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 John Simpson
Former Medical Director
C/O Southern Health and Social Care Trust
Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

19 October 2023

Dear Sir,

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.

This Notice is issued to you due to your held posts, within the Southern Health and Social Care Trust, relevant to the Inquiry's Terms of Reference.

The Inquiry is of the view that in your roles you will have an in-depth knowledge of matters that fall within our 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 detail 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 may be aware the Trust has 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 your 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 an 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 25 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: **Dr John Simpson**
Former Medical Director
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

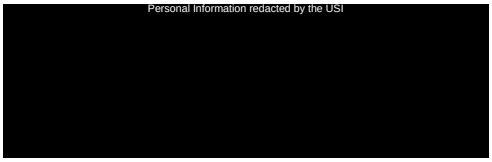
AND FURTHER TAKE NOTICE that you are entitled to make a claim to the Chair of the Inquiry, under section 21(4) of the Act, on the grounds that you are unable to comply with the Notice, or that it is not reasonable in all the circumstances to require you to comply with the Notice.

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**.

Issued by the Urology Services Inquiry on 19 October 2023. Annotated by the Urology Services Inquiry.

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 19th October 2023

Signed: 

Christine Smith QC

Chair of Urology Services Inquiry

Urology Services Inquiry

SCHEDULE

[No 25 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 [WIT54042], 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…'*

In Mr Haynes' statement to the Inquiry (at WIT-53948-53949), he states as follows:

'*In August 2015, HSS(MD)14/2015 required trusts to take action with regard to a regional policy on the surgical management of endoscopic tissue resection. For urology teams this related to switching from monopolar transurethral resection (in glycine) to bipolar resection (in saline), with the work on the policy having been commissioned following a coroners verdict in October 2013. Mr O'Brien engaged in the process of assessment of new bipolar resection equipment. However, he subsequently expressed the view that he would be continuing to use monopolar resection in glycine, thereby not conforming with the policy. On reflection, this unwillingness to conform with recommendations from others should have provoked concern regarding wider aspects of his practice, especially with regards to delivering treatment in line with NICE guidance/MDM.'*

A copy of this Coroners Verdict was sent to you, as Medical Director of the Southern Trust on the 21st October 2013. (TRU-369005)

You subsequently attended a HSC 'Medical Leaders Forum' on the 3rd November 2014 at which the use of glycine and its connection to TUR Syndrome were discussed. (TRU-396019)

Having regard to the above, and to the oral and written evidence of Mr Chris Hagan, concerning the introduction of bipolar resection located at TRA-07909 to TRA-07914 and WIT-98866 to WIT-98867, you are now asked to address the following:

(a) When did you become aware of a 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)? Please confirm when, and how, you first became aware of (i) the intention to switch from monopolar resection to bipolar resection and (ii) the policy referred to above.

(b) What action(s), if any, did you take on foot of receiving the Coroner's Verdict on 21 October 2013? To the extent that you did not take any further action at that time, please explain why.

(c) Following your attendance at the HSC Medical Leaders Forum in November 2014, what steps did you take to investigate: (i) practices in relation to the use of glycine as an irrigation fluid within the Southern Trust and (ii) potential alternatives to glycine? To the extent that you did not take any further steps, please explain why.

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) Were you aware of the issue described in Dr McAllister's communication during your time in post as Medical Director? 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.

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

Note: An addendum amending this statement was received by the Inquiry on 11 Nov 2023 and can be found at WIT-105748 to WIT-105759. Annotated by the Urology Services Inquiry.

USI Ref: Notice 25 of 2023

Date of Notice: 19th October 2023

Witness Statement of: Dr John Simpson

I, John Simpson, will say as follows:-

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 [WIT54042], 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…'*

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You subsequently attended a HSC 'Medical Leaders Forum' on the 3rd November 2014 at which the use of glycine and its connection to TUR Syndrome were discussed. (TRU-396019)

Having regard to the above, and to the oral and written evidence of Mr Chris Hagan, concerning the introduction of bipolar resection located at TRA-07909 to TRA-07914 and WIT-98866 to WIT-98867, you are now asked to address the following:

(a) When did you become aware of a 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)? Please confirm when, and how, you first became aware of (i) the intention to switch from monopolar resection to bipolar resection and (ii) the policy referred to above.

1.01 I became aware of the regional approach when it was agreed at the Medical Leader's Forum which I attended on the 4 November 2013 (see email 20131106 from Carolyn Harper to all Medical Directors of 6 November 2013 - *1.-4. 20131106 E from C Harper re ltr from J Leckey, A1-A3*) on foot of the Coroner's request for a 'collegiate' response. I was then copied into a letter from Tony Stevens, Medical Director of the BHSCT, to Carolyn Harper of the PHA on the 16 Dec 2013 where he explained that all of the Medical Directors had agreed to commission Julian Johnston (a senior anaesthetist in the BHSCT) on our behalf to coordinate a response to the Coroner.

1.02 I was aware at that point that a new policy (as referred to above) would need to be developed and that a switch from monopolar to bipolar resection would be one of the likely outcomes, but also, that the other key safety issues mentioned in the Coroner's verdict would also have to be taken into account.

(b) What action(s), if any, did you take on foot of receiving the Coroner's Verdict on 21 October 2013? To the extent that you did not take any further action at that time, please explain why.

1.03 I received the Coroner's Verdict and associated documents on the 25 October 2013 (*see 5.-8. 20131030 E re Coroner's Case LL, A1-A3*). Having studied these I then gave the documents (for scanning) to the office of the Assistant Director for Clinical Governance, Margaret Marshall, on the 30 October 2013 in order to initiate the Trust's Standards and Guidelines process for managing such notifications. Margaret Marshall confirmed with me on the 31 October 2013 (*9. 20131031 E Re Coroner's Case LL for S and G*) that this process had been initiated. This is recorded at the Standards and Guidelines meeting of the 22 Nov 2013 (*see 10.-14. 20131122 Standards and Guidelines Review Mtg re Coroner's Case, A1-A4*).

1.04 I also copied these documents on the 30 October 2013 (*see 16. 20131104 E Re Confidential Coroner's Case for SG Route*) to the Associate Medical Directors for Obstetrics & Gynaecology (Martina Hogan), Anaesthetics (Charlie McAllister) and Surgery (Eamon Mackle) as well as the Director of

Acute Services (Debbie Burns) and the Assistant Directors of Nursing for Acute (Heather Trouton and Ann McVey) for dissemination to all relevant clinicians.

1.05 I did not respond to the Coroner personally but I was in accord with the letter sent to the Coroner from Dr Charlie Martyn (Medical Director of the SEHSCT) on 1 November 2013 that all of the Medical Directors would revert to the Coroner as a group (*see 17.-18. 20131101 Letter from SE Trust re Coroner's Case LL, A1*). I was also aware that Carolyn Harper of the Public Health Agency (PHA) would be responding to the Coroner on all of the Trusts' behalf, as detailed in my email to the relevant clinical leads in the SHSCT (*see 16. 20131104 E Re Confidential Coroner's Case for SG Route*). This had been agreed by myself and the other Medical Directors at the Medical Leader's Forum of the 4 November 2013 (see email 20131106 from Carolyn Harper to all Medical Directors of 6 November 2013 - *1.-4. 20131106 E from C Harper re ltr from J Leckey, A1-A3*). Following this Tony Stevens, Medical Director of the BHSCT, wrote to Carolyn Harper of the PHA on the 16 Dec 2013 to explain that all of the Medical Directors had agreed that he commission Julian Johnston (a senior anaesthetist in the BHSCT) to coordinate a response to the Coroner on our behalf, and that Julian Johnston would update her in due course (*19.-20. 20131216 Collegiate Response from Dr Stevens, A1*).

1.06 On the 18 Dec 2013 I copied an email (*see 21.-23. 20131218 E from MH re LL Deceased Coroner's Correspondence,A1–A2*) from Julian Johnston to the relevant clinical leads in the SHSCT in order to inform them that he was commencing this work. The first draft of which was attached (*24.-26. 20131218 E from EM re LL Deceased Coroner's Correspondence, A1-A2*). This had already been shared with Carolyn Harper of the PHA.

(c) Following your attendance at the HSC Medical Leaders Forum in November 2014, what steps did you take to investigate: (i) practices in relation to the use of glycine as an irrigation fluid within the Southern Trust and (ii) potential alternatives to glycine? To the extent that you did not take any further steps, please explain why.

1.07 The product of Julian Johnston's work was presented to the Medical Leaders Forum on 3 November 2014 (*see 27. 20141108 Medical Leaders Forum 3 11 2014 Presentation*). In order to check the progress within the SHSCT on this matter I forwarded the Medical Leaders Forum minutes on the 8 Nov 2014 to Margaret Marshall (the Assistant Director for Clinical Governance) and copied to the relevant Associate Medical Directors Charlie McAllister, Eamon Mackle and Martina Hogan as well as David Sim (lead for Obs and Gynae), Michael Young (lead for Urology), Francis Rice (Director of Nursing) and Debbie Burns (Director of Acute Services) (*see 28. 20141108 Medical Leaders Forum 3 11 2014 Presentation Email*). This process was duplicated through nursing lines by the CNO to Francis Rice (*see 29. 20141112 E to MM re Medical Leaders Forum Notes 3 11 2014*). As noted by Margaret Marshall in this email, initial safety procedures had already been put in place to ensure the safe usage of glycine in SHSCT theatres and further that the relevant SHSCT clinicians would be responding in detail to Julian Johnston's proposals when in receipt of them.

1.08 I wrote to Julian Johnston on the 19 Dec 2014 to check how his liaison with clinicians in the SHSCT was going (*30. 20141219 E from JJ re Glycine Issue*) whereby he responded positively and also commended the implementation of the key safety measure of recording the patients' sodium levels (in order to alert the theatre team to any risk of hyponatreamia) during the procedures in question in SHSCT theatres.

1.09 Michael Young then responded in detail on behalf of the urologists in SHSCT on the 11 March 2015 which I duly passed on to Julian Johnston on 11 March 2015 (*31.-32. 20150311 E to JJ re Irrigation Fluid in Urology, A1*).

1.10 I then noted the email of 26 May 2015 from Julian Johnston to Paddy Woods, Deputy CMO, to confirm that he had completed the 'collegiate' response on behalf of the region's medical directors as requested by the Coroner (*see 33.-36. 20150526 E from JJ re Endoscopic Distending Fluids for Coroner, A1-A3*)

1.11 I retired from the SHSCT in July 2015. I have recently been informed that the policy letter from the CMO concerning this matter was sent to the SHSCT on the 18 August 2015.

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) Were you aware of the issue described in Dr McAllister's communication during your time in post as Medical Director? 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.

2.01 I was not made aware of the issue (described by Dr McAllister in said communication) during my time in post as Medical Director of the SHSCT.

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.

3.01 This apparent delay is not uncommon regarding the introduction of new guidelines. There are always 'early adopters' of different guidelines by different departments in different Trusts. The BHSCT possibly has an advantage in these matters being by far the largest Trust, with the largest resource, in Northern Ireland in that it hosts both regional teaching hospitals and regional specialties. By way of context, the SHSCT was in receipt of 90 new standards and guidelines between October 2013 and May 2014 (*see my Accountability Report to SHSCT Governance Committee 9th December 2014 - 37. Standards and Guidelines Accountability Report Oct 2013 - May 2014*). This would have been typical of any six months in my time as medical director. Within the Trust we must then risk assess and prioritise all of these guidelines in advance of implementation. I should add that prior to my tenure no such process to track new guidelines had been in place.

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

3.02 No, I was not aware of any reason why I should have been concerned. As mentioned previously by Margaret Marshall (see *29. 20141112 E to MM re Medical Leaders Forum Notes 3 11 2014*), initial safety measures had already been put in place, a key safety indicator being the intraoperative measurement of sodium levels. I wrote to Julian Johnston on the 19 Dec 2014 to check how his liaison with clinicians in the SHSCT was going (*30. 20141219 E from JJ re Glycine Issue*). He responded positively and also commended the implementation of that key safety measure of recording the patients' sodium levels (in order to alert the theatre team of any risk of hyponatreamia) during the procedures in question in SHSCT theatres.

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: Personal Information redacted by the USI

John Simpson

Dated: 27/10/23

S21 Notice Number 25 of 2023

Index

Stinson, Emma M

From: Carolyn Harper <Personal Information redacted by the USI>
Sent: 06 November 2013 11:10
To: Alan McKinney; Anthony.Stevens Personal Information redacted by the USI; Calum MacLeod; Charlie.Martyn Personal Information redacted by the USI; Simpson, John
Cc: michael.mcbride Personal Information redacted by the USI; 'Charlotte McArdle' (Personal Information redacted by the USI); jleckey.rc Personal Information redacted by the USI; David Stewart RQIA; Carolyn Harper; Alan Finn; brenda.creaney Personal Information redacted by the USI; Charlotte McArdle; Rice, Francis; Olive.macleod Personal Information redacted by the USI
Subject: 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

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Dear All
Please see attached correspondence from Dr Carolyn Harper.
Many thanks, Lisa obo Dr Harper

Dr Carolyn Harper FFPH
Executive Medical Director/Director of Public Health
Public Health Agency
Tel Personal Information redacted by the USI
Email Personal Information redacted by the USI

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

Dr Heaton

Coroners Service for Northern Ireland

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

Edwin Poots MLA
Minister for Health, Social Services &
Public Safety
Castle Buildings
Stormont
Belfast
BT4 3SJ

Our Ref: 1791-2011

21st October 2013

Dear Minister,

Re: Lynn Lewis, deceased

On 16th October 2013 I concluded an inquest into the death of a 38 year old woman, Mrs Lynn McClean Lewis, who died in the Ulster Independent Clinic on 7th July 2011. A subsequent post-mortem examination established that her death was due to *Haemorrhage and Hyponatremia associated with Hysteroscopic Resection of Uterine Fibroid.*

For your information I am enclosing a copy of the Verdict to which is annexed a copy of a statement dated 11th October 2013 made on behalf of the Surgeon involved, Professor Neil McClure, the Anaesthetist, Dr Damien Hughes, the Ulster Independent Clinic and the nursing staff involved. I hope you will agree that my Verdict and that statement have identified failings and shortcomings that in combination resulted in the tragic death of Mrs Lewis. You will note that in the last sentence of my finding I have stated that the failings identified were both personal and institutional.

At the conclusion of the inquest I announced that I would be making a report pursuant to the provisions of Rule 23(2) of the 1963 Coroners Rules to you as Minister, the Chief Medical Officer, the Regulation and Quality Improvement Authority and the Director of Public Health. That Rule provides as follows:-

> "A Coroner who believes that action should be taken to prevent the occurrence of fatalities similar to that in respect of which the inquest is being held, may announce at the inquest that he is reporting the matter to the person or authority who may have power to take such action and report the matter accordingly."

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

It is unclear to me what your status is in relation to a medical procedure carried out in a private medical clinic. However, I have been advised that the failings and shortcomings I identified may have relevance in relation to practices and procedures in all Northern Ireland hospitals. In view of that I am writing also to the Medical Director of all Northern Ireland Hospitals and the Northern Ireland Chief Nursing Officer providing each with a copy of my Verdict, the expert reports and offering access to the inquest papers. I will be asking the Medical Directors to provide me with a collegiate response to the surgical and anaesthetic failings that the inquest has exposed and I will be asking for a similar response from the Northern Ireland Chief Nursing Officer in relation to nursing issues. I will stipulate that these responses should set out what steps have been or will be taken to prevent a similar fatality occurring in any Northern Ireland hospital including private medical clinics. In addition I will be asking the Ulster Independent Clinic to provide me with details of what actions have been taken and will be taken by it following the death of Mrs Lewis. My expectation is that robust action will be taken to prevent the occurrence of a similar fatality or other serious adverse incident which may not result in a fatality. I stated at the inquest that I would provide you, the Chief Medical Officer, the Regulation and Quality Improvement Authority and the Director of Public Health with a copy of all responses and that I would welcome any comments in light of those responses. I require reassurance, and I am sure the family do also, that all necessary steps have been taken to ensure patient safety.

In addition to the Verdict I am enclosing copies of the following:-

1. The post-mortem reports of Professor Crane and Dr Millward-Sadler.
2. The report of Dr Leroy Edozien.
3. The report of Dr George Gardiner.
4. The report of Professor Robert Shaw.

I would be happy to make available to your officials copies of any of the inquest papers including witness statements and/or a transcript of the proceedings.

I am sending a copy of this letter to the legal representatives, the Medical Directors of Northern Ireland Hospitals and the Northern Ireland Chief Nursing Officer.

I should be grateful if you would acknowledge receipt of this letter.

Yours sincerely

J L LECKEY
Senior Coroner for Northern Ireland

Encs

Cc Chief Medical Officer
RQIA
Director of Public Health
Chief Nursing Officer
Tughans, Solicitors
Murphy & O'Rawe, Solicitors
Carson McDowell, Solictors
Campbell Fitzpatrick, Solicitors

HSC Public Health Agency

12-22 Linenhall Street
Belfast
BT2 8BS

Tel: Personal Information redacted by the USI
www.publichealth.hscni.net

VIA Email
Trust Medical Directors

6th November 2013

Dear Colleagues

Re: Lynn Lewis – deceased – Coroner's correspondence

Mr John Leckey, Senior Coroner in Northern Ireland wrote to you on 21st October 2013 following the Coroner's Inquest on the death of Lynn Lewis in the Ulster Independent Clinic on 7th July 2011 (attached). Mr Leckey requested a collegiate response to the surgical and anesthetic failings that the inquest identified, and wrote to the Chief Nursing Officer for a similar response in relation to nursing issues.

To provide the collegiate response, incorporating medical, nursing and any other issues, and as agreed at the Medical Leaders Forum meeting on 4th November 2013, please send your collegiate response to me by 30th November 2013. As agreed, I will then send the response to Mr Leckey, to RQIA and to the Chief Medical Officer and Chief Nursing Officer. CMO will convene a meeting thereafter to review actions to date and agree any further action required in the HSC and/or Independent Sector.

Yours sincerely

Personal Information redacted by the USI

DR CAROLYN HARPER
Executive Medical Director/Director of Public Health

CC: Trust Nursing Directors
CMO
CNO
John Leckey, Coroner
David Stewart, RQIA

Stinson, Emma M

From: McCooey, Blaithnid <Personal Information redacted by the USI>
Sent: 30 October 2013 12:57
To: Joyce, Barbara; McCauley, Cheryl
Cc: Simpson, John; White, Laura
Subject: *Confidential* Coroner's Case for S+G route per Dr Simpson
Attachments: Lewis 1.pdf; Lewis 2.pdf; Lewis 3.pdf

Importance: High

Barbara
The coroner has sent this information to Dr Simpson He has asked me to scan to you so that these documents can be progressed via the S+G route Can you please log and ensure this is taken forward?
Dr Simpson has given me quite a significant number of documents relating to this case Barbara – they are too big to be scanned but do you want to start a manual file for keeping them?

Dr Simpson I will keep these originals and pass to Barbara but you can print these documents attached if you wish for your own file?

Thanks
Blaithnid

Blaithnid McCooey
Governance Officer
(Mrs Margaret Marshall, Interim Asst. Director) Corporate Clinical & Social Care Governance Office Trust Headquarters College of Nursing CAH Site
68 Lurgan Rd
Portadown
BT63 5QQ

t: Personal Information redacted by the USI
e: Personal Information redacted by the USI
(Hours of work: 9am-5pm Mon-Fri)

Scan

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

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May's Chambers, 73 May Street, Belfast. BT1 3JL
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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

Form 22
01791 - 2011

CORONERS ACT (NORTHERN IRELAND) 1959

VERDICT ON INQUEST

On an inquest taken for our Sovereign Lady the Queen at **Court 1, Old Townhall Building, Belfast** in the **County Court Division of Belfast** on the **10th, 11th, 12th, 16th, 17th & 18th September and 16th October 2013,** before me **John L Leckey Senior Coroner** for **The Coroners Service for Northern Ireland** touching the death of **Lynn McClean Lewis** to inquire how, when and where the said **Lynn McClean Lewis** came to their death, the following matters were found :

Scan

1.Name and Surname : **Lynn McClean Lewis**

2.Sex : **Female**

3. Date of Death: [redacted]

4. Place of Death : **Ulster Independent Clinic, 245 Stranmillis Road, Belfast**

5. Usual Address : [redacted]

6. Marital Status : **Married**

7. Date and Place of Birth : **3 April 1973** **Banbridge**

8. Occupation : **Housewife Wife of** [redacted]

9. Maiden Surname (of woman who had married) : [redacted]

10. Cause of Death : la **Haemorrhage and Hyponatremia associated with Hysteroscopic Resection of Uterine Fibroid**

b

c

ll

Findings

At the time of her death Lynn McClean Lewis was 38 years of age. She had a nine month history of heavy menstrual bleeding coupled with inter-menstrual and post-coital bleeding. A transvaginal scan showed the presence of a fibroid and this was attributed to the use of the oral contraceptive pill. On 7th July 2011 she was admitted to the Ulster Independent Clinic for a hysteroscopic resection of the fibroid. This is a procedure that involves the removal of tissue from the cavity of the uterus using an instrument passed through the cervix. In order to view the anatomy the uterine cavity is irrigated with fluid and electrocautery is deployed in order to resect tissue and seal bleeding vessels. The procedure, known as transcervical endometrial resection, is usually performed under general anaesthetic.

Anaesthesia was induced at 08.50 and surgery commenced with the consultant surgeon, Professor Neil McClure using an operating hysteroscope. He was assisted by a Registrar. The inlet channel of the hysteroscope was connected to a bag of sterile glycine fluid for the purpose of irrigating the uterine cavity. It was positioned about 50cm above Mrs Lewis who was lying on the operating table and was under gravity pressure only. In his statement Professor McClure described how his practice was to have the tubing from the outlet irrigation channel of the hysteroscope connected to the theatre suction fluid management system "as it enables those monitoring the fluid input and output to do so with greater accuracy and efficiency". He goes on to describe a mishap relating to the spillage of glycine fluid when the suction tubing became detached from the hysteroscope for some unknown reason.

"During the early stages of the resection of the fibroid (I am not exactly sure when) the suction tubing became detached from the hysteroscope and fluid drained onto the floor and over my clothing. At most this was for a few minutes and as soon as I noticed that the tubing was detached I reattached it and proceeded to work on the sides of the fibroid as described in Para 12 above. I did not immediately notice the leakage as

my attention was focussed over the patient's leg looking at the monitor screen and the theatre lights were dimmed. Also, operating hysteroscopy equipment often leaks at some of its seals and there is usually some dampness associated with this procedure".

I am satisfied that the resultant spillage of glycine on to the Professor's clothing and the floor of the theatre, which went unnoticed for some minutes by the Professor, his Registrar, the Anaesthetist and the theatre nurses, made any accurate estimate of fluid deficit an impossibility.

