

Young, Christine

From: Garrett, Elizabeth
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To: Young, Christine
Subject: Submission-interview re Lucy Crawford



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As requested.

Liz

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From Dr M McCarthy
Senior Medical Officer

Date 25 May 2004

- 1 CMO
- 2 Secretary
3. Mrs Angela Smith

**INTERVIEW WITH THE IMPARTIAL REPORTER ON THE DEATH
OF LUCY CRAWFORD**

Issue: Minister has agreed to an interview with the
Impartial Reporter on Thursday 3 June.

Timing: Urgent

Presentational Issues: The death of Lucy Crawford and subsequent
inquest has attracted considerable media
attention particularly from UTV and the
Impartial Reporter.

Recommendation: Minister notes briefing and Q & A material.

Background

Lucy Crawford, a 17-month-old child died in April 2000, following admission to the Erne Hospital with a history of vomiting and fever. An inquest into her death, completed on 19 February 2004, concluded that Lucy died from:

(a) Cerebral oedema, (b) acute dilutional hyponatraemia, (c) excess dilute fluid.

Lucy's inquest followed the inquest into another death from hyponatraemia in a 9-year-old girl, Raychel Ferguson, who died in June 2001 following an admission to Altnagelvin Hospital where she had an appendicectomy. There were a number of similarities in the two cases, with the administration of excess dilute fluid cited in both as contributing to the deaths.

1. Hyponatraemia (a low sodium level in the blood) is known to be a risk in any child receiving prescribed fluids. It is potentially extremely serious, with a rapid fall in sodium leading to cerebral oedema, seizures and possible death. Hyponatraemia most often reflects a failure to excrete water. Stress pain, nausea and vomiting are all potent stimulators as a hormone, ADH that inhibits water excretion. Therefore a sick child, if given excess fluids, may not be able to excrete water adequately. The retention of water may, in severe cases lead to cerebral oedema (swelling of the brain) and ultimately death.
2. Lucy Crawford was admitted to the Erne Hospital on the evening of 12 April 2000 with poor oral intake, fever and vomiting. At that time a presumptive diagnosis of a viral infection was made. She was dehydrated and required intravenous fluids which were commenced about 10.30pm. At about 3.00am on 13 April Lucy collapsed, and was transferred to RBHSC at 6.00am, but in a moribund state. She was pronounced dead at 13.15pm on 14 April.
3. Lucy's death was reported to the coroner's office. Advice was sought from the State Pathologist's Department regarding the need for a coroner's post-mortem examination. Following discussion between the

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state pathologist and a consultant paediatrician at the RBHSC, it was agreed that a death certificate could be issued giving gastroenteritis as the cause of death. A coroner's post mortem was not conducted.

4. The Sperrin Lakeland Trust conducted an internal review into Lucy's death, concluding that neither the post-mortem nor an independent medical report provided could fully explain Lucy's deterioration. Specifically the review commented that the fluids Lucy received were, in both type and amount, within the accepted range, but cited poor record keeping as leading to confusion over prescribed fluids.
5. In January 2001, and again in March 2001, the Sperrin Lakeland Trust offered to meet with the Crawford family to discuss the findings of the review. No meeting was accepted but the family progressed with legal proceedings, the Trust accepting liability and settling out of court in December 2003. A statement issued by the Trust is attached at Tab 3.
6. It was only in February 2003 following the inquest into Raychel Ferguson's death that the coroner was alerted to the similarities between Lucy Crawford's case and that of Raychel Ferguson a nine year old who had died from hyponatraemia. Subsequently an inquest was opened and the case heard in February 2004.
7. Further legal proceedings have been brought against the Trust by the Crawford family, the outcome of which remains pending. A meeting between officials and Sperrin Lakeland Trust management will be held on Tuesday 1 June to clarify the sequence of events, action taken by the Trust, and the rationale underpinning decisions. Further briefing will advise Minister of any additional information obtained.

