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Public Health Agency

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Dr P Loughran
Medical Director
Southern Trust HQs
College of Nursing
68 Lurgan Road
PORTADOWN
BT63 5QQ

CONFIDENTIAL

1 September 2010

Dear Dr Loughran

In the context of the Urology Review implementation process, I was present at a recent meeting with Trust staff to discuss progress. I had already noted from the written submission that there appeared to be a high proportion of elective urology episodes at CAH which did not have an operative procedure. This is being explored further, but in a brief discussion with the Clinical Director for Surgery it appeared that the practice of some urologists of admitting patients for intravenous fluids and antibiotics as a treatment for chronic urinary tract infections has not ceased. If I understood the position correctly, some patients may now be receiving this treatment via central lines. I would be very concerned if this was the case. I forwarded to Mr Mackle the email correspondence to your secretary which set out my opinion on this practice back in January. I had assumed steps were being taken to bring this to an end.

Following the recent meeting I re-read the external expert reports relating to the use of IV therapies at CAH (Appendices of the draft document I was asked to comment on last January). There was one sentence which read "Whether these patients have been well served by the major bladder surgery they have undergone is difficult to say as the records do not include the original letters leading up to the surgery." In the context of my unease at the ongoing use of a treatment at CAH which had not been supported

by external experts, I informed Mr Mackle that I intended to seek NI-wide information on the numbers of cystectomies and ileal conduit procedures carried out by Unit and consultant across NI. I was seeking assurance that the use of operative intervention in patients with chronic cystitis at CAH was in keeping with that in other units.

I enclose data from 2005/06 to 2009/10 from all hospitals in NI, including CAH. The search criteria selected elective admissions of patients who had either cystectomy or ileal conduit formation recorded as the primary procedure code. The primary diagnosis is shown alongside. The information has been checked to exclude duplicate patients. These data have to be interpreted with caution as they are dependent on coding quality and the total numbers are very small. I have considered the possibility that patients who had had these procedures done in the past and who were admitted for another purpose might have been recorded incorrectly as having the procedures a second time, thus inflating the total numbers, but the check for duplicate cases would have been expected to minimise this possibility. If this is primarily a coding error then this would indicate a need to review coding practice in the Trust.

From this information it appears that cystectomy and conduit creation is done in the great majority of cases in NI for malignant disease. There appear to be small numbers done for other reasons, though in some cases the diagnostic coding is too vague to be sure what the true underlying diagnosis might have been, e.g. when recorded as 'peritonitis, faecal incontinence, mycobacterial infection or attention to openings of urinary tract'. The role of the regional centre seems to have become more prominent over the five year period, with cessation of cystectomy work at Altnagelvin and the Mater Hospitals. The specialist role in treating patients with spinal problems/neuropathic bladders is reflected in the BCH data.

There is no clear pattern throughout the five-year period in relation to cystectomies done for cystitis, though perhaps the first two years of that period would indicate higher proportions than expected at CAH. In 2005/06 and 2006/07 the cystectomy and/or ileal conduit creation operations recorded across NI were 32 and 41 respectively. The numbers done for reasons other than malignant disease (as per the ICD coding) were 9 and 7 respectively. Four of the 9 done in 2005/06 were for cystitis, of

whom 3 of the four had their operation at CAH. In 2006/07 three of the seven non-malignant patients operated on in NI were coded as having a primary diagnosis of cystitis, all three of whom had their operation at CAH.

From 2007 onwards the number of procedures done for non-malignant indications at CAH fell to 2, 2 and 4. In that group of 8 cases, one was for UTI unspecified and one for mycobacterial infection but none specifically for cystitis.

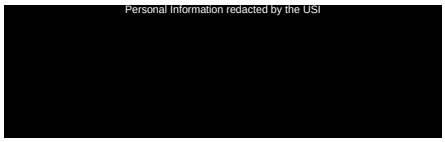
I have asked for information for the five years preceding 2005 and will forward that to you when it becomes available. In the meantime, I would be grateful if the Trust would review this information with a view to checking its accuracy, i.e. that the coding of these cases is correct. Your information department may wish to re-run the data but if they wish to cross-check this version by casenote number the latter can be made available.

Until the data have been verified it may be premature to take any further steps, however depending on the outcome the Trust might wish to consider whether it would be appropriate to seek additional advice from the GB experts who provided the earlier reports.

Following the Urology Review decision, as of March 2010 radical pelvic urology surgery for malignant disease should no longer be being done in SHSCT. This would include cystectomy. Trust staff discussed the process for cancer cases recently at a meeting chaired by Beth Malloy from PMSI Directorate of the HSCB. The rationale for this policy decision, which is in line with IOG guidance, was to concentrate the relatively small number of such cases in the hands of a small number of surgeons who could maintain specialist skills. No specific reference was made in the Urology Review to radical pelvic surgery for non-malignant disease. It was perhaps assumed to be implicit that the even smaller volume of this type of work would also be centralised. I would be grateful for an assurance that the urology team at CAH is now referring on all patients being considered for radical pelvic surgery regardless of the underlying diagnosis.

Lastly, I would be grateful for a report from the Trust detailing what steps are being taken to manage the ongoing risks associated with delivering IV therapies to the original cohort of patients. As a first step, it would be helpful to have an assurance that none are receiving this treatment via a central line. It would also be helpful to have a position statement detailing how many patients are still on this form of treatment and the expected timeframe for this to cease.

Yours sincerely



Dr D Corrigan
Consultant in PHM

Enc

cc Dr G Rankin, Director of Acute Services, SHSCT
Mr E Mackle, Clinical Director of Surgical Services

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Diane Corrigan

From: Diane Corrigan
Sent: 03 September 2010 12:17
To: Cullen, Caroline
Cc: Donnelly, Lyn; McNally, Margaret
Subject: RE: Radical pelvic surgery at CAH

Caroline - this may sound like arguing about angels on pin heads - but it appears the clinicians are now differentiating between radical pelvic surgery for 'cancer' (which unfortunately was the chapter heading under which the Urology Review recommendation sits) as opposed to 'non-cancer' cases. Although Beth is clear that she has never differentiated between the two, technically unless someone was absolutely explicit at the 1st April meeting about it covering non-cancer cases as well, then this is a loophole that was not firmly closed. Although I and Beth have written separate letters this week which now make the HSCB/PHA position clear maybe we are weak in arguing that they should have implemented this for ALL radical pelvic surgery from 1st April. Common sense would have dictated that this should have happened - but that appears to be in short supply.

