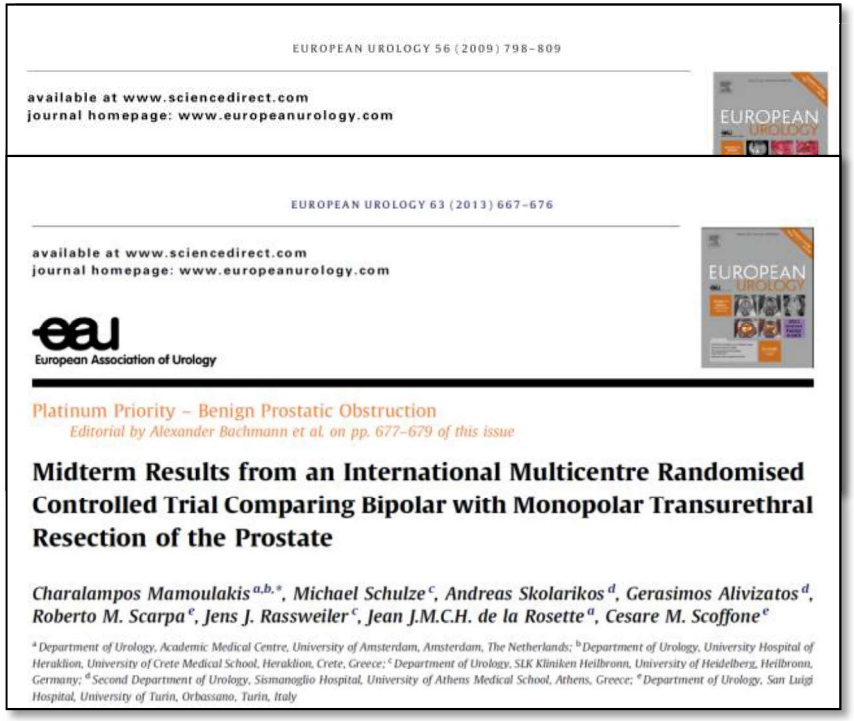
Monopolar vs Bipolar



EUROPEAN UROLOGY 56 (2009) 798–809

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

EUROPEAN UROLOGY 63 (2013) 667–676

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Platinum Priority – Benign Prostatic Obstruction

Editorial by Alexander Bachmann et al. on pp. 677–679 of this issue

Midterm Results from an International Multicentre Randomised Controlled Trial Comparing Bipolar with Monopolar Transurethral Resection of the Prostate

Charalampos Mamoulakis[a,b,], Michael Schulze[c], Andreas Skolarikos[d], Gerasimos Alivizatos[d], Roberto M. Scarpa[e], Jens J. Rassweiler[c], Jean J.M.C.H. de la Rosette[a], Cesare M. Scoffone[e]*

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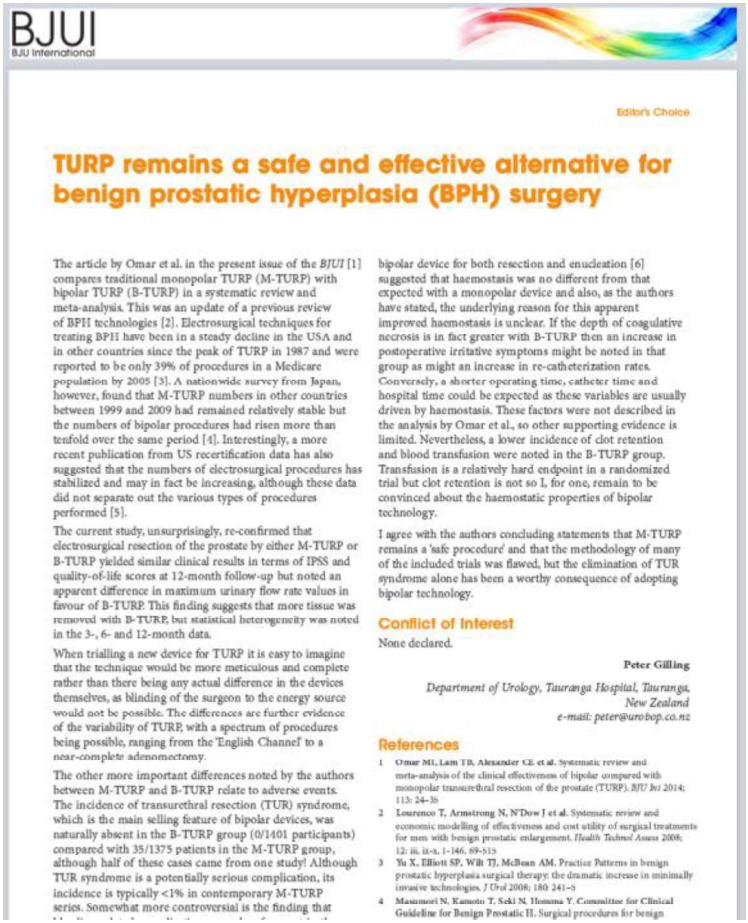
- *"No clinically relevant differences in short-term efficacy".*
- *"B-TURP is preferable due to a more favorable safety profile".*
- Well-designed multicentric / international RCTs are still needed.

Monopolar vs Bipolar



BJUI
BJU International

Editor's Choice

TURP remains a safe and effective alternative for benign prostatic hyperplasia (BPH) surgery

The article by Omar et al. in the present issue of the *BJUI* [1] compares traditional monopolar TURP (M-TURP) with bipolar TURP (B-TURP) in a systematic review and meta-analysis. This was an update of a previous review of BPH technologies [2]. Electrosurgical techniques for treating BPH have been in a steady decline in the USA and in other countries since the peak of TURP in 1987 and were reported to be only 39% of procedures in a Medicare population by 2005 [3]. A nationwide survey from Japan, however, found that M-TURP numbers in other countries between 1999 and 2009 had remained relatively stable but the numbers of bipolar procedures had risen more than tenfold over the same period [4]. Interestingly, a more recent publication from US recertification data has also suggested that the numbers of electrosurgical procedures has stabilized and may in fact be increasing, although these data did not separate out the various types of procedures performed [5].

The current study, unsurprisingly, re-confirmed that electrosurgical resection of the prostate by either M-TURP or B-TURP yielded similar clinical results in terms of IPSS and quality-of-life scores at 12-month follow-up but noted an apparent difference in maximum urinary flow rate values in favour of B-TURP. This finding suggests that more tissue was removed with B-TURP, but statistical heterogeneity was noted in the 3-, 6- and 12-month data.

When trialling a new device for TURP it is easy to imagine that the technique would be more meticulous and complete rather than there being any actual difference in the devices themselves, as blinding of the surgeon to the energy source would not be possible. The differences are further evidence of the variability of TURP, with a spectrum of procedures being possible, ranging from the 'English Channel' to a near-complete adenomectomy.

The other more important differences noted by the authors between M-TURP and B-TURP relate to adverse events. The incidence of transurethral resection (TUR) syndrome, which is the main selling feature of bipolar devices, was naturally absent in the B-TURP group (0/1401 participants) compared with 35/1375 patients in the M-TURP group, although half of these cases came from one study! Although TUR syndrome is a potentially serious complication, its incidence is typically <1% in contemporary M-TURP series. Somewhat more controversial is the finding that bipolar device for both resection and enucleation [6] suggested that haemostasis was no different from that expected with a monopolar device and also, as the authors have stated, the underlying reason for this apparent improved haemostasis is unclear. If the depth of coagulative necrosis is in fact greater with B-TURP then an increase in postoperative irritative symptoms might be noted in that group as might an increase in re-catheterization rates. Conversely, a shorter operating time, catheter time and hospital time could be expected as these variables are usually driven by haemostasis. These factors were not described in the analysis by Omar et al., so other supporting evidence is limited. Nevertheless, a lower incidence of clot retention and blood transfusion were noted in the B-TURP group. Transfusion is a relatively hard endpoint in a randomized trial but clot retention is not so I, for one, remain to be convinced about the haemostatic properties of bipolar technology.

I agree with the authors concluding statements that M-TURP remains a 'safe procedure' and that the methodology of many of the included trials was flawed, but the elimination of TUR syndrome alone has been a worthy consequence of adopting bipolar technology.

Conflict of interest

None declared.

Peter Gilling

Department of Urology, Tauranga Hospital, Tauranga, New Zealand
e-mail: peter@urobop.co.nz

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1 **Omar MI, Lam TB, Alexander CE et al.** Systematic review and meta-analysis of the clinical effectiveness of bipolar compared with monopolar transurethral resection of the prostate (TURP). *BJU Int* 2014; 113: 24–35

2 **Lourenco T, Armstrong N, N'Dow J et al.** Systematic review and economic modelling of effectiveness and cost utility of surgical treatments for men with benign prostatic enlargement. *Health Technol Assess* 2008; 12: iii, ix–x, 1–146, 69–513

3 **Yu X, Elliott SP, Wilt TJ, McBean AM.** Practice Patterns in benign prostatic hyperplasia surgical therapy: the dramatic increase in minimally invasive technologies. *J Urol* 2008; 180: 241–5

4 **Masumori N, Kumoto T, Seki N, Homma Y, Committee for Clinical Guideline for Benign Prostatic H.** Surgical procedures for benign

BJUI
BJU International

Editor's Choice

TURP remains a safe and effective alternative for benign prostatic hyperplasia (BPH) surgery

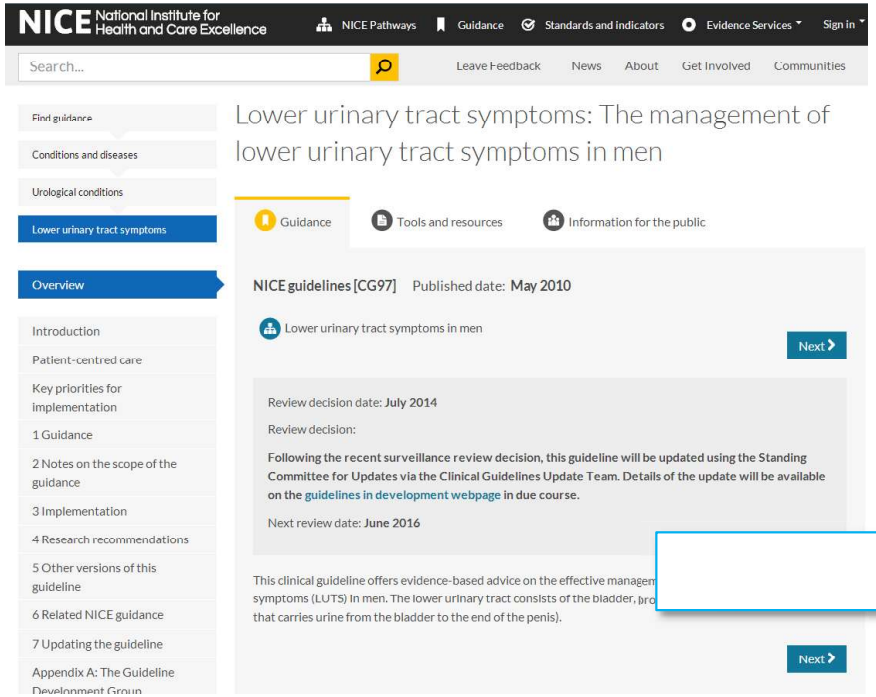
Peter Gilling

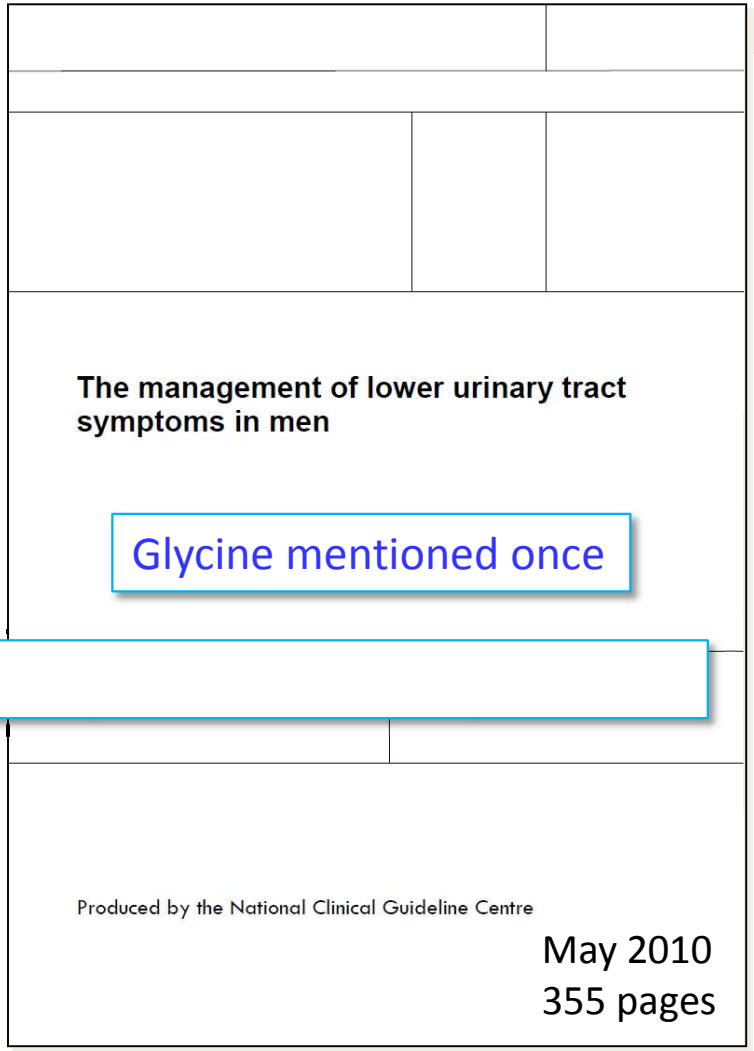
First published: 13 December 2013 Full publication history
DOI: 10.1111/bju.12310
Citing literature
Am score 1

Volume 113, Issue 1
January 2014
Pages 5–6

The incidence of transurethral resection (TUR) syndrome, ……., was (0/1401) in the B-TURP group compared with 35/1375 patients in the M-TURP group,

