

**What Other Nations Can Teach Us About a More Patient-Centered Health Care System:
The Patient Safety Agenda in the United Kingdom
November 4, 2005**

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ED HOWARD: Once again, I'm Ed Howard with the Alliance for Health Reform. We're now about to move into the area of patient safety, which at least in the United States, is not completely uncontroversial. It has a number of threads that have heated up some discussions. But we have with us to describe that issue for us, Sir Liam Donaldson. His presentation promises to be really great. He's got Pixar and Disney collaborating on the graphics and sound effects so I know that this is going to be exciting, even apart from the substance of it. Sir Liam is the chief medical officer at the UK's Department of Health, England. He's the 15th person to hold that position. He is also currently the head of the World Health Organization's Patient Safety Program. One of the finest experts in the world on this topic and a number of related ones and I give you Sir Liam Donaldson.

[Applause]

SIR LIAM DONALDSON: Thank you. Good morning, everybody. I've been asked to talk about progress of the Patient Safety Program in the United Kingdom. So I'm going to do that towards the end of my presentation. I'm just going to identify some of areas where I think further progress needs to be made and most of them are things, which would be relevant to I think all countries who are addressing a Patient Safety Agenda.

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So here is the story in the United Kingdom. Let me take you back to England in 1975 to a very happy moment for a family, the moment when a young child brings home his first school report. And this is the school report of Lee Duncan's, who is a five and-a-half-year old boy. It was a very happy moment when he passed his school report, excellent grades, from his teachers to his mother. Six months later his mother was holding a different piece of paper in her hand, which was her young son's death certificate. He died from a mix up in the administration of drugs. He was given a drug intended for intravenous use into his spine, 1975, the world's first death due to a Vincristine administration error. Let's hear briefly from Lee's mother talking. She asked if she could come and talk to me on the 30th anniversary of her son's death, which was a few months ago.

FEMALE SPEAKER: Lee was a very special little boy. He was only five when he was diagnosed with [inaudible] leukemia. He never complained through any of his regular therapy treatments, the chemotherapy. He was really good and I've kept in contact with other parents over the years, whether it be at Donca Storic [misspelled?] near Weston Park and the children's hospital in Sheffield and they've got quite a many problems with their kids, believe you me. When they were going through these treatments because they are absolute health. Lee liked school. He was a very good student at school and most of yet

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he absolutely adored his baby brother and his sister. My hope with this meeting is that Lee was the first tragic death to take place and one [inaudible] will be the last and hopefully there's some safety device can be brought into force sooner rather than later for these Vincristine injections to make it impossible for it to be given intravenously.

SIR LIAM DONALDSON: So Mrs. Duncan is talking about the loss of a precious child 30 years ago. She met with a wall of resistance at the time. The investigation that was carried out into this tragedy was quite inadequate. No lessons were learned whatsoever and she talks there haven't been denied a voice for any action or for any improvement over a 30 year period. So was Lee Duncan the first and last to die of this tragedy? Twenty-six years later this boy, a little bit older, died in Nottingham, England. But in the intervening years in the UK and other parts of the world, although this was a rare and still remains a rare tragedy, children and young adults continue to die. Wayne Gowart was a teenager living in Nottingham. He was a happy boy but was very nervous of receiving his treatment but never the less, being treated for leukemia, his prognosis was extremely good at the time. But on the 4th of January, 2001, he entered this hospital. One of our premier medical centers, an excellent reputation for teaching, research and clinical care. But on the 4th of January, 2001, 26 years after Lee Duncan had died, Wayne Gowart, with a similar

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condition, needing similar treatment, entered a hospital and did not come out alive. Why did he die? He died because he was given the wrong drug from amongst these two. Two similar syringes, similar size, both containing [inaudible] fluid, both with roughly the same amount of fluid, one syringe contained this warning: "Not for invetral [ph] use. The procedure was carried by two junior doctors—one giving the treatment and one assisting. Wayne actually came up to the hospital with his grandmother because, as I said, he missed some appointments; he was very nervous about having his treatments; he didn't like it, and his grandmother was the person who had the greatest influence over him. So she persuaded him to come out to the hospital and they arrived out of sequence, so there was no appointment for them, but because the staff didn't want to loose the opportunity for him to have this crucial treatment, they rearranged their schedules to fit him in. It took a couple of hours, so they arrived in a hospital at 3:00 pm. At 5:20 Wayne underwent the procedure. But at 5:00, 20 minutes before the procedure that took place, all the ingredients to cause his death were already in place. It was almost as if Wayne Gower was a dead patient walking. He received the injection. It was quickly realized he received the injection into his spine that should have gone into his vein. He was taken to the operating room and an attempt was made to flush the fluid out. We're going to now here briefly from Wayne's

