only need to take them one or two times a day and you should never crush them, and a bunch of other things. Note that we didn't add any new labels because that just tends to create confusion because people invariably put them in the wrong drawer. We've taken a lot of other products out that people weren't using and they were just getting in the way. And we proved that not only did this probably make patients safer, but it actually made it faster for the nurses to do their day-to-day work, so

Page 94

it had an efficiency gain, as well.

We also let ISMP Canada know. This is the same group that runs the Canadian Medication Incident Reporting Program. They sent out an alert a couple of years ago now.

I got to take this slide out because it tells you how old my case is, but it's such a good case.

And they actually, the company was excellent and redesigned the packaging within three months. It was completely redesigned and quite distinct. So that was a good story.

Okay, second case, the patient who got the wrong medicine. Same concept. Here's the nasty syringes. Why are they there? First question is always why are they there. And the answer is they're there because that's--because, because the people bring it up from stores and that's where they put it. There's no compelling logical reason for it, it's just the way things are. It's just a hole that was created for no good reason. So we got rid of them. That was easy.

Of course, you have to--they are there for a reason and they're there for nurses to

Page 95

give subcutaneous intramuscular injections, so we said, well, where do the nurses do that work? And we turned our eyes over there and the nurses told us that, "Well, actually, we do all that work over about eight, ten feet from there at our medication cart."

Just to orient you again, this is where the narcotics are that I showed you previously. This is where all the syringes are kept, and this is where all the patients' drugs are kept. And the nurse will take the drug out of there, put it up there and they need a syringe. So actually they were wasting time walking backwards eight feet to go and get a syringe when really it needed to be on the drawer, so we just put it there and now all -

The major intervention that was really required was talking to the guys who brings the stores up from downstairs. Turns out, no one ever talked to that guy. He was actually quite interested in the whole case and now he is one of our biggest converts. He's gone around to all the other people he works with telling them that they need to be more careful

Page 96

and talk to their nurses and doctors and pharmacists about where things are stored. And so even though technically it's not quite within union rules, because you're not supposed to--they're not allowed to put things anywhere else, he never puts them on the cart and he comes to a nurse and says, "Where would you like these to be put?" and the nurse shows him where to put them. So excellent example of interdisciplinary teamwork that was also a key topic.

All right. So I think I'm finished. And my main message is that the role of safety improvement is to prevent things from happening again, and the way to do that is to believe the Swiss cheese model, to study the holes and to fill the holes using human factors science.

And Tim isn't even standing up yet, so that's good because this is my last slide.

So I hope that I've outlined the three steps to safety. Swiss cheese approach, understand the holes and fill the holes. I've explained the systems approach to safety, which is a shifting of focus away from

Page 97

individual error to system-induced error while still maintaining an appropriate balance for individual responsibility. And I hope I've just given you a flavour for the important discipline of human factors science. Thank you, very much for inviting me today.

MR. CAULFIELD:

Q. That was wonderful, Ed. We've now had two, two talks that sort of set the foundation, the clinical foundation. We started very broadly. Ed gave us a little bit more of a narrow, narrow focus on the clinical experience and the kinds of things that can be done in the clinical setting. Do we have any questions? Just a couple short ones for Ed before we move on?

MR. CROSBIE:

Q. It's axiomatic that our health care systems and hospitals are resource constrained and time constrained. I'm just wondering how--who made the time to, because it took some time, I'm not sure how much time, to think about the problem and make these relative obvious, at least in hindsight, changes? Because physicians often are on fee for service, they

Page 98

don't think they're getting paid to do that. In your institution, at least, how did that work?

DR. ETCHELLS:

Q. Yeah, so Sunnybrook in 2002 funded something, it was originally called the "Error Management Unit" but I suggested that wasn't the best title for it, but we now call it "The Patient Safety Service". It's a hospital-funded program staffed by physician and nurse, a pharmacist and closely allied with our quality program. And essentially we do this kind of work, but we are a dedicated resource. Our time, our professional time is dedicated towards this and we have other duties. And I think it doesn't happen easily on its own, it does require time, effort, communication, patience.

MR. CAULFIELD:

Q. It was suggested to me that when people ask a question, perhaps say their name and say where they're from, if they'd like, unless they want to stay anonymous and also please remember to speak clearly and into a microphone. And perhaps one more question for Ed before we

Page 99

move on? No? Okay, excellent. Thanks again.

Now the next speaker is going to now move us into a legal analysis, talk about the legal norms. And we're going to start with a discussion about the basic legal norms as they relate to obligations of health care providers in the context of disclosure, which of course is very, very relevant to what's happened here in Newfoundland and with the subject matter of the Inquiry. So we are moving a little bit more into specifics. And Gerald Robertson, a colleague, a very good, close friend, a mentor from the University of Alberta is in an ideal situation to provide this opening into the legal realm. Gerald is again, a renowned health law expert, internationally renowned and author of many relevant publications. So I'll turn it over to my friend, Gerald Robertson.

ROBERTSON, Q.C.:

Q. Thank you, Tim. As you can see, the focus of my presentation is the legal duty of disclosure, and specifically the physician's duty of disclosure. If a physician makes a mistake which harms the patient or which has

Page 100

the potential to harm the patient, does the physician have a legal duty to disclose that fact to the patient?

I think a number of themes will become clear during my presentation, and the first is that the legal duty of disclosure is well established, beyond question, but secondly, a number of aspects of that duty, its precise scope are not clear and await further clarification. I think it's also important to point out that this is an area which has seen a lot of activity, a lot of developments in recent years and there is every reason to expect that that pace of development will continue. This is very much a hot area from a legal point of view and other points of view, as well.

Let's start with the duty and the well-established duty. It is well established that if a doctor makes a mistake which causes harm to the patient or has the potential to cause harm, the physician has a legal duty to disclose that fact to the patient. As I said at the outset, that is well established, beyond question, that that legal duty is

Page 101

imposed on the physician.

These are some of the cases which establish that legal principle. As you can see, the first case to establish it is an Ontario case, Stames and Davies, a decision of Mr. Justice Creever involving a case in which a physician performing a lung biopsy punctured the patient's spleen, did not reveal that to the patient, simply said that the biopsy results were not what he had expected because we didn't get what we wanted. The patient said, "Well, what did you get?" The physician said, "Something else," but did not specifically explain to the patient that he had biopsied the spleen and not the lung. Justice Creever held not only was the physician negligent in puncturing the spleen, but the physician was also negligent in failing to disclose that fact to the patient.

As you can see from the list there, a number of cases involving surgeons performing the wrong operation, so performing the operation on the wrong disc. Again, a duty to disclose that fact to the patient.

The Vasdani case, second on the list, is

Page 102

a particularly important case because of the physician's reasons for non-disclosure. In Vasdani the surgeon operated on the wrong part of the back, did not realize his mistake, but discovered that fact one year later. By then the patient was no longer the doctor's patient. The patient had moved on to the care of another physician. And for that reason the doctor decided not to disclose that fact to the patient. And the Ontario court held that that was no excuse. The fact that the patient is no longer your patient by the time you discover the error is no justification for keeping silent.

The Quebec case of Kiley and Nikkel involving a pathologist there, patient who was mistakenly diagnosed with breast cancer because of a pathologist's error. The pathologist discovered the error and informed the surgeon who said, "I will let the patient know," but didn't, and six years elapsed before the patient was finally told that she did not have breast cancer. The surgeon again was held to have been negligent in failing to disclose that fact to the patient.

Page 103

The last case, the most recent, Shobridge and Thomas, retention of abdominal roll during surgery. The surgeon discovers that fact, again, fails to disclose to the patient. The court held the doctor was negligent in failing to disclose that to the patient.

These, along with several other cases, make it beyond question that there is a legal duty of disclosure imposed on physicians.

Why? Why does the law impose a duty of disclosure on physicians? Generally speaking, civil law and particular law of tort does not require confession. For example, if I'm playing baseball in my back yard with my son and I hit the ball over the fence and it goes through my neighbour's window, the law does not require me to go to my neighbour and say it was me. Even if my neighbour comes to me and asks, I have no legal duty to tell him.

So in order to impose a duty of disclosure there has to be some principal basis for making the exception to the general rule that there is no duty of confession or disclosure. And these are the three, or at least the first two, the two basis that have

Page 104

been used by our courts to justify imposing a duty of disclosure on physicians.

The first is the concept of informed consent, the patient's right to know. And that may seem odd to use informed consent, which we tend to think of as something which arises before the treatment is performed. How can informed consent be a principal basis for saying that after the treatment is performed the physician has a duty of disclosure if something goes wrong in the course of that treatment? And the justification and the reasoning, I think, is cogent, and that is if the patient has a fundamental right to be told what may go wrong with a treatment, then surely the patient has an equal right to be told what, in fact, has gone wrong in the course of the treatment.

The informed consent basis was the one that was used initially by courts to justify duty of disclosure, but then courts started to talk more in terms of fiduciary duty. The physician/patient relationship is a relationship of utmost faith, it's a fiduciary relationship and according to several courts

Page 105

that fiduciary relationship brings with it an obligation of disclosure if the physician has made an error.

The third basis that I've put on that slide is not one that courts have yet used, but I think there is reason to believe that they will begin to use it, and that is the ordinary duty of care which a physician owes a patient. Physicians must act with reasonable care, a physician must act as a reasonable physician would do in similar circumstances. Because disclosure has now become the norm, both in terms of the legal duty of disclosure and more and more now in terms of hospitals protocols, disclosure has become the norm, it's what reasonable physicians are expected to do and therefore we might conclude simply as a matter of the ordinary duty of care which a physician owes the patient to act as a reasonable physician would do in similar circumstances, that includes disclosing error to patients.

Let me talk briefly about the legal consequence of not disclosing, what legal consequences may flow from failure to

Page 106

disclose. And by that I don't mean if the patient does not obtain necessary treatment. That's obviously one of the most serious consequences of failing to disclose. If the patient, because of the error, requires additional treatment and is not told about that, then clearly damages could be awarded for the failure to obtain treatment. But aside from that, some of the things that the courts have talked about in terms of the legal consequences are first of all, damages for the anxiety and stress in not knowing the truth. So, for example, the Quebec case that I mentioned, the pathologist's error, the patient who thinks she has breast cancer and suffers great anxiety over the course of six years worrying that the cancer may come back when all along she doesn't is entitled to damages for that needless distress and anxiety. But linked to that, aggravated damages associated with knowing that your doctor was not truthful.

In some of the cases the last one that I mentioned, the Shobridge case, the patient there received damages for the distress that

Page 107

she claimed to have suffered when she realized the truth and when she realized that the physician whom she trusted had not been truthful with her.

Some cases have even gone as far as to award punitive damages. It's fair to point out that those cases involved more than simply failing to disclose where a physician takes active steps to cover up the mistake and to try and insure that the patient does not find out. For example, altering the hospital chart as in one case or in telling nurses to keep quiet and not to chart what, in fact, happened, steps, active steps like that may result in punitive damages.

The last point is the question of fraudulent concealment which is related to the running of the limitation period. Failure to disclose has been held to be fraudulent concealment for purposes of spawning the running of the limitation period.

Let me add one other item to that list, the legal consequences of non-disclosure, and that is increasing your chances of being sued. There are many barriers to disclosure, there

Page 108

are many reasons why physicians and others do not disclose even although there is a legal and an ethical duty to do so, and one of the reasons that is often cited for failure to disclose is fear of being sued. If I tell the patient what has happened, is that not simply inviting them to sue? Whereas the literature indicates the exact opposite, that failure to disclose increases the chances of being sued. Open and candid disclosure, far from inviting lawsuits, according to the literature, tends to diminish the chance of being sued.

Let me move on to some of the areas that are not clear. I mentioned at the start that the existence of the duty is clear, but many of its aspects are not so clear. And this is the first area that's not clear, when does the duty arise specifically? Does it apply or does it arise only in cases of harm? The Canadian Medical Association Code of Ethics talks about a disclosure in cases of harm and so also do the Canadian Patient Safety Institute guidelines which came into being earlier this year, it too talks about harm.

What about cases of future harm or

Page 109

potential future harm, cases where harm may arise in the future? I put a quote there from the CPSI Canadian Disclosure Guidelines, "The need to disclose when there is no immediate harm but the potential for harm exists is influenced by the future likelihood of severe consequences, the severity of possible consequences and the potential to prevent, identify or mitigate future harm through clinical testing or treatment. When uncertain of whether harm has occurred, it is recommended that disclosure take place."

What about cases of possible harm where you're not sure of whether the patient has suffered harm or, indeed, whether they will suffer harm but there is the possibility that that has happened? There are cases on that and the Pittman case is perhaps the best example where a patient may have been transfused with HIV contaminated blood. In fact, he had been, but the physician and the hospital did not know that for certain, but they knew that there was a possibility that that had happened. And according to the court that created a duty of disclosure, a duty to

Page 110

inform the patient that there was a distinct possibility that he had received HIV contaminated blood.

Indeed, depending on how you define harm it's possible to say that the cases say there is a duty to disclose even in the absence of harm. These two cases both involving the patient whose surgeon operated on the wrong part of the back. As I say, depending on how you define harm, could you say that these cases the patient wasn't harmed, they just had the wrong operation which didn't improve their condition, but did they suffer harm? Some might suggest no, but, yet, in both these cases the court said there was a duty to disclose that fact to the patient. And the justification for that, and this is very important, is the idea of the, one of the basis for the duty of disclosure may be linked to the idea of informed consent, the patient's right to know. And if that is the basis of the duty of disclosure, then our cases tell us that when you ask what has to be disclosed, you ask the question what would a reasonable patient want to know. And if this is

Page 111

something which a reasonable patient in these circumstances would want to know, then there is a duty to disclose it. And that may go beyond cases of actual harm or even potential harm, it may indeed even include cases of near misses. If a reasonable patient in these circumstances would want to be told what happened, then arguably there is a duty to disclose it.

The timing of disclosure, again, is something that's not entirely clear, although the cases do indicate that we're talking about immediate disclosure. The BC case, Shobridge, talks about disclosure as soon as reasonably practicable and the Canadian Patient Safety Institute refer to disclosure at the earliest practical opportunity and preferably within one or two days after discovery of the adverse event.

What has to be disclosed? The cases are fairly clear that disclosure, that a legal duty of disclosure is a disclosure of fact. There is no duty to disclose opinions, there is certainly no duty to disclose that it was your fault. And indeed, the guidelines, most

Page 112

of the protocols say that fault should not be used, the term "blame" the term "fault" should not be used. This is not a disclosure of fault, it's a disclosure of fact.

Some of the cases also say there is no obligation to disclose evidence. It's facts, not evidence. But where you draw the line between fact and evidence is perhaps less clear.

Who has this duty? Well, first of all, the cases make clear that it is a delegable duty. A physician does not necessarily have to disclose this information personally. A physician has to take reasonable steps to ensure that it is disclosed, but doesn't necessarily have to do so personally. One area where the law is not clear is whether other individuals aside from the physician also have a duty of disclosure. The Shobridge case, the BC case in which the patient, an abdominal roll was left inside the patient, in that case the court held that the nurses, who were well aware of what had happened, had no obligation to disclose that fact to the patient. And this arises in two settings,

Page 113

it's really dealing with two questions here. The first is, if someone other than a physician, such as a nurse, makes an error, do they have a duty to disclose that fact to the patient? And second, if other individuals are aware that the physician is not disclosing to the patient, do those other individuals then come under a duty to disclose? As I say, the only case that touches on that suggests there is no duty on other individuals. This is a physician's duty only. I would think that is unlikely to remain the law. There is every reason to believe that as we continue to emphasize the team approach to health care there is every reason to expect that our courts will begin to say this is not an individual duty imposed only on the physician. This is a duty that is imposed on other members of the health care team and, indeed, the institution itself.

That's the conclusion that I put in the last paragraph of my paper. Canadian courts have taken a very expansive and very broad interpretation of the patient's right to informed consent and the physicians' duty,

Page 114

fiduciary duty. And both of these, as I've explained, underlie the duty of disclosure. For that reason there is a reason to expect that as our courts revisit this area, that they will broaden the duty of disclosure both in terms of when it arises, in terms of what has to be disclosed, and perhaps most importantly of all, in terms of who had this duty. So far our courts have focused very much on the physician, have seen the physician, as it were, as the captain of the ship who has this duty and they alone have that duty. That is unlikely to remain, in my opinion that is unlikely to remain the state of the law for very much longer. Other individuals clearly should have this duty of disclosure, including the institutions, as well as other individual health care members.

I'm going to stop there, but I would welcome any questions that you may have.

MR. CAULFIELD:

Q. Excellent. Thank you, very much, Gerald. So now we're getting to the heart of things. Does anyone want to start with a question? Comment? If not, I have a starter question

Page 115

for Gerald. Gerald, I wonder if you could comment on apology legislation a little more fully? It's something that you hear a lot about and it's something that Newfoundland does not have. Some jurisdictions do and some jurisdictions are considering it. I wonder if you could talk a little bit about the justifications behind it, the presumptions behind it, and perhaps the role it plays in a medical/legal setting? And then I'm also curious what both our other panel members think about apology legislation. So, Gerald?

ROBERTSON, Q.C.:

Q. Okay. Three provinces, BC, Manitoba and Saskatchewan have all introduced apology legislation. It applies not only in the health care context, but in all context, and briefly it says that the fact of an apology is not an admission of liability, nor can it be introduced into evidence as an admission of liability. I think the reasons why that legislation was introduced are very important and I think they relate to what I said earlier about the misconception that many people have that if I disclose, then I will be sued, and

Page 116

likewise, many people have felt that if they apologize, they run the risk of that apology being used in evidence against them. There is no evidence of that happening. There is no case that I'm aware of where an apology has ever been used as evidence of an admission of liability against the health care profession, yet clearly there is that perception that it might be, hence, those provinces have introduced apology legislation and many other provinces are actively considering doing likewise.

ROBERTSON, Q.C.:

Q. Ed, for you?

DR. ETCHELLS:

Q. Yeah, I think the issue of apology is important. If you read the Globe and Mail about a month ago when the Canadian Patient Safety Institute disclosure guidelines were released and the headline said something along the lines of, "Guidelines fall short of requiring doctors to say they're sorry," or something along those lines, I think it's because people aren't clear on what they're saying sorry about, so you know, in some cases

Page 117

you're just saying sorry that the patient is sick, not doing well. And why would you ever have any question about saying that? Of course you're sorry. That's not what you're all about. You want the patient to be getting better. So I always tell people you should always say that because you are sorry because they're not doing well. If there's clearly a mistake in care, that's where the--the issue is around disclosing mistakes, so the first step is figuring out whether--you have to decide whether there's been a mistake or not. And I'll be frank with you, sometimes it's not so clear and there's judgment involved. If you're not sure that there's been a mistake, you shouldn't apologize for a mistake, but if it's obvious that there's a mistake, I mean, I don't understand the issue of the wrong site surgery, to me that's an obvious mistake and there's no two ways about it. You should apologize because there's just no two ways about it. In other complex things where it's not clear whether there's a mistake that's been made, all I can say is you're sorry for the patient's current condition. For example,

Page 118

the patient developed an infection in the hospital, it's not clear whether that was related to a mistake or not, but you're certainly sorry the patient is sick and has an infection and you should say so.

MR. CAULFIELD:

Q. Peter?

DR. NORTON:

Q. We train our residents very aggressively to say they're sorry when these things happen and often focusing on we're sorry your mother is sicker, because we are sorry and we hurt. We did some very interesting work with panels of Albertans asking them about how complaint and the system dealt with complaints and injuries and it is striking to look at transcripts about the amount of pain that we cause when we don't say we're sorry, and long-term psychological effects. I think we have to say we're sorry, because we are, so it's just being honest about our own thing, and that helps people. This is horrible for families and patients and this is a step to help them heal.

DR. HEBERT:

Page 119

Q. Philip Hebert from Toronto. A related question. How--what do you think about the right of hospitals or physicians or programs to look back analysis and find mistakes in quality of care and there's some jurisdictions which have prevented those from legal discovery, from taking part in? So this is going beyond the apology, this is when you're actually doing a look-back program, finding mistakes in quality of care, you want to inform patients about that. Do we have any reassurance that that's not an area of legal jeopardy for physicians and their institutions?

