DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 26 Meán Fómhair 2018

Wednesday, 26 September 2018

The Joint Committee met at 9 a.m.

MEMBERS PRESENT:

Deputy Stephen S. Donnelly,	Senator Colm Burke,
Deputy Bernard J. Durkan,	Senator John Dolan.
Deputy Alan Kelly,	
Deputy Margaret Murphy O'Mahony,	
Deputy Kate O'Connell,	
Deputy Louise O'Reilly,	

DEPUTY MICHAEL HARTY IN THE CHAIR.

Business of Joint Committee

General Scheme of the Patient Safety Bill 2018: Department of Health

Chairman: This morning we are meeting with officials from the Department of Health as part of the committee's pre-legislative scrutiny of the general scheme of the Patient Safety Bill 2018. The Bill covers a number of patient safety priorities, including mandatory open disclosure of serious, reportable patient safety incidents, the notification of reportable incidents to the regulator, the use of clinical audit to improve patient care and outcomes and the extension of HIQA's remit to private hospitals.

On behalf of the committee, I would like to welcome Dr. Tony Holohan, chief medical officer; Mr. David Keating, head of patient safety and advocacy policy unit; and Ms Elizabeth Adams, patient safety and advocacy officer of the Department of Health.

I draw the attention of witnesses to the fact that by virtue of section 17(2)(*l*) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of their evidence to the committee. However, if they are directed by the committee to cease giving evidence on a particular matter and they continue to so do, they are entitled thereafter only to a qualified privilege in respect of their evidence. They are directed that only evidence connected with the subject matter of these proceedings is to be given and they are asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person, persons or entity by name or in such a way as to make him, her or it identifiable.

I wish to advise the witnesses that any opening statements they make to the committee may be published on the committee's website after the meeting.

Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the Houses or an official either by name or in such a way as to make him or her identifiable.

I now ask Dr. Holohan to make his opening statement.

Dr. Tony Holohan: I thank the Chairman and the committee for the opportunity to come before you today on the legislative provisions proposed within the general scheme of the Patient Safety Bill. I will keep this statement short and I am happy, as we all are, to reply to any questions.

As the Chairman has said, I am joined by Mr. David Keating and Ms Elizabeth Adams from the patient safety, policy and advocacy unit in the Department of Health.

The Government directed the Department to undertake the development of the Patient Safety Bill in May of this year. This Bill incorporates the patient safety elements of the Health Information and Patient Safety Bill which introduces a requirement for external notification of patient safety incidents to the appropriate regulator and to the State Claims Agency. It also

empowers the Minister for Health to issue guidance with respect to clinical audit and extends the remit of HIQA to private hospitals on top of HIQA's existing statutory powers.

These elements in fact previously underwent pre-legislative scrutiny in January 2016 when consideration was given to the full Health Information and Patient Safety Bill. In addition, the Patient Safety Bill now also provides for mandatory open disclosure of serious reportable events. That is the added part since the pre-legislative scrutiny in January 2016. As such, this legislation complements the measures contained within the justice legislation, the Civil Liability (Amendment) Act 2017, which was passed by the Houses last year and which provides protections from liability for clinicians engaging with open disclosure and important elements of that were commenced in the early part of this week.

I wish to alert the committee to an additional aspect that has emerged since the Government approved the Bill. Earlier this month, the High Court overruled the Minister's decision to require HIQA to undertake a section 9(2) investigation into the circumstances surrounding the death of Mrs. Malak Thawley at the National Maternity Hospital in May 2016. This judgment has revealed that there may be a need to enhance powers in relation to section 9 of the Health Act 2007. This may require amending legislation. While the Department is still in the process of considering how best to address this, it might be that some modifying provisions will be brought forward within this Bill and that is under consideration.

I now turn to the primary elements of the Bill before us, beginning with open disclosure. Creating a culture of open disclosure and learning from things that go wrong is the bedrock of making services safer. In line with the long-standing approach of the Department on this issue, open disclosure should be an open and consistent approach to communicating with patients and their families when things go wrong in healthcare. This includes expressing regret for what happened, keeping patients informed, providing feedback on investigations and the steps taken to prevent recurrence of adverse events.

I would like to recall that, last year, the Houses of the Oireachtas provided protections, as I have briefly mentioned, from liability for clinicians making a disclosure through the Civil Liability (Amendment) Act of 2017. During the passage of that Act, a number of Deputies sought to amend the legislation to provide for a mandatory approach. As that legislation was extremely broad and applicable to a wide variety of health and social care settings, it was ultimately decided by the Oireachtas not to be the appropriate vehicle for mandatory open disclosure. The Minister for Health did, however, undertake to bring forward legislation to provide for a mandatory duty to disclose at an early opportunity and hence the Bill that we have before the committee today for its consideration.

It should be noted that, with the commencement of part 4 of the Civil Liability (Amendment) Act, the regulations arising from it and their provision for a framework to support openness, transparency, timely disclosure and an apology for unintended or unanticipated injury have come into effect earlier this week.

Mandatory open disclosure is about building patient and public trust in the health system. The recently published report of Dr. Scally's scoping inquiry provides a clear analysis of the system failures that occurred in CervicalCheck, based on patient and family accounts of their experiences. We must now ensure that the learning from this report is used to drive the changes we want to see so as to ensure that patient safety is a primary element driving and shaping policy for the health service.

I would like to reassure the committee that the Department has taken close note of Dr. Scally's findings and, in particular, regarding the primacy of the right of patients to have full knowledge as to their healthcare as and when they wish. While the current approach to disclosure within the health service has had positive impacts within and across the service, the Scally report has identified significant issues which now need to be remedied and this Patient Safety Bill, while in development prior to the receipt of the Scally report, will now be one of the primary means for responding to important aspects of his report and will provide the legislative underpinning for mandatory open disclosure.

Fundamentally, the Bill will introduce a requirement for disclosure of serious patient safety incidents. The definition of a serious patient safety incident includes the death of an individual; a permanent lessening of bodily, sensory, motor, physical or intellectual functions; and, harm which is not severe but which otherwise results in, for example, an increase in the requirement for treatment or a requirement for treatment to prevent death or injury.

The Minister for Health will prescribe the specific incidents to be disclosed in secondary legislation under the powers conferred upon him in this legislation. This definition is in line with recent legislative definitions incorporated in Scotland in their Act of 2016 which, in turn, builds on the duty of candour arrangements in operation in England since 2015.

The Bill provides the legislative framework for a number of recommendations of the Scally report on placing a statutory duty of candour on individual healthcare professionals and healthcare organisations. The Bill provides that it shall be an offence for a health service provider to fail to make a mandatory open disclosure or notify a reportable incident to the external authority. A registered health service provider guilty of an offence will be subject to penalties in the form of a fine or imprisonment. It is similar to the approach of the UK, where the duty of candour regulation seeks to hold providers and directors to account. It is a mechanism to hold the owner, management or board of an organisation to account and ensure that the individuals at the top of the organisation are invested in quality and patient safety.

Regarding individual health practitioners, the policy is to distinguish between genuine unintentional acts of omission or commission that can lead to harm and the much rarer acts of wilful negligence or deliberate breach of acceptable practice. In the drafting of the Bill, the inclusion of a defence will also be incorporated.

In terms of the notification of reportable patient safety incidents, the report of the Commission on Patient Safety and Quality Assurance - the so-called Madden commission report - recommended that provision should be made for the mandatory reporting to the appropriate regulatory body of adverse events that resulted in death or serious harm. The commission also recommended that provision be made on a voluntary basis for other less serious, as it were, adverse events and "near misses". The commission concluded that a mandatory system would improve patient safety and ensure greater accountability by requiring specific reports of serious injury to be made by healthcare organisations, with disseminating lessons to be learned throughout the health system. The Bill provides for mandatory notification of serious patient safety incidents to a number of bodies, including the State Claims Agency, HIQA and the Mental Health Commission, depending on the nature of the incident.