If you have any recollection on the non-cancer case issue being mentioned it would be helpful to know.

Diane

-----Original Message-----
From: Cullen, Caroline [redacted]
Sent: 03 September 2010 11:15
To: Corrigan, Diane
Cc: Donnelly, Lyn; McNally, Margaret
Subject: RE: Radical pelvic surgery at CAH

Personal Information redacted by the USI

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Hi Diane

Yes it was stated very clearly at both the meeting which Mark Fordham attended and at the most recent meeting (26 July) in CAH when we were all squeezed into the small room.

As a matter of fact what happened at the Mark Fordham meeting was that the Trust disclosed that they had performed radical pelvic surgery in April. The Trust was asked to forward details of the circumstances and the matter was investigated through Heather Trouton and Gillian Rankin - I have copies of the various emails and responses between Beth and the Trust (see attached).

Let me know if I can be of any further help

Talk soon

Regards

Caroline Cullen
Senior Contracts Manager

Contracts Department
Tower Hill
ARMAGH
BT61 9DR

Personal Information redacted by the USI
Direct Line: Personal Information redacted by the USI

-----Original Message-----
From: Corrigan, Diane Personal Information redacted by the USI
Sent: 01 September 2010 21:30
To: Cullen, Caroline
Subject: Fw: Radical pelvic surgery at CAH

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Caroline
You were at the meeting mentioned below by Beth where Mark Fordham discussed these issues. Sometimes people's recollections of what was said differs. Do you think it was as clearly stated as Beth has said? I spoke to Eamon today and if he had got that message clearly he wouldn't have gone over it again with me I think.

Were there any minutes of the meeting?
Diane

----- Original Message -----
From: Beth Malloy Personal Information redacted by the USI
To: Corrigan, Diane Personal Information redacted by the USI
Cc: Little, Janet Personal Information redacted by the USI
Sent: Wed Sep 01 18:19:28 2010
Subject: Re: Radical pelvic surgery at CAH

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Diane
I agree with this point

I have been explicit at all times it is all radical pelvic surgery and have not diffferentiated cancer or other elective. Mark Fordham also reiterated this to the Trust when we meet with them re the review (I think date was 1 April). We discussed at this meeting the lack of MDM and links into Belfast and Mark was clear they needed to refer the patient as they would refer other patients to Belfast and delay due to lack of MDM was not an option. Eamon, Gillian and others from the Trust including 2 of Cons were at this meeting(Aiden was not at the meeting but we met with him and Michael later the same day.)

I spoke to Heather in Southern Trust last Friday and reiterated this point and said it was for all radical pelvic surgery. My e-mail on Friday confirmed this point. The Cons are saying to her this is not possible because they don't have oncologist link for the MDM. I said this was not acceptable and they needed to make arrangements to refer outside this in the interim. The Trust are stating this will be resolved by October. I said that the Board would not support this delay and would the Board had been clear of the actions the Trust were required to take. It is another example of difficulties getting the Cons to change. This is also highlighted by their lack of workload as compared to BAUS suggested levels.

I also raised this issue at the Belfast Trust meeting and made it clear they needed to accomodate/treat these patients within an agreed timeframes. They are stating they need the resources etc. I highlighted that they would

need to explain to the Board what would need to transfer out to allow them to do these cases and it was not acceptable to leave the patients to wait. The Review was clear that this was to be from March 2010.

Thanks

Beth

Sent by Blackberry
Beth Malloy
Performance Management and Service Improvement Directorate
Health and Social Care Board
Personal Information redacted by the USI

----- Original Message -----
From: Corrigan, Diane
To: Beth Malloy
Cc: Little, Janet
Sent: Wed Sep 01 18:06:47 2010
Subject: Radical pelvic surgery at CAH

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Beth

For information.

I spoke to Eamon Mackle this evening. I had sent a detailed letter today to the Trust's Medical Director covering issues related to IV treatment of urinary tract infection and cystectomy rates. In that I had asked for an assurance that there were no further radical pelvic surgery cases being undertaken within the Trust.

Interestingly he too had picked up on the issue we discussed last week that the Urology Review recommendation only related to cancer cases. As a result SHSCT urologists appear to believe that they have not received an instruction to cease radical pelvic surgery for non cancer cases. I said that if that was the case it had been unintentional and we agreed that good practice would have suggested that once the cancer caseload (already small) was removed, then it would not be appropriate to continue to do an even smaller number of complex cases on a DGH site even if their diagnosis was not cancer-related..

The explanation given by the urologists as to why they had not referred on all complex cancer cases since March 2010 appears to be that they believe that the central MDT is not fully functioning and/or they haven't been informed that BCH is ready to receive their referrals. I said that I did not accept that argument. The March 2010 deadline was an explicit recommendation in a review approved by the Minister and it was expected that SHSCT clinincans would be able to demonstrate that they had attempted to refer on such patients to BCH colleagues. If the latter then start to refuse the cases because of capacity constraints that is a different problem, but it would not be

acceptable to make assumptions that the centre could not accept the work as a rationale for continuing to do it at CAH. Do you agree with the line I have taken on this?

The urologists have been invited to meet with the senior management team on Monday to clarify these issues.

Diane

Dr D Corrigan BA MPH FFPH

Consultant in Public Health Medicine

Public Health Agency

Tower Hill

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Diane Corrigan

From: Beth Malloy [Personal Information redacted by the USI]
Sent: 23 July 2010 13:17
To: Trouton, Heather
Cc: Rankin, Gillian; Corrigan, Diane; Cullen, Caroline; David McCormick
Subject: RE: Urology radical pelvic surgery patient

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Heather

Thanks very much for this brief update. I am assuming you are confirming this only affects one patient and no other radical pelvic patients were treated in addition to this?

As you appreciate the review was clear that radical pelvic surgery should only be done in one centre from 1 April 2010.