UNKNOWN SPEAKER:

Q. You do first.

UNKNOWN SPEAKER:

Q. That was a legal question.

ROBERTSON, Q.C.:

Q. A legal question so I'll give it a legal answer.

DR. ETCHELLS:

Q. By the way, he's a speaker this afternoon, so you can get back at him.

ROBERTSON, Q.C.:

Page 120

Q. That's not fair.

UNKNOWN SPEAKER:

Q. (Inaudible).

ROBERTSON, Q.C.:

Q. I know Bernard Dickens will be touching on the institutional obligation. But if we were to say that the institution has an obligation of disclosure, then you're right, we then have to deal with the issue what happens to look-back programs, quality assurance programs where institutions discover that errors have been made. How do you deal with that? Do you say that there is a duty of disclosure in those circumstances or do you protect that with the same protection that's given to quality assurance? I'm sure Dr. Dickens will be dealing with that when he speaks this afternoon.

DR. NORTON:

Q. Phil will remember this. During the work for the adverse events study, of course, we had to deal with this. We went through 40 ethics reviews across the country to carry that study out. And we were seriously concerned about not the fact we'd find adverse events, but we

Page 121

might find cases where there was clear liability in a health care professional. And the ethics committees were very worried about that. And you may know that in most jurisdictions health professionals who know someone else was liable are required to report that to the regulatory college. And we spent a long time talking to the ethics group about how to handle it. What was finally done to do the study was to establish a panel, a wise panel, at arm's length from the researchers who would, if a health professional became aware of a case where they thought there had been serious impropriety by a health professional, one of our reviewers could contact that panel. The procedure was roughly if a reviewer saw something that was disturbing and they thought they should report it but weren't sure, they reported it to the provincial site coordinator who was an MD in all case. If they couldn't make a decision, it was referred to the study team who would refer it to this panel. The panel consisted of an eminent legal, medical/legal person and eminent clinician and a public advocate. We

Page 122

only had one case that was sent forward and they dealt with it effectively. But that handled the ethical considerations about trying to do this look-back kind of work. It is very important, as we talked earlier, that we can do it so that we can learn from things, but we have to protect--it's a complex issue, I think, is what I would say, Bernard and Gerald.

MR. CAULFIELD:

Q. I have a question, I don't want to jump in if there's one that is pending. But I'm curious about the perceptions that--I know there's a lot of health care providers here. The perception that the health care providers themselves have about their obligation in the context of disclosure. I'm not aware of any empirical research and I'm curious if the panel members are, of their own perception of disclosure. My own experience working with health care providers is perhaps there is a lack of clarity out there. So my question, I guess, would be, and I'm curious what the audience thinks, the health care providers out there that experience this day to day, what

Page 123

they--how they perceive their own obligations and if there is some work to be done on explaining those obligations and I guess the specific question is, is there any empirical research about those perceptions?

DR. ETCHELLS:

Q. I can start. I mean, I think, I don't think there's a lot of debate about the requirement to disclose adverse events. I think the grey area falls into disclosing potential for harm events or close calls, because that does require judgment and that judgment will be biased by your own view on the case, so I think that's one place where people struggle. Once a decision has been made that disclosure should occur, I think the hard parts are, you know, who should be doing it, how should it be done, where should it be done, when it should be done, those are really tough decisions. I think the hardest is the who should be involved. If we're going to embrace this systems approach and this team approach to patient safety on one hand, which I think is the only way to go, yet on the other hand we're hearing--I appreciate that you modified

Page 124

your comments to say it's going to change, but right now it seems to be the physicians' duty to disclose. I have a problem with that. It doesn't really mesh with the systems approach at all. I think, you know, from a hospital point of view we have to figure out a way to present the hospital as taking responsibility for its performance along with the front-care providers. I don't think we've figured out how to do that perfectly at Sunnybrook, but we're trying. It doesn't make sense to me to just leave it to the physician who probably doesn't even understand all the holes. How could you possibly know that? The analogy to me is asking the Air Canada clerk why your luggage got lost. How is that -

UNKNOWN SPEAKER:

Q. Do that all the time.

DR. ETCHELLS:

Q. - person possibly going to know? But the mechanism by which that occurred and the way to prevent it from happening in the future is something that person couldn't possibly answer. So you know, the physician's job may be to initiate the process, but there's a

Page 125

whole subsequent process of investigation, iterative communication with the family, this is what we've learned over the last few weeks. It takes a lot of time and a lot of effort that requires active management, it requires commitment of resources and people with expertise in these really delicate communication matters. I know the University of Michigan in US has done a very good job not just with the proactive disclosure but really committing resources and expertise to doing this well and their experience was written up in the New England Journal of Medicine two years ago. Interestingly, a co-authored article by Barack Obama and Hilary Clinton, which is the only article that I think they've ever written together.

MR. CAULFIELD:

Q. They're not going to be doing a lot together, I don't think, in the near future.

DR. ETCHELLS:

Q. Yeah. So it's worth a read. But it was around their health care tort reform legislation which didn't go anywhere in the United States. So I think there's a problem

Page 126

with the entire process of disclosure. It's not just the doctors saying they're sorry and you're sick, there's a lot more to it than that, and I don't think that's being worked out.

MR. CAULFIELD:

Q. Gerald.

ROBERTSON, Q.C.:

Q. I was just going to add, I think it's understandable why the law has developed the way it has. The duty has to be imposed on some entity. I think it's understandable that that entity would be seen to be the physician initially. And so I don't find it surprising that the law so far as focused on the physician as being the one who has the duty of disclosure. But equally, as I said in my comments, there is every reason to believe that the next logical step is to say that that duty is not the physician's duty alone, it is an institutional duty.

DR. ETCHELLS:

Q. Can I have one other comment? In Ontario I believe as of July 1st of this year all Ontario hospitals will be required to

Page 127

demonstrate that they have a process in place for disclosing what are called critical incidents, which I would think are just really bad adverse events, under the Public Hospitals Act, which is the act that allows you to continue to keep your hospital open and it's-- so it's a pretty important act and CEOs and VPs pay very close attention to it. So I suspect over the next year a lot of Ontario hospitals will be fretting over this and developing procedures to really manage this properly, which is a good thing.

UNKNOWN SPEAKER:

Q. Do you have a comment to make?

DR. NORTON:

Q. You asked for some evidence. In the study that Baker and I did that ended up with the 2002 report that I discussed, one of the things we asked was about the health professionals was about disclosure. We had hypothesized that the fear of litigation was a major deterrent and it appears in the qualitative data that it is a deterrent. However -

MR. CAULFIELD:

Page 128

Q. It is?

DR. NORTON:

Q. It is. However, there is a much bigger deterrent and that is losing your standing in the profession. The health professionals are more worried about not being a nurse, not accepted as a nurse, a therapist, a pharmacist after they have disclosed an error. And the pain that physicians carry and nurses carry and pharmacists carry from these things is immense. And we have been very, very poor as health professions at helping our colleagues find places where they can discuss this and express it. And there aren't that many health professionals, so we must take care of them. We carry out some very interesting--well, I have to go back a bit. A colleague I met from South Africa talked about using traditional healing circles to help people discuss, health professional discuss their experience with this. And we, using Blackfoot techniques, have carried those out with health care learners in Alberta. So healing circles have some rules that you can only speak when you hold the totem. In the Blackfoot case, of

Page 129

course, it's an eagle feather. That there is a facilitator essentially who makes sure that it passes. And it's astounding--and furthermore, everything that's said in the circle, stays in the circle. So there's some rules that we put on. It's astounding the anger and the pain that health, young health care professionals in their training experience because of being close to these. So we have some things to do about that with disclosure. A final thing I should tell you is work we've done in Alberta through the Health Quality Council asking both physicians and--well, first asking the public who do they want to disclose. There's no question, they want docs, they don't want anyone else at the present time.

MR. CAULFIELD:

Q. They want doctors?

DR. NORTON:

Q. Doctors, doctors, doctors. "What if it was a pharmacy error?" "I want the doctor to tell me." That is consistent. These are focus group work. It just, it's true, at the moment in Alberta. So as you were saying, there's

Page 130

some distance, I think, to go. The second thing is when we ask patients, citizens, what they want disclosed, they want everything disclosed. Harm is not--if they got two Tylenol tablets and there was one ordered, they want know about it.

MR. CAULFIELD:

Q. I think that's, the last points are interesting. I hope we can come back to that because I think that that, the perceptions of what need to be disclosed, I think, and again, it's something that's very relevant to the Inquiry. We had a question here. And perhaps your name and where you're from?

MR. SIMMONS:

Q. Sure. My name is Dan Simmons. I'm one of the lawyers involved in the Commission of Inquiry here. And I do have a question about the timing of disclosure, when the obligation arises. The presentation deals pretty directly with what the obligations are once it's known that an adverse event has occurred. But you can have a situation where a suspicion has arisen that there may be an adverse event and there's going to be some opportunity to

Page 131

investigate or take some steps to determine if, in fact, there has been an adverse event involving a patient. And I'm wondering if there's any guidance or if you have any comments on what the nature of the disclosure obligations may be in that circumstance?

ROBERTSON, Q.C.:

Q. I can't give you any guidance in terms of what the case law says because as far as I'm aware, it doesn't deal with that specific issue, what if you suspect that there may have been an error but want to take steps to inquire further. My own view is that if that determination can be made quickly, then I would see it as justifiable to delay disclosure pending that determination so when the disclosure is made, it can be made more fully and on a more informed basis. But again, I emphasize, if that determination can be made quickly. And if it cannot, if it's going to be involve a period of time to make that determination, then my own view is that there could well be situations where the people who may have been affected would want to know that they may have been affected and

Page 132

that steps are being taken to determine whether they have been affected by an adverse--again, I go back to this idea that if we take our guidance from would a reasonable person want to be told that, would a reasonable person in these circumstances want to be told that there is the possibility that an adverse event has occurred, we are taking steps to determine if one has occurred and, if so, who may have been affected, would a reasonable patient want to be told that. I think there are circumstances where you might well conclude a reasonable patient would want to know about the possibility of an adverse event having occurred.

MR. CAULFIELD:

Q. We have a couple of questions over here. Do you mind if he goes first, sir?

DR. GALLAGHER:

Q. Tom Gallagher from University of Washington. I just wanted to circle back to this issue of evidence and what we know about health care workers' attitudes. And there are actually several good sources of information about health care workers' attitudes about

Page 133

disclosure, including Canadian health care workers. I was pleased to work with Wendy Levinson, who is chair of medicine at the University of Toronto, on a survey of a few thousand physicians in both the US and in Canada asking about their attitudes about disclosure and how they would respond to a variety of disclosure situations. So there is that large data set that does support that health care workers and physicians, in particular, really endorse the concept of disclosure but struggle with its implementation. We did a second study where we watched surgeons disclose errors to standardized patients and analyze those tapes qualitatively. And then Sherry Espin, who is one of the other presenters, has done some really nice work watching and talking with operating room teams about disclosure. So there are several sources of empiric evidence available about health care workers in Canada and their attitudes about disclosure.

MR. CAULFIELD:

Q. Thanks, Tom.

MR. RITTER:

Page 134

Q. I have a couple of observations and questions. The first one, what I could gather from the presentation today and from some of the material that I'd had a chance to read in advance of the meeting is that a lot of the work in disclosure from a legal perspective, from a ethical perspective is in many respects still maybe not in its infancy, but certainly in its adolescence and hasn't quite matured yet. And as much as we have--we look to you for answers you also have presented us with still many outstanding questions. And I guess the observation or question I would ask is, you know, with the sort of the revolution on privacy that's boomed in the last number of years, we've created a new discipline called, you know, privacy and you have privacy directors and privacy managers. I'm just wondering, I'm thinking, you know, in terms--I'm trying to empathize with the physicians who are busy enough as it is trying to be clinical people and do clinical work. You know, these questions that we're asking without very clear, precise guidelines, you know, are not easy questions to answer, and

Page 135

I'm sure that often times physicians find themselves very conflicted. And I wonder whether hospitals now are considering or whether you're recommending the creation of disclosure consultants where people can turn or physicians or nurses or anyone can turn and say, "Here's my situation. How do I deal with it?" The second observation I just wanted to make, if I may raise the issue of aviation once again, my son is an airline pilot so I get into this stuff, but the issue of near misses and the need to disclose close calls and near misses, my understanding is, and I think I'm right, that in aeronautics when they'd have near misses, they investigate them but they don't necessarily publicize them, and I think for obvious reasons. And I would be a little concerned in the area of close calls and near misses--I agree totally that they'd need to be investigated. The amount of work and the potential alarm that that could create I think really needs to be examined carefully because it may well do more harm than good. That's just an observation open for debate.

DR. ETCHELLS:

Page 136

Q. I'll speak to the second point. Around--it's really an issue of the threshold for disclosure and we've struggled with this. I think the right answer is asking yourself first whether the error reached the patient, and we've defined reached in two ways. Either the patient actually received care that was unintended, for example, they got the wrong medicine, it might just be a laxative that probably causes no harm, but we feel because it entered the patient's body, they actually received it, they should be told, and not speculating whether it may cause harm or not. We just think that's being truthful. The second form of reach the patient is if they did not get something that was intended. So if a medication was ordered but not given, we also feel the patient should be told that. Obviously harm is speculative there; it depends on what wasn't give. But we think they should know and then it gives you an opportunity to tell the patient what care is intended and they have an opportunity to speak up if things aren't happening correctly the next day, so it has some advantages. Moving

Page 137

backwards then, if it's an error that's visible but did not reach the patient, I just think it's kind of polite and silly not to comment on it. So I've had situations where we've gone in the room and we've been about to do something and then we've said, you know what, this is the wrong person or it's just the wrong thing or we're in the wrong place. You might as well just apologize and move on. Even though there is no--there might be some psychologic harm from that and you should assume that there is. But then all other things we feel there's no real value in disclosing to the patient and it would probably cause more harm than good, so errors that do not reach patients, that are not visible to patients, it's our job to fix them, but not necessary to disclose them. It's not the patient's job to worry about them. And that's kind of how we've drawn the line.

MR. CAULFIELD:

Q. And I want to clarify, so you're saying if it's an error that reaches the patient, the default is disclosure?

DR. ETCHELLS:

Page 138

Q. Absolutely.

MR. CAULFIELD:

Q. Regardless of whether it necessarily has harm -

DR. ETCHELLS:

Q. Because you don't know, you can't--it's so speculative whether harm could occur.

MR. CAULFIELD:

Q. Yeah.

DR. ETCHELLS:

Q. Plus it's just polite.

MR. CAULFIELD:

Q. Gerald, I don't know if you wanted to comment on that in the context of the legal obligation and would a reasonable patient want to know being (unintelligible).

ROBERTSON, Q.C.:

Q. Well, as the questioner pointed out, there's certainly very good reason for internal disclosure of a near miss, for purposes of investigation, to minimize the chance of it happening again. But in terms of whether there is a legal duty to disclose to the patient they almost suffered harm, personally I doubt it. Because, you know, even if we, as

Page 139

I've said many times, even if we look to the hypothetical reasonable patient to answer that question, is this something that a reasonable patient would want to know, as has been pointed out, studies tell us that patients want to have a great deal of information, so it might well be that most people would want to know about the near miss that almost reached them. That doesn't necessarily mean that the law should impose that duty. You know, if we move out of the health care context and look at the obligations that the law imposes on the legal profession, lawyers equally have a well established ethical and legal duty to inform their clients if they've made a mistake that has the potential to cause harm, financial harm to the patient (sic.). But I think it's pretty farfetched to say that if I almost forget to file the statement of claim before the limitation period expires and at that last minute I remember I haven't filed it and so I run off to the courthouse and just in time I file it, I think it's pretty farfetched to say I have an obligation to tell my client that I almost missed the limitation

Page 140

period. They might be interested in knowing that, but to say that the law imposes that duty on me as a lawyer I think is a bit farfetched.

MR. CAULFIELD:

Q. You can tell all the lawyers in the audience because they're laughing, because they've all experienced that.

ROBERTSON, Q.C.:

Q. So why isn't it farfetched to say that, you know, a physician has a duty to disclose near misses?

DR. NORTON:

Q. The issue of what to investigate, which you brought up, is a critical one. The academics who are now thinking about the adverse event rate that you find by the method I described, which is retrospective chart audit, structured retrospective chart audit, would probably today say that finds approximately a quarter to a third of the adverse events. So that means in Canada one in four, one in three patients are having an adverse event. Most of those are rather minor. It may be as the case where Ed said, they got the laxative by

Page 141

mistake and they have diarrhoea so they have a one-day extended health care episode at the hospital. We can't afford too many of those given the stressed resources, though. So there's a lot. And if you add near misses to that, you end up with rooms full of reports. And so we need to define strategies, develop and use strategies to sort out the ones that give us the maximum benefit. So it's clear if it's something to do with the product, if the amount of harm, and I don't just mean personal harm, it can be system-based harm, times the frequency, that should indicate when we investigate and start patching the holes. And we haven't done a lot of work in that area yet.

MR. CAULFIELD:

Q. Um-hm.

DR. NORTON:

Q. We tend to spend a lot of time on the big events and not very much on the small grinding things, which may in the end have a bigger impact on the health of the population. So I think it's a very interesting question that I don't think we know how to handle at the

Page 142

moment.

DR. ETCHELLS:

Q. Can I just jump in on the -

MR. CAULFIELD:

Q. Please, please.

DR. ETCHELLS:

Q. We've spent years trying to get people to agree on the definition of near miss, and I gave up, precisely because of these sorts of discussions. I actually try not to use the term any more and I go back to error that reached patient and caused harm, error that reached patient but did not cause obvious harm, error that was visible to the patient but did not reach them. I actually find it makes the conversation more clear in terms of disclosure and investigation because I can't anyone to agree what a near miss is. To me any time a patient gets the wrong medication, doesn't matter whether it's a laxative or a beta blocker or insulin, like, something's not working. Thank God it was a laxative because then they're probably not going--they're going to be okay, but why did that happen is really the big issue, so but it reached the patient,

Page 143

so they should be informed. If the nurse picked up the laxative in the cart, said, "This isn't for Mr. Jones," that's an error that did not reach the patient, but certainly had the potential to cause harm and some people call it a near miss. I don't care what you call it, but it's an error that did not reach the patient, so it does not require disclosure; had the potential to cause harm to the patient, therefore it requires investigation. I don't know if anyone's come up with a better definition for near miss. Love to hear it.

MR. CAULFIELD:

Q. Did you have a comment, Peter?

DR. ETCHELLS:

Q. It just drives me crazy.

DR. NORTON:

Q. I just had Ed reminded me of one other thing, and that's in this discussion we need to clearly differentiate three things. There's first of all the obligation of the health professionals to tell each other and tell their organization that something's happened.

MR. CAULFIELD:

Page 144

Q. Um-hm.

DR. NORTON:

Q. That's an obligation. And I don't--maybe Bernard can say what the law says about these. Then there's the obligation to tell the patient's family that something has happened. But thirdly, and I haven't heard any discussion yet, there's also the obligation, I think, maybe not be legal, it's certain moral, of the organization to inform this is at large what happened. And if we don't sort of separate those out, we sometimes get confused about what we're talking about here. We worked very hard in Calgary to try to separate those and have a different track, understand the timing and the level of detail that's needed in each of those disclosure activities. But they are separate and I think that we need to think about them. I don't know if you -

MR. CAULFIELD:

Q. Daryl.

DR. PULLMAN:

Q. Daryl Pullman from Memorial. It's clear that this is an evolving environment in terms of disclosure and, you know, a more open

Page 145

environment that's developing here and we're still trying to work out, you know, what needs to be disclosed, when and how much and so forth. But it goes back again to the earlier question that I asked around, you know, these diagnostic labs and so forth where we know around certain kinds of tests and so forth that there' an error rate of, you know, significant error rates in certain respects. And so when--I mean, you can tell that to a patient when they're going for a test, say, "Well, you know, nine times out of ten this is okay, but, you know, sometimes it's a false positive." Patients tend not to hear that kind of thing. Their expectation is that their result is going to be correct. I'm just curious about from both a legal and a sort of clinical perspective where our duty comes in in that respect, do we just tell people up front and then it's their responsibility to follow up and see, "Are you sure that's my result?" and so forth? Because it seems the further we go down this road, which we have to go down, and as you pointed out, you know, it just becomes more and more complex all the

Page 146

time about, you know, who--what do we disclose. And the other part is what does the patient actually understand when they've been told, you know. Around this ER/PR stuff, you know, patients have been calling, they've got a negative result on that and some of them have interpreted that meant that they didn't have cancer. Well, no, it didn't mean you didn't have cancer, but they heard, well, it's a--you know, you did a test and it was negative, you know, and it--so again, it goes to that standard of information disclosure which, I mean, a reasonable person for sure, but once you move that the duty of the disclosure from the physician to the team, to the institution and then it's, well, how far do we have to go to insure that this patient who, you know, doesn't have, you know, for whatever reason doesn't understand or appreciate this, you know, just a lot of different questions around that kind of thing.

