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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Stinson, Emma M

From: Patrick Keane [redacted]
Sent: 28 May 2015 17:32
To: john mcknight
Cc: Brian Duggan; [redacted] Sam Gray; [redacted] colin mulholland; [redacted]; Trevor thompson; hugh o' kane; alex macleod; ajay pahuja; david connolly; chris hagan; ODonoghue, JohnP; Haynes, Mark; Ali Al-Inizi; siobhan woolsey
Subject: Re: Endoscopic Distending fluids for the Coroner

Tutus for me whenever possible for prostates and therefore the same for TURBT

Sent from my iPhone

On 28 May 2015, at 17:25, john mcknight [redacted] wrote:

> Attached is email form J Johnston re TUR.
>
> I think all agree that there should be a move towards TURis for prostates. Previous discussions suggest that many would like to still have the ability to use glycine for TURPs as a back up. The complication profile for TURP in the literature used to support the NICE application is interesting.
>
> More concerning is the extrapolation to use for TURB, which is un-evidenced and not standard practice. Informal discussions with BAUS section of Oncology are not aware of any significant reason to recommend such a change.
>
> The gynae change is unchallenged.
>
> If a clear picture of concern is not again fed back, the current document will be seen as a final document and will see glycine removed or at best see those that use it for bladder tumours or prostates it as unsupported.
>
> I would be grateful if all would reply to me with there current position of TURis for both prostates and bladder tumours, with or without retention of ability to use glycine. Or if there is any other comment about this issue.
>
> John
>
> John McKnight
> Belfast N.Ireland
> Mob [redacted]

From: [redacted]
To: [redacted]

Colin Pendergast's email address
Raymond McClelland's email address
Keith Johnston's email address
Gary Dorman's email address
John J McKnight's email address

Subject: RE: Endoscopic Distending fluids for the Coroner
Date: Tue, 26 May 2015 16:41:46 +0000

Distending Fluids for Endoscopic surgery

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

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

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Assistant Medical Director

BHSCT

Julian Johnston's email address

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Sent: 27 February 2015 16:58
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Cc: Brian Duggan; [Fl Alar's email address]; [Ram Suresh's email address]; [Franz Schattka's email address]; colin mulholland; [Paul Downey's email address]; [Tony Glackin's email address]; [Aidan O'Brien's email address]; [Michael Young's email address]; Trevor thompson; hugh o' kane; alex macleod; ajay pahuja; p keane; david connolly; chris hagan; ODonoghue, JohnP; Haynes, Mark; Ali Al-Inizi; siobhan woolsey
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[redacted]

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From: ajay pahuja [Ajay Pahuja's email address]
Sent: 28 May 2015 21:37
To: Sam Gray
Cc: john mcknight; Brian Duggan; [Fl Alar's email address]; [Ram Suresh's email address]; [Franz Schattka's email address]; colin mulholland; [Paul Downey's email address]; [Tony Glackin's email address]; [Aidan O'Brien's email address]; [Michael Young's email address]; Trevor thompson; hugh o' kane; alex macleod; p keane; david connolly; chris hagan; ODonoghue, JohnP; Haynes, Mark; Ali Al-Inizi; siobhan woolsey
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Hi john

Been a huge fan of M- TURP until I got my hands on the Olympus B TURP kit.

Once u have witnessed a tur syndrome - u remember it for life!!
I think it's an under recognised complication and we prob don't record the subtle ones.

With my modest experience of having done approx 80-90 cases using the bipolar saline technology, I am certainly impressed with it. It's only a minor adjustment to the overall technique and Having the right kit (Olympus) makes a huge difference.

In my view there are some advantages over monopolar for eg
duration of postop catheterisation (approx 24 hrs in most cases), less peri operative blood loss, readmission rates seem low (so i feel but will need audited). I have not had a single tur syndrome or any blood transfusions - last 16 months and now feel very convinced (and sleep well too !!) that TURIS is the way forward.

Mixed feelings about Saline TURBT though, no doubt it is safe but I would agree with Sam that sometimes it is difficult to judge the depth of resection. Maybe it's again a case of the 'more you do the better you get'. ! I would feel more secure to have glycine available for my turbts

Thx
Ajay

Sent from my iPhone

On 28 May 2015, at 17:41, "Sam Gray" [Sam Gray's email address] wrote:

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From: [Julian Johnston's email address]
To: [Michael Young's email address]
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[David Glenn's email address]
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Stinson, Emma M

From: colin mulholland [redacted]
Sent: 28 May 2015 22:30
To: john mcknight; [redacted]; sam gray; [redacted]; michael young; [redacted]; hugh o' kane; alex macleod; [redacted] Patrick Keane; david connolly; [redacted] ODonoghue, JohnP; Haynes, Mark; Ali Al-Inizi; siobhan woolsey
Subject: RE: Endoscopic Distending fluids for the Coroner

Hi John

I now use saline for turps and turbts -- so nearly everything, since it avoids the hassle that comes with (or will come with using glycine! I still feel that glycine is as safe in experienced and competent hands but the olympus kit is better than mono-polar in my view. It does take a bit of time to learn how to get the best out of it and even the loop thickness you use can have a significant effect. Still think glycine should be available for selected cases if deemed necessary.