Within about 10 minutes of the commencement of surgery unusually heavy bleeding was noted. The source of the bleeding could not be identified and was eventually controlled with difficulty at about 09.40. At that stage Mrs Lewis's observations were stable. Shortly afterwards at about 10.00 concerns materialised that a significant amount of the glycine irrigation fluid may have been absorbed into the bloodstream. The anaesthetist then stopped the intravenous fluids, administered a diuretic (Furosemide) to assist in the offloading of excess fluid from the circulation and catheterised the bladder. Initially the observations remained stable though it was recognised there was a potential for deterioration. In the course of taking an arterial blood sample the anaesthetist noticed froth coming from the tube of the Laryngeal Mask Airway. Additional anaesthetic help was summoned. At 10.25 Mrs Lewis suffered a cardiac arrest. Cardiopulmonary resuscitation was commenced immediately and the Advanced Life Support algorithm was followed. She was attended by a consultant cardiologist and a consultant cardiothoracic surgeon. An ultrasound scan showed no tamponade but a very dilated heart. After some 90 minutes resuscitation was discontinued and death was pronounced at 12.04.

A subsequent post-mortem examination established that death was due to Haemorrhage and Hyponatraemia associated with Hysteroscopic Resection of Uterine Fibroid. The State Pathologist, Professor Jack Crane, confirmed the presence of a large benign fibroid in the uterus. He was able to conclude that in one small area the full thickness of the uterine wall had almost been penetrated and, in particular, the muscular part of the uterine wall which was thick and vascular. Whilst penetration had occurred the wall had not been perforated. However, this penetration would have precipitated a substantial haemorrhage. A tear or laceration in the neck of the uterus (cervix) was identified and the pathologist opined that this was possibly caused by the introduction of the hysteroscope. This too would have led to a substantial haemorrhage. Therefore, in his opinion almost certainly Mrs Lewis was haemorrhaging from two sources, the site of the resected fibroid and the cervical tear. In addition evidence was found of a biochemical disturbance known as hyponatraemia which is characterised by a low sodium level. This is a recognised complication of hysteroscopy when hypotonic fluids such as glycine are introduced into the uterus and then absorbed into the bloodstream. Hyponatraemia predisposes to cerebral oedema, which was found in the case of Mrs Lewis, and it is recognised that this condition is potentially fatal if untreated. Whilst death was due to the combined effects of haemorrhage and hyponatraemia I accept the opinion of Dr GH Millward-Sadler who is a pathologist with a specialist expertise in maternal deaths that hyponatraemia was the principal cause of death. In relation to the haemorrhage he said this:

"Both sites could be the source of the bleeding but in my opinion the lower uterine tear is a probable significant source. However the Hb only dropped to 6.9gm which, without blood replacement, would imply a loss of between a third to a half of total blood volume - approximately 1.5 to 2 litres. Though not insignificant, in pregnancy when the uterus is much more vascular, women have survived such losses. Maternal deaths from haemorrhage have frequently lost greater amounts and usually succumbed to disseminated intravascular coagulation. The Scottish Confidential Audit of Severe Maternal Morbidity defined major obstetric haemorrhage as 2.5 litres or more and recorded 167 cases in their second year (2003) (Why Mothers Die 2000 - 2002, Confidential Enquiry into Maternal and Child Health, p267 -271, 2004). As there were only 17 maternal deaths from obstetric haemorrhage in the whole UK between 2000 and 2002 (CEMACH, 2004), it is likely that this lady's haemorrhage was a contributory factor to death rather than the prime cause."

That statement leads me to conclude that viewed in isolation the haemorrhage Mrs Lewis suffered was potentially survivable but the untreated hyponatraemia was not. I accept without reservation the joint view of Professor Crane and Dr Millward-Sadler that the fatal consequences of the combined effects of haemorrhage and hyponatraemia flowed directly from the gynaecological procedure carried out. Moreover, it was the manner in which that procedure was carried out.

I obtained two expert reports, one from Dr Leroy Edozien who is a Consultant Obstetrician and Gynaecologist attached to St Mary's Hospital Manchester and one from Dr George Gardiner who is a Consultant in Anaesthetics and Intensive Care Medicine in Belfast City Hospital. In the course of the inquest I was provided with an expert report obtained on behalf of the Ulster Independent Clinic from Professor Robert W Shaw, formerly Consultant Obstetrician and Gynaecologist with Derby Hospitals NHS Foundation Trust and Professor of Obstetrics & Gynaecology at the University of Nottingham. All three reached similar conclusions to those of Dr Millward-Sadler in relation to hyponatraemia being the principal reason why Mrs Lewis died. They found that she had suffered two complications from the surgery, namely,

haemorrhage and hyponatraemia due to glycine absorption with the effects of the hyponatraemia being the more serious and the more life-threatening.

At a stage in the proceedings when the nursing staff had concluded their evidence but before Dr Edozien had concluded his evidence and before either Dr Gardiner or Professor Shaw had been examined in relation to their respective reports I acceded to an application from the legal representatives for Professor McClure, Dr Damien Hughes (the Anaesthetist), the Ulster Independent Clinic and the bereaved family that the proceedings should be adjourned for a short period to see if an agreed position could be reached that would satisfy the requirements of a coroner's inquest and would satisfactorily explain to the family of Mrs Lewis what caused her death. At a subsequent hearing on 11th October 2013 in relation to this I was provided with a lengthy statement signed on behalf of Professor McClure, Dr Hughes and the Ulster Independent Clinic which is a candid acknowledgement by Professor McClure, Dr Hughes, the Ulster Independent Clinic and the nursing staff of their failings, both personal and institutional, in relation to the care, treatment and management of Mrs Lewis in the course of the surgical procedure. In summary it was sub-standard.

I have carefully considered this statement for the purpose of reaching a conclusion as to whether it obviates the need for any continuation of the inquest. I have been informed that it satisfies the family of Mrs Lewis which is a most important consideration for me. Taking into account the detailed and candid nature of the statement, the views of Mrs Lewis's family and the fact that it has been read openly in court, I am satisfied that the inquest hearing can conclude at this juncture and that I am able to give this verdict. I am annexing a copy of the statement to this verdict. In my opinion an inquiry has taken place that satisfies the legitimate public interest in the circumstances that led to the unexpected death of a 38 year old woman.

In relation to Dr Edozien's report Professor Shaw had commented that whilst they have "some difference of opinion as to when and what could have caused the cervical tear, but this is not as important as the fact that one occurred." Otherwise, "Dr Edozien has identified the issues raised in my report concerning a lack of attention to obtaining information on potential fluid deficit, questions over how the other injuries in the uterus occurred and over decision making processes. The apparent lack of team working and knowledge of the potential problems with the TCRE procedure by the nursing staff were also contributory aspects to the case." In my view those remarks constitute a succinct and accurate summary of the acknowledged failings of surgeon, anaesthetist, the Ulster Independent Clinic and nursing staff which I adopt.

As I have stated above I see no reason not to accept the findings and conclusions of the two pathologists as to why Mrs Lewis died and their formulation of the cause of death. No contrary opinion was expressed. For the purpose of this verdict I have taken the view that it is not necessary for me to give a ruling on every disputed opinion as to what constitutes good or bad clinical practice whether in relation to surgery or anaesthesia, whether one surgical technique or procedure is to be preferred to another, the role and duties of theatre nurses in relation to fluid management or in relation to every disputed interpretation of the clinical record or chronology of events in theatre. However, I would add this. Both Dr Edozien and Professor Shaw identify good and effective team work as being the gold standard all engaged in any surgical procedure should aspire to and they identified significant deficiencies in team work and team dynamics when Mrs Lewis was in theatre. I hope it will be of some comfort to the family of Mrs Lewis that deficiencies and failings have been acknowledged.

Whilst I accept that no medical procedure is risk-free I have no doubt that Mrs Lewis would not have died if the appropriate measures and precautions had been taken. In his speech in Jordan v Lord Chancellor [2007] UKHL 14 at paragraph 14 Lord Bingham said this in relation to the purpose or scope of an inquest:

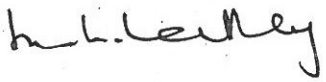
"The coroner must decide how widely the inquiry should range to elicit the facts pertinent to the circumstances of the death and responsibility for it."

It may be argued that this important statement of Lord Bingham is at variance with the provisions of Rule 16 of the Coroners (Practice and Procedure) Rules (NI) 1963 which provides:

"Neither the coroner nor the jury shall express any opinion on questions of criminal or civil liability ..."

However, I have concluded that any determination by me of responsibility for the death of Mrs Lewis would not offend the provisions of that Rule provided I do not comment on questions of criminal or civil liability. I do not intend to do so other than to say that the candid statement I received on behalf of Professor McClure, Dr Hughes, the Ulster Independent Clinic and the nursing staff speaks for itself on that issue. As I have said the failings were both personal and institutional.

Date : 16th October 2013

Signed :  Senior Coroner for **Coroners Service for Northern Ireland**

SCAN

INQUEST OF LYNN LEWIS – AGREED STATEMENT

1. Responsibility of the Surgeon, Prof Neill McClure

i. Prof McClure accepts there was a failure in relation to the planning of the operation in so far as he failed to ensure that blood testing was undertaken, prior to admission, in order to assess haemoglobin and for group and save where it was known that the patient was anaemic and the fibroid was sizeable.

ii. Prof McClure was, at the time of the operation, aware of the risks of fluid absorption in the course of a TCRE and Prof McClure accepts that such risks were well recognised and described in the literature.

iii. Prof McClure accepts that measures can be taken in order to recognise fluid absorption and reduce risks associated with fluid absorption.

iv. Prof McClure accepts that it is a fundamental requirement that a fluid balance/deficit be maintained intermittently, in real time, during the course of a TCRE.

v. Prof McClure accepts that in the case of Lynn Lewis that was not done.

vi. Prof McClure accepts that the Surgeon should have clearly instructed nursing staff of his particular requirements in respect of monitoring the fluid balance/deficit and should have ensured that the nursing staff understood those requirements. Those requirements ought to have been made clear at the beginning of the operation during the course of the "Surgical Pause".

vii. Prof McClure accepts that fluid deficit ought to have been ascertained at the end of each bag, during the course of the operation, and if the information was not voluntarily provided by the nursing staff, then ought to have been sought by the Surgeon.

viii. Prof McClure accepts that he should have suspended the operation if he was not provided with a fluid balance during the course of the procedure.

ix. Prof McClure accepts that he ought to have been able to obtain real time point of care information in relation to blood chemistry during the course of the operation.

x. Prof McClure accepts that he should have abandoned the operation after discussion with the Anaesthetist, Dr Hughes, if and when blood results became available

indicating hyponatremia or when the Surgeon became aware that the fluid deficit had exceeded the "trigger point".

xi. Prof McClure accepts that the record of the operation ought to have been recorded in a formal "Operation Note". It is accepted that such note is usually prepared at the conclusion of the operation, however on this occasion and in light of the circumstances pertaining, Prof McClure prepared a hand written record.

xii. Prof McClure accepts that as a consequence of the failure to monitor fluid deficit during the course of the operation, Lynn Lewis was permitted to develop hyponatremia which, in combination with the haemorrhage, caused her death.

2. Responsibility of the Anaesthetist, Dr Damien Hughes

i. Dr Hughes admits that, together with the surgeon and the members of the theatre team, he had a responsibility to ensure the overall safety of the patient in the course of the operation.

ii. Dr Hughes accepts that he was aware on the day of the operation of the risk posed to Lynn Lewis as a consequence of fluid absorption/intravasation.

iii. In acknowledging such a risk, Dr Hughes should have been aware of the fluid volumes and deficits, during the course of the operation, as part of his overall obligation to ensure patient safety.

iv. Dr Hughes should have been aware of the availability of point of care blood testing at the Ulster Independent Clinic.

v. Dr Hughes accepts that the blood test undertaken at 0910 hrs was performed in accordance with reasonable practice and that the results reported are correct.

vi. Dr Hughes accepts that had he been aware of point of care testing at the time of the operation, he would have sent the blood test at 0910 hrs for iSTAT testing immediately.

vii. Had he done so, Dr Hughes accepts that he would have been aware of the developing hyponatremia and would have advised the Surgeon accordingly.

viii. Dr Hughes also accepts that he should have been aware of the full results of the blood testing undertaken, by iSTAT, at 0955 hrs and should have undertaken immediate

measures to address electrolyte imbalance. Dr Hughes did administer Frusemide within a very short period in any event.

ix. Dr Hughes accepts that had he recognised developing hyponatremia in and around 0910 hrs, this would ultimately have led to a discussion with the Surgeon, which Professor McClure accepts should have led to him taking a decision to abandon the operation, thereby avoiding the patient's death.

3. Ulster Independent Clinic / Nursing Staff

i. The Ulster Independent Clinic accepts that there was an absence of policy or procedure dealing with fluid management in the course of TCRE and similar operations performed at the Ulster Independent Clinic.

ii. The Ulster Independent Clinic acknowledges that there was a lack of formal training for nursing staff in respect of fluid management in TCRE operations and similar operations prior to the date of the death.

iii. The Ulster Independent Clinic and the nursing staff acknowledge the failure of the nursing team to adequately communicate fluid monitoring figures to the Surgeon during the course of the operation and the nursing staff acknowledge that this was not in accordance with good practice.

iv. The Ulster Independent Clinic failed to ensure that all personnel present, at the time of the operation, were aware of the availability of point of care testing, for bloods, at the Clinic.

v. The Clinic acknowledges that there was a failure to develop guidelines in respect of fluid management during the course of TCRE and similar operations, at the Clinic, prior to the incident. The Ulster Independent Clinic acknowledges that the risk of fluid absorption during the course of such operations was well recognised and documented in the literature.

vi. The Ulster Independent Clinic acknowledges that there was a failure to ensure that the role of team leader was properly allocated on the day of the operation.

vii. The Ulster Independent Clinic acknowledges that there was a failure to ensure adequate continuity of care, during the course of the operation, as a consequence of staff leaving and joining the operation.

viii. The Ulster Independent Clinic acknowledges that there was a failure to ensure that medical staff operating, and assisting, at the Clinic were kept informed of the acquisition of new equipment.

ix. The Ulster Independent Clinic acknowledges the failure to ensure that the Surgical Pause conducted prior to the commencement of the operation included discussion on fluid balances.

x. As a consequence of same The Ulster Independent Clinic acknowledges that there was a failure on its part in the arrangements made for the performance of the operation, contributing to the death of Lynn Lewis.

Signed: Personal Information redacted by the USI

Dated:- 11/10/13

On behalf of the Professor McClure.

Signed:- Personal Information redacted by the USI

Dated:- 11/10/13

On behalf of Dr Damien Hughes

Signed:- Personal Information redacted by the USI

Dated:- 11/10/13

On behalf of the Ulster Independent Clinic

Stinson, Emma M

From: Simpson, John < Personal Information redacted by the USI >
Sent: 31 October 2013 13:04
To: Marshall, Margaret; Wright, Fiona
Subject: RE: IN FRANCIS' ABSENCE: Letter from Mr John Leckey Senior Coroner following Inquest

Agreed,
John

-----Original Message-----
From: Marshall, Margaret
Sent: 31 October 2013 13:00
To: Simpson, John; Wright, Fiona
Subject: RE: IN FRANCIS' ABSENCE: Letter from Mr John Leckey Senior Coroner following Inquest

Hi All,

It would be my understanding that this request would be logged and managed through the S&G process. I note that there is no timescale for reply on Mr Lecky's letter, therefore the information will be screened at the SG meeting lead directors identified and change leads suggested. I would suggest that the lead Directors to which it applies decide on our Trusts timescale for reply. What do you think? Hopefully we have already a range of mechanisms in place to prevent or minimise a situation like this occurring.

Regards
Margaret

-----Original Message-----
From: Simpson, John
Sent: 31 October 2013 12:36
To: Wright, Fiona
Cc: Marshall, Margaret
Subject: RE: IN FRANCIS' ABSENCE: Letter from Mr John Leckey Senior Coroner following Inquest

No it's not needed for mon,
John

-----Original Message-----
From: Wright, Fiona
Sent: 31 October 2013 12:13
To: Simpson, John; Marshall, Margaret
Cc: Shine, Eileen; White, Laura
Subject: FW: IN FRANCIS' ABSENCE: Letter from Mr John Leckey Senior Coroner following Inquest
Importance: High

Hi John/Margaret, in Francis absence I note that there is to be a joint medical / nursing response to this inquest but am just checking that this isn't needed for the Medical Leaders Form on Monday but will be collated after this?

Regards
Fiona

Fiona Wright
Assistant Director Nursing Governance & Connect Coach

Tel – Personal Information redacted by the USI or Personal Information redacted by the USI

-----Original Message-----
From: Griffin, Tracy

Sent: 31 October 2013 11:41
To: Wright, Fiona
Cc: McShane, Wendy
Subject: IN FRANCIS' ABSENCE: Letter from Mr John Leckey Senior Coroner following Inquest
Importance: High

Fiona, as Francis is on leave could you please advise if we should be sending any comments back by Monday?!

Thanks
T

-----Original Message-----
From: Henderson, Elizabeth [mailto:Personal Information redacted by the USI]
Sent: 31 October 2013 11:15
To: 'Pat.Cullen Personal Information redacted by the USI; Alan Finn; Angela Young (PA to Brenda Creaney); Brenda Creaney; Debbie Cousins (PA to Nicki Patterson); Rice, Francis; Katrina Quinn (PA to Alan Finn); Lorna Bates (PA to Olive Macleod); Nicki Patterson; Olive MacLeod; Griffin, Tracy
Cc: Katie Haas Sentance; 'glynis.henry Personal Information redacted by the USI; maura.devlin Personal Information redacted by the USI; lorna.byrne Personal Information redacted by the USI; .Meleady Deirdre; McArdle, Charlotte
Subject: Letter from Mr John Leckey Senior Coroner following Inquest

SENT ON BEHALF OF THE CHIEF NURSING OFFICER

Please see letter from Charlotte McArdle and attachments. Could you please forward any input for the response as soon as possible as this will be raised by CMO at the Medical Leaders Forum on Monday.

Thank you

Elizabeth Henderson
PS/Charlotte McArdle, CNO
Office of the Chief Nursing Officer
DHSSPS
Tel. Personal Information redacted by the USI

------< TRIM Record Information >------

Record Number : DH1/13/292204
Title : Inquest of Lynn Lewis - Agreed Statement

------< TRIM Record Information >------

Record Number : DH1/13/292197
Title : Letter to Edwin Poots from Mr J L Leckey dated 21 October 2013

------< TRIM Record Information >------

Record Number : DH1/13/292190
Title : Letter to Medical Directors from Mr J L Leckey dated 21 October 2013

------< TRIM Record Information >------

Record Number : DH1/13/292163
Title : Hyponatraemia re Medical meeting - letter to Executive Directors of Nursing PHA and HSC Trusts from CNO dated 30 October 2013

Stinson, Emma M

From: Joyce, Barbara <[redacted]>
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
Attachments: Doc 3.pdf; Doc 1.pdf; Doc 2.pdf; Risk Proforma - Learning from Coroners Cases.docx

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

[redacted]

[redacted]

SCAN

INQUEST OF LYNN LEWIS – AGREED STATEMENT

1. Responsibility of the Surgeon, Prof Neill McClure

i. Prof McClure accepts there was a failure in relation to the planning of the operation in so far as he failed to ensure that blood testing was undertaken, prior to admission, in order to assess haemoglobin and for group and save where it was known that the patient was anaemic and the fibroid was sizeable.

ii. Prof McClure was, at the time of the operation, aware of the risks of fluid absorption in the course of a TCRE and Prof McClure accepts that such risks were well recognised and described in the literature.

iii. Prof McClure accepts that measures can be taken in order to recognise fluid absorption and reduce risks associated with fluid absorption.

iv. Prof McClure accepts that it is a fundamental requirement that a fluid balance/deficit be maintained intermittently, in real time, during the course of a TCRE.

v. Prof McClure accepts that in the case of Lynn Lewis that was not done.

vi. Prof McClure accepts that the Surgeon should have clearly instructed nursing staff of his particular requirements in respect of monitoring the fluid balance/deficit and should have ensured that the nursing staff understood those requirements. Those requirements ought to have been made clear at the beginning of the operation during the course of the "Surgical Pause".

vii. Prof McClure accepts that fluid deficit ought to have been ascertained at the end of each bag, during the course of the operation, and if the information was not voluntarily provided by the nursing staff, then ought to have been sought by the Surgeon.

viii. Prof McClure accepts that he should have suspended the operation if he was not provided with a fluid balance during the course of the procedure.

ix. Prof McClure accepts that he ought to have been able to obtain real time point of care information in relation to blood chemistry during the course of the operation.

x. Prof McClure accepts that he should have abandoned the operation after discussion with the Anaesthetist, Dr Hughes, if and when blood results became available

indicating hyponatremia or when the Surgeon became aware that the fluid deficit had exceeded the "trigger point".

xi. Prof McClure accepts that the record of the operation ought to have been recorded in a formal "Operation Note". It is accepted that such note is usually prepared at the conclusion of the operation, however on this occasion and in light of the circumstances pertaining, Prof McClure prepared a hand written record.

xii. Prof McClure accepts that as a consequence of the failure to monitor fluid deficit during the course of the operation, Lynn Lewis was permitted to develop hyponatremia which, in combination with the haemorrhage, caused her death.

2. Responsibility of the Anaesthetist, Dr Damien Hughes

i. Dr Hughes admits that, together with the surgeon and the members of the theatre team, he had a responsibility to ensure the overall safety of the patient in the course of the operation.

ii. Dr Hughes accepts that he was aware on the day of the operation of the risk posed to Lynn Lewis as a consequence of fluid absorption/intravasation.

iii. In acknowledging such a risk, Dr Hughes should have been aware of the fluid volumes and deficits, during the course of the operation, as part of his overall obligation to ensure patient safety.

iv. Dr Hughes should have been aware of the availability of point of care blood testing at the Ulster Independent Clinic.

v. Dr Hughes accepts that the blood test undertaken at 0910 hrs was performed in accordance with reasonable practice and that the results reported are correct.

vi. Dr Hughes accepts that had he been aware of point of care testing at the time of the operation, he would have sent the blood test at 0910 hrs for iSTAT testing immediately.

vii. Had he done so, Dr Hughes accepts that he would have been aware of the developing hyponatremia and would have advised the Surgeon accordingly.

viii. Dr Hughes also accepts that he should have been aware of the full results of the blood testing undertaken, by iSTAT, at 0955 hrs and should have undertaken immediate

measures to address electrolyte imbalance. Dr Hughes did administer Frusemide within a very short period in any event.

ix. Dr Hughes accepts that had he recognised developing hyponatremia in and around 0910 hrs, this would ultimately have led to a discussion with the Surgeon, which Professor McClure accepts should have led to him taking a decision to abandon the operation, thereby avoiding the patient's death.