MR. CAULFIELD:

Q. Comments from the -

DR. NORTON:

Q. I could speak clinically to this, in my day-

Page 147

to-day practice. So let me suppose you were my patient and you were coming in and you're at the right age to have some screening done for cancer of the colon. And I have to have a very complex discussion with you about how accurate the two tests that are available, one called faecal occult blood, meaning you give us some stool samples and we find out if there's minuscule amounts of blood in it versus colonoscopy, which has some small risk and some people dislike that, some people dislike the other test. And I have to try to explain to you small margin benefits for those two things and how many times do you miss the cancer if you use each of them. And I think it's very hard and I don't think it--I work really hard with my patients to make sure they make an informed choice. I think my duty is to do that, but I'm not sure I can do it.

MR. CAULFIELD:

Q. Gerald?

ROBERTSON, Q.C.:

Q. Comment from a legal point of view. As a questioner pointed out earlier, although it's true to say that the legal duty of disclosure

Page 148

of error is in its infancy or adolescence, the idea of disclosure and disclosing information to patients has been around for a long time. There's a lot of case law dealing with the obligation of disclosure in terms of disclosing risk. And one of the most important developments in that area in recent years is the emphasis, the shift in emphasis away from disclosure to understanding. And case law now makes it very clear that the obligation on physicians in terms of disclosing risk to patients is not simply a disclosure of information, it includes a duty to take reasonable steps to insure the patient actually understands the information that's being disclosed. And if that emphasis on insuring patient understanding continues and begins to crop up in the area of disclosure of medical error, you'll see the same thing, that it's not simply--it's not good enough simply to disclose the information, you have to take steps to insure that the patient actually understands the implications of what is being disclosed.

DR. NORTON:

Page 149

Q. Can I ask if it's this, the risk, is it risk of if I don't explain carefully enough to a patient their risk of cancer and why they should have this test, would I have obligation--have not met my obligation?

ROBERTSON, Q.C.:

Q. No, what I'm saying is that -

DR. NORTON:

Q. I'm saying the omission, does the omission and the commission work the same way?

ROBERTSON, Q.C.:

Q. I think they do. I think if you're dealing with a situation where you have reason to believe that this patient does not understand that there is a ten percent chance of a false positive, then you have to take steps not only to disclose that to the patient, but to insure the patient actually understands the implication of what you're telling him.

MR. RITTER:

Q. Can I just make a quick observation in response to that? And I agree and accept what you're saying, but the reality is, again, if you look at, for instance, an oncologist or a team of oncologists that at the present time

Page 150

are working--are seeing about 40 percent more patients than the national standards would dictate, suddenly are sort of confronted with having to explain, not just to disclose but to explain in a way that the patient truly understands, if they have to do that with 1000 patients, I would say from a purely practical perspective, to really get them to understand you're probably looking at a couple of hours per patient, maybe more. The dilemma is an operational dilemma. Do you immediately start dealing with all that at the expense of all the people who are waiting to see you and have potential malignancies and whatnot? How do you deal with it? You know, it's a push and pull situation that's really very delicate and very conflicting, especially for the physicians.

MR. CAULFIELD:

Q. That's a tough one, so maybe we'll leave that one hanging. Good point.

DR. WARD:

Q. Steve Ward, UBC. Peter, I want to pick you up on your talk about the three levels, particularly disclosure to citizens, general,

Page 151

which is, I agree, I think this Inquiry, it's a huge issue for this Inquiry. At what point, at what time is there a duty on the part of health professionals or institutions to go public, what the content of that communication should be and also do the arguments for disclosure and certain criteria such as reasonable patient test, informed consent, do those justifications for going to the citizens extend over into the public realm, in other words, or do we move on to different arguments for disclosure to the citizens separate from the justifications for telling patients, such things as public trust in the system, such things as accountability of public institutions. Have your colleagues looked into that, these issues at all?

DR. NORTON:

Q. Well, we have a nascent policy about that in Calgary, which is available on our web site, you can read it. But I must say that the debate is not finished, I think, about that. I personally believe that the public trust is best served by the institutions, the regions or the hospitals being honest about these

Page 152

things. Clearly, there clearly is a different time because I think the story has to include, in most cases, what you've done to remove it, because you need to show that and it tends to get lost otherwise, they aren't linked enough. But I don't think I know, I'd be very interested in your feeling about it because of your perspective, whether you're going to say that today or tomorrow, on what you think about that. But it is a separate step, I think, from telling the involved individuals that we need to consider.

MR. CAULFIELD:

Q. I think this is an interesting question that I think will come up perhaps in Bernard's talk and certain tomorrow morning. I have a question I want to get in for sure before the lunch break, which is an e-mail question. And it has to do with the tension between privacy that you brought up, and I don't think we actually touched on this, privacy and the obligations that you have to an individual which is a fascinating question, particularly in a situation like this where you may have not 10, not 100, but perhaps even thousands of

Page 153

people could be implicated. So how you play that tension between the obligation obviously to respect patient confidentiality, to disclose information only with explicit consent and this sort of broader, broader disclosure obligations that may not just be disclosure to individual patients on a broad scale but disclosure to society. So you really have some interesting tensions. I don't know if anyone wants to comment, Gerald, maybe the legal obligation and then others on how that may play out in a system level?

ROBERTSON, Q.C.:

Q. Well, in terms of disclosing to the public at large, I would imagine in most circumstances that could be done without disclosing details which would breach patient confidentiality. Obviously the identity of the patients would not be revealed. But, you know, there may well be circumstances where the public's need to know might be paramount and might supplant the individual patients' right to confidentiality, but I can't see why that would necessarily be a concern. I would think in most circumstances, it would be possible to

Page 154

discharge the obligation to the public so the public has information and is aware of what has happened without endangering individual patient's right to confidentiality.

MR. CAULFIELD:

Q. So you're saying that not--this is actually--I think you touched on it a little bit in your paper, Sherry, the idea--do you really think in a legal perspective there could be any situation where either the institution or the physician or the health care provider is justified in releasing confidential information without disclosure for the good of the system or society? And perhaps practically this won't be an issue because you can deal with it within the bounds of the legal obligation, but let's just say hypothetically, can you ever see that playing out so the patient doesn't want anything disclosed but would say for the good of the system, we're going to disclose this error?

PROFESSOR ROBERTSON:

Q. Well, certainly, if you're talking about public safety, if it were a situation where the public needed to know this because there

Page 155

were issues of public safety, then it's well established in those circumstances, the individual's right to privacy might have to take a backseat to the public's interest in public safety, but it would be difficult to conceive of a situation where the public's right to know, because this is a matter of public interest, would be seen to be more important than the patient's, individual patient's right to confidentiality. There might be, but you know, I just find it difficult to conceive of a situation where that would arise.

DR. ETCHELLS:

Q. I can't think of a scenario where there'd be an issue of public health importance where you would need to identify the name of the patient involved in the hospital. I can't think of one. The public health issues with -

MR. CAULFIELD:

Q. You could see a public health scenario, but I--I'm with Gerald. It's hard to see a situation where it's a system error problem that would require a disclosure, but--Gerald, Bernard, I'm sorry.

Page 156

PROFESSOR DICKENS:

Q. Bernard Dickens, Toronto. We had a case of this with the SARS outbreak in Toronto where a woman flying back from China was infected and the family agreed that her details should be disclosed. She died of the condition, so did her son, who she infected, and the family agreed that it was in the public interest to identify this person by name so that her family members and neighbours would know, so that the flight that she was on would be identified, so that other passengers would know. The challenge would have arisen had the family said that they didn't want her identity to be disclosed.

MR. CAULFIELD:

Q. But in some respects, that's different, right, Bernard, because the public health norms kick in. Infectious disease kind of traditional norms kick in, and it's a very interesting question whether those kinds of norms and ethical standards sort of morph now into patient safety questions. So I don't want to beat this to death with five minutes to go and lunch to come, so I'm going to turn it over to

Page 157

you.
MS. NEWBURY:
Q. Thanks. Jennifer Newbury, I'm one of the lawyers involved in the Inquiry. I have a two-part question. Number one, has there been or is there still a real legal or policy debate about whether or not wrong site surgery causes harm? I'm not sure--that was raised, I think, by Dr. Etchells during the presentation.
DR. ETCHELLS:
Q. Legally, to me, there's no issue. I mean, obviously if the patient got the wrong procedure, the error reached the patient and at a minimum, caused them unnecessary discomfort and suffering, and at maximum, they still have the condition that they were supposed to get treated and it's still there. I don't see any issue about disclosing that at all. I've never heard anyone argue about that, to be honest with you.
MS. NEWBURY:
Q. Okay, that's what I was curious about.
DR. ETCHELLS:
Q. I think it was just that specific legal case.

Page 158

MS. NEWBURY:
Q. The second issue, and it deals with that generally, have there been any protocols built in place to take into account potential bias by people deciding whether or not there has been harm or some event that should be disclosed to a patient? And I'm thinking, you hear about research bias or specialist bias, you know, there tends to be a thinking, you want a certain outcome and because you want a certain outcome, then you might be bias to interpret that outcome, and of course, I assume that no physicians or other health care providers ever want harm to be caused by a patient. So is there any concern about whether that decision maker having to look back at his or her own work might have a bias wanting to conclude there hasn't been any harm?
DR. NORTON:
Q. This is a big issue in the retrospective chart reviews, and essentially to determine if there's an adverse event, the chart reviewers have to look at the three conditions I put down: was there an injury, unintended; was

Page 159

there consequences, which I outline death, disability and prolonged hospital stay; and was it caused by medical management. And in the Canadian study, we did some very careful work to try to see how reliable, i.e. how much bias those three decisions were, and I must say, this is done in a very structured way. You can't make the decision without answering a bunch of questions first to frame it, each of those three questions. The agreement on the first, was there an injury which was unintended or a complication, the agreement among reviewers is quite acceptable. It's a complex statistic, but it doesn't really matter, it's acceptable. The agreement on the second issue, did the injury cause death, disability or prolonged hospital stay, is still in the acceptable range, from a scientific point of view, but the reviewers would agree about 75 percent of the time. The agreement on the third issue, was it caused by medical management and not the patient's underlying condition, drops down to about 60 percent. It's the highest that anyone's got in those studies, but it still leaves open to

Page 160

me the question of even if you're not involved with the case, how objective can you be? Now let me say when you are involved in the case, your objectivity gets shot in the foot, and in fact, people, in my experience dealing primarily with learners who've been in bad situations, is that they over call this. They over call it, and I think that's true with professionals as well. So that an objective person moving back says "actually, no," but they're very sensitive. You teach, Ed, do you find that as well?
DR. ETCHELLS:
Q. Yes, I think there's just when one is reflecting on one's own work, the bias is as much to be overly critical as it is to be overly positive, but it's going to depend on the personality as much as anything. One trick we tried to use in a different retrospective chart review study I was involved with is after the reviewers had done all their work, we then said, okay, imagine that the patient did perfectly well, would you still have any concerns about the processes of care? And that's the control for the problem

Page 161

of hindsight bias. You always tend to take a dimmer view of things when the outcome was unfavourable. That seemed to be helpful to the reviewers because they were focused on the processes of care, not the outcomes initially and that was a useful question.

MR. CAULFIELD:

Q. Excellent question. Next please? I'll give you the last one before lunch.

MR. SINGLETON:

Q. Great. Rick Singleton, I work in Pastoral Care and Ethics with Eastern Health. Just want to take a moment. Most of your examples and so on speak to individual cases, and a lot of the papers did as well, but I just want to ask about the domain of ethics in the issues and the decisions about disclosure and so on.

A lot of what we've heard this morning pertains to the law and the kind of legal obligations which would be on the floor level at which we have to start off, but it seems in some ways that the discussions kind of make the floor to ceiling, that you know, if there isn't a legal obligation, then it doesn't go much beyond that. I'd like you to address the

Page 162

kind of scope of ethics that might happen and one example that was used, it wasn't really-- it was to make the point about, you know, someone breaks a window next door with a ball. I guess if you owned the window next door, you'd like to know who broke it, and you'd have a kind of expectation and whether or not there is a legal obligation to say you broke the window, are there other considerations that would lead you to consider that? But the flip side of it being are there ethical considerations as well about not disclosing that in some cases would challenge--especially when we look into the domain of broader issues, things that are more complex than the individual cases of individual patient with an individual physician and a specific team and specific times and places. Are there ethical issues and considerations and frameworks that might inform us about what would be the appropriate thing to do and the extent of legal obligation and the extent of moral obligation? It's 12:30, so you know, a ten-second answer would be adequate, I'm sure.

MR. CAULFIELD:

Page 163

Q. So brief, efficient, accurate responses.

PROFESSOR ROBERTSON:

Q. Well, let me start. The Canadian Medical Association amended its code of ethics in 2004 to explicitly provide for a duty of disclosure on physicians if they cause harm. It's my understanding that other health care professionals, including nurses, also have a similar ethical duty of disclosure in their codes of ethics. So the ethical position is as clear as the legal position. There is a duty of disclosure.

MR. CAULFIELD:

Q. And we will be hearing about this more from future speakers. Okay, it's a wonderful time to stop. I'd like to again thank our panel and we'll start back at 1:30 sharp. Thanks to everybody.

(LUNCH BREAK)

MR. CAULFIELD:

Q. Good afternoon. I hope everyone had a nice lunch, and you're rearing to go for another set of great talks. We started the day talking about patient error, patient safety in a broad sense. We moved into a clinical

Page 164

perspective. We then started talking about specific legal obligations for health care providers, and now we're going to talk--open up a little bit again and talk about how--what the obligations are of other entities, of the system, of regional health authorities, politically, and to lead us through that discussion, we're going to start with Professor Bernard Dickens who is a law professor from the University of Toronto, and I think it's fair to say, and all the health law lawyers in the room I'm sure will agree with me, is truly one of the fathers of health law, not just in Canada, but around the world. He really is a seminal figure in this field and it's a great honour to have him here. My friend, Bernard Dickens.

PROFESSOR DICKENS:

Q. Thank you, Tim. The real honour is to have been invited to participate in this stimulating discussion, clearly based on the most regrettable of circumstances, but if it's an ill wind that blows no good, the good for this for me is the opportunity to become involved in some of the details and in

Page 165

particular, the broader principles, and I really am going to be dealing with the setting, a number of the background circumstances that have conditioned the more detailed inquiry. I'm also indebted to Tim for having invited me here and I'll be even more indebted if he keeps me to a good time discipline, because this is fascinating and I'm disposed to ramble on, and a time will come when I have to stop. There was an occasion once, admittedly chaired by a friend, who not very discreetly pushed a little note to me, simply said "shut up and sit down already," and this is a variance of the two-minute warning, I think.

The background with the provincial health authorities and the government lies in the conditioning of the Canada Health Act. The Canada Health Act doesn't impose obligations on provinces. It empowers the federal government to make contributions, increasingly modest, to reimburse provinces for their expenditures, and the provinces equip themselves to receive federal grants by conforming to the Canada Health Act, and the

Page 166

Act essentially has two preconditions for payment.

The first is that there is eligible for coverage and coverage is relatively comprehensive, would have reasonable access. That's not necessarily immediate access. It's not necessarily local access. It is, in whatever the circumstances are, reasonable access to medically necessary services, and although we speak about the Canada Health Act and in the Province of Ontario, for example, we have the Health Insurance program. It's only covering medical health. It doesn't cover general dental health. It doesn't cover a variety of services that we would regard as meeting the World Health Organization definition of health, a state of--the WHO definition uses the word "complete, physical, mental and social well being." The health plans, as we call them, are simply medical plans and under particular circumstances. So we're looking at medically necessary. They have to medical and they have to be necessary. We've seen that in recent litigation involving autism where the treatment, if not medically

Page 167

advised, was not given by physicians and a number of Courts have concluded that the provinces equipping themselves to be reimbursed don't have to cover autism treatment because it's not medical and it's not clear that it's necessary. Of course, families would disagree quite fundamentally on that.

The government powers, and I apologize for those who've done anything on civics, to say nothing of first year constitutional law, but governmental powers tend to be divided into three, and we speak about doctrines of the separation of powers: the power to make law that is vested in the legislature; the power to discharge the functions of government, that is the executive function; and the judicial function, and of course, judicial independence of government and of the legislature becomes quite important.

The history of the separation of powers are really we shouldn't go into, but we see a contrast between countries from the Anglo-Canadian tradition, if I'd call it that, and the United States. It has a more strict

Page 168

separation of powers in that in the United States, the secretaries of state, the ministers of the executive, are not part of Congress and not part of the legislature. In Canada, we have a parliamentary executive, that is the government is the government because it can control a majority vote in the legislature, and that means that the policies it proposes, it has a fair chance of implementing because it has the persuasiveness within the legislature. Really then, we have interactive powers and it's the way these different powers intersect that we have to deal with.

The Courts are independent. They, of course, have to interpret legislation. They have to see how legislation fits within the background law, that is does the legislation change the background law, which is has the power to do, or does it consolidate, does it codify the background law. Is it subject to the background law? A number of our laws, for example, dealing with adolescence right to medical treatment, the Courts have interpreted to accommodate the common law, the customary

Page 169

law principle of the mature minor. So though the legislation may say that people below the age of 16 need a written parental consent, the Courts may interpret that and sometimes the legislation will specifically provide that this is subject to the maturity of the individual, the mature minded doctrine. So the Court, though independent of the legislature, interpret what the legislature has done. If the legislature doesn't approve what the Courts have done, it's open to the legislature to change the legislation, and whether the new legislation consolidates previous judgments. If, for example, the legislature approves of the interpretation the Courts have given, they may reenact the provision in identical language and that locks in the interpretation the Courts have given. If the legislature disapproves of the interpretation by the Courts, then they will use different language and different concepts, and although we've been accustomed to the concept of legislative supremacy, legislative sovereignty, that of course is now subject to the Charter, the Canadian Charter of Rights

Page 170

and Freedoms, which doesn't bind you and me as individuals. It only binds government and those discharging governmental functions, but government is subject to the Charter, which the Courts will interpret. It came as a great surprise to many Canadians in January 1988, in the Morgentaler decision, when the Courts declared provision of a criminal code on the very sensitive issue of abortion as inoperative, and many people didn't understand that that was an implication of the Canadian Charter enacted in 1982.

So really, we have to deal with the way the different powers of government interact with each other. The executive power vested in a minister primarily, but also back-bench members, and of course, we're aware that back-bench members, if successful in the lottery, can introduce private members bills that may attract a majority support in the Legislative Assembly. The minister will propose law. This is what the executive does. The legislature may enact the law. If a minister proposes legislation that doesn't attract majority support, that could mean that the

Page 171

government falls. If it is deemed to be a vote of confidence in the government, a government that cannot govern loses its credentials to claim to be the government.

The legislation then will represent, not just the wishes of the minister, but the wishes of the Parliament, which includes, of course, non-governmental members of the government party, members of the official opposition, members of other parties, and the Courts have to interpret the intention of the legislature, which is not necessarily the intention of the minister.

So the involvement of government in implementing its policy becomes a matter that has political and legal dimensions. That is the government is accountable to the legislature politically, but it can also be sued in Court, that is, is accountable to the judiciary.

A contrast has been recognized with the abolition of historical claims of governmental immunity. This is based on the rather pedantic proposition with the supremacy of the Royal Courts among other courts in the United

Page 172

Kingdom and England that the monarch could not be sued in the monarch's own courts. And we still have retentions of governmental immunity from legal liability, but the Courts have recognized that with the involvement of government in so many matters affecting individuals, affecting families, affecting communities, that a claim that the government cannot be liable in the courts simply is intolerable. There has to be a level of governmental accountability to law, and the Courts have recognized the contrast between policy decisions and operational decisions.

Now there's a permeable barrier between what is policy and what is operational, and functions of advocacy become relevant here. That is an advocate has to persuade a court, if defending the government, that it's a policy decision for which the government is politically accountable, but not accountable to the Courts, and advocates for those asserting governmental liability will say "this is not policy. This is the implementation of policy. This is operational." And this is a contrast that

Page 173

becomes quite important.