I would need to know the details for the patient, what was the diagnostic pathway in Southern Trust, when the patient was referred to Belfast, what means was used, date of ITT, and who this was referred to, or was it discussed at the MDM, who from Belfast confirmed they were not able to perform the operation and what reasons given, with the proposed date, when was the final treatment date. This should be readily available from CaPPS

I am assuming now that the Trust is now linking into the local section of the Belfast MDM. Please confirm from what date.

Regards

Beth

Mrs Beth Malloy
Assistant Director Scheduled Services
Performance Management and Service Improvement Directorate Health and Social Care Board
[Personal Information redacted by the USI]

-----Original Message-----
From: Trouton, Heather [Personal Information redacted by the USI]
Sent: 23 July 2010 09:44
To: Beth Malloy
Cc: Rankin, Gillian
Subject: RE: Urology radical pelvic surgery patient

Beth

I have contacted Martina re this patient (she is currently on annual leave). She has advised that she had replied some time ago to say that this issue had been resolved. The patient referred to was scheduled and operated on by Mr Young in Craigavon because Belfast at that time could not accommodate and it had been agreed that Mr young could go ahead in this case.

I hope that this resolves the issue.

Best regards

Heather

Heather Trouton
Acting Assistant Director of Acute Services Telephone ext [redacted]Mobile [redacted]-----Original Message-----
From: Beth Malloy [redacted]
Sent: 21 July 2010 17:43
To: Clayton, Wendy; Trouton, Heather; Rankin, Gillian
Cc: Porter, Alison
Subject: Re: Urology radical pelvic surgery patient

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I refer to my earlier e-mails please could the information requested be submitted to me by Friday 23 July at 12 noon.
Regards
Beth

Sent by Blackberry
Beth Malloy
Performance Management and Service Improvement Directorate Health and Social Care Board
[redacted]

----- Original Message -----
From: Beth Malloy
To: 'Clayton, Wendy' <[redacted]>; Trouton, Heather
<[redacted]>; 'Rankin, Gillian'
<[redacted]>
Cc: Porter, Alison <[redacted]>
Sent: Tue Jun 29 12:50:10 2010
Subject: RE: Urology radical pelvic surgery patient

Dear all

I am assuming that since I have not received any information for this patient pathway the matter is resolved.

If not please send me this information as a matter of urgency so that I can discuss this with Belfast.

Regards

Beth

Mrs Beth Malloy
Assistant Director Scheduled Services
Performance Management and Service Improvement Directorate Health and Social Care Board
[redacted]

-----Original Message-----
From: Clayton, Wendy [redacted]
Sent: 14 June 2010 12:48
To: Trouton, Heather
Cc: Porter, Alison; Beth Malloy
Subject: FW: Urology radical pelvic surgery patient

Heather

Can you forward the name of this patient so I can pull out the cancer pathway for Beth?

Thanks

Wendy

Wendy Clayton
Operational Support Lead - Cancer & Clinical Services SHSCT
Tel: Personal Information redacted by the USI
Mob: Personal Information redacted by the USI

-----Original Message-----
From: Beth Malloy [Personal Information redacted by the USI]
Sent: 14 June 2010 12:37
To: Trouton, Heather; Clayton, Wendy
Cc: Porter, Alison
Subject: RE: Urology radical pelvic surgery patient

"This email is covered by the disclaimer found at the end of the message."

Dear all

Please could I have the details of this urology patient pathway?
I need to discuss with Belfast

Regards

Beth

Mrs Beth Malloy
Assistant Director Scheduled Services
Performance Management and Service Improvement Directorate Health and Social Care Board
Personal Information redacted by the USI

-----Original Message-----
From: Beth Malloy
Sent: 08 June 2010 09:25
To: 'heather.trouton [Personal Information redacted by the USI]
'Wendy.Clayton [Personal Information redacted by the USI]
Cc: 'Alison.Porter [Personal Information redacted by the USI]
Subject: Urology radical pelvic surgery patient

Heather
Further to our meeting yesterday re the urology. Please can you advise me of the patient pathway so I can formally discuss with Belfast.

Wendy would it be possible to provide a pathway report to show the pathway prior to discussion at MDM and at what timescales were proposed by Belfast and when these were advised, was this at the MDM?

Thanks

Beth

Sent by Blackberry
Beth Malloy
Performance Management and Service Improvement Directorate Health and Social Care Board
Personal Information redacted by the USI

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Diane Corrigan

From: Diane Corrigan
Sent: 07 September 2010 17:41
To: pat.cullen Personal Information redacted by the USI
Subject: FW: Confidential: Concern re Urology at CAH
Attachments: urologyletterploughran1sept2010.doc; NI cystectomy andor creation of an ileal conduit as a primary procedure 200506 to 200910.xls

Dear Pat

I tried to contact you by phone to discuss this but keep missing you hence the email.

I have been involved in a clinical governance/clinical performance issue relating to SHSCT. This is not an SAI (as yet) though may become one. I realised last week that I am not sure if I should have also been keeping you informed, given your PHA Quality and Safety role, as to what was happening. I had already shared the data I had found with Carolyn and Janet. In Carolyn's absence on a/l Janet agreed that I should go ahead to write to the Trust (copies enclosed).

I subsequently shared the correspondence with Lyn Donnelly and now she is asking if she should inform Dean. Normally these sorts of issues would not have gone to a Dir of Commissioning until there was clarity on the scale of the problem, but that was maybe because the Dir of P health and/or the Dir of nursing would have been leading on their management as full members of the Board Exec team.

Apologies if you feel I should have informed you earlier. It might be helpful sometime for us all (HSCB and PHA) to have guidance on how we are supposed to handle these things in the new world so all the right people are kept informed while at the same time ensuring we deal with things in a coordinated way.

Happy to discuss.

BW
Diane

From: Diane Corrigan
Sent: 03 September 2010 12:25
To: Donnelly, Lyn
Subject: Confidential: Concern re Urology at CAH

Lyn

I thought that I should make you aware of a concern I have about urology at CAH. I enclose a letter sent to the Trust this week which is hopefully self-explanatory. I have been told that the morning before the letter arrived Dr Loughran, Dr Rankin and Mr Mackle had met to discuss the same issues. They have directed the consultants concerned to attend a meeting with them next Monday evening.

