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“FILE ON 4”

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RICHARDS-EVERTON: The doctor came into the room and he said to me that Paul’s organs was closing down. I just went into shock and I couldn’t stop shaking.

O’HALLORAN: A case in which a medical mistake caused a cancer patient to receive too much of a powerful drug.

RICHARDS-EVERTON: He came in and he sat down and said that they’d tried to resuscitate him three times and that they’d lost him. At that point I knew that there was something wrong, Paul hadn’t just died. I knew that there was something wrong with the drug he’d been given.

O’HALLORAN: Official figures say over 3,500 people die each year from medical blunders, but independent experts say the true figure could be 25,000. Eight years ago, the National Patient Safety Agency was created to analyse these cases and send out alerts to NHS trusts to prevent the same mistakes being repeated. However, new figures show many NHS trusts have failed to act on those warnings.

WALSH: We hoped to find out that there’d been almost total compliance with the alerts. What we found was really quite a shock. Frankly, lives are being put at risk and NHS bodies are not taking patient safety seriously enough.

O'HALLORAN: Tonight, File on 4 asks why more hasn't been done to force health service trusts to carry out lifesaving safety measures.

SIGNATURE TUNE

EXTRACT FROM RADIO 1'S NEWSBEAT

RADIO IDENT: Radio 1 Newsbeat.

NEWSREADER: A coroner has ruled that a man who was given a lethal overdose by a German out-of-hours doctor was unlawfully killed. Dr Daniel Ubani gave seventy year old

O'HALLORAN: The case of David Gray, which hit the headlines this month. A Cambridgeshire man who died when a foreign out-of-hours doctor made a grave error with a painkilling injection.

GRAY: My father was an averagely fit seventy year old. He was active. A German out-of-hours doctor, on his first shift in the UK, gave him diamorphine, a painkilling drug. The doctor had no previous experience with diamorphine and my father died within minutes of the administration of the drug.

O'HALLORAN: When Stuart Gray's father died, it was a shock to the family. David Gray was killed by a massive overdose of diamorphine, possibly ten times what he should have been given. Most interest focused on the background of the doctor who treated him at home, his lack of competence and a system which allowed a doctor from Germany to arrive in Britain and start work without adequate checks. But Stuart Gray, himself a family doctor, says one vital aspect of his father's case has been ignored. The fact that the medical bag issued to the visiting doctor contained a massive 100mg ampoule of diamorphine, a dose far greater than required for everyday therapeutic pain relief.

GRAY: Diamorphine is used in a therapeutic dose usually of 5mg but in somebody of bigger build can be used up into a maximum of 10mg.

O'HALLORAN: So how did it come about that this doctor administered 100mg – ten times more than could have been right?

GRAY: Firstly because the doctor had no knowledge of the drug or its dosage, and secondly because this large dose of diamorphine, this 100mg of diamorphine that would only be used in palliative care, was mixed in the same box as therapeutic doses. I can see no reason for the need to carry 100mg of diamorphine. I've never actually seen one myself, and if you did need stronger doses, you could always mix two or three 10mg together.

O'HALLORAN: Two years before David Gray's death, the grave risks posed by large doses of diamorphine were the subject of a country-wide alert by the National Patient Safety Agency.

READER IN STUDIO: There have been a number of reports of deaths and harm due to the administration of high dose – 30mg or more – of diamorphine or morphine injections to patients who have not previously received doses of opiates.

O'HALLORAN: The document, sent to hundreds of NHS trusts, went on to highlight the dangers of storing ampoules of 30mg or more alongside smaller doses, and it gave detailed advice about how to reduce the risks.

GRAY: The alert specifically stated that therapeutic doses of diamorphine and palliative doses should not be carried in the same container or box.

O'HALLORAN: That was a clear warning well over year, nearly two years before your father died?

GRAY: Absolutely, yes. If the alert had been responded to by the primary care trust and the out-of-hours provider, my father would not have died of this overdose.