In my paper, I've given an example that had arisen quite recently and I'm sorry, this is quite parochial, in Ontario, and in particular, in Toronto, the question of garbage disposal, toxic garbage, and there was an intention to take it out of the province, to ship it elsewhere, to the United States, to other areas, and dispose of it in contrast to incinerating it. And whether one goes for an incineration policy or whether one goes for an exportation policy is a question that governments have to decide. If we disapprove of their decision, then we could take account of that in the next election, and to that extent, if governments make policy decisions, the Courts will not scrutinize them for their wisdom, for their economic implications. Governments make policies and they're politically accountable and that's why we vote them into office and vote them out of office, on the basis of their promises and on the basis of their record.

In contrast are the way that decisions are actually put into effect. That is if a

Page 174

decision is made that there will be incineration of toxic products, then that could cause a nuisance, a public nuisance, that could be subject to litigation, a private nuisance in some circumstances, and the Courts may review how the incineration process operated, not whether it was a good policy or not, but whether it was operationalized with due respect to individual interests.

If we accept that the contrast, we then have to ask whether operational decisions involve private law duties of care and Joan Gilmour is going to be addressing duties of care in much more detail.

We had an instance of the Ontario government again, I apologize for the parochialism of this. In Canada, you can't criticize decisions for being provincial in quite the way you can in the United Kingdom. In the United Kingdom, to be provincial is very negative. In Canada, it's perfectly legitimate.

There was a government proposal on how to deal with West Nile virus. There was an instance of infection and family members of

Page 175

the infected person sued the government saying that the government should have been more active in promoting its policy. The action failed on the basis that whether and how policies developed with regard to this onset of infection is a policy decision and it didn't create rights of litigation for individuals. That is, the general assessment was that at most this is a policy. The Court found that in fact it wasn't even policy. It was simply a proposal for those at the municipal level who wanted to implement it. It imposed no duties. But the Court said that had it been a question of policy, then that would be in the political realm, not the legal, and it wouldn't give rise to successful litigation.

But if we actually look at the background juris prudence, we find that the Courts are entitled to take account of policy factors, even at the operational level, and an example of that, or two examples, come first of all from the evolution of legal concepts of vicarious liability, in particular, in master servant relationship. If a servant employed

Page 176

by a trucking company drives negligently, is the company liable for that or is it a liability simply of the truck driver? There's a matter of policy. The Courts have said that if there is to be justice, if there's to be any prospect of compensation for those who have suffered injury because of careless or negligent driving, then to require the plaintiff to sue against the resources of the truck driver would create little prospect of compensation. The truck driver is employed to promote the interests and the commercial profits of the trucking company. The trucking company makes the profits. They pay the truck driver an employment wage, perhaps modest. The company would have insurance for its trucks and therefore, as a matter of policy, the Courts have said that within a master/servant relationship, if in the course of discharging the functions of the master, the servant creates liability, then the liability vicariously is borne by the employer. That is the agency better equipped for protection, better equipped to pay compensation, and to have insurance for legal

Page 177

insurable interests.

We've also found policy coming into the operation of the Charter. The Canadian Charter of Rights and Freedoms provides a number of entitlements, for example, protection against discrimination, and also protection of rights to life, liberty and security of the person. But this is also subject to Section 1 of the Charter and a crude paraphrase of Section 1 is that those governed by the protection of the Charter have all of the rights and freedoms embodied in the Charter unless they don't, and they don't if it is demonstrably justifiable in a free and democratic society that they don't have those entitlements. So if there is no Charter breach, the issue doesn't have to be addressed. But if the Court finds that there has been a breach of one of the protections of the Charter, protections perhaps against discriminatory behaviour, then the Courts have to see whether that discrimination is demonstrably justifiable in a free and democratic society, and although that invites international comparisons, it essentially

Page 178

turns on the free and democratic society that Canadians enjoy. And the Courts have to make an assessment, and sometimes they say this is demonstrably justifiable; in other cases, not.

A leading case on this establishing that hospitals, as such, are not actually governed by the Charter was the case from Vancouver, Stoffman against the Vancouver General Hospital. That was allied with cases involving the University of Guelph and the University of Toronto on the question of mandatory retirement. People were entitled to employment up to the age of 65 and after 65, they were not entitled. And the claim was made that this is a violation of (unintelligible) discrimination on grounds of age. And the Court said three things. They need only have said the first thing, that this is a Charter claim against the Vancouver General Hospital, and although it has essentially public funding, it is a private corporation. It's not government and therefore the Charter doesn't apply.

The case was in the early years of Charter litigation and therefore the Court

Page 179

went further and said that if the Charter did apply, then this would be discrimination on grounds of age. But third, the Court said this discrimination on grounds of age is demonstrably justified in our free and democratic society because what doctors have in hospitals are called privileges, and within the university setting, faculty have the protection of tenure, and there comes a point when the people at the top of the ladder can be required to leave. It is justifiable that privileges not be permanent, that they eventually have to yield. Those who have the protection of tenure must give way to the students they are responsible for training to replace them, and if there is to be any progress on the ladder, if those seeking a place in the lower rungs are to be accommodated, it has to be that those at the top leave. And so the Court said, if this was a Charter case, this would be discrimination on grounds of age, but demonstrably justified in a free and democratic society.

In a subsequent case, also involving British Columbia, the Eldridge case, the Court

Page 180

went back to its language in Stoffman and interpreted it more explicitly. There were provisions in the Stoffman judgment that a number of people, and I say including myself, didn't pay special attention to, and the primary judge who drafted the Stoffman judgment went back to his language in Eldridge and said that although public hospitals, being private corporations, are not themselves a branch of government in their policies of hiring and firing and contracting for services, when they are discharging governmental functions, then they are bound by the Charter because governments can't evade their Charter responsibilities by delegating functions to other agencies, and the functions, in particular, concern the supply of health care. Governments are not licensed to practice medicine, nor are hospitals, but hospitals employ, under various contractual terms, doctors who are licensed to practice medicine and that is a function that governments have taken responsibility for under the provisions of the Canada Health Act. This is a governmental function and

Page 181

governments can't evade their Charter responsibilities by delegating the discharge of them to private agencies.

So in Eldridge, it was found that there was discrimination on grounds of hearing disability in that case, and the Charter did apply, and again, we can see the policy implications of that.

Legal liability can be established in accordance with a variety of different principles. Liability for failure to meet the standard of care is the key issue and again, Joan Gilmour is going to be dealing with that. Standards of care are set by the Courts and although they have to meet a criterion of adequacy, they don't necessarily have to be excellent. Courts will set the standards. Clearly if agencies could themselves set the standards that would measure their liability for negligence, they would have self-protective incentives to set very modest standards. So the standard of care is determined as a matter of law by the Courts. It needn't be cutting edge. It is essentially one of adequacy in the circumstances, not

Page 182

necessarily the best, but good enough.

There can also, of course, be liability for error, but we've heard this morning that not every error is a consequence of negligence. There are wide categories of non-negligent error and whether the error was negligent or not is what litigation will essentially focus on.

There can also be liability for misfeasance of public officers, and this is a tort that has come to recognition relatively over recent times and the Courts are still working through the more detailed juris prudence of it.

Litigation, whether for negligence, for misconduct in public office, can be pursued by class actions and the Courts will certify by legislative criteria whether the case is appropriate for a class action suit or not, and there can also be non-delegable duties of care. That is, if hospitals delegate their functions to doctors who are not servants of the hospitals, in some circumstances, they may be, if they're salaried or they may be analogous to servants. Many doctors are what

Page 183

are described as independent contractors. That is, they will contract what services they will deliver, but they deliver them in accordance with their ethical and legal duties as doctors. Servants are represented by nurses. Nurses are told what to do and how to do it. Doctors agree what they will do, but they do it as doctors, as the qualified physicians and medical scientists they are, governed by their code of ethics. And if hospitals delegate functions to doctors who are not servants, it's not obvious that hospitals will bear vicarious liability, or for that matter, health authorities will bear vicarious liability for the negligent errors and other legal wrongs, breach of fiduciary duty, for example. But the Courts will recognize some categories of non-delegable duties and in those circumstances, even if the person discharging that duty is an independent contractor, so the ordinary rules of vicarious liability won't arise, the Courts may say that this is an area of direct liability because the function is not delegable. Now again, whether the Courts will say that is a legal

Page 184

issue.

To come to ethics. Ethics sometimes coincide with law. The concept of fiduciary duty comes not from the historic or customary law of the Anglosaxon community. It is a product of equity; a product of the course of conscience, and individual conscience is often guided by ethical considerations. So many duties, fiduciary duties, ethical duties could coincide or could show a coincidence of ethics and law. But ethics often requires more than law. The law will sometimes say what must be done and the other side of that, of course, is what must not be done, but frequently, the law is simply empowering. The law says that things may be done, but don't necessarily have to be done, and whether one uses one's legal powers or not is an ethical choice.

We've had a number of instances, the case involving a woman who was sterilized without her consent in Alberta, under legislation, the Meil (phonetic) case, was a good example of the Government of Alberta recognizing liability, not defending on the merits, conceding that what was done was wrong, even

Page 185

at the time it was done, and simply dealing with what compensation to award. And the Court said that although the wrong conceded by government was compensable, they were not going to award punitive damages because the government had done the decent thing. The Court said that government had a watertight defence under the Limitation Act. The action was commenced out of time and it would have been certainly within its legal powers of the government to invoke the limitation period saying the action is brought too late, end of case. The Government chose not to do that and that was an honourable, just thing to do. That was an ethical exercise of a legal discretion, the discretion not to use legal powers, and the Court recognized that in saying this is not a case for punitive damages. The government has behaved very decently. It did not invoke a defence to which it had entire legal access, but is undertaking compensation. Whether Alberta taxpayers would see the issue in the same light is a political question.

The major ethical principles tend to be

Page 186

reduced to what's often called the Georgetown mantra. This is a somewhat humourous, not necessarily, denigrating description. It goes back to a report of the U.S. Government on research in medical and biosocial sciences, the so-called Belmont report. Many of the authors came out of the Georgetown University Kennedy Institute of Ethics. So it was called the Georgetown mantra. It has either three or four principles. I'd prefer to identify it as four principles.

The first is respecting people, and the governing principle is the autonomy of individuals. The autonomy principle is so dominant in the United States that many citations, recitations of the Georgetown mantra call the first principle autonomy, but it actually fits within the broader context of respect for persons. That is the autonomy of people capable of exercising autonomy, but also due protection of those who are vulnerable, those who are incapable of exercising their full autonomy, and there are circumstances in which each one of us is vulnerable, in particular, when we're sick and

Page 187

go to doctors and hospitals for care. So this is a principle that has a double aspect, but of course, the precondition for autonomy, the precondition for exercise of one's own choice is that one receive appropriate information and Gerald Robertson touched on that this morning, saying that disclosure of error can fit within this important concept of informed, free and informed consent, and that's a major feature of autonomy.

The second principle is the duty to do good, and in Belmont, that folds within it the third principle, which I prefer to isolate, the principle that historically going back to the Hypocractic environment, was taken as the primary duty, to do no harm. The fancy philosophical language is non-maleficence, in the same way that the duty to do or to maximize good is beneficence. But doing good and avoiding harm are important values and the two don't necessarily coincide.

The fourth principle is the ethical principle to which the law claims to devote itself, the ethical principle of justice. That is to treat like cases alike and this, of

Page 188

course, is the root of the legal preoccupation with precedence and that if cases are like each other, they should be governed in the same way. The other side of that, of course, is to recognize ethically significant differences. That is if treating the like cases differently is unethical, it could be equally unethical to treat different cases as if they're alike, subordinating one to the other.

And the principle that the health agencies are very much concerned with is the duty sometimes described as distributive justice. That is the fair allocation of burdens and benefits. We see this in the research context. One population group should not be exposed to unproven treatment to develop therapies from which different population groups will benefit. That is those who bear the risks, those who bear the burdens, should have equitable ethical entitlement to appropriate benefits.

But we've had developments of the Georgetown mantra into the modern administrative ethic and a lot of this is

Page 189

associated with the writing of Norman Daniels, a philosopher, historically at Tuft's University, recently transferred to Harvard, who emphasizes, and this is relevant to governments, accountability for reasonableness. That is the decision should be made reasonably on the basis of evidence, not just doctrine, not just ideology, but there has to be an empirical basis for policies, to show that they are factually reasonable and they have to be transparent. They have to be adequately explained to those affected by them, which is the broader public in general, and particularly individuals. And the result of this concept of accountability for reasonableness is that although governments are not necessarily at fault for making bad decisions, in good faith, they may pursue policies that seem appropriate that worked disastrously. So there may not be accountability for making bad decisions, there can be accountability for making decisions badly. That is not based on evidence and not adequately communicated.

Tim has stepped forward very ominously

Page 190

and I'd be foolish to disregard that. Let me come to the final issue then that we're very much concerned with, the disclosure of information and of course, this is an issue that was explored, not exhausted, but well explored this morning and that we're going to be very much concerned with for the rest of today and tomorrow.

It's clear that the public has a right to information of error in a general sense. In fact, there is a recently developed Canadian institute, the Canadian Institute for Health Information, that will publicize data of infection rates, of treatment rates, not specifying individual hospitals or health facilities, not identifying individual health care providers, clearly not identifying individual patients, but presently global data for the public at large.

We have to remember though, and this is relevant to the shift that Gerald Robertson touched on this morning of the Courts emphasizing the patient should not simply be given information, but should be given an opportunity to understand it, that not all

Page 191

data will be informative. That is we have sometimes incomprehensible data. We've got findings, but we don't know what they mean. We don't know how they fit into a wider context. And in that sense, simply producing data will not necessarily be informative and much research is promoted, is propelled by the need to understand how particular findings of an individual case or a pattern fit into a wider framework. Simply giving data won't mean anything unless it's put in a broader context. If, for example, you're told that the recording here is calculated, it quantifies at 18, 18 out of 20. 18 out of 20 is low. 18 out of 40 is middling, but to say the finding is 18 doesn't mean anything unless it's put into a wider context. If that wider context hasn't been researched and doesn't exist, the data will not be informative. So what has to be disclosed is information and data will not necessarily constitute information.

Clearly, if patients ask for information, they have a right to be given it truthfully and the Courts have established that. A 1992

Page 192

case of McInarney and MacDonald made it clear that patients have a right, not necessarily to raw data, but to have their medical records interpreted to them by a medium that they have confidence in.

Whether patients have a right to their own information is the issue that we began exploring this morning. If patients are affected by the error, then clearly they have to be informed of it. Again, Gerald Robertson put it primarily in the context of informed consent. If an error requires a patient to have additional treatment or have treatment managed in a particular way, in consequence of the error, then the patient is entitled to know that this has been necessary. This is not indicated or recommended because of errors that were previously made, and that would explain how the subsequent management is being undertaken, in the framework of informed consent.

Whether the patient ought to be disclosed or ought to be informed of near misses, if Dr. Etchells will let me use the expression, is a question of judgment and if I could just take

Page 193

a minute to respond to the invitation of Professor Robertson. If hospitals undertake techniques of risk management or quality assurance to see how safe and effective their therapists have been by retrospective file examinations, they may find that mistakes were made, either negligent or non-negligent, but errors were found, and plaintiffs' lawyers will want evidence of that in litigation. As a matter of policy, the Courts, not invariably, but generally, say that on policy grounds, this information ought not to be admissible because it could have the harmful effect of discouraging agencies from undertaking quality assurance and monitoring the safety and efficacy of their procedures. That is if those that have the integrity and the conscientiousness to check safety and efficacy will have those records used against them, but those who don't bother to check adverse outcomes will not be vulnerable, then this provides a road for disregard of patients legitimate interests.

So Courts generally will say that records of quality assurance, records of inquiries

Page 194

into adverse events will generally not be admissible. But this falls into wider questions of policy and this is subject to legislation. If on grounds of policy, governments decide that there ought to be required disclosures or there ought to be principles of legal admissibility, then they can enact it and the Courts will interpret it.

Good. Thank you for your attention.

MR. CAULFIELD:

Q. Thank you, Bernard. I didn't have the guts to put a "shut up" sign up, so I thought my presence might. But thank you, that was superb and I'm sure there's many, many questions. What I'm going to do is ask people to hold them so we can hear from Joan, so we're sure to have time to have lots of room for discussion.

Now Joan also is a renowned health law expert, an individual that I've had the opportunity to work with many times, and we're actually capturing Joan at a perfect time in her career, because she has just spent I guess a little over a year, right, Joan, doing an analysis of patient safety issues, and she's

Page 195

starting a research release in the fall on the very issues that we're discussing. So we're capturing an expert at an expert moment in her career. So perfect. Over to you, Joan.

PROFESSOR GILMOUR:

Q. Thank you. Now I may be an expert in health law, but I'm not so much an expert in technology. So I need to get out of Bernard's and into mine. And just as I'm getting under way, I want to thank the Commission and Tim Caulfield for the opportunity to think about these issues in more depth and in particular, in a context that I had spent less time on, that being the background of laboratory testing that has given rise to this inquiry, and when we think--my topic today is the duty of care and standard of care and it brings us to think about not just the nature of error more generally, but also what flows from it in law, and how we establish what is owed to people, in terms of the care that they are entitled to and the care that must be taken and also how we establish what the standards are that must be met.

Duty of care and standard of care, though

Page 196

they have larger meanings, arise particularly in connection with negligence law as part of what someone who is suing, a plaintiff, has to prove in order to establish negligence. And although I'm not going to be dwelling on negligence itself as a whole, I did want to just set out what the analytical framework is. So in a negligent suit, the plaintiff has to prove, on a balance of probabilities, that the defendant, so the person being sued: owed the plaintiff a legal duty of care; the defendant breached the standard of care that is required by law; the defendant's breach caused the plaintiff injury or loss, so damages; and that the plaintiff's damages are not too remote as a matter of law to be recoverable. And then the burden of proof is on the defendant to establish any defences, for instance, compliance with approved practice or that it's too late to start a law suit.

In terms of duty of care, the doctor-patient relationship is really a long established, well recognized category in law in which a duty of care is owed, and so generally, the existence of a duty of care is

Page 197

not a question at all. The scope of that duty of care, what in fact is included within it, may give rise to more contention. And the duty of care will extend beyond acting in ways that will avoid harming patients to include a requirement that health care providers take affirmative steps to protect their patients as well.

When we refer to standard of care, standard of care that is required of health professionals is an obligation to take reasonable care to avoid a risk of foreseeable injury to patients, and in determining the standard of care that is to be met, they are held to the standard of a reasonably competent member of their profession. So a physician would be held to the standard of a reasonably competent physician. If someone is a specialist, they would be expected to have a higher level of care, higher standard of care.

A laboratory technologist would be held to the standard of a reasonably competent member of that profession. So it applies to other types of professions as well.

One thing to remember about the standard

Page 198

of care, and Bernard Dickens was commenting on this as well, is that the standard expected is not a standard of perfection. So it's not a guarantee of the patient's safety.

When we think about how we establish whether or not the standard of care has been breached, generally in order to assess the standard that's required, you're going to need expert evidence. So expert evidence that the practitioner did or didn't comply with generally approved practice in questions of treatment and care, and if it is a situation where the common practice is divided, where there's a difference of opinion in terms of what might be appropriate care and what would be inappropriate care, it would not constitute negligence if the practitioner had followed a body of thought that was accepted by a reasonable and competent sector of the profession, even if that is a minority sector.

However, our Courts have held that if the standard of care is, as it's termed, fraught with obvious risks, such that anyone is capable of finding it negligent without the need for clinical or diagnostic expertise,

Page 199

then a Court can find an approved practice and the defendant who followed it to be negligent, and there's a case from Manitoba that gives us an example of that. It arose in the context of laboratory testing and in that case, a physician and a hospital were held liable when they failed to ensure that proper systems were in place to follow up on abdominal test results, and that had decreased the patients chances of survival, that would have followed on an early diagnosis. That was a case in which the Manitoba Court of Appeal noted that this failure to provide for a reasonably effective follow-up system on the part of the physician and on the part of the hospital that had no system to make sure the test results ever got to the doctor who ordered them was an obvious and reasonable precaution that was readily apparent to the ordinary finder of fact.

Now it's important to remember, and as Bernard Dickens had pointed out, that an error in judgment is not necessarily going to equate with negligence, nor will it give rise to liability. And that's the case, unless the

Page 200

error is such that a reasonable health care provider would not have made it in similar circumstances, and so what that means is that sometimes it can be difficult to distinguish between what would simply constitute an error in judgment, which does not amount to negligence, and what has gone beyond that and actually constitutes negligence.

