Urology Services Inquiry

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB
T: 02890 251005 | E: info@usi.org.uk | W: www.urologyservicesinquiry.org.uk

Dr. Charles McAllister
C/O Southern Health and Social Care Trust
Craigavon Area Hospital,
68 Lurgan Road, Portadown,
BT63 5QQ

12 October 2023

Dear Dr. McAllister,

Re: The Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

Provision of a Section 21 Notice requiring the provision of evidence in the form of a written statement

I am writing to you in my capacity as Solicitor to the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust (the Urology Services Inquiry) which has been set up under the Inquiries Act 2005 ('the Act').

I enclose a copy of the Urology Services Inquiry's Terms of Reference for your information.

You will be aware that the Inquiry has commenced its investigations into the matters set out in its Terms of Reference. The Inquiry is continuing with the process of gathering all of the relevant documentation from relevant departments, organisations and individuals. In addition, the Inquiry has also now begun the process of requiring individuals who have been, or may have been, involved in the range of matters which come within the Inquiry's Terms of Reference to provide written evidence to the Inquiry panel.

The Urology Services Inquiry is now issuing to you a Statutory Notice (known as a Section 21 Notice) pursuant to its powers to compel the provision of evidence in the form of a written statement in relation to the matters falling within its Terms of Reference.

The Inquiry is aware that you have held posts relevant to the Inquiry's Terms of Reference. The Inquiry understands that you will have access to all of the relevant information required to provide the witness statement required now or at any stage throughout the duration of this Inquiry. Should you consider that not to be the case,

please advise us of that as soon as possible.

The Schedule to the enclosed Section 21 Notice provides full details as to the matters which should be covered in the written evidence which is required from you. As the text of the Section 21 Notice explains, you are required by law to comply with it.

Please bear in mind the fact that the witness statement required by the enclosed Notice is likely (in common with many other statements we will request) to be published by the Inquiry in due course. It should therefore ideally be written in a manner which is as accessible as possible in terms of public understanding.

You will note that certain questions raise issues regarding documentation. As you are aware the Trust has already responded to our earlier Section 21 Notice requesting documentation from the Trust as an organisation. However if you in your personal capacity hold any additional documentation which you consider is of relevance to our work and is not within the custody or power of the Trust and has not been provided to us to date, then we would ask that this is also provided with this response.

If it would assist you, I am happy to meet with you and/or the Trust's legal representative(s) to discuss what documents you have and whether they are covered by the Section 21 Notice.

You will also find attached to the Section 21 Notice a Guidance Note explaining the nature of a Section 21 Notice and the procedures that the Inquiry has adopted in relation to such a notice. In particular, you are asked to provide your evidence in the form of the template witness statement which is also enclosed with this correspondence. In addition, as referred to above, you will also find enclosed a copy of the Inquiry's Terms of Reference to assist you in understanding the scope of the Inquiry's work and therefore the ambit of the Section 21 Notice.

Given the tight time-frame within which the Inquiry must operate, the Chair of the Inquiry would be grateful if you would comply with the requirements of the Section 21 Notice as soon as possible and, in any event, by the date set out for compliance in the Notice itself.

If there is any difficulty in complying with this time limit you must make application to the Chair for an extension of time before the expiry of the time limit, and that application must provide full reasons in explanation of any difficulty.

Finally, I would be grateful if you could acknowledge receipt of this correspondence and the enclosed Notice by email to Personal Information redacted by the USI.

Please do not hesitate to contact me to discuss any matter arising.

Yours faithfully

Personal Information redacted by the USI

Anne Donnelly
Solicitor to the Urology Services Inquiry

Tel: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI

THE INDEPENDENT PUBLIC INQUIRY INTO
UROLOGY SERVICES IN THE
SOUTHERN HEALTH AND SOCIAL CARE TRUST

Chair's Notice

[No 19 of 2023]

pursuant to Section 21(2) of the Inquiries Act 2005

WARNING

If, without reasonable excuse, you fail to comply with the requirements of this Notice you will be committing an offence under section 35 of the Inquiries Act 2005 and may be liable on conviction to a term of imprisonment and/or a fine.

Further, if you fail to comply with the requirements of this Notice, the Chair may certify the matter to the High Court of Justice in Northern Ireland under section 36 of the Inquiries Act 2005, where you may be held in contempt of court and may be imprisoned, fined or have your assets seized.

TO:

Mr. Charles McAllister
C/O Southern Health and Social Care Trust
Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

IMPORTANT INFORMATION FOR THE RECIPIENT

1. This Notice is issued by the Chair of the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust on foot of the powers given to her by the Inquiries Act 2005.

2. The Notice requires you to do the acts set out in the body of the Notice.

3. You should read this Notice carefully and consult a solicitor as soon as possible about it.

4. You are entitled to ask the Chair to revoke or vary the Notice in accordance with the terms of section 21(4) of the Inquiries Act 2005.

5. If you disobey the requirements of the Notice it may have very serious consequences for you, including you being fined or imprisoned. For that reason you should treat this Notice with the utmost seriousness.

WITNESS STATEMENT TO BE PRODUCED

TAKE NOTICE that the Chair of the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust requires you, pursuant to her powers under section 21(2)(a) of the Inquiries Act 2005 ('the Act'), to produce to the Inquiry a Witness Statement as set out in the Schedule to this Notice by **noon on 2nd November 2023.**

APPLICATION TO VARY OR REVOKE THE NOTICE

AND FURTHER TAKE NOTICE that you are entitled to make a claim to the Chair of the Inquiry, under section 21(4) of the Act, on the grounds that you are unable to comply with the Notice, or that it is not reasonable in all the circumstances to require you to comply with the Notice.

If you wish to make such a claim you should do so in writing to the Chair of the Inquiry at: **Urology Services Inquiry, 1 Bradford Court, Belfast, BT8 6RB** setting out in detail the basis of, and reasons for, your claim by **noon on 26th October 2023**.

Upon receipt of such a claim the Chair will then determine whether the Notice should be revoked or varied, including having regard to her obligations under section 21(5) of the Act, and you will be notified of her determination.

Dated this day 12th October 2023

Signed: 

Christine Smith QC
Chair of Urology Services Inquiry

Urology Services Inquiry

SCHEDULE

[No 19 of 2023]

Monopolar and Bipolar Resection

1. The Policy on the Surgical Management of Endoscopic Tissue Resection HSS(MD)14/2015 was introduced in May 2015 (WIT-54032-54055].

   The policy refers to the 'significantly improved safety profile' for bipolar techniques, noting that *'Significantly, the TUR syndrome has not been reported with bipolar equipment. A recent systematic review and meta-analysis comparing traditional monopolar TURP with bipolar TURP established in 22 trials that the TUR syndrome was reported in 35/1375 patients undergoing M-TURP and in none of the 1401 patients undergoing B-TURP. Even taking into account that one study alone was responsible for 17 of the 35 cases, the accompanying editorial states, "the elimination of TUR syndrome alone has been a worthy consequence of adopting bipolar technology.'"* [WIT-54041]

   At [WIT-54042], it is noted that: *'NICE, in February 2015, also issued guidance for the public on this topic. They indicated that, "the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate'. Healthcare teams may want to use the TURis system instead of monopolar TURP because there is no risk of a rare complication called transurethral resection syndrome and it is less likely that a blood transfusion after surgery will be needed. Therefore, the case for moving from a monopolar to bipolar technique for resection of the prostate would appear to be well established as safer with regard to the development of the TUR syndrome…'*

   Having regard to the above, you are now asked to address the following:

   (a) When did you first become aware of the regional approach, led by Dr Julian Johnston, to develop a policy on the use of irrigating fluids and the Coroner's decision which prompted it? (WIT-99100-WIT-99101)?

(b) Did you believe the use of monopolar with glycine irrigation was a safe method of performing TURP procedures?

(c) When did the Southern Trust direct the cessation of monopolar procedures?

(d) Were you aware of any monopolar TURP procedures having been carried out after this date? If so, please provide full details.

(e) What was your view on the introduction of bipolar resection with saline? Did you believe it to be a suitable alternative? Why/ why not?

(f) Was training required to adapt to the new equipment and technique? If yes, please provide details of all such training offered to relevant colleagues within the Trust.

2. In his statement to the Inquiry (at WIT-98867), Mr Chris Hagan states as follows:

'Some years after the policy was developed I was contacted by phone by Dr Charlie McAllister, a consultant anaesthetist in CAH. I cannot be sure when exactly I received this call, but I believe it was sometime between 2017 and 2019. Dr McAllister wished to discuss TUR surgery, TUR syndrome and use of bipolar resection. He explained that they had an issue in CAH with an individual surgeon carrying out prolonged TURP resections with glycine and some "bad" TUR syndromes. He did not name the surgeon specifically. He wanted to know my experience with introducing TURP in saline. I explained that the experience in Belfast was good, that the technique was similar to monopolar TURP with glycine and that with modern equipment, in my view, it was unjustified and unsafe to continue to use glycine due to the safety profile of it as an irrigating fluid. From a personal perspective, I have carried out TURP in saline for around 10 years and see no justification for the use of glycine.'

(a) Please provide full details of the telephone conversation referred to by Mr Hagan. Your answer should address the following:

i. Do you agree that Mr Hagan's account of the telephone call is accurate?

ii. To the extent that your answer is affirmative, please address the following:

a. When did this conversation take place?

b. In what capacity did you contact Mr Hagan? What was your role at the time?

c. Why did you seek to discuss this matter with Mr Hagan?

d. Please provide full details of the conversation with Mr Hagan.

e. Please identify the individual surgeon referred to.

f. How many 'prolonged TURP resections with glycine' were you aware of?

g. How many 'bad TUR syndromes' were you aware of at that time?

h. Please provide full details of all procedures captured by (v) and (vi) above to include: (a) the HCNs of relevant patients, (b) the length of the procedures, if known, (c) the patient outcomes in each case.

i. Did any further discussion occur between you and Mr Hagan on this, or any other occasion?

iii. Regardless of the date of any such contact, do you recall engaging with Mr Hagan on the issues of TUR surgery, TUR syndrome and resection in glycine?

iv. Whether or not you recall the conversation described by Mr Hagan, do you recognise the issues identified by Mr Hagan?

v. Whether or not you recall the conversation described by Mr Hagan, do you accept that those issues identified were issues that you were concerned about in your role as AMD for Anaesthetics?

(b) Did you discuss the issue with the clinician whose practice was causing concern? If so, please provide full details, to include details of the response received and any further action taken.

(c) Did you seek to discuss your concerns with anyone else within the Southern Trust? If so, please provide full details of all discussions relating to this issue, to include dates, the identities of parties to the discussions, the content of those discussions and any actions taken by you, or others, on foot of same. If you did not seek to discuss your concerns with others within the Southern Trust, please explain why this was the case.

(d) Were you aware of others within the Southern Trust who held similar concerns in respect of the ongoing use of monopolar resection techniques at that time? Please provide details.

(e) Please provide copies of any relevant correspondence or other documentation in which your concerns are contemporaneously recorded. If it is the case that no such documentation exists, please explain why.

3. In oral evidence to the Inquiry on Day 61 (19th September 2023, Mr Hagan described the introduction of bipolar technique within the Belfast Trust ('BHSCT') as follows:

'We introduced bipolar in Belfast in 2013, we took all the monopolar sets out and the whole team moved over to bipolar without any real issue.' [TRA-07913]

'I didn't find it difficult introducing it in Belfast, because all the team that I work with focus on patient safety and they put patient safety before their own personal preferences. And the data was compelling on this. And I think it's really important to use data to inform your decisions. And if you have a technique that's demonstrably safer, I don't understand why you wouldn't adopt it.' [TRA-07914]

(a) To the extent that you are able to assist the Inquiry, please explain the reason(s) for the apparent delay in introducing the bipolar approach within the Southern Trust, as compared with BHSCT.

(b) Were you concerned by any delay in the introduction of this approach?

NOTE:

By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers, as well as those sent from official or business accounts or numbers. By virtue of section 21(6) of the Inquiries Act 2005, a thing is under a person's control if it is in his possession or if he has a right to possession of it.