Evidence - NICE





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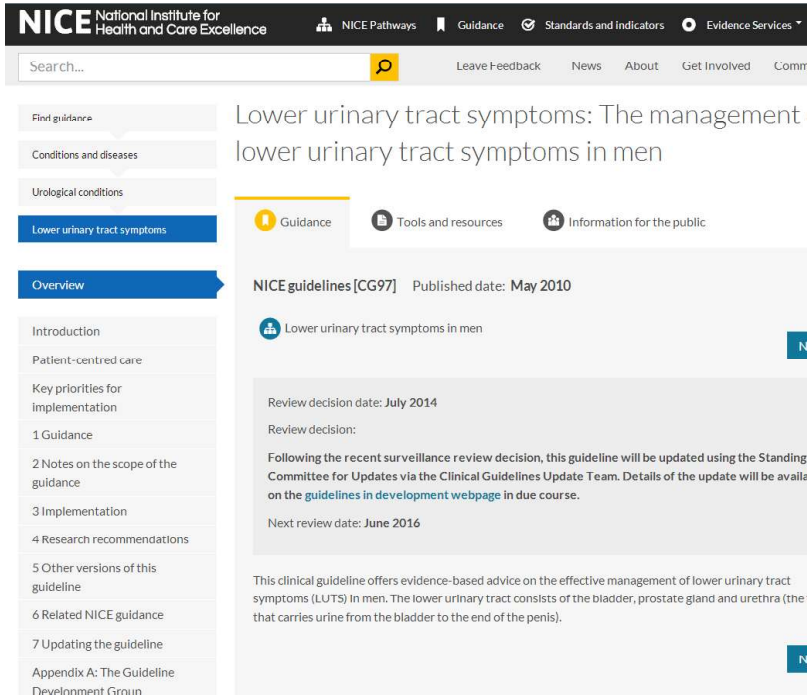
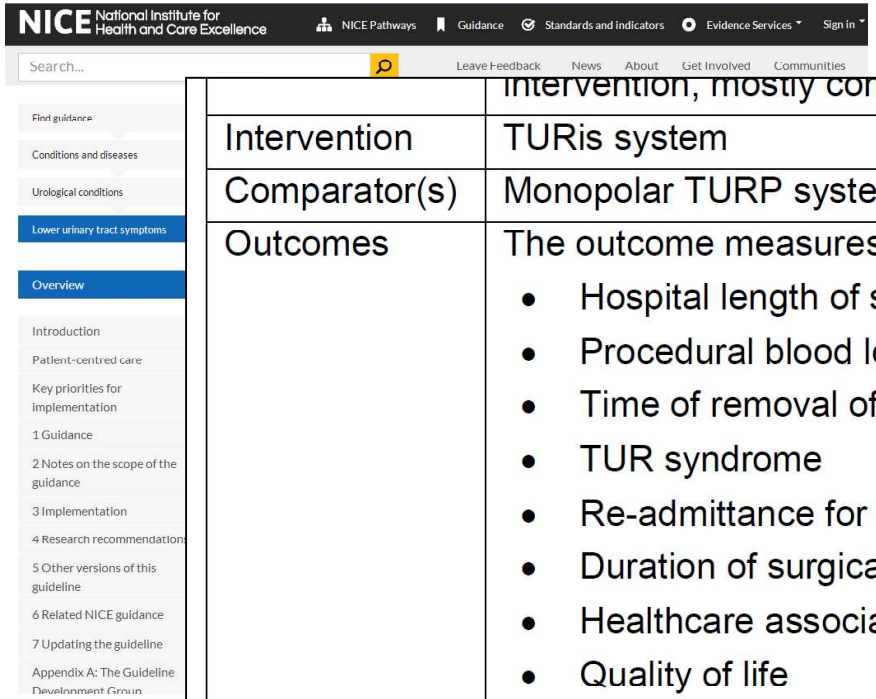
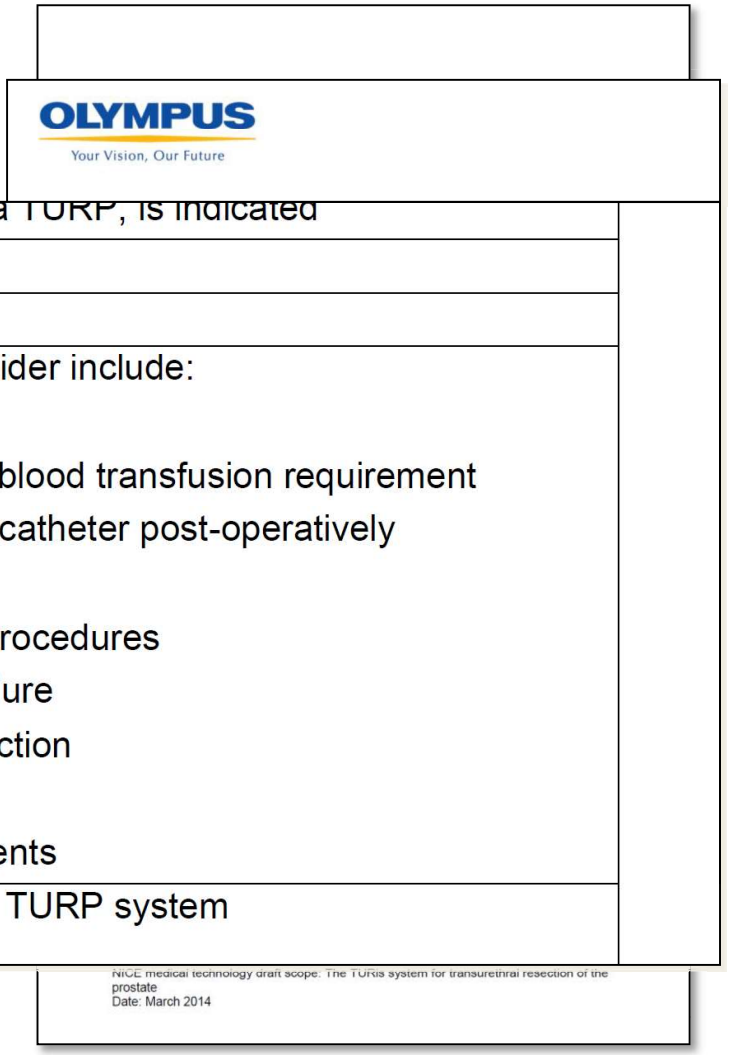


Key message	Effect on guidance: Potential change	Effect on guidance: No change
Desmopressin • There is limited evidence that the number of nocturnal voids may be reduced with desmopressin[4] treatment for nocturnal polyuria.		✓
Surgery for voiding symptoms ***Laser vaporisation*** • There is limited evidence that a method of laser vaporisation using the green light laser technique may be as effective as transurethral resection of the prostate (TURP).		✓
Holmium laser enucleation • Holmium laser enucleation of the prostate (HoLEP) and TURP appear to be equally effective in the treatment of LUTS. There is limited evidence that HoLEP may be associated with shorter catheterisation times and hospital stay.		✓
Bipolar versus monopolar TURP • Bipolar and monopolar TURP may be equally effective in improving symptoms of LUTS, but bipolar TURP may be associated with lower rates of complications.		✓
Cost effectiveness of surgical treatments • Diathermy vaporisation with subsequent HoLEP if initial treatment fails may be a cost-effective approach to surgical treatment for LUTS.		✓
Alternative and complementary therapies • *Serenoa repens* does not seem to improve symptoms of LUTS.		✓

www.evidence.nhs.uk NHS Evidence – provided by NICE

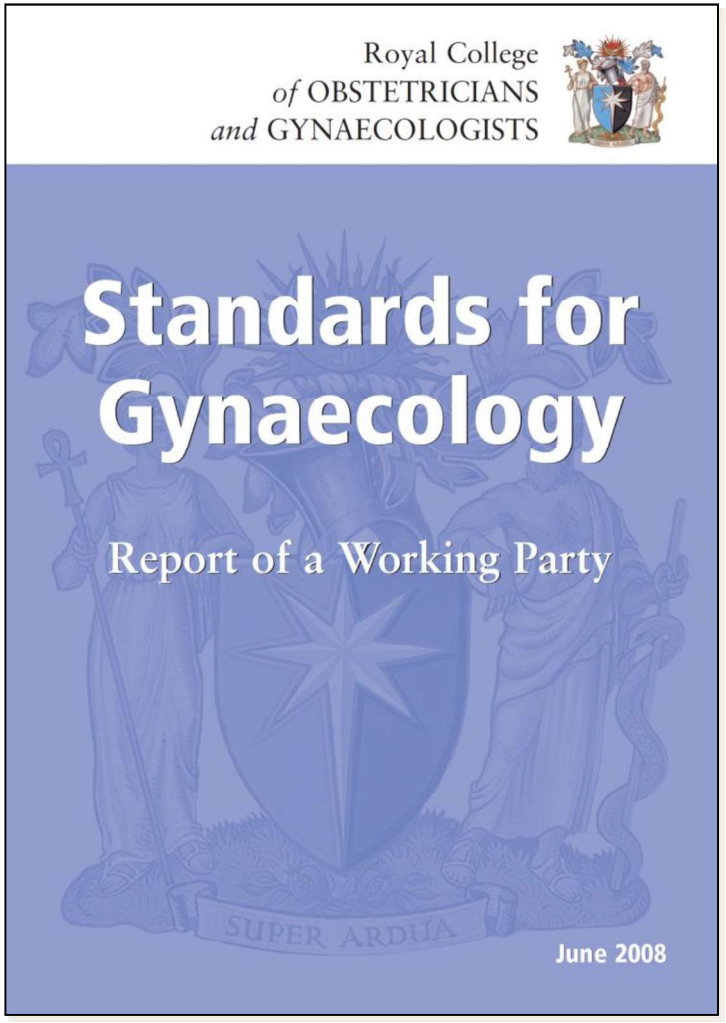
Evidence - NICE





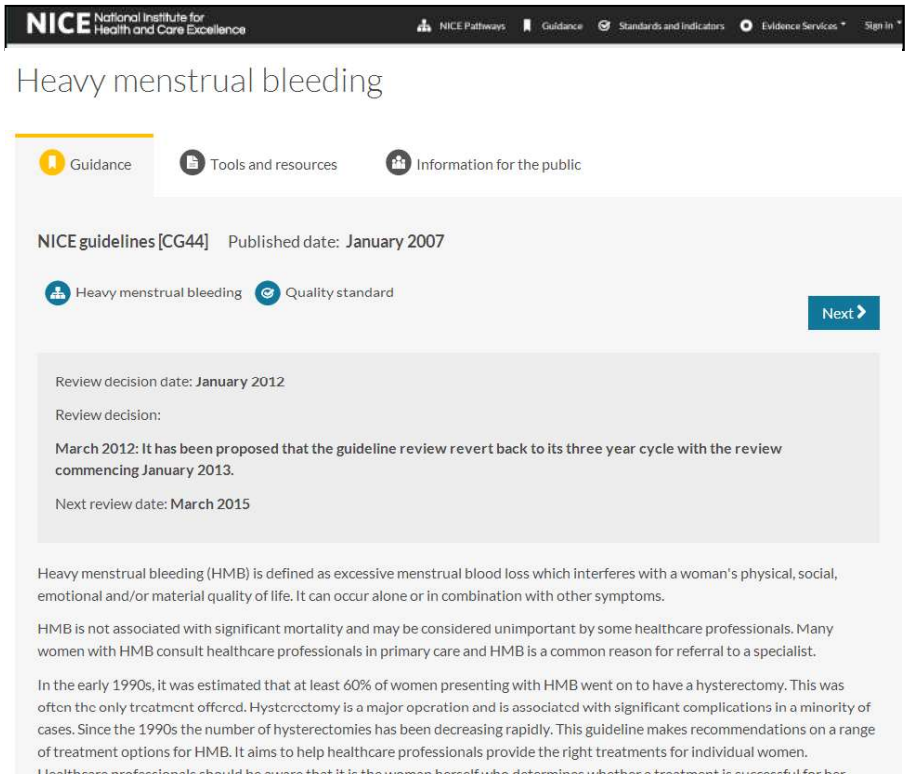
	intervention, mostly commonly a TURP, is indicated
Intervention	TURis system
Comparator(s)	Monopolar TURP system
Outcomes	The outcome measures to consider include: • Hospital length of stay • Procedural blood loss and blood transfusion requirement • Time of removal of urinary catheter post-operatively • TUR syndrome • Re-admittance for repeat procedures • Duration of surgical procedure • Healthcare associated infection • Quality of life • Device-related adverse events
Cost analysis	The comparator is a monopolar TURP system