When assessing the care that has been provided, the assessment is conducted effectively trying to take one's self back to the point at which these events, acts or omissions occurred. So the timing of the assessment is--and the standard by which the practitioners are to be judged, is the standard that applied at the time that these acts or omissions occurred. The advances in medicine are rapid and there are lots of them and not thought to be fair or appropriate to be judging what has occurred sometimes years in the past by what we now know.

Now with respect to the duty of care that is owed by physicians, when we think about what that includes, commonly and I take this actually from Gerald Robertson's book that he

Page 201

has co-authored with Ellen Piccard on the legal liability of doctors and hospitals, the most common components of the doctors' duty of care would be the duty to attend, to diagnose, to refer, to treat, to instruct. That's, however, not an exhaustive list, nor did Gerald mean it to be so, and there are other aspects to the duty of care as well. It's also important to note that physicians and other health care providers can rely on each other to discharge their professional responsibilities in a non-negligent manner. In other words, if we expected health care providers to be always checking up on each other, the health care system itself wouldn't be able to carry on for very long. That said, there will be circumstances that arise that perhaps should have twigged a health care practitioner to the fact that there is something potentially wrong here, and in those instances, it may be, and it would be dependent on the facts, that the health care provider should have been alert to that possibility.

Let me see where I am here. In terms of

Page 202

the duty of disclosure that both Gerald Robertson and Bernard Dickens have spoken of, I would agree that this is an aspect of the duty of care that is owed by the health professional, certainly when a patient has been caused harm or there is a potential that the patient will suffer harm from the care that has been provided or that has not been provided, and I'd agree that the basis for that duty are several. One would be the duty of obtaining informed consent. Another would be fiduciary duty that is owed to the patient, that kind of duty of loyalty that brings with it a duty of candour, and also the duty to disclose risks and to warn the patient of risks that may be ongoing.

Now Gerald Robertson, having spent considerable time on that this morning and that being the subject of his paper, I'm not going to dwell more on it at this point, though I'm happy to take questions.

Turning to the issue of laboratory testing and the standard of care. One thing to bear in mind is that the standard of care to which laboratories would be held will be

Page 203

affected by the nature of lab testing and also limits on its reliability. So there are some types of laboratory testing that will involve an inherent element of subjectivity, so that staff interpreting those results may legitimately differ in their conclusions. So that may mean that then there is an error rate that occurs in the testing and it may not indeed involve negligence.

However, where the error rates in a particular laboratory are considerably in excess of what might be anticipated in the normal course, with proper procedures in place, that could be indicative of substandard practices.

In New Zealand, several years ago now, there was a committee of inquiry appointed to look into instances in which screening of PAP smears that women had undergone was conducted because a particular laboratory had missed diagnoses of cancer that should have been apparent on the slides that were examined, and the committee of inquiry in that case identified a number of both errors on the part of the individual laboratory and systemic

Page 204

errors in the system that had contributed to the errors occurring.

And in terms of how the analysis is conducted, the analysis of whether or not there is a breach of the standard of care, I referred here to an English case, Penney and East Kent. That also involved a case where the screening for cervical cancer had missed cases in which women had cancer and they sued the health authority, and the English Court of Appeal examining this case, in talking about how you decide whether or not there was a breach of the standard of care, said that there really were three questions that had to be answered.

The first would be what did the slides show. The second, at the relevant time could the screener, exercising reasonable care, because remember that is the standard of care to which one is held, fail to see what was on the slides. And third, could a reasonably competent screener, aware of what a reasonably careful screener would see on the slide, treat this slide as negative. So those were the three questions that in that case the Court

Page 205

considered to be the ones that had to be determined in order to decide whether or not there was a breach of the standard of care, and as I'd indicated, the first of those questions certainly involved a question of fact, but the second two involved questions of fact and opinion, some of those being obviously matters on which expert opinion was needed.

In the end result, the Court concluded that there was negligence in that case because the abnormalities that were apparent on the slide should have been seen by a reasonably competent screener at the time.

Turning to the duty of care and standard of care expected of hospitals and health authorities, they are determined essentially in the same way that it would be with respect to an individual and in terms of assessing the direct liability, and that's liability for their own deficiencies of a hospital or a health authority, plaintiffs essentially have to prove all of the elements of a negligence action.

The responsibilities of a hospital or

Page 206

health authority, and I'm just using those terms interchangeably because it would depend on what responsibilities have been assigned to them and what responsibilities they have assumed to patients, but the responsibilities certainly will include selecting competent staff and monitoring their competence, and also establishing the systems that would be necessary for the safe operation of the hospital, and that is a duty that has been interpreted increasingly expansively over time, but that obligation to ensure safe systems within a hospital may encompass everything from proper maintenance of equipment to making sure that nurses have been scheduled such that they can still get a coffee or a lunch break without leaving patients in unsafe situations. And so, an example of that would again be the Manitoba case that I referred to earlier, Braun Estate and Vaughn, in which one of the reasons that the hospital was held liable was because it didn't have any system in place to make sure that test results were actually going to get to a physician who had ordered them.

Page 207

Now Bernard Dickens has already spoken about vicarious liability and non-delegable duties of care, and so I just want to touch on those areas very briefly. As he indicated, hospitals can be held vicariously liable and vicarious liability doesn't depend on any deficiencies on the part of the hospital or health authority itself. What vicarious liability flows from is the relationship between that entity for whom it is responsible and someone who was deficient in their care. Most commonly, it would be in the case of an employer and an employee. So that the employer would be vicariously liable for the substandard care that an employee provided that in fact injured a patient.

Generally, vicarious liability is not imposed on the principal, as between a principal and an independent contractor, as opposed to an employee, and most often doctors who are not employees are considered to be independent contractors to whom the hospital has granted privileges, and so there certainly are cases, probably the longest standing authority would be one called Yepremian and

Page 208

Scarborough General Hospital where hospitals have been held not liable for the negligence of non-employed physicians.

The characterization of the relationship will depend on all of the circumstances, and I think it's fair to say that recent developments in judicial analysis of the vicarious liability may support an expansion of hospital and other health care organizations liability to include responsibility for the negligence of non-employed physicians. But, as I say, from existing juris prudence that would, at this point, amount to an expansion of what is commonly understood.

Now Bernard Dickens had also commented on non-delegable duties of care, and so those would be instances in which defendants have been held liable on the basis that the nature of the defendant's relationship with the plaintiff means that the duty of care the defendant was under was non-delegable. It couldn't be delegated to somebody else. The duty on the defendant is to ensure that care was taken. There are some non-delegable

Page 209

duties of care that are quite well recognized in the area of health care. However, non-delegable duties of care have also been undergoing an expansion in other areas of the law and they too are an area where there may be some expansion of liability for non-delegable duties of care as well.

Now, one of the things that flows from this potential--and I'm speaking in legal terms, as opposed to ethical or practical policy terms, but one of the things that may flow from an expansion of hospital liability is that in many ways it can accord more with how care is actually delivered in a hospital. And we've heard this morning, both from the speakers and some of the questions that were put, that care is much more delivered in a team environment and it may not be really possible to evaluate someone's actions or omissions without looking at the environment and the people with whom they were practising and what they did or didn't do and what constraints the environment imposed on them as well. So in that sense, expanding liability in that way to include the organization makes

Page 210

some sense, and I think it would also respond to advances in our understanding of how errors and adverse events in health care occur, and we have heard already how frequent errors are and how frequent the adverse events that result are, and we have also heard from this morning's speakers about the importance of moving away from at least a sole focus on personal responsibility for health care providers because, in many cases, in fact in most cases, it may well be the institutional systems within which health care providers operate that cause the harm. So we've already heard speakers talk about the importance of broadening the focus from the sharp end, where you've got the people who actually deliver the care, to the blunt end, where you've got regulators, policy makers, funders, technology suppliers, people who determine what the number of workers will be on a particular shift, people who determine things like is the work force casualized and this person hasn't been on this service for a long period of time. And I think that those are all important initiatives.

Page 211

So we ask ourselves then, well, can the law accommodate that? Certainly the traditional focus on the law has tended to be on personal responsibility of those who are involved, but I think it certainly can. Our courts have long recognized that most things don't have just one cause, that there are many causes that will contribute to harm occurring. So it certainly seems to me then that existing legal analysis could take into account the importance of systemic factors and systemic causes. That said, it often doesn't because the focus tends to be on who precisely was involved in what had gone wrong in the system. But it could do so. It does, I think, require though an openness to and an awareness of the important role that systemic factors play.

Then finally, looking forward, yes, legal analysis can accommodate an acceptance of the role played by multiple causes and that may more accurately reflect what the causes of the injury were. But I think it's also important that we make sure, through whatever processes, and they're certainly not limited to law suits as the very fact of this Commission of Inquiry

Page 212

points out, we need to ensure that there is both accountability in the system and accountability for making the system better as it moves forward. That accountability then is, in important ways, systemic as well as it is individual and as some of the earlier speakers were saying, if we don't pay attention to that, well, you may fix what went wrong with this patient and that physician, but you won't have made things better for the future and you don't want to end up with the same things going wrong again.

Thank you.

MR. CAULFIELD:

Q. Okay. Wonderful. So we've had two very legal discussions. You're now all experts on the relevant law. Questions to start, I certainly have some I would like to put forward. I see one right away.

MR. PETER BROWNE:

Q. I'm interested in the panel's analysis on quality assurance protections vis-a-vis individual patients' incidents versus systemic incidents, and I see a big distinction there in some of the comments and wondering whether

Page 213

you see a distinction there as well.
PROFESSOR GILMOUR:
Q. Can I just ask if by quality assurance protections you mean protection from disclosure to either -
MR. PETER BROWNE:
Q. Yes
PROFESSOR GILMOUR:
Q. - the patient or the--so that type of privilege.
MR. PETER BROWNE:
Q. Peer review protection type of thing.
PROFESSOR GILMOUR:
Q. I have a bit of a mixed response on this, and I did do an extensive patient safety study for Health Canada and it was an international study, so in addition to Canada, looked at the United States and Australia and England and New Zealand, where they have a no-fault system, and what became very apparent to me was that even in jurisdictions where there was legislated protection from disclosure, there was a great deal of non-disclosure. So in other words, if you are protecting from disclosure, the idea of that is to get more

Page 214

information out. As we've heard this morning, it's important to surface the information so that you know what you're trying to fix. So the problem was that even with the legislated protection, there wasn't a whole lot more disclosure and that may be particularly because the American environment is especially worried about litigation. But it wasn't a sure thing that if you had this kind of protection from disclosure that the disclosures would increase.

That said, I do think that it is really important to get more disclosure. I think that it is absolutely crucial to get this information so that you know what to fix, and so in that sense, there's a balancing. And so in the report that I did, one of the things that I recommended is that if you're going to have legislation that expands this qualified privilege as we become aware of the need to share among institutions and so on, that perhaps we should include an incentive for disclosure in it. So that perhaps we could include something like a sunset clause, use it or lose it. If we aren't getting disclosure

Page 215

here, then maybe this isn't a privilege that we should continue because when you keep relevant information from being disclosed, that also has costs, right, and I don't mean financial costs. It has costs in terms of we don't get at things that we're used to getting at in a law suit. We don't get at other information available to the public and so on. So I'm not against that kind of legislation, but I think that we need to establish that it's working or increase the incentive so that it works.
MR. CAULFIELD:
Q. Interesting. Bernard?
PROFESSOR DICKENS:
Q. To approach it initially from the ethical perspective, quality assurance perhaps an aspect of risk management, clearly fits the goal of beneficence. It is a good thing to learn from errors. The United States Institute of Medicine's report on errors was titled Learning From Errors. That requires that they be disclosed to those who can learn from them. That is individual physicians ought to be encouraged to disclose among

Page 216

colleagues the errors that have occurred, negligent or non-negligent, so that one could learn from them, and minimize, if not entirely avoid their repetition. And of course, that fits into the related ethical principle of non-maleficence, that is reducing the incident of repetition of errors.

Equally, there has to be disclosure to the hospital administration. There had to be disclosure, on occasion, to licensing authorities to see whether individuals are in need of retraining. So clearly the duty to maintain, conscientiously and effectively, a system of quality assurance, quality securing is within an ethical framework. One could go beyond saying this is ethically justified to say that it's ethically required.

The question of legal admissibility fits into the policy framework that I've mentioned, that if those who undertake identification of errors, including negligent errors, are going to make themselves legally liable to pay compensation and those agencies that don't undertake this don't provide that evidence against themselves, then there's a negative

Page 217

incentive, an incentive not to follow up.

At the level of clinical care, in the doctor-patient relationship, although we have clear demonstration of the legal requirement of adequate disclosure to achieve informed consent, there is a narrow margin of so-called therapeutic privilege that is the duty--not the duty, the power that the physician has not to disclose information that would be counter-therapeutic and the incentive of the courts, for obvious reasons, is to keep a so-called therapeutic privilege of non-disclosure in a very narrow range because of the risk, as the courts have said, that this so-called privilege could overwhelm the duty of disclosure and destroy it.

In the context of disclosure to individual patients of errors from which they were not harmed, we get back into exploring the discussion that we launched this morning of whether it would make patients anxious and worried to know that there was a near miss, whether there was a failure of the system. And of course, if one actually has systems to check errors so that the pharmacist gets back

Page 218

to the doctor and says "I'm not clear from this prescription whether you're prescribing 2.5 milligrams or 25 milligrams," and the doctor said "2.5" and the pharmacist said "but the document here could be understood as 25," then that is a check that has worked effectively. That is the system has worked.

Is it beneficial to tell the patient, "gee, there could have been an error that we avoided." Is that reassuring? Does the passenger--just to go back to the airplane analogy, getting on the plane or close to schedule, landing safely on schedule and going about his or her business, need to be told that as you were coming in to land there was another plane within a prohibited distance of your plane, and there could have been a disastrous collision, but there wasn't, so you're fine. Do you really want to know that? And if one doesn't need to know, as one walks out of the airport that you could have been carried out in a coffin, is this something that the public at large is entitled to know?

Now I think one could make a case for the latter. That is, and again this is consistent

Page 219

with the Canadian Institute for Health Administration, publicizing data. One knows that there will be errors, negligent and non-negligent, in the system. One shouldn't suppose that there is a record of perfection. One shouldn't anticipate perfection. This is part of education of the public at large that mistakes occur. Bad stuff happens, and that's simply a reality check, and this is something that I think there's a legitimate case to present to the public in quantified terms, if need be, that one in thirteen patients going into hospital is at risk of suffering or will suffer an adverse event. Whether individual patients ought to be told is an area, I think, of more clinical judgment. That is if it makes patients anxious about any repeat treatment, then it well could be that this is a dysfunction and this was something that was touched on this morning.

In the context of informed consent, and this is a very narrow instance, if a surgeon made a mistake and the surgery has to be repeated, then the patient may have an interest in not having the surgery undertaken

Page 220

by that same surgeon who made the mistake. That itself could be an error.

If I could just comment on experience in the United Kingdom, the idea of publicizing hospital mortality rates and mortality rates, adverse events specific to individual surgeons, this has been recommended. But it risks the dysfunction that the really difficult cases will be sent to the major hospital through referral hospitals and they will have the deaths rather than the local community hospital that doesn't want to take the chance. There is evidence, and this is something that perhaps Peter Norton could comment on, that the hospitals with the least impressive looking mortality rate and adverse incident rate will in fact be the better hospitals. But this is a question that could be resolved by some evidence.

DR. ETCHELLS:

Q. Perhaps I could speak to that (inaudible).

MR. CAULFIELD:

Q. Sure.

DR. ETCHELLS:

Q. There is no relationship between hospital

Page 221

mortality rates and quality of care in the literature right now. So it's not a good (inaudible) cardiac surgery.

MR. CAULFIELD:

Q. Does everyone hear that? Turn around and say it loudly.

DR. ETCHELLS:

Q. There's no relationship between hospital mortality rates and quality of care.

MR. CAULFIELD:

Q. No relationship between mortality rates and quality of care.

DR. ETCHELLS:

Q. That doesn't mean mortality is not important.

MR. CAULFIELD:

Q. Mortality is important.

MR. ROB RITTER:

Q. I have two related questions. First of all, in the work that you're doing, Dr. Gilmour, are there issues in terms of defining an employee-employer relationship or is there a standard definition that can be used in the work that you're doing? The second piece of my comment, then question, is in cases where we're talking about non-employed or non-

Page 222

salaried physicians, people who have privileges with an institution, in the context of the privilege, is there not some kind of implicit contractual or an inherent contractual element that the institution that's granting the privileges for that physician to do their work, whether it's in a laboratory or in an operating room, is being provided with, you know, high quality equipment, adequate support staff, adequate professional staff and so on? Is that not part of an implicit contractual arrangement that in a way might preclude the need to have an employee-employer relationship in order for the vicarious liability to remain with the institution, as opposed to the professional? Is that confusing or does that make -

PROFESSOR GILMOUR:

Q. Okay. If I'm not clear in my answer on the second one, in particular, we'll see if we can work this forward.

In terms of whether or not there's a standard definition of who is and who isn't an employee, usually there is and usually it's quite clear whether somebody is an employee.

Page 223

Nurses, for instance, are generally employees of hospitals. There have been cases where the status has been a little more questionable. For instance, an intern or resident who may be considered both an ongoing student of the university and a hospital employee and so on. And there have been enough cases in which, for the most part, someone like an intern or resident has been held to be an employee and therefore the institution is vicariously liable for their negligence and there have been also other types of physicians, like some anaesthetists, not all anaesthetists, who have been held to be in an employment relationship. So you need to look at the particular relationship between whoever it is you're considering.

When it comes to the question of privileges, and it used to be that it was just doctors who got privileges and then dentists for some sorts of things, and now midwives in some provinces and so on. We can expect, I think, that that will continue to expand as the recognized health professions and their relationships with hospitals continue to

Page 224

expand.

You were talking first in terms of is there a contract relationship. This is not consistent across all provinces, but in most-- in a number of provinces, that relationship of the hospital grants privileges to the practitioner actually isn't considered to be one of contract. So it's an odd duck in the law. There are some jurisdictions where it is, and so you need to look at a particular jurisdiction. But in terms of what's required in the relationship of well, doesn't that mean the practitioner will get high quality equipment and all, certainly the hospital has its own responsibilities and as I said when I was speaking, part of its responsibility, much more towards the patient, is to make sure that safe systems are in place for the patient, as well as selecting competent staff and monitoring their competence. Part of ensuring safe systems are in place is to ensure that the facilities are appropriate for the care that is being provided and that is much more of an obligation that flows to the patients who are being treated.

Page 225

That said, we recognize that there are financial realities and that the whole health care system is working under those straightened financial circumstances that will sometimes mean the reality of the care that's being provided isn't the very best one could think of, because of that reality.

CROSBIE, Q.C.:

Q. Professor Gilmour, Ches Crosbie. I'm one of the legal counsel involved in the Inquiry. Two questions which may possibly be related to each other. First is, and it may be just that I missed what you said or I didn't read your paper carefully enough. Have we arrived at the point in Canadian law where there is a positive or affirmative duty now imposed on hospitals to promote safety? And I guess the second question would be, to the extent that it's in the public interest to promote the focus for safety promotion purposes to be on systems, would it be a good thing to shift the focus when litigating liability from individuals, for example, doctors, onto the enterprise, namely the hospital, which I think is more the case in the United Kingdom?

Page 226

MR. CAULFIELD:

Q. Actually, that was my question too I was going to pose to you.

PROFESSOR GILMOUR:

Q. Okay, just a second. Okay. First, is there an affirmative duty or a positive duty on hospitals to promote safety, and I don't mean to dance away from the question, but that's a very big term, promote safety, and so I think you'd need to give some content to that. What hospitals do, I think, have a duty to their patients to do is to provide safe systems and to then take steps within the hospital to make sure that those systems are safe, and I think that that is a duty that has not been worked out in detail yet, in terms of what in particular circumstances that's going to require of a hospital. So my answer is somewhat narrower than promoting safety to providing systems that are safe.

Your second question, I think, is should we shift focus from individual liability to some form of enterprise liability. There's a couple of ways that can be done, so I was certainly talking about the importance of

Page 227

moving from recognizing that an individual may be at fault to also paying attention to systemic factors that have contributed to the result, and I think that of the ways that could be achieved, one is to say we're only going to focus on the enterprise, and in fact, the enterprise is liable for everybody who's working there, whether they're there as an employee or with privileges or whatever else, and we're just looking at the enterprise.