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Section 21 Notice Number 19 of 2023
Date of Notice: 12th October 2023

Monopolar and Bipolar Resection

1. **The Policy on the Surgical Management of Endoscopic Tissue Resection HSS(MD)14/2015 was introduced in May 2015 (WIT-54032-54055].**

   The policy refers to the 'significantly improved safety profile' for bipolar techniques, noting that *'Significantly, the TUR syndrome has not been reported with bipolar equipment. A recent systematic review and meta-analysis comparing traditional monopolar TURP with bipolar TURP established in 22 trials that the TUR syndrome was reported in 35/1375 patients undergoing M- TURP and in none of the 1401 patients undergoing B-TURP. Even taking into account that one study alone was responsible for 17 of the 35 cases, the accompanying editorial states, "the elimination of TUR syndrome alone has been a worthy consequence of adopting bipolar technology."'* [WIT-54041]

   At [WIT-54042], it is noted that: *'NICE, in February 2015, also issued guidance for the public on this topic. They indicated that, "the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate'. Healthcare teams may want to use the TURis system instead of monopolar TURP because there is no risk of a rare complication called transurethral resection syndrome and it is less likely that a blood transfusion after surgery will be needed. Therefore, the case for moving from a monopolar to bipolar technique for resection of the prostate would appear to be well established as safer with regard to the development of the TUR syndrome…'*

   Having regard to the above, you are now asked to address the following:

   (a) **When did you first become aware of the regional approach, led by Dr Julian Johnston, to develop a policy on the use of irrigating fluids and the Coroner's decision which prompted it? (WIT-99100-WIT-99101)?**

1.01 Based on the emails and letter attached below I believe that the regional approach was intimated on the 3rd December 2013 and confirmed on the 16th December 2013 in Tony Stevens's letter to Carolyn Harper, so I would have been aware on or shortly after the 3rd December 2013..The Coroner's letter was dated the 21st October 2013, received by the SH&SCT on the 25th October so I would have been aware of the Coroner's decision on or shortly after the 25th October 2013.

From: Simpson, John [redacted]

Sent: 04 December 2013 10:12

To: Johnston, Julian; McAllister, Charlie; 'alan.mckinney [redacted]'; 'calum.macleod [redacted]'; 'Martyn, Charlie'

Cc: Jack, Cathy; Stevens, Tony; Kelly, SharonA; Gardiner, George

Subject: RE: L L Inquest

Sensitivity: Confidential

Very happy with this Julian. Thank you for taking the lead,

John

From: Johnston, Julian [mailto:[redacted]]

Sent: 03 December 2013 17:16

To: McAllister, Charlie; 'alan.mckinney [redacted]' 'calum.macleod [redacted]'; Simpson, John; 'Martyn, Charlie'

Cc: Jack, Cathy; Stevens, Tony; Kelly, SharonA; Gardiner, George

Subject: RE: L L Inquest Sensitivity: Confidential

Dear Colleague,

Following on from

- · Tony's email below to the CMO,
- · Carolyn Harper's letter to the Coroner (attached),
- · Carolyn's request from the 5 Trusts for the 'collegiate' response requested by the Coroner to the surgical and anaesthetic failings,
  and after reading the recent series of emails emanating from the 5 Trusts/HSCB on this topic, can we agree that we:-

1. Leave the matter of how clinical problems identified within a Coroner's court are disseminated throughout the HSC system and any learning lessons taken on board, to steps Carolyn is taking to establish more formal lines of communication with the Coroner's Office.

2. Commence work on producing a,
a. regional policy on the management of endoscopic tissue resection, for example during urological, gynaecological and other relevant surgery. This could take the form of identifying short term aims that can be instituted now and also a more medium/longer term strategy. The short term issues could be establishing agreed time limits, volume limits, early termination of surgery along with stricter monitoring and recording protocols. The longer term items would involve changes to the procedures and equipment and would depend on the availability of finance. This policy would be multidisciplinary in nature.
I would plan to have a draft for circulation to each of the 5 Trusts by the end of this week and I imagine it would be February 2014 before we can realistically agree this policy.

b. guideline on the governance issues raised at the inquest. Items such as team working, record keeping, the availability of medical and nursing knowledge and expertise at surgical procedure, staff turn around during surgery, familiarity of the working conditions etc. are much more nebulous and will take more time to develop into a standard.

1

They all relate to what is good and effective team work during a surgical procedure i.e. what theatre practices and behaviour is acceptable and what is not; in NHS and in independent hospitals.

Each Trust could review their own governance arrangements taking into account established standards such as WHO check lists and fluid management.
However, there will still be items relating to theatre practices identified during this inquest that I have never seen written down, certainly in the BHSCT. I am thinking of topics such as staff familiarity with surgical procedures and staff changeover during surgery. They should apply in NHS and independent hospitals.

A draft guideline or discussion document could be tabled, based on these issues which were raised at this inquest and which would set out proposals for good theatre 'practice'. Thoughts? If you are content with that approach I will communicate that to the CMO and Director of PH.

Regards,

Julian R Johnston MD FCARCSI FRCA Assistant Medical Director
BHSCT julian.johnston[redacted]

Co-Chair Standards and Guidelines Committee Standards, Quality and Audit department Telephone: [redacted]
If unanswered, contact Christine Murphy : [redacted] or Jill Shaw O'Doherty : [redacted] or Simon Dunlop : [redacted]

BHSCT Litigation Management Office
Telephone: [redacted]

From: Kelly, SharonA

Sent: 04 November 2013 09:04

To: michael.mcbride[redacted]

Cc: Rocks, Dennis <[redacted]> ([redacted]); Carolyn Harper; Johnston, Julian; Jack, Cathy; Stevens, Tony

Subject: L L Inquest Importance: High Sensitivity: Confidential

Dear Michael

I will not be at Forum meeting this afternoon. Preparation for Banbridge intrudes. Cathy Jack will be there on my behalf.

I am aware that the Lewis inquest will be referred to. I had asked Julian to do some preliminary work – see attached.

Following the inquest into the death of Lynn Lewis, the Coroner wrote to each of the Medical and Nursing Directors (attached) and to the Minister, CMO, RQIA and the PHA. He asks for

1. a collegiate response to the surgical, anaesthetic and nursing failings.
2. reassurance that we work towards preventing a similar death or near miss in the future.

1. The first point raises a question about the most appropriate mechanism for distributing the learning lessons written down, voiced and discussed during a Coroner's or Clinical negligence hearing to the wider medical, nursing and healthcare community in the province. There is no current routine mechanism for providing the Coroner with a 'collegiate' response from all of the 5 Trusts, however, in the short term I am sure that we can find a work around for this case.

The Lynn Lewis case is a useful one to examine. A series of issues resulted in a death. Ordinarily the verdict would only be shared with those clinical teams that were directly involved. However, in this case there are crucial lessons that also apply to other different clinical teams who were not involved in this case.

The BHSCT is completely open to being part of any agreed mechanism for sharing learning lessons. Some of these will arise through the existing SAI process. Otherwise we would be content to take responsibility to prepare a learning summary for any case relating to a death in Belfast, for sharing with system.

2. The specifics of this particular case are dealt with in the attached document, prepared by Julian. He has produced a list of all the issues highlighted in all of the reports. The list is wide-ranging and includes items that may have only had a peripheral impact in this case. A view would have to be taken as to which of these would reap a real benefit from any changes made.

The BHSCT will start work through its standards and guidelines committee, but is very open to adoption by a regional working group.
Regards Tony

Sharon Kelly
PA to Dr Tony Stevens
Medical Director, Belfast HSC Trust, Trust HQ, A Floor, Belfast City Hospital 51 Lisburn Road, Belfast, BT9 7AB

Tel Personal Information redacted by the USI (Dir)

From: Kelly, SharonA
Sent: 31 October 2013 09:15
To: Alan McKinney (Personal Information redacted by the USI); Calum Macleod; Charlie Martyn; Simpson, John
Cc: Stevens, Tony; michael.mcbride Personal Information redacted by the USI ; Carolyn Harper; Donnelly, Martin (DHSSPS) (Personal Information redacted by the USI); Johnston, Julian; 'charlotte.mcardle Personal Information redacted by the USI ; 'louise.herron Personal Information redacted by the USI ; alison.mcmaster Personal Information redacted by the USI ; dorothy.killough Personal Information redacted by the USI ; laura.white Personal Information redacted by the USI ; Orlaith Morrow

Subject: L L Inquest

Dear colleagues

You will have received the coroners letter re Lynn Lewis Inquest. I have asked Julian Johnston to consider a response from a Belfast Trust perspective, including steps to manage or eliminate risk at theatre/Trust level; both in gynae or urology. This might form a basis for a collegiate response.

I understand that the matter will be raised at Medical Leaders Forum next week.

Regards

Tony

Sharon Kelly
PA to Dr Tony Stevens
Medical Director, Belfast HSC Trust, Trust HQ, A Floor, Belfast City Hospital 51 Lisburn Road, Belfast, BT9 7AB
Tel Personal Information redacted by the USI (Dir)

1.02 The first communication that I can find that it was confirmed that Julian Johnston was leading a Regional as opposed to a BH&SCT approach is as follows:

Belfast Health and Social Care Trust

Medical Director's Office
Belfast City Hospital
A Floor
51 Lisburn Road
Belfast
BT9 7AB
Tel: Personal Information redacted by the USI

16 December 2013

Dr Carolyn Harper
Executive Medical Director/
Director of Public Health
Public Health Agency
12-22 Linenhall Street
Belfast

Dear Carolyn

Re Lynn Lewis – Deceased – Coroners Correspondence

On behalf of the Medical Directors of HSC Trusts in Northern Ireland, I am providing a collegiate response as requested by the Coroner in this case. I would first wish to acknowledge the very significant failings that occurred in this case and if it is possible to provide any comfort to the family of Mrs Lewis then I would wish to provide them with an assurance that all the Trusts in Northern Ireland are determined to learn lessons from this case. We will also offer our report to the independent sector and our colleagues who work both within Health and Social Care and the private sector to ensure that the highest standards of care are provided.

In providing this response we have reviewed the Coroner's correspondence and his verdict in the inquest of Lynn Lewis. We also viewed the agreed response of Professor McClure, Dr Hughes and the Ulster Independent Clinic.

We also had an opportunity to read relevant reports and the medical scientific literature in respect of absorption of fluids in endoscopic surgery.

We have identified a number of procedures where fluid intravascular absorption and extravasation are a risk. These include trans cervical resection of the endometrium, and transurethral resection of the prostate and bladders tumours. There may be some other procedures of less significance.

Considering the issues identified in the Lynn Lewis case we would recognise concerns regarding preoperative assessment, haemorrhage, dilutional hyponatraemia, fluid overload, decision making processes, team dynamics and a lack of knowledge of the potential problems. In addition in respect of the use of glycine there is the potential for toxicity.

Before considering our response to the issues arising, I would first wish to provide you with some audit data taken from the gynaecology service at the Belfast Trust - 921 cases over a period of 6 years where TCRE procedure was involved. There were no cases of fluid overload. The most senior surgeon with 20 years experience using these procedures in gynaecology was able to identify only one case of minor fluid management difficulties but with no adverse outcome.

Belfast Health and Social Care Trust

In terms of responding to the issues arising we can advise work has started on developing regional policy on the management of endoscopic tissue resection. This will include short term aims that can be instituted including establishing agreed time limits, volume limits, early termination of surgery, along with stricter monitoring and recording protocols. We will be building on the existing protocols that exist.

In the longer term we will consider the practical and resource issues that will allow a change in technique to eliminate the use of glycine.

Dr Julian Johnston, Assistant Medical Director, Belfast Trust, on behalf of the five Trusts, is leading on the development of a regional policy in conjunction with colleagues from gynaecology. He has also approached the Ulster Independent Clinic to see if there is an opportunity to work collaboratively.