O'HALLORAN: Four years ago, when the safety alert was issued, David Gray's area was covered by East Cambridgeshire and Fenland Primary Care Trust. It organised out-of-hours doctors through the NHS in Suffolk, which in turn engaged a private contractor. The GP service in Cambridgeshire has since been reorganised into one large county-wide body, Cambridgeshire Primary Care Trust. Its Medical Director, Dr Christine Macleod, concedes that Mr Gray's death revealed serious flaws in the system for sending patient safety alerts to all the services actually treating patients.

Was your trust able to prove that the out-of-hours doctor service had in fact been informed and alerted about that warning from the agency?

MACLEOD: We were able to show that the alert had been sent across for distribution and when we checked ...

O'HALLORAN: Sent across?

MACLEOD: Sent across into Suffolk, and Suffolk said that they did send the alert out, but that was four years ago and none of us seem now to have a record that that alert was actually acted on, so we've learned from that.

O'HALLORAN: Did your trust have any system whatsoever for confirming that alerts had actually been received?

MACLEOD: We do now, because we have monthly contract quality meeting

O'HALLORAN: But did they at the time?

MACLEOD: They had contract quality meeting, but I'm not sure that they discussed that alert at the quality meeting.

O'HALLORAN: So there wasn't really a system four years ago for checking whether such alerts had been received?

MACLEOD: It seems as though the closing of the loop was not as good then as it is now.

O'HALLORAN: Stuart Gray, the son of the dead man, and a family doctor himself, reckons that if that 2006 alert had been fully implemented, it's more than likely that his father would still be alive today. There wouldn't have been that 100mg ampoule in that medicines box, would there?

MACLEOD: I think the alert says you can reduce the risk by separating the vials.

O'HALLORAN: So Stuart Gray is right to this extent; the risk that caused his father to die would have been substantially reduced if the alert of 2006 had been acted on?

MACLEOD: Yes, you can say that.

O'HALLORAN: In 2002, the Government set up a system to keep close tabs on cases where treatment had gone wrong, and to try and ensure that the whole of the health service did what was required to prevent any repetition.

ACTUALITY OUTSIDE NPSA

O'HALLORAN: The headquarters of the National Patient Safety Agency, the body trying to learn the lessons from clinical blunders, is a stylish, glass-fronted office block here in the West End of London, just off the Tottenham Court Road. It's actually a branch of the Department of Health. It receives a truly staggering number of reports of medical mistakes and so-called untoward events affecting patients – getting on for a million incidents a year.

WOODWARD: Setting up the national system means that we can actually look at things from across the board and aggregate that data to advise the NHS on where they could make changes in terms of harm and risk.

O'HALLORAN: Suzette Woodward is Director of Patient Safety at the Agency. She says her staff carefully review the most serious cases reported to them and then draw up warning messages called alerts, which are sent out to both Primary Care and hospital trusts.

WOODWARD: The alerts that we send out are about reducing harm and providing people with potential solutions for reducing that harm within either their system or their practice.

O'HALLORAN: It's about saving lives as well?

WOODWARD: Yes. When I describe reducing harm, I mean both reducing the chance of error, the actual error and then the harm that occurs as a result of that error, which could be anything from minor harm to severe harm or death.

O'HALLORAN: How important is it, do you think, that the staff in these hospitals and Primary Care Trusts around the country actually carry out, implement your alerts?

WOODWARD: Of course it's highly important otherwise we wouldn't have created them or sent them out.

O'HALLORAN: The overwhelming majority of mistakes currently reported to the Agency are events which take place in hospitals.

CAMERON: Peter's only medical problems were mild atrial fibrillation and slight high blood pressure, and he was lucid, he was looking after himself. He really was just himself, but short of breath.

O'HALLORAN: When Heather Cameron's husband, Peter, went into Hinchingsbrooke Hospital in Cambridgeshire in 2006, he was 75 years old. At first, she didn't think his life was in danger. However, there were complications and he began losing weight, so at times he was given a naso-gastric tube, which sends liquid food straight into the

O'HALLORAN cont: stomach. One Saturday afternoon when she saw him, he had no feeding tube and was in a cheerful mood. But when she returned that evening a new tube had been fitted and there was a dramatic change.