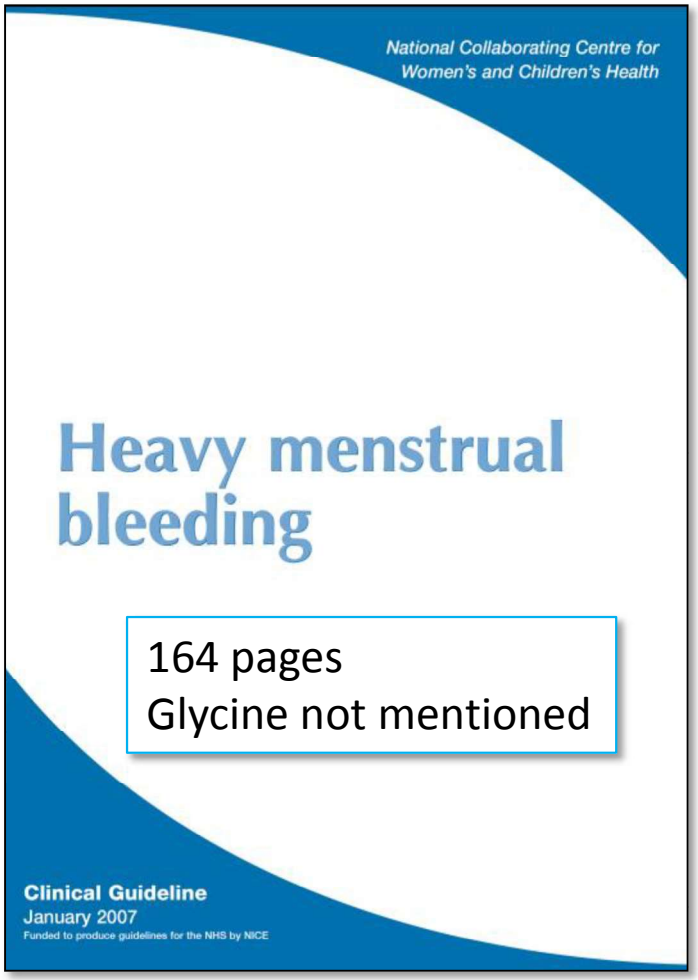
Standards for Gynaecology



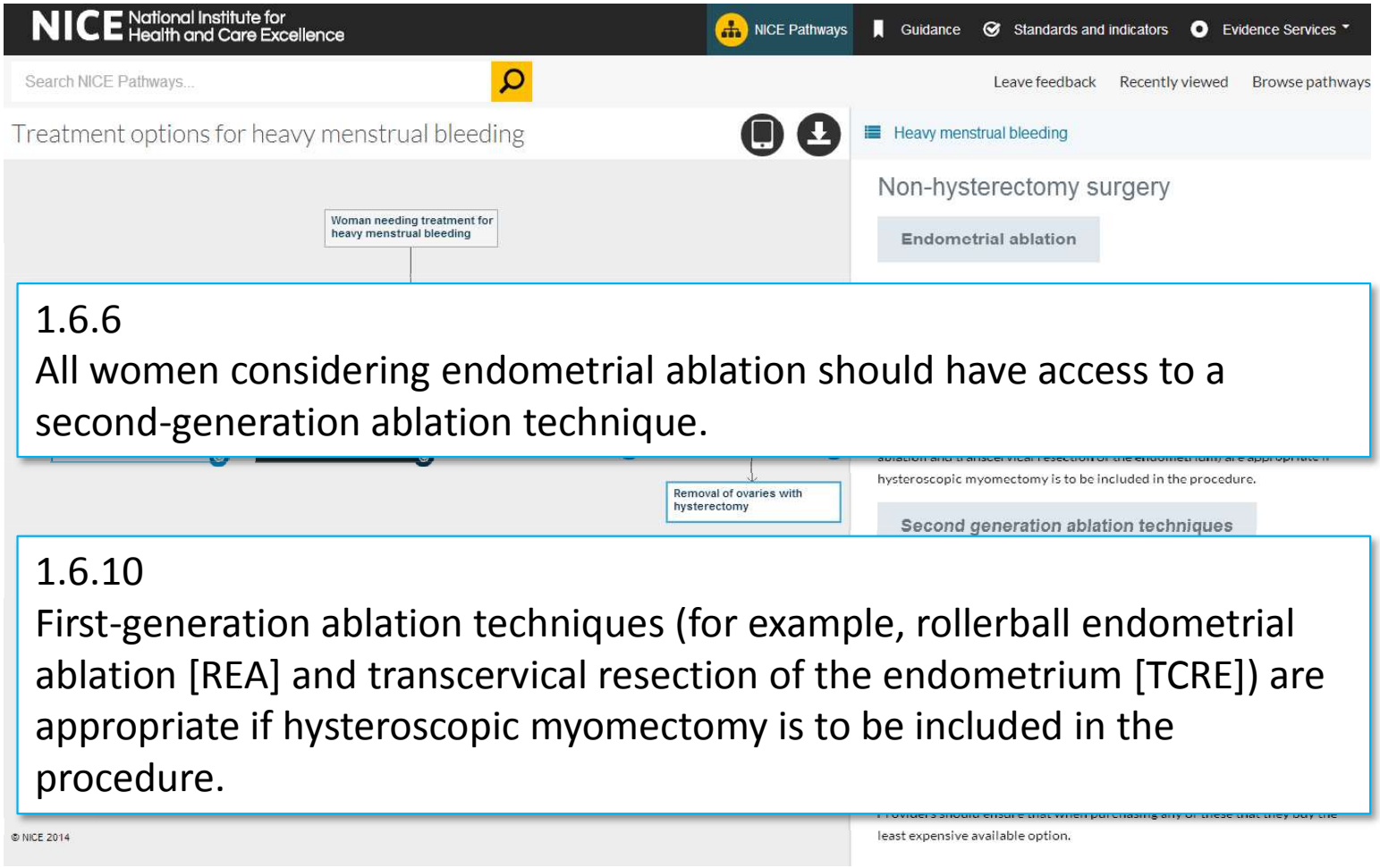
- Glycine not mentioned

Evidence - NICE

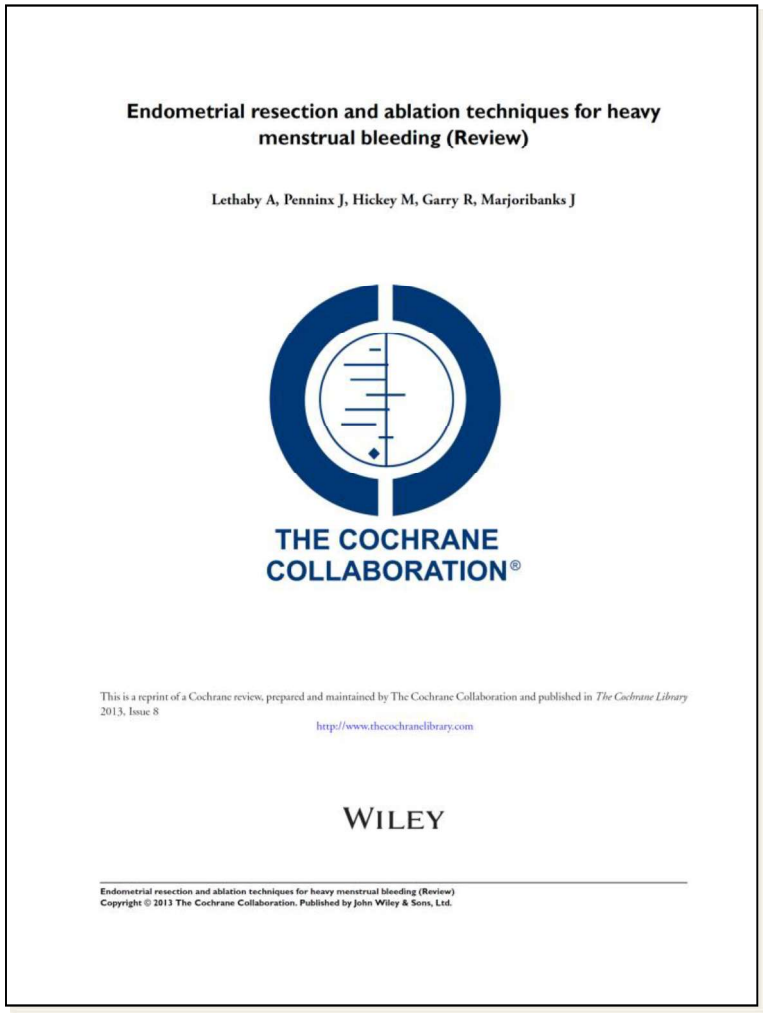




Evidence - NICE

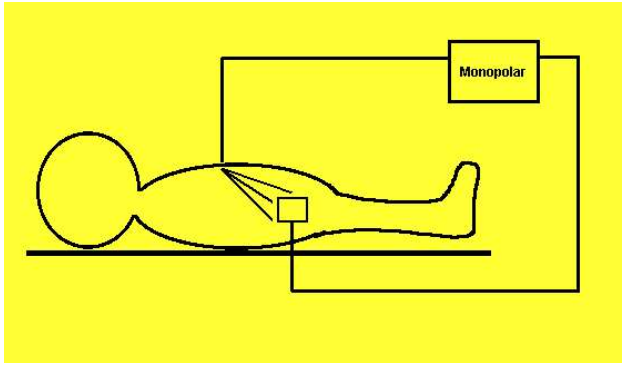


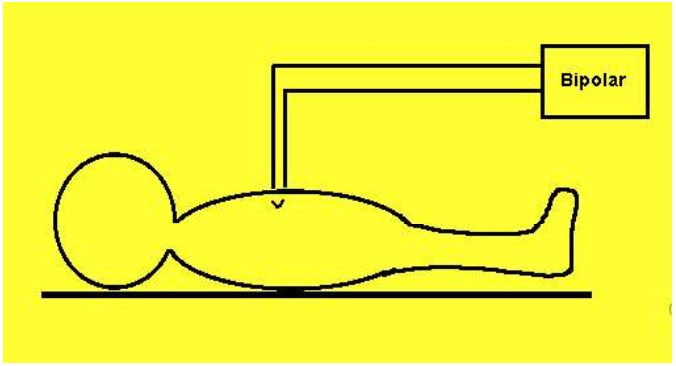
Evidence - Cochrane



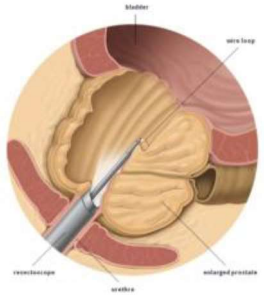
- 25 RCTs in 4040 women.
- TUR syndrome not mentioned
- Glycine mentioned x2 (not relevant)
- Women undergoing newer (second-generation) ablative procedures were less likely to have fluid overload.

Monopolar vs Bipolar

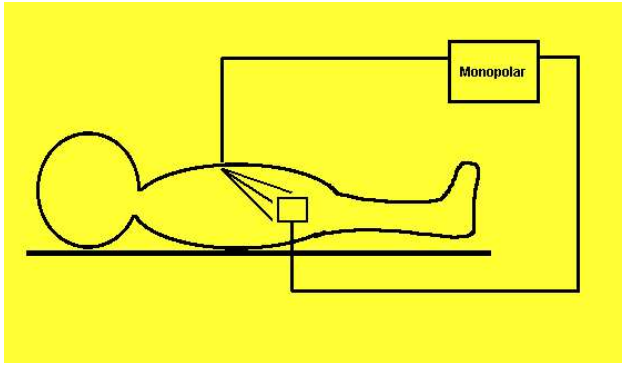


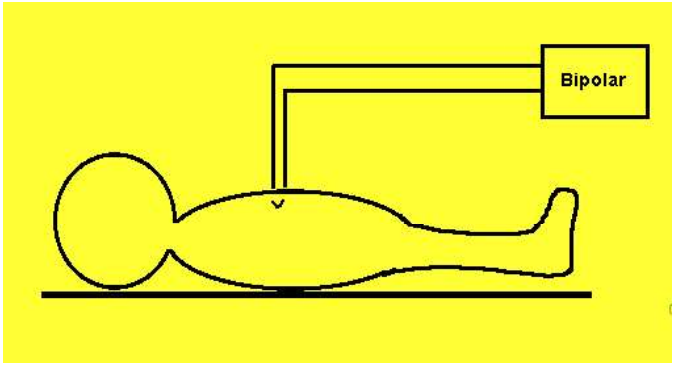


	BHSCT = 8
WHSCT for TURBT	WHSCT for TURP
	NHSCT purchasing
	SEHSCT 2 of 3 wish
SHSCT	
COST	
£91 - 120	£313

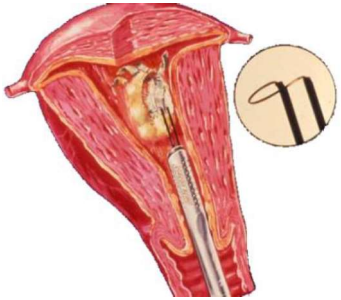


Monopolar vs Bipolar





BHSCT	JP evaluating
	WHSCT trialling
	NHSCT evaluating
SHSCT follow BHSCT	
COST	



Procedural factors

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

Fluid dynamics

- Investigate and establish most appropriate method(s) for measuring fluid volume gain.
  - volumetric fluid balance
  - serum sodium dilution
  - breath-alcohol level
  - CVP trend
  - plasma electrolyte concentrations (e.g. Mg, Ca)
  - irrigation solutes [glycine, sorbitol]
  - transthoracic impedance change
  - patient's weight gain

Fluid dynamics

- Investigate and establish most appropriate method(s) for measuring fluid volume gain.
  - volumetric fluid balance
  - serum sodium dilution
  - breath-alcohol level
  - CVP trend
  - plasma electrolyte concentrations (e.g. Mg, Ca)
  - irrigation solutes [glycine, sorbitol]
  - transthoracic impedance change
  - patient's weight gain

Measuring volumetric fluid balance

- Difficult to measure,
  - Cannot collect all fluid media.
  - Spillage.
  - Volume of bags is often not 3L.
  - Fluid left in bags.

Measure	
Yes	No
SEHSCT urol.	BHSCT urol.
BHSCT gyn.	

- Opinion is divided on the value of volumetric fluid measurement.
- Need increasing use of automated fluid measurement systems.
- If not available, need some form of measurement.
  - Especially if continue to use glycine

Fluid dynamics

- Investigate and establish most appropriate method(s) for measuring fluid volume gain.
  - volumetric fluid balance ✓ **If use glycine**
  - serum sodium dilution
  - breath-alcohol level
  - CVP trend
  - plasma electrolyte concentrations (e.g. Mg, Ca)
  - irrigation solutes [glycine, sorbitol]
  - transthoracic impedance change
  - patient's weight gain

Serum Sodium Concentration

- Point of care - close at hand
  - Theatre
  - Recovery Ward
- Preop. [Na^+]
- Early intraop. [Na^+]
- Intermittently [Na^+]
- Postop. [Na^+]

- Not needed if use saline fluid.

ABBOTT POINT-OF-CARE TESTING

2nd January 2014

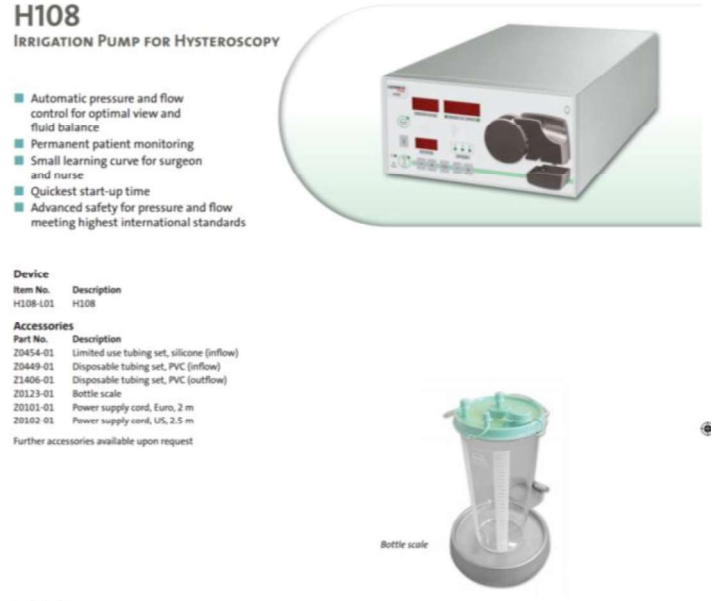
- Further incident
- Alerted through SAI process
- Hysteroscopic transcervical resection of fibroid (TCRF)
- Significant absorption of Glycine = 1300 mls.
- Patient discharged unharmed
- Delay and difficulty in calculating exact amount of fluid deficit.
- Performed in day case surgery unit.
- Sodium analysis unavailable close to hand.
- Unsuitable suction unit.

2nd January 2014

SEA Actions

- Point of care analysis.
- TCRE/TCRF performed in a suitable theatre.
- Trained nurse dedicated for monitoring I/O.

  Name on theatre white board.
- Specialised irrigation pump.



H108

IRRIGATION PUMP FOR HYSTEROSCOPY

- Automatic pressure and flow control for optimal view and fluid balance
- Permanent patient monitoring
- Small learning curve for surgeon and nurse
- Quickest start-up time
- Advanced safety for pressure and flow meeting highest international standards

Device

Item No.	Description
H108-L01	H108

Accessories

Part No.	Description
Z0454-01	Limited use tubing set, silicone (inflow)
Z0449-01	Disposable tubing set, PVC (inflow)
Z1406-01	Disposable tubing set, PVC (outflow)
Z0123-01	Bottle scale
Z0101-01	Power supply cord, Euro, 2 m
Z0102-01	Power supply cord, US, 2.5 m

Further accessories available upon request

Bottle scale

August 2014

- Point of care analysis.