Senior colleagues in the PHA are aware of what I have done. I will keep you updated on developments.

Diane

Dr D Corrigan BA MPH FFPH
Consultant in Public Health Medicine
Public Health Agency
Tower Hill
Armagh
BT61 9DR
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GMC no. 2758116

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Diane Corrigan

From: Diane Corrigan
Sent: 08 September 2010 17:57
To: 'Donnelly, Lyn'
Cc: 'Campbell, Mareth'
Subject: RE: Confidential - Urology CAH

Lyn

Just for clarity, the IV therapy would be expected to be phased out in an orderly fashion so some of that may still go on, albeit hopefully coming to an end within a matter of weeks. My letter to the Trust did ask the Medical Director to confirm a timescale for that to happen.

As regards radical pelvic surgery, the implications of this are well understood by the two senior medical managers (the Trust's Medical Director and the Clinical Director of Surgery) and the acting Director of Acute Services who also happens to be a doctor. I believe that all three would be aware that they could have professional questions to answer if they permitted any further radical surgery cases to take place in the light of the correspondence I have sent. I know that they had arranged to meet the urologists on Monday evening the 6th September to discuss the issues I raised. Having said that, as I have yet to receive a written reply to my letter seeking formal confirmation that steps have been taken to ensure no further cases are done I will follow this up asap.

Regards

Diane

-----Original Message-----
From: Donnelly, Lyn [Personal Information redacted by the USI
Sent: 08 September 2010 17:24
To: Corrigan, Diane
Cc: Campbell, Mareth
Subject: Confidential - Urology CAH

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Diane

Spoke to Dean on this issue and he asked me to just keep a file note on it while it develops, so I will retain all your / my e-mail correspondence on this issue and file notes of my conversations with him.

Understandably he has asked that HSCB can be assured that we are content that the SHSCT Management is taking all appropriate steps to ensure processes are now in place to ensure that no unsafe or inappropriate procedures are being carried out by any Urologist in SHSCT, pending the validation of the data on the specific procedures in question, which you are awaiting.

I have advised that you and the PHA are monitoring this situation and that you will advise me in the first instance of any concerns the PHA has once the validation processes is complete and the true nature of the situation is ascertained and also of any action /recommendations / directives which PHA advises should be taken as a consequence of it and the processes agreed with SHSCT to ensure that this is implemented. As appropriate, I will discuss any emerging issues of concern with Dean.

Can we be assured that the Urology surgeons in question are not currently carrying out any of these procedures now?

Thanks

Lyn

Mrs Lyn Donnelly

Commissioning Lead Southern Area

HSCB

Tower Hill

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Email: Personal Information redacted by the USI < Personal Information redacted by the USI >

Website: www.hscboard.hscni.net <http://www.southernifh.com/>

15

Diane Corrigan

From: Trouton, Heather < Personal Information redacted by the USI >
Sent: 17 September 2010 13:53
To: Corrigan, Diane; beth.Malloy Personal Information redacted by the USI
Cc: sarah.williamson Personal Information redacted by the USI Rankin, Gillian
Subject: RE: Urology cystectomies

Diane

Thank you for this.

These patients will be referred to BHCST Cancer services , through Sarah this afternoon.

Heather

Heather Trouton
Acting Assistant Director of Acute Services Telephone ext Personal Information redacted Mobile Personal Information redacted by the USI

-----Original Message-----
From: Corrigan, Diane [Personal Information redacted by the USI
Sent: 17 September 2010 13:38
To: Trouton, Heather; beth.Malloy Personal Information redacted by the USI
Cc: sarah.williamson Personal Information redacted by the USI
Subject: Re: Urology cystectomies

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Heather
The patients need to be referred asap to the BCH service. I would suggest contacting Sarah Williamson the BHSCT cancer services coordinator (that not may be her correct title) by phone and email to ensure that the referrals are channelled swiftly within BHSCT. If there is any delay in accepting them that will be followed up by Beth on her return.
Regards
Diane

----- Original Message -----
From: Trouton, Heather < Personal Information redacted by the USI >
To: Beth Malloy < Personal Information redacted by the USI >
Cc: Corrigan, Diane < Personal Information redacted by the USI >
Sent: Fri Sep 17 11:26:07 2010
Subject: Urology cystectomies

Beth,

We have two patients with our Urology Service who require a cystectomy due to malignancy. They will require their surgery as soon as possible.

As agreed during our conversation a few weeks ago , we were hoping that with the commencement of the oncologist that the regional MDM could finally commence in October and this would be the mechanism for transfer of patients requiring radical pelvic surgery to Belfast.

We have just recently been advised that the new oncologist will not now be starting her post until December. We will therefore have to agree an interim process with Belfast as I agree patients should have their surgery there.

I am mindful however of the timeliness of required surgery for the 2 patients now identified and would seek direction as to whether we should treat these 2 patients within the Southern Trust now or refer them to Belfast by written referral.

I know you are on annual leave at present , so I would greatly appreciate a response on your return on Monday.

Thank you and Best regards

Heather

Heather Trouton

Acting Assistant Director of Acute Services

Telephone ext Personal Information redacted by the USI

Mobile Personal Information redacted by the USI

Diane Corrigan

From: Diane Corrigan
Sent: 29 March 2011 17:25
To: Lyn Donnelly
Subject: FW: UROLOGY
Attachments: 20110311_Ltr_dcorrigan_urology_PLABlw_.doc

Lyn
For the file
Diane

-----Original Message-----
From: White, Laura [Personal Information redacted by the USI]
Sent: 11 March 2011 13:04
To: Corrigan, Diane
Cc: Rankin, Gillian; Mackle, Eamon; Brennan, Anne
Subject: UROLOGY

Dear Dr Corrigan

Please find attached letter from Dr Loughran in relation to the above.

Laura

Ms Laura White

Personal Assistant to

Dr Patrick Loughran

Medical Director

Southern Health & Social Care Trust

FIRBANK HOUSE

Craigavon Area Hospital

68 Lurgan Road

PORTADOWN

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Southern Health and Social Care Trust

Medical Directorate

Dr D Corrigan
Consultant in Public Health Medicine
Public Health Agency
Southern Office
Towerhill
Armagh

Dear Dr Corrigan

The following is an updated position of the Trust's investigation and resolution of clinical matters within our urology services, about which we have spoken and corresponded. I refer to your letter of 01st September 2010.