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father and then from his mother and they're talking to me couple of months ago on the fourth anniversary of their son's death. Mr. Gowers is explaining how he was called to the hospital after Wayne had been to the operating room and then taken to intensive care, and he's talking about what he was told by different members of the medical team about Wayne's prognosis. And then you'll hear Wayne's mother, and she's describing the conversation that she had with her son while he was lying in intensive care having had this attempt to wash out the toxic drug.

MALE SPEAKER: We've seen other doctors and they tried to explain that if they forced this drug out there's a chance that he could survive. There's a lot of confliction between the doctors on what was going to happen. The intensive care doctors seemed very negative to us and the consultant doctor, this consultant, was more positive, so honestly we were going on and taking in what they were saying. And 24 hours went by and the consultant who transferred the drug out, he examined Wayne, and thought Wayne was all right, and he thought at first it's all out. And then the consultant offered to see us and I thought he was going to eat his words. They said my son would die.

FEMALE SPEAKER: You know we had to be prepared that they had put the Vincristine into the wrong part of his body and there was just no way he could survive this, what had

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happened. So we were prepared to—we knew then he wasn't going to come around and just a matter of time and waiting. And that was terrible, [inaudible] watch this young boy die and need to go. He was nearly over the treatment. I think he probably got two more visits and it could be discharged or would be over, the worst of it, and that, terrible, terrible. And to have to tell, I mean he knew there was something wrong, when he knew there was something wrong and he said to me, he said "Mum, Mum, what's happening? Am I going to die?" And I had to tell my son that he was going to die.

SIR LIAM DONALDSON: So there you see one family member talking about the information that they were given in the immediate aftermath of the tragedy, quite typical of these sort of situations, conflicting information, some giving a positive message, others a negative message, all of which compounds the distress in situations like this, but culminating with the unbelievable horror of a mother having to tell her own son that he's going to die. Patients like the Gowarts and the Duncans have been helpless with out health care systems over the last 30 years. They've had no power; they've had no influence; they've had no ability to make sure that the experience of their families isn't repeated to another family. They have to struggle even to get their stories into the public domain because they're often denied information and resisted by lawyers who want to stop them finding out too much about what's

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happened.

Vincristine errors are rare events. Some very angry doctors have accused me over the years in the United Kingdom. "Why are you bothering with this? These things happen rarely. Just accept them." And obviously our philosophy's to address the more common problems in patient safety, but also we have to set ourselves the challenge of being able to eliminate some of the things that are perfectly preventable. A US researcher has discovered more cases of Vincristine around the world we didn't know about. So my original figure of 24 has gone up to 49 and probably there are many others that haven't been reported into medical journals, which is the main way that these cases have been detected.

Now turning to what we did about this in the UK, we did set a target to eliminate this error, although it's very rare, it's almost like an air plane crash, they don't happen very often. We set a target to eliminate it. We haven't yet been able to produce a design solution for reasons that I can go into and equipment solution, so we sent out tough new standards for ensuring that people gave this medication safely, including that people did so have to be accredited. We couldn't have had a more high profile story in our system than Wayne Gowards'. So we issued the guidance and the standards. We issued it on the back of a lot of publicity and awareness raising and we gave a very sharp deadline for our hospitals to implement the

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new standards to prevent this from happening again. They overshot the deadline by two years. Full compliance was only achieved by me personally as chief medical officer telephoning the noncompliances and asking them what was happening, why weren't they complying. They're response was, "Well, we've got many priorities and this is just one them Liam." And when I said, "Do you realize you could be responsible for a child's death?" they said, "Okay, we'll comply." And they all complied in the end. After they were all compliant we sent out an inspection team to check on whether they were compliant and a third despite saying they were compliant, were not compliant with these standards and guidance. A very depressing story, I think, that tells us a lot about the state of the local culture on patient safety, that we still need to address. The more positive side of it, I think, is that in some ways why should this be any surprise? We know how difficult it is to spread good practice, an evidence based practice into our system. Perhaps we were being unduly optimistic to believe that spreading action to prevent unsafe care would be any easier. So, we're addressing this but it's very important that we did look and we didn't just take things on trust. Our system, let me just highlight some of the things that we've aligned on patient safety, behind our program on patient safety. Our first report, an organization with a memory came out about the same time as your institute of health report, to err is human.

