Urology Services Inquiry

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB
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Mr. Michael Young
Consultant Urologist
Southern Health and Social Care Trust
Craigavon Area Hospital,
68 Lurgan Road, Portadown,
BT63 5QQ

10 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.

The Inquiry is aware that you have held posts relevant to the Inquiry's Terms of Reference. The Inquiry understands that you will have access to all of the relevant information required to provide the witness statement required now or at any stage

throughout the duration of this Inquiry. Should you consider that not to be the case, please advise us of that as soon as possible.

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

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

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

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

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

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

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

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

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

Yours faithfully

Personal Information redacted by the USI

Anne Donnelly
Solicitor to the Urology Services Inquiry

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

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

Chair's Notice

[No 18 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:

Michael Young
Consultant Urologist
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 31st October 2023.**

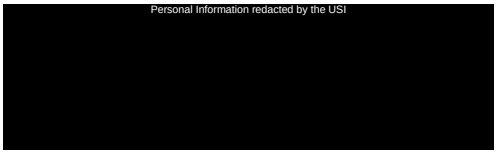
APPLICATION TO VARY OR REVOKE THE NOTICE

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 24th October 2023**.

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

Dated this day 10th October 2023

Signed: 

Christine Smith QC
Chair of Urology Services Inquiry

Urology Services Inquiry

SCHEDULE

[No 18 of 2023]

Knowledge of Concerns

1. In his statement to the Inquiry, at WIT-98844, Mr Chris Hagan discusses a series of issues which concerned him when he was working as a trainee with Mr O'Brien in Craigavon Area Hospital in 2000:

   '… there were a number of situations that arose that caused me to feel concerned about some of the practices of Mr O'Brien. With the passage of time it is not now possible for me to recall all the details. I did not keep a formal record at the time. I am afraid it would not have occurred to me to do so. I did raise issues that concerned me with Mr. O'Brien himself, and also with Mr. Young about Mr. O'Brien, during my 6 months rotation. In 2000 that would have seemed like a brave or courageous step from a higher surgical trainee.'

   Mr Hagan proceeds to list the issues of concern at paragraph 31 of his statement. The issues which he may have raised with you are: benign cystectomy on young women; excessive time performing TURP with risk of TUR syndrome; Mr O'Brien's approach to ureteric stone treatment; and priapism and penile disassembly.

   In oral evidence on Day 61 (19th September 2023), Mr Hagan stated: *'So, undoubtedly, you know, because of the joint ward rounds, I would have expected that Mr. Young would have been aware of some of these patients. And when I did raise concerns with Mr. Young, as I've said in my statement, his response was "That's just Aidan".* [TRA-07907]

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

   (a) Do you recall any occasions on which Mr Hagan spoke to you regarding concerns? Please provide full details of all such discussions.
   (b) Do you recall others having shared concerns with you in respect of the various issues described by Mr Hagan in his evidence?

(c) To the extent that it is your evidence that you do not recall such interaction with Mr Hagan, please clarify whether it is your evidence that: (i) you do not recall any such interaction or (ii) that no such interaction occurred.

2. At WIT-98846, Mr Hagan describes his concerns in respect of benign cystectomy being performed on a young woman:

'There was a young woman, in her early 20s, who had this procedure before I arrived to do my rotation at CAH, but who then had subsequent admissions for fluids and antibiotics during the time I was in CAH … The young woman made a lasting impression on me as she was really miserable, especially as she was continuing to have UTIs notwithstanding the major operation she had been put through. The predominant indication for cystectomy and neobladder is for treatment of bladder cancer and I was disturbed that this major procedure had been undertaken for recurrent UTIs in a young woman. I could find no evidence base in the literature for this… I did speak to Mr. Young during my rotation about various concerns I had about Mr. O'Brien, but I cannot say whether this was one of the matters that I spoke to Mr. Young about. I may have, but I cannot say that I did. Looking back now, with 17 years' experience as a Consultant Urological Cancer Surgeon, I can see no justification for the operation.'

(a) Do the circumstances described by Mr Hagan give rise to any concern from your perspective? Please explain your answer.
(b) Do you recall this issue being raised with you by Mr Hagan? If so, please provide full details of all discussions with Mr Hagan.
(c) To the extent that it is your evidence that you do not recall such interaction with Mr Hagan, please clarify whether it is your evidence that: (i) you do not recall any such interaction or (ii) that no such interaction occurred.
(d) Do you recall any discussions around this issue with anyone else? If so, please provide full details.

3. At WIT-98847, Mr Hagan describes his concerns in respect of excessive time performing TURP with risk of TUR syndrome:

'I was therefore disturbed as a trainee in CAH when a TURP that Mr. O'Brien was carrying out involved a resection that lasted significantly greater than 1 hour. The case I recall involved resection time approaching 2 hours, and the anaesthetist and nursing

staff expressing concerns to Mr. O'Brien about the length of operating time, but Mr. O'Brien continued. I thought this was a patient safety issue because it was putting the patient at what I considered to be unnecessary risk … I believe I did speak to Mr. Young about this issue (I did speak to him a number of times during my rotation about different issues) and my recollection is of him saying "that's just Aidan". I cannot say for certain that the remark from Mr. Young that I recall was definitely in connection with this issue, but it is definitely a phrase that Mr. Young used to me when I raised an issue about Mr. O'Brien during my time in CAH.'

(a) Do the circumstances described by Mr Hagan give rise to any concern from your perspective? Please explain your answer.
(b) Do you recall this issue being raised with you by Mr Hagan? If so, please provide full details of all discussions with Mr Hagan.
(c) Do you recall responding to Mr Hagan in the manner he has suggested?
(d) To the extent that it is your evidence that you do not recall such interaction with Mr Hagan, please clarify whether it is your evidence that: (i) you do not recall any such interaction or (ii) that no such interaction occurred.
(e) Do you recall any discussions around this issue with anyone else? If so, please provide full details.

4. In oral evidence on Day 61 (TRA-07937), Mr Hagan stated as follows:

"So, I know I discussed issues with Michael Young, and stone treatment was one of them, and the use of EHL in the ureter, you know, would have been part of that conversation because it wasn't something that I had ever encountered before. And I know that I had discussions about purchasing a lithoclast and safer ureteric surgery."

Having regard to the above, and Mr Hagan's evidence at WIT-98848 in respect of Mr O'Brien's approach to ureteric stone treatment, which he describes as 'very different', please address the following:

(a) Please provide a narrative account of your experience of ureteric stone treatment using electrohydraulic lithotripsy. Please provide any comments you may have in respect of the safety of the use of EHL in the ureter.
(b) Did you consider Mr O'Brien's approach to ureteric stone treatment to be 'very different'? If so, please explain, providing full details.

(c) Please provide any further comments you may have in respect of Mr Hagan's comments regarding the use of lithoclast.

5. At WIT-98850, Mr Hagan describes a case involving priapism and penile disassembly which caused him concern. He states: *'This patient will have been on the Urology ward for a period of time post his operation, so it may well be that Mr Young or others will recall the case because of its unusual features.'*

(a) Were you aware of this case at the time? If so, please provide full details of your knowledge and indicate whether this case gave you cause for concern, and, if it did, why?
(b) Do you recall discussing this case with anyone? If so, please provide details of all conversations in respect of same.
(c) If you were not aware of this case at the time, please explain how you would not have been so aware if the patient had spent a period of time on the ward, as suggested by Mr Hagan.

Monopolar and Bipolar Resection

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

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

At [WIT-54042], it is noted that: *'NICE, in February 2015, also issued guidance for the public on this topic. They indicated that, "the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate'. Healthcare teams may want to use the TURis system instead of monopolar TURP because there*

is no risk of a rare complication called transurethral resection syndrome and it is less likely that a blood transfusion after surgery will be needed. Therefore, the case for moving from a monopolar to bipolar technique for resection of the prostate would appear to be well established as safer with regard to the development of the TUR syndrome…'

In his statement to the Inquiry (at WIT-53948-53949), Mr Haynes 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 2015. 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.'*

In your witness statement at WIT-51735, you refer to your role in facilitating conversion from the use of glycine to saline for irrigation in endoscopic resections. The Inquiry notes that you chaired a Departmental Meeting on 22nd September 2016 in relation to saline resection. The minutes of the meeting are available at WIT-54057-54059.

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) Please provide a narrative account of your experience initially with the use of monopolar resection instruments within the Southern Trust.

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

(c) Were you 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.

(d) Please provide full details of your involvement in the process of trialling new bipolar resection equipment to include details of:

i. The nature and purpose of this assessment;
ii. When the assessment took place and the duration of same;
iii. The identities of others involved in assessing the equipment;
iv. Any conclusions reached as a result of this assessment.

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

(f) Did you continue to undertake monopolar resection in glycine beyond this point?

(g) Were you aware of others continuing to undertake these procedures beyond this point?

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

(i) Was training required to adapt to the new equipment and technique? If yes, please provide details of all such training you received.

(j) With regard to Mr McAllister's discussion with Mr Hagan:

a. Were you aware of the concerns described by Mr McAllister (risk of TUR syndrome posed by the clinician who continued to undertake monopolar resection in glycine)?
b. Were you aware of the identity of the clinician? If so, please explain how you were so aware and state the identity of the clinician.
c. Had this issue been brought to your attention as Clinical Lead, prior to Mr McAllister's communication? If so, please provide full details of all discussions relating to this issue, to include dates, the identities of the parties to the discussions, the content of those discussions and any actions taken by you, or others, on foot of same. If the issue had not been brought to your attention, should it have been?

d. Was this issue brought to your attention after Mr McAllister's discussion with Mr Hagan? If so, please provide full details of all discussions relating to this issue, to include dates, the identities of the parties to the discussions, the content of those discussions and any actions taken by you, or others, on foot of same. If the issue had not been brought to your attention at that stage, should it have been?
e. What action was taken by the Trust in respect of this clinician?
f. Did the clinician ultimately change their practice in light of the Trust's policy, action plan, and purchase of bipolar instruments?
g. Provide any further comments you may have in respect of this issue.

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

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

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

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

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

NOTE:

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

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Section 21 Notice Number 18 of 2023

Date of Notice: 10th October 2023

Witness Statement of: Michael Young

I, Michael Young, will say as follows:-

Knowledge of Concerns

1. In his statement to the Inquiry, at WIT-98844, Mr Chris Hagan discusses a series of issues which concerned him when he was working as a trainee with Mr O'Brien in Craigavon Area Hospital in 2000:

'… there were a number of situations that arose that caused me to feel concerned about some of the practices of Mr O'Brien. With the passage of time it is not now possible for me to recall all the details. I did not keep a formal record at the time. I am afraid it would not have occurred to me to do so. I did raise issues that concerned me with Mr. O'Brien himself, and also with Mr. Young about Mr. O'Brien, during my 6 months rotation. In 2000 that would have seemed like a brave or courageous step from a higher surgical trainee.'

Mr Hagan proceeds to list the issues of concern at paragraph 31 of his statement. The issues which he may have raised with you are: benign cystectomy on young women; excessive time performing TURP with risk of TUR syndrome; Mr O'Brien's approach to ureteric stone treatment; and priapism and penile disassembly.

In oral evidence on Day 61 (19th September 2023), Mr Hagan stated: *'So, undoubtedly, you know, because of the joint ward rounds, I would have expected that Mr. Young would have been aware of some of these patients.*

And when I did raise concerns with Mr. Young, as I've said in my statement, his response was "That's just Aidan". **[TRA-07907]**

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

(a) Do you recall any occasions on which Mr Hagan spoke to you regarding concerns? Please provide full details of all such discussions.
(b) Do you recall others having shared concerns with you in respect of the various issues described by Mr Hagan in his evidence?
(c) To the extent that it is your evidence that you do not recall such interaction with Mr Hagan, please clarify whether it is your evidence that: (i) you do not recall any such interaction or (ii) that no such interaction occurred.

1.01 (a) There is always the expectation that a registrar, as part of their training, will inquire about care-pathways for patients. For instance, I recall that Mr Hagan would have discussed prostate cancer management with Mr O'Brien on ward rounds. However, I did not ever interpret this as a concern and I do not recall Mr Hagan, during his six-month attachment, ever raising any serious issues because I would have acted upon them.

1.02 (b) I do not recall anyone else raising the points he comments upon.

1.03 (c) I do not recall any occasions when Mr Hagan raised the concerns mentioned.

2. At WIT-98846, Mr Hagan describes his concerns in respect of benign cystectomy being performed on a young woman:

'There was a young woman, in her early 20s, who had this procedure before I arrived to do my rotation at CAH, but who then had subsequent admissions for fluids and antibiotics during the time I was in CAH … The young woman made a lasting impression on me as she was really miserable, especially as she was continuing to have UTIs notwithstanding the major operation she had been put

through. The predominant indication for cystectomy and neobladder is for treatment of bladder cancer and I was disturbed that this major procedure had been undertaken for recurrent UTIs in a young woman. I could find no evidence base in the literature for this… I did speak to Mr. Young during my rotation about various concerns I had about Mr. O'Brien, but I cannot say whether this was one of the matters that I spoke to Mr. Young about. I may have, but I cannot say that I did. Looking back now, with 17 years' experience as a Consultant Urological Cancer Surgeon, I can see no justification for the operation.'

(a) Do the circumstances described by Mr Hagan give rise to any concern from your perspective? Please explain your answer.

(b) Do you recall this issue being raised with you by Mr Hagan? If so, please provide full details of all discussions with Mr Hagan.

(c) To the extent that it is your evidence that you do not recall such interaction with Mr Hagan, please clarify whether it is your evidence that: (i) you do not recall any such interaction or (ii) that no such interaction occurred.

(d) Do you recall any discussions around this issue with anyone else? If so, please provide full details.

2.01 a) I agree with Mr Hagan that the predominant indication for cystectomy and neobladder is in the treatment for bladder cancer. However, in the benign arena, cystectomy is still part of the treatment pathway for such conditions as interstitial cystitis (an inflammatory condition of the bladder), or as part of bladder augmentation in patients with, for instance, spinal injury. Cystectomy and neobladder reconstruction in the younger person is indeed part of the therapy where bodily image may be important for the patient. Cystectomy purely for recurrent urinary tract infections is not standard practice. However, I personally have had only one patient in 30 years of practice who has had a cystectomy for recurrent UTI and this was because of recurrent sepsis and Intensive Care Unit admissions.

2.02 (b and c) I do not recall Mr Hagan raising this issue with me.

2.03 d) I do not recall anyone else raising this issue.

3. At WIT-98847, Mr Hagan describes his concerns in respect of excessive time performing TURP with risk of TUR syndrome:

'I was therefore disturbed as a trainee in CAH when a TURP that Mr. O'Brien was carrying out involved a resection that lasted significantly greater than 1 hour. The case I recall involved resection time approaching 2 hours, and the anaesthetist and nursing staff expressing concerns to Mr. O'Brien about the length of operating time, but Mr. O'Brien continued. I thought this was a patient safety issue because it was putting the patient at what I considered to be unnecessary risk … I believe I did speak to Mr. Young about this issue (I did speak to him a number of times during my rotation about different issues) and my recollection is of him saying "that's just Aidan". I cannot say for certain that the remark from Mr. Young that I recall was definitely in connection with this issue, but it is definitely a phrase that Mr. Young used to me when I raised an issue about Mr. O'Brien during my time in CAH.'

(a) Do the circumstances described by Mr Hagan give rise to any concern from your perspective? Please explain your answer.

3.1 From my perspective, the circumstances as described by Mr Hagan would give rise to a concern in respect of the duration of the operative procedure. The reason I would be concerned is that TUR Syndrome (hyponatraemia) is a well-recognised entity in urology and teaching and conversations between registrars and consultants would be expected. It is therefore highly likely that this topic in general was discussed with Mr Hagan and any subsequent registrars. Several features are relevant, one of which is the duration of resection. Teaching and part of any conversation is that TURP is ideally less than an hour in duration, as the risk of TUR Syndrome increases with time. The critical point, however, is the fluid balance as opposed to the precise timescales, as an imbalance can still occur within an hour. It is the aim to finish within the hour but sometimes it is necessary to go beyond this

time point if there is bleeding or if a little extra time is required to complete the procedure.

3.2 I am aware Mr O'Brien could on occasions perform TURP for more than an hour, however, I was not aware of the duration mentioned by Mr Hagan. It is likely that all Units will have examples of TUR Syndrome but I am not aware of Mr O'Brien having a higher incidence of TUR Syndrome than anyone else.

(b) Do you recall this issue being raised with you by Mr Hagan? If so, please provide full details of all discussions with Mr Hagan.

3.3 I do not recall a precise conversation on this case as it was 23 years ago, however, if Mr Hagan had raised an issue such as this I would have asked him had there been TUR Syndrome with this patient.

(c) Do you recall responding to Mr Hagan in the manner he has suggested?

3.4 With regards to the phrase "that's just Aidan", it is a phrase that I, as well as others, would have used in general terms. However, it certainly would not have been a phrase I would have used when responding to someone commenting upon a TURP of that duration.

(d) To the extent that it is your evidence that you do not recall such interaction with Mr Hagan, please clarify whether it is your evidence that: (i) you do not recall any such interaction or (ii) that no such interaction occurred.

3.5 I do not recall any such interaction regarding the TURP case that Mr Hagan has raised.

(e) Do you recall any discussions around this issue with anyone else? If so, please provide full details.

3.6 I have no recollection of having discussions regarding this issue with others. As indicated at 3.2 above, I recall being generally aware that Mr O'Brien had on occasions taken more than 1 hour for a TURP. I believe I was aware of this informally (e.g., through theatre tea room chat) and, as also mentioned at 3.2 above, not because of any awareness of Mr O'Brien having any higher incidence of TUR Syndrome.

4. In oral evidence on Day 61 (TRA-07937), Mr Hagan stated as follows:

"So, I know I discussed issues with Michael Young, and stone treatment was one of them, and the use of EHL in the ureter, you know, would have been part of that conversation because it wasn't something that I had ever encountered before. And I know that I had discussions about purchasing a lithoclast and safer ureteric surgery."

Having regard to the above, and Mr Hagan's evidence at WIT-98848 in respect of Mr O'Brien's approach to ureteric stone treatment, which he describes as 'very different', please address the following:

(a) Please provide a narrative account of your experience of ureteric stone treatment using electrohydraulic lithotripsy. Please provide any comments you may have in respect of the safety of the use of EHL in the ureter.

4.1 EHL was one of the accepted technologies used to fragment stones in the urinary tract in 2000. There were different electrode probe sizes available to be used depending upon which part of the urinary tract they were to be used in. Most Registrars would have seen it used in bladder stone fragmentation. The probes for ureteric use were very fine so they could be passed up the thin ureteroscope and were flexible. This flexibility aided use in the proximal ureter or within the kidney if used with a flexible uretero-renoscope.

4.2 This was the technology available when I arrived in the Unit, having been used to a flexible laser fibre during my training.

4.3 I personally found the ureteric probe had to be handled with care and would instruct registrars very precisely on its use and techniques, namely single pulses, using as low an energy level as possible and location of the probe upon the stone.

4.4 I also instructed registrars to have a safety guidewire in position before performing any fragmentation; this was to aid vision and the ureteroscope direction for the EHL probe at endoscopy. It also was in place so that a stent could be inserted if there was any issue such as loss of vision, an extravasation of contrast or perforation. In addition, during endoscopy I performed these procedures with x-ray screening.

(b) Did you consider Mr O'Brien's approach to ureteric stone treatment to be 'very different'? If so, please explain, providing full details.

4.5 I found Mr O'Brien's approach was different in that he did not use a safety guidewire nor x-ray screening for ureteroscopy in my early days as a Consultant. X-ray screening was one of the earliest features I introduced and Mr O'Brien in due course moved to using the x-ray screening. I am unsure as to whether he ever moved to using a safety guidewire.

4.6 Other than the above, I did not find Mr O'Brien's approach to be very different in respect to the timing of intervention. For inpatient admissions with colic there will be a discussion between clinician and patient on their care-pathway with regards to a conservative *vs.* an interventional approach. I believe that the use of medication to aid ureteric stone passage did not come into vogue until mid-to late 2000s.