3. Ulster Independent Clinic / Nursing Staff

i. The Ulster Independent Clinic accepts that there was an absence of policy or procedure dealing with fluid management in the course of TCRE and similar operations performed at the Ulster Independent Clinic.

ii. The Ulster Independent Clinic acknowledges that there was a lack of formal training for nursing staff in respect of fluid management in TCRE operations and similar operations prior to the date of the death.

iii. The Ulster Independent Clinic and the nursing staff acknowledge the failure of the nursing team to adequately communicate fluid monitoring figures to the Surgeon during the course of the operation and the nursing staff acknowledge that this was not in accordance with good practice.

iv. The Ulster Independent Clinic failed to ensure that all personnel present, at the time of the operation, were aware of the availability of point of care testing, for bloods, at the Clinic.

v. The Clinic acknowledges that there was a failure to develop guidelines in respect of fluid management during the course of TCRE and similar operations, at the Clinic, prior to the incident. The Ulster Independent Clinic acknowledges that the risk of fluid absorption during the course of such operations was well recognised and documented in the literature.

vi. The Ulster Independent Clinic acknowledges that there was a failure to ensure that the role of team leader was properly allocated on the day of the operation.

vii. The Ulster Independent Clinic acknowledges that there was a failure to ensure adequate continuity of care, during the course of the operation, as a consequence of staff leaving and joining the operation.

viii. The Ulster Independent Clinic acknowledges that there was a failure to ensure that medical staff operating, and assisting, at the Clinic were kept informed of the acquisition of new equipment.

ix. The Ulster Independent Clinic acknowledges the failure to ensure that the Surgical Pause conducted prior to the commencement of the operation included discussion on fluid balances.

x. As a consequence of same The Ulster Independent Clinic acknowledges that there was a failure on its part in the arrangements made for the performance of the operation, contributing to the death of Lynn Lewis.

Signed: Personal Information redacted by the USI

Dated:- 11/10/13

On behalf of the Professor McClure.

Signed:- Personal Information redacted by the USI

Dated:- 11/10/13

On behalf of Dr Damien Hughes

Signed:- Personal Information redacted by the USI

Dated:- 11/10/13

On behalf of the Ulster Independent Clinic

Scan

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

Form 22
01791 - 2011

CORONERS ACT (NORTHERN IRELAND) 1959

VERDICT ON INQUEST

On an inquest taken for our Sovereign Lady the Queen at **Court 1, Old Townhall Building, Belfast** in the **County Court Division of Belfast** on the **10th, 11th, 12th, 16th, 17th & 18th September and 16th October 2013,** before me **John L Leckey Senior Coroner** for **The Coroners Service for Northern Ireland** touching the death of **Lynn McClean Lewis** to inquire how, when and where the said **Lynn McClean Lewis** came to their death, the following matters were found :

1.Name and Surname : **Lynn McClean Lewis**

2.Sex : **Female**

3. Date of Death: [redacted]

4. Place of Death : **Ulster Independent Clinic, 245 Stranmillis Road, Belfast**

5. Usual Address : [redacted]

6. Marital Status : **Married**

7. Date and Place of Birth : **3 April 1973** **Banbridge**

8. Occupation : **Housewife Wife of** [redacted]

9. Maiden Surname (of woman who had married) : [redacted]

10. Cause of Death : la **Haemorrhage and Hyponatremia associated with Hysteroscopic Resection of Uterine Fibroid**

b

c

ll

Findings

At the time of her death Lynn McClean Lewis was 38 years of age. She had a nine month history of heavy menstrual bleeding coupled with inter-menstrual and post-coital bleeding. A transvaginal scan showed the presence of a fibroid and this was attributed to the use of the oral contraceptive pill. On 7th July 2011 she was admitted to the Ulster Independent Clinic for a hysteroscopic resection of the fibroid. This is a procedure that involves the removal of tissue from the cavity of the uterus using an instrument passed through the cervix. In order to view the anatomy the uterine cavity is irrigated with fluid and electrocautery is deployed in order to resect tissue and seal bleeding vessels. The procedure, known as transcervical endometrial resection, is usually performed under general anaesthetic.

Anaesthesia was induced at 08.50 and surgery commenced with the consultant surgeon, Professor Neil McClure using an operating hysteroscope. He was assisted by a Registrar. The inlet channel of the hysteroscope was connected to a bag of sterile glycine fluid for the purpose of irrigating the uterine cavity. It was positioned about 50cm above Mrs Lewis who was lying on the operating table and was under gravity pressure only. In his statement Professor McClure described how his practice was to have the tubing from the outlet irrigation channel of the hysteroscope connected to the theatre suction fluid management system "as it enables those monitoring the fluid input and output to do so with greater accuracy and efficiency". He goes on to describe a mishap relating to the spillage of glycine fluid when the suction tubing became detached from the hysteroscope for some unknown reason.

"During the early stages of the resection of the fibroid (I am not exactly sure when) the suction tubing became detached from the hysteroscope and fluid drained onto the floor and over my clothing. At most this was for a few minutes and as soon as I noticed that the tubing was detached I reattached it and proceeded to work on the sides of the fibroid as described in Para 12 above. I did not immediately notice the leakage as

my attention was focussed over the patient's leg looking at the monitor screen and the theatre lights were dimmed. Also, operating hysteroscopy equipment often leaks at some of its seals and there is usually some dampness associated with this procedure".

I am satisfied that the resultant spillage of glycine on to the Professor's clothing and the floor of the theatre, which went unnoticed for some minutes by the Professor, his Registrar, the Anaesthetist and the theatre nurses, made any accurate estimate of fluid deficit an impossibility.

Within about 10 minutes of the commencement of surgery unusually heavy bleeding was noted. The source of the bleeding could not be identified and was eventually controlled with difficulty at about 09.40. At that stage Mrs Lewis's observations were stable. Shortly afterwards at about 10.00 concerns materialised that a significant amount of the glycine irrigation fluid may have been absorbed into the bloodstream. The anaesthetist then stopped the intravenous fluids, administered a diuretic (Furosemide) to assist in the offloading of excess fluid from the circulation and catheterised the bladder. Initially the observations remained stable though it was recognised there was a potential for deterioration. In the course of taking an arterial blood sample the anaesthetist noticed froth coming from the tube of the Laryngeal Mask Airway. Additional anaesthetic help was summoned. At 10.25 Mrs Lewis suffered a cardiac arrest. Cardiopulmonary resuscitation was commenced immediately and the Advanced Life Support algorithm was followed. She was attended by a consultant cardiologist and a consultant cardiothoracic surgeon. An ultrasound scan showed no tamponade but a very dilated heart. After some 90 minutes resuscitation was discontinued and death was pronounced at 12.04.

A subsequent post-mortem examination established that death was due to Haemorrhage and Hyponatraemia associated with Hysteroscopic Resection of Uterine Fibroid. The State Pathologist, Professor Jack Crane, confirmed the presence of a large benign fibroid in the uterus. He was able to conclude that in one small area the full thickness of the uterine wall had almost been penetrated and, in particular, the muscular part of the uterine wall which was thick and vascular. Whilst penetration had occurred the wall had not been perforated. However, this penetration would have precipitated a substantial haemorrhage. A tear or laceration in the neck of the uterus (cervix) was identified and the pathologist opined that this was possibly caused by the introduction of the hysteroscope. This too would have led to a substantial haemorrhage. Therefore, in his opinion almost certainly Mrs Lewis was haemorrhaging from two sources, the site of the resected fibroid and the cervical tear. In addition evidence was found of a biochemical disturbance known as hyponatraemia which is characterised by a low sodium level. This is a recognised complication of hysteroscopy when hypotonic fluids such as glycine are introduced into the uterus and then absorbed into the bloodstream. Hyponatraemia predisposes to cerebral oedema, which was found in the case of Mrs Lewis, and it is recognised that this condition is potentially fatal if untreated. Whilst death was due to the combined effects of haemorrhage and hyponatraemia I accept the opinion of Dr GH Millward-Sadler who is a pathologist with a specialist expertise in maternal deaths that hyponatraemia was the principal cause of death. In relation to the haemorrhage he said this:

"Both sites could be the source of the bleeding but in my opinion the lower uterine tear is a probable significant source. However the Hb only dropped to 6.9gm which, without blood replacement, would imply a loss of between a third to a half of total blood volume - approximately 1.5 to 2 litres. Though not insignificant, in pregnancy when the uterus is much more vascular, women have survived such losses. Maternal deaths from haemorrhage have frequently lost greater amounts and usually succumbed to disseminated intravascular coagulation. The Scottish Confidential Audit of Severe Maternal Morbidity defined major obstetric haemorrhage as 2.5 litres or more and recorded 167 cases in their second year (2003) (Why Mothers Die 2000 - 2002, Confidential Enquiry into Maternal and Child Health, p267 -271, 2004). As there were only 17 maternal deaths from obstetric haemorrhage in the whole UK between 2000 and 2002 (CEMACH, 2004), it is likely that this lady's haemorrhage was a contributory factor to death rather than the prime cause."

That statement leads me to conclude that viewed in isolation the haemorrhage Mrs Lewis suffered was potentially survivable but the untreated hyponatraemia was not. I accept without reservation the joint view of Professor Crane and Dr Millward-Sadler that the fatal consequences of the combined effects of haemorrhage and hyponatraemia flowed directly from the gynaecological procedure carried out. Moreover, it was the manner in which that procedure was carried out.

I obtained two expert reports, one from Dr Leroy Edozien who is a Consultant Obstetrician and Gynaecologist attached to St Mary's Hospital Manchester and one from Dr George Gardiner who is a Consultant in Anaesthetics and Intensive Care Medicine in Belfast City Hospital. In the course of the inquest I was provided with an expert report obtained on behalf of the Ulster Independent Clinic from Professor Robert W Shaw, formerly Consultant Obstetrician and Gynaecologist with Derby Hospitals NHS Foundation Trust and Professor of Obstetrics & Gynaecology at the University of Nottingham. All three reached similar conclusions to those of Dr Millward-Sadler in relation to hyponatraemia being the principal reason why Mrs Lewis died. They found that she had suffered two complications from the surgery, namely,

haemorrhage and hyponatraemia due to glycine absorption with the effects of the hyponatraemia being the more serious and the more life-threatening.

At a stage in the proceedings when the nursing staff had concluded their evidence but before Dr Edozien had concluded his evidence and before either Dr Gardiner or Professor Shaw had been examined in relation to their respective reports I acceded to an application from the legal representatives for Professor McClure, Dr Damien Hughes (the Anaesthetist), the Ulster Independent Clinic and the bereaved family that the proceedings should be adjourned for a short period to see if an agreed position could be reached that would satisfy the requirements of a coroner's inquest and would satisfactorily explain to the family of Mrs Lewis what caused her death. At a subsequent hearing on 11th October 2013 in relation to this I was provided with a lengthy statement signed on behalf of Professor McClure, Dr Hughes and the Ulster Independent Clinic which is a candid acknowledgement by Professor McClure, Dr Hughes, the Ulster Independent Clinic and the nursing staff of their failings, both personal and institutional, in relation to the care, treatment and management of Mrs Lewis in the course of the surgical procedure. In summary it was sub-standard.

I have carefully considered this statement for the purpose of reaching a conclusion as to whether it obviates the need for any continuation of the inquest. I have been informed that it satisfies the family of Mrs Lewis which is a most important consideration for me. Taking into account the detailed and candid nature of the statement, the views of Mrs Lewis's family and the fact that it has been read openly in court, I am satisfied that the inquest hearing can conclude at this juncture and that I am able to give this verdict. I am annexing a copy of the statement to this verdict. In my opinion an inquiry has taken place that satisfies the legitimate public interest in the circumstances that led to the unexpected death of a 38 year old woman.

In relation to Dr Edozien's report Professor Shaw had commented that whilst they have "some difference of opinion as to when and what could have caused the cervical tear, but this is not as important as the fact that one occurred." Otherwise, "Dr Edozien has identified the issues raised in my report concerning a lack of attention to obtaining information on potential fluid deficit, questions over how the other injuries in the uterus occurred and over decision making processes. The apparent lack of team working and knowledge of the potential problems with the TCRE procedure by the nursing staff were also contributory aspects to the case." In my view those remarks constitute a succinct and accurate summary of the acknowledged failings of surgeon, anaesthetist, the Ulster Independent Clinic and nursing staff which I adopt.

As I have stated above I see no reason not to accept the findings and conclusions of the two pathologists as to why Mrs Lewis died and their formulation of the cause of death. No contrary opinion was expressed. For the purpose of this verdict I have taken the view that it is not necessary for me to give a ruling on every disputed opinion as to what constitutes good or bad clinical practice whether in relation to surgery or anaesthesia, whether one surgical technique or procedure is to be preferred to another, the role and duties of theatre nurses in relation to fluid management or in relation to every disputed interpretation of the clinical record or chronology of events in theatre. However, I would add this. Both Dr Edozien and Professor Shaw identify good and effective team work as being the gold standard all engaged in any surgical procedure should aspire to and they identified significant deficiencies in team work and team dynamics when Mrs Lewis was in theatre. I hope it will be of some comfort to the family of Mrs Lewis that deficiencies and failings have been acknowledged.

Whilst I accept that no medical procedure is risk-free I have no doubt that Mrs Lewis would not have died if the appropriate measures and precautions had been taken. In his speech in Jordan v Lord Chancellor [2007] UKHL 14 at paragraph 14 Lord Bingham said this in relation to the purpose or scope of an inquest:

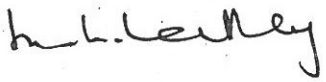
"The coroner must decide how widely the inquiry should range to elicit the facts pertinent to the circumstances of the death and responsibility for it."

It may be argued that this important statement of Lord Bingham is at variance with the provisions of Rule 16 of the Coroners (Practice and Procedure) Rules (NI) 1963 which provides:

"Neither the coroner nor the jury shall express any opinion on questions of criminal or civil liability ..."

However, I have concluded that any determination by me of responsibility for the death of Mrs Lewis would not offend the provisions of that Rule provided I do not comment on questions of criminal or civil liability. I do not intend to do so other than to say that the candid statement I received on behalf of Professor McClure, Dr Hughes, the Ulster Independent Clinic and the nursing staff speaks for itself on that issue. As I have said the failings were both personal and institutional.

Date : 16th October 2013

Signed :  Senior Coroner for Coroners Service for Northern Ireland

SHSCT S&H / Safety Alerts Review Team: In attendance

Date & time of Meeting:	22/11/2013		
Assistant Director for CSCG	☒	Governance Co-ordinator - MHD	☐
AMD for Clinical Standards & Guidelines	☒	Governance Co-ordinator - OPPC	☐
Governance Co-ordinator - Acute	☒	Medicines Governance Pharmacist	☒
Governance Co-ordinator - CYP	☒	Patient Safety & Quality Officer	☒
Senior Manager – Medical Directorate	☐	Estates Risk & Governance Manager	☐
	☐	Effectiveness & Evaluation Manager	☒

Categorisation

CMO / CNO Letter	☐	Professional Estates Letters / Estate & Facility Alerts	☐
Drug Alerts	☐	SABS alert / Field Safety Notices	☐
NICE Guidelines	☐	SQS Learning Letters	☐
NICE Technology Appraisals	☐	Safety Quality Standards (SQS) Guidance & Letters	☐
NPSA Alerts	☐	Safety Quality Professional Letter from DHSSPS/PHA/HSCB	☐
Other Specify Below:		Letter from Coroners Service Northern Ireland	

Circular Reference	Not specified
Title	Letter from Coroner re Inquest 1791-2011
Date of Issue from DHSSPSNI	21/10/2013

Directorate Applicability *(tick)*

Acute Services:		☒	Medical		☒
Division	CCS	☐	Mental Health & Disability		☐
	Facilities Management	☐	Older Persons and Primary Care		☐
	IMWH	☐	Performance & Reform		☐
	MUSC	☐	Children's & Young Peoples Services		☐
	Pharmacy	☐	Finance		☐
	SEC	☐	Human Resources		☐

Agreed Lead Director:	Dr Simpson, Debbie Burns, Francis Rice

For safety alerts with multi-directorate applicability there will be a need to gain agreement between SMT members to confirm the appointment of a Lead Director. This is to be confirmed following the meetings.

Risk Assessment Required to determine Organisational Impact of Risk

Yes	☒	No	☐

Working Group Membership

Nominated Change Leader/Working Group Members	Ronan Carroll, Dr McAllister, Dr Michael Young, Dr Martina Hogan, Fiona Wright
Stipulated Date for Implementation	Not specified
If not specified determine SHSCT timescales	
Date to be presented at SMT/SMT Governance	
Interim progress report required by:	

Any additional information:

A Trust Working group is to be established to take forward the learning associated with this correspondence.

Signature (Chairperson of review team):	Personal Information redacted by the USI
Date:	**22/11/2013**

Stinson, Emma M

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: Simpson, John
Sent: Wednesday, October 30, 2013 2:53 PM
To: McCooey, Blaithnid; Joyce, Barbara; McCauley, Cheryl
Cc: White, Laura; Burns, Deborah; Hogan, Martina; McAllister, Charlie; Mackle, Eamon; McVey, Anne; Trouton, Heather
Subject: RE: *Confidential* Coroner's Case for S+G route per Dr Simpson

Thanks.
I think these documents will be of greatest interest to the acute directorate ie Obs and gynae, surgery and anaesthetics john

From: McCooey, Blaithnid
Sent: 30 October 2013 12:57
To: Joyce, Barbara; McCauley, Cheryl
Cc: Simpson, John; White, Laura
Subject: *Confidential* Coroner's Case for S+G route per Dr Simpson
Importance: High

Barbara
The coroner has sent this information to Dr Simpson He has asked me to scan to you so that these documents can be progressed via the S+G route Can you please log and ensure this is taken forward?
Dr Simpson has given me quite a significant number of documents relating to this case Barbara – they are too big to be scanned but do you want to start a manual file for keeping them?

Dr Simpson I will keep these originals and pass to Barbara but you can print these documents attached if you wish for your own file?

Thanks
Blaithnid

Blaithnid McCooey
Governance Officer
(Mrs Margaret Marshall, Interim Asst. Director) Corporate Clinical & Social Care Governance Office Trust Headquarters College of Nursing CAH Site
68 Lurgan Rd
Portadown
BT63 5QQ

t: Personal Information redacted by the USI
e: Personal Information redacted by the USI
(Hours of work: 9am-5pm Mon-Fri)

Stinson, Emma M

From: Simpson, John [redacted]
Sent: 01 November 2013 14:23
To: Marshall, Margaret
Cc: Brennan, Anne
Subject: FW:
Attachments: Document.pdf

Fyi
j

-----Original Message-----
From: McMaster, Alison [mailto:[redacted]
Sent: 01 November 2013 11:07
To: Kelly, SharonA [redacted]); Stevens, Tony [redacted]); Dr Alan McKinney; calum.macleod [redacted]; Simpson, John; Carolyn Harper; charlotte.mcardle [redacted]
Subject: FW:

Please find attached copy of correspondence to Mr Leckey, Senior Coroner for Northern Ireland, in relation to Lynn Lewis, deceased, for information.

Charles J Martyn
Medical Director

South Eastern Health and Social Care Trust

1 November 2013

Strictly Private & Confidential

Mr J L Leckey
Senior Coroner for Northern Ireland
Coroners Service for Northern Ireland
May's Chambers
73 May Street
BELFAST
BT1 3JL

Dear Mr Leckey

Re: Lynn Lewis, Deceased

I write to acknowledge receipt of your letter dated 21 October 2013, in relation to the above.

I will work with the other Medical Directors in Northern Ireland to provide a collegiate response to the issues that you have raised. We will revert to you as a group in due course.

Yours sincerely

Personal Information redacted by the USI

Mr C J Martyn
Medical Director

cc: Dr T Stevens, Medical Director, BHSCT
Dr J Simpson, Medical Director, SHSCT
Dr A McKinney, Medical Director, WHSCT
Dr C MacLeod, Medical Director, NHSCT
Dr C Harper, Executive/Medical Director of Public Health
Mrs C McArdle, Chief Nursing Officer

South Eastern Health & Social Care Trust, Trust Headquarters, Ulster Hospital
Email: Personal Information redacted by the USI **Tele:** Personal Information redacted by the USI

Stinson, Emma M

From: Kelly, SharonA <Personal Information redacted by the USI>
Sent: 16 December 2013 16:14
To: 'Carolyn Harper'
Cc: 'Christine Thompson (Personal Information redacted by the USI)'; Johnston, Julian; Stevens, Tony; Alan McKinney (Personal Information redacted by the USI); Calum Macleod; 'Charlie Martyn'; Simpson, John
Subject: RE: Lynn Lewis - deceased - Coroner's correspondence
Attachments: BELPRTBCH01_BCH_AFLR_M_03_3763_001.pdf

Further to previous email please find attached signed copy.

Regards

Sharon

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: 16 December 2013 11:41
To: Carolyn Harper
Cc: Christine Thompson (Personal Information redacted by the USI); Johnston, Julian; Stevens, Tony; Alan McKinney (Personal Information redacted by the USI); Calum Macleod; Charlie Martyn; Simpson, John
Subject: FW: Lynn Lewis - deceased - Coroner's correspondence

Dear Dr Harper

Further to your letter of 6 November 2013, please find attached collegiate response from Dr Stevens and the other Medical Directors of the HSC Trusts.

Signed copy to follow.

Regards

Sharon

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: Carolyn Harper [mailto:Personal Information redacted by the USI]
Sent: 06 November 2013 11:10

To: Alan McKinney; Stevens, Tony; Calum MacLeod; Charlie.Martyn[redacted]; john.simpson[redacted]
Cc: michael.mcbride[redacted]; 'Charlotte McArdle' ([redacted]); jleckey.rcj[redacted] David Stewart RQIA; Carolyn Harper; Alan Finn; Creaney, Brenda; Charlotte McArdle; Francis.Rice[redacted]; Olive.macleod[redacted]
Subject: Lynn Lewis - deceased - Coroner's correspondence

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

Dear All
Please see attached correspondence from Dr Carolyn Harper.
Many thanks, Lisa obo Dr Harper

Dr Carolyn Harper FFPH
Executive Medical Director/Director of Public Health Public Health Agency Tel [redacted]
Email [redacted]

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.

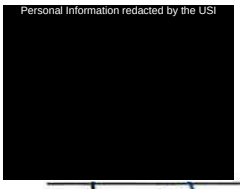
In the longer term we will consider the practical and resource issues that will allow a change in technique to eliminate the use of glycine.