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It sent out the agenda; it scoped the subject, set targets, and it let to the creation of a national patient safety agency.

And amongst other things, set up a national reporting system.

So far, as they're had some technical problems with rolling all of this out, they're recorded 320,000 adverse events. We'd

earlier put in place legislation which was to create for the first time a duty of quality on every hospital in England,

including duty to provide safe care. We have an inspectorate a little bit like the Joint Commission, and that inspector's

fundamental purpose is to promote improvements in quality and safety of care. And we also we dealt with a strand, which was

to do with clinical incompetence by because we've had a lot of problems in the Bristol's system's heart service and other

isolated cases where individual practitioners had provided unsafe care. So we set up a new agency to provide support to

local NHS organizations when they're faced with concerns over the incompetence of performance of an individual doctor. We

were also told that there was nothing in the training programs of health professionals to deal with patient safety, clinical

quality, and therefore we extended the curriculum of trainees in post graduate medicine beyond the traditional areas of

clinical skills to set competency standard for clinical governance, patient safety, for communication, for team

working, and for multiprofessional practice. And that's being implemented now over the next few months. It's just recently

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been put into place. And we also, in producing a core set of standards for health care in the National Health Care Service. The very first standard, and these are being inspected for by the Health Care Commission, is to do with patient safety and you can see it set out there, the very first standard on this new set of standards. And we've been greatly assisted in promoting a culture and climate on national patient safety by some of our nongovernmental organizations, but particularly the Health Foundation, who have set up a program to major on creating some beacons in four hospitals to make them demonstration centers for improving patient safety. So we couldn't have done more, I don't think, to align our policies and our programs and the roles of our agencies and the professional bodies behind this agenda. But even despite that, we're not there yet, and think this is where the lessons come in. Where have we fallen down so far? Well, judging by the audio I showed you on intricacy called *Guidance*, we haven't yet fully engaged the CEO community, nor probably some of the professional leaders. We haven't got patient safety mattering as much to managers in the health service as hitting their access targets and reducing their waiting time. They don't live in fear of unsafe care in their hospitals, but they live in fear of not meeting their waiting time targets. And until we embed patient safety within the performance management structure and our incentive systems, we won't get anywhere. I

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don't think we've yet achieved the cultural transformation. I think things have improved but at the level of health organization and at the level of the clinical team, we have a lot further to go. Creating a more open climate for reporting, that's getting better. But the role of reporting systems, I think, given that we've accumulated all this national data, we still have a way to go in deciding how we move from that massive data into analyzing it and creating actionable findings. And I don't think we're doing as well as we could be in the vital task of communicating what we found back to the people who have made the reports. The Alliance industry gave great emphasis to that as a way of reinforcing feedback. And then, finally, I don't think we've embedded yet the consumer as demonstrated by some of those lonely voices that we heard in the system in the way that some other parts of the world have.

Finally, what are the leading edge issues in patient safety? Well, in many other fields of safety, the problem is solved not by human behavior, but by designing the unsafe situation out. And I think we've underplayed bringing in people who understand design, engineering, and things of that sort. It's not applicable to everything but it is applicable to some of the situations we found. Secondly, it is a battle to the health professions, particularly the medical profession, to remove their autonomy and stand to die some practice. I think we've got to face that challenge, however bloody the

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battle will be. I think we've got to see some form of standardization of some procedures. Picked up earlier in the conference, we don't train in teams and yet safe care is provided by good teams, good effective teams. Dysfunctional teams are a risk to the patient safety. The whole question of simulation is widely used in the air line industry. At the moment we can simulate some things, and simulation technologies are developing very rapidly. Perhaps we should set the challenge of saying that all major sources of unsafe care should be simulated in five years' time. I'm really trying to drive this technology towards what we want it to do. The implementation between what we know will improve the safety of care and what we do is a big gap just as it is on the field of spreading good practice. We're tending to look retrospectively at the things that go wrong, but there's a lot of skill in other fields in looking proactively. Some hazard analysis experts could walk into an operating theater tomorrow and point to the 50 things in the space of two hours, which were posing a risk to patients. We tend not to work like that; we tend not to think like that. Maybe we should. And then, finally, in most of the fields of safety where we're operating, we don't have a base-line measure of what we're trying to improve; we don't have an after figure; we don't have before and after; we just don't have the metrics and we need to put time into that. Was Wayne Gerard the last patient to die due to intravascular