(c) Please provide any further comments you may have in respect of Mr Hagan's comments regarding the use of lithoclast.

4.7 I agree with Mr Hagan that the Lithoclast has a better safety history, however no ureteric procedure is without the risk of perforation. Even with the modern modalities of lasertripsy there is still a risk and it should be noted on all current

consent forms. It should also be acknowledged that the Lithoclast is a straight, rigid instrument and that it does not work when flexed i.e., for upper ureteric or renal stones via the ureteric approach.

4.8 All of the instruments mentioned above cost money. The Trust did purchase an ultrasound disintegrator (a version of the lithoclast) for renal surgery in January 2006. However, the main goal for the stone service in Craigavon Area Hospital was to purchase a Holmium laser which was the safest and most efficient modality to use in any part of the urinary tract. A Holmium laser machine was purchased in 2006 and the same laser machine has been in use in the department ever since. I remember discussing with registrars, (and this would have included Mr Hagan), over the preceding years my plans for purchasing a laser and noting the expense.

4.9 EHL has not been used by any urologists for ureteric stone procedures since the Holmium laser arrived to the best of my knowledge.

5. At WIT-98850, Mr Hagan describes a case involving priapism and penile disassembly which caused him concern. He states: *'This patient will have been on the Urology ward for a period of time post his operation, so it may well be that Mr Young or others will recall the case because of its unusual features.'*

(a) Were you aware of this case at the time? If so, please provide full details of your knowledge and indicate whether this case gave you cause for concern, and, if it did, why?

(b) Do you recall discussing this case with anyone? If so, please provide details of all conversations in respect of same.

(c) If you were not aware of this case at the time, please explain how you would not have been so aware if the patient had spent a period of time on the ward, as suggested by Mr Hagan.

5.1 a) I have no recollection of this case.

5.2 b) Since I do not recall the case, further comment is not possible.

5.3 c) Mr Hagan stated it was at the end of his tenure and this therefore would have been in July. I normally took my summer holidays in July and possibly into August time.

Monopolar and Bipolar Resection

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

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

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

In his statement to the Inquiry (at WIT-53948-53949), Mr Haynes 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 2015. 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.'

In your witness statement at WIT-51735, you refer to your role in facilitating conversion from the use of glycine to saline for irrigation in endoscopic resections.
The Inquiry notes that you chaired a Departmental Meeting on 22nd September 2016 in relation to saline resection. The minutes of the meeting are available at WIT-54057-54059.

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) Please provide a narrative account of your experience initially with the use of monopolar resection instruments within the Southern Trust.

6.1 In my experience, the use of monopolar resection for TUR prostate and resection of bladder tumours with glycine in Craigavon was the same as in my urological training in the Belfast City Hospital. There was an improvement in the resectoscope design with a continuous irrigating system which allowed for a lower pressure and overall reduction in resection time (the previous system required an

intermittent stoppage to empty the bladder). This was approximately in the late 1990s, I believe. The resectoscopes required replacement intermittently and this was done on a rotational basis. During surgery, there was an active monitoring of fluid volumes being irrigated so as to report to the surgeon and the anaesthetist on any imbalance. All theatre staff were very aware of the importance of this feature. There are specific theatre nursing staff assigned to do the fluid monitoring. I found the monopolar resectoscopes to be reliable and had effective cutting and coagulation mechanisms.

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

6.2 The use of glycine for irrigation to perform TURP procedures was used for decades. The important issue was a close monitoring of the fluid balance, including bleeding, during its use and the assessment of blood chemistry as necessary. Providing there was close monitoring of the fluid balance, the use of glycine was safe. Glycine was the only irrigating fluid available until the saline procedure was introduced. Although TUR Syndrome with Glycine had a low incidence, the saline procedure was noted to be safer.

(c) Were you 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.

6.3 I was aware of the Coroner's case which related to a significant gynaecological incident and can see from correspondence in January 2014, and email correspondence in May 2015, that there was a regional response in the middle of 2015. In advance of the regional response, the Urologists met in January 2014 and we prepared a paper entitled 'Irrigating Fluids used in urological procedures' and I

forwarded this on behalf the team to the Medical and Acute Services Directors on 17 February 2014. (WIT-52825) *See:*

1.-4. 20140122 - E Further incident relating to use of distension fluid, A1-A3.

5.-8. 20150526 - Endoscopic Distending Fluids for the Coroner, A1-A3

9.-10. 20140217 - email trust response to glycine, A1

6.4 On 26th May 2015 I was copied into an email from Dr Julian Johnston attaching the final report with its recommendations.

(d) Please provide full details of your involvement in the process of trialling new bipolar resection equipment to include details of:

i. The nature and purpose of this assessment;
ii. When the assessment took place and the duration of same;
iii. The identities of others involved in assessing the equipment;
iv. Any conclusions reached as a result of this assessment.

6.5 The urological team were aware of several bipolar systems on the market. We wished to assess which one best suited the Craigavon site in terms of surgeon's preference for ease of use and effectiveness as well as other factors such as cost of the resectoscopes, disposables and generators, as we knew there was not going to be any additional monies from the Department of Health to cover the project and it would therefore need to be purchased from our existing funds. We were aware that a completely new set of resectoscopes were to be purchased and this would potentially be a large capital expenditure. We did not want the suppliers who were unsuccessful in the award of the contract to have any challenges to our process. The assessment took approximately a year to complete and involved trialling four systems. This was from 2015 into the mid part of 2016. The assessment took longer than expected as we wanted to ensure all the surgeons involved (Mr Young, Mr O'Brien, Mr Suresh, Mr Glackin, Mr O'Donoghue and Mr Haynes) as well as the

theatre nursing staff, had adequate time and numbers of cases with each resectoscope system to make a meaningful assessment. There were some supply issues from the companies regarding the equipment which contributed to the protracted period of assessment. We regarded that our appraisal was robust for ease of use, effectiveness, and taking into account the cost of these systems. We noted that the interchange of equipment with our existing glycine system was a feature we wished to maintain, as we had noted the coagulation mode for the saline system was not as efficient as the glycine system in our initial assessment. This would therefore allow the surgeon to switch mid-procedure, if necessary. This was a specific safety point raised by Mr O'Brien but we felt it was a safety feature that should be available for all the surgical team in the unit. *See:*

11.-13. 20161012 Urology Department Minutes 22 9 2016, A1-A2

6.6 We all realised that there was an adaptation to our surgical technique to be required but, overall, the majority observed that it wasn't a major issue.

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

6.7 To the best of my knowledge I am not aware of the Southern Trust ever directing cessation of monopolar procedures. There was a delay in the supply of the resectoscopes due to purchasing issues from the Trust. In December 2017 we had a Urology Departmental meeting at which we agreed that we would stop doing TURP until the new saline equipment was in place. Please see correspondence from myself to Ronan Carroll relating to this (*see 14. 20171116 - E MY - saline TURP issue*). The scopes system was eventually installed in April 2018. There was however a proviso that saline was the principle medium to be used but if, for example, the surgeon felt there was a tissue coagulation issue at the time of surgery, this could be changed to glycine. This was to accommodate all members of the team.

(f) Did you continue to undertake monopolar resection in glycine beyond this point?

6.8 I personally discontinued the use of glycine when the new resectoscope system was on site.

(g) Were you aware of others continuing to undertake these procedures beyond this point?

6.9 I understood that the other Urologists had also changed to using the saline system. I was however aware that Mr O'Brien did not like the saline system as he regarded it as an inferior system. I personally thought he needed a further period of time to get used to the saline system. It has only come to my knowledge recently that he never did convert to using saline and continued to use glycine. *See:*

15. 20160207 E from AOB Re SOP for Fluid Management during Urology Surgery

16. 20160330 Response from AOB re Bipolar Resection

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

6.10 I regarded the TUR with saline as a suitable alternative. It required a slight adaptation to the surgical technique. The cut and coagulation mode I thought were not as good as with glycine, but it only took a little time to adapt. The advantage of a safer system was paramount. It was clear to me that saline was a safer modality to use.

(i) Was training required to adapt to the new equipment and technique? If yes, please provide details of all such training you received.

6.11 The basic technique was the same as the previous system. The representatives from the companies supplying the equipment explained what they noted other surgeons had commented upon and this was adequate to enable me to adapt my technique. There is an element of self-learning (as there is with all surgical techniques) which was all that was required. I personally felt there was a fairly short learning curve.

(j) With regard to Mr McAllister's discussion with Mr Hagan:

a. Were you aware of the concerns described by Mr McAllister (risk of TUR syndrome posed by the clinician who continued to undertake monopolar resection in glycine)?

6.12 I was unaware of any discussions between Dr McAllister and Mr Hagan on this subject. From the introduction of the saline system in April 2018, I am unaware of any 'bad TUR syndromes' nor prolonged procedure within the unit.

b. Were you aware of the identity of the clinician? If so, please explain how you were so aware and state the identity of the clinician.

6.13 I thought all the Urologists had converted to using the saline system on its instalment. However, Mr O'Brien had previously emailed the urology team in 2016 (as referenced in para 6.9 above) to note his dissatisfaction with the saline system and saying he was not going to use it.

c. Had this issue been brought to your attention as Clinical Lead, prior to Mr McAllister's communication? If so, please provide full details of all discussions relating to this issue, to include dates, the identities of the parties to the discussions, the content of those discussions and any actions taken by you, or others, on foot of same. If the issue had not been brought to your attention, should it have been?

6.14 The issue described by Mr Hagan at WIT-98867 para 59 was not brought to my attention. If it was an issue, it ought to have been. I also note that Dr McAllister retired in April 2018 (WIT-14848 para 1.1) and would therefore be surprised if he would have had any opportunity to become aware of anyone continuing to use monopolar resection in glycine at a time when bipolar resection equipment was

available (i.e., the concern described in para (j)a. of this question rather than the concern described by Mr Hagan at WIT-98867 para 59).

d. Was this issue brought to your attention after Mr McAllister's discussion with Mr Hagan? If so, please provide full details of all discussions relating to this issue, to include dates, the identities of the parties to the discussions, the content of those discussions and any actions taken by you, or others, on foot of same. If the issue had not been brought to your attention at that stage, should it have been?

6.15 I refer you to my responses above.

e. What action was taken by the Trust in respect of this clinician?

6.16 I refer you to my responses above.

f. Did the clinician ultimately change their practice in light of the Trust's policy, action plan, and purchase of bipolar instruments?

6.17 I refer you to my responses above. In respect of Mr O'Brien, I refer to my response at 6.9 in particular.

g. Provide any further comments you may have in respect of this issue.

6.18 Dr McAllister and myself were very much involved in driving forward an action plan to provide a comprehensive review of safety net factors for patients having had such procedures. This related specifically to the monitoring of patient safety factors during their surgery. The monitoring related to fluid balance and biochemical blood analysis. There was a full discussion in respect of the action plan with anaesthetists, surgeons, theatre staff and recovery staff all being involved. The action plan was already in place by early 2016 when the protocol was endorsed. This included live monitoring of the fluid balance and the anaesthetist would take blood samples every fifteen to twenty minutes. See:

7. 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]**

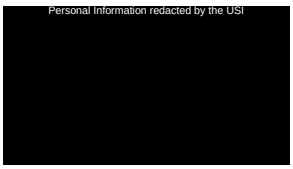
(a) To the extent that you are able to assist the Inquiry, please explain the reason(s) for the apparent delay in introducing the bipolar approach within the Southern Trust, as compared with BHSCT.
(b) Were you concerned by any delay in the introduction of this approach?

7.1 (a) Clinicians were aware of the index gynaecological case and the subsequent review. We, as urologists, awaited the outcome of the review, from a urological perspective, before proceeding as this had been a gynaecological issue. We had taken action in 2014 to evaluate a pump mechanism to measure input and output of fluids and for the pump to provide a low pressure for both urology and gynaecological procedures. The trialling of various saline resectoscope systems was prolonged by a supply issue with some of the companies, however, within this time period an enhanced safety net of measures were put in place. Having decided which system to purchase in September 2016 there was a delay and this related to the Trust having to prioritise equipment to purchase from their existing capital budget. See:

7.2 (b) The purchasing was outside of the control of the Urology Department. I raised my concerns at the Theatre Users Group meeting *(see 21. 20150305 THUGS Mtg Notes).* I had made a comment to transfer to the use of saline in 2015, this delay I regarded as relating primarily to funding issues. The Urology Department met in December 2017 and raised the concern of patient safety caused by the delay. Mr Haynes as AMD along with myself raised this with the Assistant Director, Mr Ronan Carroll. Following this escalation, the Acute Director and the Director of Performance re-prioritised the equipment purchase list and the resectoscopes were installed in 2018 as described above.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed: 

Date: 31.10.2023

Section 21 Notice Number 18 of 2023 – Michael Young

Index

Corrigan, Martina

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

Importance: High

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

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

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

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

Margaret for S&G process

Mairead

From: Carolyn Harper [redacted]
Sent: 22 January 2014 16:57
To: Hugh McCaughey SE Trust; [redacted] Elaine Way Western Trust; McAlinden, Mairead; Glenn Houston RQIA
Cc: Simpson, John; Tony Stevens; [redacted] Dr Alan McKinney; [redacted] Rice, Francis; [redacted] Burns, Deborah; Beattie, Caroline; [redacted] Patricia Donnelly [redacted] ; Seamus.McGoran setrust; [redacted] Burns, Deborah; [redacted] Anne Friel; Boyce, Tracey; Jill Macintyre SE Trust; Dr Michael Scott Northern Trust; David Stewart RQIA; [redacted] owen Barr [redacted] Eddie Rooney; Carolyn Harper; Janet Little; Pat Cullen; John Compton; Safety and Quality Alerts HSCB; [redacted] Michael Bloomfield; Gavin Lavery
Subject: Further incident relating to use of distension fluid

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

Dear all,

Please see attached correspondence from Dr Carolyn Harper for your attention.

Thank you

Christine obo Dr Harper

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

Received from Michael Young on 01/11/2023. Annotated by the Urology Services Inquiry.

From the Chief Medical Officer
Dr Michael McBride

Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

Castle Buildings
Stormont
BELFAST
BT4 3SQ
Tel: Personal Information redacted by the USI
Fax
Email: Personal Information redacted by the USI
Your Ref:
Our Ref:
Date: 15 January 2014

BY EMAIL

Mr John Leckey
Senior Coroner for Northern Ireland
Coroners Service
Mays Chambers
73 May Street
BELFAST, BT1 3JL

Dear Mr Leckey

LYNN LEWIS (DECEASED)

Thank you for your letter of 21 October 2013 enclosing the verdict on the Inquest into the death of Lynn Lewis at the Ulster Independent Clinic.

We wish to update you on our actions to date following receipt of your letter.

The matter of your verdict in this case was raised with my UK CMO colleagues at a meeting on 27 November 2013. In researching the background to the use of distending media, there is no relevant NICE or RCOG guidance.

There is guidance from JMIG (Journal Minimally Invasive Gynaecology) March/April 2013 that replaces Hysteroscopic Fluid Monitoring Guidelines, J Am ASSOC Gynecol Laparsoc 2000
www.aagl.org/wp-content/uploads/2013/03/aagl-Practice-Guidelines-for-the-Management-of-Hysteroscopic-Distending-Media.pdf

We convened a meeting with colleagues from the PHA, UICand RQIA on 18 December 2013.

We have identified the following :

- There are currently no UK guidelines on the use of distending media
- Some units in Northern Ireland have local guidelines on the use of distending media
- The use of distending fluids, and therefore their attendant risks, are not confined to gynaecological procedures
- The BHSCT has audited some 900 gynaecology cases involving the use of distending media which did not identify any cases of fluid overload.

A NI regional group has been set up to develop guidelines on the use of distending fluids. The group will engage with relevant professional bodies, including Royal Colleges.

We propose to develop common arrangements for information sharing and escalation between Coroner/HSC/DHSSPS/independent clinics, independent hospitals and independent medical agencies and will include colleagues from the wider Independent Healthcare Sector in this work

Dr Carolyn Harper has advised that she has engaged with your office to develop a more systematic arrangement for communication between Coroners Office and the HSC. The DHSSPS is involved in these discussions.

We will provide you with further response in due course. Thank you for bringing the matter to our attention.

Yours sincerely

Personal Information redacted by the USI

Personal Information redacted by the USI

DR MICHAEL McBRIDE
Chief Medical Officer

MRS CHARLOTTE McARDLE
Chief Nursing Officer

cc: Dr Paddy Woods, Deputy Chief Medical Officer
Dr Martin Donnelly, DHSSPS Medical Officer
Caroline Lee , Nursing Officer responsible for regulation
Dr David Stewart, RQIA
Dr Carolyn Harper, PHA
Diane Graham, Matron CE, Ulster Independent Clinic
Mr Colin Russell, Board member and Chair of Clinical Governance subcommittee

Health and Social Care Board

Public Health Agency

RE: Further incident relating to use of distension fluid – Distribution List – [insert √ as appropriate]

	To – for Action	Copy		To – for Action	Copy
HSC Trusts			**PHA**		
CEXs	√		CEX		√
Medical Director		√	Medical Director/Director of Public Health		√
Directors of Nursing		√	Director of Nursing/AHPs		√
Directors of Social Services			PHA Duty Room		
Governance Leads		√	AD Health Protection		
Directors of Acute Services		√	AD Service Development/Screening		√
Directors of Community/Elderly Services			AD Health Improvement		
Heads of Pharmacy		√	AD Nursing		√
NIAS			AD Allied Health Professionals		
CEX			Clinical Director Safety Forum		√
Medical Director			**HSCB**		
RQIA			CEX		√
CEX	√		Director of Integrated Care		
Medical Director		√	Director of Social Services		
Director of Nursing		√	Director of Commissioning		
Director for Social Care			Alerts Office		√
NIMDTA	√		Dir PMSI & Corporate Services		√
CEX / PG Dean			**Primary Care (through Integrated Care)**		
QUB			GPs		
Dean of Medical School		√	Community Pharmacists		
Head of Nursing School		√	Dentists		
Head of Social Work School			**Open University**		
Head of Pharmacy School		√	Head of Nursing Branch		
Head of Dentistry School			**DHSSPS**		
UU			CMO office		√
Head of Nursing School		√	CNO office		√
Head of Social Work School			CPO office		√
Head of Pharmacy School		√	CSSO office		
Clinical Education Centre		√	CDO office		
NIPEC		√	**NI Social Care Council**		
GAIN Office		√	**Safeguarding Board NI**		

HSC Public Health Agency

12-22 Linenhall Street
Belfast
BT2 8BS

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

By email to attached list

22 January 2014

Dear Colleague

Further incident relating to use of distension fluid

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

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

Action Required

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

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

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

Yours sincerely

[redacted]

DR CAROLYN HARPER
Medical Director/Director of Public Health

Corrigan, Martina

From: Johnston, Julian <Personal Information redacted by the USI>
Sent: 26 May 2015 17:42
To: Young, Michael; 'McKnight, John'; McAllister, Charlie; Hagan, Chris; 'Darling, John'; 'david.morgan Personal Information redacted by the USI'; 'david.glenn Personal Information redacted by the USI'; 'd.glenn Personal Information redacted by the USI McCracken, Geoff; 'michael.parker Personal Information redacted by the USI'; 'colin.prendergast Personal Information redacted by the USI'; McClelland, Raymond; 'Keith.Johnston Personal Information redacted by the USI'; 'Gary.dorman Personal Information redacted by the USI'; 'johnjmcknight Personal Information redacted by the USI'
Subject: RE: Endoscopic Distending fluids for the Coroner
Attachments: Letter from Mr Leckey re L Lewis 21 10 13.pdf; Policy on surgery for endoscopic tissue resection V0.4.docx; NICE 2015 - The TURis system for transurethral resection of prostate.pdf

Distending Fluids for Endoscopic surgery Please find attached my final document with 12 recommendations which I propose represents the required 'collegiate ' response to the failings surrounding the death in the UIC. This is in response to the Coroner asking the CMO that 'the Medical Directors to provide me with a collegiate response to the surgical and anaesthetic failings that the inquest has identified and ….. similar response from the NI CNO in relation to nursing issues'.