CAMERON: When we came back, he had a really vicious sore throat. He could only croak, and he'd been fine before. When my friend, who's a nursing sister, told me about naso-gastric feeds, she said, 'Always beware of a sudden sore throat,' and so I questioned the staff and I said, 'Look, Peter's very bad.' I told them what I'd been told – to always watch for a sudden sore throat and it could mean that it's gone into the lung, and it's quite possible.

O'HALLORAN: That the feeding tube has accidentally gone into the lung instead of?

CAMERON: Into the stomach.

O'HALLORAN: So when you raised the possibility of the feeding tube having gone into the lung or being incorrectly fitted, what did the staff say?

CAMERON: They dismissed the idea. It was nothing to worry about, Peter had just caught another infection.

O'HALLORAN: In the next 36 hours, Peter Cameron's condition got rapidly worse. While staff tried to reverse his decline, she maintained her vigil. Peter Cameron suffered severe mental and physical distress. Eventually, she was told, the battle to save his life had been lost.

CAMERON: When I went into that side ward, his body looked so horrible, it shocked me. I couldn't move, it was like having concrete boots on. That was my husband lying there, I suddenly realised it was Peter. He looked absolutely tortured and he was pretty thin as it was, but he was stretched out and absolute agony on his face.

O'HALLORAN: At first Heather Cameron says she was given to understand her husband had died from pneumonia. But later she learned that police had impounded hospital records and x-rays. She discovered within two days there had been a serious error with the feeding tube.

CAMERON: The last x-ray taken of Peter showed quite clearly the tube piercing Peter's lung. It had gone straight through his lung and speared him, basically.

O'HALLORAN: So what did that mean had happened to all the feed that had been fed through the tube?

CAMERON: It had gone into the pleural space around it and there was something like three litres of fluid.

O'HALLORAN: Which caused the lung to collapse?

CAMERON: Yes.

O'HALLORAN: At a later inquest, the coroner ruled the tube had been incorrectly fitted and that the monitoring of Peter Cameron's case could have been better. Heather Cameron also learned that in 2005, a year before her husband died, the National Patient Safety Agency had put out a specific alert about the right way to test the position of feeding tubes. Hinchingsbrooke Healthcare NHS Trust claimed its staff had followed national and local guidelines on feeding tubes. But File on 4 obtained an unpublished internal inquiry made by the Trust into Peter Cameron's death, which stated that its own guidelines were:

READER IN STUDIO: Not fully compliant to the National Patient Safety alert issued in 2005. The Trust policy, therefore, requires updating and reissuing.

O'HALLORAN: The national alert to NHS trusts had stressed that no feed should be put into the tube until staff were sure it had gone into the stomach. The alert called for a special type of testing paper to be used on fluid from the feeding tube to establish it was in the right place. But Heather Cameron's solicitor, Richard Follis, says the Trust had

O'HALLORAN cont: failed to implement that aspect of the alert, even though the Agency had drawn attention to a history of fatalities caused by misplaced feeding tubes.

FOLLIS: It made clear that eleven deaths had been identified due to problems with feeding tubes, and that's the difficulty here. Just because a procedure is routine, commonplace, doesn't mean to say that if it's done badly or incorrectly it could not have fatal consequences.

O'HALLORAN: And how did the Trust modify its own policy once it saw the national alert that was put out by the Agency?

FOLLIS: Well, we've seen no evidence at all that they did modify their policy until Peter Cameron died and they realised that they had missed implementing this particular aspect of the 2005 National Patient Safety Agency guidelines.

O'HALLORAN: So what is your impression about what happened in that Trust when the national alert on feeding tubes arrived on someone's desk in 2005?

FOLLIS: Well, because of the very peculiar facts of this case, we can say absolutely that they did not update their own guidelines. Now if the starting point is that their guidelines are not updated, one is tempted to question to what extent that information was cascaded down to staff to reinforce in them the importance of the basic procedures they were required to undertake. Were staff told about there having been eleven deaths? Was this underlined and brought home to staff that these guidelines are not optional but are mandatory?