Presentation Issues

8. Both UTV and the Impartial Reporter have taken a particular interest in this case. The Impartial Reporter and the Irish News have run a number of articles (Tab 4) and has requested an interview from Minister on several occasions. UTV featured Lucy's case on an edition of the programme 'The Issue' on which the CMO was interviewed. A transcript of this and other CMO interviews are attached (Tab 5).
9. Following the broadcast of 'The Issue' Secretary wrote to Alan Bremner at UTV to complain about the programme, specifically the aggressive line of interviewing that prevented Dr Campbell presenting relevant information to the viewing audience. A copy of correspondence between Secretary and Mr Bremner is attached at (Tab 6). I also attach correspondence from CMO to the Crawford family (Tab 7).
10. Both UTV and the Impartial Reporter maintain a high level of interest in this case and would appear to be co-ordinating their activities. CMO agreed to be interviewed by Denzil McDaniel on 25th May. An article is expected in tomorrow's Impartial Reporter (27 May) and will be forwarded to you prior to tomorrow's pre-brief. Also, I understand that UTV are now making another television programme on this.

In Minister's upcoming interview Denzil McDaniel is likely to focus on a number of issues including:

- The clinical management of Lucy
- The Trust's accountability and accountability in the HPSS. **DHSSPS-C Gowdy**
- The action taken to ensure a similar incident will not happen again.
- The reporting of untoward events in the HPSS.

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- His assertion that the CMO did not fully accept the coroner's verdict and that her comments on hyponatraemia were inconsistent with those of some paediatricians.

I will briefly summarise the current position on each of these issues. Relevant Q&A material is attached at Tab 6 and key messages are summarised in Tab 7.

Clinical management of Lucy

12. As legal proceedings are still ongoing Minister is advised not to comment on the specific detail of Lucy's hospital admission or subsequent death. The Trust has accepted liability for the events, which caused Lucy's death as evidenced by the out of court settlement and the case was fully investigated by the coroner.
13. Detail of the conduct of the consultant paediatrician involved in Lucy's management has been referred to the General Medical Council, which will through its normal procedures consider the case and whether there are grounds for disciplinary action.

The Trust's accountability and accountability in the HPSS

14. In 2000, at the time of Lucy's death, the statutory Duty of Quality on HPSS providers had not been introduced. The Trust did however take appropriate steps to investigate the reason for Lucy's death. A case review was conducted and a paediatrician from Altnagelvin Hospital was invited to act as an independent medical assessor.
15. Following the case review and subsequent legal proceedings the Trust accepted liability for Lucy's death and paid an out-of-court settlement to the Crawford family. In a recent interview for the Impartial Reporter,

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Mr Hugh Mills, Chief Executive of the Sperrin Lakeland Trust accepted that the Trust was responsible for Lucy's death.

16. Since 2000, extensive work has been undertaken by the Department to raise the quality of services and tackle poor performance across the HPSS. The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 which came into effect in February 2003:

- placed a statutory Duty of Quality on all HPSS providers;
- strengthened the existing system of regulation and inspection by creating an independent Regulation and Improvement Authority; and
- gave the Department powers to set minimum standards against which the delivery of health and social care services will be inspected and monitored.

17. The HPSSRIA is an independent, non-departmental public body, and will be accountable through the Department to Minister. In delivering on its responsibilities, the HPSSRIA will exercise two main functions:

- to inspect the quality of health and social care services provided by Health and Personal Social Services (HPSS) bodies in Northern Ireland. These inspections will address arrangements for clinical and social care governance within HPSS bodies.
- to regulate (register and inspect) a wide range of health and social care services delivered by HPSS bodies and by the independent sector. Registration, inspection, complaints investigation will be carried out to consistent standards across Northern Ireland with the regulated services provided by both the HPSS and independent sectors being treated in the same way.

18. Mr Brian Coulter, recently appointed by Minister as the first Chairman of HPSSRIA, will take up post from the 1st June 2004. The Authority will assume powers on a staged basis from Spring 2005.
19. Clinical and Social Care Governance is a framework within which HPSS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment.
20. Clinical and Social Care Governance is underpinned by a statutory duty of quality. The HPSSRIA will review governance arrangements within the HPSS and in cases where it finds problems with services, will have the ability to issue improvement notices and to bring this problem to the attention of the Department.
21. To help develop clinical and social care governance in Northern Ireland, the Department has engaged with the NHS Clinical Governance Support Team (part of the Modernisation Agency), to establish a similar multi-disciplinary Support Team for the HPSS. By linking up with the NHS in this way as we develop our own local arrangements, we will have access to several years of experience, knowledge and tools, as well as individual expertise.
22. In addition to leading the development and implementation of clinical and social care governance in the HPSS, it will work to sustain longer-term cultural change and organisational development so as to ensure continuous improvement in health and social care services.