I presented draft work at 2 recent Medical Leader Forums. After the last one I received further feedback regionally. Thank you to those who sent in comments to the draft policy for Distending Fluids for Endoscopic surgery. I have responded to those who sent in comments with a further amended document.

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

I have taken account of the comments from the region and incorporated them, along with the guidance from NICE, into this final document.

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

I have now shared this with the DHSSPSNI and all the Medical Directors.

Regards,

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

BHSCT Litigation Management Office
Telephone: Personal Information redacted by the USI
If unanswered, contact Ann Maginnis: Personal Information redacted by the USI or Amanda Lennon (Coroner's Office): Personal Information redacted by the USI
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: Johnston, Julian

Sent: 27 February 2015 16:58
To: 'Michael.Young[redacted]'; 'McKnight, John'; 'McAllister, Charlie'; Hagan, Chris; 'Darling, John'; 'david.morgan[redacted]'; 'david.glenn[redacted]'; 'd.glenn[redacted]'; 'geoff.mccracken[redacted]'; 'michael.parker[redacted]'; 'colin.prendergast[redacted]'; McClelland, Raymond; 'Keith.Johnston[redacted]'; 'Gary.dorman[redacted]'; 'johnjmcknight[redacted]'
Cc: 'Simpson, John'; 'Alan McKinney ([redacted])'; Jack, Cathy; 'Martyn, Charlie <[redacted]> ([redacted])'; 'ken.lowry[redacted]'
Subject: Endoscopic Distending fluids

Please attached a second draft policy setting out a proposed 'collegiate' view for managing endoscopic tissue resection.
I have taken into account views expressed to me following the first time I sent out a draft policy.
I have also examined in detail the recent literature and documents from NICE and the Cochrane Collaboration.
This document has been substantially modified and forms the basis of presentations to the Medical Leaders Forum.

It details a direct of travel. My inquiries and those of leaders in urology and gynaecology indicate that there is now support for what is described.
If a sizeable majority of urologists and gynaecologists are in agreement, then that will be the direction proposed to the Trusts MDs and the CMO.

I would like views expressed to me by 15th March 2015 please.
Please circulate this to interested colleagues who are not on the email list above. I think I am missing the names of some Urologists.

Regards,

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

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

BHSCT Litigation Management Office
Telephone: [redacted]
If unanswered, contact Ann Maginnis: [redacted] or Amanda Lennon (Coroner's Office): [redacted] or Susan McCombe (Clinical Negligence): [redacted] or Lorraine Watson (BCH Clin. Neg./Coroner's) [redacted].

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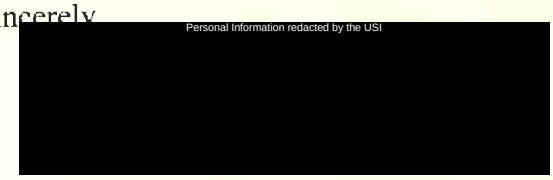
everything possible has been done or will be done to prevent the occurrence of a similar fatality or other serious adverse incident that has not resulted in a fatality.

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

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:	May 2015		**Next Review:**	May 2017
Version No.	V0.4	**Supercedes**	Any legacy policies.	
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.
01/02/2015	0.3	JRJ	Following 3/11/14, 19/01/2015 MLF meetings
20/03/2015	0.4	JRJ	Following regional feedback, NICE publication

Recommendations

This policy sets out a regional co-ordinated 'collegiate' improvement programme for surgical endoscopic tissue resection, with,

- a plan to use the safest resection technique currently available with its attendant irrigation fluid.
- establishing a set of safe practice standards and set of precautions to minimise the risk of intravascular absorption.

1. Preoperative workup **must** be geared towards prevention of the TUR syndrome.
2. Introduce Bipolar equipment using saline, regionally; curtail the use of glycine as a irrigant, strictly monitor when it is still used and eventually stop when there ceases to be circumstances when glycine use is considered the safest.
3. Engineer changes in the type of procedures performed.
    a. More secondary procedures for management of heavy menstrual bleeding as per NICE recommendations.
4. Increase vigilance when significant haemorrhage is a feature.
5. If continue to use glycine, the following **MUST** be used,
    a. Measure POCT serum sodium,
        i. preoperatively.
        ii. if the surgery is longer than 30 minutes as a routine.
        iii. intermittently throughout the surgery.
        iv. if there is a 1000 ml fluid deficit.
    b. Dedicated staff for transporting specimens and results.
    c. Surgery, including TURP, TCRE & TCRF must be performed in a 'main' theatre where POCT equipment is immediately available.
6. Limiting the distension pressure by,
    a. maintaining it below the mean arterial pressure (MAP).
    b. attempting to limit the height of the irrigating solution container to 60 cm above the patient and certainly never above 100cm.
    c. Theatre teams must have a procedure for checking and maintaining an agreed height.
    d. not applying pressure bags to the irrigation fluid bag.
7. Investigate instilling irrigation fluid by using a pressure controlled pump device and purchasing flow/pressure controllers.
8. The theatre team **must**,
    a. be aware of the distending fluid input & output and deficit.
    b. contain a dedicated nurse for fluid balance and deficit calculation, who remains in theatre for the duration of the procedure.
9. If continue to use glycine, the following **MUST** be used, throughout the procedure,
    a. Accurate irrigation fluid input & output measurement and deficit calculation.
10. Preoperatively, there **must** be an agreed maximum fluid deficit threshold for action. The surgeon and anaesthetist **must** be informed by the nurse when the threshold is reached.
11. Operations should not last longer than 60 minutes
    a. Theatre teams **must** have an established mechanism for measuring time and procedures for alerting surgeon and anaesthetist.
12. Completion of the WHO surgical checklist **must** be adhered to. Adoption of a modified WHO checklist for this kind of procedure should be investigated and piloted.

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

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

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

Endoscopic operations where there is tissue resection can lead to serious complications such as haemorrhage, fluid overload, hyponatraemia, cerebral oedema and death. This policy concentrates on a subset of these; the transurethral resection (TUR) syndrome[1], when systemic intravascular absorption of irrigation fluid can cause serious symptoms.

This policy sets out the steps needed to improve the safety profile of this type of surgery. Using national policies, guidelines and evidence identified in section 7 along with on-going work within the province, its aim is to establish a regional 'collegiate' improvement strategy for all surgical (urology, gynaecology) teams in NI practicing this type of surgery to,

- use the safest resection technique with its attendant irrigation fluid.
- agree a programme of change for the cessation of glycine use.
- develop or adopt techniques that do not rely on glycine as an irrigant.
- use equipment designed to control or reduce vesical or uterine pressure.
- establish a set of safe practice standards and precautions to minimise the risk of intravascular absorption.

Some of the recommendations can be instituted now and some will depend on the 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 non-haemolytic and will not lead to haemolysis if it enters the circulation.

Until relatively recently, the standard equipment used to resect tissue was of a **monopolar electrode** design which requires an electrically nonconductive irrigating fluid so the electrical current is not dissipated and can remain concentrated at the cutting point. As described below, use of this type of fluid bears the risk of the TUR syndrome.

Recently introduced **bipolar resection equipment** is different to the monopolar type in that it incorporates both active and return poles on the same electrode. This allows a conductive fluid medium (normal saline) to be

used for the irrigating fluid instead of a 'conventional' nonconductive irrigation fluid (glycine, sorbitol or mannitol).

Irrigating fluids
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 has been 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 $mOsm.kg^{-1}$ which is much lower than that of blood [Plasma = 290 $mosmol.kg^{-1}$] and large amounts of this hypotonic irrigation fluid, required to facilitate the procedure, may be absorbed systemically through a vascular bed[2]. 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. It is associated with fewer unfavorable changes in serum sodium and osmolality than is the case when electrolyte-free media are used with monopolar systems[3] e.g. glycine. Its use, however, does not eliminate the need to prevent excess absorption or to closely monitor fluid balance, as overload can occur. Pulmonary oedema is a reported consequence.

1.3 TUR syndrome[4]

The transurethral resection (TUR) syndrome is an iatrogenic form of acute water intoxication from a combination of fluid overload and hyponatraemia. While first recognised in urology, hence its name, it can occur in other surgical specialties e.g. gynaecology.

It 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. Its metabolism yields water (worsening fluid overload) and ammonia.

The incidence of TUR syndrome for TURP appears to have reduced over the last two decades with recent studies demonstrating incidence rates of 0.8% -

1.4%. The occurrence of the TUR syndrome following bladder tumour resection (TURBT) is thought to be rarer but can occur, probably via either an intraperitoneal or extraperitoneal bladder perforation.

There is a observation that the incidence and effects of this syndrome are more pronounced in gynaecological than in urological surgery. Fluid absorption is slightly more common during TCRE than during TURP, with transcervical resection of fibroids (TCRF) being at a further increased risk over TCRE. Whereas hyponatraemia occurs with equal frequency in men and women, it is more likely to produce severe complications in premenopausal women[3]. Nevertheless, the necessity to constantly seek best and safest practice and to encourage change and improvement is the same for both specialties.

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.
- electing to use surgical equipment which allows the use of irrigation fluid which will not give rise to the TUR syndrome.
- the application of monitoring aimed at detecting the early warning signs of the TUR syndrome.
- 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 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 of the TUR syndrome.

3.0 ROLES/RESPONSIBILITIES

Medical staff to,

- ensure they are fully cognisant of the risks of the TUR syndrome.
- undertake careful consideration of the therapeutic choices when planning the service for endoscopic resection in order to reduce the likelihood of the development of the TUR syndrome.

Management – 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 involved with this kind of surgery 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 adverse incident form must 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 that found in normal cells.

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

Hyponatraemia: Lower sodium concentration than normally found in plasma.

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 (RF) electrosurgical generator which can be either monopolar or bipolar.

4.2 Policy Principles

An 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.
    - distension pressure applied to the irrigation fluid.

For safe endoscopic resection using irrigation fluid, consideration of the following topics needs covered,

a. Preoperative workup.
b. Selection of surgical technique.
c. Identification, control and management of haemorrhage.

d. Control of the absorption of irrigation fluid.
    a. Dilutional Hyponatraemia.
    b. Fluid overload.
    c. Glycine toxicity.
e. Theatre environment.
    a. Decision making processes.
    b. Team dynamics.
    c. Knowledge of potential complications.

4.2.1 Preoperative workup

Careful preoperative workup of the patient must 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 before surgery commences.

Recommendation 1
Preoperative workup **must** be geared towards prevention of the TUR syndrome.

Urology

These procedures are carried out on a predominantly elderly population with a high 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.

Gynaecology

Consideration should be given to the timely commencement of any adjuvant therapy prior to the surgery[3], 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

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[1].

One of the most important recent improvements in this field has been the introduction of bipolar electrode technology (B-TURP). This addresses the

fundamental flaw of monopolar equipment (M-TURP) by allowing resection in a normal saline irrigation. Therefore, the adoption of bipolar TURP/TURBT allows NS irrigation 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.

There are several manufacturers who have developed bipolar endoscopy systems. Early local adopters of this type of equipment have experience of several of them and have observed a progressive and continuing development cycle which has now resulted in really excellent systems. They also observe that some other manufacturers have not kept pace. It is important that views on the performance of these bipolar systems are based on the most modern examples and on those manufacturers who have managed to develop the most efficient systems.

B-TURP is the most widely and thoroughly investigated alternative to M-TURP[5]. There is now increasing recent evidence[6 - 9] for the effectiveness of bipolar systems as their technical performance has been developed and improved. Indeed there is some evidence[9] that bipolar may be better at improving urine flow rates and also reducing bleeding related complications as well as eradicating the TUR syndrome. With reduced bleeding and improved visibility, resection time can be decreased.

Moreover, recent systematic reviews[7, 9] are not only repeatedly describing equal effectiveness between monopolar and bipolar techniques but are also pointing out the significantly improved safety profile for bipolar.

Significantly, the TUR syndrome has not been reported with bipolar equipment[5]. A recent systematic review and meta-analysis[9] 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."*

This is supported by recommendations within the European Association of Urology guidelines[5] on TURP management of April 2014. "*B-TURP has a more favourable peri-operative safety profile compared with M-TURP."*

In 2012, NICE recommended[10] that bipolar techniques are associated with lower rates of complications and in October 2014 they opened up support[11] for the use of transurethral resection in saline which eliminates the TUR syndrome and may also reduce length of stay as well as having cost benefits.

In February 2015, they published their medical technology guidance[12] on a transurethral resection in saline system. They point out that the case for adopting the transurethral resection in saline (TURis) system for resection of the prostate is supported by the evidence.

They also indicate that,

- the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate' (or monopolar TURP).
- 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.
    - it is less likely that a blood transfusion after surgery will be needed.

NICE used an External Assessment Centre to analyse the clinical evidence and concluded that their meta-analysis found a statistically significant effect in favour of TURis: relative risk 0.18 (95% CI 0.05 to 0.62, p=0.006), corresponding to a number needed to treat to prevent 1 case of TUR syndrome compared with monopolar TURP of 50 patients.

The External Assessment Centre did not identify any special additional training needs for a switch to the TURis system from monopolar transurethral resection of the prostate (TURP). The NICE Committee received expert advice that confirmed that little training is needed for surgeons who are already performing monopolar TURP procedures.

The sources of evidence considered by the NICE committee included expert personal views from at least 5 clinical experts from the British Association of Urological Surgeons (BAUS).

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. 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.

Also, queries have been expressed over a potential degradation of pathological specimens with the use of this new technology which might have staging implications for bladder tumour management. However, the experience of both surgical and pathology staff within the BHSCT has been that they have not noticed any major difference. There is also no evidence based literature to support the view that bipolar resection causes any more damage and in fact the incidence of severe cautery artefact was significantly lower in the bipolar resections[13], a view subsequently supported in an accompanying editorial[14] which also exhorts, "*as urologists we have shown again and again that we are quick to adopt new technologies in routine practice*".

Therefore (as long as they are proven to be safe and effective as judged by the NICE interventional procedure programme), bipolar RF systems and other techniques e.g. laser systems, should be introduced regionally. By introducing the, as effective, but safer bipolar equipment, this should, by necessity, reduce and curtail the use of glycine as a irrigant. Its continuing use should be strictly monitored and eventually terminated when there ceases to be circumstances when its use is considered the safest.

Recommendation 2
Introduce Bipolar equipment using saline, regionally; curtail the use of glycine as a irrigant, strictly monitor when it is still used and eventually stop when there ceases to be circumstances when glycine use is considered the safest.

Gynaecology

The first generation endometrial ablative techniques including transcervical resection of endometrium (TCRE) and rollerball endometrial ablation (REA) are all endoscopic procedures. Fluid absorption is slightly more common during TCRE than during TURP, with transcervical resection of fibroids (TCRF) being at a further increased risk over TCRE. As TCRE often evolves into a TCRF when fibroids are found during hysteroscopy, it means the same safety procedures need to be put into place for both TCRE and TCRF.

Their effectiveness in the management of heavy menstrual bleeding (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.

However, 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.

A Cochrane Collaboration review (2013)[15] concludes that "*Overall, the existing evidence suggests that success, satisfaction rates and complication profiles of newer techniques of ablation compare favourably with hysteroscopic techniques.*"

NICE[16] in their online guidance for Heavy Menstrual Bleeding recommend,

- First-generation ablation techniques (e.g. rollerball endometrial ablation [REA] and TCRE) are appropriate if hysteroscopic myomectomy (TCRF) is to be included in the procedure.

- All women considering endometrial ablation should have access to a second-generation ablation technique.

Recommendation 3
Engineer changes in the type of procedures performed. • More secondary procedures for management of heavy menstrual bleeding as per NICE recommendations.

If hysteroscopic procedures such as TCRE and TCRF are considered to be the best options and a distending fluid is required, the choice of fluid then comes under the same scrutiny as above for Urology. The choice of using a monopolar scope system using glycine versus bipolar equipment using saline becomes the choice. Evidence is now emerging from gynaecology units in Northern Ireland that are measuring the serum sodium intraoperatively during every case, that there can be concerning incidences of acute hyponatraemia when glycine is used as the distending agent during TCRE[17]. With the development of newer bipolar systems it is recommended that saline has a better safety profile[3].

Therefore, this policy recommends that, (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 curtailed, strictly monitored when it is still used and eventually terminated when there ceases to be circumstances when its use is considered the safest.

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 the generalised physiological effects of haemorrhage and the increased likelihood of fluid absorption when using irrigation fluid in the presence of 'open' vasculature, 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.
- control of the bleeding which may need cessation of the operation.

Recommendation 4
Increase vigilance when significant haemorrhage is a feature.

4.2.4 Control of the absorption of irrigation fluid

To control the effects of fluid absorption, the theatre team should pay particular attention to,

a) hyponatraemia.
b) limiting the volume of fluid absorbed.

a. Hyponatraemia

The uptake of 1000 ml of fluid would generally correspond to an acute decrease in the serum sodium concentration of 5-8 mmol/L.[2] Encephalopathy, seizures and even cerebral oedema may develop when the sodium concentration falls below 120mmol.L^{-1}. 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[4].

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 – postoperatively, 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[3]. This effect is compounded because fluid absorption is slightly more common during TCRE than during TURP, and especially so with TCFR.

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 120mmol.L^{-1} 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 increasing the likelihood that the patient, physician, and care team will receive the results in minutes, enabling diagnosis of hyponatraemia as early as possible and allowing immediate clinical management decisions to be made. They can be used to measure haematocrit, determine haemoglobin and measure serum electrolytes.

Serum sodium is often only measured at the end of surgery but, in the surgical settings pertaining herein, this monitoring technique is best applied before and repeatedly during surgery so that it can act as a warning system for hyponatraemia. Trusts already operating this method of monitoring have uncovered episodes of unsuspected hyponatraemia; highlighting the need to be wary of glycine and to monitor accordingly. Previous audits that have not

measured serum sodium as part of their audit criteria are thus likely to have given a false sense of security when using glycine.

Any patient receiving glycine in theatre **must** have such POCT equipment readily available and a measurement(s) made,

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

Staff must be readily available who are trained to use this POCT equipment and indeed immediately available to transport the samples and result to and from the machine.

NOTE: Measurement of serum sodium is not required when using a bipolar technique and saline[8].

Recommendation 5
If continue to use glycine, the following **MUST** be used, • Measure POCT serum sodium, i. preoperatively. ii. if the surgery is longer than 30 minutes. iii. intermittently throughout the surgery as a routine. iv. if there is a 1000 ml fluid deficit. • Dedicated staff for transporting specimens and results. • Surgery, including TURP, TCRE & TCRF must be performed in a 'main' theatre where POCT equipment is immediately available.

b. <u>Limit the volume of fluid absorbed.</u>
The choice of surgical technique and equipment may reduce the complications from irrigation fluid by limiting the use of glycine but continued attention to controlling fluid absorption will still be needed if normal saline is used as the distending fluid.

Basic principles govern the amount of fluid absorbed[18].

i. The hydrostatic driving pressure of the distending fluid. This is often a feature of the height of the container but the pressure may be controlled mechanically.
ii. Measurement, monitoring and documentation of the fluid volumes and deficits.
iii. The length of the surgical procedure.

i. Hydrostatic driving pressure of the distending fluid
Surgeons have a vital role in minimising absorption by keeping the cavity distention pressure at the lowest pressure necessary to distend, consistent with good visualisation. Even though the disruption in the vascular system is venous, the best strategy is to measure arterial pressures (which is easy to

do) and to maintain distending pressure 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.

There exist a number of fluid delivery systems, ranging from those based on simple gravity to automated pumps that are designed to maintain a pre-set intra-cavity pressure. Methods of instilling the distention fluid include,

- continuous-flow by gravity,
- continuous-flow infusion pump,
- pressure-controlled or pressure-sensitive fluid pumps.

Continuous-flow by gravity

In continuous-flow gravity systems, pressure is controlled by the height of the fluid source above the bladder or uterus and is measured from the height of the highest portion of the continuous column of fluid (fluid bag) to the level of the uterus or bladder – approximately 30 cms height is equivalent to 25 mm Hg pressure[19]. If the bag is 60 cms above the patient's uterus, this results in approximately 50 mm Hg of pressure.