In dealing with the wider governance issues raised by this case, each Trust will review their own governance arrangements taking into account established standards such as the WHO checklist and protocols for fluid management. We will consider whether any further and new policies or procedures are required. We are considering a discussion document which could set out proposals for standards for good theatre practice which would deal with issues such as team working, record keeping and availability of medical and nursing knowledge and expertise at the surgical procedure, staff turnaround during surgery and communication. Dr Julian Johnston is preparing a draft of this discussion document for further consideration by colleagues.

I hope this response will provide some assurance to yourself and the CMO and provide a basis for responding to the concerns raised by the Inquest into Mrs Lewis' death. If I can provide any further assurance to Mrs Lewis' family or if they wish to engage with us in policy development we would be happy to consider this.

Yours sincerely

Dr A B Stevens
Medical Director of Belfast Trust

On behalf of:-

Mr Charlie Martyn, Medical Director of WHSCT
Dr Calum Macleod, Medical Director of NHSCT
Dr Alan McKinney, Medical Director of SEHSCT
Dr John Simpson, Medical Director of SHSCT

Cc Dr Julian Johnston, Assistant Medical Director, BHSCT

S Carr

Coroners Service
for Northern Ireland

JOHN L LECKEY LL.M.
SENIOR CORONER
FOR NORTHERN IRELAND

Dr Tony Stevens, Medica Director, BHSCT
Dr Charlie Martin, Medical Director, SEHSCT
Dr John Simpson, Medical Director, SHSCT
Dr Alan McKinney, Medical Director, WHSCT
Dr Calum MacLeod, Medical Director, NHSCT
Dr Carolyn Harper, Executive/Medical Director of Public Health
Ms Charlotte McArdle, Chief Nursing Officer

Our ref: 1791-2011

21st October 2013

Dear Medical Director
and Chief Nursing Officer,

Re: Lynn Lewis, deceased

On 16th October 2013 I concluded an inquest into the death of a 38 year old woman, Mrs Lynn Lewis, who died in the Ulster Independent Clinic on 7th July 2011.

I believe sufficient background information is contained in the Verdict to which is annexed a copy of a statement on behalf of Professor Neil McClure the Surgeon, Dr Damien Hughes the Anaesthetist, the Ulster Independent Clinic and the nursing staff (copies enclosed). Also, I am enclosing a copy of a letter I have sent to the Minister for Health together with copies of the enclosures therein referred to.

At the conclusion of the inquest I stated that in addition to making a report pursuant to the provisions of Rule 23(2) of the 1963 Coroners Rules to the Minister, the Chief Medical Officer, the Regulation and Quality Improvement Authority and the Director of Public Health I would be writing to the Medical Director of all Northern Ireland Hospitals and the Northern Ireland Chief Nursing Officer. I would ask the Medical Directors to provide me with a collegiate response to the surgical and anaesthetic failings that the inquest has identified and I would ask for a similar response from the Northern Ireland Chief Nursing Officer in relation to nursing issues.

I should be grateful if you would acknowledge receipt of this letter and confirm that you will be responding in the manner I have requested. I, and no doubt the family also, require reassurance that all steps have been taken to ensure patient safety and

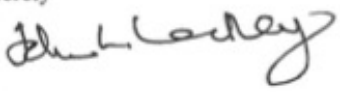
Tel: 028 9044 6800 Fax: 028 9044 6801
May's Chambers, 73 May Street, Belfast. BT1 3JL
www.coronersni.gov.uk

everything possible has been done or will be done to prevent the occurrence of a similar fatality or other serious adverse incident that has not resulted in a fatality.

I am sending a copy of this letter to the Minister, CMO, RQIA, Director of Public Health and the legal representatives.

I will look forward to hearing from you.

Yours sincerely



J L LECKEY
Senior Coroner for Northern Ireland

Encs

(b) **Did you believe the use of monopolar with glycine irrigation was a safe method of performing TURP procedures?**

1.04 Having regard to the above (1), monopolar with glycine irrigation for performing TURP procedures had been widely used for over 40 years and neither the NICE guidance (Feb 2015) nor the Policy on the Surgical Management of Endoscopic Tissue Resection HSS(MD)14/2015 produced in May 2015 stated that the technique was unsafe or that it should be stopped forthwith so I would have inferred that both these sources considered the technique safe, the latter providing additional Regional safeguards (serial perioperative blood/serum sodium levels etc) that were not in place in the rest of the UK. In addition, in his email included below at 2(e) (Sent: Tuesday, November 19, 2013 2:16 PM) Dr Bob Darling noted that '*We have been asked to review the management of patients at risk of toxicity from glycine irrigation fluid. Ie TURP Syndrome. There is little in the literature since Ananthanarayan et al Can J Anaesth 1996; 43: 56-64*'. The safety or otherwise of monopolar with glycine irrigation had not been causing a stir in the literature between 1996 and 2013.

1.05 That is not to say that I did not consider bipolar resection with saline safer with respect to the risks of hyponatraemia, I did, because it obviously was. The 'Normal Saline' proposed or used in bipolar diathermy has a higher sodium concentration than blood so hyponatraemia is impossible following absorption.

(c) **When did the Southern Trust direct the cessation of monopolar procedures?**

1.06 I apologise but I am unable to assist the Inquiry in this regard as I do not know the answer to this for gynaecology or urology.

(d) **Were you aware of any monopolar TURP procedures having been carried out after this date? If so, please provide full details.**

1.07 As I do not know the date the Southern Trust directed the cessation of monopolar procedures (if it did), I would not know of any monopolar TURP procedures having been

carried out after that date.

(e) **What was your view on the introduction of bipolar resection with saline? Did you believe it to be a suitable alternative? Why/ why not?**

1.08 Mrs Lynn Lewis had died from hyponatraemia as a direct consequence of the use of unipolar resection in glycine. Bipolar resection in saline makes blood monitoring of sodium perioperatively redundant as hyponatraemia is impossible and there is a larger fluid absorption tolerance so, I was positive. Please see my emails attached below under 2 e. It was a most suitable alternative from the anaesthetic point of view. I was not a Urological Surgeon, still less a Gynaecologist so I would not have had an opinion on whether it was suitable from the surgical point of view.

(f) **Was training required to adapt to the new equipment and technique? If yes, please provide details of all such training offered to relevant colleagues within the Trust.**

1.09 I would not have known personally if training was required to adapt to the new equipment and technique as I was not a Urological Surgeon or Gynaecologist nor was I involved in the introduction of the new equipment and techniques nor do I know when this took place. However, 'with regard to the above' (1) I would quote the third paragraph, page 9, of the Policy on surgery for endoscopic tissue resection which states 'The External Assessment Centre (NICE) did not identify any special training needs for a switch to the TURis system from monopolar transurethral resection of the prostate (TURP). The NICE Committee received expert advice that confirmed that little training is needed for surgeons who are already performing monopolar TURP procedures.' The Policy does not comment that I could find, on the training requirements for the new equipment and technique for gynaecological endoscopic resection.

2. **In his statement to the Inquiry (at WIT-98867), Mr Chris Hagan states as follows:**

'Some years after the policy was developed I was contacted by phone by

Dr Charlie McAllister, a consultant anaesthetist in CAH. I cannot be sure when exactly I received this call, but I believe it was sometime between 2017 and 2019. Dr McAllister wished to discuss TUR surgery, TUR syndrome and use of bipolar resection. He explained that they had an issue in CAH with an individual surgeon carrying out prolonged TURP resections with glycine and some "bad" TUR syndromes. He did not name the surgeon specifically. He wanted to know my experience with introducing TURP in saline. I explained that the experience in Belfast was good, that the technique was similar to monopolar TURP with glycine and that with modern equipment, in my view, it was unjustified and unsafe to continue to use glycine due to the safety profile of it as an irrigating fluid. From a personal perspective, I have carried out TURP in saline for around 10 years and see no justification for the use of glycine.'

(a) **Please provide full details of the telephone conversation referred to by Mr Hagan. Your answer should address the following:**

i. **Do you agree that Mr Hagan's account of the telephone call is accurate?**

2.01 No. I have no memory of this telephone call as characterized by Mr. Hagan so I am unable to agree that Mr. Hagan's account is accurate.

ii. **To the extent that your answer is affirmative, please address the following:**
a. **When did this conversation take place?**

2.02 As stated above my answer is not affirmative to any extent. However, in trying to be helpful I would say:

1) If we consider the first two sentences - '*Some years after the policy was developed I was contacted by phone by Dr Charlie McAllister, a consultant anaesthetist in CAH. I cannot be sure when exactly I received this call, but I believe it was sometime between 2017 and 2019.'* Any such telephone contact could not have been 'some years' after the Policy was developed nor could it have been 'sometime between 2017 and 2019.'

2) It could not have been in 2019 as I was not employed by CAH/SH&SCT (or any other Trust) in 2019.
3) It could not have been 2018 as I gave my notice in January 2018 and retired from CAH/SH&SCT in April 2018. I had no urology lists in my job plan in Jan-April 2018.
4) It could not have been 2017 or early 2018 as from October 2016 I was no longer AMD for anaesthetics and had no management responsibility, consequently had no mandate to contact anyone about issues out-with my own practice or out-with the Trust and urology lists were not in my job plan that year.
5) Had there been such a telephone call it could, in theory, have been between May 2015 (when the Policy was released) and October 2016 except that would not have been 'some years after the policy was developed' and it would have been a redundant conversation as the policy had only been sent out in May 2015 and whilst the fluid and sodium monitoring and management was implemented relatively quickly to expect CAH or the SH&SCT to move on acquiring new equipment/change technique as recommended in the policy in less than 18 months would have been optimistic in the extreme. It took nearly 2 years for Julian Johnston to get consensus and publish the policy.
6) Furthermore, the steps described and prescribed in the policy to avoid TUR/TURP syndrome were clear and expected to be very effective so significant TUR/TURP syndrome should have been a thing of the past following the implementation of the glycine fluid management aspect of the May 2015 Policy. If there were even significant (as opposed to 'bad') TUR/TURP syndromes despite application of the steps agreed in the policy then the policy was flawed and would have needed revision. I'm not aware that this was the case, but that would be easy to check.

b. **In what capacity did you contact Mr Hagan? What was your role at the time?**

2.03 I have no memory of contacting Mr. Hagan regarding this matter following the introduction of The Policy on the Surgical Management of Endoscopic Tissue Resection HSS(MD)14/2015 because I believe it did not happen.

c. **Why did you seek to discuss this matter with Mr Hagan?**

2.04 I have no memory of seeking to discuss 'this matter' as per (2) above, Mr Hagan's statement, with Mr. Hagan following the introduction of the Policy.

d. **Please provide full details of the conversation with Mr Hagan.**

2.05 Since I do not recall a conversation with Mr. Hagan some years after the introduction of the Policy (and I do not believe such a conversation took place at that time) I am unable to provide any details of the conversation.

e. **Please identify the individual surgeon referred to.**

2.06 As per above since I do not recall this conversation, I am unable to identify the individual surgeon referred to as I didn't refer to one.

f. **How many 'prolonged TURP resections with glycine' were you aware of?**

2.07 As per above, in the context of Mr. Hagan's statement I cannot answer this as I do not recall saying it, nor was I aware of it. I did not have a urology list in my Job Plan following the introduction of the policy. It would be easy to check the CAH TMS (Theatre Management System) to see If I anaesthetised any patients for a TURP after the introduction of the policy, I certainly don't remember any, so I would have been unaware of length of any TURP resections directly and I do not recall anyone sharing with me their experience or concerns. Of the c1500 pages of documentation, emails, correspondence, discovery documents etc provided to me for this Inquiry I am not aware of any that refers to prolonged TURP resections by one or more surgeons being raised with me by Mr. Weir (CD Urology), Mark Haynes, a Urologist, Urology Head of Service, Theatre Lead, AD for Surgery Mr. R Carroll or the Director of Acute Services or the Medical Director Richard Wright following the introduction of the policy. I infer from question (h) below that the Inquiry is trawling for length of TURP procedures by specific surgeons. I had no such knowledge at the time, I do not know if it was collected and analysed at the time and if it was it was never shared with me.

g. **How many 'bad TUR syndromes' were you aware of at that time?**

2.08 I'm unsure what constitutes a 'bad TUR syndrome', apart from death, fitting/admission to ICU with TUR/TURP Syndrome as a primary cause. I do not recall any 'bad TUR syndromes' at that time – 'some years after the Policy was developed'. In fact, I do not recall any TUR syndrome patients after the Policy was implemented, nor would I have expected to see any if all the Theatre team/Anaesthetists were doing their jobs as per the Policy which was designed to prevent TUR syndromes, bad or otherwise. If any of these patients died, then I would have expected there to have been a SAI report and investigation and I do not recall any of those either but that should be easy to check. Nor am I aware of any SH&SCT anaesthetists being referred to the GMC for allowing 'bad TUR syndromes' to develop following the introduction of the glycine fluid management recommendations in the policy. Monitoring the blood sodium is only one half of the equation, anaesthetists are expected to DO something if the sodium falls below critical levels or falls too quickly. Anaesthetists were very well aware of the coroner's (Mr. Lecky) expectations of them. Also, the Public Health agency were all over this subject. For example, in the following letter sent by Carolyn Harper and attached to Debbie Burns' email below dated 22nd January 2014:

HSC Public Health Agency

12-22 Linenhall Street
Belfast
BT2 8BS

Tel: [redacted]
Website: www.publichealth.hscni.net

By email to attached list

22 January 2014

Dear Colleague

Further incident relating to use of distension fluid

The attached letter from CMO and CNO to Coroner John Leckey relates to the death of Lynn Lewis in an independent sector provider due to fluid over-load associated with intra-operative distension fluid.