Another way to do it is to maintain both a focus on an individual and on the enterprise. If you think about someone who is recognized now as a employee, like a nurse, right, a nurse working in a hospital might be sued for negligence, but the hospital would be maybe sued as well and it may be sued for not providing safe systems in which she worked. It may be sued as being vicariously liable for that nurse's negligence. So it doesn't seem to me that those two are mutually exclusive. In other words, you could have a system in which you are looking at individual liability as well looking at the systemic factors that the organization could be held liable for. So

Page 228

both.

PROFESSOR DICKENS:

Q. The last two questions weren't directed to me and I'm not claiming to answer them, but they do raise some interesting features in the context of looking forward. One is moving doctors from a fee-for-service to a salary basis. Some hospitals, I know, have done that. Health ministers like it because fee-for-service is very open-ended. That is if instead of a doctor saying you should come back following today's treatment in six months and twelve months, if a doctor says come back in four months, eight months and twelve months, then on a fee-for-service basis, the doctor's income has increased 50 percent from treating that patient. So health ministers like salaried doctors because they know in advance what doctors are going to cost them.

One legal effect of this is that if doctors are not being paid on a fee-for-service basis, there's no contractual relationship between them and the patient. You're still a contractor even if the fees are not freely negotiated, and even if the payment

Page 229

isn't coming from the patient, it's still a contractual relationship. If doctors are paid on a salaried basis, then the contractual underpinning of the doctor-patient relationship is gone, and perhaps one consequence of that is the courts elaborating the fiduciary duty that binds the doctor to the patient when there's no contractual duty.

It also means, of course, that hospitals, if found vicariously liable, will want an indemnity from the doctor, and even if the doctor isn't sued by the patient, the hospital may sue the doctor through third party proceedings or independently. One consequence of this is that some hospitals, again within my experience, will contribute towards doctors' membership for the Canadian Medical Protective Association so that if the hospital is liable for what the doctor has done, the hospital can then claim against the doctor with some likelihood of there being funds to meet the perhaps high damages. If one takes mismanagement in neonatal care, child may live as an adult three score years and ten, but require 24-hour-a-day nursing and this could

Page 230

run into tens of millions of dollars. So hospitals will require members of their medical staff to be members of the Canadian Medical Protective Association or a comparable professional self-defence organization and may contribute towards their membership fees.

The other issue beyond encouraging doctors to move, requiring doctors to move to a salary basis is the recommendation of the Krever Commission, dealing with contaminated blood supply, where Krever recommended a shift to no-fault liability. If it happens, there's compensation. Not for vast amounts of pain and suffering, the difficult to quantify claims, but claims for prompt recovery and full recovery of expenses actually incurred. This built on the recommendations of an earlier commission set up by the federal, provincial and territorial governments, the--what would I call it, the Prichard report, recommending that an option of no-fault liability. That is if it happens, then you're covered for costs actually incurred, again modest payment for pain and suffering, but out-of-pocket expenses fully and promptly

Page 231

reimbursed, and Prichard recommended that those who claim injury can either opt for prompt full payment of expenses incurred or they can invest in what Prichard called the forensic lottery. That is you can sue with the chances of losing and being liable for your own costs and the other side, or you may be awarded some monumental sum, including aggravated and punitive damages going beyond the injuries actually incurred.

Krever recommended the option--I beg your pardon, Krever recommended against the option saying there ought to be mandatory no-fault coverage for medical mal-occurrences and that would mean that having to prove fault, having to prove negligent error or other wrong would be no more part of the system.

There is some experience of this in New Zealand that others here may comment on. I'm not certain the New Zealand experience adds any special encouragement to the recommendation of moving to no-fault insurance because that hasn't reduced litigation in New Zealand. In New Zealand, one now litigates about whether the injury occurred within the

Page 232

no-fault compensation scheme or outside it. So there's still work for lawyers in this, but this is something that perhaps one might think as part of a broader frame of reference.

MR. CAULFIELD:

Q. Lawyers always seem to be able to find work.

MS. JENNIFER NEWBURY:

Q. Thank you. Professor Dickens, I believe you surmised in your paper that a decision to cease to monitor quality of a program could be construed either as a policy decision or an operational decision, based upon perhaps the circumstances or the advocacy. If a decision were made to downsize or cease to monitor quality of a program, would you see that there's a duty to notify: A. the patient who's availing of those services; or B. the public at large? And I'm thinking that a patient might choose, in light of that information, to perhaps travel to a larger centre or to seek a second opinion, and the public might want to perhaps lobby government for more money for the services. And a third aspect of that question, would there also be any sort of obligation, in light of the fact that it's a

Page 233

policy decision, to explore other alternatives, any checks and balances to make up for the fact that, for whatever reason, the particular type of monitoring couldn't be afforded by the institution?

PROFESSOR DICKENS:

Q. Yes, clearly one wants some follow-up information of decisions, both of policy and of the implementation of policy. Whether governments will accept evidence that their policies were misguided is a much wider question, but clearly this is a matter of legitimate public and political interest.

If there are failures at the level of operation, again, I think this is something that is properly within the realm of public disclosure. This is something that ought to be communicated and it ought also to come from agencies with sufficient independence of the operators to be credible. We know that when agencies are disclosing information that could implicate their own fault, they could put a favourable spin or emphasis on it. Whether this is something that feeds into litigation, I think will turn on the merits of individual

Page 234

cases. But in principle, I think there ought to be, as Norman Daniels puts it, there ought to be transparency in decision making and transparency in follow up data.

MS. NEWBURY:

Q. Thank you.

MR. CAULFIELD:

Q. Thank you very much. Now remember everyone that we have an hour and a half at the end of tomorrow, the morning session, to tackle any questions. So if you do have questions that haven't been answered and you want to make sure that they get on the table, please write them down and make sure that you get a chance to air them tomorrow.

So now we're going to have a break, but before we break, I'd again like to thank our panel members. So let's try to start back on time at as close to quarter past as we can. Thank you.

(BREAK)

MR. CAULFIELD:

Q. (Mic not turned on).

DR. GALLAGHER:

Q. Can everybody hear okay? It really is a

Page 235

pleasure to be here today and I think we're really at an exciting time when it comes to the issue of disclosure of unanticipated outcomes and harmful errors to patients. I think there's a strong awareness that there's a gap between the expectations for disclosure that you've been hearing about and the actual clinical practice, and I think that gap is somewhat surprising to people. There are some folks who look at the issue of disclosure and they think, well, what can be so hard about that? All you need to do is go tell the patient the truth. Right, but I think the clinicians in the audience know that disclosure is much more complex than that and at the same time, the implication is well, the way to improve disclosure is sort of through exhortation. We remind health care workers that disclosure is sort of an ethical mandate and the implication is well, you should just sort of pull yourself up by your boot straps, kind of screw up your moral courage and go in and do the right thing. I think there's a lot more to disclosure than that, and there are a lot of exciting programs internationally that

Page 236

get at what I think is the real gap, which is the challenge of turning the general principles of disclosure into actual practice.

We're seeing accelerating interest in disclosure in a variety of settings. There's growing experimentation with different approaches to disclosure at the level of different countries. Different health care organizations are trying difference approaches. Even different malpractice insurers are coming up with disclosure programs. There are new standards, that I'll touch on briefly, in this area that are trying to help bridge this gap between principle and practice. You've heard some about some state laws on disclosure and apology that I'll mention very briefly. Plus this all sort of fits in with a growing emphasis on transparency in health care generally, and I was interested to see that the issue of medical errors had made it to Reader's Digest, although truth be told, I was curious to know first why is it that sex only gets better, but we're still a little bit distracted and wanted to know who are those daredevil stunt sisters.

Page 237

But I collected myself and got back to the main article, Fatal Hospital Mistakes and How to Avoid Them. Turns out this was about nosocomial wound infections, many of which are not due to errors, but again dramatizes how this has hit the public's consciousness.

As I mentioned, not only are people increasingly interested in disclosure, we're increasingly aware that there's a disclosure performance gap. Harmful errors are frequently not disclosed. The best estimates that we've seen in the literature are roughly a third of harmful errors are disclosed to patients, and when disclosure does take place, we know that it frequently falls short of meeting patient expectations for what these conversations are to be like. Part of the problem is that there's really relatively little prospective evidence about what specific disclosure strategies are effective, and for the clinicians in the trenches, this makes it really difficult to know. So how do we turn this general theory of disclosure into specific words that I'm going to say to this patient.

Page 238

In addition, there's very little evidence about the impact of disclosure on outcomes, and the debate continues to rage about the impact of disclosure on litigation. As you've heard, there's some suggestive evidence that there might be a positive effect, but I think it's a little bit more complex story than that and that uncertainty, I think, really makes it hard for health care workers and organizations to know what to do, and this leads to disclosure strategies that you might describe as counterproductive. Here's a doctor who's taking the musical approach. He's got his guitar coming out of the operating room and sings "Listen up my fine people and I'll sing you a song about a brave neurosurgeon who done something wrong." Well, this is one approach that you could take. Hopefully we can think of more productive approaches to disclosure, and what I wanted to do is talk about how disclosure is rolling out internationally.

We're going to start with the United States, in part because that's the environment I'm most familiar with, but also because, as you've heard, the malpractice climate in the United States is particularly onerous and I think programs that might work in the United States have an even better chance of working in environments where the litigation climate might not be quite so problematic.

Page 239

I'm going to talk a little bit about one particular standard, one adopted by the National Quality Forum, just to give you a flavour for what some of these policies are looking like.

We'll talk very quickly about a very interesting development that takes disclosure and tries to move it forward to include not just the disclosure conversation, but disclosure and compensation, to integrate the response to the error and move beyond the disclosure process itself.

And we'll talk a little bit about state apology and disclosure laws, and then we'll move very quickly through what the apology and disclosure programs are looking like in a few other key countries, including Australia, talk very quickly about the UK, a little bit about Canada, although I'll leave that mostly to Sherry Espin who will be talking tomorrow.

Page 240

Hint very quickly at New Zealand, and then think about where we're going next.

So first, U.S. disclosure policies. Well, as you've heard, the expectation for disclosure has been a part of professional norms for a long time in many countries and the U.S. included. It wasn't until the Joint Commission, which is the organization in the U.S. that accredits hospitals and health care organizations, adopted a policy in 2001 on disclosure that the formal policy ball really got rolling, and this was a very minimalistic standard. The Joint Commission standard just said hospitals are to inform patients about all outcomes of care, including unanticipated outcomes, period. That was the extent of the standard. Didn't specify who, what, where, when, why, how, right, but this was important because it was the first attempt to articulate a policy and it had some teeth, because it was tied to hospitals accreditation status. And in response, the vast majority of hospitals and health care organizations have adopted some sort of disclosure policy in the U.S. Those policies range very widely. Some of

Page 241

them just restate the Joint Commission standard. Others outline a very elaborate disclosure policy.

The next important development in the U.S. was in 2006 when the Harvard Working Group on Disclosure released their report that was entitled "When Things Go Wrong." This was particularly important for a couple of reasons. One was that it really pushed forward the importance of accepting responsibility and apology in the disclosure process. Now the Joint Commission standard doesn't say anything about talking about preventability, error, apology, much less accepting responsibility. So the Harvard Working Group statement was really the first organization to come right out and talk about a broader process of disclosure.

This was followed up in 2007 by the National Quality Forum which adopted a new safe practice on disclosure. I was involved in the adoption of this, and let me tell you a little bit more about it, because I think it's a very interesting model where things what might be headed.

Page 242

What are the NQF safe practices? Well, they're basically a set of thirty consensus based standards for safe health care that were adopted and harmonized across a variety of organizations in the U.S. that are involved in health care. Disclosure was one of two new safe practices that came out in 2007. The other was discharge management.

The final report where this was issued was in March of 2007. They're in the midst of rewriting the standards and a new set will be out or a revised set of safe practices probably sometime this summer.

What's so interesting about the NQF safe practices is that they're used in pay-for-performance programs through the Leapfrog group and they're used in public reporting efforts, and so hospital-specific scores for these safe practices are available on the web. So if you go to the internet right now and put in my home zip code, Seattle, up pop four hospitals within ten miles of that and you see a variety of scores on CPOE, do they have an intensivist in the ICU, etcetera. So for example, if you look at University of

Page 243

Washington, we get a quarter of a circle for CPOE. I'm not quite sure how we got a quarter of a circle. I think you get a quarter of a circle if you think that CPOE is a good idea, but we haven't done anything more than that. Somehow we merited a quarter circle. But the interesting part is when you get to the safe practice score column, if you click on that button, you actually get a list of all 30 safe practices for an individual hospital. You can go down here and see patients notified of problems in care delivery. So this is University of Washington Medical Centre. You can see we've got a long ways to go. Out of the 25 possible points, we got about a quarter of those.

Now so if you're a consumer and are interested in these things, for any hospital that participates in the Leapfrog process, you can pull up these safe practice scores for all 30 safe practices and actually compare them across hospitals. Is this going to drive consumer behaviours? Are consumers going to look at this and think "wow, University of Washington, not doing so well on disclosure.

Page 244

I don't know if I want to go there?" Hard to tell. But it is an important internal motivator of prompting change.

So what's in the safe practice? Well, it emphasizes transparency as a core value, where the risk management implications of disclosure are important but they're secondary. The other important parts of the safe practice is it links disclosure with performance improvement. This is really important and it goes in both directions. So the safe practice envisions disclosure as feeding the performance improvement process. You've heard about partnerships with patients. The disclosure process can generate information about the event. You can then feed into the performance improvement process. I'm especially interested in the opposite direction, which is using performance improvement tools to actually enhance disclosure. We know that there's a gap between practice and policy in disclosure and in no other area of the hospital would we see this performance gap and not try to start measuring how is this practice going. But at

Page 245

the moment, I would be shocked if any of the hospitals you're affiliated with measure, in real time, how is disclosure going, right. This is what performance improvement really calls for. When a disclosure happens trying to see how did this go from the patient's perspective. How did this go from from the doctor's perspective? And then using that information to drive performance improvement on disclosure.

It talks a lot about the process of disclosure and it details an institutional support system for disclosure. This is important because lots of people, as I hinted at at the beginning, have sort of implied that transparency is something that resides within the individual health care worker, right, and that if you have high moral fibre and are disposed to transparency, you'll be a good discloser. That's not right. Disclosure and transparency are system properties, right, and so hospitals and health care organizations need to put the processes in place to support disclosure and transparency. The safe practice lays out what some of those might be,

Page 246

including background education, just in time coaching. So when you're at a hospital that's participating in this program, you can get a hold of someone 24/7 who's a disclosure expert to help you in real time with your disclosure decisions.

So very quickly, the content of disclosure includes empathic communication of the facts of the event and its preventability. The "and its preventability" part is huge, because as you'll see, this is an area of lots of debate and discussion across the world, right. When we're talking about disclosure, do we focus on the adverse event? Do we focus on the error? Do we tell the patient this was preventable? The safe practice comes right out and says you need to tell them about the unanticipated outcome and whether it was preventable, an expression of regret for all unanticipated outcomes, and a commitment to investigate and prevent recurrences.

Well, here's what they mean by the facts. An explicit statement about what happened, an explanation about why the event occurred and its preventability to the extent known and

Page 247

then an explanation of the consequences of the event for the patient's future health. This notion of providing information about results of analysis is an important part of the safe practice. It calls for patients being told about the results of the investigation relevant to the unanticipated outcome are communicated to the patient, including whether the unanticipated outcome resulted from an error or system failure, in sufficient detail to support informed decision making by the patient. We could have a very interesting conversation about how much of the analysis should you share with the patient. This used an informed decision making standard to try to guide that.

An apology including an expression of regret for all unanticipated outcomes, so an expression of regret is "I'm sorry this happened," right, whereas a more full apology, "I'm sorry that you were harmed by our error," is appropriate when analysis shows that there was a clear cut error or system failure.

I mentioned the support system. It really is key, providing emotional support,

Page 248

providing disclosure education and providing disclosure coaching around the clock. But even with all of those things in place, disclosure can still be difficult. So this health care team has come to the patient and says "this probably isn't going to mean much to you, but we took your brain out and misplaced it." The patient's looking, understandably, a little bit confused about all of this, and so people have been trying to think "well, what else can we do to promote disclosure?"

One thing that's happened in the U.S., and as you've heard in other countries, are adoption of apology and disclosure laws, 35 states in the U.S. and the District of Columbia have adopted some form of an apology law. The important thing to recognize about these, and this is true across the world, is that the protection varies widely. In most of the countries in the U.S. that have--excuse me, most of the states in the U.S. that have adopted these have adopted a very limited form of an apology law that just protects the expression of regret. So it protects the "I'm

Page 249

sorry," but does not protect any expression or admission of liability that's within the disclosure statement itself. So the "I'm sorry" is protected. The "about what happened" may not be protected, and even for those, there are four states in the U.S. that protect the entire disclosure and apology statement, it doesn't mean that you can't be sued because of the disclosure and that would happen if the disclosure or apology is what alerts a patient to an event that they would have otherwise been unaware of. Seven states actually mandate the disclosure of serious unanticipated outcomes. Usually the disclosure burden falls to the institution, although in Florida, I think it also--the health care worker is mentioned individually.

We're really not sure, given these limitations. These are useful public policy endorsements of transparency, but how much effect they're really going to have on the conduct of disclosure, I think is uncertain.

So now let's switch quickly and talk a little bit about some of these disclosure and offer programs. You heard a little bit about

Page 250

the University of Michigan program. They combine disclosure and an offer of compensation and reported pretty impressive results. So in the five years since implementation, here's what their litigation costs went down, three million to one million, and the timed resolution and number of claims really cut significantly down. Now there were also temporal trends in the same direction in Michigan as a whole. So this is not randomized clinical trial level data, but at least it suggests that at one institution, they adopted this policy of disclosure and full and early compensation and the sky did not fall in.

COPIC is the other example I wanted to talk about, and it's important because it's a large Colorado malpractice insurer that insures mostly private practice physicians. A lot of these disclosure programs have germinated in academic centres that are self insured. The individual providers aren't on the hook for buying their own malpractice insurance. The private practice environment in the U.S. is a little bit different. COPIC

Page 251

insures mostly private--or all private practice physicians in Colorado and they developed what they call their three R's program in the late 90s. This is a program that seeks to promote disclosure and early offers of compensation to patients. It's a no-fault program. There are some exclusions: so patient death is an exclusion; attorney involvement, a very controversial exclusion; complaint by the patient to the Board of Medical Examiners; or a written demand for payment from the patient. So these are sort of moderate level events, not super serious events. But because the patients are not asked to sign a waiver of their right to sue and because this is a payment that's not made in response to a written demand letter, these are not payments that are reportable to the National Practitioner Databank, which is an entity in the U.S. where all payments made on behalf of providers need to be reported. And so from the provider perspective, these attributes make the three R's program very attractive, because they can compensate patients without having to report the provider

Page 252

to the databank.

So how does three R's work? The event gets reported and as you'll see, this hinges on a very active and open culture of early event reporting at COPIC. The physician and COPIC need to decide whether it's appropriate. The doctor tells the patient about the program. The doctor gets some coaching and COPIC then will pay the patient up to $30,000 for lost income and other out-of-pocket expenses for the program. And let's a little bit of data from COPIC on how this works. We had a little bit more up-to-date data in our New England Journal article. Basically, there were five--roughly 4600 reported events in the 50 month period. That's a lot of events, a lot of doctor reporting to this program. Roughly half of them met the criteria for the three R's program. 1600 of them were closed with no payment to the patient, which COPIC interprets as full disclosure and apology were sufficient, right. You could test that hypothesis empirically, but that's COPIC's interpretation that we disclosed it and the patient said "that's good. I don't need any

Page 253

money." Of the 500 events closed with payment, the average payment was only $5600. So it suggests that if you provide these types of payments, patients are not going to try to max out the system, and none of these events has proceeded to a full jury trial.

So COPIC's experience with this has been positive. There are other things that make the Colorado environment particularly amenable to such a program, but I think we're really seeing this notion of coupling disclosure and compensation as one that has potential benefits. But there are also some potential problems, so here the health care team is coming to the patients and say "first the good news, we're not going to charge you anything," and this cartoonist thinks this is a time to worry, right. Where does compensation fit in this disclosure process? What sorts of events would you compensate, for how much? There's a lot of unanswered questions in this area.