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error? Intravascular vincristine error? Well let me read from you, just in conclusion, a press release dated the 2nd of November, 2005, two days ago from California. "Christopher Robin Lebido [misspelled?], age 21, died after a cancer fighting drug called Vincristine was improperly injected into his spine," said the State Department of Health Services in California. Investigators said the medication was mistakenly delivered libido's [misspelled?] bed side and doctors and nurses didn't notice the error until after the drug was administered. And the spokesperson for the state's attorney general said, "It was human error, unfortunately." The investigative report into Wayne Garrett's death showed human error was one of 40 different things that went wrong. Human error was one thing; the other 39 was systems failures. So there's the challenge; there's some of the experience in the UK, and I think those are some of the general points that we need to pursue if we're going to get the culture and the methodologies to improve patient safety in all our health care systems. And I hope that's been a helpful overview.

ED HOWARD: Thank you.

[APPLAUSE]

ED HOWARD: Extremely helpful. Thank you very much, Mr. Liam. Our two discussants offer us now some perspective on this from this side of the pond. Sean Donohue on my left is the health policy advisor to independent Senator James Jeffers

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of Vermont. Senator Jeffers is extremely active on a variety of health care issues here in Congress. Sean has held not only his current position but a variety of key positions in the Department of Health and Human Services and brings up a very rich background to this discussion. He'll be followed by David Kauffman who's a health research assistant on the Democratic staff of the Senate Finance Committee. He came to the committee from the University of California San Francisco Institute for Health Policy Studies where he had the great good luck to learn from the legendary Dr. Phil Lee, a health policy giant in this country from whom we all have learned, I think, in some way, so we're very pleased to have these representatives of Congressional viewpoints and let's start with Sean.

SENATOR JEFFERS: Thank you, Ed. And thanks to the Alliance and the commonwealth and Karen Davis for the invitation to come down and speak to all of you about what's probably one of the most compelling topics facing health policy today. Dr. Donaldson, your compelling stories showed just how it affects not just the patients that are harmed, but the parents of those patients even 30 years later and we really need to pay more attention to that. I just to briefly mention I welcome our guests from abroad but we have a few from the Washington Health Policy community here, and I just want to give my kudos again to the commonwealth fund and also the

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Alliance who do invaluable service to the Capitol Hill staff and other people. This is not the only session they do. They provide sessions throughout the year on a whole range of health policy topics that are really important for health staffers on Capitol Hill to hear so thanks—thanks again for that.

I knew you heard from Secretary Levit [misspelled?] as part of this and other leaders in our health care arena. Sounds like you've had a wonderful couple days. I wish we could have joined you. I know there were other Hill staff that wanted to sit in. Yesterday both the House and the Senate were in the midst of what we call reconciliation for our budget, which was a process of reducing funding for our health care programs; unfortunately, our Medicare program as well as our Medicaid program. So otherwise I think you've myself and some of my colleagues joining you for the sessions yesterday. It's very interesting that we're here in November because it's actually the sixth anniversary of *To Err Is Human*. Someone else may have noted that but it was in November of 1999 that that report was made available. At the time Senator Jim Jeffers, my boss, was the chairman of the health committee of the U.S. Senate, and we immediately began a number of hearings to look into the report's findings and its recommendations. In this country it was front page news on many newspapers for many, many days. The whole notion that up to 98,000 people per year were dying as a result of medical errors. It's

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interesting as well that almost six years later Dr. Burwick [misspelled?] and Dr. Lushan [misspelled?] article in the May issue of *Drama* points out that there is much left to be done, and yet in the intervening six years we have not accomplished nearly what we had hoped to get accomplished when we began these hearings into the report. I've been asked to talk to really briefly, and I'll speed this up, about a piece of legislation that Senator Jeffers was the principal sponsor along with many of his colleagues of the Patient Safety and Quality Improvement Act. That was a bill that was introduced immediately following the hearings in—I believe 2000—and it was really, I thought, done a modest bill that we'd be able to get done relatively quickly and that would address one of the key findings in the IOM report. And that was that the U.S. system for reporting patient and medical errors was burdened by the litigation of kind of atmosphere and environment that centers around health care practice in the United States. So what we sought to do, one of the principal goals was to develop a system whereby physicians and hospitals, other health care providers, might be able to report instances of errors that they were not otherwise reporting for fear of tort litigation. A report that we call patient safety organizations relatively new then, five years ago, that can then do an analysis and report back to us their findings. As Ed mentioned in the introductions, there are many controversial threats in this