This letter is to make you aware that a further incident has been notified to the HSCB/PHA through the SAI/SEA process involving hysteroscopic transcervical resection of fibroid using glycine distension fluid. During the procedure the suction machine used for the irrigation of the glycine had to be replaced. During the machine changeover, the patient absorbed a significant amount of glycine. The patient was observed overnight and discharged without compromise. The investigation is underway to establish the full circumstances of this incident and any learning from that will be disseminated in due course.

Action Required

Trust Chief Executives – please draw this further incident to the attention of relevant staff in your organisation.

RQIA Chief Executive – please disseminate this information to relevant independent sector providers.

NIMDTA Chief Executive – please disseminate this letter to doctors in training in relevant specialities.

Yours sincerely

[redacted]

DR CAROLYN HARPER
Medical Director/Director of Public Health

Improving Your Health and Wellbeing

Corrigan, Martina

From: Burns, Deborah <[redacted]>
Sent: 22 January 2014 20:58
To: McAllister, Charlie; Carroll, Ronan; Hogan, Martina; McVey, Anne; Young, Michael; Corrigan, Martina; Trouton, Heather; McGeough, Mary; Marshall, Margaret
Subject: FW: Further incident relating to use of distension fluid - urgent for dissemination and discussion
Attachments: letter from Dr Michael McBride.pdf; 220114 Further incident relating to use of distension fluid distribution list.doc; 220114 Further incidents relating to use of distension fluid.pdf

Importance: High

Hi all please find attached for urgent review with your clinical colleagues and dissemination D

Debbie Burns
Interim Director of Acute Services
SHSCT
Tel: [redacted]
Email: [redacted]

From: McAlinden, Mairead
Sent: 22 January 2014 18:33
To: Marshall, Margaret; Simpson, John; Burns, Deborah
Cc: Joyce, Barbara
Subject: FW: Further incident relating to use of distension fluid

See attached FYI – Debbie/John for any immediate action required

Margaret for S&G process

Mairead

From: Carolyn Harper [mailto:[redacted]
Sent: 22 January 2014 16:57
To: Hugh McCaughey SE Trust; Colm.donaghy[redacted] paul.cummings[redacted] mary.hinds[redacted] Elaine Way Western Trust; McAlinden, Mairead; Glenn Houston RQIA
Cc: Simpson, John; Charlie.Martyn[redacted] Tony Stevens; Calum.McLeod[redacted] Dr Alan McKinney; Nicki.Patterson[redacted] brenda.creaney[redacted] Olive.macleod[redacted] Rice, Francis; Alan.Finn[redacted] julian.johnston[redacted] june.champion[redacted] David.hill[redacted] linda.kelly[redacted] Burns, Deborah; Beattie, Caroline; jim.carson[redacted] suzanne.pullins[redacted] AcutePA[redacted] Patricia Donnelly ([redacted]; Seamus.McGoran[redacted] margaret.ohagan[redacted] Burns, Deborah; geraldine.mckay[redacted] eimear.mccusker[redacted] Anne Friel; Boyce, Tracey; Jill Macintyre SE Trust; Dr Michael Scott Northern Trust; David Stewart RQIA; kathy.fodey[redacted] p.johnston[redacted] linda.johnston[redacted] d.woolfson[redacted] owen Barr ([redacted]; p.mccarron[redacted] maura.devlin[redacted] glynis.henry[redacted] Nicola.Porter[redacted] Eddie Rooney; Carolyn Harper; Janet Little; Pat Cullen; John Compton; Safety and Quality Alerts HSCB; michael.mcbride[redacted] Charlotte.McArdle[redacted] mark.timoney[redacted] Michael Bloomfield; Gavin Lavery
Subject: Further incident relating to use of distension fluid

2.09 There was marked concern over a patient 'absorbing a significant amount of glycine' (she did not, she absorbed glycine fluid, the volume of which we do not know). In the first paragraph Dr Harper states that Lynn Lewis died of fluid overload. She did not. We are not told all of the details of this 'further incident', the procedures in place, the serum sodium, the

estimated volume of the fluid absorbed or if the patient was symptomatic. I would infer that she was not because she was discharged the next day 'without compromise'. However, this letter was sent out to all and sundry and thence to Gynaecology, Urology and Anaesthetics in the SH&SCT for 'Urgent review with your clinical colleagues and dissemination' (Debbie Burns, Director of Acute Services) and 'see attached FYI Debbie/John for any immediate action requires' (John is Dr John Simpson, the excellent Medical Director at the time) and Margaret Marshall (Standards & Governance Lead) for 'S&G process' from Mairead McAlinden, the excellent Chief Executive.

2.10 So, a relative non-event, prompting this response, where someone absorbed 'a significant amount of glycine' the quantity of which we have no idea, the serum sodium level of which we have no idea, the symptoms and treatment of which we have no idea and the procedures and policies around that procedure of which we also have no idea and this was before the policy was in place. What would the reaction have been if this had occurred after the policy was in place? What would have happened if there were SAI/SEAs in CAH/SH&SCT due to 'bad TUR syndromes', where patients were actually symptomatic from hyponatraemia, after the policy was published (May 2015) and implemented (late 2015 early 2016 from the glycine management point of view)??

2.11 There may have been follow up communication subsequent to further investigation of this case but I most certainly do not recall it being shared with me.

h. **Please provide full details of all procedures captured by (v) and (vi) above to include: (a) the HCNs of relevant patients, (b) the length of the procedures, if known, (c) the patient outcomes in each case.**

2.12 I have no wish to appear obtuse or unhelpful to the Inquiry, but I have no idea what this question means. There are no '(v) or (vi) above'. Nor is there a (vi) below. In response to (a), I do not know what procedures captured is referring to. Even if I did, I would not be able to provide the HCNs as I am not an employee of the SH&SCT and do not have access to anyone's H&CN.

2.13 In response to (b) I do not know the procedures or the patients and would not have access to the length of the procedures if I did know as I am not an employee of the SH&SCT.

2.14 In response to (c), since I do not know the patients, or the procedures and I do not have

access to patient data as I am not an employee of the SH&SCT I would not be able to provide information on patient outcomes.

2.15 Is it possible that there has been an error in this Section 21?

i. **Did any further discussion occur between you and Mr Hagan on this, or any other occasion?**

2.16 I assume what this question is asking is, was there further discussion (further to the topics outlined in Mr. Hagan's statement) between Mr. Hagan and I on the telephone conversation that is alleged to have taken place some years after the introduction of the policy (May 2015), sometime between 2017 and 2019. If this is the case then, since, as I have carefully outlined previously above, I have no recollection of any such conversation on that occasion and do not believe that one could have or did take place at that time then no, there was no further discussion 'on this occasion'.

2.17 As to whether there was further discussion on any other occasion, this I assume refers to discussion subsequent to the discussion and outlined by Mr. Hagan temporally indicated in his statement. If this is the case then the answer is no.

iii. **Regardless of the date of any such contact, do you recall engaging with Mr Hagan on the issues of TUR surgery, TUR syndrome and resection in glycine?**

2.18 No, other than being in receipt of emails from Chris Hagan [see below (2e), sent November 20th 2013 09.35 and 10.11].

iv. **Whether or not you recall the conversation described by Mr Hagan, do you recognise the issues identified by Mr Hagan?**

2.19 If this question refers to '*He explained that they had an issue in CAH with an individual surgeon carrying out prolonged TURP resections with glycine and some "bad" TUR syndromes. He did not name the surgeon specifically'* then the answer is no, I cannot recall having any such issues with any urological surgeon.

v. **Whether or not you recall the conversation described by Mr Hagan, do you accept that those issues identified were issues that you were concerned about**

in your role as AMD for Anaesthetics?

2.20 If this question refers to '*He explained that they had an issue in CAH with an individual surgeon carrying out prolonged TURP resections with glycine and some "bad" TUR syndromes. He did not name the surgeon specifically' 'Some years after the policy was developed'* then the answer is no. I do not accept that those issues identified were issues that I was concerned about in the 17 months that I was AMD for Anaesthetics following the release of the policy. As I have outlined above, I do not see how "bad" TUR syndromes could have occurred if the policy on glycine fluid and blood sodium monitoring was followed. In fact, it would be inconceivable that it was not followed. Furthermore, I would have no knowledge of the length of TURP resections.

(b) **Did you discuss the issue with the clinician whose practice was causing concern? If so, please provide full details, to include details of the response received and any further action taken.**

2.21 Since I do not recognize the issues identified in Mr. Hagan's statement and I had no knowledge of any surgeon associated with prolonged TURP surgery or "bad" TUR syndromes, hence I did not discuss the issue with any such clinician, hence there was no response that I can furnish you with, nor was any further action taken.

(c) **Did you seek to discuss your concerns with anyone else within the Southern Trust? If so, please provide full details of all discussions relating to this issue, to include dates, the identities of parties to the discussions, the content of those discussions and any actions taken by you, or others, on foot of same. If you did not seek to discuss your concerns with others within the Southern Trust, please explain why this was the case.**

2.22 Again, the premise here is that I had concerns after the introduction of the Policy. Of the many concerns I had in 2016 with regards to Surgery in general and Urology in particular (as outlined in my email dated 09 May 2016 15.41 to Esther Gishkori, Richard Wright and Ronan Carroll {referred to as the State of The Nation email by Mr Wolfe} to wit: '6. Urology. Issues of competencies, backlog, triaging referral letters, not writing outcomes in notes, taking notes home and questions being asked re inappropriate prioritization onto NHS of

patients seen privately.') concerns assigned in this question relating to Mr. Hagan's statement were not among them. Hence since I did not have the concerns characterized by Mr. Hagan based on a telephone call that did not take place following the policy, I did not discuss these non-concerns with anyone else, so the rest of this question is redundant.

(d) **Were you aware of others within the Southern Trust who held similar concerns in respect of the ongoing use of monopolar resection techniques at that time? Please provide details.**

2.23 No. I was not aware of others having concerns, or if they did they did not share them with me.

(e) **Please provide copies of any relevant correspondence or other documentation in which your concerns are contemporaneously recorded. If it is the case that no such documentation exists, please explain why.**

2.24 I have no relevant correspondence or other documentation in which my concerns following the introduction of the policy were contemporaneously recorded. I didn't have any concerns.