Action taken to ensure a similar incident will not happen again

23. When the Chief Medical Officer was made aware of Raychel Ferguson's death she immediately convened a small working group to develop

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guidance on the prevention of hyponatraemia in children. The guidance, issued in March 2002 emphasised that every child receiving fluids requires a thorough baseline assessment, that fluid requirements should be assessed by a doctor competent in determining a child's fluid requirements and that fluid balance should be regularly monitored. This guidance was introduced almost a year before the inquest into Raychel's death.

24. In March 2004, CMO wrote to Trust Chief Executives requesting assurance that the guidance had been implemented throughout Trusts, and responses received to date confirm that the guidance has been incorporated into clinical practice. Furthermore, following the inquest verdict on Lucy Crawford's death, CMO has engaged a national expert to quality assure the guidance in light of the findings of the inquest and any new or emerging evidence available.
25. The Chief Medical Officer's immediate and effective response in producing guidance following Rachel Ferguson's death will help ensure that a similar incident should not happen again.

Reporting on untoward events in the HPSS

26. In 2000 there was no rigorous system for the reporting of adverse incidents in the HPSS. Much has changed since then and a number of steps are being put in place to facilitate adverse incident reporting
 - A Safety in Health and Social Care Group (SHSCG) has been established under the auspices of Best Practice, Best Care Steering Group. The remit of this Group includes development of a strategic approach to the recording, reporting and investigation of adverse incidents and near misses.

- The SHSCG recently commissioned a report on current arrangements for the reporting and management of adverse incidents and near misses in HPSS organisations and specials agencies. This report highlighted that there is inconsistency in approach, across HPSS organisations, to “adverse incident” policies, procedures, reporting, recording and management. Having considered this Report, the Group aims to put its recommendations on the pathway forward to the Department, in the next few weeks.
- Following endorsement of the pathway forward by Minister, comprehensive guidance will be issued to the service on systems’ approaches to the prevention and management of adverse incidents, and the promotion of a learning culture.
- Part of the recommendations of the Group will be to link with a national organisation, the National Patient Safety Agency (NPSA- created in July 2001). The Group is currently working with NPSA to develop a formal agreement between this Department and NPSA, to the benefit of patients, clients and HPSS staff. Subject to endorsement by Minister, it is anticipated that formal arrangements will be agreed in the next few months.
- At NPSA, there is a recognition that healthcare will always involve risks, but that these risks can be reduced by analysing and tracking the root cause of patient safety incidents. The aim of NPSA is to raise awareness among NHS staff on “patient safety” issues and to develop training, tools and systems to prevent incidents from happening. Where incidents do occur, to promote an open and fair culture among organisations that will encourage staff to report incidents so that lessons can be learnt and staff can use this information to avoid future risks.
- The SHSCG is keen to formalise links with NPSA to enable access for the HPSS to training, tools and guidance produced by NPSA. In

addition, where solutions have been developed for high-risk areas, to facilitate local implementation of solutions.

- In the future, the HPSS may be able to link with the NPSA's National Reporting and Learning System, which is currently being rolled out to Trusts in England. This system facilitates anonymous reporting by NHS staff into a system, managed by NPSA, which is capable of collating information, thereby determining where further research and /or guidance is needed. However, any future link will not supersede the need to have robust local systems in place, which are capable of reporting, recording, investigating, and managing local adverse incidents, and cascading lessons learnt locally. Therefore, the main focus of the SHSCG, to date, has been to try and enhance local systems.
- As an initial step, the Department will issue, within the next few weeks, interim arrangements for the reporting and follow up of serious adverse incidents in the HPSS. This guidance aims to complement existing procedures. It would, however, provide an "early warning system" for the Department on major adverse incidents, which are likely to generate significant media interest and where regional guidance might be required to improve care for patients, clients and staff.

Denzil McDaniel's assertion that CMO did not fully accept the coroners verdict and that her comments on hyponatraemia were inconsistent with those of some paediatricians.