Height of fluid column	Pressure exerted
12 inches ≡ 30 cms	25 mmHg
24 inches ≡ 60 cms	50 mmHg
36 inches ≡ 90 cms	75 mmHg

Gravity based systems are very simple to assemble and operate, but require vigilant patient monitoring and frequent manual intake/output calculations, which can be imprecise.

Recommendation 6
Limiting the distension pressure by, • maintaining it below the mean arterial pressure (MAP). • attempting to limit the height of the irrigating solution container to 60 cm 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.

Continuous-flow infusion pump

Continuous-flow fluid infusion pumps provide a constant flow of distention fluid at the in-flow pressure determined by the operator, delivering the same flow rate regardless of the out-flow conditions. Continuous flow pumps do not

usually monitor or calculate the intracavity pressure. Significant fluid absorption and complications can occur with these types of systems because the team is unaware of the actual pressure being used during a prolonged or invasive procedure.

Pressure-controlled or pressure-sensitive fluid pumps
Pressure-controlled infusion pumps can be preset to maintain a desired in-flow pressure. By adjusting the in-flow pressure setting on the pump, it can be maintained below the MAP, thus reducing the likelihood of intravasation.

These pumps can weigh the fluid volume before infusion, which allows them to account for the overfill often found in fluid bags. Weight of fluid before installation and then after, accounts for the deficit, which provides a more accurate measurement of the fluid retained by the patient (fluid deficit). A continuous automated weighing system provides an easy, less time-consuming and valid method of monitoring fluid deficit[2] and an automated fluid management system is recommended[3].

Recommendation 7
Investigate instilling irrigation fluid by using a pressure controlled pump device and purchasing flow/pressure controllers.

ii. Measurement, monitoring and documentation of the fluid volumes & deficits.
If continuous irrigation using fluid filled bags and gravity continue to be used, volumetric fluid balance is based on counting the number of empty fluid bags and then subtracting the out-flow volume in the collection canister and fluid in the drapes to determine irrigation fluid deficit. Positive values are regarded as absorption. The surgeon should be notified about ongoing fluid absorption early enough for steps to be taken to prevent excessive absorption.

However[1], 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 when using fluid filled bag systems that the whole theatre team are aware of the distending fluid input & output and the irrigation fluid deficit. This is especially true for cases where glycine is used.

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.

Recommendation 8
The theatre team **must**, • be aware of the distending fluid input & output and deficit. • contain a dedicated nurse for fluid balance and deficit calculation, who remains in theatre for the duration of the procedure.

When using a pressure-controlled infusion pump to control the distension fluid with their associated continuous automated weighing system, the monitoring of the fluid deficit is easier[2], less time-consuming and thus an automated fluid management system is recommended[3].

Documentation

Each patient who has any irrigating fluid used must have documentation in the way of a dedicated fluid management chart (appendix 1) commenced. This can be either the measurement of input & outputs and calculating the deficit or recording the readings off an automated machine.

This 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 be recorded on the dedicated fluid management chart. They might also be displayed on a white marker board in the theatre.

At the end of the procedure, the final calculations or readings must be made; the inputs, outputs and deficit. These should be expressed clearly to the surgeon and anaesthetist and recorded on the chart. The operating surgeon should include the fluid deficit in the *Operative Findings* when writing the operative notes.

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.

Recommendation 9
If continue to use glycine, the following **MUST** be used, throughout the procedure, • Accurate irrigation fluid input & output measurement and deficit calculation.

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 depending on the,

- nature of the surgery,
- nature of the media (isotonic or hypotonic) ,
- patient's baseline,
- intraoperative medical condition e.g. presence of haemorrhage.

Considering glycine use, a 500 ml threshold may be appropriate for those who are older and/or medically compromised while for healthy individuals absorption of up to 1000 mL can generally be tolerated. Greater than 1000 mL of glycine intravasation results in a significant decrease in serum sodium, sufficient to bring a normo-natraemic patient into the abnormal range[1, 2, 3].

The surgeon and anaesthetist must be informed by the nurse when there is a 1000mls glycine deficit. Surgery must be brought to a close unless continuation of surgery is absolutely necessary to control the haemorrhage. 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.

Considering normal saline use, the maximum limit is unclear, but 2500 mL has been advocated[3]. Surgery must be brought to a close unless haemorrhage needs controlled.

Recommendation 10
Preoperatively, there **must** be an agreed maximum fluid deficit threshold for action. The surgeon and anaesthetist **must** be informed by the nurse when the threshold is reached.

iii. The length of the surgical procedure.
Estimates of the 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.

Operation time; procedures that last longer than 60 minutes and those that require large amounts of tissue resection are more likely to lead to fluid volume overload. Theatre teams must have an established mechanism for measuring time and procedures for alerting surgeon and anaesthetist.

Recommendation 11
Operations should not last longer than 60 minutes. Theatre teams **must** have an established 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 core member of the theatre team must be assigned to the duty of gathering together the information needed to ensure the whole theatre team are aware of the distending fluid input & output and the deficit. They will need to be proficient and practiced in this technique and must not have other duties to perform while monitoring fluid balance. 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.

4.2.6 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, to agree fluid absorption volume limits and should include any discussion of limiting intravenous fluids intraoperatively.

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.

Recommendation 12
Completion of the WHO surgical checklist **must** be adhered to. 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, fluid flow and pressure controllers and POCT monitoring equipment for theatres and training for staff.

6.0 MONITORING

Trust audit departments will need to monitor that the recommendations are implemented.

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8.0 CONSULTATION PROCESS

Consulted through the Medical Leaders Forum, DHSSPSNI, and via the Medical Directors, Directors of Nursing and Regional Urologists, Gynaecologists and Anaesthetists.

9.0 APPENDICES / ATTACHMENTS

Appendix 1 = Suggested peri-operative theatre record form template.

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:** _____

Author

_____ **Date:** _____

Director

Trust LOGO

Peri-operative fluid recording chart

Date: _____
Surgeon: _____
Anaesthetist: _____
Team Leader: _____
Circulating Nurse 1: _____
Circulating Nurse 2: _____

Addressograph Label

Fluid recorder: _____ Operation: _____

Fluid Medium: 3L 1.5% Glycine: ☐ 0.9% NaCl: ☐ Warmed: ☐

Bag Height: _____ mmHg ☐ (60 cms ≡ 50mmhg)

Preop. Serum Sodium: = _____ mmol/L Haemoglobin: _____ g/dL.

Resection: Start Time: _____:_____ Operation Finish Time: _____:_____

Irrigation fluid: Start time: _____:_____ **= 0 mins.**

Time (min)	Irrigation In	Irrigation Out	Irrigation Deficit	Running Deficit	Serum Sodium	Surg. informed	Anaes. informed	Sign
5	mls	mls	mls	mls	mmol/L			
10	mls	mls	mls	mls	mmol/L			
15	mls	mls	mls	mls	mmol/L			
20	mls	mls	mls	mls	mmol/L			
25	mls	mls	mls	mls	mmol/L			
30	mls	mls	mls	mls	mmol/L			
35	mls	mls	mls	mls	mmol/L			
40	mls	mls	mls	mls	mmol/L			
45	mls	mls	mls	mls	mmol/L			
50	mls	mls	mls	mls	mmol/L			
55	mls	mls	mls	mls	mmol/L			
60	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			

Total Fluid In =	mls	Surgeon Signature	
Total Fluid Out =	mls	Anaesthetist Signature	
Total Deficit =	mls	Nurse Signature	
		Recovery Staff Signature	

Trust LOGO

Continued.

Time (mins)	Irrigation In	Irrigation Out	Deficit	Running deficit	Serum Sodium	Surg. informed	Anaes. informed	Sign
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			

Irrigation In	Document number of mls after each fluid bag is emptied. Record amount 'in' each time use Ellick evacuator.
Irrigation Out	Record fluid in • suction canisters. • fluid in drapes. • fluid from floor suction. Record amount 'out' each time use Ellick evacuator.
Deficit	Calculate deficit or record from pump readout.
Serum Sodium	Ensure there is a Serum Sodium measurement within one bold bordered box if procedure longer than 30 mins.

Glycine		
Volume Absorbed	**Effect**	**Action**
500 mls	Limit for the Elderly : comorbidities	Continue surgery
less than 1000 mls	Well tolerated by healthy patient	Continue Surgery
greater than 1000 mls	Mild hyponatraemia	Complete surgery ASAP
1500 mls	**Severe hyponatraemia & other biochemical disturbances likely**	**Stop Surgery**
Normal Saline		
2000 mls	Limit in the healthy	Complete surgery ASAP

NICE National Institute for Health and Care Excellence

The TURis system for transurethral resection of the prostate

Issued: February 2015

NICE medical technology guidance 23

guidance.nice.org.uk/mtg23

Contents

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1.1 The case for adopting the transurethral resection in saline (TURis) system for resection of the prostate is supported by the evidence. Using bipolar diathermy with TURis instead of a monopolar system avoids the risk of transurethral resection syndrome and reduces the need for blood transfusion. It may also reduce the length of hospital stay and hospital readmissions.

1.2 Using the transurethral resection in saline (TURis) system instead of monopolar transurethral resection of the prostate (TURP) results in an estimated saving of £71 per patient for hospitals that already use an Olympus monopolar system and an estimated additional cost of £20 per patient for other hospitals. However, there is some evidence of a reduction in readmissions with the TURis system compared with monopolar TURP. If this evidence is included, using the TURis system results in an estimated saving of £375 per patient for hospitals that already use an Olympus monopolar system and an estimated saving of £285 per patient for other hospitals.

2 The technology

Description of the technology

2.1 Transurethral resection in saline (TURis, Olympus Medical) is a bipolar electrosurgery system designed for use when surgical intervention is indicated for prostatic enlargement.

2.2 The TURis system consists of an Olympus generator, a resectoscope, which incorporates the TURis active working element and electrode, a telescope, an inner and outer sheath, a light guide cable, and a saline cable. The active and return electrode are contained within the resectoscope at the site of the operation, eliminating the need for a patient return electrode because TURis uses saline irrigation fluid to conduct electrical current within the resectoscope. The surgeon uses an endoscopic image to guide the electrode assembly through the urethra to the prostate. The electrode is then used to cut and coagulate prostate tissue and saline is used to flush the bladder free of resected prostate tissue and blood. Electrodes are available in different sizes and shapes (described as loop, button and roller) for cutting or coagulation and to take into account surgeon choice. Generally a loop is used to repeatedly cut out small chippings to create a wide channel through the prostate and a roller or button may be used to achieve haemostasis. The prostatic chippings are flushed out before inserting a urethral urinary catheter at the end of the procedure.

2.3 The components of the TURis system are covered by individual CE marks. The most recent of these was issued in 2013 for the TURis working element.

2.4 The list prices for the components of the TURis system for transurethral resection of the prostate (excluding VAT) are:

- £8905 for the resectoscope assembly (which includes the active working element, telescope, inner and outer sheath, light guide cable and saline cable).
- £14,681 for an ESG-400 Olympus generator.

- Single-use roller and loop electrodes are £156.67 and £126.67 respectively. Each TURis procedure uses 1 loop electrode and some procedures, typically 1 in 5, use an additional roller electrode.

  The ESG-400 Olympus generator is usually provided at no cost as part of contractual arrangements with Olympus to purchase electrodes at list price.

2.5 The claimed benefits of the TURis system for transurethral resection of the prostate presented by the company were:

- Reduced risk of transurethral resection syndrome through the use of saline irrigation fluid.
- Reduced risk of postoperative blood transfusion because of intraoperative bleeding.
- A shorter length of stay in hospital due to a shorter surgical procedure and fewer intra- and postoperative complications.
- Earlier catheter removal time for improved patient comfort.
- A quicker procedure compared with monopolar transurethral resection of the prostate (TURP) so more men can be treated.
- Fewer complications during and after surgery resulting in lower readmission rates.
- Reduced costs (associated with postoperative blood transfusion, healthcare-associated infection, length of hospital stay, postoperative irrigation and a patient return electrode).
- The use of saline irrigation fluid is cheaper and more readily available than glycine.

Current management

2.6 The NICE guideline on lower urinary tract symptoms defines benign prostate enlargement as an increase in the size of the prostate gland because of benign prostatic hyperplasia, and states that about 50% of men with benign prostatic hyperplasia will develop benign prostatic enlargement. It recommends that surgery is offered only if voiding lower urinary tract symptoms are severe or if

drug treatment and conservative management options have been unsuccessful or are not appropriate.

2.7 For surgical treatment of benign prostatic enlargement, the NICE guideline on lower urinary tract symptoms recommends the use of monopolar or bipolar TURP, monopolar transurethral vaporisation of the prostate or holmium laser enucleation of the prostate.

2.8 The NICE guideline on lower urinary tract symptoms also recommends some alternative options:

- Transurethral incision of the prostate (TUIP) can be offered as an alternative to other types of surgery to men with a prostate estimated to be smaller than 30 g.
- Open prostatectomy should only be offered as an alternative to other types of surgery to men with prostates estimated to be larger than 80 g.
- Other alternatives such as laser vaporisation techniques, bipolar transurethral vaporisation of the prostate or monopolar or bipolar transurethral vaporisation resection of the prostate should only be considered as part of a randomised controlled trial that compares these techniques with TURP.

3 Clinical evidence

Summary of clinical evidence

3.1 The key clinical outcomes for the transurethral resection in saline (TURis) system for transurethral resection of the prostate presented in the decision problem were:

- hospital length of stay
- procedural blood loss and blood transfusion
- time to removal of urinary catheter postoperatively
- transurethral resection syndrome
- readmission for repeat procedures
- duration of surgical procedure
- healthcare-associated infection
- quality of life
- device-related adverse events.

3.2 The company identified a total of 1116 studies in their database searches, and presented 24 studies in their submission as relevant to the decision problem. These included 14 randomised trials, not all of which were published in full or in English, with a total of 3032 patients (Abascal Junquera et al. 2006; Akman et al. 2013; Chen et al. 2009, 2010; Fagerstrom et al. 2010, 2011; Goh et al. 2009, 2010; Gulur et al. 2010a, 2010b; Michielsen et al. 2007, 2010a, 2010b; Rose et al. 2007) and 10 observational studies (Bertolotto et al. 2009; Fumado et al. 2011; Giulianelli et al. 2012; Ho et al. 2007; Jun Hyun et al. 2012; Lee et al. 2011; Michielsen et al. 2010c, 2011; Petkov et al. 2011; Puppo et al. 2009).

3.3 The External Assessment Centre considered the 14 randomised trials described in the submission. It established that the 3 randomised studies and

2 observational studies published by Michielsen reported on various stages and subgroups of the same study population. It also considered that the 2 papers from Fagerstrom were based on the same study population, and that the 4 conference abstracts (Goh et al. 2009, 2010; Gulur et al. 2010a, 2010b) were based on the same study population. Two studies were not published in English but have English abstracts (Abascal Junquera et al. 2006; Rose et al. 2007). The External Assessment Centre considered that, of these, only the Rose et al. (2007) paper contained pivotal results and it obtained a translation of the paper; the other was not considered pivotal. A literature search by the External Assessment Centre identified 2 further randomised studies (Geavlete et al. 2011; Ho et al. 2006). In total the External Assessment Centre considered that there were 10 unique randomised studies (1870 patients) relevant to the decision problem, 9 published as papers (including 2 foreign language papers with English abstracts) and 1 abstract.

3.4 The company presented 10 observational studies, 5 of which were published in full and 5 of which were abstracts only. The External Assessment Centre established that the Michielsen et al. (2010 and 2011) studies reported on subgroups from the randomised study by Michielsen et al. published in 2007. A literature search by the External Assessment Centre identified 1 additional observational study (Shum et al. 2014). The External Assessment Centre considered that there were 4 published papers and 5 abstracts describing relevant observational studies. It agreed with the company's conclusion that the outcomes reported from the observational studies were consistent with those from the randomised trials. The observational studies are summarised in the assessment report and are not considered further here.

Randomised trials: published papers

3.5 Akman et al. (2013) reported a Turkish study of 286 men (143 in each group) randomised to have either TURis or monopolar transurethral resection of the prostate (TURP) who were followed-up for 12 months. The mean procedure duration was 54.0 minutes for TURis and 58.7 minutes for monopolar TURP, p=0.03. The incidence of TUR syndrome was 0% for TURis and 1.5% for monopolar TURP (no p value reported). There was no statistically significant difference in the length of hospital stay for the TURis group compared with the monopolar TURP group (2.5 days compared with 2.7 days, no p value

reported). The rate of blood transfusion was lower in the TURis group (2.4% compared with 6.2%) but the difference was not statistically significant (p=0.2). There were lower rates of clot retention (0.8% compared with 1.5%, p value not reported) and mean time to catheter removal (2.4 days compared with 2.6 days, p value not reported) for TURis.

3.6 The Chen et al. (2009) study was done in China on 45 men with symptomatic benign prostatic hypertrophy and a large prostate gland, randomised to have either TURis or monopolar TURP. Results were analysed for 40 men, with reasons given for withdrawals. The results showed that average procedure duration was shorter in the TURis group compared with the monopolar TURP group (88 minutes compared with 105 minutes, p=0.001). No men in the TURis group had TUR syndrome, compared with a 5% rate (n=1/19) in the monopolar TURP group. Fewer men had a blood transfusion in the TURis group (4.8% compared with 15.5%, p value not reported). There was no statistically significant difference between groups in the time to catheter removal (2.5 days compared with 3.4 days, p=0.11). However there was a statistically significant reduction in length of hospital stay for the TURis group (3 days compared with 4.2 days, p=0.001).

3.7 Chen et al. (2010) reported a separate study of 100 men in China randomised to have either TURis or monopolar TURP. There was no statistically significant difference in procedure duration in the TURis group compared with the monopolar TURP group (59 minutes compared with 60 minutes, p=0.82) or weight of tissue resected (40 g compared with 38.9 g, p=0.31). No patient in either group had TUR syndrome. One man in the TURis group and 3 men in the monopolar TURP group needed a blood transfusion (2% compared with 6%, p=0.62).

3.8 The Fagerstrom et al. (2009 and 2011) studies were performed in Sweden on 202 men randomised to have either TURis or monopolar TURP. Results were analysed for 185 men, with reasons given for withdrawals. Results showed that there was no statistically significant difference between the TURis and monopolar TURP group in mean procedure time (62 minutes compared with 66 minutes, p not significant) or weight of tissue resected (27.3 g compared with 26.3 g, p not significant). No patient developed TUR syndrome in the

TURis group, but 3 did so in the monopolar TURP group. A statistically significantly lower proportion of men in the TURis group had a blood transfusion (4% compared with 11%, p<0.01). Median time to catheter removal was the same in both groups (20 hours), and the length of stay in hospital was similar (51 hours compared with 52 hours). There was a statistically significant reduction in the rate of readmission in the TURis group (n=5/98 compared with n=14/87, p<0.011).

3.9 The Geavlete et al. (2011) study involved 510 men in Romania who were randomised to 3 study arms (170 in each arm). Results are reported here for the TURis and monopolar TURP arms (340 patients), but not for the bipolar plasma vaporisation of the prostate arm which was considered to be outside the scope. Statistical analysis was performed on the difference between the 3 groups and is not reported here. The average procedure duration was 52.1 minutes in the TURis group and 55.6 minutes in the monopolar TURP group. No men had TUR syndrome in the TURis group compared with 3 men (1.8%) in the monopolar TURP group. In the TURis group 3 men (1.8%) needed a blood transfusion, compared with 11 men (6.5%) in the monopolar TURP group. In the TURis group 2 men (1.2%) had clot retention compared with 7 men (4.1%) in the monopolar TURP group. The mean time to catheter removal was 46.3 hours (range 36–72 hours) in the TURis group compared with 72.8 hours (range 48–96 hours) in the monopolar TURP group. In the TURis group length of stay in hospital was 3.1 days compared with 4.2 days in the monopolar TURP group.