2.25 However, for completeness I include relevant emails for part of the period before the release of the policy.

2.26 At Dr Simpson's behest (Medical Director) I initiated communication with the SH&SCT gynaecologists via Dr Martina Hogan, AMD O&G., – see first email below:

From: Simpson, John <[redacted]>
Sent: 04 November 2013 17:44
To: McAllister, Charlie
Cc: McCooey, Blaithnid; Joyce, Barbara; McCauley, Cheryl; Marshall, Margaret; QUINN, Anne M; Burns, Deborah; Hogan, Martina
Subject: RE: *Confidential* Coroner's Case for S+G route per Dr Simpson

Carolyn Harper will be writing to us to look for our current position by end of nov as a first step. She will be responding to the coroner on all trusts' behalf,

John

From: McAllister, Charlie

Sent: 01 November 2013 21:47 To: Simpson, John
Cc: McCooey, Blaithnid; Joyce, Barbara; McCauley, Cheryl; Marshall, Margaret; QUINN, Anne M; Burns, Deborah
Subject: RE: *Confidential* Coroner's Case for S+G route per Dr Simpson

Intriguing!

Blaithnid/Cheryl could I have sight of a copy of these please?

Charlie

From: McAllister, Charlie
Sent: 05 November 2013 15:04
To: Hogan, Martina
Cc: McVey, Anne
Subject: FW: *Confidential* Coroner's Case Importance: High

Dear Martina

Could I ask you to study the attached documents and then get back to me as a matter of some urgency regarding the following questions:

1. Is this procedure performed in the SH&SCT?
2. Which sites?
3. What SOP is followed?
4. Is this SOP compliant with the best practice as outlined in these documents?
5. If not what are the deficiencies?
6. If there are deficiencies how may these be addressed and in what timeframe?

Many thanks

Charlie

2.27 This resulted in the following reply where the answers were appended in my original email:

From: Hogan, Martina
Sent: Tuesday, November 05, 2013 4:13 PM To: McAllister, Charlie
Cc: McVey, Anne; Sim, David; McCracken, Geoff; Sidhu, Harmini Subject: RE: *Confidential* Corone

Charlie

1. Is this procedure performed in the SH&SCT? Yes
2. Which sites? DHH and CAH
3. What SOP is followed? Within DHH there is an automated fluid management system, on CAH site, fluid discrepancy is estimated manually. Request for an automated system has been undertaken
4. Is this SOP compliant with the best practice as outlined in these documents? With DHH yes, in CAHh manual satisfactory not optimal

5. If not what are the deficiencies? As above automated system required for CAH
6. If there are deficiencies how may these be addressed and in what timeframe? Presently gone to tender, time frame unknown ? could Ronan or Anne assist

Geoff Mc Cracken advised and David Sim was also consulted – Geoff rang him. David is on annual leave today I hope this is helpful

Martina

From: McAllister, Charlie
Sent: 20 November 2013 11:18 To: Hogan, Martina
Cc: McVey, Anne
Subject: RE: *Confidential* Coroner's Case

Hi Martina

Thanks for this reply. At the last THUGS meeting Geoff did not wish an automated system for CAH so this is not being progressed.
Also, the Urologists in other Trusts are moving to saline instead of glycine for endoscopic procedures because of this case.
Since this case was a gyne case has this been considered either locally or Regionally in Gyne?

Thanks

Charlie

2.28 So in the above email I raised the subject of using saline (and consequently bipolar diathermy) in place of glycine.

From: Hogan, Martina
Sent: 21 November 2013 11:11
To: McCracken, Geoff; Sim, David
Cc: McAllister, Charlie; McVey, Anne; McStay, Patricia; Sidhu, Harmini

Subject: FW: *Confidential* Coroner's Case

Dear Geoff and David ,

Can you respond to Dr Mc Allister please

Thanks

Martina

From: Sim, David
Sent: 21 November 2013 22:48
To: Hogan, Martina; McCracken, Geoff
Cc: McAllister, Charlie; McVey, Anne; McStay, Patricia; Sidhu, Harmini Subject:
RE: *Confidential* Coroner's Case

Moving to saline involves different equipment and still carries risks of overload and embolization. Unaware of any local or regional consideration.

David

From: McCracken, Geoff
Sent: 25 November 2013 14:44
To: Sim, David; Hogan, Martina; Clayton, Wendy
Cc: McAllister, Charlie; McVey, Anne; McStay, Patricia; Sidhu, Harmini

Subject: RE: *Confidential* Coroner's Case

Dear All

At the last THUGS meeting I stated that at present we do manual assessment of fluid levels but I would be keen for an automated system.
I agree with Mr Sim that even if we moved to saline system we would still have to assess fluid levels as the risk of fluid overload still exists.
For us to move to a saline system we would have to change all our resectoscopes from monopolar to bipolar and as many of these systems have just been purchased this would seem to be an ineffective use of funds.

Regards

Geoff

2.29 So, David Sim was the lead Gynaecologist (CD) in DHH and Geoff McCracken was the lead Gynaecologist (CD) in CAH. No great enthusiasm apparent to move to saline. Appears that there was a difference in recall of Dr McCracken's position at the THUGS (Theatre UserS Group) meeting prior to the 20th November. There would be minutes of that meeting so it should be easy to check if thought important.

From: Sidhu, Harmini
Sent: Monday, November 25, 2013 4:42 PM
To: McCracken, Geoff; Sim, David; Hogan, Martina; Clayton, Wendy Cc: McAllister, Charlie; McVey,

Anne; McStay, Patricia
Subject: RE: *Confidential* Coroner's Case

Dear All,

Have been following this: just as a precaution, would it not be prudent also to check what other units are doing? They are also in the same position as us. If we have an issue in the future, we may be quoted what has/is happening in other units since this particular event.
Have to be seen to be proactive.

Mini

From: McAllister, Charlie
Sent: 25 November 2013 22:43
To: Sidhu, Harmini; McCracken, Geoff; Sim, David; Hogan, Martina; Clayton, Wendy Cc: McVey, Anne; McStay, Patricia
Subject: RE: *Confidential* Coroner's Case

Dear All

Can I ask you to reconsider the position here?

I am aware that switching to Normal Saline instead of glycine would not prevent fluid overload. However – this was not the cause of death in the case in the Ulster Independent Clinic, nor was it embolization – hyponatraemia was. The use of normal saline would eliminate this risk – which is somewhat in the forefront of Mr Lecky's mind. Also, the consequences were far wider than for the Gynecologist and the patient – the Anaesthetist, nursing staff and institution were all devastatingly and intimately caught up in the fall out with significant on-going consequences.
Could I ask that that you seek opinion on this from;

1. The Professor of O&G in Belfast
2. The CD of Gyne in the Belfast Dr Johnny Price. I have – he has told me quite clearly that the Belfast Trust Gyne will be 100% saline only by the 1st April 2014 – they are in the process of securing the change in equipment and the training required for this. In the meantime there will be NO TCREs performed in the Belfast Trust until this is sorted.
3. Mr Ray McClelland who is taking the lead on this in the Belfast Trust.
   Mr Chris Hagan, Lead for urology in the Belfast Trust and who's opinion when it comes to glycine for TURP and TURB is "The technology for bipolar resection surgery is now so good (we are using Olympus) that I can see no compelling argument at all to use glycine. I'd be interested to be know of any circumstance
4. where glycine would be regarded as superior because I can't think of any."
5. Other colleagues Regionally.

I think that the decision whether this is an effective use of funds should be left to the Trust to decide on a risk/benefit analysis. The decision would be inevitable in my opinion.
Can I ask that you discuss and get back to me as soon as possible? The Public Safety Agency is looking for position statements from Trusts soon?

Many thanks

Charlie

2.30 I would suggest that this last email has various contents that are of interest:

a) There appeared to be a lack of appreciation that the focus and danger and cause of death in the index case was hyponatraemia not fluid overload. They were not alone.

b) Mr. Lecky was focusing on hyponatraemia and was perturbed to say the least with Mrs. Lewis's death.

c) The anaesthetist involved in the death of Mrs Lewis in addition to having the burden of being involved with that poor lady's death was suffering the attention of the coroner.

d) I had quoted the views of Dr Price and Mr Chris Hagan as they were in the BHSCT which as I explain in 3. (a) below was the epicentre of hyponatraemia in Northern Ireland. The quote in the line above - *'Mr Chris Hagan, Lead for urology in the Belfast Trust and who's opinion when it comes to glycine for TURP and TURB is "The technology for bipolar resection surgery is now so good (we are using Olympus) that I can see no compelling argument at all to use glycine. I'd be interested to be know of any circumstance where glycine would be regarded as superior because I can't think of any."* comes from an email from Mr Hagan to Bob Darling on the 20th November, 10.11, (see below) that I was cc'd into.

e) I believe it unlikely that there had been a telephone call at this time however a serendipitous face to face discussion may have occurred that Mr. Hagan is confusing with a phone conversation that did not take place years later.

f) Please see my email to Debbie Burns dated 25th November 2013, 11:59 below (c page 35) where I say 'I have very clear views on this subject. I have had several discussions with Gynae/Anaesthetics and emails re Urology Regionally'. Not a phone call or conversation re Urology but emails.

g) The argument regarding ineffective use of funds is quaint in this context. That was a

decision for the trust non-clinical managers to prioritise not clinicians as clinicians did not hold a budget. However, there is no doubt that funding was always an issue and frequently prioritised by the SH&SCT trust in non-frontline clinical areas. I would be surprised if one of the factors in any tardiness in the introduction of bipolar diathermy was not debate about funding.

From: McCracken, Geoff
Sent: Tuesday, November 26, 2013 11:18 AM
To: McAllister, Charlie; Sidhu, Harmini; Sim, David; Hogan, Martina; Clayton, Wendy Cc: McVey, Anne; McStay, Patricia
Subject: RE: *Confidential* Coroner's Case

Dear All

I have sought some clarification from the BCH.
At present TCRE's in BCH are being undertaken, using monopolar energy using automated technology.
Ray McClelland is undertaking a review of practice at present and when it is concluded he will happily supply us with its conclusions and I will be happy to follow these conclusions.
Until then I feel that we should continue using the equipment that we are confident with, which is monopolar diathermy, ideally with an automated fluid management system, but at least with a dedicated nurse manually assessing fluid balances.
Before moving to something new it should be trialled and confirmed to be as good, if not better than our present surgical techniques.

Regards

Geoff

From: McAllister, Charlie
Sent: 26 November 2013 11:56
To: McCracken, Geoff; Sidhu, Harmini; Sim, David; Hogan, Martina; Clayton, Wendy Cc: McVey, Anne; McStay, Patricia
Subject: RE: *Confidential* Coroner's Case

Great, thanks Geoff

Could I just ask you to clarify;

1. Are to happy to follow Ray McClelland's conclusions (as you said in the first half) or would you need to trial any changes and confirm that they are as good if not better than the technique that led to the death of the lady in the UIC (as you said in the second half)?
2. Does anyone else in CAH do TCRE's and if yes are representing their position also or just your own?
3. David could I ask if you would also be happy to follow Ray McClelland's conclusions assuming that Geoff is?
4. Martina from the Governance perspective can I ask if you are happy with this or if have you alternative position here?

I will clarify the position in the Belfast Trust regarding TCREs currently as J Price is under a misapprehension.

Thanks!

Charlie

2.31 As far as I recall and as far as the archive is concerned there was no reply to this last email.

From: Simpson, John [redacted] >

Sent: 27 November 2013 20:58

To: Marshall, Margaret; McAllister, Charlie

Subject: FW: Lynn Lewis - deceased - Coroner's correspondence
Attachments: 21.10.13 from J Leckey re L Lewis 1.pdf; 21.10.13 from J Leckey re L Lewis 2.pdf; 061113 letter to Medical Directors re Coroners correspondance.pdf

Are we ready with an initial response?

John

From: Kelly, SharonA [mailto:[redacted]] On Behalf Of Stevens, Tony Sent: 27 November 2013 17:38
To: Alan McKinney ([redacted]); Calum Macleod; Charlie Martyn; Simpson, John

Cc: Carolyn Harper; Johnston, Julian; Murphy, Christine; Stevens, Tony; alison.mcmaster[redacted]; dorothy.killough[redacted]; White, Laura; Orlaith Morrow
Subject: FW: Lynn Lewis - deceased - Coroner's correspondence

Dear colleagues

I note we have to respond to Carolyn on the back of her letter and that of Coroner, by 30 November. Julian returns from annual leave tomorrow and is preparing to produce the collegiate response. Have you responded to him yet? I understand 1 or 2 Trusts may have responded individually. Carolyn has asked me to ensure that a single response is received.