Regarding clinical audit, it would be helpful in the first instance to give some definition of what we mean. In this context, clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit standards and acting to improve that care where these standards are identified as not

having been met. Defining clinical audit in legislation recognises the need to have a standard definition and associated methodology to ensure that there is consistency of approach across the health system. The Madden commission advocated building a positive culture of participation in clinical audit that would benefit patients and the health services as a whole, and recommended that legislation be introduced providing for: exemptions from freedom of information, FoI, legislation for records arising from clinical audit activities and related activities; and protections for these records from admissibility as evidence in civil proceedings. It was envisaged that certain legal privileges would be granted if guidance on governance, methodology and clinical standards for clinical audit was followed by the individuals undertaking the clinical audit activities. This Bill will enable the Minister to issue such guidance, subject to public consultation. Where clinical audit is carried out in accordance with that guidance and aggregate results are published, any record created solely for the purpose of the clinical audit will not be admissible as evidence in civil proceedings and the FoI legislation will not apply to that specific record. This part of the Bill will therefore support those who use clinical audit to improve the quality of care provided.

Of course, such protections do not exempt healthcare organisations or health professionals from their responsibilities where a serious patient safety incident has been discovered during the audit process. Where any serious patient safety incident is so discovered, mandatory open disclosure would clearly apply. The governance framework, methodology and reporting of clinical audit will all be incorporated into the Minister's guidance on clinical audit that will be developed by the national clinical effectiveness committee, which operates to and through the Department.

The Oireachtas committee will recall that we appeared before it recently when it examined the patient safety (licensing) Bill, which will provide HIQA with full regulatory responsibility for all hospitals, public and private. In advance of that, the Bill before us today will provide for the extension of HIQA's existing powers in respect of the setting of standards, monitoring of compliance and undertaking of investigations to the private hospital sector. It is a step along the road towards licensing. Extending these powers will ensure that all defined private and public health service activities will be subject to the same standards and be monitored by the same authority, with the exception of those that fall under the remit of the Mental Health Commission.

In conclusion, I would recall that the scoping inquiry - the Scally report - has identified what those involved in a patient safety incident want: to be told what happened and why, that is, the truth; for someone who was involved to say he or she is sorry and to mean it; and to be assured that this will not happen again to anyone else. Through this legislation and other policy and legislative steps that the Department is taking, that is exactly what we are trying to achieve.

We are happy to take whatever questions members might have.

Chairman: I thank Dr. Holohan. This Bill introduces mandatory open disclosure as opposed to the civil liability Bill, which proposed voluntary open disclosure. I believe it was Dr. Holohan's recommendation at the time that disclosure should be voluntary rather than mandatory. What issues have led to the change in recommendation?

Dr. Tony Holohan: It is not really a change. The voluntary system, as provided for in the civil liability legislation, and the mandatory system to be provided for in this Bill will sit alongside and complement each other. Voluntary disclosure and the protection it offers are about the totality of patient safety incidents. Even though we say "voluntary disclosure", we do not mean "optional". Rather, we mean that disclosure should take place in every situation, in the

right way and according to the kinds of issue that I referenced at the end of my opening statement. We are trying to determine what the evidence tells us about the best means of achieving the greatest likelihood of that happening in every situation. In policy terms, our approach is to have a combination of supports that give assurances to practitioners that, if they do the right thing and do it in the right way, protections will be offered along the lines I have described - we can set them out in more detail - from FoI, admissibility and so on. This is meant to encourage them to do the right thing, but will be complemented by an absolute requirement that makes mandatory the reporting of serious patient safety incidents as opposed to every patient safety incident. There is a difference in nature and number between serious patient safety incidents and all patient safety incidents. The two approaches are not at variance. It is not a switch from one position to another. They will sit in legislative and policy terms alongside each other and complement each other.

Chairman: Is Dr. Holohan making a distinction between voluntary disclosure to the patient or his or her relatives and mandatory reporting of the incident to the regulator?

Dr. Tony Holohan: No. In both of those situations, I am talking about the disclosure to the patient. The piece we have added to this legislation since it was before the committee in 2016 is the requirement that, for a specified number of serious patient safety incidents, it will be mandatory to report those to the patient. It was already our provision for that to be mandatory in terms of reporting to HIQA and the State Claims Agency and it is the same list, but we have added an absolute requirement of open disclosure to the patient as well. This is in addition to the supports we have in terms of voluntary open disclosure.

Many comparisons have been drawn between policy, legislation and practice in Ireland and the duty of candour in the UK. Clearly, the UK is ahead of us - it is ahead of the rest of the world - in its legislative provisions. There is value in that for us from a learning point of view. The UK's duty of candour provisions do not extend beyond requirements on organisations. Our requirements extend not only to organisations and the duty on people who have corporate responsibilities within health service organisations, but also to practitioners. When this legislation is enacted, there will be a duty of open disclosure on organisations and practitioners, which goes considerably further than the UK's duty of candour.

Chairman: I thank Dr. Holohan. We will go through the party spokespersons first. Are we agreed on five-minute exchanges between members and the witnesses? We will see how we get on.

Deputy Louise O'Reilly: Yes. Are we just taking the second part now or all of our questions? I have quite a few questions.

Deputy Stephen S. Donnelly: The Deputy can take 15 minutes.

Chairman: Deputy O'Reilly can ask questions on whatever she wishes. She will have an opportunity to contribute again.

Deputy Louise O'Reilly: I do not want to go on because I suspect that my questions will be similar to others'. I am happy to proceed in any order.

Chairman: I call Deputy Donnelly.

Deputy Stephen S. Donnelly: I thank Dr. Holohan and his officials for their time.

Dr. Tony Holohan: No problem.

Deputy Stephen S. Donnelly: I will start with the changes that have been proposed to the Bill since the last time it was discussed by the committee. They are to increase the Minister's power to direct investigations. This relates to the tragic case of Ms Thawley in the National Maternity Hospital. Dr. Holohan referred in his opening statement to the interesting judgment in that case. In his legal judgment, the judge said he was not satisfied that section 9 was complied with and directed that no section 9 investigation should be undertaken. He was scathing about the Minister. He said that the Minister was "irrational and unreasonable" and that the Minister's assertions stood up to no analysis. He said it was clear that the findings, recommendations and conclusions of the National Maternity Hospital's report were not properly considered by the Minister. It appears from the judge's scathing report that the Minister has failed entirely in his duty in this case. I am concerned that it is recommended to give such a Minister even more powers. I ask Dr. Holohan to comment on that.

Dr. Tony Holohan: I would be happy to do so. To be clear, nothing in what we are proposing in the legislation at the moment addresses this question. I am simply saying that this is now a very relevant issue in the context of the legislation. We think that when we have completed our consideration of the judgment to which the Deputy is referring - we are looking at what it means for our arrangements, such as our capacity to respond to patient safety incidents of whatever form and in whatever way - we might conclude that some additional legislation, which might include additions to the legislation here, might be necessary. That is all I am signalling.

I will comment on the substance of the point the Deputy is making. He is factually correct in his references to the terminology that was used in the judgment. I will outline my sense of how I would characterise it. The Minister has said in his public statements on this matter that he fully respects the decision of the court in all of this, as indeed does the Department. It means that the Minister's sole investigative power which is set out in legislation - the section 9 power - is rendered inoperable, in effect, from our point of view. I am giving the Deputy my assessment of things as they stand, rather than a legal judgment. We are going through the process of analysing the judgment properly. The conditions we would have to satisfy to activate the Minister's section 9 power would almost require us to have the outcome of an investigation available to us before commencing the investigation.

Deputy Stephen S. Donnelly: I take Dr. Holohan's point. Obviously, any Minister needs a suitable power to investigate.

Dr. Tony Holohan: Absolutely.

Deputy Stephen S. Donnelly: According to the judge, the Minister acted in an incompetent, irresponsible and unreasonable way.

Dr. Tony Holohan: If I may say-----

Deputy Stephen S. Donnelly: In my opinion, this weakens the argument to give the Minister further powers.