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country to patient safety and the all motion of litigation and the consumers' access and redress to the courts is what encumbered our efforts in the United States. It took us all of five years to actually get the bill passed by both chambers of Congress and signed by the President, which he did just this past July. One of the key elements that Senator Jeffers came to this effort with was the notion that in constructing a patient safety system, reporting system, that there should be nothing that either strengthens or weakens the tort litigation process. It's very heart-felt in this country the individual right to redress in the courts. And that was probably the principal element in trying to negotiate this bill that we faced in trying to do that. It was not easy. In fact, at the end of this, I'm going to burden with a definition of legalese that took many, many people five years to write two paragraphs, about a paragraph and—actually, I need to commend several other members that worked on this tradition hearing in the Senate, and it's certainly well deserved. Senator Ensy [misspelled?] of Wyoming is the current chairman of the Senate Health Committee. The ranking member is Senator Kennedy. They definitely helped carry the ball over the goal line for us this year—could not have been done without them. Senator Gregg of New Hampshire was chairman during the last Congress. He made great progress with it in getting it passed for the first time passed the U.S. Senate.

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Let me just mention a little bit about what the bill actually does. There is a article in your materials that likens the Patient and Safety Quality Improvement Act to a movie star—and that is, he becomes famous on one day and the public just doesn't realize that they've had these minor roles going for about five or six years and it's an apt metaphor for the bill because it's exactly in putting it together. In general the law provides so that a provider, physician, can collect information and provide it to patient safety organizations for analysis. This information would be privileged and confidential in the context of the legal meaning of those terms. The law protects that information as it's collected or developed as well for those same purposes. And it establishes a network of databases through which this information in a nonidentifiable form can be fabricated, analyzed, and then reported back to the health care system. It has many definitions to it, but I'm going to cut to the chase here and paraphrase the paragraphs that I mentioned to you. The whole bill resolves around a concept we call the Patient Safety Work Product, which is analogist to what lawyers have in their work products and has provided lawyer/client confidentiality privileges. So the language in the law is, "Patient Safety Work Product means any data, reports, records, memoranda, analysis or written or oral statements, which are assembled or developed by a provider reporting the Patient

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Safety Organization and are reported to a patient safety organization or are developed by a patient safety organization for the conduct of patient safety activities." Welcome to the American legalese. "And which could result and improve safety healthcare." Part 2: "Which identifier constitutes that deliberations or analysis of or identify the factor reporting presented to a patient safety evaluation system." I'm not done. Quick clarification in law, "It does not include a patient's medical record, billing and discharge information or any other original patient information or provider record. Does not include information that is collected, developed, or maintained separately or exists separately from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting, be considered patient safety work product." That took six years to write. The nature of our political system. I hope the metaphor for the movie star isn't too much because so often these movie stars come and they make one or two movies and then you never see them again. I think the bill has been well received by the provider community. I think there's great hopes among the health quality community and the patient safety community that it will make a difference, that there are many components as you've heard today and throughout yesterday and today, to patient safety—one of which is data reporting—and I believe David's going to talk

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to you about those. Thank you.

ED HOWARD: Thank you, Sean.

[APPLAUSE]

ED HOWARD: David?

DAVID KAUFFMAN: I will talk about data reporting.

First I want to thank the Alliance and the Commonwealth Fund for putting events like this on. Certainly as a health staffer, I use resources all the time and coming out of academia we sort of look to the Commonwealth Fund and the types of things that they accept and the things that help affairs publish this equal standard that we want to achieve. So, I thank them for putting events like this together. I also want to note that my comments that I'm making today are my own and off the record. With respect to data reporting, I want to make clear that data reporting certainly is only one facet of patient safety. I think Sir Liam Donaldson is right. We need to engage health professionals, engage patients, create a culture of safety as Sean mentioned, the data reporting, and the types of institutions that process that data are also key. Not surprisingly, our process of data collection in the United States is about as disaggregated as our health system. Among the vast databases of longitude [inaudible] patient safety data come from managed care organizations and PBMs. It's not collected by the government and I think that was pretty clear when we finally discovered that Vioxx finally reaffirmed that