Thank you Tony

Sharon Kelly
PA to Dr Tony Stevens
Medical Director, Belfast HSC Trust, Trust HQ, A Floor, Belfast City Hospital 51 Lisburn Road, Belfast, BT9 7AB
Tel [redacted] (Dir)

From: McVey, Anne
Sent: Sunday, December 01, 2013 10:41 PM GMT Standard Time
To: McAllister, Charlie; McCracken, Geoff; Sidhu, Harmini; Sim, David; Hogan, Martina; Clayton, Wendy
Cc: McStay, Patricia
Subject: RE: *Confidential* Coroner's Case

Dear all,

I have not to date replied to the emails in relation to this matter but feel it may be best discussed and agreed at THUGS meeting?

Regards Anne

Anne McVey
Assistant Director of Acute Services Integrated Maternity & Women's Health Craigavon Area Hospital
Tel: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI

From: McAllister, Charlie
Sent: 02 December 2013 07:42
To: McVey, Anne; McCracken, Geoff; Sidhu, Harmini; Sim, David; Hogan, Martina; Clayton, Wendy
Cc: McStay, Patricia
Subject: Re: *Confidential* Coroner's Case

I agree that it should be discussed and agreed. I do not agree that THUGS is the best/correct forum.

Charlie

From: McVey, Anne
Sent: 02 December 2013 14:12
To: McAllister, Charlie; Murphy, Jane S
Cc: McCracken, Geoff; Sim, David; Carroll, Ronan; McGeough, Mary; Hogan, Martina; Sidhu, Harmini; McStay, Patricia; Travers, Marie; McEneaney, Lorraine; Burns, Deborah
Subject: FW: *Confidential* Coroner's Case - Meeting to agree how the findings re Trans Cervical Endometrial Resection are to be addressed in SHSCT
Importance: High

Dear Charlie,

I have discussed this with Dr Hogan today and we are happy to facilitate a separate meeting to discuss and agree the findings of the Coroners verdict re Trans Cervical Endometrial Resection.

Dear Jane, can you agree a suitable date for this meeting, the following staff to attend:
Dr McAllister, Mr Sim, Dr Sidhu, Dr McCracken, Dr Hogan, Ronan Carroll, Mary McGeough and myself. I would suggest 1 hour would be adequate and telelink facilities may be required.

Regards Anne

Anne McVey
Assistant Director of Acute Service

Integrated Maternity & Women's Health Craigavon Area Hospital
Tel: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI

From: McAllister, Charlie
Sent: 05 December 2013 11:42
To: Sidhu, Harmini; Carroll, Ronan; Murphy, Jane S; McCracken, Geoff; Sim, David; McGeough, Mary; Hogan, Martina; McStay, Patricia
Cc: McVey, Anne; McEneaney, Lorraine; Travers, Marie; Conlon, Noeleen
Subject: RE: *Meeting availability* *Confidential* Coroner's Case - Meeting to agree how the findings re Trans Cervical Endometrial Resection are to be addressed in SHSCT

Dear Anne

Thank you for the invitation but I would be superfluous as Geoff has agreed that the SH&SCT will follow the BHSHT's lead on this going forward. From my end that's it.

Thanks again

Charlie

From: Sim, David
Sent: Thursday, December 05, 2013 10:17 PM
To: McAllister, Charlie; Sidhu, Harmini; Carroll, Ronan; Murphy, Jane S; McCracken, Geoff; McGeough, Mary; Hogan, Martina; McStay, Patricia
Cc: McVey, Anne; McEneaney, Lorraine; Travers, Marie; Conlon, Noeleen
Subject: RE: *Meeting availability* *Confidential* Coroner's Case - Meeting to agree how the findings re Trans Cervical Endometrial Resection are to be addressed in SHSCT

Sorry but dhh has not agreed to follow but will consider their thoughts. The coroner's concerns to me are with the staff performing the operation not the operation itself.

From:	McAllister, Charlie <Personal Information redacted by the USI>
Sent:	19 December 2013 00:28
To:	Sim, David; Sidhu, Harmini; Carroll, Ronan; Murphy, Jane S;McCracken, Geoff;McGeough, Mary; Hogan, Martina; McStay, Patricia; McVey, Anne; McEneaney, Lorraine; Travers, Marie; Conlon, Noeleen
Cc:	McVey, Anne; McEneaney, Lorraine; Travers, Marie; Conlon, Noeleen
Subject:	RE: *Meeting availability* *Confidential* Coroner's Case - Meeting to agree how the findings re Trans Cervical Endometrial Resection are to be addressed in SHSCT

Attachments: Policy on surgery for endoscopic tissue resection.docx; Letter to C Harper.docx; 21.10.13 from J Leckey re L Lewis 1.pdf; 21.10.13 from J Leckey re L Lewis 2.pdf; 061113 letter to Medical Directors re Coroners correspondance.pdf

Dear David/All

You will probably receive this under at least one different cover – but please see Draft Regional collegiate Policy on endoscopic tissue resection. As with Anaesthetics. Theatres and Surgery I'm sure that comments will be fed up through appropriate channels. However the direction of travel is very clearly laid out.

Best Regards

Charlie

2.32 So I had made it clear that it was up to each specially to feed their responses/strategies through their specialty specific management lines for which they would take responsibility. And again that I was disengaged from gynaecology on this matter.

2.33 As far as I know my last communication with gynaecology on this subject was when I sent the email below for completeness.

From: McAllister, Charlie <Personal Information redacted by the USI>
Sent: 28 May 2015 15:44
To: McCracken, Geoff; Sidhu, Harmini; Sim, David; Hogan, Martina; Clayton, Wendy
Cc: McVey, Anne; McStay, Patricia; Carroll, Ronan; McGeough, Mary; Kelly, Brigeen
Subject: RE: *Confidential* Coroner's Case
Attachments: Letter from Mr Leckey re L Lewis 21 10 13.pdf; Policy on surgery for endoscopic tissue resection V0.4.docx; NICE 2015 - The TURis system for transurethral resection of prostate.pdf

Dear All

Please see attached and email below in case you were not circulated fyi.

Charlie McA

From: Johnston, Julian [mailto:Personal Information redacted by the USI] Sent: 26 May 2015
Distending Fluids for Endoscopic surgery Please find attached my final document with 12 recommendations which I propose represents the required 'collegiate ' response to the failings surrounding the death in the UIC. This is in response to the Coroner asking the CMO that 'the Medical Directors to provide me with a collegiate response to the surgical and anaesthetic failings that the inquest has identified and ….. similar response from the NI CNO in relation to nursing issues'.
I presented draft work at 2 recent Medical Leader Forums. After the last one I received further

feedback regionally. Thank you to those who sent in comments to the draft policy for Distending Fluids for Endoscopic surgery. I have responded to those who sent in comments with a further amended document.

Other important changes have followed the publication, in February 2015, of a NICE Medical Technology Guidance note 23 where they 'point out at the case for adopting the transurethral resection in saline (TURis) system for resection of the prostate is supported by the evidence'. Furthermore they also provide similar advice to the public http://www.nice.org.uk/guidance/mtg23/informationforpublic. I regard this work by NICE as a very potent argument for proceeding in the direction I propose.
I have taken account of the comments from the region and incorporated them, along with the guidance from NICE, into this final document.

I am content now that this does represent a majority view from around the Province. Please share this with your colleagues if they are not on the list above.

I have now shared this with the DHSSPSNI and all the Medical Directors. Regards,
Julian R Johnston MD FCARCSI FRCA Assistant Medical Director
BHSCT
Personal Information redacted by the USI

BHSCT Litigation Management Office Telephone: Personal Information redacted by the USI

If unanswered, contact Ann Maginnis: Personal Information redacted by the USI or Amanda Lennon (Coroner's Office): Personal Information redacted by the USI or Susan McCombe (Clinical Negligence): Personal Information redacted by the USI or Lorraine Watson (BCH Clin. Neg./Coroner's) Personal Information redacted by the USI .

2.34 In the interest of completeness, with regard to anaesthetics, I include an email out of sequence – one from the 5th December 2013 from Dr Bob Darling in the SE trust

From: McAllister, Charlie
Sent: 05 December 2013 15:29
To: Arava, Shiva; Brown, Jeffrey; Bunting, Helen; Clarke, Chris; Donnelly, Brian; Ferguson, Andrew; Gail Browne; Gupta, Nidhi; Hinds, John (Personal Information redacted by the USI); Laure Martin; Lichnovsky, Erik; Lowry, Darrell; McAllister, Charlie; McConaghy, Paul; McKee, Raymond; Merjavy, Peter; Morrow, Michael DR; OConnor, Kieran; Orr, Des; Parks, Lorraine; Rea, Margaret; Rutherford-Jones, Neville; Scullion, Damian; Sobocinski, Dr Jacek; Winter, Colin; Carlisle, R; Kumar, Devendra; Maguire, Peter; McDonald, Neil; Siddique, Nasir; Tariq, S; Wright, J

Subject: Enoscopic Resections

Dear All

You may recall at the last CGM I raised the issue of hyponatraemia during endoscopic procedures using glycine (TCRE, TURP, TURBT and TART). This followed from an Inquest. As I said there has been a proposal that if glycine is being used then it has been proposed by the SET that we should do a Na level at induction and 30 mins intervals during the procedure thereafter.
A drop of 5 mmol from the baseline should prompt action (see Bob's email below).

Although this has not been agreed as SOP/Policy in this Trust (or any other yet) this or a variant of this is heading our way and Bob tells me that they are following this in the SET already.
Pending any agreed policy in this area individuals may think it wise to adopt this approach now.

One small point – the lower limit for sodium that Bob refers to in his email is for serum – as you know the normal reference range in whole blood on the Radiometer is 133-146 mmol/l so the threshold of 130 proposed below will have to be adjusted down to 128.

I'll keep you updated as I get more information.

Many thanks

Charlie

From: Darling, John [mailto: Personal Information redacted by the USI] Sent: Tuesday, November 19, 2013 2:16 PM
To: gregory.furness Personal Information redacted by the USI ; stephen.austin Personal Information redacted by the USI ; McAllister, Charlie; paul.mcsorley Personal Information redacted by the USI
Cc: chris.hagan Personal Information redacted by the USI ; michael.morrow Personal Information redacted by the USI Subject: FW:

Dear All,

We have been asked to review the management of patients at risk of toxicity from glycine irrigation fluid. Ie TURP Syndrome.

There is little in the literature since Ananthanarayan et al Can J Anaesth 1996; 43: 56-64
A suggestion is that we move to bi-polar techniques where possible using saline irrigation fluid. In those patients requiring glycine irrigation fluid, fluid balance is recorded and a point of care serum sodium concentration taken at induction of anaesthesia and repeated if:

(i) 1000ml deficit is noted on fluid input output measures.
(ii) Procedure lasts more than 30 minutes
(iii) The surgeon notes unexpected complications such as bleeding

A drop of serum sodium of 5 mmol/l or a serum sodium of 130 mmol/l should lead to the cessation of glycine irrigation where possible. The surgeon should alert the team if a major vein is opened.
In cases where regional anaesthesia is used, serum sodium concentration should be measured as above and cessation of glycine irrigation should take place if visual disturbances, nausea, vomiting, seizures or other signs of encephalopathy become apparent.

I would value your opinion on:

Do you think this is a reasonable approach?
Is a drop of serum Sodium of 5 mmol/l or a serum sodium of 130 mmol/l the correct threshold?
We need to do a baseline sodium at induction of anaesthesia as there is significant diurnal variation in serum sodium levels (Page 109. Clinical Investigation and Statistics in Laboratory Medicine. Jones R, Payne B. ACB Venture Publications, 1997. ISBN 0902429213.)

Bob Darling

2.35 As for urology, please see the email trail below.

Stinson, Emma M

From: Corrigan, Martina <[redacted]>
Sent: 21 November 2013 08:45
To: McAllister, Charlie; Young, Michael
Subject: RE: Re:

Michael

Can we discuss this at departmental meeting please?