- Significant hyponatraemia
- during a TCRE
- Serum Sodium 139 to 121

Fluid dynamics

- Investigate and establish most appropriate method(s) for measuring fluid volume gain.
  - volumetric fluid balance ✓ **If use glycine**
  - serum sodium dilution ✓ **If use glycine**
  - breath-alcohol level
  - CVP trend
  - plasma electrolyte concentrations (e.g. Mg, Ca)
  - irrigation solutes [glycine, sorbitol]
  - transthoracic impedance change
  - patient's weight gain

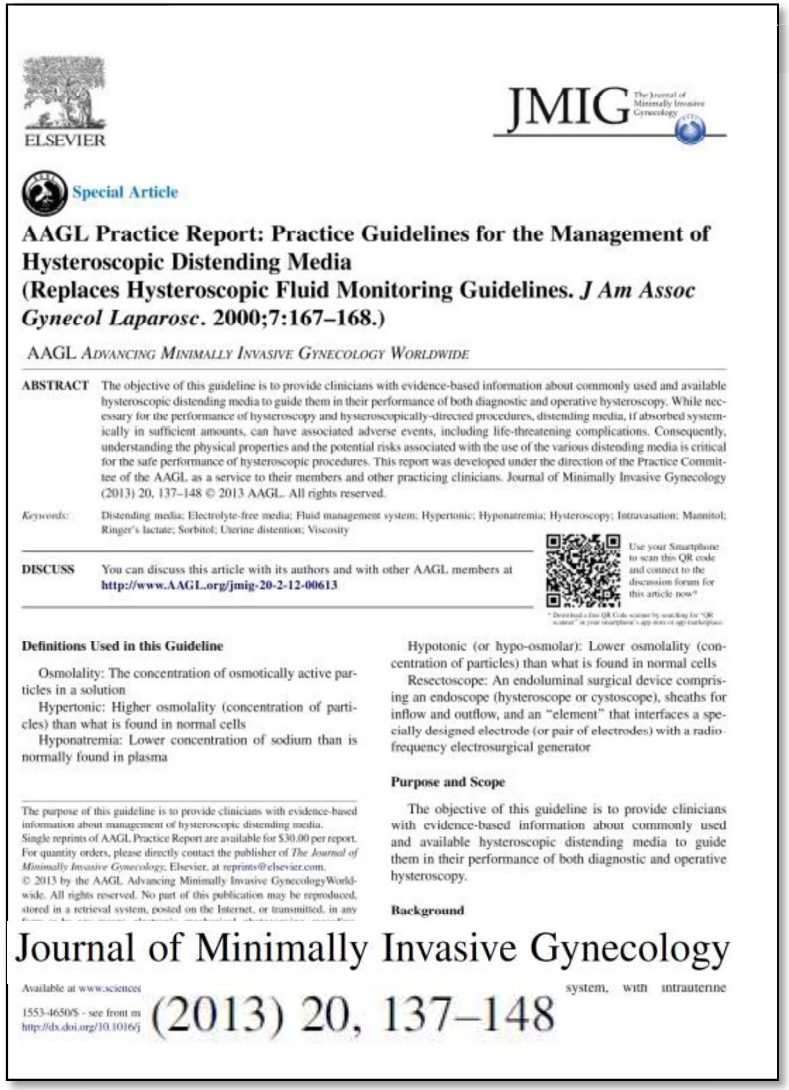
Fluid dynamics

- Investigate and establish most appropriate method(s) for measuring fluid volume gain.
- Evaluate and establish mechanism for recording and displaying fluid input/output.
- Monitor fluid input and output during (intermittently and in real time) case.
- Establish a lead in theatre for fluid monitoring and assessing fluid balance
- Set limits on amount of infused glycine.
- Establish maximum height for infusion bag.
- Establish procedure for checking and maintaining height of infusion bag.

Fluid dynamics

- Investigate use of equipment and techniques to limit intravesical / intrauterine pressures.
- Establish and set time limits for procedures (range and absolute along with associated influencing factors e.g. vascularity of operative organ).
- Establish mechanism for measuring time and procedures for alerting surgeon and anaesthetist.
- Establish mechanism for intraoperative (intermittently and result available in minutes) measurement, display and alerting medical staff of haemoglobin and electrolytes (sodium) (and osmolality?).
- Establish pros & cons and role for intraoperative suction attached to resectoscope.

Standards for Gynaecology



ELSEVIER

JMIG The Journal of Minimally Invasive Gynecology

Special Article

AAGL Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media
(Replaces Hysteroscopic Fluid Monitoring Guidelines. *J Am Assoc Gynecol Laparosc*. 2000;7:167–168.)

AAGL *Advancing Minimally Invasive Gynecology Worldwide*

ABSTRACT The objective of this guideline is to provide clinicians with evidence-based information about commonly used and available hysteroscopic distending media to guide them in their performance of both diagnostic and operative hysteroscopy. While necessary for the performance of hysteroscopy and hysteroscopically-directed procedures, distending media, if absorbed systemically in sufficient amounts, can have associated adverse events, including life-threatening complications. Consequently, understanding the physical properties and the potential risks associated with the use of the various distending media is critical for the safe performance of hysteroscopic procedures. This report was developed under the direction of the Practice Committee of the AAGL as a service to their members and other practicing clinicians. Journal of Minimally Invasive Gynecology (2013) 20, 137–148 © 2013 AAGL. All rights reserved.

Keywords: Distending media; Electrolyte-free media; Fluid management system; Hypertonic; Hyponatremia; Hysteroscopy; Intravasation; Mannitol; Ringer's lactate; Sorbitol; Uterine distention; Viscosity

DISCUSS You can discuss this article with its authors and with other AAGL members at http://www.AAGL.org/jmig-20-2-12-00613

Use your Smartphone to scan this QR code and connect to the discussion forum for this article now.*

Definitions Used in this Guideline

Osmolality: The concentration of osmotically active particles in a solution

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

Hyponatremia: Lower concentration of sodium than is normally found in plasma

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

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

Purpose and Scope

The objective of this guideline is to provide clinicians with evidence-based information about commonly used and available hysteroscopic distending media to guide them in their performance of both diagnostic and operative hysteroscopy.

Background

Journal of Minimally Invasive Gynecology

Available at www.sciences

1553-4650/$ - see front m
http://dx.doi.org/10.1016/j

(2013) 20, 137–148

system, with intrauterine

- The best ‘‘management’’ of fluid overload is to prevent its occurrence by constantly and accurately monitoring the distending medium input and output.
- Uterine cavity pressure should be lowest possible (Level A).
- Saline appears to have a safer profile (Level B).
- Excessive absorption of saline can cause severe complications. Still needs accurate measurement of I/O. (Level B).
- Systemic absorption increases when myometrial integrity is breached (Level B).

Complications

Complications are when problems occur during or after your procedure. The possible complications of any procedure includes an unexpected reaction to the anaesthetic, excessive bleeding or developing a blood clot, usually in a vein in your leg (deep vein thrombosis, DVT). Specific complications of TURP include the following.

Retrograde ejaculation.

TURP syndrome. This is a condition that can develop if the fluid used to flush your bladder during your procedure is absorbed into your body. This can cause changes in your blood pressure and you may feel sick or vomit. However, *this is becoming less common as a different type of fluid is often used to flush your bladder, which is less likely to cause TURP syndrome*. Please see our frequently asked questions for more information about TURP syndrome.

Urethral stricture.

Your prostate may grow again. If this happens, you may need to have another procedure if too little was removed during the first procedure.

BRITISH FIBROID TRUST GB

www.BritishFibroidTrust.org.uk

Table 1. Risks & Complications of Hysteroscopic resection	
Adverse reactions	You may get adverse reaction with anaesthetics.
Excessive bleeding during the operation	If bleeding is not controlled by diathermy coagulation, it may be necessary to use pressure from an inflated catheter that is inserted into the womb.
Infection of the womb	Small risk and usually presented as offensive vaginal discharge. This is treatable with antibiotics.
Organ perforation	Risk of puncture of the uterus occurs in 1-2 per 1000 operations. Sometimes, when this happens, there is a small risk of bowel injury at the same time. It may be necessary to perform laparoscopy to check this out.
Excessive fluid absorption	Occurs in 1-5% operations. This managed by blood test monitoring and diuretics. Your hospital stay may prolonged as a result.

BRITISH FIBROID TRUST GB

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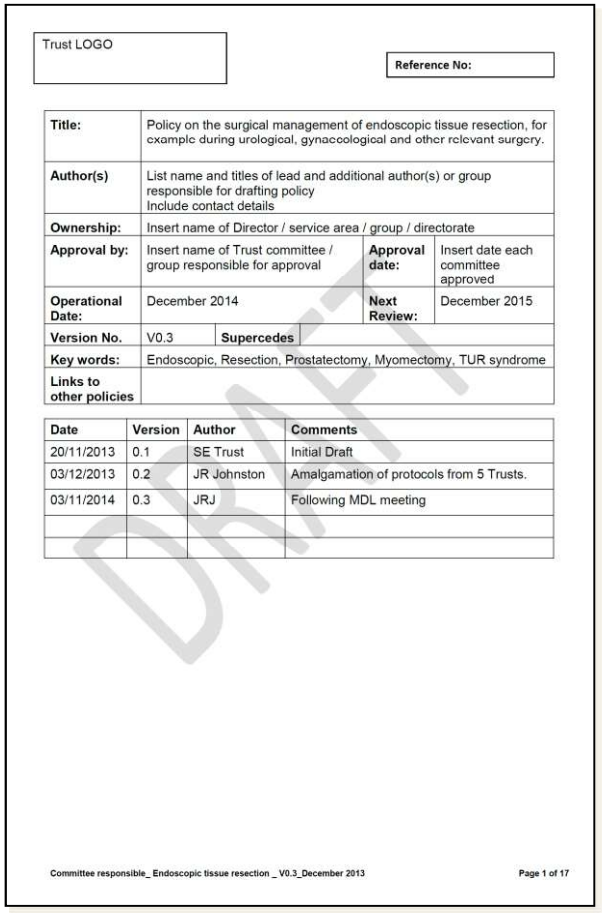
What happens DURING the operation?

- Under general anaesthetics, the cervix is gently stretched by a number of gradually increased size dilators one after the other.
- When sufficient stretch is achieved, the surgeon inserts a resectoscope into the womb. The resectoscope is connected to the fluid system which is used to distend the womb to allow the surgeon a clearer view. The view of the inside of your womb is also aided by a camera system connected to the resectoscope and a monitor.
- Pictures are taken for comparison later.
- The surgeon starts to shave off the fibroid by passing an electrical current through the cutting loop attached to the resectoscope and remove it bits by bits (piecemeal) if it is larger than 5 cm. The electrical current in the cutting loop helps to ensure a cleaner cut and seal the blood vessels at the same time.
- Pictures are taken to see the effects of the treatment.
- A sample of the removed fibroid(s) is taken to send to the labs to check for abnormality.
- Endometrial ablation may also be carried out at the same time to thin the lining of the womb to make your periods lighter. This is ONLY done if you have consented to it and suitable when you have completed your family or do NOT wish to become pregnant later.
- A dose of antibiotics is given during the procedure.
- *During and at the end of the operation, all fluid used is collected and checked for fluid balance.*
- The whole procedure takes about 30 minutes to complete but may take a little longer for larger fibroids.

Endoscopic Tissue resection policy

Urology further on than Gynaecology

- Engineer change in procedures.
- Engineer change to Saline. £
- Investigate flow/pressure controllers £
- If still use glycine,
  - Volumetric fluid balance
  - Measure POC serum sodium. £
- Finalise other details.



Trust LOGO

Reference No:

Title:	Policy on the surgical management of endoscopic tissue resection, for example during urological, gynaecological and other relevant surgery.		
Author(s)	List name and titles of lead and additional author(s) or group responsible for drafting policy Include contact details		
Ownership:	Insert name of Director / service area / group / directorate		
Approval by:	Insert name of Trust committee / group responsible for approval	**Approval date:**	Insert date each committee approved
Operational Date:	December 2014	**Next Review:**	December 2015
Version No.	V0.3 **Supercedes**		
Key words:	Endoscopic, Resection, Prostatectomy, Myomectomy, TUR syndrome		
Links to other policies			

Date	Version	Author	Comments
20/11/2013	0.1	SE Trust	Initial Draft
03/12/2013	0.2	JR Johnston	Amalgamation of protocols from 5 Trusts.
03/11/2014	0.3	JRJ	Following MDL meeting

DRAFT

Committee responsible_ Endoscopic tissue resection _ V0.3_December 2013 Page 1 of 17

Team dynamics

- WHO checklist : Sign In : Time Out : Sign Out.
- Dedicated role of fluid measurement and calculation of balance and deficit.
- Acceptance by all team members of their individual obligation to monitor and highlight all the safety issues occurring in the theatre, including those which may not strictly be their responsibility and ownership i.e. to work together as a team.
- Familiarity of team members with each other.
- Establish standard for maintaining continuity of patient and situational knowledge throughout surgical procedure.

Clinical Governance issues

AIM:

Good and effective team work = Gold standard in any surgical procedure.

- Establish acceptable number of cases performed by surgeon and anaesthetist when working infrequently outside their 'own' hospital.
- Familiarity of surgeon with working conditions and theatre practices in independent theatre in comparison with their 'own' hospital.
- Familiarity of anaesthetist with working conditions and theatre practices in independent theatre in comparison with their 'own' hospital.
- Familiarity of surgeon and anaesthetist in working with each other.
- Acceptable standard, accuracy and timeliness of operation and anaesthetic record.
- Ensure that there is no knowledge deficit between surgeon & surgical procedure and other theatre staff. i.e. theatre staff are aware of hazards of and equipment used for any surgical procedure before it is performed.
- Medical staff are kept aware of and completely informed about equipment available.

Stinson, Emma M

From: Simpson, John [redacted] >
Sent: 12 November 2014 22:11
To: Marshall, Margaret; Rice, Francis; Fearon, Paula
Subject: RE: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

Not yet Margaret,
John

From: Marshall, Margaret
Sent: 12 November 2014 17:53
To: Rice, Francis; Simpson, John; Fearon, Paula
Subject: RE: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

Hi Francis John,

Has Julian sent the draft regional policy and procedure as yet. When received we can then circulate to urologists and gynaecologists for consultation and comment. Although we still use glycine there was considerable work completed to ensure that there are clear guidelines in place in theatre for its management.

Paula would it be possible for you to forward the work completed on this area to myself, Francis and John.

Regards
Margaret

From: Rice, Francis
Sent: 10 November 2014 11:28
To: Simpson, John
Cc: Marshall, Margaret
Subject: RE: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

Margaret,can you advise please and happy to discuss.F

Mr Francis Rice
Director of Mental Health & Disability/Executive Director of Nursing Bannvale House Moyallen Road Gilford
BT63 5JX
[redacted]
Email: [redacted]
Copy to: tracy.griffin[redacted]

From: Simpson, John
Sent: 10 November 2014 11:21
To: Rice, Francis
Cc: Marshall, Margaret
Subject: RE: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

Yes, but exactly how I'm not sure. I'd be looking to Margaret for her views, John

From: Rice, Francis
Sent: 10 November 2014 11:10
To: Simpson, John
Subject: RE: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

Ok.Do we need to progress formally within the Trust to get agreement and if so how?

Mr Francis Rice
Director of Mental Health & Disability/Executive Director of Nursing Bannvale House Moyallen Road Gilford
BT63 5JX
Personal Information redacted by the USI
Email: Personal Information redacted by the USI
Copy to: tracy.griffin Personal Information redacted by the USI

From: Simpson, John
Sent: 10 November 2014 11:07
To: Rice, Francis
Subject: RE: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

I think we need local consensus that we will move with the region and my impression is that will be to move away from using glycine in either gynae or urology, John

From: Rice, Francis
Sent: 10 November 2014 10:48
To: Simpson, John
Subject: FW: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

John,do we need to do anything further?F

Mr Francis Rice
Director of Mental Health & Disability/Executive Director of Nursing Bannvale House Moyallen Road Gilford
BT63 5JX
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Email: Personal Information redacted by the USI
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From: McArdle, Charlotte [mailto Personal Information redacted by the USI]
Sent: 10 November 2014 09:56
To: Creaney, Brenda; Rice, Francis; Finn Corry Alan Western H.S.C. Trust; Olive.macleod Personal Information redacted by the USI ; Patterson, Nicki; Pat Cullen
Cc: Lee, Caroline (DHSSPS)
Subject: FW: DHSSPS / HSC MEDICAL LEADERS FORUM - Monday 3rd November 2014

Colleagues
Draft note of the discussion following medical leaders forum. You may remember the coroner wrote to CMO and CNO asking for a collegiate response to assurance that the situation in UIC would be learned from and steps taken to prevent it happening again.