IV fluid and anti-biotic patient group

All of these patients have been formally reviewed and the clinical management of each member of the cohort taken forward within a multi-disciplinary team chaired by the Clinical Director of Surgery [nursing, urological surgery and microbiology]. Patients are reviewed if symptomatic, and then managed on an agreed clinical pathway, which is initiated by a specialist nurse. Admission to the ward is possible but only if outpatient or day case management fails – usually in cases of severe sepsis. Antibiotic use is determined by surgeon and microbiologist in agreement and in line with the Trust's guidelines. The two patients with central venous access have had the venous cannulae removed last autumn.

There are no patients therefore remaining in the old group which was treated with episodic IV fluids and antibiotics.

Review of cystectomies.

The Trust has already confirmed that all urology patients with the potential for radical resection of the bladder for malignant disease are referred to the Belfast Trust for definitive treatment and follow up.

Also since last September 2010 all patients with benign disease and potential for cystectomy are referred to the Belfast Trust. The Southern Trust, therefore does not do any cystectomies, and this has been the position since last September 2010.

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You are also aware the Southern Trust has looked at all benign cystectomies for the past 3 years with a view to making a judgement of the appropriateness of the decision making and operative indication.

This internal review has been undertaken by our Associate Medical Director for Surgery and Elective Care who is a general surgeon. Thirteen case notes have been examined.

This review is now at the point where we need an independent assessor, and have engaged a specialist urologist with no previous knowledge of the urology service in Northern Ireland, who is expected to visit the Trust at the end of March. I will advise you when this screening has been completed.

Dr Rankin, the Director of Acute Services has endorsed the contents of this letter.

The urologist concerned is fully aware of the processes and progress as described above.

Yours sincerely

Personal Information redacted by the USI

Patrick Loughran MB FFARCSI
Medical Director

cc.
Dr G Rankin
Mr E Mackle

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
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29

From: Loughran, Patrick [Personal Information redacted by the USI]
Sent: 28 July 2011 09:03
To: Diane Corrigan
Cc: john.simpson[Personal Information redacted by the USI]Mackle, Eamon; Brennan, Anne
Subject: Urology Review

Dear Diane,

Thank you for your help with the CEA reviews yesterday. I had intended but forgot to give you an update on the above. The independent assessment of the cystectomies by Marcus Drake from Bristol is almost complete. I have seen the interim report prepared for Gillian and Eamon as I read it there are no gross errors or faults. There are some questions in relation to pre-operative alternative treatment plans and assessments. Overall I expect the final report will be supportive/indeterminate. In the meantime I can assure you that this surgery, nor will it be undertaken in the Southern Trust.

Regards, Paddy

Southern Health & Social Care Trust IT Department [Personal Information redacted by the USI]

1

Southern Health and Social Care Trust

Southern Health & Social Care Trust

Findings of the Root Cause Analysis – Personal Information redacted by the USI
Incident Ref Personal Information redacted by the USI
SAI Ref

October 2010

CONTENTS

Appendices

1 INTRODUCTION

The report presents the findings of the Root Cause Analysis (RCA) associated with the care of Personal Information in Craigavon Area Hospital (CAH) who required an emergency laparotomy for a small bowel obstruction on the 21st July 2010. During the laparotomy the cause of the small obstruction was confirmed as being due to a retained medium sized surgical swab.

Personal Information redacted by had elective major urological surgery on the 15th July 2009.

This RCA has been commissioned by the Interim Director of Acute Services, Southern Health and Social Care Trust (SHSCT).

2 TEAM MEMBERSHIP

The investigation team for this RCA is:

- Dr Charles McAllister, AMD, ATICS
- Mr Ronan Carroll, Assistant Director Acute Services, Cancer & Clinical Services, SHSCT
- Mrs Beatrice Moonan, Acute Risk Manager, SHSCT
- Sr Pamela Mulholland, Theatre Manager, CAH

3 TERMS OF REFERENCE OF REVIEW TEAM

The Terms of Reference for the investigation into the care provided to Personal Information redacted by by the Southern Health and Social Care Trust are:

- To carry out an investigation surrounding (1) Personal Information redacted by the operation on the [redacted] Personal Information redacted by the USI and (2) the care and treatment surrounding her admission from the Personal Information redacted by the USI
- To use a team approach to the investigation.
- To identify those factors that may have had an influence or may have contributed to Personal Information episodes of care and treatment on the dates above.
- To review the outcome of the investigation agreeing recommendations, actions and lessons learned
- To report the findings and recommendations of the investigation to the Interim Director of Acute Services.

4 SUMMARY OF CASE

4.1 Description of Incident

This RCA is divided into 2 separate sections
(1) The episode of care associated with [redacted] initial urological surgery [redacted] and
(2) The admission from the [redacted] – ending with [redacted] requiring a laparotomy on the [redacted]

Episode 1

[redacted] initially presented electively to CAH for investigation of frank haematuria (blood in the urine) over the previous 2/3 months. [redacted] had a cystoscopy on the [redacted] which revealed a large bladder tumour which was resected. [redacted] was discharged on the [redacted] to return on the [redacted] for planned elective surgery (right nephro-ureterectomy, anterior pelvic exenteration and ileal conduit urinary diversion) on the [redacted]

[redacted] went for surgery on the morning of the [redacted] [redacted] surgery commenced at approximately 10.20hrs and finished at approximately 15.45hrs (over five and a half hours). It is recorded that the operation on the [redacted] was unremarkable. Blood loss was estimated to be 2 litres. The surgery was performed by Mr 1.

[redacted] was admitted from theatre electively to ICU (Intensive care Unit) where she remained for 5 days. [redacted] was then transferred to a surgical ward, where her recovery was uneventful and she was discharged home on the [redacted]

[redacted] attended the histology Outpatient's clinic CAH [redacted] with a plan to have a surveillance CT scan (Computerised Tomography) in 3 months (undertaken [redacted] STH) and a review OPD appointment in 4 months **(this appointment never happened).**

Episode 2.