Thanks

Martina

Martina Corrigan
Head of ENT, Urology and Outpatients
Southern Health and Social Care Trust
Telephone: [redacted] (Direct Dial)
Mobile: [redacted]
Email: [redacted]

From: McAllister, Charlie
Sent: 20 November 2013 11:08
To: Young, Michael
Cc: Corrigan, Martina
Subject: FW: Re:

Thanks for this Michael

You are probably aware of the email trail attached below but in case you are not please see. I agree that a Regional agreed approach would be best – with Chris Hagan's views now a matter of public record without a compelling argument to use glycine I think, as a non-surgeon, it would appear to be VERY difficult to defend if there is a misadventure.

Could you review with your colleagues and get back to me please??

Thanks

Charlie

From: Young, Michael
Sent: Monday, November 18, 2013 4:41 PM
To: McAllister, Charlie
Subject: RE: Glycine use in BHSCT

Firstly BCH does not do many TURP !!!!!
Yes bipolar scopes are available but glycine cut better We would be selective about who we do

1

From: McAllister, Charlie
Sent: 18 November 2013 10:23
To: Young, Michael
Subject: FW: Glycine use in BHSCT

Hi Michael

Is this true? Is this feasible in the SH&SCT?

Charlie

From: Maguire, Peter
Sent: 18 November 2013 09:49
To: McAllister, Charlie
Subject: Glycine use in BHSCT

Charlie,

I was speaking to Steve Austin over the weekend. He was telling me that Urologists in BHSCT have moved to Saline with Bipolar diathermy for their cases and no longer use glycine (that was my understanding of what he told me). If this is the BHSCT practice we should move to a similar practice in light of the recent coroner's report associated with hyponatraemia and glycine irrigation.

Perhaps this can be discussed at CGM on Wednesday. Peter

From: Hagan, Chris [mailto:[redacted]
Sent: Wednesday, November 20, 2013 10:11 AM
To: 'Darling, John'; Austin, Stephen; 'gregory.furness[redacted]'; McAllister, Charlie; 'paul.mcsorley[redacted]
Cc: 'michael.morrow[redacted]
Subject: RE: Re:

Bob,
The technology for bipolar resection surgery is now so good (we are using Olympus) that I can see no compelling argument at all to use glycine. I'd be interested to be know of any circumstance where glycine would be regarded as superior because I can't think of any.

Chris

From: Darling, John [mailto:[redacted]
Sent: 20 November 2013 09:57
To: Hagan, Chris; Austin, Stephen; 'gregory.furness[redacted]; 'Charlie.mcallister[redacted] 'paul.mcsorley[redacted]
Cc: 'michael.morrow[redacted]
Subject: Re:

Thanks Chris,
Our urologists are moving in the same direction. We are trying to evaluate laser and put together a business case.

2

We are using the protocol below in the meantime. Do you see any circumstances where glycine is superior to saline. ie do we need to retain it at all?

As for haemorrhage, we automatically get a Haemoglobin concentration with the serum sodium and the surgeon alerts everyone if bleeding is an issue.

Bob

From: Hagan, Chris [mailto:Personal Information redacted by the USI
Sent: Wednesday, November 20, 2013 09:35 AM
To: Austin, Stephen <Personal Information redacted by the USI>; Darling, John; gregory.furness Personal Information redacted by the USI <gregory.furness Personal Information redacted by the USI>; Charlie.mcallister Personal Information redacted by the USI <Charlie.mcallister Personal Information redacted by the USI>; paul.mcsorley Personal Information redacted by the USI <paul.mcsorley Personal Information redacted by the USI>
Cc: michael.morrow Personal Information redacted by the USI <michael.morrow Personal Information redacted by the USI>
Subject: RE:

Bob

I have followed this coroner's case for some time and because of the concerns with glycine have already taken steps to attempt to eliminate it from urology theatres.

Amongst the urologists in BHSCT we have reached a consensus regarding this but I also believe that there should be a co-ordinated regional approach involving all urology units in NI to ensure similar protocols and avoid confusion.

In essence there are 2 issues to address:

1. Dilution hypnonatraemia /(neurotoxaemia?) due to the absorption of glycine causing TUR syndrome 2. Haemorrhage during endoscopic resection procedures

If we deal with point 1, TUR syndrome is completely avoidable with the use of saline irrigation, as either part of bipolar TURP or laser prostatectomy. We have stopped using glycine for TURP surgery but there is currently insufficient equipment to do all TURBT with saline irrigation. If we adopt saline irrigation for all endoscopic resection procedures in urology and remove glycine from theatre, then the risk of TUR syndrome is eliminated. This therefore obviates the need to establish methods of measuring fluid gain which have consistently been shown to be cumbersome and inaccurate anyway.
In our current practice we also use irrigating sheaths which prevent the development of high intravesical pressures, and all resections are limited to 1 hour which further minimise the risk of TUR syndrome.

Dealing with point 2, surely the best way to estimate blood loss during the procedure will be measurement of haematocrit and/or haemoglobin? This may simply be at the end of the procedure, or at time defined points during the procedure. Trying to estimate accurately the volume of fluid in/out is almost impossible and if anything is likely to cause more confusion because of the volume of fluid that tends to end up on the floor/ gowns/ drapes etc. We have for these reasons not recorded irrigating fluid in/out for many years, and I would be reluctant to recommend that we recommence that practice.

This approach is pragmatic, workable and above all, safe. There will though be some cost issues to Trusts in terms of purchase of more bipolar resection and/ or laser prostatectomy equipment .

3

Chris

From: Austin, Stephen
Sent: 19 November 2013 23:13
To: Darling, John; gregory.furness [redacted]
Charlie.mcallister [redacted] paul.mcsorley [redacted]
Cc: Hagan, Chris; michael.morrow [redacted]
Subject: RE:

Thanks
In Belfast, we are planning to move to bipolar diathermy with saline irrigation. This has already been done for TURP and we are planning to do this for the remaining urology cystoscopy cases – the hold up is the purchasing of the appropriate equipment.

This would eliminate the issue of hyponatraemia. Our urology surgeons are also investigating the use of green laser for TURP, but there is a cost issue here also.

Of course, there are also gynae irrigation procedures – hysteroscopy – which need a similar treatment if possible.

One issue would be the ease of monitoring of serum sodium and potential administration of sodium intraop – likely to be complex. Saline irrigation seems to us to be the simpler solution and may allow simpler monitoring of irrigation fluid balance.

Stephen

From: Darling, John [mailto: [redacted]
Sent: 19 November 2013 14:16
To: gregory.furness [redacted] Austin, Stephen;
Charlie.mcallister [redacted] paul.mcsorley [redacted]
Cc: Hagan, Chris; michael.morrow [redacted]
Subject: FW:

Dear All,

We have been asked to review the management of patients at risk of toxicity from glycine irrigation fluid. Ie TURP Syndrome.

There is little in the literature since Ananthanarayan et al Can J Anaesth 1996; 43: 56-64

A suggestion is that we move to bi-polar techniques where possible using saline irrigation fluid. In those patients requiring glycine irrigation fluid, fluid balance is recorded and a point of care serum sodium concentration taken at induction of anaesthesia and repeated if:

(i) 1000ml deficit is noted on fluid input output measures.
(ii) Procedure lasts more than 30 minutes
(iii) The surgeon notes unexpected complications such as bleeding

A drop of serum sodium of 5 mmol/l or a serum sodium of 130 mmol/l should lead to the cessation of glycine irrigation where possible. The surgeon should alert the team if a major vein is opened.

In cases where regional anaesthesia is used, serum sodium concentration should be measured as above and cessation of glycine irrigation should take place if visual disturbances, nausea, vomiting, seizures or other signs of encephalopathy become apparent.

I would value your opinion on:

Do you think this is a reasonable approach?
Is a drop of serum Sodium of 5 mmol/l or a serum sodium of 130 mmol/l the correct threshold?
We need to do a baseline sodium at induction of anaesthesia as there is significant diurnal variation in serum sodium levels (Page 109. Clinical Investigation and Statistics in Laboratory Medicine. Jones R, Payne B. ACB Venture Publications, 1997. ISBN 0902429213.)

Bob Darling

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5

Stinson, Emma M

From: McAllister, Charlie < Personal Information redacted by the USI
Sent: 25 November 2013 11:59
To: Burns, Deborah; Marshall, Margaret
Subject: Re: Standards & Guidelines Review Meeting Outcome - Confidential Coroner Case - 1971 - 2011

I have very clear views on this subject. I have had several discussions with Gyne/Anesthetics and emails re Urology Regionally.

There is only one inevitable outcome in the Belfast Trust. I do not see how we can be out of step with this and Dr Simpson wants a position statement by months end.
However neither urology or gyne in the SH&SCT are on the page.

This will end up either in stalemate or acrimony. I would need a clear steer from yourself before getting involved here.
We should discuss!

Charlie

From: Burns, Deborah
Sent: Monday, November 25, 2013 10:28 AM GMT Standard Time
To: McAllister, Charlie; Marshall, Margaret
Subject: FW: Standards & Guidelines Review Meeting Outcome - Confidential Coroner Case - 1971 - 2011

Would you both be happy to elad up a small working group re this as seems there may be some issues?
D

Debbie Burns
Interim Director of Acute Services
SHSCT
Tel: Personal Information redacted
Email: Personal Information redacted by the USI

From: Young, Michael
Sent: 23 November 2013 13:47
To: Burns, Deborah
Subject: RE: Standards & Guidelines Review Meeting Outcome - Confidential Coroner Case - 1971 - 2011

This is a different task and needs discussed regionally and possibly nationally

MY

From: Burns, Deborah
Sent: 22 November 2013 18:35
To: Young, Michael; Hogan, Martina; Carroll, Ronan; McAllister, Charlie

Subject: FW: Standards & Guidelines Review Meeting Outcome - Confidential Coroner Case - 1971 - 2011
Importance: High

Can I confirm you are happy to take this forward Thanks D

Debbie Burns
Interim Director of Acute Services
SHSCT
Tel: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

From: Joyce, Barbara
Sent: 22 November 2013 14:24
To: Rice, Francis; Simpson, John; Burns, Deborah
Cc: Griffin, Tracy; Stinson, Emma M; Carroll, Ronan; Young, Michael; McAllister, Charlie; Wright, Fiona; Hogan, Martina; Marshall, Margaret; Shine, Eileen
Subject: Standards & Guidelines Review Meeting Outcome - Confidential Coroner Case - 1971 - 2011
Importance: High

Dear all

Please see attached correspondence which was reviewed at the Standards and Guidelines Risk and Prioritisation Group on the 21 November 2013. Please confirm if you are happy with the suggested Change Leads/Working Group to take the learning forward.

Kind regards

Barbara

Patient & Safety Quality Officer (Acute Services) Ground Floor Trust Headquarters
68 Lurgan Road
Portadown
BT63 5QQ
Personal Information redacted by the USI

Personal Information redacted by the USI

2

2.36 Regarding my email to Debbie Burns (above) on the 25th November 2013 at 11.59 'We should discuss' my only recollection of this, and it was 10 years ago, was that Debbie conveyed to me that Martina Hogan had spoken with her and the gynaecologists in general and Martina in particular was unhappy with me and that I should back off. So, I did, and extricated myself from interacting with her/them/ as soon as possible.

Corrigan, Martina

From: Young, Michael <[redacted]>
Sent: 17 February 2014 17:45
To: Burns, Deborah; Simpson, John
Cc: Corrigan, Martina; McAllister, Charlie
Subject: hyponatraemia in urological surgery
Attachments: hyponatraemia report 5.2.14.docx

Dear Debbie and John

Please find enclosed our commentary on the use of glycine and other fluids for urological surgery. We have discussed this as a unit.

MY

Irrigating fluids used in urological procedures

Craigavon Area Hospital Urologists comments (January 2014)

A commentary from the Urology Unit, Craigavon Area Hospital has been requested with reference to the use of irrigating fluids for endoscopic procedures. The Consultants' in the unit have had the opportunity to discuss this as a group. The background to this request is understood to relate to the unfortunate death of a young lady from hyponatraemia and bleeding as part of a gynaecological procedure. We are not in a position to directly comment on this particular case, but will be passing general comments on certain principles.