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

Stinson, Emma M

From:	Hogan, Martina <Personal Information redacted by the USI>
Sent:	18 December 2013 15:40
To:	McCracken, Geoff; Sim, David; Boggs, Edgar; Sidhu, Harmini; McCormick, Tim; DeCourcyWheeler, Richard; McVey, Anne; McStay, Patricia
Cc:	Murphy, Jane S; Simpson, John
Subject:	FW: Lynn Lewis - deceased - Coroner's correspondence
Attachments:	Policy on surgery for endoscopic tissue resection.docx; Letter to C Harper.docx

Please see below email
Would it be possible to forward comments to Anne and they will be collated and sent onwards
Thanks Martina

From: Simpson, John
Sent: 18 December 2013 15:24
To: McAllister, Charlie; Hogan, Martina; Mackle, Eamon; Burns, Deborah; Marshall, Margaret
Cc: Joyce, Barbara
Subject: FW: Lynn Lewis - deceased - Coroner's correspondence

Fyi
j

From: Johnston, Julian [mailto Personal Information redacted by the USI]
Sent: 18 December 2013 14:54
To: Stevens, Tony; Alan McKinney (Personal Information redacted by the USI); Calum Macleod; Simpson, John; Charlie Martyn; McAllister, Charlie; Creaney, Brenda; MacLeod, Olive; Rice, Francis; 'Alan.Finn Personal Information redacted by the USI '; 'Nikki.patterson Personal Information redacted by the USI '; Hagan, Chris; Price, John; McClelland, Raymond; Gardiner, George; Johnson, Janet; Austin, Stephen
Cc: Christine Thompson Personal Information redacted by the USI); Carolyn Harper; Kelly, SharonA; alison.mcmaster Personal Information redacted by the USI ; dorothy.killough Personal Information redacted by the USI ; White, Laura; Orlaith Morrow; Jack, Cathy; McBride, Michael; Rocks, Dennis; 'McArdle, Charlotte'
Subject: RE: Lynn Lewis - deceased - Coroner's correspondence

Everybody,
Following the course of action agreed (attached), there were 2 items of work asked of me.

1. First draft policy for endoscopic tissue resection.
It has been written with reference to published reviews and policy work sent to me from the BHSCT and other Trusts.
Can it be shared with those working in theatres for surgery on endoscopic tissue resection – urology and gynaecology. It will impact upon and need agreement from surgeons, anaesthetists and theatre staff.
I would be grateful for comments that point out,
- errors of fact
- measures that will, if instituted, lead to a worsening of patient safety.
- measures that will, if instituted, stop surgery proceeding.

I realise that some will find differences in the document from the way they work or like to work; I hope we can achieve a consensus on safe practice that is consistent across the province – I think this is what the Coroner requires.

2. Taking a guide from the Coroner's inquest and the expert reports, I also intend to table a discussion document which could set out proposals for standards for good theatre practice guidelines.

I am also taking the opportunity to collaborate with the Ulster Independent Clinic on all of this work so that (visiting) Medical staff will follow the same guidelines, independent of where they work.

Regards,

Julian R Johnston MD FCARCSI FRCA
Assistant Medical Director
BHSCT
Personal Information redacted by the USI

Co-Chair Standards and Guidelines Committee
Standards, Quality and Audit department
Telephone: Personal Information redacted by the USI
If unanswered, contact Christine Murphy : Personal Information redacted by the USI or Jill Shaw O'Doherty : Personal Information redacted by the USI or Simon Dunlop : Personal Information redacted by the USI

BHSCT Litigation Management Office
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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 .

From: Kelly, SharonA
Sent: 16 December 2013 11:41
To: Carolyn Harper
Cc: Christine Thompson (Personal Information redacted by the USI); Johnston, Julian; Stevens, Tony; Alan McKinney (Personal Information redacted by the USI); Calum Macleod; Charlie Martyn; Simpson, John
Subject: FW: Lynn Lewis - deceased - Coroner's correspondence

Dear Dr Harper

Further to your letter of 6 November 2013, please find attached collegiate response from Dr Stevens and the other Medical Directors of the HSC Trusts.

Signed copy to follow.

Regards

Sharon

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: Carolyn Harper [mailto:[redacted]]
Sent: 06 November 2013 11:10
To: Alan McKinney; Stevens, Tony; Calum MacLeod; Charlie.Martyn[redacted]; john.simpson[redacted]
Cc: michael.mcbride[redacted]; 'Charlotte McArdle' ([redacted]); jleckey.rcj[redacted]; David Stewart RQIA; Carolyn Harper; Alan Finn; Creaney, Brenda; Charlotte McArdle; Francis.Rice[redacted]; Olive.macleod[redacted]
Subject: Lynn Lewis - deceased - Coroner's correspondence

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

Dear All
Please see attached correspondence from Dr Carolyn Harper.
Many thanks, Lisa obo Dr Harper

Dr Carolyn Harper FFPH
Executive Medical Director/Director of Public Health
Public Health Agency
Tel [redacted]
Email [redacted]

Trust LOGO

Reference No:

Title:	Policy on the surgical management of endoscopic tissue resection, for example during urological, gynaecological and other relevant surgery.		
Author(s)	List name and titles of lead and additional author(s) or group responsible for drafting policy Include contact details		
Ownership:	Insert name of Director / service area / group / directorate		
Approval by:	Insert name of Trust committee / group responsible for approval	**Approval date:**	Insert date each committee approved
Operational Date:	December 2013	**Next Review:**	December 2014
Version No.	V0.2 **Supercedes**		
Key words:	Endoscopic, Resection, Prostatectomy, Myomectomy, TUR syndrome		
Links to other policies			

Date	Version	Author	Comments
20/11/2013	0.1	SE Trust	Initial Draft
03/12/2013	0.2	JR Johnston	Amalgamation of protocols from 5 Trusts.

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Some endoscopic surgical procedures require the use of an irrigating fluid to dilate the operating field to enable a suitable field of vision and to wash away debris and blood. This includes operations such as,

- transcervical resection of the endometrium (TCRE),
- resection of prostate (TURP) and bladder tumours (TURBT),
- removal of uterine septations, polyps, endometrial ablations and also cystoscopy, arthroscopy, rectal tumour surgery, vesical ultrasonic lithotripsy and percutaneous nephrolithotripsy.

A serious complication of such irrigation is the systemic intravascular absorption of the irrigation fluid to the extent that serious overt symptoms are produced. This policy sets out the steps needed to reduce the risks of that happening. Using the national policies and guidelines identified in section 7 along with work already done within the province, its aim is to establish a regionally agreed set of precautions. Some of the recommendations can be instituted now and some will depend on longer term financing of equipment.

1.2 Irrigation fluids used

The irrigation fluid used for these electrosurgical procedures should,

- have neutral visual density so that the surgeon‘s view is not distorted.
- be nonconductive so the electrical current is not dissipated and can remain concentrated at the cutting point.
- be non-haemolytic so that haemolysis does not occur if it enters the circulation.

In the past, sterile water was used as the irrigant but was associated with significant morbidity because of water intoxication and intravascular haemolysis.

Modern non-electrolytic solutions containing glycine 1.5%, mannitol or sorbitol are optically clear and were introduced to prevent haemolysis, without dispersing the electric current used for cutting with the resectoscope. Their use in irrigation solutions has reduced the occurrence of significant haemolysis and death.

The most commonly used irrigation fluid is 1.5 % **glycine solution,** a non-essential amino acid with a low cost and lack of allergic reactions**.** However, it has an osmolality of 200 mOsm/L which is much lower than that of blood and large amounts of this hypotonic irrigation fluid, required to facilitate the procedure, may be absorbed systemically through a vascular bed. This may cause several serious complications known as the **TUR syndrome** which can occur in a variety of surgical disciplines.

Normal saline is used for irrigation with the bipolar resectoscope. Because of its greater plasma volume expansion, acute volume overload is more likely during absorption of normal saline compared with other irrigating solutions.

Moreover, it can cause hyperchloraemic acidosis due to its excessive content of chloride. Pulmonary oedema is a reported consequence.

1.3 TUR syndrome

This is manifested mainly through a classic triad of,

- fluid overload - acute changes in intravascular volume leading to circulatory overload, pulmonary oedema, cardiac failure and even cardiac arrest.
- dilutional hyponatraemia causing central nervous system (CNS) effects such as cerebral edema leading to agitation, confusion, convulsions and coma.
- direct toxicity and metabolism of glycine which may also cause CNS symptoms, most commonly transient blindness and CNS depression as it is an inhibitory neurotransmitter.

1.4 Purpose

This policy outlines a set of principles designed to reduce the development of the TUR syndrome.

1.5 Objectives

To reduce the likelihood of developing the TUR syndrome through,

- correct patient selection and preoperative preparation.
- selection of an appropriate surgical technique.
- the use of precautionary principles during the surgical procedure, including the correct procedure to follow in the safe management of irrigating fluid for urology and gynaecology.
- the application of monitoring aimed at detecting the early warning signs.
- establishing a theatre regime based on good theatre practice principles aimed at reducing the development of the TUR syndrome.

2.0 SCOPE OF THE POLICY

This policy applies to all staff who may be involved in the care of a patient in theatre who receives irrigating fluid into the bladder or uterus or any other organ where significant intravenous fluid absorption is a realistic possibility.

It applies to medical staff, nursing staff, midwives, operating department practitioners, technical staff, physicians' assistants (anaesthesia) and other theatre healthcare workers.

This policy does not cover the methods of treatment for the TUR syndrome.

3.0 ROLES/RESPONSIBILITIES

Medical staff - by careful consideration of the therapeutic choices when planning the service for endoscopic resection, can reduce the likelihood of the development of the TUR syndrome.

Management – by actively supporting the introduction of therapeutic modalities that aim to reduce the incidence of the TUR syndrome.

All staff involved in the care of the patient, especially in theatre, are responsible for implementing and adhering to the policy principles.

Each ward/theatre sister/charge nurse/clinician is responsible for ensuring staff comply with this policy and all relevant staff have the responsibility to ensure that they read and comply with the policy contents.

In the event of an untoward incident an IR1 form should be completed by either the medical officer or nurse in charge of the patient's care.

4.0 POLICY PRINCIPLES

4.1 Definitions

Osmolality: The concentration of osmotically active particles in a solution.

Hypertonic: Higher osmolality (concentration of particles) than what is found in normal cells.

Hyponatraemia: Lower sodium concentration than normally found in plasma.

Hypotonic (or hypo-osmolar): Lower osmolality (concentration of particles) than what is found in normal cells.

Resectoscope: An endoluminal surgical device comprising an endoscope (hysteroscope or cystoscope), sheaths for inflow and outflow, and an ''element'' that interfaces a specially designed electrode (or pair of electrodes) with a radiofrequency electrosurgical generator.

Policy Principles

4.2 Irrigating fluid is most frequently absorbed directly into the vascular system when a vein has been severed by electrosurgery. The driving force is the fluid pressure; the volume of fluid absorbed depending on the,

- duration of the procedure and resection time,
- degree of opening of blood vessels during surgery ,
    - vascularity of the diseased prostate, uterus, fibroid.
    - surgical disruption of the bladder, uterine vessels.
    - capsular or uterine wall perforation or apparent damage to a venous sinus.
- pressure of the distending fluid within the bladder or uterus,
    - height of the irrigation fluid bag above the patient (increased height implies increased hydrostatic pressure driving the fluid intravenously).
    - distension pressure applied to the irrigation fluid.

For safe endoscopic resection using irrigation fluid, the following topics should be covered within a set of policy principles,

1. Preoperative workup.
2. Selection of surgical technique.
3. Identification, control and management of haemorrhage.
4. Control of the absorption of irrigation fluid.

a. Dilutional Hyponatraemia.
b. Fluid overload.
c. Glycine toxicity.

5. Theatre environment.
   a. Decision making processes.
   b. Team dynamics.
   c. Lack of knowledge of the potential problems.

4.2.1 Preoperative workup

Some of these procedures are carried out on a predominantly elderly population with a higher incidence of coexisting disease. BPH affects 50% of males at 60 years and 90% of 85-year-olds and so TURP is most commonly performed on elderly patients, a population group with a high incidence of cardiac, respiratory and renal disease.

Careful preoperative workup of the patient should include, for example,

- a robust consent process leading to a truly informed patient aware of the hazards of endoscopic resection using irrigation fluids.
- a thorough physiological assessment with attention paid to risk factors such as hypertension, ischaemic heart disease, cardiac failure, anaemia.
- standard haematology and electrolyte analysis - to include a recent haemoglobin, serum sodium.
- careful consideration regarding blood grouping and cross-matching.
- recent investigations aimed at establishing the pathological anatomy and degree of surgical risk especially haemorrhage e.g. ultrasound scan.
- the ready availability of reports of such investigations.
- the timely commencement of any adjuvant therapy prior to the surgery e.g. before TCRE, especially if it helps to reduce the risk of haemorrhage and/or causes a reduction in tumour size.

4.2.2 Selection of surgical technique

All of the surgical teams (urology, gynaecology) in NI, practicing this type of surgery, should become fully cognoscente of the risks of the TUR syndrome and work together to develop a co-ordinated regional approach where they take steps to,

- agree a programme of change for the cessation of glycine use.
- develop or adopt surgical techniques that do not rely on glycine as an irrigant.
- use instruments and equipment that help to control or reduce vesical or uterine pressure.
- establish a set of safe practice standards.

Urology

Absorption in excess of 1 litre of glycine solution, which is associated with a statistically increased risk of symptoms, has been reported in 5–20% of the TURPs performed. Extravasation is the cause in ~20% of these patients.

While electrolyte-containing solutions such as normal saline (NS) are not suitable for RF surgery with monopolar RF systems, the development of

bipolar radiofrequency (RF) instrumentation for endoscopic resection procedures has allowed the application of NS as a distending medium.

Therefore, the adoption of bipolar TURP or laser prostatectomy allows NS irrigation in urology and permits the removal of glycine and its inherent risks from theatre. The risks of the hyponatraemic and hypo-osmolar aspects of the TUR syndrome are eliminated.

However, it should be remembered that the use of NS is not without risk because there will still be fluid absorption with plasma volume expansion. Some consider acute volume overload is more likely during absorption of normal saline compared with other irrigating solutions.

As long as they are proven to be safe and effective as judged by the NICE interventional procedure programme, bipolar RF systems and other technique e.g. laser systems, should be introduced regionally and the use of glycine as a irrigant terminated.

Gynaecology

Fluid absorption is slightly more common during TCRE than during TURP. The first generation endometrial ablative techniques including TCRE and rollerball endometrial ablation (REA) are all endoscopic procedures. Their effectiveness (in comparison with hysterectomy - the existing gold standard) has been demonstrated in a number of randomised controlled trials. Although less morbid than hysterectomy, they are associated with a number of complications including uterine perforation, cervical laceration, false passage creation, haemorrhage, sepsis and bowel injury and, importantly, the fluid overload and hyponatraemia associated with the use of 1.5% glycine irrigation fluid resulting in the serious and occasionally fatal consequences discussed above.

There are now second generation ablative techniques which do not require the use of electrocautery or the use of glycine or other distension fluids. They avoid the serious risk of hyponatraemia and represent simpler, quicker and potentially more efficient means of treating menorrhagia. Examples of second generation ablative techniques are fluid filled thermal balloon endometrial ablation (TBEA), radiofrequency (thermoregulated) balloon endometrial ablation, hydrothermal endometrial ablation, 3D bipolar radiofrequency endometrial ablation, microwave endometrial ablation (MEA), diode laser hyperthermy, cryoablation and photodynamic therapy.

As long as they are proven to be safe and effective as judged by the NICE interventional procedure programme, the use of second generation ablative techniques and bipolar RF systems should be introduced regionally and the use of glycine as a irrigant terminated.

4.2.3 Identification, control and management of haemorrhage.

Blood loss can be difficult to quantify and may be significant. Close attention to the patient's clinical state and good communication between surgeon, anaesthetist and the theatre team is vital.

Because of generalised physiological effects of haemorrhage and the increased likelihood of fluid absorption when using irrigation fluid, the presence of significant bleeding should act as a trigger for,

- increased vigilance for development of fluid overload, hyponatraemia.
- additional help from medical and nursing staff to assist by scrubbing in.
- increased frequency of haemoglobin and/or haematocrit measurements.
- preparation of blood for cross matching.
- cessation of the operation once bleeding is controlled.

4.2.4 Control of the absorption of irrigation fluid

The choice of surgical technique and equipment may reduce the complications from irrigation fluid especially if glycine use stops but continued attention to controlling fluid absorption will still be needed with normal saline.

Until glycine use stops, symptoms related to fluid absorption will develop in 3 – 5% of patients with neurological symptoms being prominent. To control the effects of fluid absorption, the theatre team should pay particular attention to

a) hyponatraemia
b) fluid volumes.

a. Dilutional Hyponatraemia

The uptake of 1000 ml of fluid corresponds to an acute decrease in the serum sodium concentration of 5-8 mmol.l^{-1}. Encephalopathy, seizures and even cerebral oedema may develop when the sodium concentration falls below 120mmol/l. However, even markedly hyponatraemia patients may show no signs of water intoxication. The crucial physiological derangement of CNS function is not just hyponatraemia *per se*, but also the presence of acute hypo-osmolality.

Also, a patient's serum sodium concentration and osmolality may continue to decrease for some time after the procedure because irrigant can be slowly absorbed from the perivesicular and retroperitoneal spaces. Therefore, the TUR syndrome can start 4 to 24 hours later – intraoperatively, in the recovery ward or back in the ward.

Whereas hyponatraemia occurs with equal frequency in men and women, premenopausal women are 25 times more likely to die or have permanent brain damage than men or postmenopausal women, most likely an oestrogen effect. This effect is compounded because fluid absorption is slightly more common during TCRE than during TURP.

Serum Sodium measurement

Monitoring serum sodium concentration during TURP is common practice and a low value will confirm the diagnosis of hyponatraemia and is effective for assessing intravascular absorption. Significant decreases from a normal preoperative level can occur after just 15 minutes of starting resection. Levels below 120 mmol/L are invariably symptomatic and a rapid fall is more likely to produce symptoms.

Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care. It brings the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results quicker, which allows for immediate clinical management decisions to be made. They can be used to measure haematocrit, determine haemoglobin and measure serum electrolytes.

Using POCT apparatus for the measuring and having a result in minutes is a significant aid in diagnosing hyponatraemia as early as possible. Such POCT equipment must/should be available when these techniques for tissue resection are used.

It is often only measured at the end of surgery but this monitoring technique is best applied before and repeatedly during surgery so that it can act as a warning system for hyponatraemia. Any patient receiving glycine in theatre must have a measurement(s) made,

- as a preoperative baseline prior to the start of surgery.
- intermittently throughout a case as a routine.
- if there is a 1000mls deficit.
- if the surgery is longer than 30 minutes.

Staff must be readily available who are trained to use this POCT equipment.

b. Fluid volumes

Estimates of amount of fluid absorbed range from 10 – 30 mls per minute of resection time; over a 45 – 60 minute case that could equate to 1 – 1.8 litres. The best management of fluid overload is to prevent its occurrence by constantly and accurately monitoring the distending fluid input and output. The surgeon should be notified about ongoing fluid absorption early enough for steps to be taken to prevent excessive absorption.

Volumetric fluid balance is based on the calculation of the difference between the amount of irrigating fluid used and the volume recovered. Positive values are regarded as absorption.

However, calculation of systemic absorption is complicated by 4 factors:

1. It may be difficult to collect all of the media (fluid, urine and blood) that passes out of the operative area, including that which falls on the procedure or operating room floor.
2. the actual volume of media solution in 3L bags is typically more than the labelled volume.
3. difficulties in estimating the volume of media left in a used or ‘emptied’ infusion bag.
4. systemic absorption that in some instances may occur extremely rapidly.

While these factors can make volumetric fluid balance measurement an unreliable tool, it is considered a minimum necessity that the theatre team measure fluid input and overt output during such surgery and calculate a running deficit.

Bearing these difficulties in mind, a member of staff must be assigned to this duty before the start of every case. They will need to be proficient and practiced in this technique and must take responsibility for measuring the input and output, calculating the deficit and recording these details. They should remain in theatre for the duration of the procedure, in the same fashion as the surgeon.

The simplest method of monitoring comprises manually subtracting the volume collected from the volume infused, considering all sources including the resectoscope outflow; the ‘‘perineal’’ collection drape, which includes a pouch to capture spilled fluid and special apparatus to collect fluid spilled on the floor. Specialist draping systems are readily available for such fluid collection and should be used. Even so, accurate measurement can be difficult.

Each patient who has any irrigating fluid erected must have a fluid management chart (appendix X) commenced. Measuring the input and outputs and calculating the deficit should be done as a minimum every time a bag (often 3 litre) is hung up and the details clearly expressed verbally to the surgeon and all other theatre staff. These details should also be recorded on the dedicated fluid management chart. They might also be displayed on a white marker board in the theatre.

A second bag should not be commenced until a deficit amount has been calculated and it is agreed to be safe to proceed. It should be unusual to need a third bag but if it is, it should be done under the same circumstances. (??) At the end of the procedure, the final calculations must be made; the inputs, outputs and deficit. These should be expressed clearly to the surgeon and anaesthetist and recorded on the chart.

The fluid management chart must follow the patient into the recovery ward. All fluid balances must be handed over to recovery ward staff as part of the normal nursing and medical handover. The chart is then to be filed in the clinical record.

The limitations of such manual measurement may make it preferable to use an automated fluid measurement system that takes into account an exact measurement of infused volume as well as all of the potential sources of returned media. Such systems provide continuous measurement of the amount of distending media absorbed into the systemic circulation by using the weight of the infused volume. Such systems need evaluated in NI.

Maximum fluid deficit

Prevention of the TUR syndrome requires that the team have a protocol for responding to any escalating fluid absorption and there must be agreed volume thresholds for action. These thresholds may necessarily vary somewhat, depending on a number of factors that include the nature of the surgery, the nature of the media (isotonic or hypotonic) and the patient’s baseline and intraoperative medical condition e.g. presence of haemorrhage.

It has been shown with routine postoperative CT imaging of the brain that cerebral oedema can occur with as little as 500 mL of hypotonic solutions. The surgeon and anaesthetist must be informed by the nurse when there is a 500mls deficit. The nurse must ensure that the surgeon and anaesthetist acknowledge that they have received this information. This must be documented in the notes along with any action taken.

A 500 ml threshold may be appropriate for those who are older and/or medically compromised, but for healthy individuals, absorption of up to 1000 mL can generally be tolerated. The surgeon and anaesthetist must be informed by the nurse when there a 1000mls deficit. The nurse must ensure that the surgeon and anaesthetise acknowledge that they have received this information. This must be documented in the notes along with any action taken.

For elderly (? define) patients and others with comorbid conditions including compromised cardiovascular systems, a maximum fluid deficit of 500 mL is recommended. Surgery must stop unless haemorrhage needs controlled.

For healthy patients, the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions (glycine). Surgery must stop unless haemorrhage needs controlled.

The maximum limit for isotonic solution (normal saline) is unclear, but 2500 mL has been advocated. Surgery must stop unless haemorrhage needs controlled.