27. Having interviewed the CMO on 25 May, it is unlikely that Denzil McDaniel will focus on these particular issues. It should be emphasised that the CMO did not at any time dispute the coroners findings and in fact she has confirmed that she fully accepts the coroners verdict.

28. The CMO's comments on 'The Issue' programme emphasised that severe hyponatraemia is rare, that the type of fluid prescribed to Lucy was one commonly used, and that staff were not fully aware of the risk of severe hyponatraemia at that time. Denzil McDaniel's asserts that the latter point is disputed by Dr Summer who was an expert witness at Lucy's inquest. The fact remains that there was not a widespread awareness of the risk of hyponatraemia and that the CMO's guidance, as the first of its type in the UK was welcomed and praised by many, including Dr Summer.
18. There is still considerable debate among paediatricians regarding the most appropriate fluid therapy for children, as emphasised in a recent debate featured in the Archives of Disease in Childhood, a highly respected paediatric journal.

RECOMMENDATIONS

That Minister notes the background material, Q&As and key messages in preparation for the telephone interview with Denzil McDaniel for the Impartial Reporter.

DR MIRIAM McCARTHY
Senior Medical Officer

QUESTIONS & ANSWERS

Q1 Do you think Lucy's death should be properly investigated by holding an independent inquiry.

A1 The cause of Lucy's death was fully and comprehensively investigated during the coroner's inquest. I accept the coroner's verdict and do not think that an independent inquiry will provide additional information.

I believe it is much more important that we invest our efforts in making sure that a similar tragic death does not happen again. In particular the guidance on the prevention of hyponatraemia issued by the Chief Medical Officer, and our current work to develop a system for reporting adverse incidents will help avoid a similar event in the future.

Q2 Was the Sperrin Lakeland Trust negligent in failing to report Lucy's death to your Department.

A2 At the time of Lucy's death there was no formal system for Trusts to report a death such as Lucy's. Work is currently underway to develop arrangements for the reporting and follow-up of serious adverse incidents in the HPSS. This guidance will provide an 'early warning system' for the Department on major adverse incidents. I expect advice on interim arrangement to be issued in the near future.

Q3 Are you happy with the investigation conducted by the Trust.

A3 The Trust acted correctly in conducting a case review into Lucy's death, including the involvement of an independent medical consultant. That review highlighted shortcomings in the documentation of Lucy's

medical records. I understand the Trust took appropriate steps to improve record keeping. [DN check was steps taken].

Q4 Why did Sperrin Lakeland not report Lucy's death when Altnagelvin did report Raychel's death.

A4 Ideally both deaths should have been reported. However in 2000 there was formal system for reporting such deaths. Since then much has changed and a mechanism for the reporting of adverse incidents is currently being developed.

Q5 Why was Lucy's death not reported to the coroner?

A5 Lucy's death was reported to the coroner's office. Following discussion of the case between the state pathologist and a consultant paediatrician a decision was made that a coroner's post-mortem was not required. This decision was based on the available evidence at the time of Lucy's death.

Q6 The CMO is on record as stating that she knew about Lucy's death in 2001 then corrected her statement the next day. Can you comment.

A6 Let me first emphasised the sequence of events. Lucy died in April 2000. Raychel Ferguson died in 2001 and her inquest was held in February 2003. It was only after the inquest into Raychel's death in which a verdict of hyponatraemia was reached, that the coroner was made aware that Lucy and Raychel may have both died from hyponatraemia. Therefore the CMO was informed of Lucy's death in March 2003, this she has confirmed on record.

Q7 Why was Dr Summer not called in earlier by the Department.

A8 Dr Summer is a well-recognised expert on fluid management and hyponatraemia. My Department did consult Dr Summer and other experts in paediatrics in formulating the guidance.

Q9 Will you apologise to Lucy's family for her death.

A9 I am truly sorry for the tragic circumstances around Lucy's death and I apologise on behalf of the health service.

Q10 Will you meet the Crawford family?

A10 I know that the CMO has offered to meet the Crawford family and hope they will find that of some help. However, if it is of any help to the family and they would like a meeting I would be very willing to accommodate them.

Q11 The CMO appears to disagree with the verdict of the coroner.