Dr. Tony Holohan: The judgment has to be seen in light of its assessment against the provisions of section 9. The way I would characterise this - I am not a legal person and I am not paraphrasing legally - is that the bar in respect of section 9 is so high that it is almost impossible to reach. It is significant from a patient safety point of view that a Minister is in the situation our Minister is now in. He is unable to operate or act, in legal terms, on the significant concerns he

still holds regarding a particular patient safety incident. I am not getting ahead of where we will end up when I say that this might well lead the Minister to conclude that he needs additional powers and an additional ability to act in the public interest in situations where he has genuine concerns about patient safety.

Deputy Stephen S. Donnelly: Obviously, the proposed Bill represents a cultural change for clinicians, doctors, nurses and everyone involved in the clinical world. It is a very welcome change, but it could be a very scary change. A breakdown in the information flow between treating clinicians and the women who were affected was essentially at the heart of the CervicalCheck scandal. For a variety of reasons, the treating clinicians refused to share the audit results with the women involved, or did not feel comfortable doing so. We heard from Dr. Scally that international evidence suggests that this can be partly attributed to reputational damage for the hospital or acute setting, to damage to staff, and to legal risks or concerns and so forth.

Given that the provisions of last year's Bill and the proposals in this Bill represent a move towards a change in the culture so that mandatory disclosure by clinicians is required under law, is Dr. Holohan satisfied that the supports which will be needed by those clinicians will be in place so that mandatory disclosure can be done in the right way? In a briefing on the day his report was launched, Dr. Scally made the point to us that mandatory disclosure can be very damaging if it is done in the wrong way. Is Dr. Holohan satisfied that the legal protections are in place, that the training will be in place and that all the other supports which are required for mandatory disclosure to work properly will also be included as we require our clinicians to disclose?

Dr. Tony Holohan: The straight answer to the Deputy's question is "No". I am not yet satisfied about that. The Scally report sets out some very important findings and highlights some very significant deficiencies in a number of respects. The Deputy has referenced some of the areas in question, such as training. The report brings it right back to the very point the Deputy has made about culture. Ultimately, this is about changing the culture. Things like training and changes in legislation, policy and practice contribute to that culture. Ultimately, this is about the difficult job of changing the culture. Dr. Scally has left us with a set of 50 recommendations. The Minister has publicly made clear his intention regarding the recommendation on implementation. It is intended that we will frame an implementation plan within three months of publication and bring that plan back to the Government, with all the implications that would have, including some of the things referred to by the Deputy. Perhaps it would also include a need for some additional legislative measures. I would not rule that out. The process is under way. It is happening under the auspices of the CervicalCheck steering committee, which includes patients, patient organisations, the HSE, some clinical organisations, the Department and others. The committee is overseeing the whole process of implementation planning. It will present, through the Minister, a plan for approval by the Cabinet by the end of the year. It is only when we have implemented that plan, the totality of what it provides for or implies in terms of legislation and resources and the pathway it lays out, that we will be able to say that we have assurance in respect of the things Dr. Scally has found. We are at the start of that journey.

Deputy Stephen S. Donnelly: I would like to ask a final question on the same topic. Given that the Oireachtas is proposing it will be an offence under law for doctors, nurses and allied health professionals not to disclose, those clinicians who are watching this space will want to know that the necessary legal protections and training will be in place as this becomes their legal responsibility. Can Dr. Holohan give a commitment to the clinicians who are watching this legislation unfold that adequate legal protections and training will be in place for them at

the time when mandatory disclosure will be a legal requirement for them? Is it the case that the law is going to require them to mandatorily disclose before we have all the adequate supports in place for that to happen?

Dr. Tony Holohan: It is proposed that this will be an offence in cases of serious patient safety incidents as set out in the Schedule. Clearly, the intention will be to have appropriate education and training in place. That does not just fall to the Department or the HSE. The training bodies themselves will have a significant role. For that reason, among other reasons, I engaged the leadership of the various medical colleges last week. We continue to commit to work with them to try to determine together what needs to happen. Regardless of how one might characterise what has happened in recent months, my personal view - and no criticism is implied here - is that it has first and foremost led to an erosion of societal trust in the profession. In some quarters, there has been a questioning of the extent to which the profession fully subscribes to some of the ethical principles of openness, trust, honesty, disclosure and so on. While it is clear that the Government and the health service have to do a major job of work to rectify much of that, in my view there is also a need for the profession to find a means of engaging directly with society to address these questions. This process should not be mediated through a Minister or through the HSE. It is necessary for the standing of a profession that has been questioned, at least in some quarters. I think we all hold the view that the vast majority of health professionals fully uphold the standards about which we are speaking. We have, however, been through a process whereby people have been, not unreasonably, questioning these things. It is important that the profession finds a way of addressing some of that. Part of the discussion has also led us to the question of how we, together, can support one another to achieve some of those objectives. If the colleges and other leaders within the profession are bringing forward leadership proposals in terms of their requirements in respect of education and training not just for the legislation, but for any other aspect of the response to what has happened and what is laid out in Dr. Scally's report, how can we best support those proposals? This is not something we can do separately. My own strong sense is that - and this is why we have a CervicalCheck committee organised in the way it is - it is only through patients, patient organisations, professional organisations, the HSE, the Department and others working together to the same common objective that we will achieve what Deputy Donnelly is describing.

Deputy Louise O'Reilly: Four agencies are mentioned in head 9. Those agencies are the ones which will be in receipt of the reportable incident. Will we have a very tight definition of what constitutes a reportable incident? With regard to who has ownership of the information, there is potential for two or possibly three of those agencies to be holding information at the same time. Who has ultimate responsibility for the safeguarding of that information? Where will it be stored? Who has responsibility for acting on it? With regard to the agencies, and to HIQA in particular, is it envisaged that the powers HIQA has under the 2007 Act will be enhanced or improved in any way to ensure that it can fully comply? There is a lot about monitoring but there is little about - and I hesitate to use the word but Dr. Holohan knows what I mean - enforcement. Will HIQA have any powers or will it simply record? If it is just going to be a recording and reporting mechanism with no follow-up the best use will not be gotten out of it. As I understand it, the named agencies will be setting standards. Who will be enforcing them? How is that going to happen? My reading is that there is going to be a fairly significant increase in the workload of the agencies involved. That is appropriate, obviously, but if they were here they would tell Dr. Holohan that they are stretched already. I can see he is smiling because of course they would say that but, as it goes, they are. Is it envisaged that additional resources-----

Dr. Tony Holohan: Yes.

Deputy Louise O'Reilly: -----will be provided? With regard to the publication of the clinical audit results, is it intended to publish the reasons the audit was undertaken in the first place? That might be useful information to have. With regard to HIQA and the regulation of public and private hospitals, is it intended that places that are not hospitals but smaller places where one can go for cosmetic surgery and that sort of thing will be included in such regulation? Is it intended that this will apply beyond what we would consider to be private hospitals to private healthcare facilities?

Dr. Tony Holohan: Yes.

Deputy Louise O'Reilly: The powers to monitor are important, but the powers to enforce are even more so. While the monitoring is welcome, without the powers to enforce the Bill will probably not have the desired effect. Sin é.

Dr. Tony Holohan: I will come in on a number of those questions. My colleagues may wish to come in and supplement some of what I might say. There will be a tight definition and, ultimately, a list of those. The list will be subject to change. The Deputy may be aware that there is already a list in operation on an administrative basis within the HSE. It has a governance mandate from the top of the HSE but it does not have legal standing as things stand. It would be something along the lines of that list and would not be terribly dissimilar to those that exist in other jurisdictions. My strong sense is that we would need a process to continue in order to advise on changes that would need to be made to that list on an annual basis. Things could get added or taken away but there would be a very clear list and definition of each reportable incident.

On the powers and the powers HIQA has under the 2007 Act, what we are proposing as our direction of travel in respect of licences will add substantially to the potential powers of enforcement that HIQA would have that would be relevant in this context. In the context of the powers, the powers are as they are written in the 2007 Act.