Further preventative measures

There are several precautions that reduce the risk of fluid absorption and its associated dangers. These are especially important because calculating the fluid absorption can be difficult.

These include limiting the,

1. Distension pressure by,
   - keeping the uterine cavity distention pressure at the lowest pressure necessary to distend the uterine cavity consistent with good visualisation and ideally should be maintained below the mean arterial pressure (MAP).

     It is estimated that approximately 40mmHg distending pressure is required to obtain clear vision. At pressures between 40mmHg and approximately 100mmHg (MAP), blood will continue to escape from disrupted capillaries until it is stopped by the tamponade. At this point, when continuous flow is used through the resectoscope, the blood within the cavity will be removed and a clear field of vision will be maintained. Dropping the pressure permits further bleeding. If the pressure is raised above the MAP, the pressure not only prevents the flow of blood out of disrupted vessels but actually forces the distension fluid medium in the reverse direction into the vessels.
   - attempting to limit the height of the irrigating solution container to 60 cm (figure to be agreed) above the patient and certainly never above 100cm.

Theatre teams must have a procedure for checking and maintaining an agreed height.
- not applying pressure bags to the irrigation fluid bag.
- insufflating irrigation fluid by using a pressure controlled pump device.

2. Operation time - restricting resection time to 60 minutes. Theatre teams must have an establish mechanism for measuring time and procedures for alerting surgeon and anaesthetist.

4.2.5 Theatre environment

A good theatre environment in terms of team dynamics is essential for the safe performance of these surgical procedures. There must be careful monitoring of fluid balance along with the clear communication of that balance to the surgical and anaesthetic members of the team.

- Theatre staff must always be aware of the potential hazards of, and equipment used, for any surgical procedure before it is performed.
- One member of the theatre team must be assigned to the duty of collecting, calculating and recording the irrigation volumes in/out and deficits. They will need to be proficient and practiced in this technique. It would not be expected that the surgeon should have to operate and also supervise this function at the same time. They should remain in theatre for the duration of the procedure, in the same fashion as the surgeon.
- Medical staff must always have situational knowledge of the theatre environment that they are working in and the availability (or non-availability) of any theatre equipment they consider necessary. They must be informed, in good time, of any equipment that is not working.
- Nursing staff should have a working knowledge of any equipment being used in their theatre or have the immediate presence of technical staff who do have that knowledge.

WHO checklist

Completion of the WHO surgical checklist with the sign in, time out and sign out must be adhered to. This will allow a surgical, anaesthetic and theatre team brief at the beginning for the whole theatre team and an opportunity to check that everything is in place to perform the biochemical and volumetric monitoring.

It will also ensure at the sign out that any problems e.g. over a fluid deficit, are identified early. On a regional basis, adoption of a modified WHO checklist for this kind of procedure should be investigated and piloted.

5.0 IMPLEMENTATION OF POLICY

This policy, after it is agreed, is to be implemented throughout NI in each of the 5 Trusts.

5.1 Resources

There will be resource implications in terms providing surgical equipment that can be used without needing glycine as an irrigant, POCT monitoring equipment for theatres and training for staff.

6.0 MONITORING

TBC

7.0 EVIDENCE BASE / REFERENCES

1. R. G. Hahn. Fluid absorption in endoscopic surgery. Br J Anaesth 2006; 96: 8–20.
2. Practice Committee of the AAGL Advancing Minimally Invasive Gynaecology Worldwide . Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media. Journal of Minimally Invasive Gynaecology (2013) 20, 137–148.
3. Dietrich Gravenstein. Transurethral Resection of the Prostate (TURP) Syndrome: A Review of the Pathophysiology and Management. Anesthesia & Analgesia. 1997; 84: 438-46
4. Varol N, Maher P et al. A literature review and upodate on the prevention and management of fluid overload in endometrial and hysteroscopic surgery. Gynaecological Endoscopy 2002; 11: 19-26
5. Blandy JP, Notley RG, Reynard JM. Transurethral Resection. Pub, Taylor and Francis 2005. http://www.baus.org.uk/Resources/BAUS/Transurethral%20Resection.pdf
6. Marszalek M, Ponholzer A et al. Transurethral Resection of the Prostate. European urology supplements 8 (2009) 504–512.
7. Indman PD, Brooks PG et al. Complications of fluid overload from Resectoscopic surgery. J Amer Assoc of Gynaecolig laparoscopists 1998; 5: 63-67.
8. Hawary A, Mukhtar K et al.Transurethral Resection of the Prostate Syndrome: Almost Gone but Not Forgotten. Journal of Endourology 2009; 23: 2013-20.

8.0 CONSULTATION PROCESS

Insert a list of those groupings consulted in the development of this policy e.g. Trade Unions, Specialist Committees, User groups, Section 75 groups.

9.0 APPENDICES / ATTACHMENTS

Appendix 1 = draft Theatre record form
Appendix 2 = Theatre based Summary form.
Appendix = Evidence based recommendations from AAGL Practice Committee.

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. ☐

SIGNATORIES

_____ **Date:** _____

Author

_____ **Date:** _____

Director

Trust LOGO

Peri-operative fluid recording chart

Consultant: _____ Date: _____ Ward: _____ Operation: _____	Addressograph Label

Irrigation fluid Start time: _____= 0 mins___ Type of fluid used _____

Serum Sodium: = _____ mmol/L Haemoglobin: _____g/dL.

Time (mins)	Irrigation In (mls)	Running total In	Irrigation Out (mls)	Deficit (mls)	Running deficit Out	Serum Sodium	Sign
5						Mmol/L	
10						Mmol/L	
15						Mmol/L	
20						Mmol/L	
25						Mmol/L	
30						Mmol/L	
35						Mmol/L	
40						Mmol/L	
45						Mmol/L	
50						Mmol/L	
55						Mmol/L	
60						Mmol/L	
						Mmol/L	

Total fluid In	=	Surgeon Signature	
Total Fluid Out	=	Anaesthetist Signature	
Deficit	=	Nurse Signature	

Trust LOGO

Continued.

Time (mins)	Irrigation In (mls)	Running total In	Irrigation Out (mls)	Deficit (mls)	Running deficit Out	Serum Sodium	Sign
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	

Irrigation In = after each fluid bag (mls)	Irrigation Out = record - suction canister volumes (mls) - fluid in drapes - fluid from floor suction
Record amount 'in' each time use Ellick evacuator	Record amount 'out' each time use Ellick evacuator

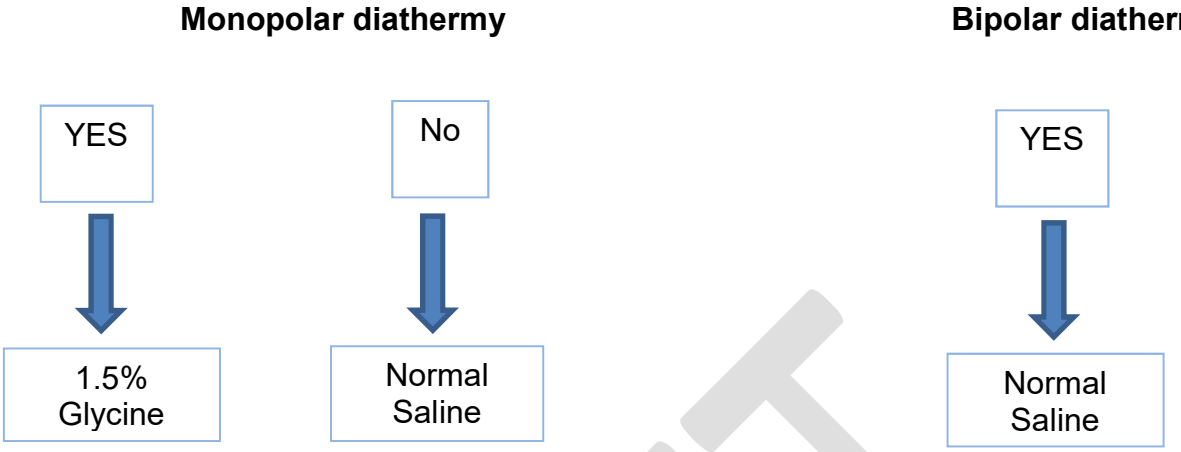
Maximum deficit: Inform surgeon before reach

1.5% Glycine	500 mls – Elderly, comorbidities. 1000 mls – healthy
Normal Saline	1000 mls

Appendix 2

Managing Fluid Media: 3 steps in Theatre

1. Choose Right Fluid



2. Minimise Absorption during surgery
   - When the Fluid bag is 100 cm above the level of the uterus, gravity creates pressure. This is approximately 60-100 mmHg and adequate for most cases.
   - A pressure cuff does not allow precise control of the pressure
   - For cases other than diagnostic hysteroscopy, a fluid management system should be used if available. If not, the lowest pressure possible should be used.

3. Recognise Early if excess absorption has occurred

   Requires accurate measurement of fluid going into the uterus and all fluid coming out, either through the outflow sheath or via the vagina into the collection receptacle.

   A team member should not have other duties to perform while monitoring fluid balance. This should use the attached sheet for intraoperative documentation.

   The operating surgeon should include the fluid deficit in the *Operative Findings* when writing the operative notes

   Complex cases such as intramural fibroids should have preoperative measurement of serum electrolytes. Team brief should include discussion of limiting iv fluids intraoperatively.

   When Glycine is used the procedure should stop when 500ml deficit is reached

   When Normal Saline is used the procedure should stop when 2500mls deficit is reached. In patients with heart failure this threshold should be reduced according to severity of their condition.

Appendix 3

Recommendations

Evidence Level A

1. Intracervical injection of 8 mL of a dilute vasopressin solution (0.05 U/mL) immediately prior to the procedure reduces distending media absorption during resectoscopic surgery. Such administration may also reduce the force required for cervical dilation
2. The uterine cavity distention pressure should be the lowest pressure necessary to distend the uterine cavity and ideally should be maintained below the mean arterial pressure (MAP).

Evidence Level B

3. Excessive absorption of hypotonic fluids such as glycine 1.5% or sorbitol 3% can result in fluid overload and hypotonic hyponatraemia, causing permanent neurologic complications or death.
4. The risk of hypotonic encephalopathy is greater in reproductive-aged women than in postmenopausal women.
5. When compared with electrolyte-free media, saline appears to have a safer profile.
6. Excessive absorption of isotonic fluids such as normal saline can cause severe complications. Although isotonic fluids do not cause cerebral oedema, there is still a mandate for continuous and accurate measurement of input and output for the calculation of fluid absorption.
7. The risk of systemic absorption varies with the procedure and increases when myometrial integrity is breached with procedures such as myomectomy. In such instances, patients should be counselled that more than one procedure may be required.
8. Due to the conflicting evidence regarding their impact on the volume of fluid deficit during resectoscopic surgery, the decision to use a gonadotropin-releasing hormone (GnRH) agonist in premenopausal patients to reduce extent of fluid deficit should be made at the discretion of the provider.

Evidence Level C

9. CO_2 is a suitable medium for the performance of diagnostic hysteroscopy but should not be used for operative hysteroscopy because of its impact on Hysteroscopic visualization and the risk of CO_2 embolus.
10. Before performing operative hysteroscopy with liquid distending medium, it is important to purge the air out of the system and during the procedure to change the liquid-containing bag before it is completely emptied.
11. The risks associated with distending media overload may be reduced by limiting the degree of preoperative hydration with oral or intravenous fluids.
12. Shortly prior to performing resectoscopic surgery, it is advisable to obtain baseline levels of serum electrolytes including sodium, chloride, and potassium in women on diuretics or with medical conditions that may predispose to electrolyte disorders.
13. The following statements on maximum fluid deficits are based on expert opinion. The patient should be carefully evaluated, with consideration to terminating the procedure expeditiously if intravasation is known or thought to reach the volume in these clinical contexts. For elderly patients and others with comorbid conditions including compromised cardiovascular systems, a maximum fluid deficit of 750 mL is recommended.

a. For healthy patients, the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions. This is based on a decrease in serum sodium of 10 mmol, with absorbed volume of around 1000 mL. The maximum limit for isotonic solution is unclear, but 2500 mL has been advocated in the previous AAGL Guidelines. Individualization and the anesthesiologist's opinion should be obtained.
b. When high-viscosity distending media are used, the maximum infused volume should not exceed 500 mL, and in the elderly and those with cardiopulmonary compromise should not exceed 300 mL.

14. When maximum absorption occurs with electrolyte-free distending media, immediate measurement of plasma electrolytes and osmolality is recommended.
15. Normal saline should be used wherever possible for operative hysteroscopic surgery to reduce the risk of hyponatremia and hypo-osmolarity. Normal saline should be used for distention during operative hysteroscopic procedures not requiring the use of monopolar electrosurgical instruments.
16. The surgical team should be prepared to accurately monitor distending fluid medium input and output, including all 3 potential sources: return from the hysteroscope, spill from the vagina, and loss to the floor. An automated system for continuous calculation of fluid deficit is recommended.
17. The use of an automated fluid management system is recommended. Such systems should ideally comprise an infusion pump that allows determination and continuous monitoring of true intrauterine distention pressure and a system for accurate measurement of fluid deficit.
18. The surgical team should, prior to the start of the case, predetermine the maximum acceptable volume of systemically absorbed distending media considering both the medical condition of the patient, and the osmolality and electrolyte content of the media to be used

From:
Practice Committee of the AAGL Advancing Minimally Invasive Gynaecology Worldwide . Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media. Journal of Minimally Invasive Gynaecology (2013) 20, 137–148.

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

Stinson, Emma M

From: Mackle, Eamon <Personal Information redacted by the USI>
Sent: 18 December 2013 17:34
To: Young, Michael; Carroll, Ronan; Brown, Robin
Cc: Simpson, John
Subject: FW: Lynn Lewis - deceased - Coroner's correspondence
Attachments: Policy on surgery for endoscopic tissue resection.docx; Letter to C Harper.docx

Hi Michael, Robin and Ronan

I know that policies have changed in light of the recent case in the UIC. I am attaching correspondence re same and in particular the Belfast Trust's policy for your comments and assuming you agree implementation.

Eamon

From: Simpson, John
Sent: 18 December 2013 15:24
To: McAllister, Charlie; Hogan, Martina; Mackle, Eamon; Burns, Deborah; Marshall, Margaret
Cc: Joyce, Barbara
Subject: FW: Lynn Lewis - deceased - Coroner's correspondence

Fyi
j

From: Johnston, Julian [mailto:Personal Information redacted by the USI]
Sent: 18 December 2013 14:54
To: Stevens, Tony; Alan McKinney (Personal Information redacted by the USI); Calum Macleod; Simpson, John; Charlie Martyn; McAllister, Charlie; Creaney, Brenda; MacLeod, Olive; Rice, Francis; 'Alan.FinnPersonal Information redacted by the USI'; 'Nikki.pattersonPersonal Information redacted by the USI'; Hagan, Chris; Price, John; McClelland, Raymond; Gardiner, George; Johnson, Janet; Austin, Stephen
Cc: Christine Thompson (Personal Information redacted by the USI); Carolyn Harper; Kelly, SharonA; alison.mcmasterPersonal Information redacted by the USI; dorothy.killoughPersonal Information redacted by the USI; White, Laura; Orlaith Morrow; Jack, Cathy; McBride, Michael; Rocks, Dennis; 'McArdle, Charlotte'
Subject: RE: Lynn Lewis - deceased - Coroner's correspondence

Everybody,
Following the course of action agreed (attached), there were 2 items of work asked of me.

1. First draft policy for endoscopic tissue resection.
It has been written with reference to published reviews and policy work sent to me from the BHSCT and other Trusts.
Can it be shared with those working in theatres for surgery on endoscopic tissue resection – urology and gynaecology. It will impact upon and need agreement from surgeons, anaesthetists and theatre staff.
I would be grateful for comments that point out,
- errors of fact
- measures that will, if instituted, lead to a worsening of patient safety.
- measures that will, if instituted, stop surgery proceeding.

I realise that some will find differences in the document from the way they work or like to work; I hope we can achieve a consensus on safe practice that is consistent across the province – I think this is what the Coroner requires.

2. Taking a guide from the Coroner's inquest and the expert reports, I also intend to table a discussion document which could set out proposals for standards for good theatre practice guidelines.

I am also taking the opportunity to collaborate with the Ulster Independent Clinic on all of this work so that (visiting) Medical staff will follow the same guidelines, independent of where they work.

Regards,

Julian R Johnston MD FCARCSI FRCA
Assistant Medical Director
BHSCT
Personal Information redacted by the USI

Co-Chair Standards and Guidelines Committee Standards, Quality and Audit department
Telephone: Personal Information redacted by the USI
If unanswered, contact Christine Murphy : Personal Information redacted by the USI or Jill Shaw O'Doherty : Personal Information redacted by the USI or Simon Dunlop : 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 .

From: Kelly, SharonA
Sent: 16 December 2013 11:41
To: Carolyn Harper
Cc: Christine Thompson (Personal Information redacted by the USI); Johnston, Julian; Stevens, Tony; Alan McKinney (Personal Information redacted by the USI); Calum Macleod; Charlie Martyn; Simpson, John
Subject: FW: Lynn Lewis - deceased - Coroner's correspondence

Dear Dr Harper

Further to your letter of 6 November 2013, please find attached collegiate response from Dr Stevens and the other Medical Directors of the HSC Trusts.

Signed copy to follow.

Regards

Sharon

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: Carolyn Harper [mailto: Personal Information redacted by the USI]
Sent: 06 November 2013 11:10
To: Alan McKinney; Stevens, Tony; Calum MacLeod; Charlie.Martyn Personal Information redacted by the USI ; john.simpson Personal Information redacted by the USI
Cc: michael.mcbride Personal Information redacted by the USI ; 'Charlotte McArdle' (Personal Information redacted by the USI); jleckey.rcj Personal Information redacted by the USI ; David Stewart RQIA; Carolyn Harper; Alan Finn; Creaney, Brenda; Charlotte McArdle; Francis.Rice Personal Information redacted by the USI ; Olive.macleod Personal Information redacted by the USI
Subject: Lynn Lewis - deceased - Coroner's correspondence

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

Dear All
Please see attached correspondence from Dr Carolyn Harper.
Many thanks, Lisa obo Dr Harper

Dr Carolyn Harper FFPH
Executive Medical Director/Director of Public Health Public Health Agency Tel Personal Information redacted by the USI
Email Personal Information redacted by the USI

Trust LOGO

Reference No:

Title:	Policy on the surgical management of endoscopic tissue resection, for example during urological, gynaecological and other relevant surgery.		
Author(s)	List name and titles of lead and additional author(s) or group responsible for drafting policy Include contact details		
Ownership:	Insert name of Director / service area / group / directorate		
Approval by:	Insert name of Trust committee / group responsible for approval	**Approval date:**	Insert date each committee approved
Operational Date:	December 2013	**Next Review:**	December 2014
Version No.	V0.2 **Supercedes**		
Key words:	Endoscopic, Resection, Prostatectomy, Myomectomy, TUR syndrome		
Links to other policies			

Date	Version	Author	Comments
20/11/2013	0.1	SE Trust	Initial Draft
03/12/2013	0.2	JR Johnston	Amalgamation of protocols from 5 Trusts.

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Some endoscopic surgical procedures require the use of an irrigating fluid to dilate the operating field to enable a suitable field of vision and to wash away debris and blood. This includes operations such as,

- transcervical resection of the endometrium (TCRE),
- resection of prostate (TURP) and bladder tumours (TURBT),
- removal of uterine septations, polyps, endometrial ablations and also cystoscopy, arthroscopy, rectal tumour surgery, vesical ultrasonic lithotripsy and percutaneous nephrolithotripsy.

A serious complication of such irrigation is the systemic intravascular absorption of the irrigation fluid to the extent that serious overt symptoms are produced. This policy sets out the steps needed to reduce the risks of that happening. Using the national policies and guidelines identified in section 7 along with work already done within the province, its aim is to establish a regionally agreed set of precautions. Some of the recommendations can be instituted now and some will depend on longer term financing of equipment.

1.2 Irrigation fluids used

The irrigation fluid used for these electrosurgical procedures should,

- have neutral visual density so that the surgeon‘s view is not distorted.
- be nonconductive so the electrical current is not dissipated and can remain concentrated at the cutting point.
- be non-haemolytic so that haemolysis does not occur if it enters the circulation.

In the past, sterile water was used as the irrigant but was associated with significant morbidity because of water intoxication and intravascular haemolysis.

Modern non-electrolytic solutions containing glycine 1.5%, mannitol or sorbitol are optically clear and were introduced to prevent haemolysis, without dispersing the electric current used for cutting with the resectoscope. Their use in irrigation solutions has reduced the occurrence of significant haemolysis and death.

The most commonly used irrigation fluid is 1.5 % **glycine solution,** a non-essential amino acid with a low cost and lack of allergic reactions**.** However, it has an osmolality of 200 mOsm/L which is much lower than that of blood and large amounts of this hypotonic irrigation fluid, required to facilitate the procedure, may be absorbed systemically through a vascular bed. This may cause several serious complications known as the **TUR syndrome** which can occur in a variety of surgical disciplines.

Normal saline is used for irrigation with the bipolar resectoscope. Because of its greater plasma volume expansion, acute volume overload is more likely during absorption of normal saline compared with other irrigating solutions.

Moreover, it can cause hyperchloraemic acidosis due to its excessive content of chloride. Pulmonary oedema is a reported consequence.

1.3 TUR syndrome

This is manifested mainly through a classic triad of,

- fluid overload - acute changes in intravascular volume leading to circulatory overload, pulmonary oedema, cardiac failure and even cardiac arrest.
- dilutional hyponatraemia causing central nervous system (CNS) effects such as cerebral edema leading to agitation, confusion, convulsions and coma.
- direct toxicity and metabolism of glycine which may also cause CNS symptoms, most commonly transient blindness and CNS depression as it is an inhibitory neurotransmitter.

1.4 Purpose

This policy outlines a set of principles designed to reduce the development of the TUR syndrome.

1.5 Objectives

To reduce the likelihood of developing the TUR syndrome through,

- correct patient selection and preoperative preparation.
- selection of an appropriate surgical technique.
- the use of precautionary principles during the surgical procedure, including the correct procedure to follow in the safe management of irrigating fluid for urology and gynaecology.
- the application of monitoring aimed at detecting the early warning signs.
- establishing a theatre regime based on good theatre practice principles aimed at reducing the development of the TUR syndrome.

2.0 SCOPE OF THE POLICY

This policy applies to all staff who may be involved in the care of a patient in theatre who receives irrigating fluid into the bladder or uterus or any other organ where significant intravenous fluid absorption is a realistic possibility.

It applies to medical staff, nursing staff, midwives, operating department practitioners, technical staff, physicians' assistants (anaesthesia) and other theatre healthcare workers.

This policy does not cover the methods of treatment for the TUR syndrome.

3.0 ROLES/RESPONSIBILITIES

Medical staff - by careful consideration of the therapeutic choices when planning the service for endoscopic resection, can reduce the likelihood of the development of the TUR syndrome.