A11 I want to emphasise that I fully and unconditionally accept the verdict of the coroner regarding the cause of Lucy's death. I also want to stress that the CMO has gone on public record to the Irish News and to yourself endorsing the findings of the coroner.

There is still ongoing debate about fluid management in children and specifically about the risk of hyponatraemia. The prevention and treatment of hyponatraemia is a complex area but I am content that the guidance issued by CMO which is currently in place will ensure that hyponatraemia can and will be prevented in children.

Q12 Do you think that Lucy's death was due to an idiosyncratic reaction to fluid.

A12 I am not of course a clinician. Hyponatraemia and its cause is a complex matter and I don't pretend to fully understand what I want to put on public record is that I fully and unconditionally accept the coroner's verdict on Lucy's death.

Q13 There is another inquest into a young boy's death being held this week. Is this yet another hyponatraemia?

A13 There is an inquest currently being held and I am content that the coroner will fully investigate the cause of death. Until its completion I cannot comment on this inquest.

Q14 Surely the Doctor should have been aware of the possibility of hyponatraemia.

A14 Hyponatraemia was not as you have said in your articles a widely known effect of fluid treatment. In fact there is still considerable debate among paediatricians regarding the most appropriate intravenous fluid therapy for children.

In fact, there is still considerable debate among paediatricians regarding the most appropriate intravenous fluid therapy for children. The area of fluid administration in a sick child remains a complex area and within the past few weeks a series of articles published in the highly respected paediatric journal.

Q15 Was the doctor involved negligent?

A15 I am not responsible for the individual actions of doctors. The coroner has referred the papers in this case to the GMC and therefore it would be inappropriate to make any further comment.

Q16 There was an article on hyponatraemia in BMJ as far back as 1992, why did it take so long to introduce new guidelines?

A16 There were some article but it was not an issue that was being widely debated at the time and it is still a subject of considerable debate among paediatricians.

Having been alerted to this issue by the coroner following the death of Raychel Ferguson the Chief Medical Officer convened an expert working group to develop guidance on the prevent of hyponatraemia. This guidance was published in 2002 providing practical advice for doctors and nurses who manage the care of children in hospital. This guidance is the first of its kind in the UK and has been commended by Ed Summer, an expert witness called by the coroner to Lucy's inquest.

Q17 Was the Trust at fault for not alerting you to Lucy's death?

A17 It was not the Trust's fault but it does point out that there was a gap in the arrangements for informing me of such events. This was hampered by the absence of a formal system to report untoward deaths within hospitals at the time of Lucy's death. In Northern Ireland there are about 15,000 deaths each year, the majority of which occur in hospital. Approximately 3,500 of all deaths each year are reported to the coroner.

Measures are being taken both by the coroner's office and by the health service to establish a system, which will identify untoward deaths and allow early action to be taken.

Q18 Should the Chief Executive of the Trust resign?

A18 I am satisfied that the Trust investigated the case properly and I see no reason for the Chief Executive to resign.

What I would say, as you have quite rightly pointed out in one of your articles, is that the Erne Hospital is a fine one, with my dedicated, able and professional staff.

Q19. Would the new arrangements you have outlined prevented events, such as the Lucy Crawford case, from happening?

A19. These arrangements, taken in conjunction with other initiatives will help to promote safety in the HPSS and should help minimise the risk of something going wrong and causing harm to a service user. No system could offer a total guarantee that nothing bad will happen. We can however make sure that through training, through good risk management, through governance and by independent inspection that the safety mechanisms designed to prevent such things from happening are as fail-safe as possible

Q20. Why has it taken so long to make decisions on Best Practice-Best Care?

A20. Since the consultation exercise was completed in 2002, there have been developments taking place elsewhere which could have a direct impact on the proposals set out in "Best Practice - Best Care". Of particular significance were changes to the directions and legislation governing NICE and the Commission for Health Improvement. Consideration of such developments needed to be taken account of before taking final decisions on the arrangements required for the HPSS.

Q21. What has been done?

A21 Legislation came into force in February 2003 placing a statutory Duty of Quality on all HPSS providers. We have also made progress towards establishing a new HPSS Regulation and Improvement Authority, developing standards against which to inspect and have put in place

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arrangements to support the HPSS in improving health and social care.