O'HALLORAN: Hinchingsbrooke Healthcare NHS Trust refused our request for an interview. It said, in a statement:

READER IN STUDIO: The case of Peter Cameron is subject to an ongoing claim for damages and therefore the Trust will be making no further comment at this time. The Trust has robust systems to ensure alerts are completed within set timeframes.

O'HALLORAN: Guidance to prevent deaths due to feeding tube mistakes is among a series of notices and alerts issued to NHS trusts by the National Patient Safety Agency over the last six years. Other warnings cover surgery on the wrong part of the body, poor management of oxygen and drugs meant for the spine being injected into the bloodstream. A total of 53 National Patient Safety alerts had been issued by the Agency by last December. A campaign group acting for patients, Action Against Medical Accidents, believes these alerts are vital to help reduce blunders, and its Chief Executive, Peter Walsh, says it's important that when NHS trusts receive these alerts, they act promptly on them and communicate the fact that they've done so.

WALSH: Each NHS body is required to notify the central alert system, which is currently maintained by the Department of Health, when they have complied with the required actions in each alert, and the central alert system is a database which collects all of that information.

O'HALLORAN: So when the hospitals get these alerts and start acting on them, they eventually get back to the Department and say, 'Yes, we've not complied with them,' do they?

WALSH: Yes. Trusts are supposed to let the central alert system know when they've complied. If there's some unusual reason why the alert isn't applicable to them, they can notify the system of that as well.

O'HALLORAN: So, to find out how well the system was working, Action Against Medical Accidents made a Freedom of Information request to the Department of Health asking for the names of NHS trusts in England that hadn't complied with patient safety alerts.

WALSH: We hoped to find out that there had been almost total compliance with the alerts. Our understanding is that they contain required actions. It is a core standard of the Department of Health that they do actually implement these patient safety alerts by a given deadline, so it's reasonable to expect 100% compliance. What we found was very much different from that and really quite a shock.

O'HALLORAN: What did you find from the answer that came back from the Department?

WALSH: What we found was that there are over three hundred trusts who haven't complied as yet with at least one patient safety alert for which the deadline has already passed. We found that there were eighty trusts who hadn't complied with ten or more alerts for which the deadline has passed.

O'HALLORAN: So there are eighty trusts who have not complied with, what, one-fifth nearly of all the alerts put out in the last eight years?

WALSH: Yes, we found, quite shockingly, that there are a small number of trusts who haven't complied with quite high numbers. For example, University Hospitals Coventry and Warwickshire NHS Trust, according to the DoH figures, haven't complied with thirty-seven of the patient safety alerts. There are two other trusts, Greenwich Teaching PCT and Lewisham Hospital NHS Trust, who are recorded as having not complied with thirty-one. So that's well over half of the patient safety alerts.

O'HALLORAN: So what do these NHS trusts have to say? Lewisham Hospital NHS Trust, listed as non-compliant with 31 alerts, said that patient safety was its top priority and it had won a high rating on beating hospital infections. But it's admitted, in a statement:

READER IN STUDIO: We acknowledge that the hospital has fallen behind on reporting our compliance to the national database. The Trust is channelling more administrative and clerical support to the reporting systems with which we must comply.

O'HALLORAN: Greenwich Teaching Primary Care Trust, also listed as non-compliant on 31 alerts, said it took patient safety very seriously, but it conceded it hadn't managed safety alerts as well as required.

READER IN STUDIO: In recent months we have redoubled our efforts to fully follow through the process of reporting our compliance to the national database. We are confident that we will be fully compliant by March 2010.

O'HALLORAN: University Hospitals Coventry and Warwickshire, listed as having 37 outstanding alerts – more than any other trust – said, in a statement, it had received 56 alerts since 2002, but some were not applicable or their deadlines weren't up.

READER IN STUDIO: Five remaining alerts have been implemented and we are presently auditing these so they can be signed off as complete. University Hospitals Coventry and Warwickshire has fully implemented 41 alerts.