Management – by actively supporting the introduction of therapeutic modalities that aim to reduce the incidence of the TUR syndrome.

All staff involved in the care of the patient, especially in theatre, are responsible for implementing and adhering to the policy principles.

Each ward/theatre sister/charge nurse/clinician is responsible for ensuring staff comply with this policy and all relevant staff have the responsibility to ensure that they read and comply with the policy contents.

In the event of an untoward incident an IR1 form should be completed by either the medical officer or nurse in charge of the patient's care.

4.0 POLICY PRINCIPLES

4.1 Definitions

Osmolality: The concentration of osmotically active particles in a solution.

Hypertonic: Higher osmolality (concentration of particles) than what is found in normal cells.

Hyponatraemia: Lower sodium concentration than normally found in plasma.

Hypotonic (or hypo-osmolar): Lower osmolality (concentration of particles) than what is found in normal cells.

Resectoscope: An endoluminal surgical device comprising an endoscope (hysteroscope or cystoscope), sheaths for inflow and outflow, and an ''element'' that interfaces a specially designed electrode (or pair of electrodes) with a radiofrequency electrosurgical generator.

Policy Principles

4.2 Irrigating fluid is most frequently absorbed directly into the vascular system when a vein has been severed by electrosurgery. The driving force is the fluid pressure; the volume of fluid absorbed depending on the,

- duration of the procedure and resection time,
- degree of opening of blood vessels during surgery ,
    - vascularity of the diseased prostate, uterus, fibroid.
    - surgical disruption of the bladder, uterine vessels.
    - capsular or uterine wall perforation or apparent damage to a venous sinus.
- pressure of the distending fluid within the bladder or uterus,
    - height of the irrigation fluid bag above the patient (increased height implies increased hydrostatic pressure driving the fluid intravenously).
    - distension pressure applied to the irrigation fluid.

For safe endoscopic resection using irrigation fluid, the following topics should be covered within a set of policy principles,

1. Preoperative workup.
2. Selection of surgical technique.
3. Identification, control and management of haemorrhage.
4. Control of the absorption of irrigation fluid.

a. Dilutional Hyponatraemia.
b. Fluid overload.
c. Glycine toxicity.

5. Theatre environment.
   a. Decision making processes.
   b. Team dynamics.
   c. Lack of knowledge of the potential problems.

4.2.1 Preoperative workup

Some of these procedures are carried out on a predominantly elderly population with a higher incidence of coexisting disease. BPH affects 50% of males at 60 years and 90% of 85-year-olds and so TURP is most commonly performed on elderly patients, a population group with a high incidence of cardiac, respiratory and renal disease.

Careful preoperative workup of the patient should include, for example,

- a robust consent process leading to a truly informed patient aware of the hazards of endoscopic resection using irrigation fluids.
- a thorough physiological assessment with attention paid to risk factors such as hypertension, ischaemic heart disease, cardiac failure, anaemia.
- standard haematology and electrolyte analysis - to include a recent haemoglobin, serum sodium.
- careful consideration regarding blood grouping and cross-matching.
- recent investigations aimed at establishing the pathological anatomy and degree of surgical risk especially haemorrhage e.g. ultrasound scan.
- the ready availability of reports of such investigations.
- the timely commencement of any adjuvant therapy prior to the surgery e.g. before TCRE, especially if it helps to reduce the risk of haemorrhage and/or causes a reduction in tumour size.

4.2.2 Selection of surgical technique

All of the surgical teams (urology, gynaecology) in NI, practicing this type of surgery, should become fully cognoscente of the risks of the TUR syndrome and work together to develop a co-ordinated regional approach where they take steps to,

- agree a programme of change for the cessation of glycine use.
- develop or adopt surgical techniques that do not rely on glycine as an irrigant.
- use instruments and equipment that help to control or reduce vesical or uterine pressure.
- establish a set of safe practice standards.

Urology

Absorption in excess of 1 litre of glycine solution, which is associated with a statistically increased risk of symptoms, has been reported in 5–20% of the TURPs performed. Extravasation is the cause in ~20% of these patients.

While electrolyte-containing solutions such as normal saline (NS) are not suitable for RF surgery with monopolar RF systems, the development of

bipolar radiofrequency (RF) instrumentation for endoscopic resection procedures has allowed the application of NS as a distending medium.

Therefore, the adoption of bipolar TURP or laser prostatectomy allows NS irrigation in urology and permits the removal of glycine and its inherent risks from theatre. The risks of the hyponatraemic and hypo-osmolar aspects of the TUR syndrome are eliminated.

However, it should be remembered that the use of NS is not without risk because there will still be fluid absorption with plasma volume expansion. Some consider acute volume overload is more likely during absorption of normal saline compared with other irrigating solutions.

As long as they are proven to be safe and effective as judged by the NICE interventional procedure programme, bipolar RF systems and other technique e.g. laser systems, should be introduced regionally and the use of glycine as a irrigant terminated.

Gynaecology

Fluid absorption is slightly more common during TCRE than during TURP. The first generation endometrial ablative techniques including TCRE and rollerball endometrial ablation (REA) are all endoscopic procedures. Their effectiveness (in comparison with hysterectomy - the existing gold standard) has been demonstrated in a number of randomised controlled trials. Although less morbid than hysterectomy, they are associated with a number of complications including uterine perforation, cervical laceration, false passage creation, haemorrhage, sepsis and bowel injury and, importantly, the fluid overload and hyponatraemia associated with the use of 1.5% glycine irrigation fluid resulting in the serious and occasionally fatal consequences discussed above.

There are now second generation ablative techniques which do not require the use of electrocautery or the use of glycine or other distension fluids. They avoid the serious risk of hyponatraemia and represent simpler, quicker and potentially more efficient means of treating menorrhagia. Examples of second generation ablative techniques are fluid filled thermal balloon endometrial ablation (TBEA), radiofrequency (thermoregulated) balloon endometrial ablation, hydrothermal endometrial ablation, 3D bipolar radiofrequency endometrial ablation, microwave endometrial ablation (MEA), diode laser hyperthermy, cryoablation and photodynamic therapy.

As long as they are proven to be safe and effective as judged by the NICE interventional procedure programme, the use of second generation ablative techniques and bipolar RF systems should be introduced regionally and the use of glycine as a irrigant terminated.

4.2.3 Identification, control and management of haemorrhage.

Blood loss can be difficult to quantify and may be significant. Close attention to the patient's clinical state and good communication between surgeon, anaesthetist and the theatre team is vital.

Because of generalised physiological effects of haemorrhage and the increased likelihood of fluid absorption when using irrigation fluid, the presence of significant bleeding should act as a trigger for,

- increased vigilance for development of fluid overload, hyponatraemia.
- additional help from medical and nursing staff to assist by scrubbing in.
- increased frequency of haemoglobin and/or haematocrit measurements.
- preparation of blood for cross matching.
- cessation of the operation once bleeding is controlled.

4.2.4 Control of the absorption of irrigation fluid

The choice of surgical technique and equipment may reduce the complications from irrigation fluid especially if glycine use stops but continued attention to controlling fluid absorption will still be needed with normal saline.

Until glycine use stops, symptoms related to fluid absorption will develop in 3 – 5% of patients with neurological symptoms being prominent. To control the effects of fluid absorption, the theatre team should pay particular attention to

a) hyponatraemia
b) fluid volumes.

a. Dilutional Hyponatraemia

The uptake of 1000 ml of fluid corresponds to an acute decrease in the serum sodium concentration of 5-8 mmol.l^{-1}. Encephalopathy, seizures and even cerebral oedema may develop when the sodium concentration falls below 120mmol/l. However, even markedly hyponatraemia patients may show no signs of water intoxication. The crucial physiological derangement of CNS function is not just hyponatraemia *per se*, but also the presence of acute hypo-osmolality.

Also, a patient's serum sodium concentration and osmolality may continue to decrease for some time after the procedure because irrigant can be slowly absorbed from the perivesicular and retroperitoneal spaces. Therefore, the TUR syndrome can start 4 to 24 hours later – intraoperatively, in the recovery ward or back in the ward.

Whereas hyponatraemia occurs with equal frequency in men and women, premenopausal women are 25 times more likely to die or have permanent brain damage than men or postmenopausal women, most likely an oestrogen effect. This effect is compounded because fluid absorption is slightly more common during TCRE than during TURP.

Serum Sodium measurement

Monitoring serum sodium concentration during TURP is common practice and a low value will confirm the diagnosis of hyponatraemia and is effective for assessing intravascular absorption. Significant decreases from a normal preoperative level can occur after just 15 minutes of starting resection. Levels below 120 mmol/L are invariably symptomatic and a rapid fall is more likely to produce symptoms.

Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care. It brings the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results quicker, which allows for immediate clinical management decisions to be made. They can be used to measure haematocrit, determine haemoglobin and measure serum electrolytes.

Using POCT apparatus for the measuring and having a result in minutes is a significant aid in diagnosing hyponatraemia as early as possible. Such POCT equipment must/should be available when these techniques for tissue resection are used.

It is often only measured at the end of surgery but this monitoring technique is best applied before and repeatedly during surgery so that it can act as a warning system for hyponatraemia. Any patient receiving glycine in theatre must have a measurement(s) made,

- as a preoperative baseline prior to the start of surgery.
- intermittently throughout a case as a routine.
- if there is a 1000mls deficit.
- if the surgery is longer than 30 minutes.

Staff must be readily available who are trained to use this POCT equipment.

b. Fluid volumes

Estimates of amount of fluid absorbed range from 10 – 30 mls per minute of resection time; over a 45 – 60 minute case that could equate to 1 – 1.8 litres. The best management of fluid overload is to prevent its occurrence by constantly and accurately monitoring the distending fluid input and output. The surgeon should be notified about ongoing fluid absorption early enough for steps to be taken to prevent excessive absorption.

Volumetric fluid balance is based on the calculation of the difference between the amount of irrigating fluid used and the volume recovered. Positive values are regarded as absorption.

However, calculation of systemic absorption is complicated by 4 factors:

1. It may be difficult to collect all of the media (fluid, urine and blood) that passes out of the operative area, including that which falls on the procedure or operating room floor.
2. the actual volume of media solution in 3L bags is typically more than the labelled volume.
3. difficulties in estimating the volume of media left in a used or ‘emptied’ infusion bag.
4. systemic absorption that in some instances may occur extremely rapidly.

While these factors can make volumetric fluid balance measurement an unreliable tool, it is considered a minimum necessity that the theatre team measure fluid input and overt output during such surgery and calculate a running deficit.

Bearing these difficulties in mind, a member of staff must be assigned to this duty before the start of every case. They will need to be proficient and practiced in this technique and must take responsibility for measuring the input and output, calculating the deficit and recording these details. They should remain in theatre for the duration of the procedure, in the same fashion as the surgeon.

The simplest method of monitoring comprises manually subtracting the volume collected from the volume infused, considering all sources including the resectoscope outflow; the ‘‘perineal’’ collection drape, which includes a pouch to capture spilled fluid and special apparatus to collect fluid spilled on the floor. Specialist draping systems are readily available for such fluid collection and should be used. Even so, accurate measurement can be difficult.

Each patient who has any irrigating fluid erected must have a fluid management chart (appendix X) commenced. Measuring the input and outputs and calculating the deficit should be done as a minimum every time a bag (often 3 litre) is hung up and the details clearly expressed verbally to the surgeon and all other theatre staff. These details should also be recorded on the dedicated fluid management chart. They might also be displayed on a white marker board in the theatre.

A second bag should not be commenced until a deficit amount has been calculated and it is agreed to be safe to proceed. It should be unusual to need a third bag but if it is, it should be done under the same circumstances. (??) At the end of the procedure, the final calculations must be made; the inputs, outputs and deficit. These should be expressed clearly to the surgeon and anaesthetist and recorded on the chart.

The fluid management chart must follow the patient into the recovery ward. All fluid balances must be handed over to recovery ward staff as part of the normal nursing and medical handover. The chart is then to be filed in the clinical record.

The limitations of such manual measurement may make it preferable to use an automated fluid measurement system that takes into account an exact measurement of infused volume as well as all of the potential sources of returned media. Such systems provide continuous measurement of the amount of distending media absorbed into the systemic circulation by using the weight of the infused volume. Such systems need evaluated in NI.

Maximum fluid deficit

Prevention of the TUR syndrome requires that the team have a protocol for responding to any escalating fluid absorption and there must be agreed volume thresholds for action. These thresholds may necessarily vary somewhat, depending on a number of factors that include the nature of the surgery, the nature of the media (isotonic or hypotonic) and the patient’s baseline and intraoperative medical condition e.g. presence of haemorrhage.

It has been shown with routine postoperative CT imaging of the brain that cerebral oedema can occur with as little as 500 mL of hypotonic solutions. The surgeon and anaesthetist must be informed by the nurse when there is a 500mls deficit. The nurse must ensure that the surgeon and anaesthetist acknowledge that they have received this information. This must be documented in the notes along with any action taken.

A 500 ml threshold may be appropriate for those who are older and/or medically compromised, but for healthy individuals, absorption of up to 1000 mL can generally be tolerated. The surgeon and anaesthetist must be informed by the nurse when there a 1000mls deficit. The nurse must ensure that the surgeon and anaesthetise acknowledge that they have received this information. This must be documented in the notes along with any action taken.

For elderly (? define) patients and others with comorbid conditions including compromised cardiovascular systems, a maximum fluid deficit of 500 mL is recommended. Surgery must stop unless haemorrhage needs controlled.

For healthy patients, the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions (glycine). Surgery must stop unless haemorrhage needs controlled.

The maximum limit for isotonic solution (normal saline) is unclear, but 2500 mL has been advocated. Surgery must stop unless haemorrhage needs controlled.

Further preventative measures

There are several precautions that reduce the risk of fluid absorption and its associated dangers. These are especially important because calculating the fluid absorption can be difficult.

These include limiting the,

1. Distension pressure by,
   - keeping the uterine cavity distention pressure at the lowest pressure necessary to distend the uterine cavity consistent with good visualisation and ideally should be maintained below the mean arterial pressure (MAP).

     It is estimated that approximately 40mmHg distending pressure is required to obtain clear vision. At pressures between 40mmHg and approximately 100mmHg (MAP), blood will continue to escape from disrupted capillaries until it is stopped by the tamponade. At this point, when continuous flow is used through the resectoscope, the blood within the cavity will be removed and a clear field of vision will be maintained. Dropping the pressure permits further bleeding. If the pressure is raised above the MAP, the pressure not only prevents the flow of blood out of disrupted vessels but actually forces the distension fluid medium in the reverse direction into the vessels.
   - attempting to limit the height of the irrigating solution container to 60 cm (figure to be agreed) above the patient and certainly never above 100cm.

Theatre teams must have a procedure for checking and maintaining an agreed height.
- not applying pressure bags to the irrigation fluid bag.
- insufflating irrigation fluid by using a pressure controlled pump device.

2. Operation time - restricting resection time to 60 minutes. Theatre teams must have an establish mechanism for measuring time and procedures for alerting surgeon and anaesthetist.

4.2.5 Theatre environment

A good theatre environment in terms of team dynamics is essential for the safe performance of these surgical procedures. There must be careful monitoring of fluid balance along with the clear communication of that balance to the surgical and anaesthetic members of the team.

- Theatre staff must always be aware of the potential hazards of, and equipment used, for any surgical procedure before it is performed.
- One member of the theatre team must be assigned to the duty of collecting, calculating and recording the irrigation volumes in/out and deficits. They will need to be proficient and practiced in this technique. It would not be expected that the surgeon should have to operate and also supervise this function at the same time. They should remain in theatre for the duration of the procedure, in the same fashion as the surgeon.
- Medical staff must always have situational knowledge of the theatre environment that they are working in and the availability (or non-availability) of any theatre equipment they consider necessary. They must be informed, in good time, of any equipment that is not working.
- Nursing staff should have a working knowledge of any equipment being used in their theatre or have the immediate presence of technical staff who do have that knowledge.

WHO checklist

Completion of the WHO surgical checklist with the sign in, time out and sign out must be adhered to. This will allow a surgical, anaesthetic and theatre team brief at the beginning for the whole theatre team and an opportunity to check that everything is in place to perform the biochemical and volumetric monitoring.

It will also ensure at the sign out that any problems e.g. over a fluid deficit, are identified early. On a regional basis, adoption of a modified WHO checklist for this kind of procedure should be investigated and piloted.

5.0 IMPLEMENTATION OF POLICY

This policy, after it is agreed, is to be implemented throughout NI in each of the 5 Trusts.

5.1 Resources

There will be resource implications in terms providing surgical equipment that can be used without needing glycine as an irrigant, POCT monitoring equipment for theatres and training for staff.

6.0 MONITORING

TBC

7.0 EVIDENCE BASE / REFERENCES

1. R. G. Hahn. Fluid absorption in endoscopic surgery. Br J Anaesth 2006; 96: 8–20.
2. Practice Committee of the AAGL Advancing Minimally Invasive Gynaecology Worldwide . Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media. Journal of Minimally Invasive Gynaecology (2013) 20, 137–148.
3. Dietrich Gravenstein. Transurethral Resection of the Prostate (TURP) Syndrome: A Review of the Pathophysiology and Management. Anesthesia & Analgesia. 1997; 84: 438-46
4. Varol N, Maher P et al. A literature review and upodate on the prevention and management of fluid overload in endometrial and hysteroscopic surgery. Gynaecological Endoscopy 2002; 11: 19-26
5. Blandy JP, Notley RG, Reynard JM. Transurethral Resection. Pub, Taylor and Francis 2005. http://www.baus.org.uk/Resources/BAUS/Transurethral%20Resection.pdf
6. Marszalek M, Ponholzer A et al. Transurethral Resection of the Prostate. European urology supplements 8 (2009) 504–512.
7. Indman PD, Brooks PG et al. Complications of fluid overload from Resectoscopic surgery. J Amer Assoc of Gynaecolig laparoscopists 1998; 5: 63-67.
8. Hawary A, Mukhtar K et al.Transurethral Resection of the Prostate Syndrome: Almost Gone but Not Forgotten. Journal of Endourology 2009; 23: 2013-20.

8.0 CONSULTATION PROCESS

Insert a list of those groupings consulted in the development of this policy e.g. Trade Unions, Specialist Committees, User groups, Section 75 groups.

9.0 APPENDICES / ATTACHMENTS

Appendix 1 = draft Theatre record form
Appendix 2 = Theatre based Summary form.
Appendix = Evidence based recommendations from AAGL Practice Committee.

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. ☐

SIGNATORIES

_____ **Date:** _____

Author

_____ **Date:** _____

Director

Trust LOGO

Peri-operative fluid recording chart

Consultant: _____ Date: _____ Ward: _____ Operation: _____	Addressograph Label

Irrigation fluid Start time: _____= 0 mins___ Type of fluid used _____

Serum Sodium: = _____ mmol/L Haemoglobin: _____g/dL.

Time (mins)	Irrigation In (mls)	Running total In	Irrigation Out (mls)	Deficit (mls)	Running deficit Out	Serum Sodium	Sign
5						Mmol/L	
10						Mmol/L	
15						Mmol/L	
20						Mmol/L	
25						Mmol/L	
30						Mmol/L	
35						Mmol/L	
40						Mmol/L	
45						Mmol/L	
50						Mmol/L	
55						Mmol/L	
60						Mmol/L	
						Mmol/L	

Total fluid In	=	Surgeon Signature	
Total Fluid Out	=	Anaesthetist Signature	
Deficit	=	Nurse Signature	

Trust LOGO

Continued.

Time (mins)	Irrigation In (mls)	Running total In	Irrigation Out (mls)	Deficit (mls)	Running deficit Out	Serum Sodium	Sign
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	

Irrigation In = after each fluid bag (mls)	Irrigation Out = record - suction canister volumes (mls) - fluid in drapes - fluid from floor suction
Record amount 'in' each time use Ellick evacuator	Record amount 'out' each time use Ellick evacuator

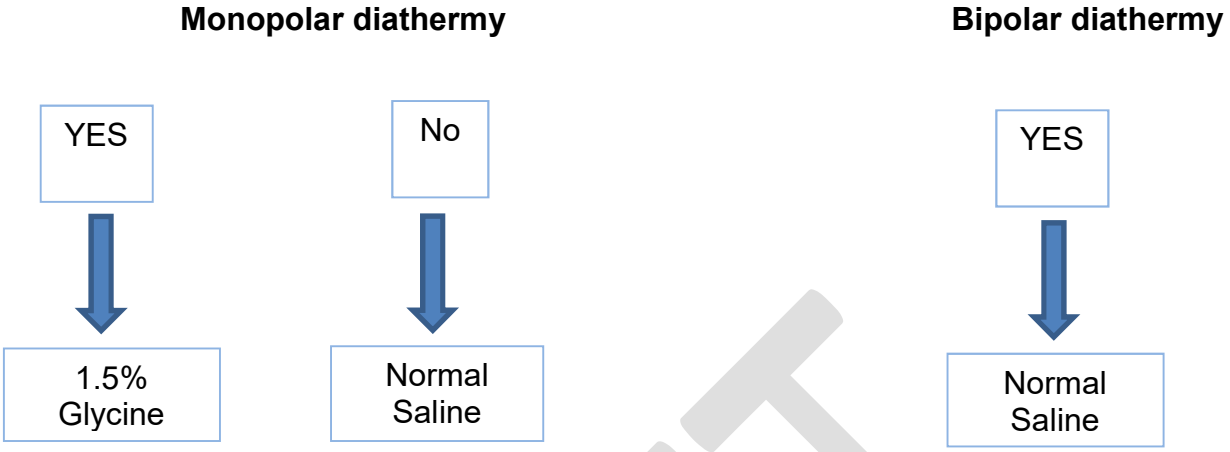
Maximum deficit: Inform surgeon before reach

1.5% Glycine	500 mls – Elderly, comorbidities. 1000 mls – healthy
Normal Saline	1000 mls

Appendix 2

Managing Fluid Media: 3 steps in Theatre

1. Choose Right Fluid



2. Minimise Absorption during surgery
   - When the Fluid bag is 100 cm above the level of the uterus, gravity creates pressure. This is approximately 60-100 mmHg and adequate for most cases.
   - A pressure cuff does not allow precise control of the pressure
   - For cases other than diagnostic hysteroscopy, a fluid management system should be used if available. If not, the lowest pressure possible should be used.

3. Recognise Early if excess absorption has occurred

   Requires accurate measurement of fluid going into the uterus and all fluid coming out, either through the outflow sheath or via the vagina into the collection receptacle.

   A team member should not have other duties to perform while monitoring fluid balance. This should use the attached sheet for intraoperative documentation.

   The operating surgeon should include the fluid deficit in the *Operative Findings* when writing the operative notes

   Complex cases such as intramural fibroids should have preoperative measurement of serum electrolytes. Team brief should include discussion of limiting iv fluids intraoperatively.