Regards
Charlotte

Charlotte McArdle
Chief Nursing Officer
Nursing, Midwifery and AHP Directorate
C5.14, Castle Buildings
Stormont, Belfast BT4 3SQ
Tel Personal Information redacted by the USI Fax Personal Information redacted by the USI
Personal Information redacted by the USI

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

All

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

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

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

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

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

The causative themes identified during the inquest were,

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

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

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

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

There was discussion on

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

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

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

Stinson, Emma M

From: Johnston, Julian <[redacted]>
Sent: 19 December 2014 15:42
To: Simpson, John
Subject: RE: glycine issue

John
Things are now coming to a head and we are moving in the direction as suggested at the CMO's meeting.

Gynaecology - Johnny Price has been polling round the Province for me for gynaecology and was talking today to Geoff McCracken who I understand tried out the new Bipolar equipment today. The gynaecology team in the DHH are voicing concerns about measuring Sodiums in theatre but that is a minority view.
I have to congratulate the SHSCT and Charlie on providing me with the data from sodium measurements in CAH during TCRE TCEF. It is probably going to be the deciding factor in moving people away from glycine towards saline. So, far from being 'out of the loop' Charlie is very much 'in the loop'!

Regarding the SHSCT Urologists I understand from the guys who work here, will move towards the Bipolar machines - it is the SEHSCT guys who are proving reluctant.

I am hoping to finish the policy document setting out the position as a majority view, over the Christmas period..
Regards,
Julian

-----Original Message-----
From: Simpson, John [mailto:[redacted]]
Sent: 19 December 2014 15:19
To: Johnston, Julian
Subject: glycine issue

Julian,
Some of our gynae and urology people are feeling a bit left out of the loop. Is there any way you could liaise with/include them in the deliberations? Or could I facilitate that?
I did share the minutes with them from the CMO's forum. I know I did give assurance there that the SHSCT will go with the regional view, and I still think that, however I would think it wise for me to do something to bring them along. Have you any suggestions?
John

Stinson, Emma M

From: Simpson, John <[redacted]>
Sent: 11 March 2015 12:46
To: Johnston, Julian ([redacted]); McCracken, Geoff
Subject: FW: irrigation fluid in urology
Attachments: irrigating fluid response document 06 03 15.docx

Fyi
j

From: Corrigan, Martina
Sent: 11 March 2015 10:38
To: Simpson, John
Cc: Young, Michael
Subject: FW: irrigation fluid in urology

Dear Dr Simpson

Please see attached from Michael who is off on annual leave and asked me to forward this to you on behalf of the Urology Consultants

Regards

Martina

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

Telephone: [redacted]
Mobile: [redacted]
Email: [redacted]

From: Young, Michael
Sent: 10 March 2015 17:11
To: O'Brien, Aidan; Glackin, Anthony; Suresh, Ram; Haynes, Mark; ODonoghue, JohnP
Cc: Corrigan, Martina ([redacted])
Subject: irrigation fluid in urology

Tony Ram John and Martina went over the Glycine paper.
I had intended to send this to John Simpson tomorrow morning and to Jullian Johnston on Thursday - Does anyone have any great objection to this documents content.

MY

Tony thank you for reviewing the 'science'

06th March 2015

JULLIAN JOHNSTON
CONSULTANT ANAESTHETIST
ROYAL VICTORIA HOSPITAL
FALLS ROAD
BELFAST

Dear DR JOHNSTON

I would like to take this opportunity on behalf of the Urology Unit in Craigavon Area Hospital to respond to the second draft document on irrigating fluids used in urological procedures. The Consultants in the Unit have had the opportunity to discuss this as a group. We had previously provided our response to your initial paper back in January 2014.

There are a few comments I would like to make before recording our response on the paper itself. In general terms, we thought that for such an important issue it would have been beneficial and deserving to have had the opportunity of a round the table consultation before such an advanced stage document was produced. This would have highlighted the significant difference and therefore an appreciation noted throughout the subsequent documentation that there is considerable difference between irrigation fluids used during urological and gynaecological procedures. It would also have been advantageous to have had a wider initial E-mail address list to include all Urologists so that they could have individually commented. There also appeared to be a very clear foregone conclusion from the first draft that Glycine was to be removed from use. In saying this, we as a Department have indeed found that this second draft report clarifies the situation better in terms of recommendations. I now include our comments on the paper itself.

The opening sentence suggests that Urologists are not currently fully cognisant of the risks. This is far from the reality. Urological teaching for several decades has included this topic in our syllabus. Urologists are fully aware of what is known as TUR Syndrome. Clinical practice and methods of treatment are ingrained in our teaching of this particular care pathway. We are not in a position to comment on this aspect of gynaecological teaching. We feel that this sentence requires alteration. We also feel this document requires a clearer statement defining that urology and gynaecology procedures have a different physiological response; we feel that the overall impression within the document is that they are one of the same.

As a point of information, in Section 1.2 we would record that Saline is a conductor and hence why it is used for bipolar resection.

In section 1.5 we would like to note that TUR Syndrome is only one risk. Other factors such as fluid overload and haemorrhage offer significant risks and we feel that these two factors are as important as TUR Syndrome. In general terms we agree with the statement recorded in recommendation 1.

We have several points to record in Section 2. We still don't quite understand what is meant by the meaning of curtailing the use of Glycine.

We do not have any particular comment on section 3.

For Section 4, we are indeed agreeable with the statement about increased vigilance. We are however very vigilant already as our teaching in urology has pointed this out as a significant issue. In this particular section, we would like to add further comments.

With respect to the Point 4.2.2, it is correct to state that TUR syndrome does not occur with bipolar TURP but fluid absorption and haemorrhage can still occur. Scrutiny of the meta-analysis[9] presented by the reports authors demonstrates that a single study accounted for 17 of 35 reported cases of TUR syndrome in the 22 trials. The forest plots for the other series do not show statistical significance in relation to the incidence of TUR syndrome between bipolar and monopolar surgery. Therefore, one might conclude that this single trial is a statistical outlier which has unduly influenced the outcome. A flaw of the methodology.

The third paragraph of this section overstates the efficacy of bipolar TURP versus monopolar TURP for clinical outcomes. Indeed, the meta-analysis[9] notes that "results for maximum urinary flow rate were significant at 3, 6 and 12 months (all $P < 0.001$), but no clinically significant differences were found and the meta-analysis showed evidence of heterogeneity". The same meta-analysis states "Several major methodological limitations were identified in the included trials; 22/24 trials had a short follow-up of ≤1 year, there was no evidence of a sample size calculation in 20/24 trials and the application of GRADE showed the evidence for most of the assessed outcomes to be of moderate quality, including all those in which statistical differences were found."

The assertion that bipolar techniques may reduce length of stay and have costs benefits, is not supported by high quality published evidence, rather it is an opinion given in a NICE technology appraisal

There is a focus in this document upon arterial pressures. From a urology perspective for endoscopic prostatic surgery, any such absorption of fluid occurs through open venous channels or into extravascular space. These are not arterial channels. Open veins or capsular perforation are in essence the main ways of absorbing fluid into the system. Surgeons should therefore be aware of the operative field. The principal of having the irrigating fluid at 60cm or less is in general practice what is indeed used. The introduction of continuous irrigating flow scopes has helped to keep pressure as low as

possible and operative time is kept to a minimum as we recognise that these potentially have a contributing effect.

Recommendations of 5, 6, 7 & 8 are agreeable. We would feel that the emphasis on continuous monitoring of the fluids is the ideal way to proceed. Our experience to date of the use of pumps has not been productive and in fact has had the opposite effect.

In point 9, we would like to state that the nursing staff should keep an on-going running account of fluid balances so that the Surgeon and Anaesthetist can assess the situation in advance of the agreed limits defined pre-operatively, as opposed to being told when the limit has been reached. This will allow for safer completion of the operation.

We would agree with Point 10, but the definition of the 'deficit fluid' needs clarification. Is the deficit the patient's fluid volume or the theatre irrigation fluid volume record? Ie if there is a disparity in the 'irrigation fluid volume', then if this recorded as less fluid returning in the suction bottle, does this mean it is recorded as a deficit? As such this is a gain to the patient.

In Section 11, it is a recommendation that operative time is limited to 60 minutes. We feel that this should not be a hard and fast rule. There is no evidence base for this but we do realise this is a target time. Sixty minutes is custom and practice to date yet surgical judgement needs to be exercised. We feel that the recommendation wording could be altered to accommodate this feature. We do feel that it would be a significant advantage to modify the WHO checklist to include the expected operation time and the agreed fluid limits. This would be defined pre-operatively and hence the Nurse in charge of the 'fluid system' would have a clear understanding and as such would have an early warning system to inform the Surgeon and the Anaesthetist that this limit was close to being reached rather than just informing this team when the limit had been reached (as per Point 9).

We regard this document has having significant implications for all Units who undertake such procedures, whether they perform a high or low volume in terms of numbers. This 'direction of travel' would solely be a Northern Ireland phenomenon. Experience locally would not necessarily agree with the overall safety aspect claimed as haemorrhage risk issues have been expressed. Also some have expressed concern over a potential degradation of pathological specimens. This would have staging implications for bladder tumour management.

From a urological perspective there is significant regard and experience with the use of glycine, which should not be overlooked. Although of secondary concern, there will be a considerable cost implication to Trusts and the Department of Health as changing over to the bipolar system will be an excessively expensive process. Provision will be required.

M Young
Lead Clinician
Responding for Southern Trust Urology Service.

Stinson, Emma M

From:	Johnston, Julian <Personal Information redacted by the USI>
Sent:	26 May 2015 11:17
Cc:	'Dr Alan McKinney - PA'; 'Dr Alan McKinney - PA'; Jack, Cathy; Kelly, SharonA; Simpson, John; Feely, Roisin; 'Dr Ken Lowry'; 'Dr Ken Lowry - PA'; 'Mr Charlie Martyn'; 'Mr Charlie Martyn - PA'; 'Carolyn Harper'; 'PA - Dr Carolyn Harper'; 'Keith Gardiner'; 'McArdle, Charlotte'; 'Bradley, Fergal'
Subject:	Endoscopic Distending Fluids for 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

Paddy
The Coroner wrote to the CMO asking 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'.

Please find attached my final document with 12 recommendations which I propose would represent the required 'collegiate ' response to the failings surrounding Lynn Lewis's death in the UIC.

I presented draft work at 2 recent Medical Leader Forums. After the last one I received further feedback regionally and, especially important, in February 2015 NICE released 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. I would counsel that the opinions and help of Mr Chris Hagan (Urology) and Mr Johnny Price (Gynaecology) could be used to promote the changes needed regionally. They are happy to provide that, if you require it.

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: [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

HSC Belfast Health and Social Care Trust
25 OCT 2013

Our ref: 1791-2011

21st October 2013

Dear Medical Director
and Chief Nursing Officer,

Re: Lynn Lewis, deceased

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

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

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

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

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

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

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

I will look forward to hearing from you.

Yours sincerely

J L LECKEY
Senior Coroner for Northern Ireland

Encs

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

NICE has accredited the process used by the Centre for Health Technology Evaluation at NICE to produce medical technologies guidance. Accreditation is valid for 5 years from November 2011 and applies to guidance produced since March 2011 using the processes described in NICE's 'Medical Technologies Evaluation Programme: methods guide' (2011) and 'Medical Technologies Evaluation Programme: process guide' (2011). More information on accreditation can be viewed at www.nice.org.uk/accreditation

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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Accountability Report

- Standards and Guidelines -

(1st November 2013 to 1st May 2014)

Contents

SUMMARY STATEMENT

From 31st October 2013 to the 1st May 2014 SHSCT has received 90 new Standards and Guidelines from the DHSSPS or other external agencies.

The table below provides a *summary of these by Type/Number:*

Type of Correspondence	Total Number
Chief Medical Officer	15
DHSSPSNI Publications	10
HSCB Circulars	15
PHA Circulars	12
NICE Clinical Guidelines	16
NICE Technology Appraisals	10
NICE Equality Screening	4
S&Q Learning Communication	6
Foundation School	1
Interface Pharmacy Network	1
Total	**90**

This brings the total number of Standards and Guidelines listed on the Trust Register to 1,034

HSCB disseminated a further 73 NICE Clinical Guidelines for implementation by March 2015. The HSCB requested that the Trust screen these 73 guidelines to identify any urgent safety issues and those which may require regional input to achieve compliance. This process has been completed by the operational directorates; no urgent safety issues have been identified to date.

The process in place for the dissemination of Standards and Guidelines

The process in place for the dissemination of Standards and Guidelines within the organisation is presented in Appendix 2.

Implementation of Standards and Guidelines

To implement and progress Standards and Guidelines, short life working groups have been established to take forward the recommendations outlined within the guidance received as appropriate. Working groups are multi-professional when appropriate and are led by an identified 'change leader' to progress implementation of recommendations.

Nominations to the groups are identified from within the operational directorates with a view that this approach will provide assurance that clinical and management ownership is embedded into everyday working practices rather than ownership outside operational structures. The nominee's skills and knowledge are considered as part of this selection process onto the implementation groups.

Line management and governance structures provide mechanisms for lead directors and "change leaders" to escalate any barriers or challenges in implementation to the Senior Management Team (SMT) and Trust Board.

Challenges

In view of the large numbers of Standards and Guidelines which require implementation within the organisation the resource is not in all cases available to undertake evaluation of the implementation process. The complexity of a number of clinical guidelines and the potential for them to encompass a range of services for a broad condition or type of patient also presents the Trust with challenges in providing evaluation of compliance.

Given this challenge to, and the limited resources for, assuring compliance with the high volume of Standards and Guidelines received from a wide range of sources, the Trust has identified the Management of Standards and Guidelines as a risk on the Corporate Risk Register. A risk-based approach is being taken by the Trust in relation to auditing compliance which is informed by intelligence flowing from incidents, complaints, etc.

A high level 'Look Back' exercise was completed in March 2013 of all Standards & Guidelines disseminated to the Trust from March 2007 until April 2013 via the above agencies. This look back exercise identified that the Trust had a number of Standards and Guidelines where full compliance had not been reported. A further piece of work will be required to provide adequate assurance on progressing the level of compliance for this cohort of guidelines. It is envisaged that this work will commence in September 2014.