[redacted] attended CAH A&E (Accident and Emergency department) on the [redacted] with a two week history of abdominal pain initially under the care of Dr 1 (consultant gastroenterologist).

[redacted] - Plain Film abdominal X-ray performed.
- Plain Film abdominal X-ray performed.
- CT scan performed.

[redacted] - [redacted] was transferred to the care of the surgeons

[redacted] – It is recorded that [redacted] condition had improved over the next couple of days - vomiting stopped and [redacted] was able to mobilise around the ward.

[redacted] – [redacted] was discharged at 14.00hrs

[redacted] – [redacted] readmitted with abdominal pain to ward 4 North CAH at 18.10hrs

Personal Information redacted by the USI - Transferred to ward 1 South at 23.20 hours with cough.

Personal Information redacted by the USI (Friday) – Personal Information redacted by the USI Plain Film abdominal X-ray was reviewed by Dr 2
Personal Information redacted by the USI (Monday) - Personal Information redacted by the USI Plain Film abdominal X-rays were re-reviewed Dr 2 – *first recorded possibility of retained surgical swab.*

21.07.10 - Personal Information redacted by the USI had an emergency laparotomy performed by Mr 2 wherein a medium swab was identified and removed.

Personal Information redacted by the USI was spoken to by Mr 1 and the finding of the laparotomy was explained in full detail to her.

4.2 Stakeholders Involved

The stakeholders involved in this incident are as follows:
S/N 1
S/N 2
S/N 3
S/N 4
Mr 1
Mr 2
Mr 3
Dr 1
Dr 2
Dr 3
Dr 4
Dr 5

4.3 Chronology of Events

4.4 The chronology of events is documented at 4.1 Description of Incident and by the timeline at Appendix 1 .

4.5 Relevant Past History

Prior to the condition requiring surgery on the Personal Information redacted by the USI Personal Information redacted by the USI had no significant past medical history. Personal Information redacted by the USI were noted in her medical notes.

4.6 Outcome, Consequences and Action Taken

The IR1 form was received by the central reporting department on Personal Information redacted by the USI

A Root Cause Analysis into this incident involving Personal Information redacted by the USI was subsequently commissioned by the Interim Director of Acute Services SHSCT.

5 METHODOLOGY FOR INVESTIGATION

This investigation is based on the best practice associated with the National Patient Safety Agency *"Seven Steps to Patient Safety."* The processes associated with this approach are documented in the sub-sections follow.

5.1 Review of Records

The RCA team reviewed the following records associated with the case:

- Medical and Nursing Notes covering both episodes of care

5.2 Review of Staff Statements

The following staff statements were reviewed:
1. AMD C&CS (Radiology).
2. AMD Post-Graduate Training
3. Consultant Urologist

5.3 Review of Relevant Reports

The RCA team reviewed Personal Information redacted by the medical and nursing notes.

5.4 Interviews

The following staff members were interviewed
S/N 1
S/N 2
S/N 3
S/N 4

5.5 Carer/User Involvement

Personal Information - Personal Information was spoken to by Mr 1 and the finding of the laparotomy was explained in full detail to her.

6 ANALYSIS

This section of the report summarises the analysis conducted during this investigation, which has been complied from a review of the materials generated as a result of the activities outlined in Sections 5.1 to 5.3 of this report. The analysis contained in this report focuses in detail on the immediate postoperative period. The analysis undertaken supports the conclusions reached by the investigation team and the recommendations identified in Section 7 of this report.

The primary issue in this incident is clearly the retention of a swab following surgery. Although the surgeon is ultimately responsible for what happens during surgery the responsibility for ensuring that the swabs are correctly counted prior, during and at the end is delegated to the scrub nurse. The outcome of the inquiry on this occasion highlighted the count was not correct. As this was a long procedure there was a change of Scrub Nurse and it is unclear from the record which of the scrub nurses was responsible when the error was made. In addition the method of counting the swabs when a swab is left in the patient's cavity was not standardised across all theatres. The method used on that day in that theatre is unclear.

The second issue was the delay in diagnosis: There was a three-month follow up CT Scan of abdomen performed on the Personal Information redacted by the USI A diagnosis of retained swab was not made on this scan but the reporting consultant radiologist described a mass measuring 6.5cm in the region of the right renal bed. The differential given for this mass included a seroma or local recurrence. The high-density areas within the mass lesion were described as multiple surgical clips.

Although a diagnosis of a retained swab was not made on the CT Scan report a pathological abnormality was described, however this report was not seen by the consultant urologist as it is his routine practice to review Radiological and Laboratory reports when the patient returns for post-operative follow up. The planned four-month follow up never took place due to the waiting times for review at Outpatients.

Personal Information subsequently presented and was admitted medically on the Personal Information (discharged on the Personal Information when eating and drinking normally) and again on the Personal Information with symptoms of sub-acute bowel obstruction. A further CT scan of abdomen was performed on the Personal Information redacted by the USI This was reported by the same consultant radiologist as showing an unusual appearance to a loop of colon within the pelvis that contained faecalent material and intraluminal linear high-density material suggestive of surgical clips. The reporting consultant radiologist and a consultant physician reviewed this scan and the diagnosis was of small bowel loops in the pelvis and a possible adhesion. She was discharged following surgical review and resolution of symptoms on the Personal Information redacted by the USI

Personal Information was readmitted medically on the Personal Information redacted by the USI with cough and green sputum for 24 hours. On the Personal Information abdominal x-rays were reviewed by the Surgical SHO on call and noted no obvious obstruction.

She continued to have episodes of vomiting. A further surgical review by Dr 2, a Surgical Core Trainee was undertaken on the Personal Information at 03.00 again regarding evidence of obstruction. There was no evidence of same initially, but he felt that there was evidence of a foreign body within the pelvis aside from surgical clips

and thought the appearances were consistent with a retained surgical swab within the abdomen and pelvis. Review of previous CT films suggested that there was material thought to be intraluminal and the consultant urologist undertook further review on the Personal Information redacted by the USI On the Personal Information surgical care was taken over by a general surgeon (Mr 2). Water-soluble contrast was administered and it was felt the appearances were consistent with a retained swab, which was retrieved at laparotomy on the Personal Information redacted by the USI

6.1 Admission

The admission details and Personal Information journey for both admissions have been described in point 4.1.