So now let's quickly move and look at a couple of programs across the country. Australia was actually in the Vanguard of developing a program for open disclosure and

Page 254

adopted its open disclosure standard in the year 2003. It focuses on adverse events. In fact, you really have to look long and hard throughout the whole standards to see the word "error" anywhere. It really is a focus on adverse event exclusively. They divide events into high and low level events and have different disclosure responses for the low level versus the high level events. It calls for an expression of regret, but does not call for a formal apology after these sorts of events, and Australia, like the UK that we'll talk about in a minute, really has done a great job of developing educational resources. So very extensive set of educational material that individual states in Australia can use to implement this open disclosure standard, and there is a little bit of pilot data coming out. So individual states were supposed to adopt a policy consistent with open disclosure.

Queensland is probably the state that's gone the furthest in this area. They have a pirate report on their website that you can download in detail, and the results of the

Page 255

pilot project show a couple of things. First, there's this ongoing tension between transparency and medical legal concerns and particularly, and this theme has already surfaced today, this issue of protecting the root cause analysis results versus sharing this information with the patient. It's really caused a lot of problems in Australia, trying to figure out how much of the root cause analysis can we share with the patient and does that eviscerate the legal protections for the root cause analysis.

The pilot results also highlight other challenges regarding implementation of this open disclosure standard. So balancing timely disclosure with the need to really conduct a thorough investigation. You'll see on the site, they report the results of, I think, 23 patient interviews and this was a pretty common complaint. It took a long time for them to get back with me with results about what happened, and I think that when you read the report, it has lots of surveys of patients--excuse me, lots of surveys of health care workers, key informant interviews.

Page 256

There's very, very, very little data from patients. And I think the concern has been, in Australia and elsewhere, that if we start asking patients about how disclosure is going, maybe bad things will happen, right. It's a little bit like, you know, the concern that if you ask a depressed patient whether they're suicidal, they'll think "well, I weren't before, but now that you mention it, that does sort of sound attractive to me." I think people worry that if you ask a patient about their satisfaction with disclosure, they'll say "oh well, now that you mention it, I really don't think Dr. Gallagher told me the whole truth," right. So that's inhibiting, I think, our efforts to learn how is the disclosure process actually going.

The UK developed its Being Open policy that was published in 2006 and really drew on the Australia open disclosure standard as a starting point, but in the UK policy, apology is really front and centre. So the policy reads "patients should receive an apology." Remember, in Australia didn't even use the word "apology" right. "Patients should

Page 257

receive an apology after the patient's safety incident has occurred and staff should feel able to apologize on the spot. Saying sorry is not an admission of liability and it is the right thing to do."

There's been some pilot evaluation ongoing in the UK as well, after extensive educational efforts were undertaken, but we, again, know relatively little about how are these events, how are these disclosures being experienced from the patient perspective.

So Canada took all that information from across the world and launched some very impressive guidelines in 2008 on disclosure, and I'll let Sherry tell you more about them tomorrow. I think what's particularly interesting about them is that they really highlight this tension between transparency and litigation and accountability and error, right, and the guidelines come right out and encourage open disclosure, but they say these guidelines purposely avoid the use of the term "error" and go on to describe a number of good reasons why the term "error" can be problematic, but it leaves health care workers

Page 258

in this sort of difficult position. We're supposed to tell patients the facts about what happened, but we're not supposed to use the word "error" and so what do we say and how do we say it? Similarly, apologies are allowed in some circumstances, but what those circumstances are and what the wording of the apology is is ambiguous, which may be good. It's nice to have some discretion and latitude, but I think this is a fundamental hurdle that we're going to need to overcome.

I don't know if the NQF policy is the right approach, that just comes right out and says you need to tell the patient what happened and whether it was preventable, right. Is that the right approach? I don't know, but I know that that's information that patients would like to hear, but they may not need to know all of the details, but what happened and was it preventable I think is information that patients want to hear about.

So lastly, New Zealand. New Zealand is particularly interesting to me because it highlights the disconnect between the medical legal climate and disclosure. As you heard

Page 259

earlier, New Zealand has adopted an essentially no-fault environment around compensating medical injuries. They have a very vigorous complaint system. It's not like litigation has gone away, but it's basically a--it's sort of as attractive a tort environment from a physician perspective as you could imagine would exist anywhere in the country, and yet, New Zealand's disclosure programs, even though they're right next door to Australia, right, are relatively early in their development. So New Zealand has endorsed disclosure, but their expectations are that district health boards need to have a disclosure policy in place by 2010. So compared with lots of countries in the world, really less well developed approach to disclosure even though the tort and malpractice environment, I think, is a little bit more favourable.

So looking across and thinking about moving forward, what do I think we can conclude? I think we can conclude that support for the concept of disclosure is high, but that there are important implementation

Page 260

challenges that people are facing and that implementation at present is really uneven. We know very little about how disclosures are currently taking place, and I think if we have any hope of closing this gap, we're going to need to start to figure out how can we take the performance improvement tools that we're used to using in other settings and start to apply them to the process of disclosure itself.

The malpractice environment, I think, is an obstacle, but I do not think it's the most important obstacle to open disclosure. I think things like clinician shame and embarrassment, lack of communication skills, are much more important. This is not to say that doctors do not worry about malpractice, but in the study I mentioned earlier during the questions, comparing U.S. and Canadian physicians' attitudes about disclosure, even though the malpractice climates in the two countries are pretty different, U.S. and Canadian doctors' attitudes about disclosure were almost indistinguishable. This is embedded in the culture of medicine and the

Page 261

way we train health care workers, and so is going to take a long time for us to try to fix.

Some of the legal barriers to disclosure turn out to be enacted from within health care, right. We need to sort out how are we going to deal with this issue of sharing the results of error analyses with patients. Patients really care a lot about knowing how, what did you find out about how this happened and how you're going to prevent recurrences. But you also heard there are very compelling reasons why this information ought to have some legal protection. We need to resolve that balance, and I think ultimately it's reasonable to say we're sort of at the beginning of the beginning of this process of trying to turn this general principle of disclosure into a system that really works to effectively disclose these events to patients all of the time.

Thank you very much.

MR. CAULFIELD:

Q. Thank you very much, Tom. Do we have any questions for Tom, before we move on to our

Page 262

final speaker? Yes, please, your name and go ahead.

MR. SIMMONS:

Q. Sure, Dan Simmons. One question. The presentation that you've given us, I take it to be addressed towards the question of disclosure to individual patients of adverse outcomes in the course of their care and it's a good review of the state of disclosure policies in various places. Has there been similar work done, and is it available, to address the issue of disclosure to the general public when there's been adverse events?

DR. GALLAGHER:

Q. And not that I'm aware of. You know, some of the principles might apply, but I think as you've heard good group discussion about how there might be important differences in those two circumstances, I think it's in part because the instances of disclosure to an individual patient are much more common than what I would call these group disclosures. Although when you look across the world, there have been a number of instances similar to the one that prompted this commission, where

Page 263

considerations had to take place about what are we going to say to a broader group of either patients or the general public. But as far as I know, other than a few individual institutions, there's no expectation, for example, in accreditation standards. Hospitals in general, maybe they developed a communication policy, but they don't think about it in the same way as they think about disclosure to an individual patient.

MR. SIMMONS:

Q. Thank you.

MR. CAULFIELD:

Q. Are there some other quick questions? If not, we'll move on to our final speaker. Always a tough spot, last speaker of the day, but I know that Philip Hebert is ideally suited for this. Now Philip is a clinician, but also a bioethics expert from the University of Toronto. He has been involved in patient safety issues for a very long time, in fact has coauthored some work with other speakers here. So over to you, Philip.

DR. HEBERT:

Q. Thank you very much. Can everyone hear me all

Page 264

right? Is the microphone okay? Thank you for the invitation to this important event.

My task is to talk about some of the ethical issues and policy issues involved in disclosure of error, and so I'm going to address some of the issues that other speakers have addressed, perhaps from a slightly different perspective.

I want to talk about the traditional ethos of medicine. Deception is never far from physician's hearts and medicine has had a hard time historically with telling the truth. I'm going to talk about the evolving standards over the past 50 years and these are still under evolution, the increasing openness with patients. I want to look at the intimate link between truthfulness and trust, trustworthiness of institutions and practitioners, and then I want to look at some policy implications as well.

So doctoring the truth, isn't that a wonderful phrase? Captures one of the ways in which physicians typically have exerted their power over disease and illness, doesn't it? By making things appear better to patients

Page 265

than they in fact are; by making them appear as if somehow a cure of their illness is somewhat magical, not purely scientific. But it also some rather bad connotations as well, to adulterate, sophisticate and to cook, and I don't know about you, but to me that's not what you should with data, but that's what physicians are well known for.

Now, you know, there's--you can find this in many writings prior to the 20th century as well. This is--Oliver Wendall Holmes is a well-known physician writer. I love his--there's such pithy phrases, right. They're wonderful. Truth is only safe when diluted. Isn't that great? I mean, that's true. You know, we don't tell people the truth all the time. We don't tell everybody the truth all the time. We do make allowances for tact and for telling things carefully in social situations, and why should physicians or health care professionals be any different? I say physicians, but really what I say applies to any health care professional. I don't think one profession is more suited to truth telling than others. I don't think dentists

Page 266

are better than doctors, are better than nurses and so on and so forth. So I think we all suffer from this. And I like this other one, I guess when you're riding your horses, you have your saddlebags. Your patient has no right to tell the truth than the--to the true--all the truth than he has to all the medicine in your saddlebags. He should only get so much as is good for him. Of course, the assumption there is there is something about medicine that requires a certain aspect of deception, and the trust involved--put into a physician or health care professional could not be there were not an aspect of deception. And of course, that's probably not surprising because medicine, up until this century, really could do very little for patients anyway. So if you were going to get better, you had to hope you were going to get better.

Why was deception advised? Well, I think it had to do with attitudes and beliefs about patients. The belief--and of course, these are true to some extent today as well. I mean, you ask physicians why you didn't tell patient the whole truth about the situation or

Page 267

a better approximation to the whole truth, if not the whole truth itself. They will say things, well, patients can't really understand. I'll be there all day explaining things, you know. So they tend to exaggerate the difference between patients and physicians, even in these days of lots of information providing, and they think that patients are only capable of understanding or accepting so much of the truth. The truth is a harsh reality and patients are like children and they have to be treated in that kind of way when it comes to information practices. And then physicians engage in all sorts of protective behaviour, vis-a-vis patients as well. And this is just one study from sometime ago, not that long ago, 60 years ago, published in JAMA was a survey of physicians who wouldn't, at that time, disclose a diagnosis of cancer to patients, and why? Well, not surprisingly, there wasn't much treatment for cancer, even at that time, and there was also worries about the effect the truth would have upon patients, deny them any hope, and they'd give up and they'd die

Page 268

sooner. And you still find these attitudes. The view is that the truth, the uncomfortable truth is really unbearable for patients and part of the job as a physician as being a healer, is not to do harm to patients and to protect them from these uncomfortable truths, and the Courts sometimes accepted this. They went along with this.

This is a case I found when I was looking through an old BMJ journal for 1950s, and the patient had--a physician had left a large needle inside the patient's perineum. Not supposed to do that. And the physician didn't want to tell her about this because that would cause her excessive worry, and the Court agreed. The Court went along with the physician, said that was all right. Said, I cannot (unintelligible) any abstract duty to tell patients what's the matter with them. It depends on the circumstances, a patient's character, health and social position, and so on and so forth. Well, we're not talking about patients generally, we're talking about what about this patient. Anyway, he got away with it. Of course, you wonder is this

Page 269

deception really for the good of the patient or is for the good of the practitioner.

So I mean, at this time in medicine, and I think this is still why it's so difficult sometimes for physicians or health care practitioners generally to hear this message. We still have this belief that do no harm is the most important principle. Of course, I think everything we do in medicine has some risk of harm. So if you're going to try to do no harm, you'd probably do nothing in medicine. Of course, that involves risks too, right? So in the middle of the road, you may get run over in both directions.

But this is a prioritization of the patient's wellbeing over the information provided to the patient that the view is the truth won't do much good and if it won't do much good, why would we tell, especially if there may be some harms. So you could argue there is an argument from tact here. Deception is helpful because it prevents these uncomfortable truths from being known to patients. And of course, this is much influenced by the meagre impact of therapy at

Page 270

that time upon disease. Just because we couldn't do very much, why would we tell patients about this? There's no good will come from the truth.

So sea-change (phonetic) began in the late 1960s, influenced by many things. Certainly a big element was the improvements in care. We could actually do things that made a difference to patients. We could actually improve their care, improve their length of life. There were options they could choose between. There was no--just one way of proceeding. There was different ways of proceeding and so some difficult decisions had to be made. You had to make risk balance assessments and you could actually perhaps help patients, but more importantly, I think there are also social trends as well towards greater democratization in society generally and a greater interest in autonomy and wellbeing. Wellbeing is defined from the patient's perspective, so there's no longer a physician-based perspective. It was increasingly expected you'd incorporate the patients' perspective into decision making and

Page 271

of course, if a patient is going to make decisions, then they need information for that decision making, and if you didn't provide them with it, then they couldn't make informed choices or informed about what care they could receive.

Patients generally have not been shy of wanting to know the truth. Studies going back before the Oken study, and this is just a couple of studies from sometime ago, one from the late 1950s, that showed that most patients and their families wanted to know the diagnosis of cancer. These are American studies, of course. The U.S. President's Commission on Ethical Problems in Medicine in 1982 commissioned a number of papers and they found at that time too that many patients want to know the diagnosis of cancer. So the attitude towards truth telling was important for patients and has always been important for patients, hasn't required the therapeutic rationale physicians seem to want.

Now this is a sea change. It's not a wall. It's not a tsunami. It's not all of a sudden everything changed in medicine.

Page 272

Nothing changes that quickly. Some fields of medicine have been more open and more able to adopt patient-based decision making. Others have been less able to do so, and certainly some parts of the world are more comfortable with this perspective, and you'll still find the paternalistic kind of doctor knows best perspective in many parts of the world. And then there's parts of medicine which have less direct patient contact, such as radiology and pathology, which has typically not been involved in the disclosure process and probably should be and will be in the future. I'm going to talk about that in a few minutes, but in the past, they really have been free from, as it were, the autonomy principle of medicine.

So I think there's a revolution in medicine around information providing that is still spreading. It's not finished, and it will take some time to undergo, but we're still in the process of seeing this principle of truthfulness through, and just a survey the changes in American physicians again attitude towards truth telling, here's 20 years after

Page 273

the Oken study, again another diagnosis. This time physicians are quite prepared to tell patients the diagnosis of cancer. So there's almost a complete reversal in how physicians approach at least this diagnosis.

So what do patients want? Well, I think many studies show that patients want to be informed, not necessarily to make the decisions themselves. In fact, there's some evidence that if you try to get patients to make decisions that may raise their anxiety levels and so on, but at least when it comes to information providing, most patients want that, if they don't necessarily want to make the decision themselves. And they also want to feel supported. Who can I rely upon? Who can I trust? Who can I fall back upon if things don't go well? And trust goes along with information provision.

What does trust in medicine require? Does it require that uncomfortable truths be hidden, which was true in the past? That patients be protected from negative emotions, is that what disclosure is all about? I don't think so. Or should, as Cabot said, a

Page 274

physician in the early part of the last century, professionals should strive to create a true impression in their patient's mind. So not necessarily telling the patients the whole truth, but creating a true impression in the patient's mind, and that's what disclosure is all about. And we'll find this in modern ethical codes as well, the British Medical Association. Relationship of trust depends upon reciprocal honesty between patient and doctor. Canadian Medical Association emphasizes in its code of ethics about the requirement for disclosure to patients where it may have a bearing upon medical decision making. Some would argue truth telling goes beyond that, it's not just medical decision making. It's how patients want to live and how they see their life in the world as a whole, so really probably truth telling goes beyond what's in the CMA's code of ethics. And they must communicate that information in a comprehensible way.

So truth and trust go together. Trust is necessary for the therapeutic relationship. Patients, if they don't think that physicians

Page 275

are going to be entirely honest with them or open with them about what's going on, they're less likely to share intimate details of their life with physicians, health care practitioners generally. So it's important for that therapeutic relationship to take place that there be this relationship of truth between patients and health care practitioners. They really are inseparable and truth telling has been defined as not necessarily telling patients everything or telling patients everything, but as Cabot suggested, trying to create a truth impression in the minds of patients, intending not to mislead or to deceive, and that may be quite different than medicine in the past.

The primary ethical principle, of course, these days is respect to persons. I think that is--that's not the only ethical principle by any means, but it is a primary one these days in western medicine, and the patients are adults, they're not children. They need to be treated like adults and information is important for adults to make decision, and while in the past it might have been said how

Page 276

can the patient stand being told, the new principle is now how can the patient stand not being told. So the assumption is that disclosure should be this default position and non-disclosure only the exception to this.

The role of truth telling has--there's many ethical rationales for truth telling disclosure in medicine and Bernard mentioned these principles already, but to see how they capture--fit into the scheme of truth telling. Obviously the most important thing is that it enables patients to live their lives as they see fit. That's what decision making is all about. It's not about making--having patients make the right decisions or having information that's not going to upset them. It's about helping them to see their lives as they truly are, if they want to know that, of course, and to help them make informed decisions is a secondary part of that. Not just to make decisions about their lives, but to make decisions about therapy and information may be important for that.

Another reason is from the principle of beneficence, that truth telling fosters good

Page 277

decision making, improves clinical outcomes. There have been many studies showing this, some which I detail in my paper, and encourages better, which now call it concordance between doctor and patient, not compliance, not patient compliance, but concordance, agreement between the physician and the patient.

And the last issue is one really of justice (phonetic) or maybe also the principle of autonomy as well. Patients, when asked why do you want to know? Well, they say why do I have to tell you why? There's no reason. One study in multiple sclerosis patients say "why should I have to explain why. I just want to know." Not necessarily they're going to do anything with all that information, but they just want to know what their diagnosis is or what their problem is. Whether they can do anything with that information is up to them to decide. So there's really a right to know there which comes, you can say is an element of natural justice or maybe respect due persons.

So the many worries in the past about

Page 278

psychological harm or the harms caused by disclosure haven't been borne out by studies. Most people want to know. There is, however, ten to twenty percent of patients who don't want to know the truth. I think that's important for any decisions about how to proceed in this matter. It's particularly difficult when there are populations at risk, when it's not just one patient you need to tell, but a group of patients. There may be some people in that group who don't want to be informed, who don't want to know the truth, and what do you do about that? I think it's hard to answer that question generally, but to say you have to have good information sharing practices. I'm going to talk about those--can minimize the harm to those patients who perhaps don't want to know.

It's not just important for trust. Truth is not just important for trust between patients and health care providers. It's also between patients and institutions, and patients will experience a betrayal of trust if they think that institutions of medicine aren't acting in ways that are solely

Page 279

conducive to a patient's interest. In other words, if they think the institutions are acting in self-protective and deceptive ways, it will undermine their trust in the medical system, which of course undermines the health care system generally.

So faced with hazardous situations, what are the responsibility of institutional officials? I want to give you a little case here, which I'll--it's difficult for you to read, but this case comes from an article written in the 19th century by a mathematician. It's actually the only paper he ever wrote. I'm getting dry. While you're reading, I'll drink some water. I thought it was particularly (unintelligible) Newfoundland since it concerned a ship.

But he had this ship, he used it many times to ferry immigrants from somewhere in Europe to North America, and he knew there had been problems raised about the ship. The ship not that well made in the first place, needed repairs, and some doubts were raised about its safety, and he managed--and he thought about this and was worried about it, whether it cost

Page 280

great expense to overall this ship and he managed, through thinking about this, to realize, well you know, the ship has sailed many times. You know, doubts have been raised before. They've not been realized, and he managed to convince himself prior to the ship sailing that everything would be okay. That it sailed every other voyage, why wouldn't it sail in this one. The passengers are eager to go anyway. Everybody was willing to go, why would he say no to the ship going forward, and he decided, as we see in the last sentence there, in the last few sentences, he acquired a sincere and comfortable conviction that his vessel was thoroughly safe and seaworthy and watched her departure with a light heart and benevolent wishes for the success of the exiles in their strange new home that was to be, and he got insurance money when she went down mid ocean and told no tales.