Deputy Louise O'Reilly: Additional powers will be introduced via the licensing.

Dr. Tony Holohan: Substantial additional powers will arise through the licensing legislation.

Deputy Louise O'Reilly: What will the sequencing of that be?

Dr. Tony Holohan: That is also in drafting as things stand. It is a longer process so we expect this to be drafted and enforced before that. From our point of view that is the logical step. We are moving in the direction of a full licensing system so the step of extending the existing powers to bring in more private providers - and I will come back to the Deputy's question on that - is a step along the way to ultimately having a fully licensed arrangement where, at least from the licensing point of view, it will not matter if the provider is in the ownership of the State or in the ownership of some other organisation in terms of the standards that have to apply and the protections for the patients using those services.

Deputy Louise O'Reilly: This will come first and the powers will come after, or not.

Dr. Tony Holohan: Exactly. To deal with the Deputy's question in relation to cosmetic surgery providers, the definition of what would come under this provision will include private hospitals and other activities of a kind one would expect to see happening in hospital-type environments. For example, the use of general anaesthesia would be the kind of thing that would

ultimately determine the requirement for a licence in full licensing terms. We would not see this just applying to buildings. It covers activities and the nature of the risk that attaches to those activities more than anything else.

Deputy Louise O'Reilly: I do not want people to think I have a particular interest in cosmetic surgery but is it the intention that it will apply to those smaller-----

Dr. Tony Holohan: Yes.

Deputy Louise O'Reilly: -----facilities where what one could consider to be surgical procedures are carried out? It is.

Dr. Tony Holohan: We were before this committee some years ago in respect of a breast implant issue with a number of private providers. The Deputy might recall that engagement. We had engagements to try to address that issue. All we were really doing at the end of the day was appealing to the providers' better nature. That is a good example of why we need powers that enable us to intervene on safety issues that arise.

Mr. Keating might deal with the resources issue in a moment. On the reasons for the audit, a requirement to set that out will not be specified. Many of the audits we could be talking about would be systematic audits that are ongoing and designed into the system on a continuing basis. An example might be - dare I say it? - the audit process around screening. This is designed to give assurance to individuals that if they participate in the audit they will not be contributing to their own risk and liability in the conduct of that audit. It is to give them that assurance and to encourage people into the safe space. I think I have covered everything. Mr. Keating might come in on the resources.

Deputy Louise O'Reilly: I had also asked about the holding of information.

Dr. Tony Holohan: The requirements in respect of any organisation which holds patient information are such that they will each have a responsibility arising from the GDPR, the legislation and the legal framework that operates in that area.

Deputy Louise O'Reilly: My question was more about the fact that four agencies could potentially all have the same piece of information. Is there going to be a link-up between them? The last thing we want is for four agencies which all have the same piece of information to be looking at the other agencies and thinking that it is the other agencies' job to deal with it rather than their own. Where the information is stored is as important as identifying who will be acting on it. It is not the intention of the Bill - and we could perhaps make it a bit stronger - to ensure that this does not happen but there has to be some responsibility attached to the legislation beyond only the responsibility to store information in line with the GDPR. It also has to include a responsibility to ensure that information is acted on so that people do not look to their left or right and think that, even though they have the information, another body also does and then assume that the other body is acting on it. We saw that with CervicalCheck. There were people who should have been advising but who were looking at it and saying that they did not think it was definitively their job to deal with it and then putting it to one side. It is not just a matter of taking responsibility for storing the information but also for acting on it. Perhaps we could do a bit of work on tightening that up.

Dr. Tony Holohan: I take that point completely. We have strengthened some provisions in the Department and the patient safety office in respect of what we call patient safety surveillance because of what we uncovered in Portlaoise. I refer to the deaths of the four babies that

came to public notice in the early part of 2014. When we had an opportunity to ask a number of agencies, each of which had a different relationship with the hospital, whether they had a concern, it became clear that there were a number of pieces of a jigsaw that had not been put together. Therefore, our intention in creating a patient safety surveillance function is to try to put all the information on one table so there is as much early warning as possible. As the Deputy rightly said, there is little point in having one organisation understanding something if another that could act does not have access to the information. We are committed to addressing this.

Mr. Keating might speak about resources.

Mr. David Keating: On the point on HIQA, the Mental Health Commission and so on requiring additional resources, I would be more familiar with HIQA than the State Claims Agency or the Mental Health Commission. As Dr. Holohan said, we are travelling in a certain direction with HIQA in that it is going to be moving towards licensing. It is taking on other roles in respect of undertaking a national patient experience survey. It is the competent authority for ionising radiation. This year an additional 47 posts have been sanctioned, or will be sanctioned by the end of the year. There has been an increase of approximately €3.4 million over the 2018 budget. We are currently considering what the 2019 budget might be.

Deputy Alan Kelly: A number of my questions have already been asked. From a legislative point of view, we will be debating a lot of terminology and definitions. That will come out in the wash. Some work probably needs to be done in this regard.

I have a general concern. The legislation will have to be drafted in such a way that makes it flexible enough to be adaptable from a ministerial point of view. It will change all the time. The witnesses should bear that in mind. It is an important point because definitions and terminology will change. Court cases will arise that will have consequences. We need to bear this in mind in the drafting of the legislation to allow for direct ministerial powers to make changes quickly.

The real issue, the real nut, concerns how the legislation will be implemented, reporting back and the volume of resources. How will we ensure that the organisations across the health service will be resourced to deal with this? Is there a plan in place? Dr. Holohan might answer that first. I will come back to my other questions.

Dr. Tony Holohan: That is something we will have to do as part of the preparation for implementation. A large part of that will fall into the work we will do after the Scally inquiry. As I am sure the Deputy has seen, the recommendations in the Scally report and the findings cover three separate chapters that deal with different aspects of open disclosure as it applies to different parts of the system. Dr. Scally has certainly more than ten specific recommendations that relate to open disclosure. There is a substantial job now happening on open disclosure preparation. It will include revisions of the policies. We have gone a step into the specifics of how we might consider doing that, bearing in mind what the Minister announced in the very early days after the publication of the Scally report. A big job of work will have to be undertaken. It will include planning for whatever resources will be needed and go beyond some of the organisations mentioned in the report. Disclosure is a reality for some organisations and will be very-----

Deputy Alan Kelly: This goes way beyond the Scally report. We will not be implementing this on the back of the Scally report. It is specific. I have read the Scally report and know the recommendations inside out. Of course, it is a kick up the backside to say we have to go in a certain direction but that is what it is. This is a mammoth task. It has to be done pretty quickly.

How are we to resource the organisations to do it, even from an administration perspective alone?

Dr. Tony Holohan: My comments concerned the open disclosure components and where they overlap with Scally. The Deputy is correct, however, that the broader requirements in terms of reporting and auditing will present a substantial implementation challenge. We will do as we do with every Act. Our implementation planning is done for the most part but not only with the HSE and in parallel with the process of drafting so we will have prepared the ground as best we can to try to enable the effective implementation of the legislation when commenced.

Deputy Alan Kelly: Dr. Holohan should flag with his Minister the fact that this has to be done and that it is a priority given what has transpired over recent months. It is a priority for us as a country. I am not confident that the resources will be in place to implement the legislation. This is not a reflection on anyone. I am not confident that from an organisational point of view, the work can be done in the time required. There will also be a significant cost. It will all require resources and staff time. It will create different pathways for managing information and it will create electronic and technical requirements. There is an overlap with GDPR. A range of issues will arise. It will take time and resources, and there will be costs. I want to feel confident that will we will be able to deliver. Will we?

Dr. Tony Holohan: I assure the Deputy that we will do the best job we can in planning for the resource requirements, and we will set them out in the way we have to.

Deputy Alan Kelly: Has that planning started?

Dr. Tony Holohan: Yes. It is an ongoing process.

Deputy Alan Kelly: How? If I ring up the CEOs of the acute and non-acute sides in the mid-west or south east - I am in a dual jurisdiction - and ask a question for the Minister, I am sure I will discover they will have had multiple meetings on this.

