

Bill, Jonathan

From: McCann, Noel
Sent: 01 June 2004 14:32
To: McCarthy, Miriam
Cc: Bill, Jonathan
Subject: FW: Hyponatraemia

Miriam

Good work. I have made some suggestions on the Q & A which I hope are useful. I think the interim guidance **has to be out** before the interview.

One or two points in your briefing will need to be revised to reflect the date on which you are now submitting it (eg paras 7 and 10 - I haven't touched these).

NOEL

-----Original Message-----

From: McCarthy, Miriam
Sent: 01 June 2004 13:50
To: Sullivan, Dean; Shannon, Colm; Mulhern, Kevin; McCann, Noel; Bill, Jonathan
Subject: Hyponatraemia



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FYI,

I note the Q&A on apoligy has not been changed

Happy to discuss- I will be ammending some of the Q&A in light of this mornings discussions with Trust and will attach revised Q&A to additional briefing.

Happy to have input or help with this as it must be finalised by 5pm

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QUESTIONS & ANSWERS

Q1 Are you happy with the investigation conducted by the Trust?

A1 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 steps taken to be checked when officials meet with Trust on 31st May].

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Q2 Do you think Lucy's death should be properly investigated by holding an independent inquiry?

A2 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.

Q3 Was the Sperrin Lakeland Trust negligent in failing to report Lucy's death to your Department?

A3 No. At the time of Lucy's death there was no formal requirement for Trusts to report a death such as Lucy's to the Department. The reporting of such a case was a matter of judgement for the Trust concerned. Since then, we have decided to strengthen the arrangements and recently my Department issued guidance requiring all serious adverse incidents to be reported.

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Q4 Without a formal system how do your Department expect to hear of untoward deaths?

Deleted: 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.

A4 The in which untoward deaths are reported to the coroner's office provides a mechanism by which unexplained deaths are appropriately investigated. Each year, there are about 15,000 deaths in Northern Ireland, the majority of which occur in hospitals. Almost 3,500 deaths are reported to the coroner annually and approximately 1,400 coroners post-mortems are concluded.

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The existing system of reporting deaths is to be strengthened. The Home Office proposals *Reforming the Coroner and Death Certification Service*, proposes that all deaths will be reported to the coroner's office through newly established medical examiners. This will be introduced over a number of years.

Q5 Why did Sperrin Lakeland not report Lucy's death to your Department when Altnagelvin did report Raychel's death?

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A5 Ideally both deaths should have been reported. The reporting of such cases was, however, a matter of judgement for the Trust concerned, based on the facts they knew at the time. Since then, we have decided to strengthen the reporting arrangements and recently my Department issued guidance requiring all serious adverse incidents to be reported.

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Deleted: However in 2000 there was no formal system for reporting such deaths. Since then much has changed and a mechanism for the reporting of adverse incidents is currently being developed

Q6 How many untoward deaths are reported to your Department each year?

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A6 There are only a small number of deaths reported directly to the Department each year. I know that the Northern Ireland Adverse Incident Centre, which receives reports of any untoward incidents associated with medical equipment and devices, received 241 reports of incidents. Since 1998 there have only been 4 reported cases of deaths related to medical devices.

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Q7 Why was Lucy's death not reported to the coroner?

A7 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.

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Q8 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?

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A8 Let me emphasise 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, and this she has confirmed on record.

Q9 When were you informed of Lucy's death?

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A9 I was formally notified of Lucy's death following her inquest in March 2004. However, the Chief Medical Officer was informed in March 2003 and her office very appropriately brought Lucy's death and Rachel's to the attention of

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the National Patient Safety Agency, which is responsible for the Safety of patients in the NHS.

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Q10 Why was Dr Sumner not called in earlier by the Department?

A10 When CMO's guidance was being developed the working group included paediatricians, paediatric intensive care specialists, a specialist in laboratory medicine and a nurse. Dr Sumner, a well-recognised expert on fluid management and hyponatraemia, made a valuable contribution in formulating the guidance and he has recently praised it.

Q11 Will you apologise to Lucy's family for her death?

A11 I apologise for the tragic death of Lucy although I know that no words will ease the loss for her family.

Q12 Will you meet the Crawford family?

A12 Yes, I have written to Mr and Mrs Crawford and I have offered to meet with them.

Q13 The CMO appears to disagree with the verdict of the coroner, can you comment?

A13 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.

Q14 Do you think that Lucy's death was due to an idiosyncratic reaction to fluid?

A14 I am not of course a clinician. Hyponatraemia and its cause is a complex matter that 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. I do know that 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 the CMO which is currently in place will ensure that hyponatraemia can and will be prevented in children.

Q15 Surely the doctor treating Lucy should have been aware of the possibility of hyponatraemia?

A15 Hyponatraemia was not as you have said in your articles, a widely known risk of fluid administration. 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.

Q16 Was the doctor involved negligent?

A16 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.

Q17 There was an article on hyponatraemia in BMJ as far back as 1992, why did it take so long to introduce new guidelines?

A17 Yes, there were some articles on hyponatraemia but it was not something known widely. Following the death of Raychel Ferguson the Chief Medical Officer convened an expert working group as a matter of urgency 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 Dr Sumner, an expert witness called by the coroner to Lucy's inquest.

Q18 There is another inquest into a young boy's death being held this week. Is this yet another death from hyponatraemia?

A18 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.

Q19 Was the Trust at fault for not alerting you to Lucy's death?

A19 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 here or anywhere else in the UK 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.

Q20 Should the Chief Executive of the Trust resign?

A20 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 dedicated, able and professional staff.

Q21. Would the new arrangements you have outlined prevented events, such as the Lucy Crawford case, from happening?

A21. 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. But no system can offer a total guarantee that nothing untoward will happen. We can however make sure that through training, through good risk management, through governance and by

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independent inspection that the safety mechanisms designed to prevent such things from happening are as fail-safe as possible

Q22. Why has it taken so long to make decisions on Best Practice-Best Care?

A22. 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.

Q23. What has been done?

A23 Legislation came into force in February 2003 placing a statutory Duty of Quality on all HPSS providers. From April next the new Regulation and Improvement Authority will be working to improve standards of treatment and care. Just last week, I announced that Brian Coulter would be the Chairman of the new body and work is now under way to get the new organisation established.

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Q24. What is the duty of quality on the HPSS?

A24. 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.

Q25. To which organisations will the statutory duty apply?

A25. 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.

Q26. What is Clinical and Social Care Governance?

A26. 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.