O'HALLORAN: However, File on 4 learned that its responses to more than 30 of the alerts, going back as far as 2004, were not sent to the Department until February 2nd – five days after File on 4 questioned the Trust on its record. The importance of NHS trusts reacting swiftly to national safety alerts is highlighted by a tragic case in Midlands – that of 35 year old IT consultant and father of three children, Paul Richards. One day, in 2007, coming home from work, he began to feel very ill and had tingling in his head and arms. When he failed to get better at home, he was admitted to hospital for tests.

RICHARDS-EVERTON: Paul rang me up and I could tell from his voice that there was something wrong. He told me to come up to the hospital straightaway, don't come on my own, come with my mum, and that's what I did, and he told me at that point what the consultant had told him. When you first hear the words 'possible cancer' you feel like your whole world is ending.

O'HALLORAN: Lisa Richards-Everton says that for the next few months her husband's condition fluctuated. At first he seemed to respond well to chemotherapy, but later the precise cancer diagnosis changed and his medication was altered. One Friday in July, he texted her from Birmingham Heartlands Hospital to say he'd been put on a new drug.

RICHARDS-EVERTON: I was a bit concerned, but later that evening, about 8.30, Paul's mum called me and advised me she had gone up to the hospital and Paul had had a reaction to the drug that he was being given. She said that Paul was violently shaking and she was very distressed and a nurse came into the room and said, it's okay, another man had had the same drug and the same reaction and he's now okay, so that reassured both Paul and Paul's mum that Paul was going to be okay.

O'HALLORAN: But the same night, at three in the morning, she was woken by a phone call from the hospital asking her to come at once.

RICHARDS-EVERTON: We got to the hospital and we just ran straight into Paul's room and he was lying on the bed, he was freezing cold and he was sweating, and I was rubbing his hands to try and get him warm, and I actually said to Paul he was okay before he had this drug, and his answers were, 'I know I was.'

O'HALLORAN: Paul Richards' condition went rapidly downhill that Saturday, as frantic efforts were made to save his life.

RICHARDS-EVERTON: I was asked to go into a waiting room just at the side, so I went into that waiting room, I was on my own, and I was just praying, asking God to help Paul, and at that point I then heard Paul's name being called.

O'HALLORAN: What did you hear?

RICHARDS-EVERTON: I heard a nurse, I heard them shouting, 'Paul, Paul, Paul,' and I walked towards where he was and I saw them resuscitating him, and I just, I just then started screaming for him.

O'HALLORAN: But despite three attempts to revive him, he was declared dead. Lisa then recalled the other man who had had the same drug.

RICHARDS-EVERTON: When I then seen Paul, his consultant was sitting at his bedside with his head in his hands. He just looked like he was shocked, he wasn't expecting Paul to die, and I shouted across to him, 'What have you done to my husband?' and he just didn't know what to say. I also asked, 'Has the other man died?' and he said, 'Yes.' As soon as he said yes, the other man had died, I knew there was something wrong.

O'HALLORAN: It later emerged that Paul Richards had received five times the correct dose of an antifungal drug called amphotericin. There'd been a mix-up over the correct dosage involving a junior doctor and nurses. A coroner ruled last year there'd been gross failings and neglect by hospital staff. Four months before the two men died, there'd

O'HALLORAN cont: been a country-wide alert from the National Patient Safety Agency, focusing on injectable medicines like amphotericin. It called for heightened precautions with a range of these drugs. Trusts were given an implementation deadline of a year. But Tony Hall, a solicitor acting for Paul Richards' widow, argues that a rapid reaction by the Trust to this warning might have saved his life.

HALL: There was indeed an alert which was issued 28th March 2007, and that highlighted around 800 reports a month to the national reporting and learning system

O'HALLORAN: Which is part of the Agency?

HALL: Indeed, yes. Relating to injectable medicines between January 2005 and June 2006. In that same period there were 25 incidents of death and 28 of serious harm reported, and as a result of that it was felt that the NPSA should issue this alert, which they circulated for response by all NHS organisations in England and Wales.