Dr. Tony Holohan: No. We would not have had multiple meetings with people in the mid-west on this but I can tell the Deputy-----

Deputy Alan Kelly: How are we planning for resources throughout the country in that case?

Dr. Tony Holohan: There is a couple of ways. The general approach is what we have been trying to do. One will see it if one looks back through the HSE service plans for recent years. It involves trying to ensure the so-called patient safety programme, which runs right through the organisation from the top and should be running down into the CHO areas and local hospital groups, results in the putting of warm bodies and real capacity into enabling the implementation of a range of patient safety measures, including the one in question.

Deputy Alan Kelly: Dr. Tony Holohan is saying there is a pathway already in place and that the same one is to be used.

Dr. Tony Holohan: Yes, the pathway is in place. The pathway essentially comprises the capacity needed at national level, which we have, and the capacity needed at the level of each individual group. I have said to this committee before that the most important place to put our capacity, in terms of people working on patient safety, is at the front line. One needs to have people who have expertise in these areas working on implementation.

I cannot tell the Deputy that the level of resources and capacity we have in this regard are sufficient for the plans we have, which is why we have an ongoing process of planning. Ultimately, that finds expression in the context of the Estimates each year. Each year, we have to make a case overall for whatever public funding is available to support implementation, not just of this measure but of everything else that has to happen through the health system. It is a matter of trying to ensure that adequate priority is given to this in line with all the competing interests.

Deputy Alan Kelly: Is there a ballpark figure for how much it will cost to implement?

Dr. Tony Holohan: I could not give the Deputy an end-to-end figure on this specific legislation as we have not costed it that way. We have, however, set out-----

Deputy Alan Kelly: I presume it will be costed.

Dr. Tony Holohan: Yes, but we do not just cost this in isolation. Ultimately, the work that has to happen on patient safety in support of all this is the same work that has to happen on every other aspect of patient safety that has to feature on the ground.

Deputy Alan Kelly: I accept that but there will be extra costs, let us be honest.

Dr. Tony Holohan: Absolutely.

Deputy Alan Kelly: Surely, as part of a budgetary process-----

Dr. Tony Holohan: We engage with the HSE. As Mr. Keating said in the context of HIQA, there is a process whereby we are trying to finalise our estimates for everything in advance of the budget. The part for which we will have responsibility is ensuring there is adequate-----

Deputy Alan Kelly: In the next couple of weeks, as part of the budgetary process, we will be able to isolate the extra cost of the implementation of this.

Dr. Tony Holohan: It is in the budgetary process that our ask for the additional piece we believe is necessary for the purpose of implementing a range of patient safety measures has got to find its-----

Deputy Alan Kelly: Including this.

Dr. Tony Holohan: Exactly.

Deputy Alan Kelly: Surely, because I am aware-----

Dr. Tony Holohan: There is one additional thing I want to say.

Deputy Alan Kelly: I am aware of the pathways. I am not trying to catch Dr. Holohan out. If anything, I am trying to flag things. I know the patient safety pathways that exist but, let us be honest about it, this takes it to another level given previous decisions to not go in this direction. Some of the work is being done. The health budget is under serious stress and we all know this. We have to get real. If we want to implement this, which we do and which we have to, we must acknowledge it will come and there will be a significant cost. I presume the Minister will be fighting budgetary-wise and stating we have to do this and it is a requirement. We will introduce this legislation. The cost needs to be identified and isolated. Otherwise, the Minister will be left hanging with regard to trying to absorb it in other areas.

Dr. Tony Holohan: The Minister has made clear the priority he attaches to this work and the extent to which recent events have highlighted and escalated the priority we all have to give to ensuring, whatever limited amount of resources are available in the budgetary context in any given year, that we make sufficient provision for implementation of this.

In preparation for some of the provisions of the Bill and other legislative provisions I referenced earlier, the HSE and the Department are working on preparing the system and issuing communications to ensure that clinical directors, colleges and people in leadership positions at the hospital group and CHO levels described by the Deputy have a clear understanding of what the legislation is and are making the necessary arrangements.

Deputy Alan Kelly: In the context of individual health practitioners, Dr. Holohan said that the inclusion of a defence will be incorporated in the drafting of the Bill to distinguish between genuine unintentional acts of omission or commission that can lead to harm and the much rarer acts of wilful neglect or deliberate breaches of acceptable practice. I presume there will be variations. This will be quite conditional because so many variables are at play. The drafting of this part needs a lot of thinking.

Dr. Holohan said the patient safety Bill will provide for mandatory notification of serious patient safety incidents to the appropriate authority, and the State Claims Agency, HIQA and the Mental Health Commission are mentioned. I agree with all of this; it is not a problem. I presume that in some quite limited circumstances there is a possibility the Department should be added to this list.

Dr. Tony Holohan: There is no reason to include the Department, to be honest, because we do not have authority or a set of powers invested in us to operate. All of the organisations mentioned have the power to act in-----

Deputy Alan Kelly: I know that. I am not disputing that the Department does not have the powers. Surely, however, the Department of Health, although it is not a place of investigation, should be aware . Take CervicalCheck as an example. The Department was not aware of what was happening. It is not a case of having investigative powers, it is to state there may be cases where it should be aware. The Garda Commissioner has powers under legislation, which have been used on only three occasion, to notify the Minister of a specific major issue. Surely a similar situation should occur here. I ask Dr. Holohan to bear it in mind.

Deputy Margaret Murphy O'Mahony: I thank the witnesses for giving of their time to come before the committee. If, as Dr Holohan said, with regard to the recent High Court ruling, that the Minister's request was overruled, does he believe the Bill is moot from the outset? Does strengthening the ability to compel open disclosure need to be considered? I note Dr. Holohan's comments on the empathy of professionals with patients and their families. How can this be measured? Would it require training? Dr. Holohan advised that the Civil Liability (Amendment) Act 2017 was too broad to ensure a mandatory approach that would capture all social care settings. Will the Bill achieve this objective? In light of the Scally report, does the Bill go far enough to ensure complete transparency? Dr. Holohan advised that the approach here will be similar to the duty of candour applied in the UK. Does the Bill equal that approach? It appears that issues relating to clinical audit remain unclear. Will the definition of a clinical audit be in place prior to the implementation of this legislation?

Dr. Tony Holohan: I will address the issue on measurement first, which is a good question on how we will ultimately know. Disclosure is something that happens in the privacy of a

consulting room or clinic, and there is not a window into this. We are in the process of building intelligence capacity through the so-called patient experience survey. Mr. Keating referenced this in passing earlier. I am not saying it will provide the entire answer to the question. It is a survey of hospitals in the first instance and it is more limited than we want it to be ultimately. We want to extend it to maternity hospitals and other healthcare settings. It gets into a substantial amount of detail with patients as to a wide range of their experiences. The second report will be published in the coming weeks. The first report, published in autumn last year, showed, for example, that the quality of information given to people at the point of discharge and the understanding with which people left hospitals or healthcare institutions was very poor. I imagine the issues that reflect on disclosures and the quality of those disclosures might be something we can include and we will be able to make inferences through it. We also have HIQA. It will be empowered to inspect, have standards relating to open disclosure and will be in a position to report on this. It is a good question and one we need to keep in mind because what we are trying to do is improve the quality of the disclosure engagements that take place.

In the context of the Scally report and transparency, we cannot say yet - because of the process of implementation planning we are going through - that all of the legislative requirements we may need to respond to all of his recommendations are contained in this. We are open to the possibility that as we do this work over the coming weeks, and we will be back to the Government with the Minister bringing his proposed implementation plan in December, that there may well be identified some additional requirement for us to add to this list of measures and to the provisions in the Bill. I am not saying "Yea" or "Nay", I am just not ruling it out. Our minds are open to that possibility. What I am saying is I cannot not sit here and state this is sufficient and we need to do nothing more with it.