6.2 Treatment

Similar to point 6.1 (admission) the care and treatment received by Personal Information has been described throughout this investigation.

6.3 Summary of Analysis

The primary issue is the retention of the swab. On the day in question, when the investigation team spoke with the nursing team, they provided a consistent account of when swabs were checked with the exception of when a swab was retained in the patient's cavity and how this was recorded and checked off.
The secondary issue is the delay in diagnosis. This was caused by a misinterpretation of the radiological findings and in addition, no routine follow up in outpatients.

6.3.1 Education and Training

Presentation of case and radiographs to consultants and trainees in Medicine, Surgery and Radiology at Morbidity and Mortality meetings.
All new and existing theatre staff are required to adhere to swab/instrument policy across all theatre departments in the Trust and there must be standardisation of all SOP's in regard to the procedure for checking swabs & instruments across the Trust.

6.3.2 Equipment and Resources

This incident did not directly involve equipment although the swabs could be considered to be either a piece of equipment or a resource, but the important point is that there was no fault with the equipment and/or resource.

However since this incident all the Theatre Department has introduced a new swab management system called 'Swabsafe' which consists of a container with 5 individual compartments which enables the nursing team to place a used swab in each compartment. This has two main benefits - one swab goes into five individual compartments and visually this can be seen if subsequent inspection/confirmation is required.

6.3.3 *Individual*

The investigation team met with the all but two (one RN had left the Trust and the other RN was on Maternity leave) of the nursing team who were present in the theatre on the Personal Information redacted by the USI

6.3.4 *Working Conditions*

The working conditions in the theatre on the Personal Information redacted by the USI were satisfactory. The nursing theatre team had a full compliment of staff and the team had a balance of senior and junior theatre nurses.

All the nursing staff interviewed could not remember the operation performed on the Personal Information redacted by the USI but knowing the surgeon all the nursing staff did not feel under pressure when it came to counting and checking swabs and equipment at the appropriate times.

6.3.5 *Task*

The counting of swabs in the operating theatre was a very familiar task performed by all the nurses interviewed on many occasions.
When asked to explain the procedure they used to check the swab all the nurses interviewed described a very similar process of checking swabs at the accepted intervals i.e. at the start of the procedure/operation, closure of cavity and closure of skin.

Yet the theatre nursing documentation has only one set of signatures for the mandatory swabs counts when there should have been another two sets of signatures at the close of cavity and skin .

However what became apparent during the interview process was that there was no agreed process for the checking of swabs which were temporarily placed in the patient's cavity. It was clear that when a swab or swabs were placed in a patient's cavity this was 'marked up' on the white board. When the swab was removed some nurses would strike through the number and leaving it on the white board whilst other would 'rub out' the number on the board when the swab was removed and accounted for.

It would be the recommendation of the investigation team the first process described is the process that is adopted.

6.3.6 *Team and Social*

From the interviews with the nursing staff all appeared genuinely distressed that this incident had happened and could provide no explanation at how it did happen.

6.3.7 *Communications*

All the nurses interviewed stated that communication was satisfactory within the theatre department and they would inform and advise the surgeon if a swab or instrument had not been accounted for.

7 Conclusions, Recommendations and Learning

The method of recording swabs which were temporarily used in the patient cavity that day in theatre is inconsistent. A standardised protocol for the counting and recording of all swabs across all theatres needs to be implemented urgently.
The responsible scrub nurse in this case is unclear because there were two scrub nurses. When the scrub nurse hands over to another scrub nurse he/she should sign off the current state of swabs in use and used.
The first post-operative scan [redacted] was not reviewed at routine follow up because there was no follow up for 12 months due to the length of the urology outpatient waiting list. The urology waiting list for post-operative follow up needs to be cleared.
Several abdominal x-rays were performed on [redacted] readmission but the swab was missed by several doctors. This is presumably because they have never seen a retained swab on a radiograph previously. This case should be presented, with the radiographs, at Surgical and Medical Morbidity and Mortality meetings to demonstrate the appearance of a retained swab.

7.1 Local Recommendations

The local recommendations are set out in table 1

7.2 Regional Recommendations

No regional recommendations are deemed necessary.

7.3 Action Planning

The action plan below sets out the proposed lead individuals and completion dates for the recommendations contained in this investigation.

Table 1 local recommendations

Recommendation	Evidence of Action	Lead Individual	Completion	Completion Date
All swab and instrument counts must be interruption free and where possible the same circulating nurse completes count –	Write SOP for all Theatre within Trust	Lead Nurse ATIC AMD's Surgery & Gynaecology	Jan 11	
Swabs that are temporarily used in a patients cavity must be recorded on the white board and struck through when removed until operation complete – the record must not be 'rubbed out'	Incorporate new SOP for all Theatres within Trust	Lead Nurse ATICs	Jan 11	
As far as is operationally	Each month five	Lead Nurse ATICs	Jan 11	

possible the same nurse should remain as the scrub nurse for the entire operation. Signing off of swab status must take place by the Scrub Nurse if there is a changeover.	patients charts will be reviewed to ensure all necessary documentation is complete			
It needs to be recognised and reaffirmed that time is required at the end of the operation to the scrub nurse to ensure that all swabs, instruments and equipment are accounted for.	This will be incorporated in WHO' Patient Safety Checklist'	Lead Nurse ATICs	Feb 11	
Where possible and practical there should be a 'surgical pause' before wound closure.	This will be incorporated in WHO' Patient Safety Checklist'	AMD's Surgery & Gynaecology	Feb 11	
Findings of the RCA will be presented at the next radiology peer review discrepancy meeting		Dr Hall	18th January 2011	
Presentation of case with radiographs at Radiology, Surgical and Medical M&M.		AMD Radiology Dr S Hall AMD Surgery Mr E Mackle AMD Medicine Dr P Murphy	18th January 2011	
Reduction in all Out-Patient waiting times		Assistant Directors Acute Services		

Time line of events beginning [redacted]
Re [redacted] Unit Number [redacted]
Datix Incident Number [redacted]

This timeline is subject to further revision as information is gathered during the review process.