3.10 The Ho et al. (2007) study was performed in Singapore on 48 men randomised to TURis and 52 men randomised to monopolar TURP. There was no statistically significant difference in mean procedure duration between the groups (59 minutes for TURis compared with 58 minutes for monopolar TURP) or in the weight of tissue resected (29.8 g TURis compared with 30.6 g monopolar TURP). There was a statistically significantly lower rate of TUR syndrome in the TURis group compared with the monopolar TURP group (0 men compared with 2 men, p<0.005). One patient in each group needed a blood transfusion. In the TURis group 3 men had clot retention compared with 2 men in the monopolar TURP group; this difference was not statistically significant.

3.11 The Michielsen et al. (2007) study recruited patients between January 2005 and June 2006 in Belgium. However, recruitment into the study continued until August 2009, leading to subsequent papers reported as randomised (Michielsen et al. 2010a, 2010b) and observational studies (Michielsen et al. 2010c, 2011). In total 550 patients were included in the study; 285 in the TURis group and 265 in the monopolar TURP group, but some outcomes were reported on smaller groups. There was no significant difference between the TURis group (n=263) and monopolar TURP group (n=255) in mean procedure duration (52.1 minutes compared with 50.9 minutes, p=0.357) or mean weight of tissue resected (17.6 g compared with 19.2 g, p=0.173). TUR syndrome did not occur in the TURis group and occurred twice (0.8%) in the monopolar TURP group (p value not reported). In the TURis group (n=118) 4 men (3.4%) needed a blood transfusion compared with 1 patient (0.8%) in the monopolar TURP group (n=120, p=0.211). There was no statistically significant difference in mean length of hospital stay: 3.72 days in the TURis group (n=263) and 3.89 days in the monopolar TURP group (n=255, p=0.773). No patients in the TURis group (n=118) and 2 patients in the monopolar TURP group (n=120) needed a repeat procedure because of incomplete resection (p value not reported).

3.12 The Rose et al. (2007) study was published in German and the External Assessment Centre obtained an English translation. It included 38 men who had TURis and 34 men who had monopolar TURP (the remainder had treatment for bladder cancer) in Germany. Mean procedure duration was longer in the TURis group than in the monopolar TURP group (55 minutes compared with 35 minutes, p=0.005), but the mean weight of tissue resected tended to be greater in the TURis group (42 g compared with 31 g, p value not reported). No men had TUR syndrome in either group. The mean time to catheter removal was longer in the TURis group (64 hours compared with 49 hours, p value not reported) and the TURis group had a higher rate of readmission because of haemorrhage (n=4/38 compared with n=1/34, p value not reported).

3.13 The Abascal Junquera et al. (2006) study was published in Spanish with an English abstract that had limited information on the statistical analysis. The External Assessment Centre considered that the study did not provide

additional important data and the paper was therefore not translated. In this study 45 men were prospectively randomised, with 24 men having TURis and 21 men having a TURP procedure using a monopolar system. TURis was a slightly quicker procedure compared with monopolar TURP (39.7 minutes compared with 42.7 minutes) based on a similar resection weight (13 g for TURis compared with 12.6 g for monopolar TURP). The time to removal of the catheter was similar between the groups (2.92 days for TURis compared with 3.1 days for monopolar TURP, not statistically significant) as was the length of hospital stay (3.63 days for TURis compared with 3.67 days for monopolar TURP).

Randomised trials: abstracts

3.14 The Goh et al. (2009 and 2010); and Gulur et al. (2010a and 2010b) conference abstracts relate to the same multicentre study (country not reported). In this study, 210 men with benign prostatic obstruction were randomly allocated to TURis (n=110) or monopolar TURP (n=100). The study reported a similar procedure duration for TURis compared with monopolar TURP (38 minutes compared with 35 minutes, not statistically significant). There were no cases of TUR syndrome in the TURis group and 3 (3%) in the monopolar TURP group (p value not reported). Men in the TURis group tended to have a shorter time to catheter removal (48 hours compared with 52 hours, p=0.97), and a shorter hospital stay (90 hours compared with 103 hours, p=0.06) but neither result was statistically significant.

Meta-analysis of evidence

3.15 The company presented fixed-effect meta-analyses of the randomised studies for procedure-related outcomes between TURis and monopolar TURP for TUR syndrome, clot retention, procedure duration, time to catheter removal, length of hospital stay and procedural blood loss. The results are described in sections 3.17–3.22 with further details in the assessment report on pages 81–98. A summary of the results is presented in table 1.

3.16 The External Assessment Centre did not agree with the included studies used for some outcomes in the company meta-analyses. It did revised meta-analyses with changes in the selected studies, investigated additional

outcomes and explored using either fixed- or random-effects methods. The results of the External Assessment Centre revised meta-analyses are shown in table 1.

Table 1 Results of company's meta-analyses and the External Assessment Centre revised meta-analyses (all fixed effects)

Outcome	Company's meta-analysis		External Assessment Centre's revised meta-analysis	
	Studies (n)	**Relative risk for TURis (95% CI)**	**Studies (company studies)**	**Relative risk for TURis (95% CI)**
TUR syndrome	6	0.28 (0.08 to 1.02)	6 (2)	0.18 (0.05 to 0.62)
Blood transfusion	3	0.36 (0.16 to 0.80)	6 (3)	0.35 (0.19 to 0.65)
Clot retention	2	0.63 (0.21 to 1.90)	5 (2)	0.55 (0.26 to 1.15)
	Studies (n)	**Mean difference for TURis (95% CI)**	**Studies**	**Mean difference for TURis (95% CI)**
Hospital stay (days)	3	−0.52 (−0.74 to −0.30)	2 (2)	−0.19 (−0.46 to 0.07)
Time to removal of catheter (days)	3	−0.23 (−0.38 to −0.08)	2 (2)	−0.09 (−0.25 to 0.06)
Procedure time (minutes)	4	−1.68 (−4.18 to 0.81)	5 (4)	−1.36 (−3.70 to 0.98)
CI, confidence interval; TURis, transurethral resection in saline; TUR, transurethral resection.				

3.17 The company included 6 studies presenting results assessing the risk of TUR syndrome (Abascal Junquera et al. 2006; Akman et al. 2013; Chen et al. 2010; Goh et al. 2010; Michielsen et al. 2011; Rose et al. 2007). The company applied a continuity correction to account for the zero event rate in all TURis arms, replacing nil values with 0.5. They found a non-statistically significant lower pooled relative risk in favour of TURis of 0.28 (95% confidence interval

[CI] 0.08 to 1.02). The External Assessment Centre repeated the company's meta-analysis, excluding 4 studies: 3 studies in which there were no cases of TUR syndrome in either arm, and the results from the conference abstract by Goh et al. (2010). The External Assessment Centre added data from 4 randomised studies that the company did not include (Ho et al. 2006; Chen et al. 2009; Fagerstrom et al. 2011; Geavlete et al. 2011). This revised meta-analysis found a statistically significant effect in favour of TURis: relative risk 0.18 (95% CI 0.05 to 0.62, p=0.006), corresponding to a number needed to treat to prevent 1 case of TUR syndrome compared with monopolar TURP of 50.

3.18 The company's meta-analysis of trials presenting data on blood transfusion gave a pooled relative risk of 0.52 (95% CI 0.26 to 1.04) in favour of TURis based on 4 studies (Akman et al. 2013; Chen et al. 2010; Fagerstrom et al. 2011; Michielsen et al. 2007). The company re-ran this analysis, excluding Michielsen et al. (2007) because a higher proportion of procedures were carried out by trainee surgeons in the TURis arm of that study. This gave a pooled relative risk of 0.36 (95% CI 0.16 to 0.80) in favour of TURis. The External Assessment Centre agreed with this approach and repeated the analysis, adding data from 3 further studies (Chen et al. 2009; Ho et al. 2006; Geavlete et al. 2011). The result was a statistically significant effect in favour of TURis with a relative risk of 0.35 (95% CI 0.19 to 0.65, p=0.0008). The External Assessment Centre calculated the number needed to treat to prevent 1 case of blood transfusion compared with monopolar TURP) as 20.

3.19 For clot retention, the company's meta-analysis included 2 studies (Akman et al. 2013; Michielsen et al. 2007) and found a relative risk in favour of TURis of 0.63 (95% CI 0.21 to 1.90; not statistically significant). The External Assessment Centre re-ran the meta-analysis adding 3 further studies (Chen et al. 2010; Geavlete et al. 2011; Ho et al. 2006) giving a revised pooled relative risk of 0.55 (95% CI 0.26 to 1.15, p=0.11).

3.20 For length of hospital stay, the company conducted a meta-analysis on 3 trials presenting data on length of hospital stay (Akman et al. 2013; Chen et al. 2009; Michielsen et al. 2011) which revealed a pooled mean difference between the groups (TURis minus monopolar TURP) of −0.52 days (95% CI

−0.74 to −0.30, p=0.0001). The External Assessment Centre examined the impact of the study by Chen et al. (2009), which was a source of significant heterogeneity and considered that it should be excluded. The External Assessment Centre calculated a pooled mean difference in length of hospital stay between the groups (TURis minus monopolar TURP) of −0.19 days (95% CI −0.46 to 0.07, p=0.16) which was not statistically significant.

3.21 The company included 3 randomised studies (Akman et al. 2013; Chen et al. 2009, Michielsen et al. 2010) in its analysis of mean time to removal of the urinary catheter and reported a significantly shorter time in favour of TURis of −0.23 days (95% CI −0.38 to −0.08). The External Assessment Centre excluded the Chen et al. (2009) study because it introduced significant heterogeneity to the analysis and presented a result based on 2 studies (Akman et al. 2013; Michielsen et al. 2010) which gave a non-statistically significant pooled mean difference (TURis minus monopolar TURP) for time to catheter removal of −0.09 days (95% CI −0.25 to 0.06).

3.22 The company's meta-analysis of trials presenting data for procedure duration included 4 papers (Akman et al. 2013; Chen et al. 2010; Fagerstrom et al. 2011; Michielsen et al. 2010), and found a non-significant mean difference (TURis minus monopolar TURP) of −1.68 minutes (95% CI −4.18 to 0.81). The External Assessment Centre agreed with the exclusion of Michielsen et al. (2007) in the company's initial analysis but considered the addition of 2 further studies (Chen et al. 2009; Ho et al. 2006). After the External Assessment Centre explored the heterogeneity of the meta-analysis calculations, it presented a result based on 5 studies, which gave a non-statistically significant pooled mean difference in procedure time in favour of TURis of −1.36 minutes (95% CI −3.70 to 0.98, p=0.26).

3.23 The External Assessment Centre examined 3 further outcomes that were not included in the company's meta-analysis. For readmission because of haemorrhage, data from 3 randomised studies were used (Fagerstrom et al. 2011; Geavlete et al. 2011; Rose et al. 2007) and the result was a non-statistically significant lower rate for TURis, with a relative risk of 0.53 (95% CI 0.22 to 1.25, p=0.15). The External Assessment Centre also conducted a meta-analysis on urethral strictures and bladder neck

contractures because this was highlighted as a potential concern with TURis by expert advisers. This analysis included 5 studies (Ackman et al. 2013; Chen et al. 2010; Fagerstrom et al. 2011; Geavlete et al. 2011; Michielsen et al. 2011) and found no statistically significant difference between the groups, with a relative risk of 1.08 (95% CI 0.70 to 1.69, p=0.72). The third additional outcome considered by the External Assessment Centre was repeat procedure because of incomplete resection. This analysis included 3 studies (Fagerstrom et al. 2011; Geavlete et al. 2011; Michielsen et al. 2011) and found no statistically significant difference between the groups: relative risk 0.76 (95% CI 0.42 to 1.40, p=0.38).

Committee considerations

3.24 The Committee considered that the evidence demonstrated the clinical equivalence of TURis and monopolar TURP for prostatic resection. The Committee noted there was evidence showing that the TURis system reduces the risk of TUR syndrome and reduces patients' need for blood transfusion as compared with monopolar TURP.

3.25 The Committee considered length of hospital stay derived from the meta-analyses by the company and by the External Assessment Centre. It discussed the rationale for excluding the Chen et al. (2009) study. The External Assessment Centre confirmed that it excluded the Chen et al. (2009) study because it was the source of significant heterogeneity in the meta-analysis results. However, the External Assessment Centre stated that it did not differ in terms of methodological quality from the 2 included studies. The Committee noted that all the trials were based outside the UK and heard expert advice that local policies on healthcare reimbursement and hospital-specific catheter guidelines could have an effect on length of hospital stay. The Committee concluded that there was a possibility that TURis would result in shorter hospital stays, but that clinical trial data were inconclusive.

3.26 The Committee discussed readmission to hospital after resection and noted that this outcome was not included in most of the clinical trials. However, it noted a non-statistically significant lower rate of readmission because of bleeding for TURis compared with monopolar TURP in the data from 3 trials included in a meta-analysis. The Committee also noted that the readmission

rate reported in the Fagerstrom et al. (2011) study showed a statistically significant reduction in the TURis group compared with the monopolar TURP group (n=5/98 compared with n=14/87, p<0.011). In addition, it heard expert advice based on experience of the use of TURis in the NHS, which suggested that there was indeed a reduction in readmissions due to bleeding seen in clinical practice. Based on the evidence, the Committee concluded that it was plausible that TURis would result in lower readmission rates, although the evidence was not definitive.

3.27 The Committee considered the other outcomes from the meta-analysis and noted no statistically significant differences between TURis and monopolar TURP in procedure time, time to catheter removal, the incidence of clot retention and incidence of urethral stricture or bladder neck contracture.

4 NHS considerations

System impact

4.1 The company proposed that using the transurethral resection in saline (TURis) system would not result in changes to the current pathway or involve additional system resources. The External Assessment Centre agreed with these assumptions.

4.2 The company and the External Assessment Centre did not identify any special additional training needs for a switch to the TURis system from monopolar transurethral resection of the prostate (TURP). The Committee received expert advice that confirmed that little training is needed for surgeons who are already performing monopolar TURP procedures.

Committee considerations

4.3 Based on the evidence from the company and the External Assessment Centre and on expert advice, the Committee was satisfied that using the TURis system could produce benefits for patients and for the NHS and would be relatively easy to introduce, with minimal additional training requirements.

4.4 The Committee noted that the costs of adopting the TURis system were different depending on whether hospitals were already using Olympus systems. The company stated that 40–45% of UK hospitals would already have access to a component of the Olympus systems. The Committee concluded that it was important to consider both scenarios in the cost analysis.

4.5 For hospitals that currently use monopolar equipment for TURP, expert advice to the Committee was that most would wish to change to bipolar systems when their monopolar equipment needs replacing.

4.6 The Committee noted the advice that surgeons who are already skilled at performing TURP with monopolar equipment would need very little training to use the TURis system. It concluded that additional training would not be a significant consideration in the adoption of this technology.

5 Cost considerations

Cost evidence

5.1 The company presented 3 published economic studies on surgical procedures for prostate enlargement, 2 of which reported costs for bipolar transurethral resection of the prostate (TURP) compared with monopolar TURP. The External Assessment Centre identified 1 other observational study. The studies came from different healthcare systems (Japan, India and Singapore) where care pathways vary from those in the NHS. In addition, it was not clear whether patients had received treatment with the transurethral resection in saline (TURis) system and the studies did not directly compare monopolar and bipolar systems. The economic studies are summarised in the assessment report and are not considered further here.

5.2 The company submitted a de novo cost analysis comparing the cost consequences of procedures using the TURis system and a monopolar TURP system. The time horizon of the model was a non-defined short time period designed to capture procedure-related complications. Costs were modelled from an NHS perspective and a discount rate of 3.5% per year was applied. The population included in the model was men having surgical intervention for prostate enlargement. The model adopted a cost-minimisation approach based on an assumption of no difference in the efficacy of TURis and monopolar TURP in terms of resection weight or completeness of resection. The model included the cumulative costs associated with the initial surgical procedure, complications resulting from the procedure and the need for reoperation or readmission. The sensitivity analysis also included clot retention and the need for reoperation in the event that the initial procedure was stopped before completion.

5.3 The company's model contained 3 clinical parameters: length of hospital stay, rate of blood transfusion and rate of TUR syndrome. The company used 0.52 days (95% CI 0.30 to 0.74) for reduction in the length of hospital stay, from a meta-analysis of 3 studies. The reduction in the rate of blood transfusion was taken as 0.36 (95% CI 0.16 to 0.80) from a meta-analysis of 3 studies. The rate of TUR syndrome was taken as zero for TURis patients and

1.14% (95% CI 0.30 to 1.98) for monopolar TURP from a meta-analysis of 6 studies. Full details are in section 9.4.3 of the company's submission.

5.4 The equipment costs for the TURis system included capital costs and the consumable costs of the electrodes. The Olympus generator was assumed to be provided without cost. It was assumed that each hospital would need 3 complete TURis systems. The capital costs differed between hospitals that used Olympus monopolar TURP systems and those that did not since some of the components are interchangeable. The company took these costs from Olympus data on file. For hospitals with Olympus monopolar systems, the cost of purchasing a TURis system included 3 working elements and 3 saline cables at a cost of £8800. Hospitals not using Olympus equipment would additionally need 3 each of the following: a telescope, an inner sheath, an outer sheath and a light guide cable at a total cost of £26,715. These capital elements were assumed to have a mean working life of 7 years at 150 procedures a year. This resulted in a capital cost per patient of £9.68 for hospitals using Olympus systems and £29.13 for other hospitals.

5.5 The estimated cost of electrodes for each TURis procedure was based on 1 single-use loop electrode and in 22% of procedures an additional single-use roller electrode.

5.6 For monopolar TURP the company assumed that hospitals have an existing system and so capital costs were not considered. The cost of electrodes for a monopolar TURP procedure was estimated to be 50% of the TURis electrode costs; this came to £80.57 per procedure.

5.7 The company included a £1848 cost for TUR syndrome, assuming an additional 2 days in a high-dependency unit and 2 days in a general ward. The company based the cost of a blood transfusion on an estimate used in a study by Varney et al. (2003), which was £920.40.

5.8 The results of the company's base case stated that the average total cost per patient of using the TURis system was £1043.57 for hospitals using Olympus systems and £1063.01 for hospitals not using Olympus systems, compared with £1177.20 for a monopolar TURP system. TURis therefore reduced costs

for hospitals using Olympus systems by £133.63 per procedure and for hospitals not using Olympus systems by £114.19 per procedure.

5.9 The results of one-way probabilistic and threshold analyses done by the company suggested that these results were robust. The key drivers of the savings in the company's cost model were the reduction in the length of hospital stay and the cost of monopolar consumables.

5.10 The External Assessment Centre considered the company's basic model structure to be appropriate. The External Assessment Centre revised the cost model parameters based on its meta-analyses results and so used a zero difference in the length of hospital stay between TURis and monopolar TURP; a relative risk of blood transfusion for TURis compared with monopolar TURP of 0.35; and a relative risk of TUR syndrome for TURis compared with monopolar TURP of 0.18.

5.11 The External Assessment Centre considered that the company's costs for blood transfusion overestimated the true costs because several components were included that would not typically be needed. The External Assessment Centre estimated the cost of a blood transfusion to be £329, based on the cost of 2.7 units of red blood cells.

5.12 The External Assessment Centre could not find a rationale for the company's assumption that the cost of monopolar electrodes was 50% of the cost of the TURis electrode. Based on advice from the clinical experts, the External Assessment Centre assumed that all monopolar TURP procedures, in both Olympus and non-Olympus cases, involved both a loop and a roller electrode. The External Assessment Centre considered that hospitals using Olympus systems obtained the generator on loan and paid the list price for monopolar TURP consumables (£137.75). Hospitals not using Olympus systems have the option to purchase a non-Olympus electrosurgery unit generator, incurring a higher initial cost but allowing the purchase of monopolar electrodes at a lower price from NHS Supply Chain, saving money over the lifetime of the electrosurgery unit. The External Assessment Centre used a price of £66.84 for hospitals not using Olympus systems (based on the price of generic

monopolar TURP consumables [£56.84] from NHS Supply Chain and a £10 per procedure electrosurgery unit cost).