With regard to equivalence with the duty of candour, our provisions will go beyond the duty of candour in the sense they will apply not only to organisations and the duty on an organisation to make arrangements for disclosure to happen in the same way that is provided for in law in the UK but also to individual practitioners, and there will be penalties in respect of them. We will go further than the UK. Ms Adams will answer the question on the definition of clinical audit.

Ms Elizabeth Adams: The Deputy is absolutely right: it is really important to get the definition of "clinical audit" correct. At present, the Department is commissioning an international study to look at the definition of "clinical audit" throughout the world in order that we can absolutely get that definition right. There are many definitions in the system that are fairly confusing so it will be important to have one clear clinical audit definition that is recognised. That is the real starting point. That will give the Minister the power to be able to develop the guidance he has discussed. It will be a structured guidance that will sit under the definition of "clinical audit". It will be really helpful across the system for clinicians. I am glad to report we have started that work.

Senator Colm Burke: I thank our guests for their presentation. The first issue I wish to raise is open disclosure and the Medical Council. Where will practitioners stand with regard to when a complaint is filed with the Medical Council and the information given in that open disclosure? It does not appear to be mentioned in the legislation. What is the clinician's situation where that occurs? What information is there from that open disclosure? Likewise, Dr. Holohan mentioned, in the context of the clinical audit, that it cannot be used in any proceedings. What about matters that come before the Medical Council where there is a clinical audit? Will that information be made available to the Medical Council?

The second issue relates to where a death occurs in a hospital and the medical and nursing

staff are upfront that they are unsure as to what actually occurred, they want to have a review of the procedure the patient went through and there are delays in carrying out that review. What process will be put in place? One of the problems that occurs is that the family of the patient who has died believe that because there is a delay something is being hidden. This arises time and again. What process is being put in place to ensure a review is carried out in a timely manner when the practitioners and the nursing staff cannot give an explanation for what has occurred?

The third issue is inquests. I have raised this with Ministers previously. There is no legal duty on a coroner to hold an inquest within a specific period, and sometimes information relating to the autopsy might not be available until the inquest is held. I am aware of a case where a person died in a hospital and 18 months later an inquest had still not been held. What process is being put in place in that regard? Are we going to amend legislation to require coroners to hold inquests? In fairness, the vast majority of coroners will carry them out in a timely manner once all the information becomes available to them, but there is still no legislative requirement on them to hold an inquest within a particular period of time. When there is a death families can be convinced that some information is deliberatively being withheld from them. That must be clarified.

The other issue I wish to raise is accountability. We talk about medical practitioners and nursing staff being accountable but there is no process in place for accountability by management in the hospital structure. For example, when was the last time a senior official in a hospital structure or agency was brought before an inquiry? I have never heard of it happening. In some of the issues that arise medical practitioners and nurses identify to management that there is a shortfall in the support they require to provide a service. It is in writing and is sent repeatedly, yet 12 or 18 months or two or three years later nothing has changed. Nobody is held accountable for that. Portlaoise was mentioned earlier. One of the issues there was that the number of deliveries doubled in a short period, but additional staff were not provided even though the medical and nursing staff requested them. I did not hear of any management personnel suffering the consequences in any way of not taking action.

I very much welcome this Bill but there has to be a *quid pro quo* in respect of the accountability of management, and I do not see that happening in the HSE. I am aware of an incident in the last two weeks where 12 people were to meet to make a decision on one person. This issue has been ongoing for over three years. Then an individual in the HSE sent an email two days before the meeting to say that the person was now moving to a new job in the HSE and would not be at the meeting. The meeting had to be cancelled. The family ended up having to face a battle to resolve an issue relating to one person. I support this legislation but I also want a *quid pro quo* of accountability by management because I do not believe we are getting it.

Dr. Tony Holohan: On the Senator's first question, the provisions of the Civil Liability Act will give the same protections in respect of the information as will apply for their admissibility to the Medical Council. The information gathered and recorded in that way is protected from those types of processes, and those types of assurances can be given to our practitioners in that regard.

Regarding the question about the death in a hospital, I realise it was not specifically about maternity but arising from some of the work that has been done on our response to what happened at Holles Street and the death of Malak Thawley there would be an automatic requirement for an external investigation to be conducted in every situation where there is a maternal death in a maternity hospital. That has not been the standard heretofore but it will be a practice

for the future. As regards the process that will apply in respect of deaths in hospitals, I will make a number of comments although I do not wish to give a long-winded response. Work has been under way to try to develop standards for patient safety incidents that give us a much clearer sense of the type of response that is necessary in response to the type of incident, to ensure we get a proper proportional response and that people are not left for long periods of time as the Senator described. When people are looking for information following the death of a loved one in extreme situations we must see expeditious inquiry and expeditious responses. That is part of the intention of having a more appropriate set of standards that operates in the same way across the health system. The reality is that, heretofore, in some parts of the system the response is better than in other parts of it and there must be a much more standard approach to that. Part of that ultimately will be the backstop the licensing legislation will give us to be able to ensure proper enforcement of those arrangements within the health care system.

I am not sidestepping the Senator's point about inquests because I understand what he stated regarding variable practices, and no criticism of coroners is intended, in the speed at which coronial investigations take place depending on the part of the country in which one lives. They generate important information from a patient safety point of view. From our perspective, to have a means of being able to see in a more agile way the outcome of coronial processes and the intelligence that comes from the investigation of those deaths would be one of the things we would like to happen. The coronial process is under the Department of Justice and Equality. We have worked and will continue to work with that Department to ensure that as it examines policy and legislation in that area our perspectives are provided on what we would like to see happening there.

With regard to accountability, there are two dimensions to this. I will make a distinction between organisational accountability and professional accountability. The Senator's point about the need to have a system of professional accountability for managers is well made. We have a system of professional accountability for the great majority of the health care professions. Within their individual professional line there is a means of setting standards, expectations, fitness to practice arrangements, in some cases competence assurance and so forth. That is the system of professional accountability. It should complement, but is distinct from, what must then also exist within an organisation which is that individuals are held to account within that organisation for their performance whatever their background, be they managers or professionals. It may well be the case in the context of a practitioner or person who has a system of professional accountability that there are questions of performance that do not give rise to questions of competence - and are therefore questions for their regulators - but might still fall short of an appropriate standard of performance. That should apply across the board. Much work has been done within the HSE around the development of the so-called accountability framework, which the committee has probably heard about from the HSE. However, the point in ensuring that the HSE's system of accountability is more responsive and reflective of the totality of staff in the HSE is one that I would accept. The HSE has a disciplinary code and set of requirements in relation to that which it must operate itself in response to an incident if it seeks to take disciplinary action. That is a different set of arrangements to what the Senator is describing which is a set of professional standards and a professional accountability line for people in management positions, which does exist in other jurisdictions.

Chairman: Was there not a mention in the Scally report -----

Dr. Tony Holohan: Sorry?

Chairman: In the Scally report, it was noted there was a difficulty in defining the roles and

responsibilities of various personnel so it was difficult to pin down who had a responsibility in relation to deficiencies.

Senator Colm Burke: That is the exact question to which I wished to return. There is a section within the Scally report which deals with the issue of governance. While the medical practitioners on the front line are being held accountable, no one who was involved in management and governance is being held accountable on CervicalCheck. That is one issue I want to raise. I welcome this legislation but in the HSE I have seen where people are in charge of a particular area who we then find have moved on to other areas. I am seriously questioning accountability. Dr. Scally highlighted it in his report, which referred to a total lack of governance, but no one is going to be held accountable for that lack of governance because it came in under the HSE.

Dr. Tony Holohan: I take the point and particularly in relation to the Chairman's comment that Scally found that individuals are operating without clear job descriptions and clarity as to their accountability. That is a very basic level of accountability and something that must be addressed. I do not want anyone to take any implications from what I am saying in terms of anything I am hinting at, I am not hinting at anything. It may well be the case that the HSE, which is independent and separate from the Department and Government and the Minister in so doing, is operating its own disciplinary code in respect of what happened. That is still open to the HSE and I am not making any inference by saying that. At this point, I would not draw the conclusion that nothing has happened for anybody in the HSE as a consequence of what has happened and what has been found. Dr. Scally has only just produced his report. It is entirely possible that the HSE may well see the need to address issues of accountability for individuals in line with its own existing disciplinary code.