Date	Time	Event	Comments
[redacted] Tuesday		Had **pre-op CT scan abdomen** done	
[redacted] Wednesday	08.55	Elective Right Nephroureterectomy radical cystectomy & ileal conduit for bladder cancer	Anaesthetics Dr 4 – no anaesthetic issued identified on chart review Surgeon Mr 1 All swabs accounted for on 'SWAB COUNT' list **Instrument check section NOT signed at 'cavity closure' or 'Prior to closure'.**
[redacted]	12.45	1st unit packed cell erected	
	12.55	2nd unit packed cell erected	
	15.00	3rd unit packed cells erected	Operation was scheduled for 9am – 12.30 but [redacted] was In theatre until 15.40 > 6 hours with estimated blood loss 2000 mls
[redacted] Sunday		Discharged from ICU	
[redacted] 9th day post - op Friday		Discharged home	
[redacted] Wednesday		Histology Clinic	
[redacted] Thursday		**Had CT scan abdomen in STH**	Dr 3 (consultant radiologist)
[redacted] Tuesday		Attended A&E C/O abdominal pain & vomiting for 2weeks and diahorrea for 2 days	
[redacted]	11.50	Admitted to MAU under Dr 1 (physician)	
[redacted] Wednesday		**Had abdominal x-ray**	
[redacted]		**Had abdominal x-ray**	

Personal Information Friday		Transferred to surgery	
Personal Information redacted by the USI		**Had CT scan abdomen**	Reporter – Dr 3 (consultant radiologist) who compared this scan to Personal Information pre-op scan of Personal Information **** Small Bowel Obstruction likely due to adhesions
Personal Information redacted by the USI Monday		Seen by Mr 3 - Discharged 2pm	
Personal Information redacted by the USI	18.10	Readmitted with 4N abdominal pain	
		Had abdominal x-ray	
	23.20	Transferred to 1 South with cough	
Friday		**Had abdominal x-ray**	
Personal Information Monday	03.00	Dr 2 (SHO) reviewed abdominal x-ray flag raised	
Personal Information		Ward round Dr 4 – discussed abdominal x-ray with radiologists	
Personal Information redacted by the USI Tuesday		**Had abdominal x-ray**	
Personal Information Wednesday		CT R/V Dr 5 & Mr 2	
Personal Information		To theatre for laparotomy - medium sized swab found	
Personal Information	IR1 form completed by Sr 1		
Personal Information redacted by the USI Tuesday	IR1 form received in central reporting point		

Diane Corrigan

From: Diane Corrigan
Sent: 07 April 2011 07:03
To: 'cmcallister [redacted]
Subject: Re: SAI - Retained swab

I'll be on the road to Belfast so won't be able to answer till after 9.20ish. Then in a meeting from 9.30. However no rush on this. Text sometime when free over the next few days and I may be able to come out of a meeting and call you back.
Thanks
Diane

----- Original Message -----
From: CHARLES MCALLISTER [redacted]
Sent: Thursday, April 07, 2011 06:51 AM
To: Diane Corrigan
Subject: Re: SAI - Retained swab

Hi Diane

It might be better to discuss this.

Can I ring you later this morning?

Charlie

On 6 Apr 2011, at 21:33, Diane Corrigan <[redacted]> wrote:

> "This email is covered by the disclaimer found at the end of the message."
>
>
> _____
>
>
> Charlie
> I have just read the RCA report on the case on which you were lead investigator. I have a couple of queries. Normally I route those back through formal channels - but often it takes months to get a response and even then the answer tends not to address the question
>
> Would it be OK to ask you the questions 'off the record/informally'? Depending on the answer then I can either close the file or ask Paddy's office for a formal response. However if you would prefer the query was sent formally at the outset that would be fine.
>
> I knew that review appts were behind in general - but was not aware that something like a first review post major complex cancer surgery could be deferred from early Dec and not yet seen by the following July. There weren't that many major complex pelvic surgery cases per year in CAH pre-2010 - indeed that was the rationale for centralisation in the Urology Review. If that sort of patient wasn't being reviewed then who was?
>
> Am I being hopelessly naïve to suggest that having a system where test results are not reviewed - even in the most superficial way - until the patient's appointment comes round is bound to result in unpleasant surprises? Seems

fraught with medicolegal danger. Better not to do a test at all than to do it and not read the result. I know that without the notes to hand it could be argued that reviewing tests would be wasteful of time/inappropriate - but it could catch the occasional high risk problem.
>
> I suspect you must have discussed this - but the recommendation was for the Trust to put right review backlogs - which sounds like it won't happen quickly. Even if the latter was put right, a patient who cancelled and rescheduled a few times could delay their review while a seriously abnormal result sat waiting on their chart.
>
> Is any other interim action/ safetynet needed - or am I missing the point?
>
> Best wishes
>
> Diane
>
> _____
>
>
>

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Ms D Burns
Assistant Director Clinical &
Social Care Governance
Southern Health & Social Care Trust
Old College of Nursing
Craigavon Area Hospital
68 Lurgan Road
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BT63 5QQ

14 November 2011

Dear Ms Burns

I refer to the Trust's report on the Root Cause Analysis of this incident. The report is thorough, clearly identifying the chronology of events and making recommendations on actions to avoid recurrence. As might be expected, the report concentrates on the primary event, which occurred during the patient's operation on 15th July 2009 and the x-ray findings which might have aided detection prior to her emergency admissions in July 2010.

The patient was expected to have an outpatient review four months after her major complex cancer surgery in July 2009. It was also expected that at that review attendance the CT scan, undertaken three months post-operatively, would be available for the consultant urologist to see. This scan was done promptly in early October 2009 and the report identified an abnormality. Although not identified as a retained swab, one of the differential diagnoses was recurrence of the patient's cancer.

The RCA report identifies that, due to a backlog in outpatient reviews, in fact the patient was not seen at outpatients in the 12 months after surgery, at which stage she was admitted as an emergency. The recommendation relating to this issue was that outpatient backlog reviews should be cleared. This recommendation is reasonable, albeit not necessarily easy for the Trust to