Due to the large numbers of guidelines identified, and in order to manage potential risks/impact to patient safety within the resources available, a process of prioritisation has been put in place. As part of this process and in order to facilitate decision making, the following were considered:-

- Corporate patient safety work streams
- Review and prioritisation of Standards and Guidelines by the Standards and Guidelines Group

- Review and prioritisation within Directorate Governance Foras

As part of the prioritisation process the above groups considered the following:

- Areas of non-compliance identified through the “Look Back” exercise
- Impact on patient safety across all Directorates
- Learning from SAI/AI (both internal and external)
- Learning Letters
- Learning from Coroner’s Inquests
- Audit outcomes
- Regional patient safety initiatives
- Public Inquiries

As an outcome of this process the following Standards and Guidelines have been identified as priorities for implementation by the Trust:

Reference	Title of Circular	Status
Acute Services Directorate Priorities		
LL/SAI/2012/011 (AS)	Learning Letter: LL/SAI/2012/011 (AS): Regional Learning Circular - Importance of taking action on x-ray reports Implementation date: 22/03/2013 Cross ref: HSC (SQSD) 32/2007 PSA/2007/16 16/08/2007 Early identification of failure to act on radiological imaging reports	Actions 2 & 3: An audit programme is in place to assess compliance with Royal College of Radiologists guidance on reporting chest x-rays and the follow-up of patients with abnormal radiology results. The audit sample did not identify any trends relating to individual reporting, however there was variation in the format / structure of the reports. In-house reporting now follows structured pattern with recommendations and timescales when appropriate. It is agreed reports will follow RCR guidance. Discussion on and learning from radiology discrepancy forms part of M&M. The outcome of this audit was also feedback to the Independent Sector. Re-audit planned in August 2014. Barrier to full compliance with the Learning Letter Implementation of the Electronic Patient Record includes the functionality to review and sign off reports. It is anticipated that the roll out of this function will be completed by August 2014
NPSA 2009 RRR 006	Oxygen Safety in Hospitals Implementation date: 28/06/2012	The Trust is compliant with the storage of Oxygen as far as possible within the environmental constraints. An audit is in place to monitor the compliance of the NPSA Alert re prescribing of oxygen. Compliance is high in acute medical wards. Barrier to full compliance: An agreed procedure on the prescribing of oxygen in acute adult surgical wards in order to improve overall compliance results.

Reference	Title of Circular	Status
Acute Services Directorate Priorities(continued)		
HSS (MD) 17-2010 12/04/2010 **HSS (MD) 39/2012** 23/08/2012	Physiological Early Warning Systems Implementation date EWS : 21/09/12	The Trust implemented Physiological Early Warning Systems as per this correspondence.This was superseded by implementation of NEWS across all relevant inpatient areas in Acute, OPPC and MHD Directorates in August 2012. This remains a patient safety priority in acute adult in-patients wards and compliance on timely escalation and appropriate action continues to be monitored through point prevalence studies, review of cardiac arrest calls, unplanned admissions to ICU and Nursing Quality Indicators. Learning is shared across the Directorate via Governance fora and M&M meetings.
NPSA/2011/RRR 001	Essential Care after an In-patient Fall Implementation date: 01/08/2011	The SHSCT has established a multidisciplinary working group. A Policy and Procedure is in place for the Management of Bedrails within the Trust since Nov 2012 and the use of bedrails is audited. Audit on the Falls Safe Bundle A and elements of Bundle B on two pilots wards is ongoing. Four Workshops have been organised in May, September and October 2014 across all adult in patient areas to raise awareness re Falls Safe Bundle A and B and falls reporting. A phased approach has been adopted regarding the implementation of this guideline is required due to the multiple workstreams involved, both internally and regionally.
LL/SAI/2013/014 (AS) 22/01/2013	Management of head injury complicated by alcohol ingestion Implementation date: 28/03/2013	The Trust's multidisciplinary working group has developed a procedure for the management of Head Injuries. An audit is in place to monitor compliance. A programme of awareness training on the Management of Head Injuries has been delivered in ED, in CAH and DHH

Mental Health & Disability Directorate Priorities		
HSCB Letter 28/02/2014	Use of Profiling Beds/Exposed Frame Metal Bed within the Inpatient MH Setting Implementation date 31/04/2014	Current Acute MH beds are being replaced. Two profiling beds are being retained in disabled rooms in Bluestone Unit. Beds within the new PICU and IATU will be fully compliant. Haven Close, current PICU, Gillis still use these beds but patients are risk assessed as indicated
NICE CG 113 29/07/2013	Anxiety Implementation date 31/03/2015	MHD is working towards assessment of compliance and implementation. No urgent safety concerns identified to date.
NICE CG 120 29/07/2013	Psychosis with co-existing substance misuse Implementation date 31/03/2015	MHD is working towards assessment of compliance and implementation. No urgent safety concerns identified to date.
NICE CG 123 29/07/2013	Common Mental Health Disorders Implementation date 31/03/2015	MHD is working towards assessment of compliance and implementation. No urgent safety concerns identified to date.
NICE CG 159 29/07/2013	Social anxiety disorder Implementation date 31/03/2015	MHD is working towards assessment of compliance and implementation. No urgent safety concerns identified to date.
Children's & Young Peoples Directorate Priorities		
NICE CG 112 29/07/2013	Sedation in children and young people	

Older Persons & Primary Care Directorate Priorities

NPSA 2009 RRR 006	Oxygen Safety in Hospitals Implementation date: 28/06/2012	The Trust is compliant with the storage of Oxygen as far as possible within the environmental constraints. An audit is in place to monitor the compliance of the NPSA Alert re prescribing of oxygen. Compliance is high in non acute wards.
HSS (MD) 17-2010 12/04/2010 **HSS (MD) 39/2012** 23/08/2012	Physiological Early Warning Systems Implementation date EWS : 21/09/12	The Trust implemented Physiological Early Warning Systems as per this correspondence. This was superseded by implementation of NEWS across all relevant inpatient areas in Acute, OPPC and MHD Directorates in August 2012. This remains a patient safety priority in non acute adult in-patients wards and compliance on timely escalation and appropriate action continues to be monitored through point prevalence studies, and Nursing Quality Indicators. Learning is shared across the Directorate via Governance fora and M&M meetings.
NPSA/2011/RRR 001	Essential Care after an In-patient Fall Implementation date: 01/08/2011	The SHSCT has established a multidisciplinary working group. A Policy and Procedure is in place for the Management of Bedrails within the Trust and the use of bedrails is audited. Training in the post falls pathway has been completed across non acute hospital wards and all training is recorded on a database. Audit on the Falls Safe Bundle A and elements of Bundle B on Ward 3 Lurgan Hospital (pilot ward) is ongoing, with a phased roll out of these audits to all relevant acute and non-acute wards. The numbers of adult in-patient falls and patients suffering moderate to severe harm is reported as part of the Commissioning Plan. . The Trust will continue to progress modifications to the DATIX risk management system to support ongoing audit of falls work streams taking a whole systems approach All incidents of falls are reviewed for learning and this is cascaded through governance fora. A phased approach has been adopted regarding the implementation of this guideline. This approach is required due to the multiple workstreams involved, both internally and regionally.

The following tables highlight those Standards & Guidelines where input is required from external agencies, or further work is required within the Trust in order to achieve full compliance

Table 1: Overview of Standards & Guidelines which require External Agency input to achieve full compliance (excludes NICE Guidelines to be implemented by March 2015)				
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**Directorate/s to which S & G applies**	**High level supporting comments for Director's information**
20/08/2013 & 20/12/2013	DHSSPS Letter	Annual Report of the National Confidential Inquiry into Suicide & Homicide by People with Mental Illness (NCISH), 2013 cross ref NCISH Report - Patient Suicide : The Impact of Service Changes c/r - DHSSPS Letter, 20/12/2013	MHD	Additional investment is required from the Commissioners for dual diagnosis services and psychiatric liaison
22/05/2013	HSCB Implementation date: not specified	Northern Ireland Implementation of HSC (SQSD) 3/11 Adult Passport to Safer Use of Insulin	Acute Services CYP MHD & OPPC	SHSCT has implemented local guidance, pending the regional framework. Insulin passport and patient information leaflet have been issued to patients initiated on insulin in hospital/clinic - will be rolled out to existing patients at review appointments. Awareness of insulin passport, patient information leaflet and to use passport and other information to confirm the correct identify of insulin products was issued via memo. Guidelines are on the intranet for insulin passport. Guidelines for involvement of patients in adult wards in the administration of insulin was developed and implemented in Dec 2012. Audit programme underway. **Regional Barrier**: Awaiting confirmation of the regional framework for supervised administration of insulin.

Table 1: Overview of Standards & Guidelines which require External Agency input to achieve full compliance (excludes NICE Guidelines to be implemented by March 2015)				
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**Directorate/s to which S & G applies**	**High level supporting comments for Director's information**
08/10/2013	HSCB Implementation date: 18/10/2013	NICE CG129 "Multiple pregnancy: the management of twins and triplet pregnancies in the antenatal period" cross reference with CG 129	Acute Services	Regional workshop will be held on Friday, 20 June 2014 to discuss a proposed model for a regional networked service and bring the final proposed model for a regional networked service to the HSC Board's SMT for approval. Following this, a commissioner specification will be developed for 2014/15 and Trusts will be required to implement the agreed service model.
17/10/2013	HSCB Implementation date: 14/11/2013	RQIA Baseline Assessment of Children under 18 admitted to adult wards	Acute Services CYP	HSCB & DHSSPS to lead on recommendations 1, 3, 4, 8 and 9
28/02/2014	HSCB Implementation date: not specified	Medicines and compliance / adherence	Acute Services	A draft Trust letter has been compiled, addressed to the HSCB in relation to this guidance.
27/03/2014	HSCB Implementation date: 01/04/2014	Process for the managed entry of new medicines	All Operational Directorates	The Trust is compliant with all recommendations in the 'Improving Current Arrangements' section. The Trust is currently seeking clarification from HSCB in relation to the section on 'Unlicensed and Off-label Medicines'.
09/07/2013	PHA Implementation date: 31/10/2013	RQIA Review of Hospitals at Nights and Weekends	Acute Services	The Trust has progressed recommendations 2-8, 10, 18-23. 25 & 27-28. The outstanding recommendations are being led by DHSSPS, HSCB and the Regional Safety Forum

Table 1: Overview of Standards & Guidelines which require External Agency input to achieve full compliance (excludes NICE Guidelines to be implemented by March 2015)				
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**Directorate/s to which S & G applies**	**High level supporting comments for Director's information**
12/12/2013	PHA Letter Implementation date: 01/02/2014	Northern Ireland Electronic Care Record (NIECR) and Sign Off of Laboratory and Radiology Results c/r Learning Letter LL/2012/SAI/011/AS	Acute Services	HSCB has been advised Directorates expect to be compliant by August 2014, dependent on consultation and engagement with clinicians
09/09/2013	Safety & Quality Learning Letter	Safe Use of Intravenous (VI) Magnesium Sulphate Implementation date: 02/12/2013	Acute Services	Full compliance is dependent upon the introduction of electronic prescribing systems for in-patients.
09/04/2014	Safety and Quality Learning Letter Implementation date: 30/5/102	Dispensing Beta blockers-Selection Errors	Acute Services	Compliant with SHSCT action plan. Barriers Trust pharmacy team are awaiting further information from the primary care Medicines Governance Team on the agreed list of medicines that need a computer alert to highlight the risk of mis-selection.
20/01/2014	CMO Letter Implementation date:20/01/201	NICE CG 174 - intravenous Fluid therapy Fluids in Adults	Acute Services OPPC MHD	Regional feedback on this CG is being co-ordinated through GAIN. Working Group chaired by Professor Ian Young.

Table 2: Correspondence issued between May 2013 - April 2014
where Acute Directorate has achieved partial compliance
(excludes NICE Guidelines to be implemented by March 2015)

Date of Issue from External Agency	Guidance Type	Title of Circular	High level supporting comments for Director's information
14/08/2013 23/07/2013	DHSSPS Email Implementation date01/10/2013 PHA Letter	RQIA Independent Review of the Management of Controlled Drug Use (c/r - PHA Letter issued 23/07/2013) RQIA Review of the Management of Controlled Drug Use in Trust Hospitals – Published June 2013 (c/r - DHSSPS Email issued 14/08/2013)	Action Plan in place and it is predicted all elements will be in place by Dec 2014
15/10/2013	PHA Letter Implementation date: 01/01/2014	Maternity Early Warning Scores Chart (MEWS)	OEWS chart was implemented on 1 Feb 2014. Training commenced 9 Jan 2014. 90% of midwives trained; the remaining 10% of staff are on maternity or long term sick leave. 50% of doctors have been trained Challenges Release of medical staff to attend training. Training will be rolled out to remaining staff through PROMPT training and the four additional training sessions requested from the Clinical Education Centre. When the training has been completed, audit on OEWS compliance will be initiated.

Table 2: Correspondence issued between May 2013 - April 2014
where Acute Directorate has achieved partial compliance

(excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
10/01/2014	Safety & Quality Alerts Letter Implementation date 24/01/2014	Follow-up of regional learning from adverse incidents in Maternity Services c/r PHA Letter issued 04/05/2012	Update on action 4: A draft guideline has been developed and some amendments are required following feedback from Neurology, Obstetrics and Emergency Department staff. A meeting is being convened to agree final amendments to the guideline and this will be developed and in place by end of June 2014.
02/05/2013	PHA Letter Implementation date: not specified	Patient Selection & Intrapartum Care in Maternity Units c/r with Safety & Quality Learning Letter 03/01/2013	Inclusion and Exclusion Criteria are adhered to and the Trust is partaking in a regional group to Review and Agree Inclusion and Exclusion Criteria for Midwife Led Care for all Units in Northern Ireland GAIN funding has been secured for same.All staff are aware of the need to assess the whole clinical picture and interpret the CTG in light of other risk factors and to accurately record all patient assessments. There are Escalation protocols in place. Consultants do have remote access to CTG interpretation. The SHSCT led the way in devising a handover briefing based on SBAR tool. It is known as HART (History, Assessment, Referral and Transfer). This tool has been adopted regionally by The Maternity Quality Improvement Group. The Trust also developed the Antenatal CTG sticker which has been modified and adopted for use across the region by the Maternity Quality Improvement Group.
Table 2: Correspondence issued between May 2013 - April 2014 where Acute Directorate has achieved partial compliance (excludes NICE Guidelines to be implemented by March 2015)			

Date of Issue from External Agency	Guidance Type	Title of Circular	High level supporting comments for Director's information
		Patient Selection & Intrapartum Care in Maternity Units c/r with Safety & Quality Learning Letter 03/01/2013 Continuation	There is ST3 level resident cover in Obstetrics and Anaesthetics in both CAH and DHH Maternity Units Staff Grades in Paediatrics, DHH are on-call 24/7. CTG training is available on an annual basis for all staff, there is Team review and it is found to be most beneficial. The Trust protocols/policies on induction of labour are in place, plans are in place to undertake audit of Induction of labour. Case Reviews of Intrapartum care are being progressed.
09/07/2013	HSCB Letter Implementation date 30/08/2013	Know the Massive Haemorrhage Protocol	Drills in ED to be completed in CAH on 28 May 2014 and in DHH on 19 June 2014. When this training has been completed, the Trust will be compliant. Plan to video the drill and cascade to staff for learning purposes. Drills have been completed in all other relevant areas. Annual rolling programme of drills to be implemented
14/01/2014	NICE Clinical Guideline Implementation date: Sept 2014	Neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings (updates & replaces CG 96)	Working towards implementation by Sept 2014
Table 2: Correspondence issued between May 2013 - April 2014 where Acute Directorate has achieved partial compliance (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**

21/02/2014	NICE Clinical Guideline Implementation date:Nov 2014	NICE Clinical Guideline CG175 – Prostate cancer: diagnosis and treatment (updates & replaces NICE CG58)	Working towards implementation by Nov 2014
08/01/2014	Safety & Quality Learning Letter	Head Injury in Patients on Warfarin - Treat as a Medical Emergency Implementation date: 30/04/2014	Letter to HSCB highlighting the recommendations of this Safety & Quality Learning Letter conflict with NICE CG 176 Head injury: Triage, assessment, investigation and early management of head injury in children, young people and adults
22/01/2014	Safety Quality Alerts Email	Removal of Central Lines Implementation date 04/02/20	Procedure in draft presently out for consultation.
28/06/2013	PHA letter	Haemolysis during or after haemodialysis	Audit plan is in place – outcome awaited.