Deputy Kate O'Connell: The important thing is that the Bill should be fit for purpose. I am concerned about the emergence of a two-tier reporting system. I refer to page 8. I do not understand why there is not one system of logging errors. Going back to the Scally report, it reminds me of where there was a cancer registry and the CervicalCheck list. I wonder why we would have more than one list for logging errors. An error that could technically be seen as being of no harm could be extremely harmful for a particular patient. In the case of someone who is given the wrong antibiotic, it might cause no harm to that person but if he or she was allergic to it, it could kill him or her. There being more than one list to log incidents concerns me.

I refer to the emergence of a seven-day period of reporting. Why seven days? I speak from my own clinical time and if something is not acted on for seven days, there is a chance that the same error will happen again and again. Who came up with seven days? It seems too long. I cannot understand why a period of 24 to 36 hours would not be reasonable where an incident occurs. It is not comparable, but in the private sector, if one was in a factory and glass got into baby food, a week would not be acceptable. I see this seven days as cushioning for people who do not work as efficiently as people in the private sector. I do not think that seven days is acceptable. It will lead to potential further errors, which could result in a list sitting there forever with nothing being done.

Page 13 refers to a "provider" and states "Notifications must be made within seven days of the provider becoming aware of the incident." I might be wrong but my understanding is that "provider" does not refer to the doctor or whoever, but to the hospital. Page 4 states that a health services provider " means ... a person, other than a health practitioner," so technically, if a doctor made a mistake on day one and then it was reported on day six, are we then talking about day 13, which is with seven days on top? Does Dr. Holohan get me? Am I wrong? Could

we be talking about 13 days from the incident before any action is taken?

Dr. Tony Holohan: I can explain that.

Deputy Kate O'Connell: I am concerned that the audit data will not be subject to freedom of information requests or that it would be usable in court. I understand entirely where we are coming from but I am concerned that the focus is on the professional not on the patient. If everything is all open and accountable why would the information not be admissible in court? It is holding onto the past rather than looking towards the future.

Dr. Holohan referred to the erosion of societal trust. It is worth mentioning that here. I am very much pro-patient safety and open disclosure; the world and Ireland have changed in relation to the relationship between doctor and patient. There was a time when one trusted the doctor down the road implicitly. Such doctors would diagnose a person's pregnancy, weigh the babies when they were brought in and they were part of one's life. That relationship has been destroyed over time for whatever reasons. We are trying to apply open disclosure as though the relationship with the doctor was the same. However, if one considers a doctor with whom a patient may have only dealt once, that patient might be more likely to make a complaint against such a doctor compared with the general practitioner that he or she might have dealt with for 15 years. We must be conscious that the relationships have changed over time. While patient safety is to the fore in this, we must also consider our medical practitioners and that they are not overly exposed as a consequence of the throughput and the transient nature of care now.

To come back to the incidents that happen, I know from working in this area in the UK that there is an idea that an IT system would be the alert system, but I cannot see why it would not be a mobile phone. If an incident happens on one ward - it could easily be a dispensing error by the pharmacy - it would seem logical that the alert would go throughout the hospital in real time. As for the idea that somebody sits down at the end of the day and logs errors into a system, and it sits on this endless list and nothing is done, anything we are doing here has to be in real time.

Following on from that, what sort of person will be in charge of this in an organisation? Will it be a manager or a doctor? Who will be responsible for making sure the list is filled in at the end of the day and whose responsibility will it be to triage what is serious or potentially serious? If that person makes the wrong call and something that is serious is treated as minor or *vice versa*, whose responsibility is it and is there any protection for the health care professional or doctor in that case?

I have a fear that with seven days to log an error, or potentially longer, we could end up with a list of errors but no actions, no reflection and no change. I know of other jurisdictions which have tried to bring in a regularised form of reporting errors and it has led to an endless list sitting on the system, when it is really only a log and has very little purpose apart from administration. Dr. Holohan might deal with those issues.

Dr. Tony Holohan: I will deal with that last part first as it may address a number of the Deputy's questions. I take the point completely. Where the Deputy describes the creation of the list, that is exactly the culture we are trying to avoid. In some parts, it might be the culture we already have, where it is seen that the response to the patient safety incident is the filling out of the form, and once the form is filled out, the duty is discharged and that is the end of the matter. Although I do not want to keep going back to the Portlaoise example, that was absolutely the case in Portlaoise. Nobody was looking at the pile but once they looked at the pile, the patterns were obvious. Clearly, it is the use of the information that is important, and its value lies only in

whether it is used to create appropriate intelligence. There will need to be people who have appropriate patient safety expertise leading the implementation of that within the front line of the health services. However, that is not to say there is not a requirement in terms of reporting and the integrity and accuracy of the information. That responsibility has to reside with the clinical service, which has to take ultimate responsibility for the accurate reporting of the information. That is the kind of culture that is needed and that by reporting something, they are not dispensing with their responsibility to deal with whatever the information relates to.

With regard to the seven days, an obvious point to make is that it is a maximum, not a minimum. It is not setting the minium allowable period that has to elapse but the maximum, and it may well be, for the reasons the Deputy describes, much more appropriate that something happens within minutes or hours, depending on the nature of the incident. The seven days relates to the requirement on the provider around the notification to the State Claims Agency, not around the response capacity and certainly not around open disclosure, so the open disclosure engagement is not framed. That should be determined by the nature of the clinical circumstances.

Obviously, what we want to see happening is that, when the information becomes available and within the earliest possible time, the information is imparted properly by the appropriate clinical team, and there is appropriate training and so on to support people in doing that. As I have said before in this committee, this really only applies when something goes wrong. However, that is a much more frequent occurrence than people might imagine and, in general, the evidence is that up to 10% of hospital admissions have some form of iatrogenic or health service induced harm in respect of patients, so this is not an uncommon experience. There is really only one opportunity to put that right, which is the earliest engagement that happens between the clinical team and the patient or the family of the patient. We have to try to maintain trust and confidence. The moment that is eroded, for whatever reason, no amount of after-the-fact engagement can restore what has been lost. While I do not want to presume, I think that is the spirit in which the question was asked.

Deputy Kate O'Connell: I cannot understand the period of seven days. In the practical sense, I have this vision of a hospital situation where nobody dies but errors are made over a day, and then it is day six, and that one had better sit down at one's desk and fill in all one's errors. Then, a bundle of error pages gets handed to the next person, who puts them into the computer. I see that as a list that is not going to be actioned and, within that time period, another incident could happen. If a doctor makes a mistake on day one and makes the same mistake again on day five, how do we look at that family and say, "We said seven days", when, if we had said four days, the person would be alive? I do not understand the seven days and think it is inefficient.

Dr. Tony Holohan: Ms Adams may want to add something.

Ms Elizabeth Adams: On the duty of candour, in the UK when they instigate a serious report that is going to be notifiable, they are talking about 30 days. I am fully respectful that the seven days feels very long but the priority for us in considering it was to get the information to the patient first so that, with immediate effect, the practitioner can do the mandatory open disclosure with the patient. That is the priority and the primary purpose. After that, the reporting out to HIQA and other bodies is secondary, as was the intent. Nonetheless, we take the Deputy's point with regard to the information becoming a list and all of that.

Dr. Tony Holohan: On the question in regard to the audit data, while I understand the Deputy's point, the reality is that, for many practitioners, while their participation in audit is not

a given, many individuals participate in audit willingly and for the right reasons. Nonetheless, it is a reality in clinical practice that people will look at the circumstances that have arisen in the past number of months and decide that the easiest thing is not to be involved in audit, as that is the safest way for them to avoid all of this trouble. That is exactly the kind of response we do not want to see, even if we understand it. We want people to participate in audit and to investigate what they are doing. The purpose here is to try to create as much protection for them and to try to give them as much encouragement as possible. That is the spirit of where we are coming from. We want to try to address some of the known impediments to people's participation in audit, for example, the culture of fear. Whether it is justified fear or not is another matter, but it is real fear that stops them from participating. We hope that can be addressed through some kinds of assurances. In particular, this legislation will, hopefully, give more assurance that we can increase the expectation that clinical audit is happening as an embedded part of the delivery of health care, which is not the case at present.