   When Glycine is used the procedure should stop when 500ml deficit is reached

   When Normal Saline is used the procedure should stop when 2500mls deficit is reached. In patients with heart failure this threshold should be reduced according to severity of their condition.

Appendix 3

Recommendations

Evidence Level A

1. Intracervical injection of 8 mL of a dilute vasopressin solution (0.05 U/mL) immediately prior to the procedure reduces distending media absorption during resectoscopic surgery. Such administration may also reduce the force required for cervical dilation
2. The uterine cavity distention pressure should be the lowest pressure necessary to distend the uterine cavity and ideally should be maintained below the mean arterial pressure (MAP).

Evidence Level B

3. Excessive absorption of hypotonic fluids such as glycine 1.5% or sorbitol 3% can result in fluid overload and hypotonic hyponatraemia, causing permanent neurologic complications or death.
4. The risk of hypotonic encephalopathy is greater in reproductive-aged women than in postmenopausal women.
5. When compared with electrolyte-free media, saline appears to have a safer profile.
6. Excessive absorption of isotonic fluids such as normal saline can cause severe complications. Although isotonic fluids do not cause cerebral oedema, there is still a mandate for continuous and accurate measurement of input and output for the calculation of fluid absorption.
7. The risk of systemic absorption varies with the procedure and increases when myometrial integrity is breached with procedures such as myomectomy. In such instances, patients should be counselled that more than one procedure may be required.
8. Due to the conflicting evidence regarding their impact on the volume of fluid deficit during resectoscopic surgery, the decision to use a gonadotropin-releasing hormone (GnRH) agonist in premenopausal patients to reduce extent of fluid deficit should be made at the discretion of the provider.

Evidence Level C

9. CO_2 is a suitable medium for the performance of diagnostic hysteroscopy but should not be used for operative hysteroscopy because of its impact on Hysteroscopic visualization and the risk of CO_2 embolus.
10. Before performing operative hysteroscopy with liquid distending medium, it is important to purge the air out of the system and during the procedure to change the liquid-containing bag before it is completely emptied.
11. The risks associated with distending media overload may be reduced by limiting the degree of preoperative hydration with oral or intravenous fluids.
12. Shortly prior to performing resectoscopic surgery, it is advisable to obtain baseline levels of serum electrolytes including sodium, chloride, and potassium in women on diuretics or with medical conditions that may predispose to electrolyte disorders.
13. The following statements on maximum fluid deficits are based on expert opinion. The patient should be carefully evaluated, with consideration to terminating the procedure expeditiously if intravasation is known or thought to reach the volume in these clinical contexts. For elderly patients and others with comorbid conditions including compromised cardiovascular systems, a maximum fluid deficit of 750 mL is recommended.

a. For healthy patients, the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions. This is based on a decrease in serum sodium of 10 mmol, with absorbed volume of around 1000 mL. The maximum limit for isotonic solution is unclear, but 2500 mL has been advocated in the previous AAGL Guidelines. Individualization and the anesthesiologist's opinion should be obtained.
b. When high-viscosity distending media are used, the maximum infused volume should not exceed 500 mL, and in the elderly and those with cardiopulmonary compromise should not exceed 300 mL.

14. When maximum absorption occurs with electrolyte-free distending media, immediate measurement of plasma electrolytes and osmolality is recommended.
15. Normal saline should be used wherever possible for operative hysteroscopic surgery to reduce the risk of hyponatremia and hypo-osmolarity. Normal saline should be used for distention during operative hysteroscopic procedures not requiring the use of monopolar electrosurgical instruments.
16. The surgical team should be prepared to accurately monitor distending fluid medium input and output, including all 3 potential sources: return from the hysteroscope, spill from the vagina, and loss to the floor. An automated system for continuous calculation of fluid deficit is recommended.
17. The use of an automated fluid management system is recommended. Such systems should ideally comprise an infusion pump that allows determination and continuous monitoring of true intrauterine distention pressure and a system for accurate measurement of fluid deficit.
18. The surgical team should, prior to the start of the case, predetermine the maximum acceptable volume of systemically absorbed distending media considering both the medical condition of the patient, and the osmolality and electrolyte content of the media to be used

From:
Practice Committee of the AAGL Advancing Minimally Invasive Gynaecology Worldwide . Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media. Journal of Minimally Invasive Gynaecology (2013) 20, 137–148.

Belfast Health and Social Care Trust

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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

Stinson, Emma M

From:	Simpson, John < Personal Information redacted by the USI >
Sent:	08 November 2014 14:16
To:	Marshall, Margaret
Cc:	Mackle, Eamon; Hogan, Martina; Burns, Deborah; Young, Michael; Sim, David; Rice, Francis; McAllister, Charlie; Brennan, Anne
Subject:	FW: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014
Attachments:	Endoscopic Distending Fluid - 3rd Nov 2014 - Medical Leaders Forum.pdf

Margaret, where are we with this?
john

From: Rocks, Dennis [mailto: Personal Information redacted by the USI]
Sent: 07 November 2014 15:56
To: Rocks, Dennis; Dr Alan McKinney; Dr Alan McKinney - PA; Dr Alan McKinney - PA; Dr Cathy Jack; Dr Cathy Jack - PA; Dr Greg Furness; Dr Greg Furness - PA; Simpson, John; Feely, Roisin; Mr Charlie Martyn; Mr Charlie Martyn - PA; NI Ambulance Service; NI Ambulance Service - PA; Carolyn Harper; David Stewart; dawn.clarke Personal Information redacted by the USI ; Dowie Joanne; Dr Gavin Lavery; Morris Kieran; PA - Dr Carolyn Harper; PS - Dr David Stewart; Sloan Harper; Tom Trinick; Keith Gardiner; Prof. Pascal McKeown; Prof. Pascal McKeown - PA; Prof. Stuart Elborn; Pauline Dardis; PS Prof Elborn; Johnston, Julian
Cc: Boyle, Margaret (DHSSPS); Chada, Naresh; Kilgallen, Anne; Reaney, Elizabeth (Dr); McBride, Michael; McMahon, Nigel; McMaster, Ian; Woods, Paddy; McArdle, Charlotte; Henderson, Elizabeth; Bradley, Fergal; Dillon, Edmond; Wilkinson, Irene
Subject: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

All

Please see below draft account of minutes and associated Action Point of Dr Johnston's item on

Endoscopic Distending Fluids- Urology and Gynaecology
(Copy Slides attached)

Dr Julian Johnston, BHSCT, gave a presentation on risks associated with endoscopic distending fluids and a proposal on a safer approach to using endoscopic distending fluids. He advised that he has had detailed discussions with Gynaecologists and Urologists on the issue and following the outcome of this meeting would have wider discussions.

The meeting was informed that a commonly used irrigation fluid is 1.5 % glycine solution as it is non-conductive but is hypotonic & hypoosmolar and can lead to significant systemic intravascular absorption to the extent that serious overt symptoms are produced - the TUR syndrome of fluid overload, dilutional hyponatraemia and direct toxicity of glycine.

He advised that a Coroner's inquest into the death of a 38 year old female resulted in the Coroner requesting that a 'collegiate response' be provided and assurance be given that a similar fatality is not repeated.

The causative themes identified during the inquest were,

- Issues with preoperative workup.

• Haemorrhage.
• Dilutional Hyponatraemia, Fluid overload, Glycine toxicity.
• Decision making processes, Team dynamics.
• Lack of knowledge of the potential problems.

He emphasised the following requirements needed to reduce the likelihood of developing the TUR syndrome:-

• correct patient selection and preoperative preparation.
• selection of an appropriate surgical technique.
• selection of a surgical technique that allows the choice of the safest irrigation fluid.
• the use of precautionary principles during the surgical procedure which prevent significant irrigating fluid absorption.
• application of monitoring aimed at detecting the early warning signs of TUR syndrome.
• establishing a theatre regime based on good theatre practice principles aimed at reducing the development of TUR syndrome.

The presentation outlined comparisons between techniques supported by evidence, from various sources such as NICE, Royal College of Obstetricians and Gynaecologists, The Cochrane Collaboration, BUPA and the British Fibroid Trust, which supported .
• eventual cessation of the use of glycine.
• introduction of surgical techniques that allow the cessation of the use of glycine.
• theatre and surgical practices which limit the absorption of fluids.
• use of monitoring to give an early warning of hyponatraemia

There was discussion on

• the need for the monitoring and measuring of the use of fluid, especially if that fluid was glycine, • identification and elimination of deficits in team dynamics and good theatre practice • challenge of clinical governance within Trusts and Independent Sector • the overwhelming evidence to move towards Bipolar techniques with the possible phasing out of monopolar technique; if glycine is continued to be used it must be monitored in line with policy and governance.
• Funding and transitional period
• training implications, how quick this can be achieved based on BHSCT Urology switch to Bipolar technique • use of interim policy or complete piece with policy set out, issued and implemented

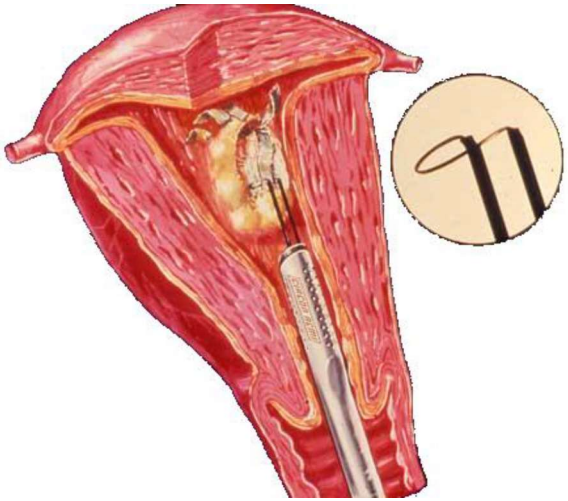
There was general agreement on the need to endorse a single regional approach with an initial need to raise awareness of this issue with relevant clinicians.

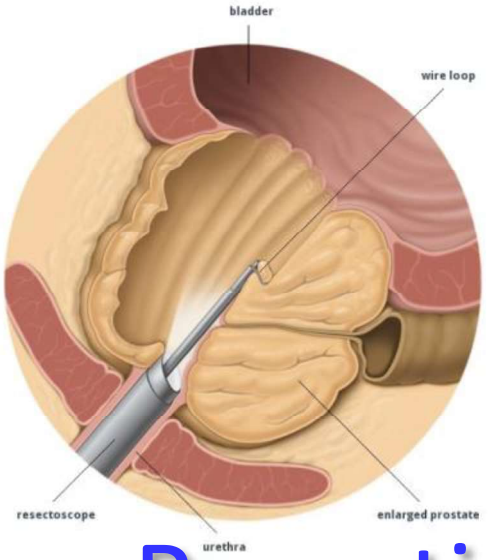
Action Point:
1. Dr Julian Johnston to further discuss first draft of regional policy with Urology & Gynaecology Consultants, relevant clinical teams and personnel in BHSCT.
2. Dr Johnston to copy draft policy and presentation to Trust Medical Directors to allow discussions with relevant teams
3. Feedback to be sent to Dr Paddy Woods and copied to Dr Johnston within 1 month

Endoscopic Tissue Resection

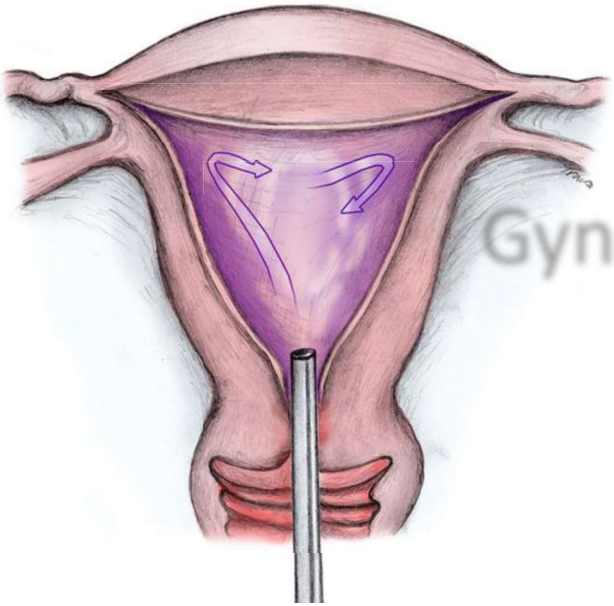
Gynaecology & Urology

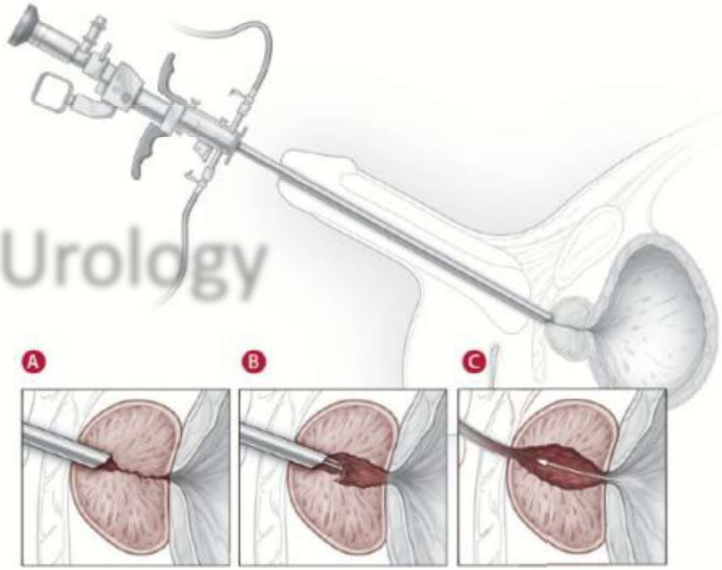
Julian R Johnston



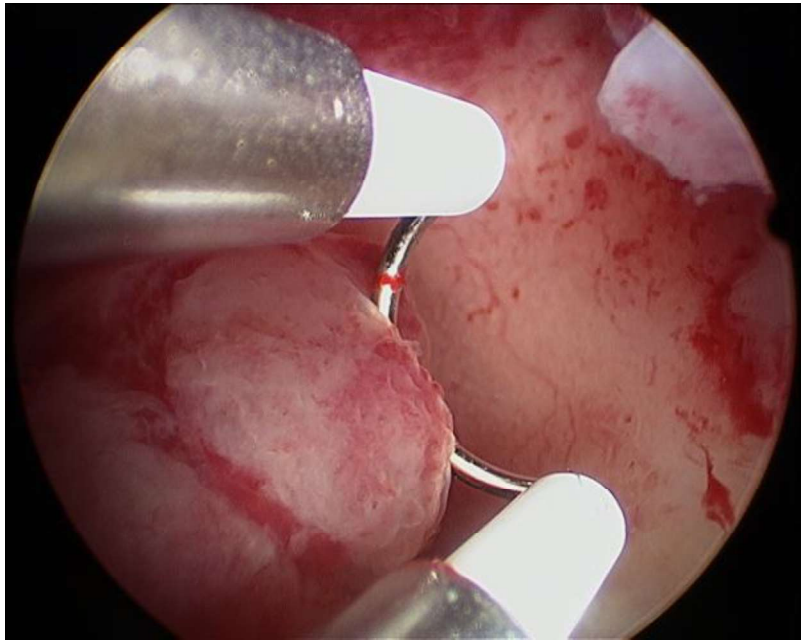


Endoscopic Tissue Resection





Distending fluid



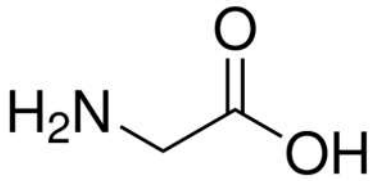
- Clear vision, transparent,
- Non-conductive,
- Electrically inert,
- Isotonic,
- Non-haemolytic

Commonest in use

- Glycine 1.5% solution

Distending fluid

Glycine 1.5% solution

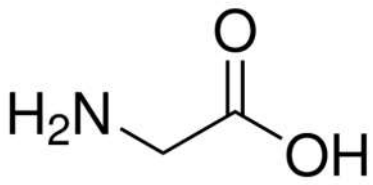


- Clear
- Non-conductive
  - Sodium free
- Non-haemolytic
- Low cost
- Non- allergic

- Hypotonic, Hypoosmolar
- 200 mosmol.kg^{-1}
- [Plasma = 290 mosmol.kg^{-1}]
- Metabolised to ammonia
- Inhibitory transmitter in retina

Distending fluid

Glycine 1.5% solution



- Clear
- Non-conductive
  - Sodium free
- Non-haemolytic
- Low cost
- Non- allergic

- **Hypotonic, Hypoosmolar**
  With
  - **Haemorrhage**
  - **Open vasculature**
  - **↑ Intrauterine pressure**
  - **↑ Intravesical pressure**

↳ Systemic absorption

↳ TUR syndrome

TransUrethral Resection (TUR) Syndrome

- Iatrogenic form of acute water intoxication
- Combination of
  - fluid overload
  - hyponatraemia

- Fluid overload
  - Cardiac failure
  - Pulmonary oedema
- Dilutional hyponatraemia
  - Disorientation, confusion
  - Cerebral oedema, death
- Glycine Toxicity
  - Hyperglycinaemia
  - Hyperammonaemia
  - Encephalopathy, blindness
- Can occur within 15 mins

Procedures involved

- Transurethral resection of prostate (TURP).
- Bladder tumours (TURBT).
- Transcervical resection of the endometrium (TCRE), (TCRF).

Procedures involved

- Transurethral resection of prostate (TURP).
- Bladder tumours (TURBT).
- Transcervical resection of the endometrium (TCRE), (TCRF).
  - Originally adapted urological resectoscope.
  - Hyponatraemia occurs with equal frequency in ♂+♀ .
  - Premenopausal ♀ x25 risk of severe TUR syndrome.

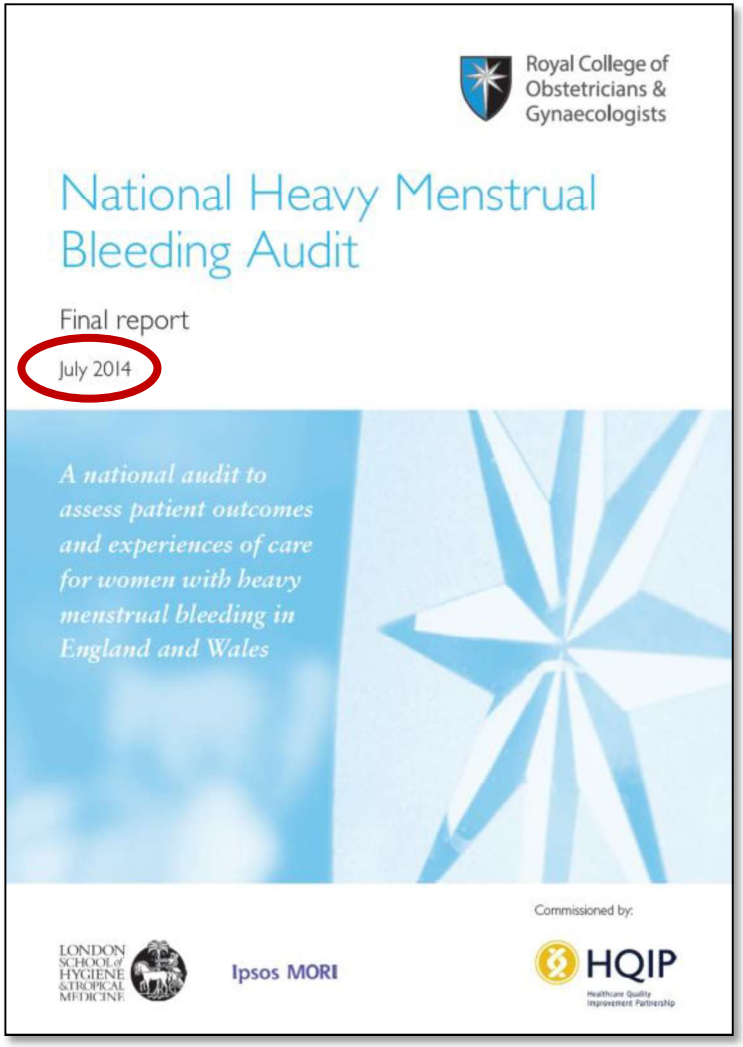
Procedures involved

- Transurethral resection of prostate (TURP).
- Bladder tumours (TURBT).
- Transcervical resection of the endometrium (TCRE), (TCRF).
  - cystoscopy,
  - arthroscopy,
  - rectal tumour surgery,
  - vesical ultrasonic lithotripsy,
  - percutaneus nephrolithotripsy.

TransUrethral Resection Prostate TURP

- Approximately 14,000 transurethral resections of the prostate (TURP) are performed annually in E&W (NICE 2014)
- 2nd most common surgical procedure in men over age 65
- Between 0.8% and 1.4% of TURP procedures are complicated by the mild → moderate TURP syndrome.
- Mortality = 0.2%
- Declining incidence

Heavy Menstrual Bleeding



- About 20%

  of the 1.2 million referrals to specialist gynaecologist services

  concern women with HMB.

- Each year,

  30,000 women undergo surgical treatment for HMB in England and Wales.