Table 3: Correspondence issued between May 2013 - April 2014 where CYP Directorate has achieved partial compliance (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
10/06/2013	Chief Medical Officer letter Implementation date not specified	Prevention of Early Onset Neonatal Group B Streptococcal Disease	Availability of blood culture results at 36 hours has been identified as an ongoing barrier to full implementation. Cross reference with Section B document CG 149 submitted to HSCB.

Table 4: Correspondence issued between May 2013 - April 2014 where MHD Directorate has achieved partial compliance (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
17/02/2014	HSCB Letter Implementation date not specified	Regional Guidelines for the Search of Patients, their Belongings and the Environment of Care within Adult Mental Health and Learning Disability Inpatient Settings	Issued to all Acute MH wards.
06/12/2013	HSCB Letter Implementation date not specified	Revised NI Primary and Secondary Care Opioid Substitute Treatment Guidelines	MHD is working towards assessment of compliance and implementation. No urgent safety concerns identified to date.

Table 5: Correspondence issued between May 2013 - April 2014 where OPPC Directorate has achieved partial compliance (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
Directorate will continue to progress cross-directorate priorities e.g. falls workstreams as outlined above			

Table 6: Correspondence issued between May 2013 - April 2014 Cross directorate where partial compliance has been achieved (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
27/01/2014	CMO Letter Implementation date not specified	Introduction of New Training Programme on Seeking and Obtaining Consent for Hospital Post-Mortem Examination HSS (MD) 48/2012	The Seeking and Obtaining consent e-learning module will be incorporated into the programme of training for medical staff hosted by the Trust on the Southern Trust e-learning platform. Senior medical staff are required to complete all training that is relevant to their practice and assurance is provided via the appraisal and revalidation process where each doctor is required to produce evidence of completed training. Junior Doctors working in Obstetrics and Gynaecology are also required to complete the online module as part of their core training prior to taking up their post with the Trust In addition to this the Trust Bereavement coordinator along with a Consultant Cellular Pathologist have prepared a face-to-face presentation on Grief Bereavement and Communication. This has been notified to medical staff via Morbidity and Mortality Meetings and will be provided on request from individuals / teams. Presentations are also scheduled bi-annually for specialties that will more often discuss post mortem examinations including Obstetrics and Gynaecology; an updated presentation containing key information is also presented on induction to all Junior Doctors.Seeking and obtaining consent for Hospital Post-Mortem is not a common occurrence for most Trust doctors however the availability of the training module will be highlighted via the face to face sessions and included in the revised Trust Verification of Life Extinct procedure which is currently being reviewed.

Table 6: Correspondence issued between May 2013 - April 2014 Cross directorate where partial compliance has been achieved (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
12/03/2014	DHSSPS Letter Implementation date 12/06/2014	Head injury: Triage, assessment, investigation and early management of head injury in children, young people and adults – (replaces CG56)	May 2014: Draft CYP, ED, Surgical protocol under consideration
15/11/2013 Implementation date – not specified	PHA Letter	Competency Framework to Reduce the Risk of Hypnonatraemia when administering IV Infusions to Children - updated version 15 November 2013 - c/r letter issued25/04/2013Framework for administering the Risk of Hyponatraemia when administering intravenous infusions to children c/r letter issued 15/11/2013 c/r PHA letter,7/11/2013	A review of IV fluid management policy for children and young people is presently under review. This work is being led by the Medical Director and will focus on: • Training and competency of Clinical and Nursing Staff • Amendment of the Policy to reflect the current Governance structures

Table 7: Correspondence issued between May 2013 - April 2014 where Medical Director is the Change Lead and partial compliance has been achieved (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
04/03/2014 02/07/2013 07/03/2014	DHSSPS Letter	NICE (Interventional Procedures Programme) c/r NICE Interventional Procedures Guidance - Bi-monthly Communication	The Trust is currently working towards developing a suitable mechanism for managing the NICE interventional procedures programme. A number of options are under consideration and a final decision is expected June 2014. .
14/05/2013 29/05/2013 (PHA)	DHSSPS Circular & PHA	CBRN preparedness for HSC organisations cross ref Circular HSC (PHD) Communication 01/2013 - CBRN Preparedness for HSC Organisations	Guidance has been disseminated to relevant staff. The Emergency Planner will seek assurances from Operational leads that the recommendations have been implemented. .
11/10/2013	HSCB Letter	Flu, weather and major event preparedness/Preparedness for Pandemic Flu	The Trust is partially compliant with this. Work to be finalised on the Corporate Pandemic Plan. Directors are responsible for ensuring the development, review and testing of directorate/division/service level emergency response (including pandemic response) and business continuity plans.

Table 7: Correspondence issued between May 2013 - April 2014 where Medical Director is the Change Lead and partial compliance has been achieved (excludes NICE Guidelines to be implemented by March 2015)			
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**	**High level supporting comments for Director's information**
07/01/2014	HSCB Letter	Northern Ireland Out-Patient Antimicrobial Therapy Recommendations	Medical Director has provided an update to the HSCB on the 14/02/2014 advising of the Trust's current position. Antimicrobial Management Team has discussed how to progress with development of a guideline to support the advice in the recommendations. Further meetings are taking place in May 2014 to agreed way forward

Table 8: Correspondence issued between
May 2013 - April 2014
where Director of Human Resources is the Change Lead and partial compliance has been achieved

Date of Issue from External Agency	Guidance Type	Title of Circular	High level supporting comments for Director's information
10/05/2013	Chief Medical Officer letter Implementation date: not specified	The Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013	The Trust is making good progress in this legislative area. A workshop was held on the 29th May 2013 to brief nominated representatives from the directorates on implementation of the legislation. An update paper was provided to SMT on the 24 June 2013. The management of sharps policy was amended to reflect the legislation and to ensure that the re sheathing of needles was prohibited (with some agreed exceptions). An e- learning package was developed to support face to face training on best practice by IPC and Occupational Health. Directors have overseen the risk assessment process within their operational divisions and assessed the use of safer sharps on a risk basis. Alternative safer sharps are available via the e- procurement system and training has been made available by Suppliers. All sharps injuries are investigated by Health &Safety and incident trends/ lessons learnt are monitored by Interface meetings held jointly by the Lead H&S Director and Governance Co-ordinators within Directorates. Assurance of compliance is currently being audited by the H&S Department and the results scheduled for SMT in June 2014

Table 9: Correspondence issued between
May 2013 - April 2014
where Director of Performance & Reform is the Change Lead and partial compliance has been achieved

Date of Issue from External Agency	Guidance Type	Title of Circular	High level supporting comments for Director's information

23/5/2013	PHA Letter LL/SAI/2013/017(FCC)	Management of Data in Community Services	The Trust is compliant with recommendations 1a and 1c. Challenges: Following audit in May 2013, a corrective action plan is in place. to address the shortfall in attendance update of the CETIS training programme. The Education, Training and Workforce Development Committee oversees uptake of training, compliance is monitored and reported to Directors and SMT on a regular basis.

Appendix 1 Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported

Date of Issue from External Agency	Guidance Type	Title of Circular
07/06/2013	Cancer Focus NI Letter	Review of Access to Medicines in Northern Ireland
14/05/2013	CMO Letter	Guidance on Health Clearance for Tuberculosis, Hepatitis B, Hepatitis C and HIV for New Health Care Workers with Direct Clinical Contact with Patients - Locum and Recruitment Agencies and Service Commissioners
23/05/2013	CMO Letter	Liothyronine (Tertroxin) 20 Microgram Tablets - Continuity of Supply
03/06/2013	CMO Letter	End of 2012/13 Flu Season and Related Issues
11/06/2013	CMO Letter	Important changes to the Seasonal Flu Vaccination Programme in 2012/13
19/06/2013	CMO Letter	Panton-Valentine Leukocidin (PVL) Staphylococcus Aureus Cases
28/06/2013	CMO Letter	Incidents potentially linked to substance misuse
30/08/2013	CMO Letter	Management of Seasonal Flu 2013/14
17/01/2014	CMO Letter	Regional Fluid Balance Charts (Letter to Dr Julian Johnson)
22/05/2013	CMO Letter	Update on Novel Coronavirus Infection and Influenza A (H7N9) Virus (c/r PHA Letter: 14/02/2013
28/06/2013	CMO Letter	Emergency Planning: Interim arrangements for downloading the patient group directions for administration of medicines by authorised healthcare personnel to patients exposed to suspected biological or radiological agents and request for annual assurance
01/07/2013	CMO Letter	Hydroxyethyl Starch Intravenous Infusion: Suspension of use advice from the UK Commission on Human Medicines
04/07/2013	CMO Letter	Medical Transfers - Possible infection risks when accepting patients from overseas
05/07/2013	CMO Letter	Diclofenac: New contraindications and warnings after a Europe-wide review of cardiovascular safety
09/07/2013	CMO Letter	Codeine for Analgesia: Restricted Use in Children and Adolescents because of Report of Morphine Toxicity
16/07/2013	CMO Letter	Introduction of Shingles Vaccine For People Aged 70 Years (routine cohort) and 79 years (catch-up cohort)
22/07/2013	CMO Letter	Tuberculosis In Northern Ireland - Updated Guidance on BCG and TB Risk Assessment for Infants and Children

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
25/07/2013	CMO Letter	Updated Guidance on the Management and Treatment of Clostridium Difficile Infection
01/08/2013	CMO Letter	Regional Fluid Prescription and Balance Charts
01/08/2013	CMO Letter	Participation in Community Skin Infection (CSI) Surveillance Programme: enhanced surveillance of PVL-SA and CA-MRSA through investigation of purulent skin infections in the community
02/08/2013	CMO Letter	Oral ketoconazole: do not prescribe or use for fungal infections − risk of liver injury outweighs benefits
02/08/2013	CMO Letter	The Seasonal Influenza Vaccination Programme 2013/14
06/08/2013	CMO Letter	RCOG patient leaflet regarding GBS infection in newborn babies
08/08/2013	CMO Letter	Introduction of the Royal College of Paediatrics and Child Health (RCPCH) School-Age (2-18 years) Growth Charts
12/08/2013	CMO Letter	Protecting Children & Young People
23/08/2013	CMO Letter	Deaths linked to consumption of 2, 4- Dinitrophenol (DNP)
23/08/2013	CMO Letter	Update on Incidents Potentially linked to Substance Misuse
07/10/2013	CMO Letter	Regional Fluid Prescription and Balance Charts - request for assurance
09/10/2013	CMO Letter	Concussion and second impact syndrome
11/10/2013	CMO Letter	Urgent Communication - Potentially fatal new substance discovered in Northern Ireland
30/10/2013	CMO Letter	Carbon Monoxide Poisoning : Ongoing vigilance to ensure recognition and prevention
18/11/2013	CMO Letter	Antiepileptic drugs: new advice on switching between different manufacturers' products for a particular drug
20/11/2013	CMO Letter	Consultation on Draft Community Resuscitation Strategy for NI
22/11/2013	CMO Letter	Appeal Court Decision on Referral of Stillbirth to Coroner
02/12/2013	CMO Letter	SMS Messaging Service for Air Pollution Alerts "Air Aware"

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
23/12/2013	CMO Letter	Confirmed influenza isolated in Northern Ireland - NICE guidance on use of antivirals now applies
23/12/2013	CMO Letter	Outbreak of multidrug resistant K.Pneumoniae in Republic of Ireland H987
13/01/2014	CMO Letter	The International Code of Marketing of Breastmilk Substitutes
22/01/2014	CMO Letter	Updated guidance from the ACDP TSE Risk Management Subgroup (formerly the TSE Working Group) c/r - CMO Letter HSS MD 16-2011 issued 15/08/11 c/r - SQSD Learning letter issued 19/08/2013 c/r – CMO Letter 22/01/2014 – Further incident relating to the use of distension fluid
27/01/2014	CMO Letter	Combined Hormonal Contraceptives: Europe-wide review confirms the risk of thromboembolism is small and agrees updated information to reflect the latest evidence
21/10/2013	Coroner's Office	Correspondence from Coroner's Inquests
07/05/2013	DHSSPS Letter	Guidance on Delegated Authority to Foster Carers in Northern Ireland
07/05/2013	DHSSPS Letter	Guidance on Delegated Authority to foster Carers in Northern Ireland
05/06/2013	DHSSPS Letter	Complaints in HSC - Standards & Guidelines for Resolution & Learning
18/06/2013	DHSSPS Letter	Review of Integrated Medicines Management Programme
01/07/2013	DHSSPS Letter	Recording medicines related admissions to hospital
02/07/2013	DHSSPS Letter	National Institute for Health and Care Excellence (NICE) Interventional Procedures Programme
01/07/2013	DHSSPS Letter	Recording medicines related admissions to hospital
02/07/2013	DHSSPS Letter	National Institute for Health and Care Excellence (NICE) Interventional Procedures Programme
17/07/2013	DHSSPS Letter	Revised process for handling of NICE Clinical Guidelines c.ref : HSCB Letter 29/7/2013, 2/12/2013

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
29/07/2013	DHSSPS Letter	Consultation on Draft Five Year Strategy "Making it better through Pharmacy in the Community"
23/05/2013	DHSSPS Circular	Safer Management of Controlled Drugs: A guide to good practice in primary care (Northern Ireland)
22/07/2013	DHSSPS Circular	Action Plan arising from the Dental Hospital Enquiry
11/12/2013	DHSSPS Letter	National Institute for Health & Care Excellece (NICE) Technology, appraisals and clinical guidelines - New processes for endorsement, implementation, monitoring and assurance in Northern Ireland (c/r HSC (SQSD) 04/2011 issued 28/09/2011)
17/07/2013	DHSSPS Letter	HSCB/PHA Protocol For Implemention of Safety & Quality Alerts (cr Letter from CMO 17/07/2013)
12/08/2013	DHSSPS Letter	NICE Guideline Development Group Members IV Fluid Therapy for Children and Young People in Hospital
02/09/2013	DHSSPS Letter	National Institute for Health and Care Excellence (NICE) Technology Appraisals and clinical guidelines -process for endorsement implementation, monitoring and assurance in Northern Ireland (cr Circular (SQSD) 04/11) - issued September 2011
26/09/2013	DHSSPS Letter	Delivering Healthcare to the Armed Forces : A protocol for ensuring equitable access to health and social care services
27/11/2013	DHSSPS Letter	Complaints Procedure amendments Directions
18/12/2013	DHSSPS Letter	College of Emergency Medicine and National Poisons Information Service: Updated Guideline on Antidote Availability for Emergency Departments
23/12/2013	DHSSPS Letter	Promoting Good Nutrition Strategy c/r - PHA letter issued 13/09/12
20/02/2014	Foundation School email	Important GMC advice on self prescribing and being registered with a General Practitioner