Deputy Kate O'Connell: In the hospital setting currently, must a consultant who is employed by a hospital group sign up to the terms and conditions of that hospital group? Is there not scope on an individual basis, when it comes to a hospital group or a trust, that the doctor would be told that if they were coming to work there, part of the contract is that they must sign up to the internal auditing process? Is that not a step in the right direction. I understand the point. If it is made more likely that people get in trouble by being on a list, they will not bother. However, I am slightly uncomfortable with the ethos of this.

Dr. Tony Holohan: I understand. There are provisions, for example, within the consultant contract, in respect of clinical audit. While those are all necessary, they are individually not sufficient to enable us to have the kind of environment we want in terms of having routine clinical audit happening everywhere it should be happening. That is why we are trying to do things through the national clinical effectiveness committee and trying to have a nationally organised system with a set of clear standards, and with this legislation creating a requirement on the Minister to produce standards that we can assess, and we can then mandate and prioritise audit. If, for example, we have a national stroke audit happening across all our stroke services, we know it is happening to a standard, we can rely on its finding, we have given protections for individuals involved in the way that we have described, we have contractual arrangements that require people to be involved and the implementation levers, if I can put it that way, are all pointing in the same direction, then we can ensure the greatest likelihood of having full participation in a full national stroke audit. I am merely using stroke as an example.

Chairman: Audit is to be encouraged because it will identify what is right and what is wrong. If audit reveals something that is wrong, that does not preclude people who have been inappropriately treated or damaged by a process from legal action. It is the audit process that is protected.

Dr. Tony Holohan: Yes.

Chairman: If audit identifies something is going wrong, that does not preclude the person damaged from taking a case, to seek redress or to pursue it.

Dr. Tony Holohan: It does not.

Chairman: It is the audit process that is being protected.

Dr. Tony Holohan: Yes.

Chairman: It is not trying to hide what the audit has revealed.

Dr. Tony Holohan: Correct. The generation of that knowledge in the audit is what is being protected.

Deputy Kate O'Connell: On the one list, why are there multiple lists? An explanatory note in the general scheme of Patient Safety Bill 2018, states, "Through Ministerial regulations, those "reportable incidents" which must be reported to the relevant reporting authority [...]" and it refers to a "detailed listing". I am uncomfortable with two lists. Who is the person who decides what is reportable and what is not? There is a blurring of the lines. I cannot understand why all incidents are not reportable in the same way and that they do not all enter the same database. Maybe I am misinterpreting this.

On page 8, where it refers to private healthcare providers, it states, "Private providers of mental health services will be required to notify the Mental Health Commission". How are they to notify it? Is it by email or letter? Would it be more logical, a bit like the yellow card system with adverse drug reactions, that there would be only one system and everyone logs on with his or her number and fills in the boxes? Has the Department any comment on why there is more than one list?

Ms Elizabeth Adams: The Deputy is absolutely right. When we originally were drafting this, we were not sure whether or not there would be a requirement to have a separate list for reporting incidents out as opposed to when we brought in the mandatory open disclosure. We are now in the position that we are clear that it is the one list whether one is to report out those mandatory open disclosures. We needed to get some advice on drafting and how that would go, and then what the Minister could do. It is clearly one list.

Deputy Kate O'Connell: One database?

Ms Elizabeth Adams: We are hoping one database. The NIMS system is the reporting one at present but it would have to be enhanced in order to be able to cope and deal with, as was raised earlier, a number of different providers using the database so that everything could be centrally kept. There is a little bit of work in doing that. I confirm we have come to the place that one list is the correct approach.

Chairman: Is there a danger that mandatory open disclosure will lead to an increase in defensive medicine and, consequently, an increase in costs to the health service? Is there a danger that patients may be over-investigated or over-treated to ensure that absolutely nothing is missed because the fear of not doing so may leave one open to litigation or to being found to be acting irresponsibly?

Dr. Tony Holohan: I would like to be able to tell the Chairman that there are multiple systematic reviews published that address these questions, but there is a lot of literature. The literature points to a situation whereby when disclosure happens in the way that I am describing where trust and confidence is maintained, it reduces the likelihood of litigation. There are examples in jurisdictions where mandatory notification has been introduced where they have been able to demonstrate that there has been a reduction in the activity in terms of litigation.

Certainly, one of the fears is that individuals may feel that by making a disclosure they are contributing in some way to their own legal risk, etc., and that is part of the reason for the protection here. It may almost be counterintuitive that a full implementation of an open disclosure with the balance between what we have struck here - mandatory in some cases but voluntary

protections in the majority - is all aimed at ensuring that it is not optional and that it happens in every circumstance, and if it happens in every circumstance that it might contribute to a reduction in the likelihood of medical legal cases.

Chairman: Before something goes wrong, the worry from a professional point of view is that if one does not undertake every investigation possible one may misdiagnose and be liable to end up making an error, for instance, delayed diagnosis. It would be an issue here with open disclosure that there was a delay in diagnosis and one would have to mandatorily disclose that there was a delay in diagnosis. There might be pressures on the clinicians to engage in defensive medicine to ensure that there is absolutely no way that they can be left open to the accusation of a late diagnosis.

Dr. Tony Holohan: The point is well made and I agree with the Chairman. These kinds of circumstances can lead sometimes to not easily foreseeable and sometimes unforeseen consequences in terms of medical practice. Without going into the details of cytology, we are moving into a different technology now in terms of the early identification of pre-invasive cervical cancer but if one looks across medical practice, there are many testings that base themselves on observer interpretation of what has been seen. Radiology is a practice. Pathology itself is a practice. Our entire diagnostic activity is heavily dependent on those. If we move the dial even a few degrees towards more conservative calling on the part of practitioners, we will subject large numbers of people to unnecessary further investigations, unnecessary treatment, etc. I have a genuine concern about that. It is easiest for a practitioner to not err and to be sure that he or she calls it in a more conservative way, if that makes sense, and leads to all sorts of consequences for patients and patient harm. That is something that, collectively, we must be conscious of.

Chairman: With the availability of more precise scanning and other testing to be absolutely sure of one's diagnosis, whereas 20 years ago one went into hospital with acute appendicitis and one's appendix was taken out that evening, now one goes into hospital and before one's appendix is taken out one must have a CT scan to confirm what is blatantly obvious, which seems like a waste of resources and a defensive way of functioning. I am merely worried that this may lead to increasing that.

Dr. Tony Holohan: I take that point.

Senator Colm Burke: Coming back to the Medical Council, I presume head 15 will include the issue about the evidence not being used in a Medical Council hearing.

Dr. Tony Holohan: It will.

Chairman: Returning to Senator Colm Burke's original question about the requirement for an inquest to be held within a specific period of time, the Coroners (Amendment) Bill 2018 is going through the Dáil at present. Perhaps that would be a good amendment to introduce in that legislation.

Senator Colm Burke: There was a particular case I came across where 18 months after a person had died in hospital, an inquest was still awaited. In fairness, the family was kept totally in the dark. Everyone was waiting for the autopsy report. It caused its own problems.

Chairman: I thank Dr. Holohan, Ms Adams and David Keating for coming in to give their evidence this morning. I am sure this is a matter we will return to in the not-too-distant future. I thank them for aiding the pre-legislative scrutiny of this Bill.

As there is no other business this morning, I adjourn this meeting until Wednesday, 3 October when we will have the Minister, Deputy Harris, in to speak on the Sláintecare implementation strategy.

The joint committee adjourned at 11.30 a.m. until 9 a.m. on Wednesday, 3 October 2018.