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Vioxx is associated with sudden cardiac death and heart attacks. That data did not come from the government. It came from Kaiser Permanente. They're a large national HMO. They had a large longitude patient safety database, and they basically used Kaiser's data to make that discovery. AHRQ, the Agency for Health Research and Quality, certainly collected a number of data, including the match database. That's available to researchers but it's not necessarily clear what they are always supposed to do with that data merely that they collected and sometimes reported. Within AHRQ we have the CERTS, which are Centers for Education and Research on Therapeutics. They are seven centers located around the country dedicated for studying drug safety and ethicist. And those centers each use their own database. Some collect from a Medicaid database, a local HMO database, each of these seven centers that study drug effectiveness and safety, each also use their own database. So we can set safety goals, but without a robust unified data collection system and its way of disseminating our analysis and feeding back to providers. These goals sometimes fall on empty ears. With the new Medicare prescription drug benefit that's set to come online January 1st, CMS—perhaps with the help of the finance committee—is hoping to link the upcoming Medicare Part B data claims with parts A and B of the Medicare system. Parts A and B work with hospitals and physician offices for those who are not familiar with the Medicare system. This would provide

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researchers with a longititude database to link pharmaceutical information with hospital, physician and other utilization data. And this would finally happen on a national scale. I think the benefits of this are pretty clear. Such a data base can provide better evidence, a need experienced Medicare beneficiaries using medications. One way this would happen is through post record surveillence of drugs and devices. Right now FDA approves drugs, sometimes mandates that the manufacturer conducts what's called Phase 4 post marketing studies. But it's up to the manufacturer to do them. Sometimes there's evidence that they aren't done as frequently as they should be or as frequently as FDA requires. And because clinical trials are handled limitedly with a few thousand patients and then moved on to perhaps hundreds of thousands of patients within a year, we need to collect this post market data, and this is an excellent system by which we could do that. Linking again, our Medicare parts A and B claims would also provide more evidence about drug use and a broader range of medical conditions as well as drug-drug and drug-disease interaction. Since these are all crucial to patient safety we would also include long-term studies of the impact on drugs on avoiding disease complications and their associated medical costs, which is again linking a little bit more towards quality, overall, as well as just safety. So it's a nice story. Perhaps we could have this national database to

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collect a variety of claims on a national scale. But that's only part of the story because if we're going to work with CMS on doing this or if we're going to write legislation from the finance committee to actually mandate that this happens, it's not all together clear who should get that data yet. We have [inaudible] database, which is simply provided through ARHQ researchers, and it's a great database that can be useful, but that's sort of an ad hoc system of just throwing ARHQ the research committee and letting them study as they wish. We could also give it to CMS. We could make it available to FDA. But it's not clear who has the most direct mandate to analyze data and certainly it's not clear who has a mandate to set goals in study how the United States is progressing towards those goals. We have a number of great institutions out there that are dedicated towards quality. We've heard from many of them at this conference saying, 'Oh, we have AHRQ, IOM, The National Quality Forum, The Institute for Healthcare Improvement, Don Burrick's [misspelled?] Institution, we have Leap Frog, just to name a few. Also we have CMS, the FDA; and with respect to licensing physicians, we have the Federation of State Medical Boards and the National Board of Medical Examiners." Quite the infrastructure and that's only a few of those that are out there. And when I think about what Sir Liam Donaldson said when they had recognized problem and it was very clear where NHS mandated that they have a national patient

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safety agency, a health care commission, a national clinical assessment authority, and each of these institutions had very clear mandates of what their role was and what they were supposed to do. And when we look at the problem in the United States, we certainly recognize the need for patient safety. But we don't know, necessarily, who to implement each of these programs. So I think that we face the same challenges as the UK trying to improve coordination between institutions and to focus on quality. But I don't think we're quite as far along as to finding which institution has which responsible and who conducts post market surveillance of pharmaceuticals and devices, who should set the goals, and who monitors progress towards these goals. So I would leave it at that. I think we're on the verge of being able to collect more data through the Part B benefit, but we need to make our institutions more robust and give them specific mandates of what each institution's role is in moving towards patient safety goals.

ED HOWARD: Thanks very much, David. While we have a few moments for questions, and I want to give you a chance to do that, there is a gentleman there, if you would identify yourself and use the microphone.