5.13 The results for the base case in the External Assessment Centre's revised model found a total cost per TURis procedure in hospitals using Olympus systems of £1183.99 and in other hospitals of £1203.44. The total costs for a monopolar TURP were £1196.60 for hospitals using Olympus systems and £1125.69 for other hospitals. TURis was cost saving for hospitals using Olympus systems by £12.60, but added costs of £77.75 for other hospitals. The savings are driven by a reduction in risk of TUR syndrome and blood transfusion.

5.14 The External Assessment Centre reported an additional scenario involving readmissions for all causes, based on data from the Fagerstrom et al. (2011) study. The rate of readmission (all causes) for TURis was 5.1% and for monopolar TURP was 16.1%, giving a relative risk for TURis of 0.31, p=0.011. The External Assessment Centre estimated the cost of a readmission (all causes) as £2781, based on the NHS reference cost 2012/13 code LB20D. Results obtained when readmission from all causes was included in the model revealed that TURis saved £319.62 per procedure for a hospital with an existing Olympus monopolar TURP system and £229.27 per procedure for other hospitals.

5.15 The External Assessment Centre calculated a further revision to the model at the request of the Committee, with a change to the mean difference in hospital stay from zero to 0.19 days in favour of TURis, based on the External Assessment Centre's meta-analysis. The results for the recalculated base case in the External Assessment Centre's revised model found a total cost per TURis procedure in Olympus centres of £1126.04 and in non-Olympus centres of £1145.49. The total costs for a monopolar TURP were £1196.60 for a hospital using Olympus systems and £1125.69 for other hospitals. TURis was cost saving for a hospital using Olympus systems by £70.55, but added costs of £19.80 for other hospitals.

5.16 The External Assessment Centre calculated a revised result based on the meta-analysis results for the reduction in readmissions associated with TURis,

including data from the Fagerstrom et al. (2011) study at the request of the Committee. The results showed TURis was cost saving by £375.02 per procedure for a hospital with an existing Olympus monopolar TURP system and by £284.66 for other hospitals.

Committee considerations

5.17 The Committee agreed with the External Assessment Centre's conclusions that the published economic studies did not contain relevant evidence. It also agreed with the revisions suggested by the External Assessment Centre in terms of the costs of the consumables and blood transfusion costs. It heard expert opinion that patients having a blood transfusion may also have an increased length of stay in hospital and it noted that this was not included in the model. The Committee considered it was quite likely that TURis could be cost saving, but noted the uncertainties in the External Assessment Centre and company meta-analyses for length of hospital stay. At the draft guidance meeting the Committee considered that the cost model should include the 0.19 days difference in the length of hospital stay in favour of TURis compared with monopolar TURP. Results from the revised model showed that TURis saved around £71 per patient for hospitals that already use Olympus systems and has an additional cost of around £20 per patient for other hospitals (see section 5.15). The Committee concluded that, although uncertainty remained in the cost model, the use of the TURis system is likely to generate cost savings compared with the monopolar TURP system.

5.18 The Committee noted that the data available to estimate differences in readmission rates between TURis and monopolar TURP were limited in quantity, but it received expert advice that a reduction in readmissions was likely if TURis was used, instead of monopolar TURP. From the results of the External Assessment Centre's scenario analysis based on the Fagerstrom et al. (2011) study it considered that it was plausible there would be cost savings for hospitals with TURis, attributable to fewer readmissions, whether or not the hospitals were already using Olympus equipment.

6 Conclusions

6.1 The Committee concluded that the evidence demonstrated that the transurethral resection in saline (TURis) system was of equivalent efficacy to the monopolar system for transurethral resection of the prostate (TURP). It noted the important clinical advantages of TURis are reducing the risk of TUR syndrome that exists with monopolar TURP and reducing the need for blood transfusion. The Committee considered that it is plausible that TURis will also reduce length of hospital stay and reduce readmissions after surgery, although the evidence on these outcomes was limited.

6.2 The Committee accepted the External Assessment Centre revised model and sensitivity analyses and judged that, although uncertainty remained in the cost model, the use of the TURis system is likely to generate cost savings compared with the monopolar TURP system. It acknowledged that cost savings would be easier to achieve in hospitals that currently use Olympus monopolar systems. The Committee concluded that the case for adoption of the TURis system for transurethral resection of the prostate was supported by the evidence.

Andrew Dillon
Chief Executive
February 2015

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Ms Susan Bennett
Lay member

Dr Keith Blanshard
Consultant Interventional Radiologist, University Hospitals of Leicester NHS Trust

Mr Matthew Campbell-Hill
Lay member

Mr Andrew Chukwuemeka
Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Dr Fiona Dennison
Consultant Obstetrician and Gynaecologist, University of Edinburgh

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Jerry Hutchinson
Independent Medical Technology Adviser

Dr Cynthia Iglesias
Health Economist, University of York

Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Greg Irving
General Practitioner, University of Liverpool

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, ScHARR, University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Dr Rory O'Connor
Senior Lecturer and Honorary Consultant Physician in Rehabilitation Medicine, University of Leeds

Mrs Karen Partington
Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

Mr Brian Selman
Managing Director, Selman and Co

Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Mr John Wilkinson
Director of Devices, Medicines and Healthcare Products Regulatory Agency

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Manchester

Dr Amber Young
Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Paul Dimmock
Technical Analyst

Bernice Dillon
Technical Adviser

Neil Barber and Ian Pearce
Lead Expert Advisers

Shaheen Hamdy
Non-Expert MTAC Member

Andrew Cleves and Grace Carolan-Rees
External Assessment Centre Representatives

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Cedar:

- Cleves A, Morgan H, Poole R et al. The TURis system for transurethral resection of the prostate, June 2014

Submissions from the following company:

- Olympus Medical

The following individuals gave their expert personal view on The TURis system for transurethral resection of the prostate by providing their expert comments on the draft scope and assessment report.

- Mr Neil Barber, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Andrew Dickinson, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr John McGrath, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Ian Pearce, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Mark Speakman, British Association of Urological Surgeons (BAUS) – clinical expert

The following individuals gave their expert personal view on the TURis system for transurethral resection of the prostate in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Mr Neil Barber, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Andrew Dickinson, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr John McGrath, British Association of Urological Surgeons (BAUS) –clinical expert
- Mr Ian Pearce, British Association of Urological Surgeons (BAUS) – clinical expert
- Mr Mark Speakman, British Association of Urological Surgeons (BAUS) – clinical expert
- Hannah Winter, Prostate Cancer UK – patient expert

About this guidance

This guidance was developed using the NICE medical technologies guidance process.

It has been incorporated into the NICE pathway on lower urinary tract symptoms in men, along with other related guidance and products.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Related NICE guidance

For related NICE guidance, please see the NICE website.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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ISBN: 978-1-4731-1007-6

Corrigan, Martina

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

Dear Debbie and John

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

MY

Irrigating fluids used in urological procedures

Craigavon Area Hospital Urologists comments (January 2014)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M Young on behalf of the Urologist Southern Trust 5.2.2014

Stinson, Emma M

From: Young, Michael <[redacted]>
Sent: 12 October 2016 12:48
To: O'Brien, Aidan; Glackin, Anthony; Haynes, Mark; ODonoghue, JohnP; Corrigan, Martina
Subject: DeptMinutes 22 09 16 - saline resection
Attachments: DeptMinutes 22 09 16 - saline resection.docx; Saline resection Trial review and evaluation sept'16.docx

Please review document for sign off and final decision at next dept meeting

MY

DEPARTMENTAL MEETING 22nd SEPTEMBER 2016

Chair: Mr Young

Present: Mr Glackin, Mr O'Brien, Mr Suresh, Mr O'Donoghue, Pamela Johnston, Theatre Manager & Sr. England

Apologies: Mr Haynes , Mrs Corrigan

TOPIC: SALINE RESECTION

The specifications for the saline resectoscope system were presented. Mr Young outlined the history behind the move to the saline resection, also explaining that the last year had been spent trialling the various resectoscopes. Mr Young asked the forum if they had regarded enough time had been given to each of the resectoscope providing companies so that an adequate assessment could be made for each of the scopes. The unanimous decision was that the trial period for each of the resectoscopes was adequate to make an opinion.

We all agreed that the appraisal form used was of a good standard and certainly adequate to make a surgeons' assessment of each scope. The overall assessment looked at scope quality, ease of use, product design and effectiveness of the core principal of diathermy and resection of tissue. Second component to be evaluated were costs of generators and disposables. Thirdly was the topic of CSSD and backup. Scoring was undertaken from the feedback forms with the result that the WOLF system was the poorest and was not fit for purchase. In third place was the TONTARRA system which was described as having a variable performance with regards to the resection loop activity. The STORZ and the OLYMPUS system scored virtually equally on the various points with an overall equal score. It was recorded that there was no cystoscope present on the OLYMPUS resectoscope tray for evaluation but we generally felt that this was not an issue to take into account. There was general record of a fairly good ease of use and that the vaporisation module component was good. Several negative points related to the working element of inflow/outflow not being ideal; there were some comments on excessive bubble formation on the resectoscope loop as well as some other comments relating to slow resection. Overall however this was a system that could be purchased. With regards to the STORZS system, it was felt that the cutting modality of the resectoscope loop was excellent. Overall the scope components were easily constructed and there was a generalised good ease of use. Comments with regards to consistency and haemostasis had been positive. One of the major points in its favour was that the STORZ system could be easily changed if required on an urgent basis to the use of glycine. This in the current climate of change from one system to another in association with the range of urologists within the unit was a more suitable system for the team in Craigavon Area Hospital. The STORZ system certainly was a system that could be purchased.

Purely on the ease of use principal, excluding other criteria (i.e. cost and CSSD), the option came down to either STORZ or the OLYMPUS system, the other two being excluded. Four surgeons voted for the STORZ, one electing for the OLYMPUS. Mr Haynes was not present for this vote but on subsequent conversation later in the day, Mr Young put the same question to Mr Haynes asking for his comments on ease of use and again he had no particular preference and was happy to run with the global opinion.

On reviewing the various costs, it was noted that the disposables did have a variable range. It was accepted that loop quality did vary and that loops could be purchased from different sources. We all felt that this was not a particularly focused point for making a decision (namely cost of loop).

The price of the individual resectoscope systems was recorded noting that the OLYMPUS system was significantly more expensive in totality. The OLYMPUS system would have to be purchased completely whereas the STORZ system could be involve both new scopes and modification of current sets. (The costs set out for this meeting were significantly in favour of the STORZ system but it was appreciated that if a STORZ completely new systems was to be included that this information was to be presented to the forum before a final decision was made).

A further significant contributor to decision making was the generator needed for the electrical input. Although the OLYMPUS company was going to offer a free £40,000 generator, we did record that we may need up to three generators in view of the amount of urology sessions occurring at the same time. (The forum did not know if the company would supply three free generators. They felt it unlikely but enquiries would be made). The current generator system available within the Trust is multifunctional and therefore would already suit the STORZ system more appropriately. Even with the OLYMPUS generator system, this would result in increased machinery parking within the theatre environment. Overall this was regarded as a fairly substantive pointer in favour of the STORZ system.

CONCLUSION

In concluding, the vote on several aspects namely ease of use, cost, generator type were all in favour of the STORZ system. All the urologists have backed this decision with a unanimous vote.

This decision was based on the information supplied with a final decision pending the outstanding enquiries, namely the cost of a completely new STORZ resectoscope system and the cost of the OLYMPUS cystoscope. This would give a truly like for like comparison. The additional enquiry related to the OLYMPUS generator issue.

Mr Young will add an addendum to this document when the above information becomes available before final sign off.

The paperwork with regards to this has been forwarded to the Service Administrator, Martina Corrigan and to Pamela Johnston, Theatre Manager.

M Young
22nd September 2016
Chair of Session

ADDENDUDEM to outstanding information in relation to Saline resection Systems

1/ Full cost specification for STORZ and OLYMPUS resectoscope systems (excluding generator) have now been supplied and presented by the Theatre management. This is included on the updated evaluation sheet. (see enclose document)

(*The conclusion of the forum group remains the same – namely that STORZ is less expensive*)

2/ OLYMPUS will only supply one free generator

This information is to be presented at the next Departmental meeting for ratification

M Young

12th October 2016

Saline Resection Trial evaluation- Date: 15th Sept'16 Review

Selection Criteria	Storz	Wolf	Olympus	Tontarra	Comments
Ease of Use: Quality and Design and ease of use with active resecting mechanism	**Score 45**	30*	44	38	*Wolf rep unavailable to support trial with generator. No extra electrodes sent for trial despite requests- company sent incorrect electrode
Fit for Purpose: • Continuous Flow System	**44**	25	44 *	34	*Olympus did not have cystoscope available on tray for trial
Product Quality: Loop and Ball Electrode ○ Quality and Design and ease of use ○ Precision of Cut	**45**	27	45	33	Tontarra- reusable breakages (single use electrode now available)
Overall performance	**43**	24	44	35	
TOTAL	**177**	106	177	140	

Received from Michael Young on 01/11/2023. Annotated by the Urology Services Inquiry.

Selection Criteria	Storz	Wolf	Olympus	Tontarra	Comments
Cost: Bi-Polar Resection Kit	**£2006.69**	£4925	£8575.65	**£4880 (Trade in £4000)**	• Storz- only need lead and resect scope (kit items required telescope/working element, continuous flow sheath, obturator, view obturator, light guide, bipolar cable, basket)
Consumables- per loop electrode **Coagulation ball**	**£47.50** **£47.50**	£77 £71	£126.66 £156.66	£53 £53	Updated 15/
Generator	**Not required- Erbe/Covidien compatible**	**Erbie with Booster * Costs not**	Free of cost £40,000 (approx.)	**Not required- Erbe/Covidien compatible**	

		supplied			
Support and Service a. Responsiveness b. Training	**Good-** support for each day of trail	**Poor-** limited support	**Fair-** inexperienced rep	**Good-** regular rep support and good knowledge	
CSSD Comments:	**No issues**	**No issues**	**No issues**	**No issues**	**No issues**
Urology Consultants preference 1-4 Rationale 15/9/16					

Specification Required for Saline Resection Trial evaluation

2. Resection using Saline irrigation

3. Continuous Flow System

4. Quality and Design and ease of use with active resecting mechanism

5. Disposable/Reusable Loop and Ball Electrode
    a. Quality and Design and ease of use
    b. Precision of Cut

6. Dual foot pedal

7. Support and Service
    a. Responsiveness
    b. Training

8. CSSD Issue - Sterilisation Process

9. NHS Framework

10. COST: Equipment and Consumables (Based on average 300 cases per year)

11. Service Contracts

Received from Michael Young on 01/11/2023. Annotated by the Urology Services Inquiry.

Corrigan, Martina

From: Young, Michael <[redacted]>
Sent: 16 November 2017 17:55
To: Carroll, Ronan
Cc: Corrigan, Martina
Subject: saline TURP issue

Dear Ronan
I write with regards to the saline TURP issue.
As you are aware the DoH had undertaken a review of irrigation fluid used for TURP surgery a few years ago after a significant adverse event in which a young lady died. As a result a clearly documented pathway noted that hospitals in Northern Ireland should move to using saline as opposed to glycine for irrigation. In the Southern Trust we have been using glycine and therefore it has been necessary for us to convert over to new equipment for our Consultants and team to be compatible with DoH guidelines.

Several saline resectoscope systems are available. We have proceeded through a process of trialling each of these. We have considered several factors, including efficiency of use through to the financial impact, before coming to a conclusion. We as a department felt this was important to undertake as there would be long term implication to our decision. In saying all of this, we still felt that a defined date to transfer over to the new system was needed. We defined this date as 1st January 2018. This date was defined as fitting a timeline that allowed for the trail period, quotes to be received, assessment and providing the Trust a reasonable period of time to purchase the equipment.

The move to using Saline for TURP resection has been dictated by the DoH. The consequences of not moving to its use will leave Consultant Urologists at risk as if another significant adverse incident occurs they will feel very much exposed. I am not sure the Southern Trust would be able to cover them properly if such an event occurred when it is clear the DoH had made their stipulation.

We were under the distinct impression that having gone through our selection process and giving adequate notice, as discussed at the Theatre Users group, that this date was reasonable and would be compliant with the DoH documentation and hence for the Trust to be able to report back to DoH on the same.

It has now come to my attention that the Trust is not able to or in a position to proceed with the purchase of this equipment. It is not clear why this is the case as we have been instructed to move over to this system by the Trust itself.

Urologists in the department will be maintaining their position for a switch to using saline to perform TURP as of 1st January 2018. If the new equipment is not available the Urologists will cease the current type of TURP surgery. I am sorry this appears a little dogmatic, but the DoH and Coroners case that has sparked this course has been clearly set out and leave Consultants vulnerable if they do not attempt to comply.

M Young
Lead Clinician Urology

Stinson, Emma M

From: O'Brien, Aidan <Personal Information redacted by the USI>
Sent: 07 February 2016 21:22
To: Corrigan, Martina; Glackin, Anthony; Haynes, Mark; ODonoghue, JohnP; Suresh, Ram; Young, Michael
Subject: RE: Standard Operating Procedure for Fluid Management during Urology surgery

Dear All,

I suspect that any comments from me will be perceived to have been prejudicial.
However, I honestly did approach using the much hailed Olympus with a view to giving it a fair wind.
And was I bowled over?
No!
I resected two small prostates.
I found it deficient in two respects:

1. It is my understanding that there is no blended current on cutting with the result that haemostasis was inferior to monopolar during cutting
   You resect, it bleeds and you coagulate.
   This slowed the resection.
   It also had me wondering whether one would have increased fluid absorption as a consequence.

2. The rate of irrigation was much slower than with the monopolar resectoscopic, with the result that there was an intermittent fog which I had to stop resecting to wait for it to clear.

I was so glad that neither prostate was large, as I certainly would not have used the Bipolar.

The Audit asks the question whether the trialist would be 'happy' to use it.
My answer was a definite 'No'.
I will do if I have to.
I just do hope that the Operating procedure will allow me to continue to use Monopolar, as it is very much superior,

Aidan

From: Corrigan, Martina
Sent: 07 February 2016 17:55
To: Glackin, Anthony; Haynes, Mark; O'Brien, Aidan; ODonoghue, JohnP; Suresh, Ram; Young, Michael
Subject: FW: Standard Operating Procedure for Fluid Management during Urology surgery

Any comments?

Martina

Martina Corrigan
Head of ENT, Urology and Outpatients
Southern Health and Social Care Trust
Craigavon Area Hospital

Telephone: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

From: Brown, Robin
Sent: 05 February 2016 16:54
To: Corrigan, Martina
Subject: RE: Standard Operating Procedure for Fluid Management during Urology surgery

Bit late with my reply
Looks fine to me
There's a lot of work for the nurses to do.
If we are shifting to bipolar I wonder if I should soon stop doing unipolar TURBT
You can advise me

Robin

From: Corrigan, Martina
Sent: 15 January 2016 13:47
To: Brown, Robin; Glackin, Anthony; Haynes, Mark; O'Brien, Aidan; ODonoghue, JohnP; Suresh, Ram; Young, Michael
Cc: Trouton, Heather
Subject: FW: Standard Operating Procedure for Fluid Management during Urology surgery
Importance: High

Dear all

Please see attached and below. Can you send any comments to me and we can do a co-ordinated response back to Mary before 29 January.

Thanks

Martina

Martina Corrigan
Head of ENT, Urology and Outpatients
Southern Health and Social Care Trust
Craigavon Area Hospital

Telephone: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

From: McGeough, Mary
Sent: 15 January 2016 13:41
To: Young, Michael
Cc: Carroll, Ronan; Trouton, Heather; Corrigan, Martina; Johnston, Pamela; Madine, Mary; Gildernew, Ursula; Kelly, Brigeen; Beattie, Caroline
Subject: Standard Operating Procedure for Fluid Management during Urology surgery
Importance: High

Mr Young

Attached is the final draft of the Standard Operating Procedure for Fluid Management during Urology surgery and the relevant Appendices. Could you please discuss with Mr Brown and all of the Urology Consultants who undertake this surgery and advise if any amendments are required? I would be grateful if all comments could be emailed to me by **Fri 29th January '16.** If no amendments are required it will be circulated for immediate implementation.