O'HALLORAN: Now did the hospital in question and the Trust in question, did they receive that alert, as far as you know?

HALL: As far as I'm aware they did. It wasn't cascaded down to relevant individuals, and medical and nursing staff it would seem, because plainly it wasn't followed on the case of Paul Richards.

O'HALLORAN: Looking at it from the hospital trust's point of view, this was a very detailed alert. It could have taken a long time to implement a robust reaction to it.

HALL: It could have taken some time, but a plan should have been commenced very promptly after the issue of the paper on 28th March 2007.

O'HALLORAN: And you never found any evidence that any sort of action plan was underway in the following months?

HALL: No.

O'HALLORAN: Until these two men died?

HALL: Yes.

O'HALLORAN: Heart of England NHS Foundation Trust, which runs Heartlands Hospital, rejected our request for an interview. The Trust emphasised the year-long deadline that had been given for compliance with the March 2007 safety alert.

READER IN STUDIO: Actions in response required wholesale system review and planning rather than actions that could be completed within days or weeks. The incident sadly happened in July 2007, partway through the action period and before the alert was fully implemented. We have an ongoing commitment to make our prescribing and medication management safer.

O'HALLORAN: After the two deaths at Heartlands Hospital, the National Patient Safety Agency issued, within a few weeks, a further alert, this time focused on amphotericin. It pointed out there were different forms of the drug in use of varying strengths and it listed actions to be taken to eliminate the risk of overdoses. This time, trusts were told to take measures within weeks with a completion deadline of October 2007. However, last month Lisa Richards-Everton says she was horrified to hear that ten NHS trusts have still not reported compliance with the alert well over two years later.

RICHARDS-EVERTON: It's evident that trusts still haven't followed the alerts that were sent out in August 07. There are still trusts that haven't acted upon those alerts. The Government needs to give the National Patient Safety Agency or the Care Quality Commission power to enforce hospitals to make changes. How many more people have got to die and go through what I'm going through right now and be in the same situation after they have lost their loved ones to know that their death could have been prevented?

O'HALLORAN: That's a view echoed by Peter Walsh of Action Against Medical Accidents, who says some hospitals were allowed to go on for years without compliance.

WALSH: What we found through our research was that there is actually no system in place to systematically monitor compliance and follow up with trusts. For one thing, the National Patient Safety Agency doesn't have the powers to regulate and they're very clear about not being a regulator.

O'HALLORAN: So the Agency doesn't have the power to enforce its own advice in its alerts?

WALSH: No. The Department of Health, when it set up these bodies, rightly or wrongly, decided to completely separate the regulatory function from the educational and guidance function, and so the NPSA can't follow up on its own alerts and regulate them.

O'HALLORAN: Suzette Woodward of the National Patient Safety Agency accepts that its powers are limited.

WOODWARD: It is our responsibility to follow up in terms of support trusts, to find out where they are at the various stages of implementation, so that we can offer advice, guidance and support. It is the Department of Health's current responsibility and the Care Quality Commission to actually regulate the compliance with the alerts that we send out.

O'HALLORAN: See, one hospital trust has not complied apparently – or had not complied – with 37 national patient safety alerts. That's a majority of them, I think, by the end of last year.

WOODWARD: I'm not aware of what that organisation is or whether they have or whether they haven't. I couldn't comment.

O'HALLORAN: Does it worry you?

WOODWARD: What worries me is that organisations are finding it hard to comply with our alerts and what worries me is whether we actually have created a system in which we are supporting people to do so, and I think that what they haven't had to date is as much support as they could have done by various national organisations, including ours.

O'HALLORAN: We wanted to ask the Government why so many NHS trusts have been allowed to evade complying with safety alerts for so long, but the Department of Health rejected our request for an interview. It said, in a statement, that the vast majority of patients receive high quality, safe and effective care. But, it went on:

READER IN STUDIO: We expect all NHS trusts to comply with the safety alerts and to record and action them. However, not all organisations may be updated the system reliably and in a timely fashion. The Department will shortly be issuing all NHS organisations a formal reminder of their obligations to do this.