STEPHEN: Thank you, Stephen Fultz [misspelled] from the Health Foundation. Liam, I'd like to thank you for your presentation, in particular, I continue to thank you for bringing those personal moving stories to us all. It reminds

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us all of why we're still in the healthcare business. I've got three comments on your presentation. The first is just to ask a simple question and I imagine it's quite a complicated answer, which is why, in particularly in the Vincristine situation, we haven't been able to find a physical design solution for that. The second comment was to say that I agree with your really long list of reasons of why we haven't got there yet, but I'm going to add one more thing to that list and it comes from experience from the four sites in the UK that we're supporting at the Foundation, and that's that people really do need a considerable amount of technical assistance at the graduate level to be able to achieve some of these changes and that support comes in two forms. And it's in the sort of softer organizational development requirements but it's also in the hard clinical process redesign that changes are needed. My third comment is to agree with you that we ought to start thinking much more about training people in clinical teams and in the Health Foundation, we've just launched a new program whereby we'd be supporting clinical teams and diabetes care across the UK and providing funding to train them and in leadership develop to ram [misspelled?] quality, to do that not as individuals but as whole teams. Thanks.

SIR LIAM DONALDSON: Thank you, Stephen. And we need to learn from what you're doing in your four beacon sites and we'll take the last part of your question as comments.

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On the first part, Vincristine, three reasons, 1 that we can't do it in the UK alone because we have to go through the European Device Regulation System. Secondly, some of the early technical assessments have tried to produce a syringe that connects uniquely to a spinal connection when it's the right drug. You see what I mean? The technical device was because of the luer system of connections it could have adverse effects in other areas, but those could possibly be taken account of. And the third reason is because we were repeated by the Device Manufacturers that there wasn't a market for this. So there was no prospect of them being able to sell a product like this. Well, I hope we're about to change that by showing this isn't purely a UK problem. Although it's rare, it does happen in other parts of the world. So we're still working in, but it's very frustrating that five years on we still haven't gotten that design solution that would eliminate this error completely.

ED HOWARD: Yes, sir!

PHILIP DAVIS: Thank you. Philip Davis from the Department of Health in Australia. Thanks, Liam, for a compelling presentation there. I'd just like to pose a question whether we just heard about the arrangements to protect data provided for quality improvement. And I guess it's fair to say it's almost axiomatic in the quality arena. Not to find blame, or to punish in order to encourage reporting

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and ultimately quality improvement. But I do find my self wondering as I listened to your presentation and the 30 years of history in this particular circumstance, if there's a point when a risk is sufficiently well known, and the causes of the error are sufficiently congregated, it is in fact sustainable to continue to exempt people from being sanctioned from making errors. So I guess the question that I'm saying is there a point when an error moves from being an opportunity for learning and improvement and does actually become a matter of professional incompetence and perhaps ultimately tort?

SIR LIAM DONALDSON: Well, I think on the tort, even in the situation it's pretty clear-cut that an individual has been at the end of the chain of events, there is still a systemic chain of causation [misspelled?]. These doctors—maybe they should have checked more carefully—but who put inexperienced doctors into that situation telling them that patient had to be treated on that day otherwise he would go away without his treatment. I mean, it was a catalog of errors including there was meant to be a supervising doctor but a message went to his office. He didn't receive the message. The two drugs were brought to the clinical area in the same plastic container. They should have been separated. There was meant to be a nurse supervising the checking procedure. She was called away to something else. So, in fact the doctor at the end of the chain went to jail. I don't think that was fair or reasonable. But

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that's what happened and that's what will continue to happen. I think we do have to roll back the blame culture and I think we still have to persist with yes, we have to be sure that there are conscientious well trained safety conscious staff, but we also need to redress the balance where the system needs to be strengthened. And the accountability needs to be placed not on the person that made the error, but the accountability needs to be placed on the organization to learn. And where an organization hasn't learned, repeatedly, the CEO should loose their job in my view.

ED HOWARD: Sean, you have a comment?

SEAN DONOHUE: Not so much a comment as just a question for Dr. Donaldson. Medical malpractice looms large in the United States in a huge way. It influenced our patient safety effort and it is the most contentious debate going on certainly in our Congress right now. Could you just briefly, for my benefit, characterize how malpractice is dealt with in Britain, or the UK? Do people have access to tort litigation? You mentioned this fellow went to jail. We don't send ours to jail; we just make them pay a lot of money.