Many thanks

Mary

Mary McGeough
Head of Anaesthetics, Theatres and Intensive Care
Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

Tel: Personal Information redacted by the USI
Email: Personal Information redacted by the USI ;

Stinson, Emma M

From: O'Brien, Aidan <[redacted]>
Sent: 30 March 2016 16:17
To: Young, Michael; Corrigan, Martina
Cc: Glackin, Anthony; Suresh, Ram; Haynes, Mark; ODonoghue, JohnP
Subject: Bipolar Resection

Michael and Martina,

I wish to take the opportunity to update you on my experience of trying bipolar resection systems.
I have tried the models on trial to date, and did so having disabused myself of any prejudice against their use.
As reported previously, I found their performance inferior to monopolar mainly as a consequence of the intermittency of the current, the lack of any small vessel fulguration whilst cutting and the much reduced rate of continuous irrigation.
I last use bipolar two weeks ago to resect the moderately enlarged prostate gland of an elderly patient.
I had to abandon bipolar resection after 10 minutes because of bleeding, poor irrigation and visualisation.
The intraoperative comparison of both systems was remarkable.
Bipolar resection placed this patient in intraoperative danger, and salvaged by monopolar resection.

I have therefore pledged not to do so again.
I will not use or try bipolar resection again,

Aidan.

Stinson, Emma M

From: Corrigan, Martina <Personal Information redacted by the USI>
Sent: 15 January 2016 13:47
To: Brown, Robin; Glackin, Anthony; Haynes, Mark; O'Brien, Aidan; ODonoghue, JohnP; Suresh, Ram; Young, Michael
Cc: Trouton, Heather
Subject: FW: Standard Operating Procedure for Fluid Management during Urology surgery
Attachments: Appendix 2.docx; REVISED Policy on surgery for endoscopic tissue resection V0 5 after PHA comments (Appendix 1).pdf; SOP 1 Urology Fluid Management Final Draft.doc; image002.png

Importance: High

Dear all

Please see attached and below. Can you send any comments to me and we can do a co-ordinated response back to Mary before 29 January.

Thanks

Martina

Martina Corrigan
Head of ENT, Urology and Outpatients
Southern Health and Social Care Trust
Craigavon Area Hospital

Telephone: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

From: McGeough, Mary
Sent: 15 January 2016 13:41
To: Young, Michael
Cc: Carroll, Ronan; Trouton, Heather; Corrigan, Martina; Johnston, Pamela; Madine, Mary; Gildernew, Ursula; Kelly, Brigeen; Beattie, Caroline
Subject: Standard Operating Procedure for Fluid Management during Urology surgery
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Many thanks

Mary

Mary McGeough
Head of Anaesthetics, Theatres and Intensive Care Craigavon Area Hospital
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Appendix 2

The Monitoring of Serum Sodium Levels during the timespan of Glycine Fluid Irrigation

EVENT	ACTION
Base line Serum Sodium taken on day of surgery or peri-induction of anaesthesia by anaesthetist	• Sample to be taken to the nearest blood gas analyser by a member of the nursing team
Repeat Serum Sodium required: 1. At 30 minute intervals during procedure 2. ≥ 1000ml deficit noted in fluid input output measurements 3. Unexpected complications such as bleeding	REPEAT SERUM SODIUM 1 Repeat Serum Sodium 2. The circulating nurse alerts the team if this occurs 3. The surgeon alerts the team if this occurs
Major vein is opened	• Surgeon to alert entire Team • Consider repeat sample at this stage
Serum sodium drops to 130mmol/litre (adjusted to 128 for whole blood) ***Or*** By 5mmols	• Glycine should be stopped as soon as possible
REGIONAL ANAESTHESIA In addition to the above parameters if there are signs of encephalopathy including: ▪ Visual Disturbance ▪ Nausea ▪ Vomiting ▪ seizures	• Glycine irrigation should be stopped
Monitoring patients who demonstrate a drop in serum sodium during/following glycine infusion	• Repeat serum sodium at one hourly intervals for 2 hours or until sodium level is >130 serum or 28 whole blood (whichever is longer) • Record Central Nervous Observations at 15 minute intervals for 2 hours or until normal

Insert Trust LOGO	SAMPLE POLICY	**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:	May 2015		**Next Review:**	May 2017
Version No.	V0.5	**Supercedes**	Any legacy policies.	
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.
01/02/2015	0.3	JRJ	Following 3/11/14, 19/01/2015 MLF meetings
20/03/2015	0.4	JRJ	Following regional feedback, NICE publication
August 2015	0.5	PHA	Review by PHA

Recommendations

This policy is part of a region-wide 'collegiate' improvement programme for surgical endoscopic tissue resection, including:

- a plan to use the safest resection technique currently available and its attendant irrigation fluid.
- establishing a set of safe practice standards and precautions to minimise the risk of intravascular absorption.

1. Preoperative workup **must** be geared towards prevention of the TUR syndrome.
2. Introduce Bipolar resection equipment. During the switchover to bipolar equipment, limit the use of glycine following careful risk assessment of individual patients. If glycine is still being used, strictly monitor as detailed in recommendation 5.
3. Engineer changes in the type of procedures performed.
    a. More secondary procedures for management of heavy menstrual bleeding as per NICE recommendations.
4. Increase vigilance when significant haemorrhage is a feature.
5. If continue to use glycine, the following **must** be used.
    a. Measure point-of-care testing (POCT) serum sodium,
        i. preoperatively.
        ii. if the surgery is longer than 30 minutes as a routine.
        iii. intermittently throughout the surgery.
        iv. if there is a 1000 ml fluid deficit.
    b. Dedicated staff for transporting specimens and results.
    c. Surgery, including TURP, TCRE & TCRF must be performed in a 'main' theatre where POCT equipment is immediately available.
    d. Accurate fluid input & output measurement and deficit calculation.
6. For both mono- and bi-polar techniques, limit the distension pressure by,
    a. maintaining it below the mean arterial pressure (MAP).

    and with continuous-flow gravity systems,
    b. limit the height of the irrigating solution container to 60 cm above the patient and certainly never above 100cm;
    c. theatre teams must have a procedure for checking and maintaining an agreed height;
    d. not applying pressure bags to the irrigation fluid bag.
7. Investigate instilling irrigation fluid by using a pressure controlled pump device and purchasing flow/pressure controllers.
8. The theatre team **must,**
    a. be aware of the distending fluid input & output and deficit;
    b. contain a dedicated nurse for fluid balance and deficit calculation, who remains in theatre for the duration of the procedure.
9. If continue to use glycine, the following **must** be used, throughout the procedure,
    a. accurate irrigation fluid input & output measurement and deficit calculation.
10. Preoperatively, for each individual patient, there **must** be an agreed maximum fluid deficit threshold for action. The surgeon and anaesthetist **must** be informed by the nurse when the threshold is reached.
11. Operations should, if possible, not last longer than 60 minutes,
    a. Theatre teams **must** have an established mechanism for measuring time and procedures for alerting surgeon and anaesthetist.
12. Completion of the standard WHO surgical checklist **must** be adhered to. Adoption of a modified WHO checklist for this kind of procedure should be investigated and piloted.

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

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

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

Endoscopic operations where there is tissue resection can lead to serious complications such as haemorrhage, fluid overload, hyponatraemia, cerebral oedema and death. This policy concentrates on a subset of these, the transurethral resection (TUR) syndrome[1], when systemic intravascular absorption of irrigation fluid can cause serious symptoms.

This policy sets out the steps needed to improve the safety profile of this type of surgery. Using national policies, guidelines and evidence identified in section 7 along with on-going work within the province, its aim is to establish a regional 'collegiate' improvement strategy for all surgical (urology, gynaecology) teams in NI practicing this type of surgery to,

- use the safest resection technique with its attendant irrigation fluid;
- agree a programme of change for the cessation of glycine use;
- develop or adopt techniques that do not rely on glycine as an irrigant;
- use equipment designed to control or reduce vesical or uterine pressure;
- establish a set of safe practice standards and precautions to minimise the risk of intravascular absorption.

Some of the recommendations can be instituted now and some will depend on purchase 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 non-haemolytic and will not lead to haemolysis if it enters the circulation.

Until relatively recently, the standard equipment used to resect tissue was of a **monopolar electrode** design which requires an electrically nonconductive irrigating fluid so the electrical current is not dissipated and can remain concentrated at the cutting point. As described below, use of this type of fluid bears the risk of the TUR syndrome.

Recently introduced **bipolar resection equipment** is different to the monopolar type in that it incorporates both active and return poles on the same electrode. This allows a conductive fluid medium (normal saline) to be

used for the irrigating fluid instead of a 'conventional' nonconductive irrigation fluid (glycine, sorbitol or mannitol).

Irrigating fluids
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 has been 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 $mOsm.kg^{-1}$ which is much lower than that of blood [Plasma = 290 $mosmol.kg^{-1}$] and large amounts of this hypotonic irrigation fluid, required to facilitate the procedure, may be absorbed systemically through a vascular bed[2]. 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. It is associated with fewer unfavorable changes in serum sodium and osmolality than is the case when electrolyte-free media are used with monopolar systems[3] e.g. glycine. Its use, however, does not eliminate the need to prevent excess absorption or to closely monitor fluid balance, as overload can occur. Pulmonary oedema is a reported consequence.

1.3 TUR syndrome[4]

The transurethral resection (TUR) syndrome is an iatrogenic form of acute water intoxication from a combination of fluid overload and hyponatraemia. While first recognised in urology, hence its name, it can occur in other surgical specialties e.g. gynaecology.

It 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. Its metabolism yields water (worsening fluid overload) and ammonia.

The incidence of TUR syndrome for TURP appears to have reduced over the last two decades with recent studies demonstrating incidence rates of 0.8% -

1.4%. The occurrence of the TUR syndrome following bladder tumour resection (TURBT) is thought to be rarer but can occur, probably via either an intraperitoneal or extraperitoneal bladder perforation.

There is a observation that the incidence and effects of this syndrome are more pronounced in gynaecological than in urological surgery. Fluid absorption is slightly more common during TCRE than during TURP, with transcervical resection of fibroids (TCRF) being at a further increased risk over TCRE. Whereas hyponatraemia occurs with equal frequency in men and women, it is more likely to produce severe complications in premenopausal women[3]. Nevertheless, the necessity to constantly seek best and safest practice and to encourage change and improvement is the same for both specialties.

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;
- electing to use surgical equipment which allows the use of irrigation fluid which will not give rise to the TUR syndrome;
- the application of monitoring aimed at detecting the early warning signs of the TUR syndrome;
- 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 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 of the TUR syndrome.

3.0 ROLES/RESPONSIBILITIES

Medical staff to,

- ensure they are fully cognisant of the risks of the TUR syndrome;
- undertake careful consideration of the therapeutic choices when planning the service for endoscopic resection in order to reduce the likelihood of the development of the TUR syndrome.

Management – 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 involved with this kind of surgery 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 adverse incident form must 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 that found in normal cells.

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

Hyponatraemia: Lower sodium concentration than normally found in plasma.

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 (RF) electrosurgical generator which can be either monopolar or bipolar.

4.2 Policy Principles

An 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;
    - distension pressure applied to the irrigation fluid.

For safe endoscopic resection using irrigation fluid, consideration of the following topics needs covered,

a. Preoperative workup;
b. Selection of surgical technique;
c. Identification, control and management of haemorrhage;

d. Control of the absorption of irrigation fluid;
    a. Dilutional Hyponatraemia;
    b. Fluid overload;
    c. Glycine toxicity;
e. Theatre environment;
    a. Decision making processes;
    b. Team dynamics;
    c. Knowledge of potential complications.

4.2.1 Preoperative workup

Careful preoperative workup of the patient must 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 before surgery commences.

Recommendation 1
Preoperative workup **must** be geared towards prevention of the TUR syndrome.

Urology

These procedures are carried out on a predominantly elderly population with a high 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.

Gynaecology

Consideration should be given to the timely commencement of any adjuvant therapy prior to the surgery[3], 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

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[1].

One of the most important recent improvements in this field has been the introduction of bipolar electrode technology (B-TURP). This addresses the

fundamental flaw of monopolar equipment (M-TURP) by allowing resection in a normal saline irrigation. Therefore, the adoption of bipolar TURP/TURBT allows NS irrigation 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.

There are several manufacturers who have developed bipolar endoscopy systems. Early local adopters of this type of equipment have experience of several of them and have observed a progressive and continuing development cycle which has now resulted in really excellent systems. They also observe that some other manufacturers have not kept pace. It is important that views on the performance of these bipolar systems are based on the most modern examples and on those manufacturers who have managed to develop the most efficient systems.

B-TURP is the most widely and thoroughly investigated alternative to M-TURP[5]. There is now increasing recent evidence[6 - 9] for the effectiveness of bipolar systems as their technical performance has been developed and improved. Indeed there is some evidence[9] that bipolar may be better at improving urine flow rates and also reducing bleeding related complications as well as eradicating the TUR syndrome. With reduced bleeding and improved visibility, resection time can be decreased.

Moreover, recent systematic reviews[7, 9] are not only repeatedly describing equal effectiveness between monopolar and bipolar techniques but are also pointing out the significantly improved safety profile for bipolar.

Significantly, the TUR syndrome has not been reported with bipolar equipment[5]. A recent systematic review and meta-analysis[9] 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."*

This is supported by recommendations within the European Association of Urology guidelines[5] on TURP management of April 2014. "*B-TURP has a more favourable peri-operative safety profile compared with M-TURP."*

In 2012, NICE recommended[10] that bipolar techniques are associated with lower rates of complications and in October 2014 they opened up support[11] for the use of transurethral resection in saline which eliminates the TUR syndrome and may also reduce length of stay as well as having cost benefits.

In February 2015, they published their medical technology guidance[12] on a transurethral resection in saline system. They point out that the case for adopting the transurethral resection in saline (TURis) system for resection of the prostate is supported by the evidence.

They also indicate that,

- the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate' (or monopolar TURP);
- 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;
    - it is less likely that a blood transfusion after surgery will be needed.

NICE used an External Assessment Centre to analyse the clinical evidence and concluded that their meta-analysis found a statistically significant effect in favour of TURis: relative risk 0.18 (95% CI 0.05 to 0.62, p=0.006), corresponding to a number needed to treat to prevent 1 case of TUR syndrome compared with monopolar TURP of 50 patients.

The External Assessment Centre did not identify any special additional training needs for a switch to the TURis system from monopolar transurethral resection of the prostate (TURP). The NICE Committee received expert advice that confirmed that little training is needed for surgeons who are already performing monopolar TURP procedures.

The sources of evidence considered by the NICE committee included expert personal views from at least 5 clinical experts from the British Association of Urological Surgeons (BAUS).

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. 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.

Also, queries have been expressed over a potential degradation of pathological specimens with the use of this new technology which might have staging implications for bladder tumour management. However, the experience of both surgical and pathology staff within the BHSCT has been that they have not noticed any major difference. There is also no evidence based literature to support the view that bipolar resection causes any more damage and in fact the incidence of severe cautery artefact was significantly lower in the bipolar resections[13], a view subsequently supported in an accompanying editorial[14] which also exhorts, "*as urologists we have shown again and again that we are quick to adopt new technologies in routine practice*".

Therefore (as long as they are proven to be safe and effective as judged by the NICE interventional procedure programme), bipolar RF systems and other techniques e.g. laser systems, should be introduced regionally. By introducing the, as effective, but safer bipolar equipment, this should, by necessity, reduce and curtail the use of glycine as an irrigation fluid. Its continuing use should be strictly monitored and eventually terminated when there ceases to be circumstances when its use is considered the safest.

Recommendation 2
Introduce Bipolar resection equipment. During the switchover to bipolar equipment, limit the use of glycine following careful risk assessment of individual patients. If glycine is still being used, strictly monitor as detailed in recommendation 5.

Gynaecology

The first generation endometrial ablative techniques including transcervical resection of endometrium (TCRE) and rollerball endometrial ablation (REA) are all endoscopic procedures. Fluid absorption is slightly more common during TCRE than during TURP, with transcervical resection of fibroids (TCRF) being at a further increased risk over TCRE. As TCRE often evolves into a TCRF when fibroids are found during hysteroscopy, it means the same safety procedures need to be put into place for both TCRE and TCRF.

Their effectiveness in the management of heavy menstrual bleeding (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.

However, 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.

A Cochrane Collaboration review (2013)[15] concludes that "*Overall, the existing evidence suggests that success, satisfaction rates and complication profiles of newer techniques of ablation compare favourably with hysteroscopic techniques.*"

NICE[16] in their online guidance for Heavy Menstrual Bleeding recommend,

- First-generation ablation techniques (e.g. rollerball endometrial ablation [REA] and TCRE) are appropriate if hysteroscopic myomectomy (TCRF) is to be included in the procedure;

- All women considering endometrial ablation should have access to a second-generation ablation technique.

Recommendation 3
Engineer changes in the type of procedures performed. • More secondary procedures for management of heavy menstrual bleeding as per NICE recommendations.

If hysteroscopic procedures such as TCRE and TCRF are considered to be the best options and a distending fluid is required, the choice of fluid then comes under the same scrutiny as above for Urology. The choice of using a monopolar scope system using glycine versus bipolar equipment using saline becomes the choice. Evidence is now emerging from gynaecology units in Northern Ireland that are measuring the serum sodium intraoperatively during every case, that there can be concerning incidences of acute hyponatraemia when glycine is used as the distending agent during TCRE[17]. With the development of newer bipolar systems it is recommended that saline has a better safety profile[3].

Therefore, this policy recommends that, (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 curtailed, strictly monitored when it is still used and eventually terminated when there ceases to be circumstances when its use is considered the safest.

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 the generalised physiological effects of haemorrhage and the increased likelihood of fluid absorption when using irrigation fluid in the presence of 'open' vasculature, 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;
- control of the bleeding which may need cessation of the operation.

Recommendation 4
Increase vigilance when significant haemorrhage is a feature.

4.2.4 Control of the absorption of irrigation fluid

To control the effects of fluid absorption, the theatre team should pay particular attention to,

a) Hyponatraemia;
b) limiting the volume of fluid absorbed.

a. Hyponatraemia

The uptake of 1000 ml of fluid would generally correspond to an acute decrease in the serum sodium concentration of 5-8 mmol/L.[2] Encephalopathy, seizures and even cerebral oedema may develop when the sodium concentration falls below 120mmol.L^{-1}. 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[4].

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 – postoperatively, 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[3]. This effect is compounded because fluid absorption is slightly more common during TCRE than during TURP, and especially so with TCFR.

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 120mmol.L^{-1} 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 increasing the likelihood that the patient, physician, and care team will receive the results in minutes, enabling diagnosis of hyponatraemia as early as possible and allowing immediate clinical management decisions to be made. They can be used to measure haematocrit, determine haemoglobin and measure serum electrolytes.

Serum sodium is often only measured at the end of surgery but, in the surgical settings pertaining herein, this monitoring technique is best applied before and repeatedly during surgery so that it can act as a warning system for hyponatraemia. Trusts already operating this method of monitoring have uncovered episodes of unsuspected hyponatraemia; highlighting the need to be wary of glycine and to monitor accordingly. Previous audits that have not

measured serum sodium as part of their audit criteria are thus likely to have given a false sense of security when using glycine.

Any patient receiving glycine in theatre **must** have such POCT equipment readily available and a measurement(s) made,

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

Staff must be readily available who are trained to use this POCT equipment and indeed immediately available to transport the samples and result to and from the machine.

NOTE: Measurement of serum sodium is not required when using a bipolar technique and saline[8].

Recommendation 5
If continue to use glycine, the following **must** be used. a. Measure POCT serum sodium, i. preoperatively; ii. if the surgery is longer than 30 minutes as a routine; iii. intermittently throughout the surgery; iv. if there is a 1000 ml fluid deficit. b. Dedicated staff for transporting specimens and results; c. Surgery, including TURP, TCRE & TCRF must be performed in a 'main' theatre where POCT equipment is immediately available; d. Accurate fluid input & output measurement and deficit calculation.

b. <u>Limit the volume of fluid absorbed.</u>

The choice of surgical technique and equipment may reduce the complications from irrigation fluid by limiting the use of glycine but continued attention to controlling fluid absorption will still be needed if normal saline is used as the distending fluid.