Q22. What is the duty of quality on the HPSS?

A22. By placing a statutory duty of quality on chief executives of HPSS organisations we will for the first time be able to ensure the quality of services delivered, in the same way that financial probity is adhered to. The introduction of clinical and social care governance will bring together all existing activity relating to the delivery of high quality services such as education, training, audit, risk management and complaints management.

Q23. To which organisations will the statutory duty apply?

A23. This statutory duty will cover both Health and Social Services and will apply to HSS Boards, HSS Trusts and those Special Agencies which provide services directly to users e.g. The Northern Ireland Blood Transfusion Agency.

Q24. What is Clinical and Social Care Governance?

A24. Clinical and Social Care Governance is a framework within which HPSS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment. Clinical and Social Care Governance is about organisations taking corporate responsibility for performance and providing the highest possible standard of clinical and social care.

Q25. What role will standards and guidelines play in promoting quality in Health and Social Care services?

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A25. Standards and guidelines are essential to both the regulation of services and also to the development of governance arrangements within the

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HPSS. Registration and inspection will be against compliance with minimum standards of care. Inspection of governance within the HPSS will also include assessing compliance against relevant standards and guidelines.

Q26. What are the functions of the HPSS Regulation and Improvement Authority?

A26. The core functions of the HPSSRIA are to:

- regulate services;
- conduct reviews;
- undertake investigations; and
- undertake inspections.

Q27. What will it actually do?

A27. The new Authority will have a key role in promoting the quality of services delivered here both by the HPSS and by the independent sector. This will be achieved through a combination of regulating a range of services and also inspection of the effectiveness of governance within the HPSS. The Authority will be required to advise and inform the Department with regard to the quality of services and to support service users by investigating complaints and ensuring adequate information is available to them. It will report on service performance against standards and the requirements set out in clinical and social care governance guidelines and will advise the HPSS and other service providers on how they can comply with those standards and governance requirements.

Q28. How will all this help service users?

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A28. Service users will benefit from the new system in a number of ways.

The regulation of services in accordance with published minimum care

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standards will mean that service users will know what they can expect from providers, wherever they are in NI. The same applies to the HPSS where standards and governance guidelines will also be published setting out the quality of services which users should expect to receive from the HPSS.

Q29. Why not regulate hospitals as well?

A29. The basic problem is that hospitals do not provide a service; they provide hundreds of different services.

Q30. What will the HPSS Regulation and Improvement Authority investigate?

A30. The HPSSRIA will have power to investigate, report and/or advise on matters relating to the delivery and management of health and social care services provided by or on behalf of one or more HPSS bodies at the request of the Department such as an investigation into a specific complaint or incident.

Q31. So if the HPSSRIA had been in existence it could have investigated the death of Lucy Crawford?

A31. Yes.

KEY MESSAGES

- The death of a child is tragic and I want to offer my most sincere sympathy to Lucy Crawford's family.
- I fully accept the coroner's verdict on the cause of Lucy's death.
- I acknowledge that my Department did not know of Lucy's death until 2003. In 2000 there was no formal system for reporting deaths such as Lucys. Today we are developing a mechanism for the reporting of untoward events in the Health Service.
- I am satisfied that the cause of Lucy's death was fully and comprehensively investigated by the coroner and I do not think that any further investigation is required.
- The circumstances surrounding Lucy's death and the subsequent inquest raised a number of important issues, which my Department is addressing, including the reporting of untoward events in hospitals; and good records management.
- It is important that we learn from the lessons of Lucy's death and we have done so. Following the death of Raychel Ferguson from hyponatraemia in 2001, the Chief Medical Officer acted immediately to develop guidance that would prevent a similar incident happening again. This guidance has incorporated into clinical practice since 2002 and is currently being reviewed in light of the verdict on Lucy's death and any emerging evidence.
- Under clinical governance arrangements introduced last year, my Department is strengthening the systems for quality assurance with

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Trusts. In particular, work is underway to improve the mechanism for reporting and investigating untoward incidents in hospitals.

- Accurate record keeping, found seriously lacking in Lucy's case, very important matter within the health service. My Department is currently working to ensure that measures are in place to maintain good medical record keeping.

Distribution List

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