O'HALLORAN: The Department says, from April this year, the reporting of serious patient safety incidents will become mandatory, and it claims new measures will allow the regulator, the Care Quality Commission, to improve the monitoring of safety incidents and the process of ensuring compliance with alerts. But what exactly have the Commission and its predecessor – the Healthcare Commission – been doing up to now to bring NHS trusts into line on patient safety alerts? The Commission's Director of Registration is Linda Hutchinson.

What did you do to get those trusts to actually comply with all these alerts that millions of money are being spent on producing at the Patient Safety Agency?

HUTCHINSON: Well, where we have identified that there was non compliance, we have asked for action plans from those trusts about what they are doing to address that.

O'HALLORAN: But how on earth could hospital trusts get away with failing to comply with absolutely basic Patient Safety Agency alerts year after year? Some of these go back to the middle of the last decade.

HUTCHINSON: Well absolutely. It is the trusts, the trusts have a duty to have, you know, make sure that patients in their organisations are safe. The Healthcare Commission also published a report in March 2009 called Safely Does It, which looked very specifically at patient safety. So it was very aware of the issues that you are raising and was reporting on them, doing further investigations.

O'HALLORAN: Mustn't there have been a lot of trusts that simply ignored all this encouragement, advice and so on, whether it came from you or the Agency?

HUTCHINSON: There may be trusts who weren't doing all that they could on patient safety, and absolutely we would expect that they are addressing that.

O'HALLORAN: See, the widow of a man who died as a result of a drug mix-up, Lisa Richards-Everton, is saying a government body needs to go into all these trusts and check they are complying. Is that really what you're going to be doing or are you just going to be asking them whether they're complying and then signing off on it?

HUTCHINSON: I think it would be inappropriate for us to be in all trusts each day, every day. That's clearly not the role of the regulator. The primary responsibility for implementing patient safety systems is with the trusts themselves. Our role will be focusing our attention on those ones where we feel that there's a risk they're not complying. In addition, we will be doing some random checks, so even those trusts where we feel there aren't problems, we will be able to go in and see and check for ourselves.

O'HALLORAN: And what about all those trusts who profess they are complying with safety alerts? How much reliance can be placed on a system based largely on self-certification? Last year the regulator inspected just fourteen acute trusts on this issue. Of those it found four – more than a quarter – which it judged not to be in compliance, despite their claims to the contrary. Figures which, if replicated across hundreds of trusts, would mean that scores were in breach of the process. However, Linda Hutchinson of the Care Quality Commission is inclined not to judge them harshly.

HUTCHINSON: That's something that we do find sometimes, that when you sort of shine a particular light on something then you can find gaps that the trusts themselves may not have identified. That doesn't necessarily mean that they are trying to cover anything up or lying. It's just that when we look at it in more detail, then gaps are identified.

O'HALLORAN: Is it fair to say that some trusts have driven a coach and horses through your system of self-certification?

HUTCHINSON: The role of the Healthcare Commission and the role we inherited from them around the annual health check and the reporting and the monitoring ...

O'HALLORAN: I mean, is there a yes or no to that?

HUTCHINSON: I wouldn't say it was riding a coach and horses. We know that self certification, self assessment, self declaration carries the risk that some trusts do not do thorough enough checks for themselves in order to make their declaration. We hope that where trusts have made unrealistic declarations we would want to investigate that and look at it quite seriously.

O'HALLORAN: Up until now, the system of learning the lessons from medical mistakes appeared to be working smoothly. Thousands of reports flooded in each day, the worst incidents were analysed and alerts were sent out to tell staff how to cut the risks. But when it came to ensuring the learning was actually being done, there were serious gaps, only now exposed. A failure which may have cost many lives, whether you accept the official number of under 4,000 deaths a year due to medical blunders or the much higher independent estimate of around 25,000. Now the Government suggests it's moving fast to try and put things right. But the impression remains that medical mistakes remain a serious, though largely hidden threat to the lives of patients, and that officials may so far have seen only the tip of the iceberg.

SIGNATURE TUNE