Irrigating fluids are used in an array of urological endoscopic procedures. These procedures include cystoscopy, TUR Prostate, TUR for Bladder Tumours, Bladder Neck Incision, Rigid Ureteroscopy, Flexible Ureterorenoscopy and Percutaneous Renal Surgery. Irrigating fluids used are Glycine, Normal Saline and Water. The particular choice of irrigating fluid to be used is chosen depending on the particular action to be carried out during the endoscopic procedure.

Water is infrequently used but its properties are similar to Glycine in terms of electrical impedance. It is use, in small volumes (300 mls), to flush specimen samples of prostatic chippings or bladder tumour out of the bladder at the end of a procedure.

The choice between Glycine and Normal Saline pertains to the precise technology to be used for a procedure. Normal Saline is used for ureteroscopic surgery as well as percutaneous renal surgery. This is because the use of laser fragmentation of stones and ultrasound disintegration of stones is best achieved in this fluid medium as well as noting it is as isotonic and compatible with human blood.

Glycine is used for resection of prostatic tissue and bladder tumours. It is used because of its compatibility with monopolar diathermy resection. Normal Saline for resection is used with a bipolar diathermy technology and would be used as part of laser endoscopic prostatectomies.

It is understood that Glycine is hypotonic and if absorbed can cause hyponatraemia. Glycine has been used for several decades as an irrigating fluid for resection surgery in urology. The condition of TURP Syndrome is indeed well recognised and in urological terms has been used as opposed to the term hyponatraemia. Glycine is used worldwide and urologists, as part of their training, are taught to recognise how this occurs, avoidance principles, its signs and symptoms and to lay out a management plan for its therapy.

It is appreciated by all that technologies and techniques change, but this does not necessarily negate the need for older techniques and technology to be lost.

All the urologists in Craigavon throughout their training and in consultant practice have been using Glycine for endoscopic resection. It is appreciated that a few patients have had TURP Syndrome but to our knowledge there have been no adverse long-term effects from this in any patient.

There are several key points to highlight in our practice in Craigavon. Firstly, it is recognised that there is a team approach to providing patient care. It starts with a team briefing i.e. the WHO checklist, all personel in the theatre environment are therefore aware of the operation and the need for a coordinated patient management policy. The commencement of resection time is noted and throughout the whole procedure it is appreciated that time is a significant factor. With regards to TUR Prostates, we will generally not resect beyond the hour. The 'clock is watched' throughout the procedure. The irrigating fluid bag is hung between 50 and 100cm above the patient's waist. The matching of the fluids running in and the fluids retrieved have in recent years not been precisely monitored but in general terms, nursing staff will monitor what is known as the in's and out's and surgeons generally ask if there is any mismatch throughout the procedure. The specific recognition of excessive bleeding and a capsular perforation is of particular importance to the operating surgeon. This bleeding risk, capsular perforation, and the increase in resection time, are all recognised as causing an increased risk of absorption. We also regard the use of the continuous irrigating scope as a major advance in TUR Prostate procedure. The use of the continuous irrigating scope has resulted in resection time being shortened and also keeps the bladder pressure constant. This we regard as decreasing the risk of absorption.

The surgical technique of bipolar TURP using Saline and monopolar TURP using Glycine is by the same surgical technique i.e. loops of prostate or bladder tumour being resected and these chips are then washed out. However on looking at the finer nuances of the procedure commented on by severalurologists, do note that the cutting mechanism is not as precise especially in the setting for bladder tumours and that the haemostasis diathermy used is not as good when using the bipolar technology in Saline. This is noted both intra-operatively as well as in the post-operative phase and as such has led to the complication of excessive bleeding. This extrapolated would theoretically increase the risk of transfusion and potential return to theatre for cautery.

We do appreciate that there could be room for improvement in intra-operative monitoring e.g. more precise real time regard for the fluid input matching output and the potential for intra-operative blood testing. There are several scientific papers dating back over the decades on these precise topics. Our understanding is that this has not been particularly productive albeit that we recognise it is a very reasonably practical monitoring modem.

Our experience tells us that the 3 litre bags do not precisely contain 3 litres, inadvertent irrigation fluid spillage on the floor from inadequate capture by the drape system combined with the natural production of urine and surgical blood loss volumes, will all lead to a discrepancy in the input/output volumes.

Re-instigating the previous regime of the theatre staff more formally being in charge of monitoring, in real time, the number of bags used and volume drained out would keep a closer 'eye on' the situation. We are aware of new technologies that monitor the fluids 'in and out', in real time, are now available but these have not been trialled by our department nor are we aware of other units using them. Intra-operative intravenous sampling to measure sodium and other electrolytes has been researched in the past and could be re-introduced and we would welcome our anaesthetic colleagues view on this.

We would like to point out that we regard TUR Prostate and bladder tumour to be a different operation to the gynaecological TCRE, albeit that they are all endoscopic resection techniques. We regard the TCRE as endoscopy in a smaller cavity where the tissue is more vascular and sinusoidal in its anatomical configuration. All these features we regard as increasing the risk of absorption. TUR Prostate, especially with the continuous irrigating scope is at a lower pressure. Deep resection and capsular perforation are much less of a feature in modern day TUR Prostates. The use of haemostatic diathermy in the procedure is more often performed. In conclusion Transurethral Resection of Prostate and bladder tumours are one of the main core surgical techniques taught during urology training. All aspects of management are taught to a high level; this includes surgical technique and management of potential complications. The use of Glycine has been used worldwide for TUR Prostates and bladder tumours for decades. Surgical technique has been well tried and tested. We appreciate that some urologists may wish to use the bipolar Saline surgical technique but this should not hinder others from using Glycine, a surgical technique they have been well used to using.

Since we first discussed this topic in our department a month ago (hence the above notation), changes have already been proactively undertaken. Fluid management is dynamically monitored with a record being written on a specifically designed fluid chart. This is formally recorded after each 3l bag of Glycine but is also inspected continuously via the suction drainage bottle. Spillage is kept to a minimum by capture in the drape system. Being conscious of the bag height being kept at less than 100cm is also at the forefront in setting up for the procedure. Surgeons are kept informed about the time as the procedure progresses rather than being told 'it's coming close to an hour'. The anaesthetic service has already introduced blood sampling before and at defined time intervals throughout the procedure (and more often if clinical thought prudent) as a mechanism of identifying the potential for this particular risk occurring. Therefore the theatre department in Craigavon Area Hospital has proactively taken measures to reduce the

risk of hyponataemia occurring in the first place and the risk of its development is continuously assessed throughout the procedure and into the recovery ward. Identification using these assessment tools will identify if there is an issue as soon as possible.

M Young on behalf of the Urologist Southern Trust 5.2.2014

3. **In oral evidence to the Inquiry on Day 61 (19th September 2023, Mr Hagan described the introduction of bipolar technique within the**

Belfast Trust ('BHSCT') as follows:

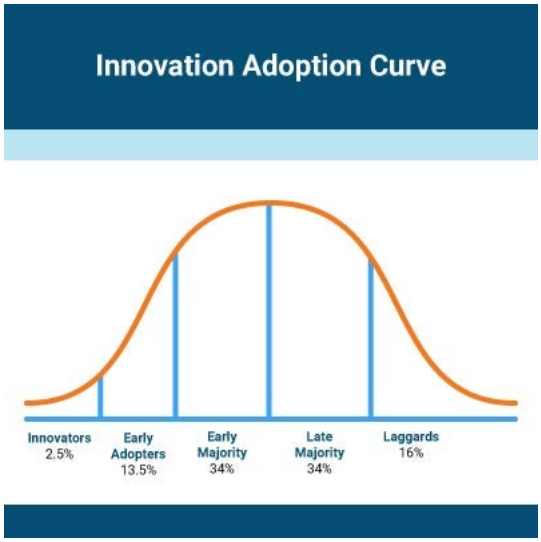
'We introduced bipolar in Belfast in 2013, we took all the monopolar sets out and the whole team moved over to bipolar without any real issue.' **[TRA- 07913]**

'I didn't find it difficult introducing it in Belfast, because all the team that I work with focus on patient safety and they put patient safety before their own personal preferences. And the data was compelling on this. And I think it's really important to use data to inform your decisions. And if you have a technique that's demonstrably safer, I don't understand why you wouldn't adopt it.' **[TRA-07914]**

(a) **To the extent that you are able to assist the Inquiry, please explain the reason(s) for the apparent delay in introducing the bipolar approach within the Southern Trust, as compared with BHSCT.**

3.1 I would imagine that this apparent delay was multifactorial:

1. Rogers diffusion of innovation theory (1962) will be well known to the members of the Inquiry. It describes how individuals adopt new innovations and the percentage in each group. The Belfast Trust was referred to as "early local adopters in the Policy (page 8, paragraph 2) so they would have been in the first 16% of adopters.



2. Mr. Hagan was the CD in Urology in the Belfast Trust. He was young (under 40 I believe) and persuasive. Classic features of early adopters. The two most senior Urologists in CAH were much more senior – heading towards 60. Classic feature of late adopters. Surgeons who have been using a particular technique for many years successfully and safely are reluctant to change a winning formula. Young surgeons are much more open to learning new techniques as they have not become wedded to one. What the excuse was for the Gynaecologists I cannot say.

3. This was the period after July 7th, 2011 (the death of Mrs Lynn Lewis in the UIC) and through much of that decade. Another public Inquiry was running over that time- The Hyponatraemia Inquiry. It had been set up in 2004 and was grinding its way through the 2010s until publication in 2018. The Belfast trust was at the epicentre of that maelstrom that had been running for some 9 years in 2013 (year of introduction of bipolar approach in BHSCT). By that stage the picture was becoming increasing clear and it was obvious

that there was going to be marked criticism and fall out. Although Mrs. Lewis died in the Ulster Independent Clinic the Gynaecologist who operated on her was Professor Neil McClure who was based in the BHSCT for his NHS employment. The coroner in Mrs. Lewis's case was Mr. Lecky who had also been involved in several of the children's cases that led to the public inquiry. To say that he was perturbed about Mrs. Lewis's case in 2013 would be an understatement. The very last thing the BHSCT needed or wanted was another death or even misadventure from hyponatraemia. The Inquest into Mrs. Lewis's death was held in 2013, the same year that bipolar diathermy was introduced into the BHSCT. There was significant motivation to move away from glycine in the BHSCT and cost would not have been a consideration.

4. The BHSCT had one excellent full time substantive Chief Executive (CX) at that time – Colm Donaghy. He was the CX in the SH&SCT before moving to Belfast. They also had one excellent full time substantive Medical Director , Tony Stevens over that time who was on the ball.

5. I am not clear that there was an implementation date/timeframe indicated in the policy.

6. I do not know when the other trusts in N. Ireland removed monopolar and glycine so I do not know where the SH&SCT sat on the Innovation Adoption Curve.

(b) **Were you concerned by any delay in the introduction of this approach?**

3.2 In Gynaecology yes. It was a gynae patient who died that led to the policy (some 4 years later). Women of childbearing age are far more susceptible to injury or death from hyponatraemia than older women or men. Elderly men are

even less susceptible than younger men in my experience. However, I did what I could in gynaecology before being discouraged by Debbie Burns following Martina Hogan's intervention. I was not concerned by a reasonable delay in urology to achieve consensus, appropriate equipment choice and trust funding because of the nature of the patients (elderly men where the risks are significantly less and are well recognised and understood) and the advice included in the email I forwarded from Bob Darling on the 19th November 2013 initially and then following the application of the policy sent out in May 2015. Compliance with the glycine fluid additional monitoring recommendations should have made the process safe whilst the Gynaecologists and Urologists switched to saline, if everyone did what they were supposed to.

NOTE:

By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers, as well as those sent from official or business accounts or numbers. By virtue of section 21(6) of the Inquiries Act 2005, a thing is under a person's control if it is in his possession or if he has a right to possession of it.

Signed: Charles McAllister

Dated: 01/11/201