Basic principles govern the amount of fluid absorbed[18].

i. The hydrostatic driving pressure of the distending fluid. This is often a feature of the height of the container but the pressure may be controlled mechanically.
ii. Measurement, monitoring and documentation of the fluid volumes and deficits.
iii. The length of the surgical procedure.

i. Hydrostatic driving pressure of the distending fluid

Surgeons have a vital role in minimising absorption by keeping the cavity distention pressure at the lowest pressure necessary to distend, consistent with good visualisation. Even though the disruption in the vascular system is venous, the best strategy is to measure arterial pressures (which is easy to

do) and to maintain distending pressure 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.

There exist a number of fluid delivery systems, ranging from those based on simple gravity to automated pumps that are designed to maintain a pre-set intra-cavity pressure. Methods of instilling the distention fluid include,

- continuous-flow by gravity;
- continuous-flow infusion pump;
- pressure-controlled or pressure-sensitive fluid pumps.

Continuous-flow by gravity

In continuous-flow gravity systems, pressure is controlled by the height of the fluid source above the bladder or uterus and is measured from the height of the highest portion of the continuous column of fluid (fluid bag) to the level of the uterus or bladder – approximately 30 cms height is equivalent to 25 mm Hg pressure[19]. If the bag is 60 cms above the patient's uterus, this results in approximately 50 mm Hg of pressure.

Height of fluid column	Pressure exerted
12 inches ≡ 30 cms	25 mmHg
24 inches ≡ 60 cms	50 mmHg
36 inches ≡ 90 cms	75 mmHg

Gravity based systems are very simple to assemble and operate, but require vigilant patient monitoring and frequent manual intake/output calculations, which can be imprecise.

Recommendation 6

For both mono- and bi-polar techniques, limit the distension pressure by,

a. maintaining it below the mean arterial pressure (MAP).

and with continuous-flow gravity systems,

b. limit the height of the irrigating solution container to 60 cm above the patient and certainly never above 100cm;
c. theatre teams must have a procedure for checking and maintaining an agreed height;
d. not applying pressure bags to the irrigation fluid bag.

Continuous-flow infusion pump

Continuous-flow fluid infusion pumps provide a constant flow of distention fluid at the in-flow pressure determined by the operator, delivering the same flow rate regardless of the out-flow conditions. Continuous flow pumps do not usually monitor or calculate the intracavity pressure. Significant fluid absorption and complications can occur with these types of systems because the team is unaware of the actual pressure being used during a prolonged or invasive procedure.

Pressure-controlled or pressure-sensitive fluid pumps

Pressure-controlled infusion pumps can be preset to maintain a desired in-flow pressure. By adjusting the in-flow pressure setting on the pump, it can be maintained below the MAP, thus reducing the likelihood of intravasation.

These pumps can weigh the fluid volume before infusion, which allows them to account for the overfill often found in fluid bags. Weight of fluid before installation and then after, accounts for the deficit, which provides a more accurate measurement of the fluid retained by the patient (fluid deficit). A continuous automated weighing system provides an easy, less time-consuming and valid method of monitoring fluid deficit[2] and an automated fluid management system is recommended[3].

Recommendation 7
Investigate instilling irrigation fluid by using a pressure controlled pump device and purchasing flow/pressure controllers.

ii. Measurement, monitoring & documentation of the fluid volumes & deficits.

If continuous irrigation using fluid filled bags and gravity continue to be used, volumetric fluid balance is based on counting the number of empty fluid bags and then subtracting the out-flow volume in the collection canister and fluid in the drapes to determine irrigation fluid deficit. Positive values are regarded as absorption. The surgeon should be notified about ongoing fluid absorption early enough for steps to be taken to prevent excessive absorption.

However[1], 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 when using fluid filled bag systems that the whole theatre team are aware of the distending fluid

input & output and the irrigation fluid deficit. This is especially true for cases where glycine is used.

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.

Recommendation 8
The theatre team **must**, • be aware of the distending fluid input & output and deficit; • contain a dedicated nurse for fluid balance and deficit calculation, who remains in theatre for the duration of the procedure.

When using a pressure-controlled infusion pump to control the distension fluid with their associated continuous automated weighing system, the monitoring of the fluid deficit is easier[2], less time-consuming and thus an automated fluid management system is recommended[3].

Documentation

Each patient who has any irrigating fluid used must have documentation in the way of a dedicated fluid management chart (appendix 1) commenced. This can be either the measurement of input & outputs and calculating the deficit or recording the readings off an automated machine.

This 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 be recorded on the dedicated fluid management chart. They might also be displayed on a white marker board in the theatre.

At the end of the procedure, the final calculations or readings must be made; the inputs, outputs and deficit. These should be expressed clearly to the surgeon and anaesthetist and recorded on the chart. The operating surgeon should include the fluid deficit in the *Operative Findings* when writing the operative notes.

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.

Recommendation 9
If continue to use glycine, the following **must** be used, throughout the procedure, • accurate irrigation fluid input & output measurement and deficit calculation.

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 depending on the,

- nature of the surgery;;
- nature of the media (isotonic or hypotonic);
- patient's baseline;
- intraoperative medical condition e.g. presence of haemorrhage.

Considering glycine use, a 500 ml threshold may be appropriate for those who are older and/or medically compromised while for healthy individuals absorption of up to 1000 mL can generally be tolerated. Greater than 1000 mL of glycine intravasation results in a significant decrease in serum sodium, sufficient to bring a normo-natraemic patient into the abnormal range[1, 2, 3].

The surgeon and anaesthetist must be informed by the nurse when there is a 1000mls glycine deficit. Surgery must be brought to a close unless continuation of surgery is absolutely necessary to control the haemorrhage. 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.

Considering normal saline use, the maximum limit is unclear, but 2500 mL has been advocated[3]. Surgery must be brought to a close unless haemorrhage needs controlled.

Recommendation 10
Preoperatively, for each individual patient, there **must** be an agreed maximum fluid deficit threshold for action. The surgeon and anaesthetist **must** be informed by the nurse when the threshold is reached.

iii. The length of the surgical procedure.

Estimates of the 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.

Procedures that last longer than 60 minutes and those that require large amounts of tissue resection are more likely to lead to fluid volume overload. Theatre teams must have an established mechanism for measuring time and procedures for alerting surgeon and anaesthetist.

Recommendation 11
Operations should, if possible, not last longer than 60 minutes. Theatre teams **must** have an established 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 core member of the theatre team must be assigned to the duty of gathering together the information needed to ensure the whole theatre team are aware of the distending fluid input & output and the deficit. They will need to be proficient and practiced in this technique and must not have other duties to perform while monitoring fluid balance. 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.

4.2.6 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, to agree fluid absorption volume limits and should include any discussion of limiting intravenous fluids intraoperatively.

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.

Recommendation 12
Completion of the standard WHO surgical checklist **must** be adhered to. 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, fluid flow and pressure controllers and POCT monitoring equipment for theatres and training for staff.

6.0 MONITORING

Trust audit departments will need to monitor that the recommendations are implemented.

7.0 EVIDENCE BASE / REFERENCES

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8.0 CONSULTATION PROCESS

Consulted through the Medical Leaders Forum, DHSSPSNI, and via the Medical Directors, Directors of Nursing and Regional Urologists, Gynaecologists and Anaesthetists.

9.0 APPENDICES / ATTACHMENTS

Appendix 1 = Suggested peri-operative theatre record form template.

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:** _____

Author

_____ **Date:** _____

Director

Insert Trust LOGO

Peri-operative fluid recording chart

Date: _____
Surgeon: _____
Anaesthetist: _____
Team Leader: _____
Circulating Nurse 1: _____
Circulating Nurse 2: _____

Addressograph Label

Fluid recorder: _____ Operation: _____

Fluid Medium: 3L 1.5% Glycine: ☐ 0.9% NaCl: ☐ Warmed: ☐

Bag Height: _____ mmHg ☐ (60 cms ≡ 50mmhg)

Preop. Serum Sodium: = _____ mmol/L Haemoglobin: _____ g/dL.

Resection: Start Time: _____:_____ Operation Finish Time: _____:_____

Irrigation fluid: Start time: _____:_____ **= 0 mins.**

Time (min)	Irrigation In	Irrigation Out	Irrigation Deficit	Running Deficit	Serum Sodium	Surg. informed	Anaes. informed	Sign
5	mls	mls	mls	mls	mmol/L			
10	mls	mls	mls	mls	mmol/L			
15	mls	mls	mls	mls	mmol/L			
20	mls	mls	mls	mls	mmol/L			
25	mls	mls	mls	mls	mmol/L			
30	mls	mls	mls	mls	mmol/L			
35	mls	mls	mls	mls	mmol/L			
40	mls	mls	mls	mls	mmol/L			
45	mls	mls	mls	mls	mmol/L			
50	mls	mls	mls	mls	mmol/L			
55	mls	mls	mls	mls	mmol/L			
60	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			

Total Fluid In =	mls	Surgeon Signature	
Total Fluid Out =	mls	Anaesthetist Signature	
Total Deficit =	mls	Nurse Signature	
		Recovery Staff Signature	

Insert Trust LOGO

Continued.

Time (mins)	Irrigation In	Irrigation Out	Deficit	Running deficit	Serum Sodium	Surg. informed	Anaes. informed	Sign
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			
	mls	mls	mls	mls	mmol/L			

Irrigation In	Document number of mls after each fluid bag is emptied. Record amount 'in' each time use Ellick evacuator.
Irrigation Out	Record fluid in • suction canisters. • fluid in drapes. • fluid from floor suction. Record amount 'out' each time use Ellick evacuator.
Deficit	Calculate deficit or record from pump readout.
Serum Sodium	Ensure there is a Serum Sodium measurement within one bold bordered box if procedure longer than 30 mins.

Glycine		
Volume Absorbed	**Effect**	**Action**
500 mls	Limit for the Elderly : comorbidities	Continue surgery
less than 1000 mls	Well tolerated by healthy patient	Continue Surgery
greater than 1000 mls	Mild hyponatraemia	Complete surgery ASAP
1500 mls	**Severe hyponatraemia & other biochemical disturbances likely**	**Stop Surgery**
Normal Saline		
2000 mls	Limit in the healthy	Complete surgery ASAP

Southern Health and Social Care Trust

Quality Care - for you, with you

Standard Operating Procedure		
Title	Management of irrigation fluids for patients undergoing Trans Urethral Resection of Prostate (TURP) / Trans Urethral Resection of Bladder Tumour (TURBT) Procedures	
Appendix 1	Regional Policy Version 5 Surgical Management of Endoscopic Tissue resection during Urology, Gynaecology and other relevant surgery May 2015.	
Appendix 2	The Monitoring of Serum Sodium Levels during Glycine Fluid Irrigation	
Document No	*NO 1*	
Revision Status	Yearly	
Authors	Pamela Johnston, Brigeen Kelly, Ursula Gildernew, Mary McGeough	
Date	16-12-15	
Review Date	16-12-16	
Scope of the Procedure	To ensure a standardised approach for the monitoring of irrigation fluids in Urology surgery in line with the Regional Policy Version 5 Surgical Management of Endoscopic Tissue resection during Urology, Gynaecology and other relevant surgery May 2015.	
Qualifications Required	Registered General Nurse	
Risks and Countermeasures	**Risks**	**Countermeasures**
	• **Faulty Equipment** • **Incorrect fluids** • **Deficit in fluid management** • **Drop in Patient's Serum Sodium level**	• **All equipment to be checked prior to use and documented in patient notes** • **Fluids to be checked by 2 registered nurses.** • **Peri-Operative Fluid Recording Chart to be used and any concerns regarding any fluid deficit are to be highlighted immediately to Anaesthetist and Surgeon.** • **Monitor Patients Serum Sodium Level in line with Regional Policy and Appendix 1.**
Emergency Shut Down Procedure (if equipment)	N/A	

Step No	Instruction	Photograph / Diagram
1	Check theatre has the correct equipment needed for TURP/TURBT and is full working order. • Suction Carousel available with 4 suction 3 litre canister ensuring liners are expanded. • Drip stand to hold the Glycine 1.5% Sodium Chloride 0.9% for irrigation (from Fluid warming cabinet). • Ensure adequate supply of 3 Litre Glycine/Sodium Chloride 0.9% for Irrigation is available in the fluid warming cabinet. • Check & record the temperature of the warming cabinet daily. .	
2	For both mono and bi-polar techniques, limit the distension pressure by: • Maintaining it below the mean arterial pressure (MAP) and with continuous - flow gravity systems. • Limit the height of the irrigating solution	

	container to 60cm above the patient and never above 110cm. • Theatre teams must have a procedure for checking and maintaining an agreed height. • Not applying pressure bags to the fluid irrigation bag.	
3	• Anaesthetic nurse to complete anaesthetic checklist with patient and accompany the patient into theatre. • Patient cannulated and blood sample taken for baseline Sodium using the Point of Care Testing (POCT) For Day Surgery patients this sample is taken on Admission following patient cannualtion. • Part 1 of ***WHO Surgical Safety Checklist*** is read aloud by the Anaesthetic nurse the patient and the Anaesthetist. • Assist with patient positioning on operating table in supine/Lithotomy position. • Patient is then anaesthetised. • A maximum fluid deficit threshold is to be agreed for each individual patient.	
4	Part 2 ***WHO Surgical Safety Checklist*** completed. Fluid management to be monitored by **one** 'dedicated' **registered nurse** who has been allocated to closely monitor irrigation fluid input/output and deficit calculation whiteboard as – 'Fluid Management'. This Nurse must remain in Theatre for the duration of the procedure and have no other duties. All fluid input/ output to be recorded on Peri-operative fluid Recording chart. Any concerns regarding any fluid deficit are to be highlighted immediately to the Anaesthetist and Surgeon.	
5	**Nurse in charge:** The timer clock on surgeon's panel is commenced at beginning of **resection** by nurse in charge and time will be recorded on Theatre fluid Management Chart.	
6	**The scrub nurse**: • Monitors the clock and informs the surgeon & anaesthetist 5 minutes before completion of 1 hour resection time. • Observes for any fluid spillage that may not have been included in the fluid calculations and inform Fluid Management Nurse	
7	**Dedicated Fluid Management Nurse:** Informs the surgeon when changing each bag of Glycine/Saline & checks fluids with scrub nurse. Records fluid on Peri-operative Fluid Recording Chart and cross references it to the Patient's Regional Fluid Balance Chart Record Ellik evacuator fluid after each use. Ensures that no empty Glycine/Saline bags or suction	

	canisters are removed from theatre until the end of the procedure. Records fluid output when all suction canisters have been removed. All used suction canisters must be gelled before disposal. **Reporting fluid deficits to Surgeon & Anaesthetist:** Inform surgeon and anaesthetist of 250 mls incremental differences which occurs between input and output. Informs surgeon and Anaesthetist when the maximum fluid deficit threshold has been reached.	
8	**Anaesthetist:** Bloods for sodium levels: • Baseline taken a prior to the start of surgery case • If surgery is longer than 30 minutes • Intermittently throughout the case as a routine • If there is a 1000ml fluid deficit These results are verbally relayed by the Anaesthetist to the surgeon and theatre team and then recorded by Anaesthetist on Anaesthetic record sheet. Fluid management Nurse to record the Serum sodium results on the Peri-operative Fluid Record Sheet. The anaesthetist will also remind the surgeon of resecting time prior and after 1 hour period has lapsed.	
9	Part 3 ***WHO Surgical Safety Checklist*** completed prior to leaving Theatre and record any post – operative concerns. Surgeon, Anaesthetist and Fluid Management Nurse must sign the Peri-operative Fluid Record sheet at end of procedure.	
10	All documentation kept with patient and sent to Recovery. Patient transferred to recovery ward with anaesthetist and registered nurse. Recovery Nurse must sign the Per-operative Fluid Record sheet at handover from Theatre.	

Acute Services Operating Theatre Users Committee
SOUTHERN TRUST

Notes of the Theatre User Group Meeting 5th March 2015 at 4:30pm, Meeting Room, Admin Floor, CAH

Presents

Mr S Hall (Chair)	Ronan Carroll	Mary McGeough
Wendy Clayton	Mr A Neill	Ursula Gildernew
Helena Murray	Pamela Johnston	

Agenda	Discussion	Action
Apologies	Dr Tariq, Dr Scullion, Emma-Jane Kearney, Brigeen Kelly, Mr Bunn, Mr Young, Dr Boggs	
Matters Arising	**Transport to STH** Mary advised there is a contracted taxis in place. Pamela and Ursula advised from their experience the service works. Mr Hall advised still ongoing issues from STH. **Surgical gowns** Mr Hall advised that the 'red' gowns are still in progress	
Acute Pain Strategy	Defer to next month	
TMS Update	New version is going live this weekend. Contingency forms to be used over the weekend Differences: Can now record planned surgery and actual surgery	
DHH Emergency Theatres	No issues	
Issues	**Theatre/Endoscopy DHH** No rep present	
	Theatres 2-8 & Recovery CAH **Red line** There will be a temporary red line in the corridor, as relatives were walking into theatres. **Scrubs** Theatres have gone live with scrub-x today – so far all has gone well **Operating Lists** There was an operating list found out in the corridor **Consenting** All patients to be consented before they leave the ward, including all endoscopy patients. An email to be circulated to all users on behalf of the Theatre Users Group re consenting **Theatres 1** On schedule, by mid April 2015 Theatre 1 will be ready for use	
	DSU, CAH Ursula was welcomed the group.	
	Theatre / DPU STH No rep was present	
G&S savings project update	Saved £190k for 2014/15. Starting on 2015/16 savings but becoming more difficult	
G&S Requests	**Arcos revision implants to be consigned at CAH (Dr Bunn)** Agreed for purchase	Agreed for purchase

	Oxford microplasty UKA system to replace Zimmer UKA system (Dr Bunn) Just an upgrade – new generation to replace the Zimmer. Agreed for purchase **ETT anchors** Agreed for purchase	Agreed for purchase Agreed for purchase
Surgical First Assistants	Mary advised the Trust is hoping on recurrent funding. Once agreed EOI will be circulated and recruitment commenced.	
Fluid Monitoring Gyane/Urology	Gynae is moving over to saline Mary advised that she read new NICE guidelines re: use of saline in prostate surgery – benefits shorter stay in hospital	
Paediatric Centre DHH	Plans almost complete for sign off and starting to do C-sheets. Mary advised there the following bed space: 4 bed spaces in recovery 4 in the Paediatric ward. Mr Hall expressed concerned regarding number of available beds for am and pm theatre sessions.	
AOB	**Breast implants G&S request** To date the breast team have ordered and used 9 implants, however the Theatre User Group only authorised 4, and stock was to be reviewed after 4 had been used. Breast reconstruction is no unfunded service. Ronan queried if the equipment was part of the breast reconstruction bid. It was agreed to use current stock, not to book any further patients until full conversation undertaken with Breast team and if there was any funding in the breast reconstruction paper. Mr Eamon Mackle to discuss with the Breast Team **<u>Trials</u>** All trials to go through the Theatre User Group; to ensure standardisation and agreed way forward for all Surgeons. **<u>Saline – Urology</u>** 2nd document out, urology team drafting a response before 15/3/15. Response to go to Dr John Simpson as a Trust response. Wanting to phase out glycine use. Will be allowed to use glycine under strict control, better in/output control rather than a machine. The bottom line is that if going to a saline system will be very expensive to switch for hypernatreamia. A generator is £40k and resectoscope is £10k. The Belfast City have moved towards this but TURPs are less in number in Belfast. TURPs will be an issue. **<u>Radiographer for theatres</u>** Radiographers have not been round to theatres until 9am, is supposed to be there for 8am. Ronan to discuss with Jeanette **<u>New theatre and sessions</u>** Mr Hall requested if specialities will have a chance to move theatre sessions to a Monday when the new theatre is opened. Assessment of the allocation of theatre space to be brought to Theatre User Group.	Mr Mackle to discuss with the Breast Team
Date of next meeting	**Thursday 2nd April 2015** **4:30pm** **Meeting Room, Admin Floor, CAH**	