So what the writer wrote at the time is that really what are the ethics of that belief? What are the ways in which--was this a right judgment, a proper judgment in the shipowner's case? And Clifford said no, it

Page 281

wasn't. He had no right to that belief. He should have looked at the evidence and explored it more carefully and not simply accept--the fact that he believed, genuinely believed the ship was safe was not grounds for allowing that ship to go forward. He should have examined the basis of the doubt, examined his evidence and Clifford said that he had no right to believe in such evidence before--and that's sort of an interesting statement, when you think about it. What are the ethical aspects of belief and statements in truth? And I think we can make some--a jump from that to suggesting there are certain duties of trustees or people who look after institutions is that they have to exercise appropriate supervision, to act reasonably and to prevent harm and when doubts arise, ignore them at your and your patients peril. So you should take those doubts carefully into account and not assume that everything is going to be okay because everything has been okay in the past.

So adverse events in disclosure, just to end on this. We've heard about how common errors are. Really the problem for patients

Page 282

isn't so much the occurrence of errors, although that is clearly a problem when they get harmed by it, but it's the attitude to error that upsets patients the most, when they feel that they're not taken seriously, then the public is dismayed by lack of accountability, and the secretativeness around some of these events. So I think that's a disservice to patients and the public. It isn't the errors themselves, but how we deal with them.

Critical incidents aren't as harmful to patients. They do cause harm to patients. They're also a threat to our institutions as well. They can undermine public confidence in the institutions and really it should be looked at as kind of an medical emergency, as it were. Not emergency just from the patient's perspective, making sure they get better, but also seeing them as potential threats to the acceptability of our institutions and if we don't deal with these openly and honestly, that will undermine that institutional legitimacy on which so much depends and especially medicine depends.

Page 283

So there are certain things that--yeah, so there are certain things can be said about truth telling, in terms of policy, developing policies in this area, and basically, these policies help assure the public that we take these events seriously and they also allow us to outline what a timely response to these events might be and to prevent harms to future patients, and the general policy here would be the more serious the harms or potential harms to patients, the more thorough going and the faster the response should be from people responsible for those incidents.

Individual institutions must notify any affected at risk patients. Again, when you do that depends upon your definition of timeliness, but the more serious event, the quicker that notification must be. So as soon as after the event has been identified, most policies suggest there should be a time element here, relatively rapid notification, especially in the occurrence of serious events. It's best done in person with adequate time in a comfortable, private setting which allows the empathic relationship

Page 284

between patient and health care providers and also encourages that trusting relationship, and there are other ways which you can communicate this information to patients, which I think indirectly is probably less acceptable because they don't provide that support that often patients or families need, and certainly, if you phone patients up or families up about these events, I think that's the least helpful ways in which--one of the least helpful ways in which communication can be done because it's so impersonal, and the patient and their family may not know who's calling anyway. Media notification happens in some cases, but I think this is less acceptable as well because--unless all other means of contacting patients have been exhausted.

Disclosure is clearly a process and I don't think you should wait for definitive answers. I think that's come up more in the presentations already. Answers are important and it's important for patients and families to know that "we understand the complaint. We're looking into it. Here's what we know so

Page 285

far. Here's what we need to find out," and where there are serious events, the disclosure should take place as quickly as possible.

So I think honesty is the best policy, and not everybody is convinced, and these folks think "okay, what's the second best policy?" My view is you don't settle for second best. The first policy is the only one you need.

So just in conclusion, patient safety is the responsibility of all health care professionals, whether they're directly involved in patient care of not. Professionals and institutions must have a system in place for which hazardous findings and incidents can be communicated to patient and all the treating team, and this may apply to other specialities that may not have direct patient care, such as radiology or pathology, which comes up with abnormal results are hazardous findings. They need to make sure that there's some ways in which patients may find out about these events.

And lastly, the public's trust in health care requires transparency and truthfulness.

Page 286

Thank you very much.

MR. CAULFIELD:

Q. Thank you, Phil. So we have about a half hour for a final set of questions, if people have them. I know I have a couple, but I'd like to--oh, good, go ahead.

DR. ETCHELLS:

Q. My question is directed to Dr. Gallagher and it speaks to the issue of judging preventability. So I'm going to give you a case, and I'd be interested to hear your thoughts because I find it very difficult. So suppose a patient has cardiac surgery. They have an infection in their breast bone after the surgery. Clearly that's an adverse event, and on review of the chart, the sternum was--the hair was clipped. The antibiotics were given about 30 minutes late because of a variety of delays. The blood glucose was elevated above ten twice and the body temperature was kept normal throughout. So my question is, is that a preventable adverse event? I think it's very difficult for a clinician to judge that when a statistician can't even judge that. How do you go about

Page 287

disclosing those sorts of complex, non-specific outcomes to patients and putting a label of preventability on it?

DR. GALLAGHER:

Q. One of the reasons that I said I thought we were at the beginning of the beginning is, you know, we talk about disclosure using these paradigm cases where the preventability is clearly known and medicine, as you all know, lives in the grey areas, you know, and that's a perfect example, you know, and you can extend that example to the compensation side of things. So if the patient has an additional two weeks in the hospital because of this sternal wound infection, does the hospital need to cover all the costs and pay for their lost wages? I think it's terribly difficult to know. You know, it's this very difficult balancing act between timeliness of disclosure and providing accurate information, and we actually, you know, are--the policy at UW tends, in part, to put the brakes on the disclosure process a little bit. We see a variety of different errors in error disclosure. The one that people think about

Page 288

the most is what we call hypo disclosure. We need better terms for this, by the way, so if you have good ones, I'm open to your ideas. So hypo disclosure, not saying enough information. But there's clearly hyper disclosure, telling the patient way more information than they wanted to know or, I guess, mal-disclosure, misdisclosure, telling them information that, on later reflection, turns out to be wrong. How does that happen? Oftentimes, junior physicians feel terrible about an event. They rush into the patient's room and say "I made a terrible mistake. I'm so sorry about this," and then when the dust settles and patient safety analysts have had a chance to look at this, it turns out it wasn't preventable, or even worse, we don't know whether it was preventable, right, and then as the risk managers say, you're in the unenviable task of having to "unring the disclosure bell." Go into the patient and say "we thought this was an error. It turns out it's not an error." If your credibility was not high before, now it's, you know, now it's zero, zero.

Page 289

I think the issue you raise of so what do you do when you're uncertain, I think it's a great area for collaboration. Do you share that uncertainty with patients? We do in the informed decision making process sometimes, and other times, we keep the uncertainty to ourselves.

MR. CAULFIELD:

Q. I'd like to get a question in because I think it's a great topic, and it's one that both Philip touched on and I'm curious how the legal experts think. It's when there's a group of patients that may or may not want to know and it builds on what you were just talking about, with sort of an added complexity. Over lunch, we were talking about the experience in Alberta with mad cow disease, CJD and blood products being exposed and this is a completely theoretical risk and did the public want to know. Well, it's interesting because there was threats of legal action, both from individuals that weren't told and from individuals that were told. You've made me worry when I didn't--shouldn't have had to worry. So what do you do, both

Page 290

from a legal perspective and from a system policy perspective with that uncertainty, particularly when there may be groups of individuals that don't want to know?

DR. HEBERT:

Q. I think that's an area of fertile discussion at this time. I think most of us would say that when--I mean, I guess when you're relatively certain an event has happened or you are certain an event has happened, the more certainty the better, it does put the onus upon disclosure and non-disclosure would only be the exception. When it comes to groups of patients as a whole, I think you want to apprise the community of risks to their health. If you know a specific group of--are you talking about a specific group of individuals or some more general threat to the population?

MR. CAULFIELD:

Q. Well, both, and I think that there may be a situation--I'm curious what the group thinks, the legal scholars think. Can a person say, "look, I don't want to know about risks?"

DR. HEBERT:

Page 291

Q. Well, an individual can say that though when--if there's implications for other people, I think it less--it would sit less well. The greater the risk to those other people would be. So that would be my general statement. So the more patent the risk is to individuals, then the more--the less, and the greater the threat is to other people, the less you can reign in that disclosure to people at risk.

DR. GALLAGHER:

Q. Yeah, I think it's a real challenge in a variety of ways. You know, when we videotape surgeons, including Canadian surgeons, disclosing hypothetical events to standardized patients, there seem to be sort of three basic approaches. One was what we call sort of the nuclear bomb of disclosure. The doctor would go in and just sort of tell the patient everything they know in one fell swoop, kind of (unintelligible - making sound) and just dump it all on the patient and the patient kind of had the hair blown back look, like they'd just gotten way too much information. Some of the doctors their disclosure skills were so poor, we had designed the cases, we

Page 292

couldn't even tell what they were talking about. But there was this middle group of doctors who took the sort of graded approach to disclosure, where they would start with a little information, wait to see what the patient said, provide a little bit more information, wait to see what the patient said, and I think that approach makes a lot of sense. Physicians want to customize these conversations based on what they know of their patients preferences. The down side of that though is that if physicians don't accurately predict their patients preferences for information in other areas, right, so if you studied patients--physicians, do they accurately predict patients preferences for information about end of life care, you might as well flip a coin. Doctors think they know, but they don't. That's why I think it would be helpful to have some basic guidelines or standards about what information needs to be conveyed, and if you get there all at once or if you get there in a conversation gradually, I think that doesn't matter as much.

For example, patients, I think, need to

Page 293

know was this preventable, if we know, right, and I think you can get there lots of different ways, but to not get there at all because you think "oh, the patient wouldn't want to know this," I think is potentially problematic.

MR. CAULFIELD:

Q. I think that's a really good point and it ties in with Gerald and others were talking about with if the standard is what a reasonable person in the patient's position would want to know, how can you make that judgment, and likely should err on the side of, obviously of disclosure. So other comments? I know it's been a long day.

MR. RITTER:

Q. I have a corollary that I want to introduce here. We've been talking a lot about adverse events and how we report when an adverse event occurs. We also talked this morning about preventing adverse events, and we also talked about the evolution or the growing consciousness about the systemic side of things, rather than the individual side of things. So within that particular frame of

Page 294

reference, when a professional person or when someone in an institution recognizes a hazard or a risk, what is their obligation to disclose? There are obviously internal--I mean, within current institutions, there are mechanisms where people are supposed to report up the system. Sometimes what happens is a professional may report it to the system, but the system sort of sits on it for a while, sometimes for a long while. I think we seen this happen many places. What is the obligation of, let's say a physician, and what kind of protection in the form of whistle blowing or something along those lines should be available for them?

I know that at the present time, there's some activity going on in our province with respect to physicians signing non-disclosure--you know, signing confidentiality agreements and they're not totally clear, and there could well be a bit of, sort of, suppressing of certain kinds of information, apart from, you know, patient confidentiality type things. So I'm just wondering whether there's been any discussion within the community of sort of

Page 295

medical safety and disclosure experts on this particular subject.

DR. HEBERT:

Q. I think in particular, there's--certainly, if you're talking about a harm to a particular patient, if a physician becomes aware of that, then I think he/she has some obligation to act upon that, to ensure the patient safety and wellbeing is looked after first and foremost. Now how that takes place will depend upon the institution. I mean, there may be a perfectly good mechanism within the hospital to do that, but there have been several cases, I know more American than anywhere else, where say, for example, a radiologist who hasn't--who noticed some abnormality on an x-ray, a serious abnormality and for whatever reason, the ordering physician never gets the original report, the patient never finds out about it until it's too late to help them, and there have been a number of cases where physicians are found liable for fail--radiologists have been found liable, even though they're not doing direct patient care, because they didn't ensure the patient was cautioned about this.

Page 296

Now you know, this creates some controversy because radiologists aren't directly responsible for the patient. Why should they suffer any legal consequences? Well, I think there can be a strong ethical argument there, where you know someone is at risk of serious harm, you don't do what you could have done to have made that person aware of it. Not that it's necessarily your duty to do so first and foremost, It may be (unintelligible) someone else's, but if you can't reach the ordering physician or the patient's x-ray has not been acted upon, you bear some responsibility for that. But it's hard to figure out how that would actually work in reality. Does that mean radiologists have to phone every patient with a serious diagnosis to make sure it was acted upon?

So the limits of that duty are quite unclear at this time, but I think there is some ill-defined obligation to act upon that information. If it's a hazardous situation, such as, you know, ill run laboratory or something like that, then again, there's a hazard to a group of patients. An institution

Page 297

has to do something about that, but again, if the institution doesn't act upon it, there is--there is whistle blowing legislation actually in the UK to protect people against who report a hazardous situations, because there's a number of disasters in the UK where people had tried to warn hazardous situations and they suffered job consequences. I don't know whether that whistle blowing legislation has been very effective or not, but there is legislative protection now in some jurisdictions.

DR. GALLAGHER:

Q. We had a paper in health affairs a few months back about physicians attitudes about reporting systems. I use reporting for informing the institution about these events and physicians, we didn't include the Canadian physicians in this paper, but their attitudes were relatively similar to the U.S. physicians. They had very low confidence and awareness about hospital reporting systems. They wanted reporting systems that were fast and easy to use, that were voluntary and confidential. The most important thing they

Page 298

wanted was feedback. They wanted to know that if I report something into this system, I see that it drives performance improvement and I hear back what was--what came of it. I think one of the earlier speakers mentioned this sort of reporting fatigue that we've seen at a number of institutions where systems have been set up that generate mountains of reports, way more than any institution could analyze, and this is counterproductive because the health care workers get frustrated and stop reporting.

MR. RICK SINGLETON:

Q. I'd be interested in hearing a few comments about the situation--some of your comments and the earlier panel has spoke of some of the ethical frameworks and principles and so on that apply to disclosure, but my sense of it is that most of the comments have been addressing individual situations, and they're interesting and informative, but I'd like to hear a few comments about the situation that's really relevant to why we are here and what's going on in our local community where, for a lot of reasons, and complex reasons that

Page 299

requires a commission of inquiry to try and figure it out and make recommendations, that in itself indicates the size of it and the scope of it and that in many ways, the beginning of the beginning is kind of what's happening here, that this is a whole new field to be on to try and figure out how to move forward.

Now particularly what I'm interested in hearing your comments on is that there are ethical frameworks that you've described that apply to individual situations, but I'm thinking in the--I'm asking about situations where there are many patients and many complex issues and unfortunately, and I think we would all acknowledge unfortunately, things have slipped along that it isn't handled face to face, at the bedside, clinician to patient and so on. It has become bigger than that and far more complicated than that, and I think in some ways, to my observation, I'd say that the Commission of Inquiry itself even has become part of disclosure now, at least in terms of public disclosure, but in some cases as well, it seems that the people who have been

Page 300

personally connected and impacted, there's kind of an element of disclosure that's happening through the Commission itself and through the way that it is publicized and the comments and the scrums and all of the things that are happening. People are finding out things that are very relevant to their own lives and things that are relevant to the community and to, you know, our public health system and what have you.

With all of that said and done, my question is, is there or ought there be a more specific ethics consideration of things as big and as broad and as complex as the situation we are in here now and the public disclosure piece that is happening along with, if not through or because of the Commission of Inquiry? And I'm thinking specifically of things such as, you know, the issues around harm or the potential for harm that comes from the new complications or the intensified complications that we have in our province around recruitment and retention, adding of course, also to the issues of trust and those things that are important to the maintenance

Page 301

of an already very stretched and strained health care system. I know my question is -

DR. HEBERT:

Q. Well that's a bit of a--yes, well, could you rephrase the question?

MR. SINGLETON:

Q. No, no, no.

DR. HEBERT (phonetic):

Q. I see where you're going. Are you saying does the system and even inquiries like this need to consider the broad system impact of disclosure, the broad social impact of disclosure, and the way that it unfolds and having a complicated inquiry such as this, you have to be even more sensitive to its long-term ramifications, both in the individual level, at the system level and at the social level.

MR. SINGLETON:

Q. It's the long term and the immediate. I mean, this is having day-to-day fall out on people. We see it in the media each day, you know, how people are distressed and who are, you know, on leaves and what have you, and that's having an impact on client care and what have you.

Page 302

So I think in the short term and in the long term and I doubt that there's very much in the literature to go to and that's why, you know, people like yourself might cast a bit of light on it for us because it is evolving. We are at the beginning of the beginning, so it's an opportunity probably to make some corrective adjustments as we move on through this.

DR. HEBERT:

Q. Well, whether system based or individual based, I think that anybody who deals with these problems of adverse events in health care want to do it in a facilitative kind of way. We don't want to do it in a way that undermines other people's ability to do their work and, you know, I think especially with these kind of events, we know they're not individually based failures. There are all sorts of systemic reasons why that happened, and we would hopefully have a mutual understanding and approach to these things that doesn't set out one person or one group of people and say what a nasty job you done. Rather look at the kind of--the system factors that allow this situation to take place and

Page 303

hopefully do it in a way that is supportive of those people, not undermining their work, because nobody goes to work in health care wanting to know who they can harm that day. (Unintelligible) did these--you know, these harms happened for any reasons of intention. So you're trying to figure out in the best possible way and the most systemic way possible what happened, and I guess some people may experience that as stressful. Some people may see it as an attack upon them or their position, but I guess that is a risk of sometimes making these things public. But on the other hand, I think there's much greater risks to the health care system if you don't deal with these things openly and it's just left to fester.

DR. GALLAGHER:

Q. Sorry, Philip, I didn't mean to cut you off there.

DR. HEBERT:

Q. That's okay.

DR. GALLAGHER:

Q. I think this is--it's really complex and I think in part, it has to do with trying to at

Page 304

least start to resolve the underlying tension between disclosure as informed consent and disclosure as a fiduciary obligation/right to know truth telling, you know, because they lead you in somewhat different directions. If the focus is really around harm and decision making, then I think the framework that we heard earlier that was sort of a public health framework of sort of what's the likelihood that this information--that disclosing this information would allow patients to avoid future harm, how severe is that harm, etcetera, makes a lot of sense. If this is really about a fiduciary responsibility and truth telling and right to know, that might have different implications. But what I've been impressed by is how helpful sort of a public patient advisory panel can be in making some of these determinations because when we've looked at disclosure to individual patients, doctors and patients are on different pages on this issue, i.e. doctors really think about the informed consent implications of disclosure because if the information "wouldn't matter" maybe we don't

Page 305

need to tell the patient. Patients really downplay the informed consent dimensions and they think much more about disclosure as this is my body. I have a right to know. You need to tell me. Who cares what I'm going to do with the information. But so I think given that bias that's built into health care to prefer informed decision making rationale over fiduciary truth telling rationale, having a relatively sort of neutral group that can guide some of these decisions, I think helps a lot.

UW had a similar, thankfully a little less severe, incident a few years back where there was a breakdown in sterilizing endoscopes, where six or seven hundred patients were affected and there the problem was the risk was thought to be infantesimally low of patients being infected, but ultimately the medical centre thought "well, we really need to let people know about this and make testing available to them and set up a hotline," and I think the sense was that this disclosure was probably the right thing to do on the public trust and honesty and integrity

Page 306

side. It may have led to a hit to UW's reputation in terms of providing competent medical care. So trust has more than one dimension, right, trust and competence, trust and honesty and integrity, and for a fair number of patients, it generated a lot of anxiety, and some patients, a ton of anxiety. You know, they kept calling, were very concerned, wanting to be retested over and over and over and over again, and so there was clearly some harm to a group of patients that came with this public disclosure.

Now the situations are not exactly comparable to the situation under consideration here, but I think the mix of benefits and burdens is complex and I think having someone neutral to help sort some of these things out is helpful.

MR. CAULFIELD:

Q. Excellent, and perhaps a good way to end the day, unless there's any other pressing questions? No. Well, let's give this panel a round of applause.

Now we're going to start at 9:00 tomorrow and we're going to be exploring things like

Page 307

disclosure processes and also the involvement of the media in disclosure, which has been very interesting, both in this context, but in the broader context, and then we're going to have a panel discussion. We're going to invite all the panellists up and this is also a warning to the panellists. I'm going to ask you for your one sentence key message for looking forward and if you have any questions, really any questions, anything that you want answered, anything that you would like on the table, please bring them tomorrow morning and we'll try to address them. So thanks very much and have a very nice evening everybody.

(UPON CONCLUSION AT 4:36 P.M.)

Page 308

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript of the Inquiry on Hormone Receptor Testing, Part II, Symposium, heard on the 22nd day of April, A.D., 2008 at the Memorial University of Newfoundland and Labrador, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 30th day of April, A.D., 2008

Judy Moss

-E-

-F-

-G-

-Q-

-T-

-U-