DONALDSON: Well, the family, Gowarts, they did sue though a lot of their money was taken away in lawyers' fees, but they did get some money in the end. But the criminal for manslaughter was brought against the doctor. It wasn't a civil procedure. Yes, we do have a system or tort legislation. It

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isn't quite as fierce as yours but we're trying in some ways to bring in elements of no fault to try and water down the blame and retribution and increase the neutrality and learning, which I think is very essential. But I think just picking up the comment you made earlier, what you described as far as legislation to protect reporting is very important, very important, but it is only one strand of the things we need to do on patient safety. And reporting systems are only one aspect of learning. I think it's very important we don't put all our eggs into one basket, but the opportunity, as I said in the final slide for proactive hazard analysis, looking at things before they go wrong, is equally important and if we have tunnel vision on reporting systems, we'll lose a big opportunity there.

ED HOWARD: Yes, sir! Probably going to be the last question so I know it's going to be a great one.

ADAM SHEFFLER: [Interposing] Adam Sheffler [misspelled?], here from Chicago, I just want to back up what you just said and compliment David's presentation and the concepts of your work, ask Sean what kind of technical assistance for doing proactive hazard analysis in addition to analyzing any reports coming into patient safety organizations, because the bill, as you know, or you don't know, doesn't provide any funds to set up patient safety organizations which is going to make it certainly not an incentive to create them.

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The motivation, as Dr. Burwicks said, has to come from within the health care's community regional state or otherwise to create these things, but they have to have funds to operate, to hire and train analysts, and to do technical assistance with all the health care providers and administrators in their regions. So where do you see that money coming from? Is that a role for foundations to step up right now before this whole idea just stays on the shelf.

SIR LIAM DONALDSON: Well, I've got two suggestions.

ADAM SHEFFLER: I was asking Sean.

SIR LIAM DONALDSON: I'm so sorry.

SEAN DONOHUE: Like so many other programs in our country we do fairly a good job authorizing and creating them and not such a great job funding them. We collectively were told, actually during the hearings, the original was for us to do a mandatory reporting system which was the key recommendation on the IOM report and we were quickly told that wasn't going to work out. In the ensuing years in trying to draft this, the hospital community in particular told us of what great value this would be to them in improving their own patient safety activities and would ultimately reduce, not only increase quality, but would reduce associated costs, insurance, litigation, things like that. So we were persuaded part by politics and part by the desire of the practitioners themselves, the providers themselves. It's a free market

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system if you will and there are hospital systems that are interested in doing, that are already doing it, and this should help promote that. We, Senator Jeffers, was among other colleagues thought that there should be other funding available and there should be greater tie in with our whole e-health initiative. The wheels of government move slow, particularly these days.

SIR LIAM DONALDSON: Just two thoughts really. Very, very quickly because I know we short of time. Firstly is the discipline of health of economics hasn't yet been brought to the field of patient safety in any big way and I think until we get some simple economic analysis of the harm and the benefits of programs to reduce harm, I think we haven't got the evidence to persuade for investment. The second thing is a suggestion. You seem to be quite keen on passing laws here in the United States. I would suggest you pass a law to make a proportion of litigation awards be invested in measures to improve patient safety.

ED HOWARD: That'll take more than six years [laughter]. David, you going to mark that one up next week?

DAVID KAUFFMAN: Oh, sure, we'll jump on that right away, yes. [laughter] I'll just add right away because we treat healthcare some much as a consumer good, a lot of the local quality incentives are driven by market forces and that tends to be through the contact of HMOs saying, "Gee, if we

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market ourselves as a leader of quality in the area, we can perhaps bring more patients into our network." And really, you do see some great improvements. Kaiser Permanente comes into mind, specific care they're doing, a variety of paper and performing measures. It in fact just opened their doors a little bit and let patients see what they're doing. And I think that these local initiatives have really been more effective than anything that's come out of the government, thus far. And it's been driven completely by the market. The market's not necessarily the solution, certainly what any just is done through really a command in program is sounds phenomenal. But it's the system we have right now. You go to the healthcare system you have, not the healthcare system you want sometimes.

ED HOWARD: Well, thank you very much, all of our panelists, especially Sir Liam, and join me in thanking them for what I thought was very useful conversation.

[APPLAUSE]

[END RECORDING]

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