Heavy Menstrual Bleeding

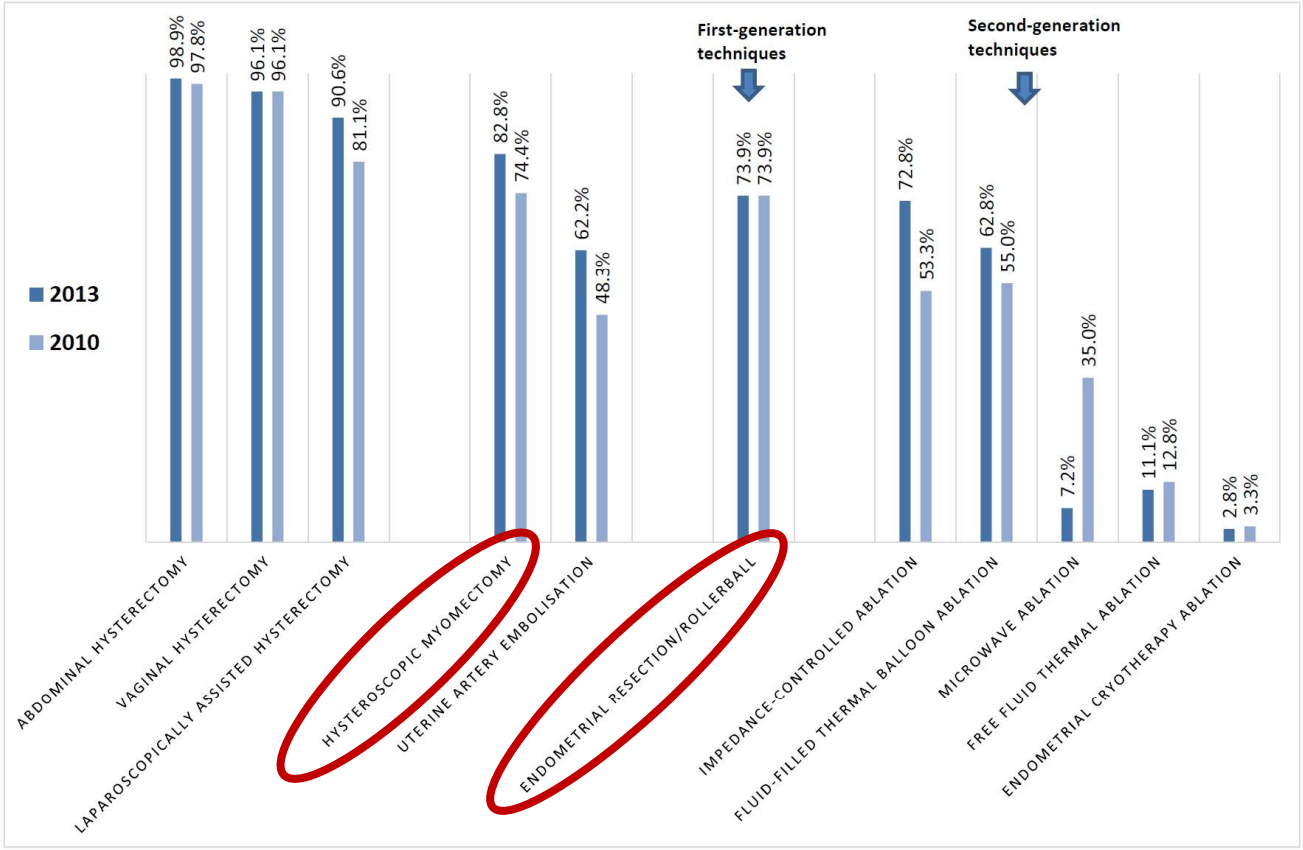
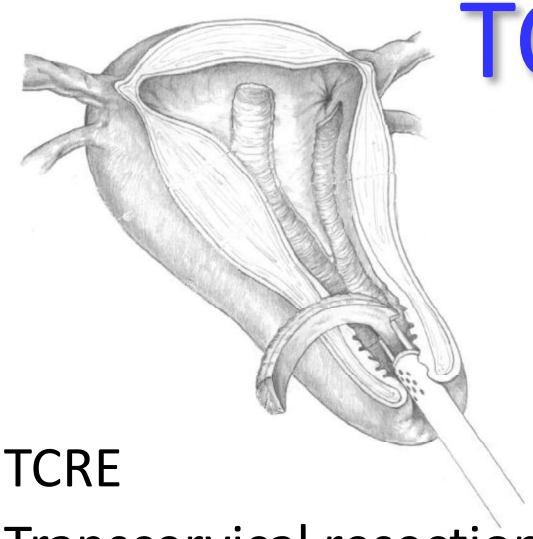
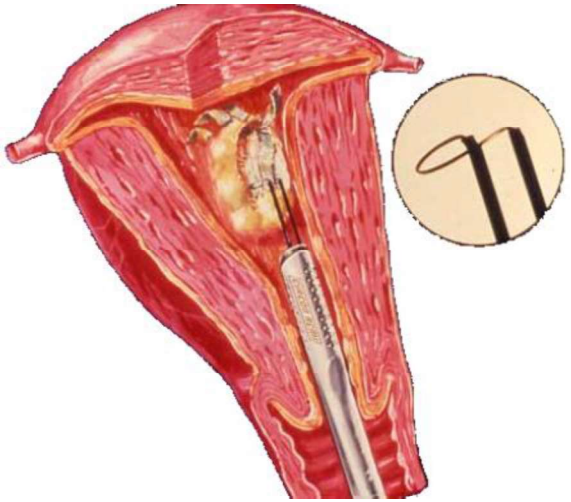


Figure 2.1 Available surgical options for women with HMB at NHS hospitals in England and Wales

TCRE vs TCRF



- TCRE
- Transcervical resection of Endometrium
- Quick procedure
- Less risk
- But not “no risk”.



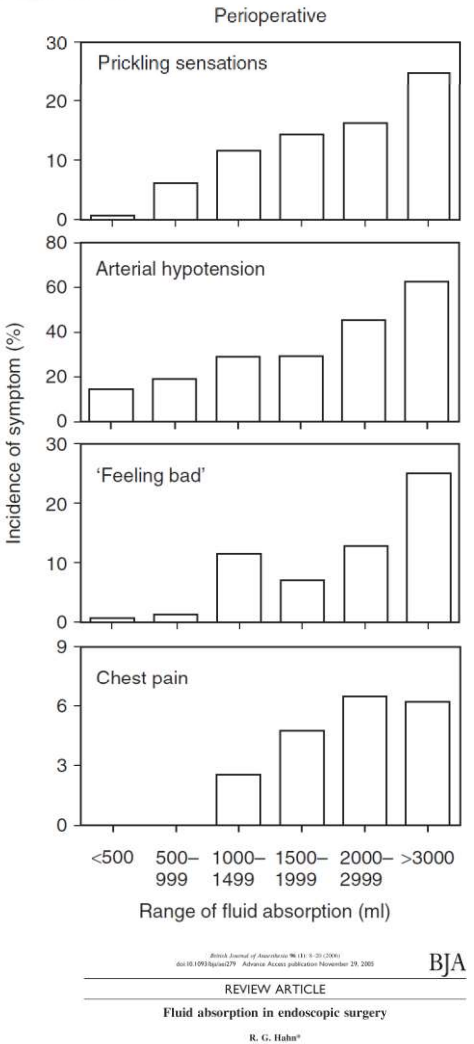
- TCRF
- Transcervical resection of Fibroids
- More vascularity
- More disruption of vessels
- ↑ absorption
- Bleeding obscures field
- Greater risk of TUR syndrome

Fluid absorption

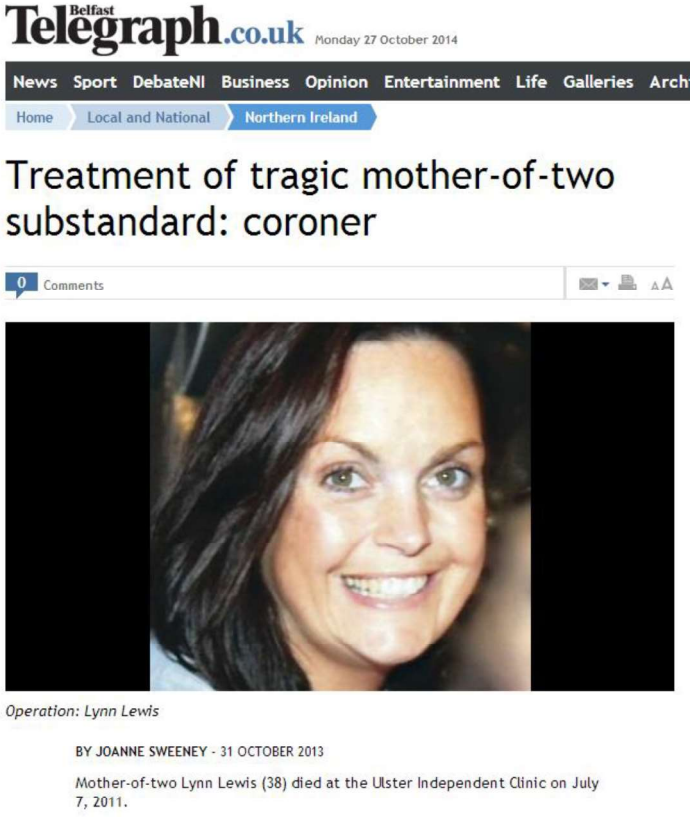
- Average 10 – 30 mls per hour
- Average ~ 400 – 700 mls.
- >1000 mls → ↑ risk of symptoms.

TCRF > TCRE > TURP

TURBT> TURP



Lynn McClean Lewis



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Treatment of tragic mother-of-two substandard: coroner

0 Comments

Operation: Lynn Lewis

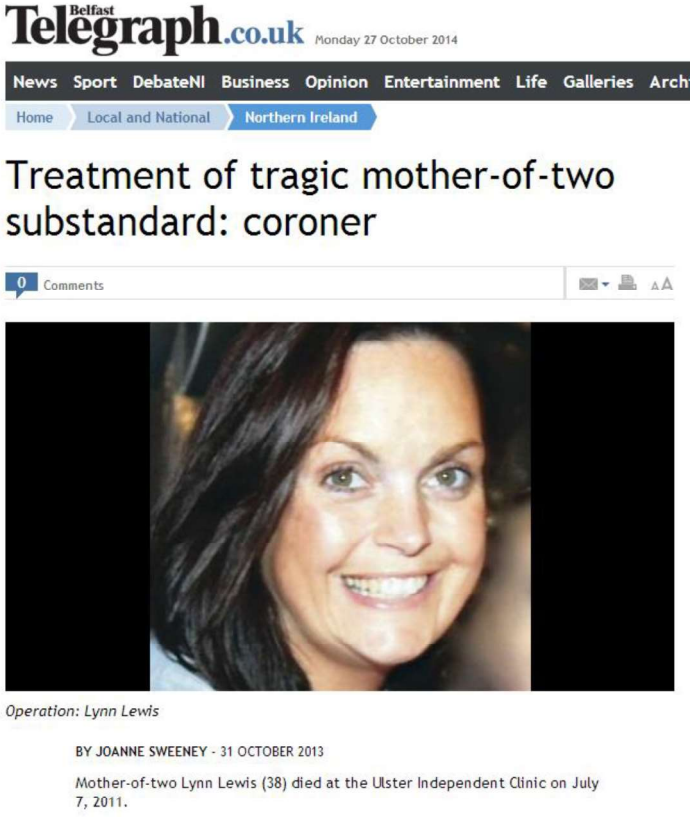
BY JOANNE SWEENEY - 31 OCTOBER 2013

Mother-of-two Lynn Lewis (38) died at the Ulster Independent Clinic on July 7, 2011.

- 38 years old
- 07/07/2011 - date of surgery
- 9/12 h/o menstrual bleeding
- Fibroids
- Caesarean Sections x2
- OCP : BMI = 30
- 'Fit'

- Hysteroscopic resection of fibroids, TCRF
- Glycine used = 11,500 mls
- Fluid collected = 5,700 mls

Lynn McClean Lewis



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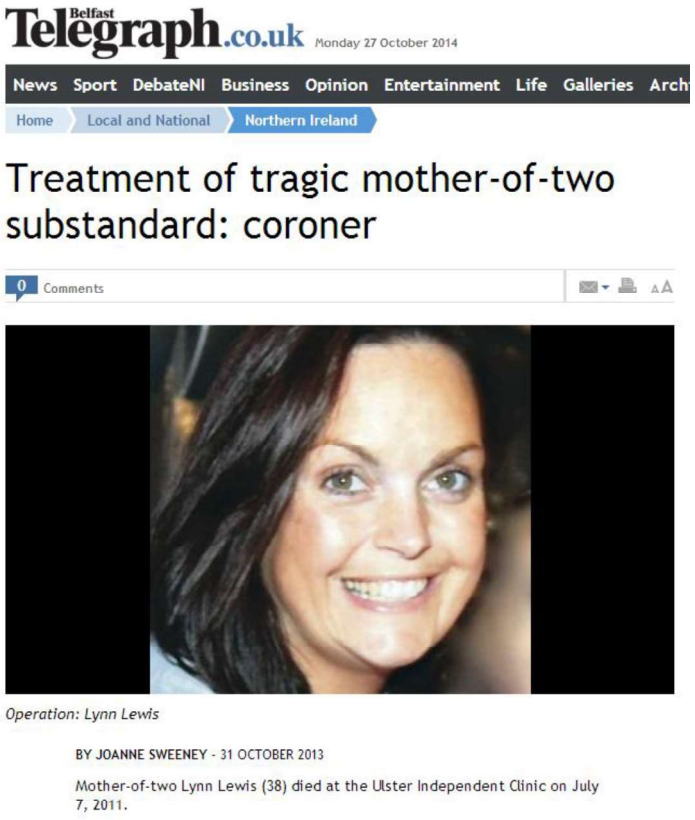
Mother-of-two Lynn Lewis (38) died at the Ulster Independent Clinic on July 7, 2011.

- Intraoperative death.
- Letter to Minister Edwin Poots.
- Coroner's Verdict (JLL) 16/10/2013
- Death due to,

  Haemorrhage and Hyponatraemia associated with Hysteroscopic Resection of Uterine Fibroid.
- "*hyponatraemia was principal cause*".
- Failings personal and Institutional.
- Asked for a '*collegiate response to the surgical and anaesthetic failings ……. and also nursing failings*'.

Lynn McClean Lewis



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Time	Serum Sodium mmol/L	
	Lab	iStat
am	? 135 – 145 ?	
08.55	General Anaesthesia	
09.10	127	
09.55		103
10.25	Cardiac Arrest	111
10.32		111
10.46		109
11.04		109
11.14		113
11.32		113
11.50		157

Lynn McClean Lewis

- Letters from Coroner to Medical Directors and Minister.
- Coroner's Verdict on inquest of Lynn Lewis
- Agreed statement of Prof McClure, Dr Hughes and UIC clinic.

Reports

- Autopsy report – Prof. J. Crane
- Dr GH Millward-Sadler – PM expert.
- Dr George Gardiner – Coroner's Expert.
- Dr Leroy Edozien – Coroner's Expert.
- Prof. Robert W Shaw – obo UIC.

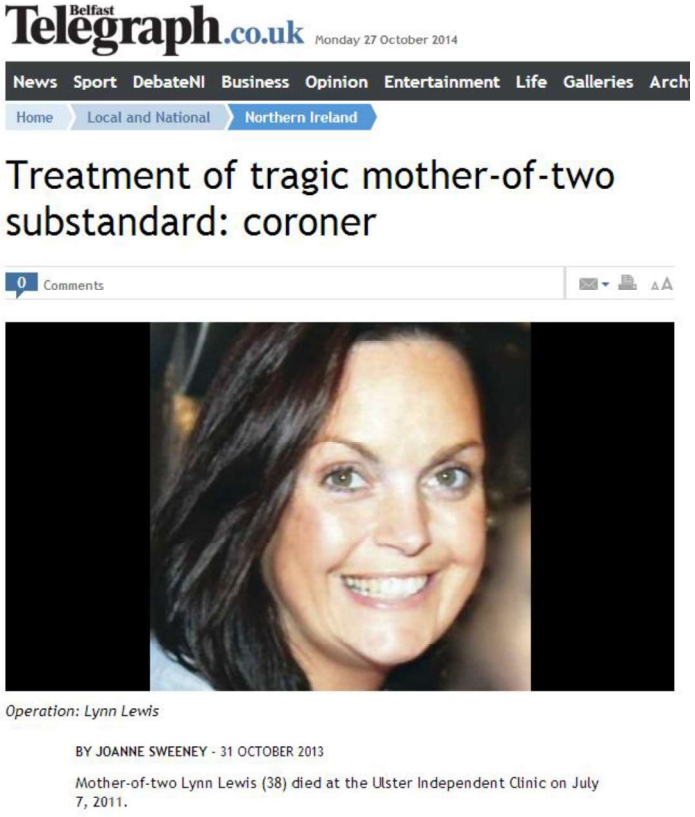
Papers

- Fluid absorption in endoscopic surgery. Hahn RG. BJA 2006; 96: 8-20
- A Literature review and update on the prevention and management of fluid overload in endometrial resection. Varol N et al. Gynaecological Endoscopy 2002; 11: 19-26.

Causative Themes

- Preoperative workup
- Haemorrhage – 2 sources
- **Dilutional Hyponatraemia**
- **Fluid overload**
- **Glycine toxicity**
- **Decision making processes**
- **Team dynamics**
- **Lack of knowledge of the potential problems**

Lynn McClean Lewis



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Mother-of-two Lynn Lewis (38) died at the Ulster Independent Clinic on July 7, 2011.

- Focus on prevention
- *"The best way to manage the TURP syndrome is to prevent it."*

<u>Prevention</u>

1. Preoperative workup
2. Procedural factors
3. Fluid dynamics
4. Team dynamics
5. Clinical Governance issues

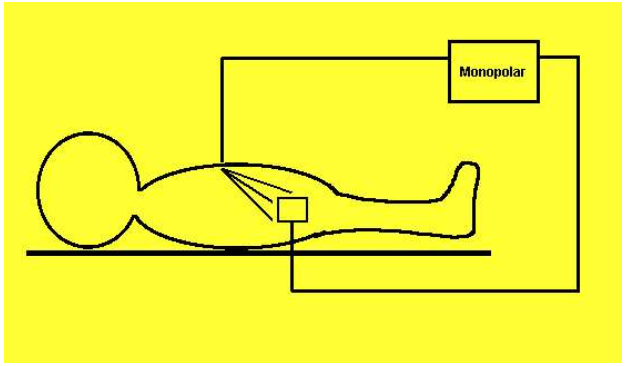
Preoperative workup

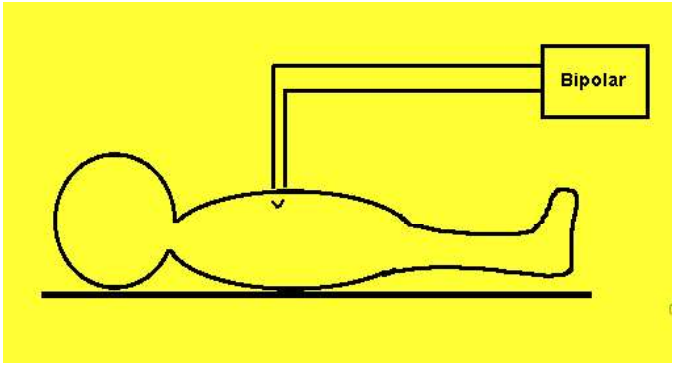
- Correction of anaemia, hyponatraemia.
- Patient evaluation.
- Patient preparation including pharmacological.

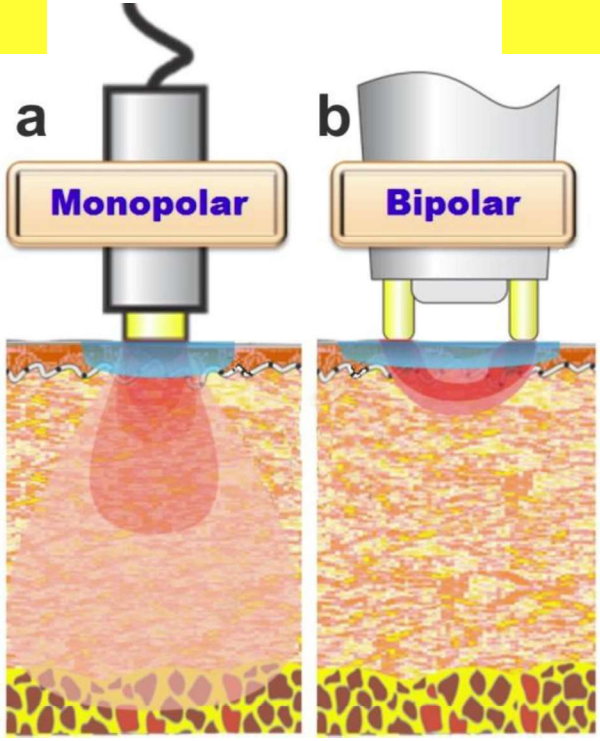
Procedural factors

- Identify any contraindications.
- Investigate alternative methods for endometrial, fibroid, prostate resection, tumour resection.
- Establish risks of alternative methods.
- Investigate alternative irrigation solutions.
- Audit practice and use of techniques.

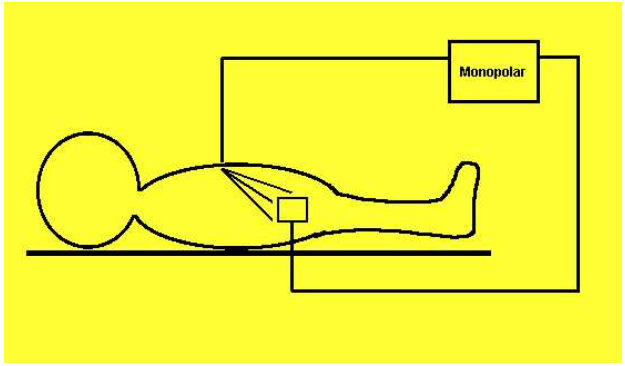
Monopolar vs Bipolar

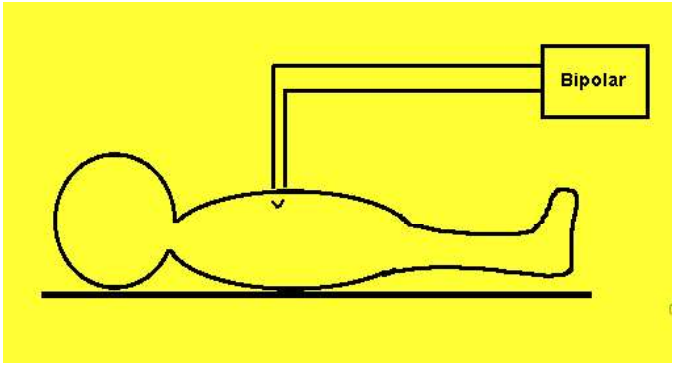


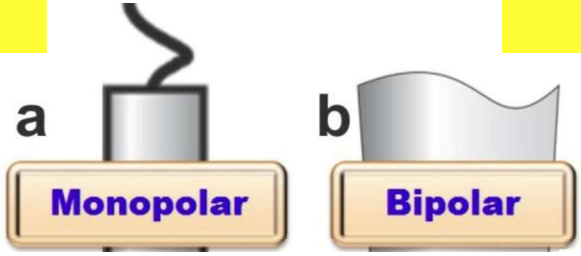




Monopolar vs Bipolar

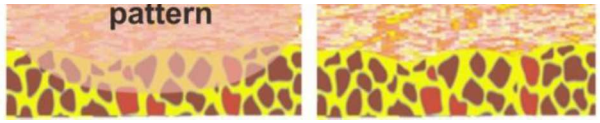






5 types of bipolar resection devices have been developed:

1. Plasmakinetic (PK) system Gyrus (ACMI Southborough, MA, USA),
2. Vista Coblation/CTR system (ACMI, Southborough, MA, USA) [withdrawn],
3. Transurethral resection in saline (TURis) system (Olympus, Tokyo, Japan),
4. Storz (Karl Storz Endoscope, Tuttlingen, Germany),
5. Wolf (Richard Wolf GmbH, Knittlingen, Germany)



Bipolar Distending fluid

Normal Saline

- Conductive
- Isotonic
- Non-haemolytic
- Low cost
- Non- allergic

- **No hyponatraemia**
- **Volume expander**
- **Overload more likely ??**
- Hyperchloraemia acidosis ???