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
25/11/2013	HSCB Email	Licensed Medicines in possible circulation on black market
26/07/2013	HSCB Learning Report	Serious Adverse Incident Learning Report: October 2012 - March 2013
27/06/2013	HSCB letter	Letter to service formulary update June 2013
29/07/2013	HSCB Letter	Revised process for handling of Nice Clinical Guidelines c.ref : HSCB Letter 2/12/2013
20/09/2013	HSCB Letter	Revised procedure for the reporting and follow up of Serious Adverse Incidents - October 2013
01/10/2013	HSCB Letter	Referral of patients requiring oral medicine services
08/10/2013	HSCB Letter	Patient Access Schemes - confidentiality clauses
10/10/2013	HSCB Letter	Proton pump inhibitors (PPIs) in children - action for Trusts
10/10/2013	HSCB Letter	Management Of Seasonal Flu 2013/14 - reporting arrangements
01/11/2013	HSCB Letter	Confidentiality Waiver for Informing the Health and Social Care Board and PHA of persistent Unsatisfactory EQA Laboratory Performance
02/12/2013	HSCB Letter	Revised process for handling of Nice Clinical Guidelines c.ref : HSCB Letter 29/7/2013
09/12/2013	HSCB Letter	Use of Brentuximab in Northern Ireland c/r - HSCB Letter issued 26/06/2012
14/04/2014	HSCB letter	commissioning of Fampridine for the use in the treatment of Multiple Sclerosis
20/05/2013	HSCB Letter	Management of Status Epilepticus in General Dental Practice
17/07/2013	HSCB Letter	Complaints in the HSC, Appointment of Layperson

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
		Title of Circular
05/08/2013	HSCB Letter	Revised HSCB/PHA Process for Developing Prescribing Guidance and Formulary Chapters
21/08/2013	HSCB Letter	Suspected Ovarian Cancer Pathway Scoping Exercise August 2013
06/11/2013	HSCB Letter	Follow up to September Bi-monthly meeting - Implemenation of NICE TAs
13/11/2013	HSCB Letter	Launch of Enhanced 24/7 Paediatric and Neonatal Critical Care Transfer Service
19/12/2013	HSCB Letter	Serious Adverse Incident Learning Report : 1 April 2013 – 30 September 2013 c/r HSCB Letter 26/07/2013 ref MB122
06/03/2014	Interface Pharmacist network	Prescribing and supply arrangements for specialist medicines in NI - Update to red, amber list - issue 23 Feb 2014
06/01/2014	NICE Clinical Guideline	Myocardial Infarction Secondary Preventation (Updates & Replace CG 48)
12/06/2013	NICE Clinical Guideline	Equality Screening Questionnaire - The assessment and prevention of falls in older people
10/07/2013	NICE Clinical Guideline	Equality Screening Questionnaire -Myocardial Infarction with ST-segment elevation (STEMi)
24/07/2013	NICE Equality Screening Questionnaire	Varicose Veins in the Legs
16/08/2013	NICE Equality Screening Questionnaire	Crizotinib for the treatment of previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene
28/08/2013	NICE Equality Screening Questionnaire	Acute Kidney Injury
28/08/2013	NICE Equality Screening Questionnaire	Autism - Management of Autism in Children & Young People
30/08/2013	NICE Equality Screening Questionnaire	Ocriplasim for Treating Vitreomacular Traction
01/10/2013	NICE Equality Screening Questionnaire	Bosutinib for previously treated chronic myeloid leukaemia
01/10/2013	NICE Equality Screening Questionnaire	Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy (Rapid review TA271)

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
13/11/2013	NICE Equality Screening Questionnaire	Myocardial Infarction Secondary Preventation (UPDATE)
09/12/2013	NICE Equality Screening Questionnaire	Teriflunomide for treating relapsing forms of multiple sclerosis
10/12/2013	NICE Equality Screening Questionnaire	Intravenous fluid therapy in adults in hospital
08/01/2014	NICE Equality Screening Questionnaire	Prostate Cancer Diagnosis and Treatment
10/05/2013	NICE TA	Implementation of NICE Technical Appraisal 267: Ivabradine for the treatment of chronic heart failure
10/05/2013	NICE TA	Implementation of NICE Technical Appraisal 266: Mannitol dry powder for inhalation for treating cystic fibrosis
21/06/2013	NICE TA	Implementation of NICE TA/265:Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours
21/06/2013	NICE TA	Implementation of NICE TA/268: Ipilimumab for previously treated advanced (resectable or metastatic) melanoma
21/06/2013	NICE TA	Implementation of NICE TA/269: Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation malignant melanoma
27/06/2013	NICE TA	Not recommended - Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of advanced ovarian cancer
27/06/2013	NICE TA	Not recommended - Bevacizumab in combination with gemcitabine and carboplatin for treating the first recurrence of platinum-sensitive advanced ovarian cancer
08/07/2013	NICE TA	Everolimus in combination with an aromatase inhibitor for the treatment of HER2 negative, oestrogen receptor positive locally advanced or metastatic breast cancer after prior endocrine therapy

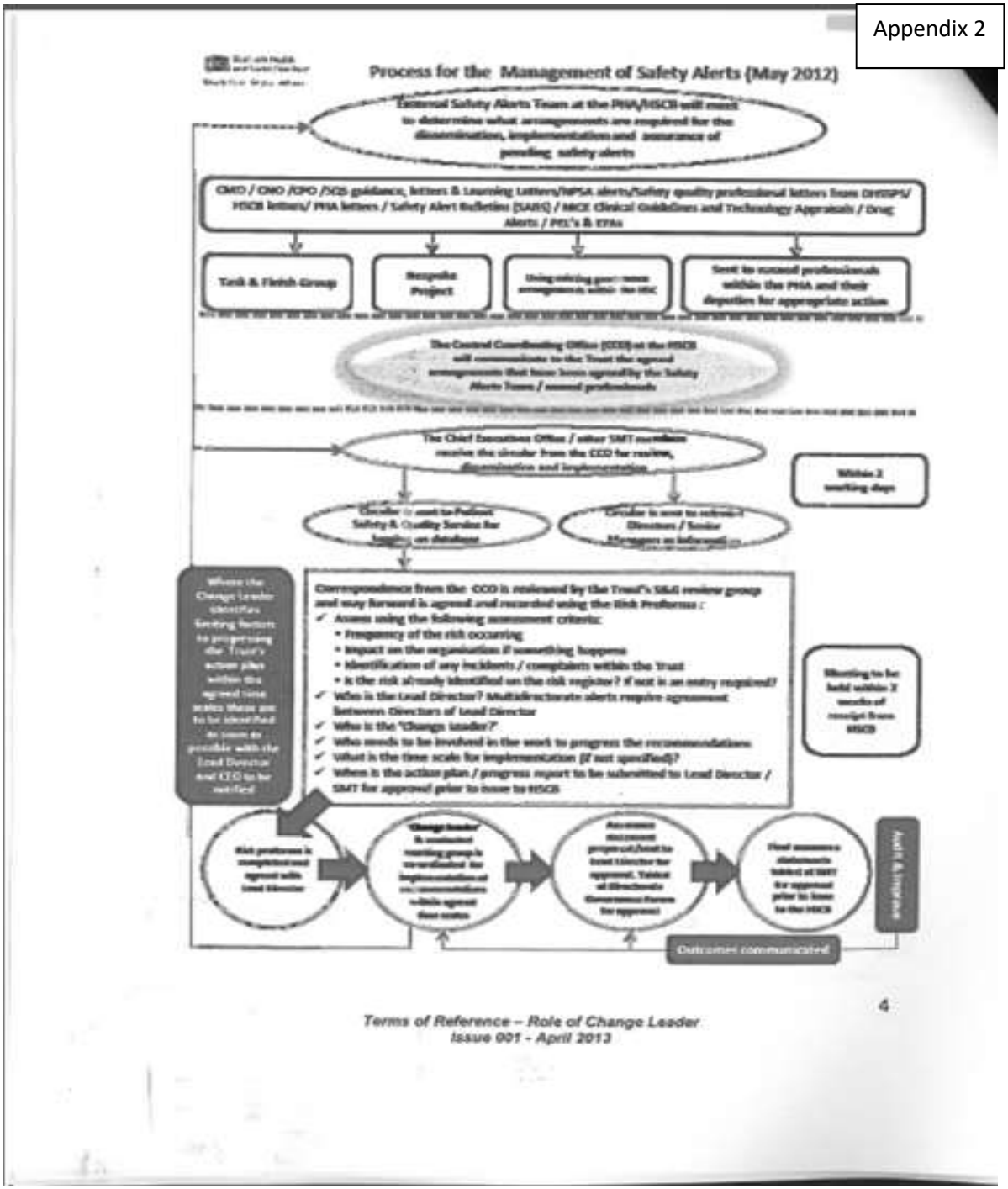
Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
11/07/2013	NICE TA	Apixaban for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation - 275 - c/r NICE TA Wave 27/9
11/07/2013	NICE TA	Ranibizumab for treating diabetic macular oedema (rapid review of technology appraisal guidance 237) c/r NICE TA 237
26/07/2013	NICE TA	Not recommended - Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis
26/07/2013	NICE TA	Not recommended - Pegloticase for treating severe debilitating chronic tophaceous gout
21/08/2013	NICE TA	Implementation of NICE Technology Appraisal 276: Colistimethate sodium and tobramycin dry powders for inhalation for treating pseudomonas lung infection in cystic fibrosis
11/09/2013	NICE TA	Abatacept for treating rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs (rapid review of technology appraisal guidance 234)
11/09/2013	NICE TA	Omalizumab for the Treatment of Severe Persistent Allergic Asthma (review of technology appraisial guidance 133 & 2010)
24/09/2013	NICE TA	Everolimus in combination with an aromatase inhibitor for the treatment of HER2 negative, oestrogen receptor positive locally advanced or metastatic breast cancer after prior endocrine therapy (C/R - NiCE Equality Screening template issued 08/07/2013)
25/09/2013	NICE TA	Percutaneous vertebroplasty and percutaneous balloon kypoplasty for treating osteoporotic vertebral compression fractures
30/09/2013	NICE TA	Implementation of NICE Technology Appraisal 282: Pirfenidone for treating idiopathic pulmonary fibrosis
14/10/2013	NICE TA	Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion
14/10/2013	NICE TA	Aflibercept solution for injection for treating wet age related macular degeneration
22/10/2013	NICE TA	Crizotinib for the treatment of previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
08/11/2013	NICE TA	Rivaroxaban for treating Pulmonary embolism and preventing recurrent venous thromboembolism - 287
08/11/2013	NICE TA	Mirabegron for treating symptoms of overactive bladder
25/11/2013	NICE TA	Implementation of NICE Technology Appraisal 288: Dapagliflozin in combination therapy for treating type 2 diabetes
25/11/2013	NICE TA	Implementation of NICE TA 293: Eltrombopag for the treatment of chronic idiopathic (immun) thrombocytopenis purpura (review of TA 205)
13/12/2013	NICE TA	Aripiprazole fortreating moderate to severe manic episodes in adolescents with bipolar disorder
07/01/2014	NICE TA	Not recommended - Bosutinib for previously treated chronic myeloid leukaemia
05/02/2014	NICE TA	Ocriplasmin for treating vitreomacular traction
05/02/2014	NICE TA	Ranibizumab for treating choroidal neovascularisation associated with pathological myopia
31/03/2014	NICE TA	Implementation of NICE Technology Appraisal (TA) 301: Fluocinolone acetonide intravitreal implant for treating chronic diabetic macularoedema after an inadequate response to prior therapy
21/02/2014	PHA Letter	HSC Pathway for Investigating Possible Ovarian Cancer
11/10/2013	PHA Correspondence	Shingles vaccine and immunocompromised patients
03/10/2013	PHA Email	Use of Immunoglobulin (IVIG) c/r DHSSPS Publication: Prescribing of Intravenous Immunoglobulin, published 07 June 2011
21/10/2013	PHA Email	Detection of Flu viruses following Fluenz Administration
08/11/2013	PHA Email	Cluster of Polio Cases in Syria
03/02/2014	PHA Email	DAMIS Alert - Red Mortal Kombat Pills
15/11/2013	PHA Email	Professional Guidance for those working with Stimulant Users

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
		Title of Circular
02/05/2013	PHA Letter	Continuation of Flu Vaccination Programme
16/05/2013	PHA Letter	Newborn Blood Spot Screening Programme: 2011/12 UK Performance Report: Key Findings and Further Action
23/05/2013	PHA Letter	Loss of Data from the Twinkle Paediatric Diabetic Database managed by BSO ITS SAI BS808
23/05/2013	PHA letter	Thematic Review: Relating to Identifying and responding to Deteriorating Patients within Acute Services (c/r HSS (MD) 39/2012 & HSS (MD) 17/2012
05/07/2013	PHA Letter	Flu Vaccine and Shingles Vaccine Training
16/07/2013	PHA Letter	New Northern Ireland Guidelines for the Management of HIV Positive Pregnant Women and their Infants
17/07/2013	PHA Letter	Medical transfers – possible infection risks when accepting patients from overseas (c/r with HSS(MD) 24/2013)
05/08/2013	PHA letter	Funding for medical physics review of breast screening equipment 2013/14
13/02/2014	PHA Letter	Parovirus B19 in Pregnant Woman
26/07/2013	PHA Letter	Use of Rotavirus Vaccine in Neonatal Units
20/08/2013	PHA Letter	Northern Ireland Newborn Hearing Screening Programme (NHSP): Guidance on responsibilities for referral and follow up of infants resident in Northern Ireland up to 6 months of age
30/08/2013	PHA Letter	Live Attenuated Influenza Vaccine - Fluenz (cr HSS (MD) 32/2013 issued 02/08/2013)
27/09/2013	PHA Letter	Shingles Vaccination Programme
16/10/2013	PHA Letter	Quality 2020 - Phase Trust Annual Quality Report
05/11/2013	PHA Letter	Coroner's Cases Inquest findings with implications for Health and Social Care Practice
20/03/2014	PHA Letter	Increase in scarlet fever notifications 2013/14
27/03/2014	PHA Letter	Ebola haemorrhagic fever outbreak in Guinea

Appendix 1 (continued): Standards & Guidelines issued between May 2013 - April 2014 where full compliance has been reported		
Date of Issue from External Agency	**Guidance Type**	**Title of Circular**
22/08/2013	Safety & Quality Learning Circular	Regional templates for CME/McKinley T34 Syringe Pump Prescription and Administration (c/r RRR HSC (SQSD) 18/10 issued 21/01/2011)
28/08/2013	Safety & Quality Learning Circular	Care Planning for Adult Mental Health Patients
13/08/2013	Safety & Quality Learning Letter	Child Centred Decision Making
19/08/2013	Safety & Quality Learning Letter	Communication of Patients' Risk Status for CJD
16/12/2013	Safety & Quality Learning Letter	Safe management of lower bowel dysfunction including Digital Rectal Examination (DRE) and Digital removal of faeces (DRF)
16/01/2014	Safety Quality Alerts Email	Medical Device Alert - OPTEASE retrievable Vena Cava Filter
18/04/2014	CMO Letter	Reporting deaths to the Coroner
11/02/2014	CMO Letter	Water Systems : Health Technical Memorandum 04:01: Addendum - Pseudomonas Aeruginosa - Advice for Augmented Care Units c/r - HSS MD 16/2012 Cross ref DHSSPS Letter of 22/11/2013 - Management of Water Systems cross ref with HSS(MD)5/2014
26/11/2013	HSCB Implementation date: not specified	NPSA safety alert 18 "Actions that can make anticoagulant therapy safer"

Appendix 2



Terms of Reference – Role of Change Leader
Issue 001 - April 2013