Colin

From: [redacted]
To: [redacted]
Subject: FW: Endoscopic Distending fluids for the Coroner
Date: Thu, 28 May 2015 16:25:35 +0000

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From: Alex Macleod's email address
Sent: 29 May 2015 16:08
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Cc: Brian Duggan; FI Alar's email address Sam Gray; Ram Suresh's email address Franz Schattka's email address colin mulholland; Paul Downey's email address Tony Glackin's email address Aidan O'Brien's email address Michael Young's email address Trevor thompson; hugh o' kane; ajay pahuja; p keane; david connolly; chris hagan; ODonoghue, JohnP; Haynes, Mark; Ali Al-Inizi; siobhan woolsey
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I agree that TURis should be adopted for TURP as it is safer. However, I disagree that monopolar TURP is 'unsafe' in those trained to use it for TURP. The bipolar technology is by no means a recent development, nor the knowledge that it eliminates TUR syndrome, and to say that we have been continuing with an 'unsafe technology' in many units when this alternative technology has been available on the market could be criticised. There is no doubt that TURis eliminates the rare but potentially fatal complication of TUR syndrome, and given that otherwise it is essentially the same procedure with other benefits (decreased bleeding etc) I cannot really see a reason not to use it.
TURis and the NICE guidance refers to the Olympus system which all here have said is great. I recall MY saying that the bipolar Wolf system was so poor as to be unusable and less safe than their monopolar kit, and we need to be careful that it is this Olympus system that is advised rather than any bipolar technology. Colin Mulholland has said on occasion he has had to use the monopolar kit for troublesome bleeding, particularly for those that come in with bleeding prostatic tumours that have been taken to theatre for TURP as an emergency/urgent case. It is notable that although all the guidelines say bipolar is safer they all continue to recommend monopolar as an option (even the risk averse in America).
With regard to TURBT there is no evidence that TURis is safer. TUR syndrome is not even listed as a complication on the BAUS leaflet. Using TURis if you are using it for TURP has advantages in terms of set up, using same equipment for both cases etc, and eliminated the hassle of Glycine use. I have been doing TURBT with the same TURis kit we use for TURP for quite a while now and really have not noticed any difference. Our trainees have also been using it for TURBT and again there have been no issues there either. Occasionally we use glycine for electrode diathermy or when using the coagulating biopsy forceps, so its availability is useful and required from time to time.

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

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

Regards,

Julian R Johnston MD FCARCSI FRCA
Assistant Medical Director
BHSCT
Julian Johnston's email address

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

From: Johnston, Julian
Sent: 27 February 2015 16:58
To: Michael Young's email address 'McKnight, John'; 'McAllister, Charlie'; Hagan, Chris; 'Darling, John'; David Morgan's email address David Glenn's email address D Glenn's email address Geoff McCracken's email address Michael Parker's email address Colin Pendergast's email address McClelland, Raymond; Keith Johnston's email address Gary Dorman's email address John J McKnight's email address
Cc: 'Simpson, John'; 'Alan McKinney Alan McKinney's email address Jack, Cathy; Charlie Martyn's email address Ken Lowry's email address
Subject: Endoscopic Distending fluids

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Stinson, Emma M

From: Ali Al-Inizi [redacted]
Sent: 29 May 2015 17:41
To: john mcknight
Cc: Brian Duggan; [redacted] Sam Gray; [redacted]; [redacted] colin mulholland; [redacted] [redacted] [redacted]
Trevor thompson; hugh o' kane; alex macleod; ajay pahuja; p keane; david connolly; chris hagan; ODonoghue, JohnP; Haynes, Mark; siobhan woolsey
Subject: Re: Endoscopic Distending fluids for the Coroner

Hi John

Personally I think TURPis is now here to stay and replace the monopolar resection. I don't mind selling it as the new "gold standard" for TURPs, but I'm personally against banning monopolar TURP. Recently I had to change from bipolar to monopolar in order to stop bad bleeding TURP!.

No evidence to set bipolar TURBT as the gold standard, gut I guess we would be delaying the inevitable!

Similarly I would not categorise monopolar TURBT as unsafe.

There's some evidence to suggest reducing the bipolar power from 180/60 to 50/40 w in order to minimise incidence of bladder perforation. However, my experience is limited with bipolar TURBT.

Ali

Sent from Ali's iPhone

> On 28 May 2015, at 17:26, "john mcknight" [redacted] wrote:
>
> Attached is email form J Johnston re TUR.
> I think all agree that there should be a move towards TURis for prostates. Previous discussions suggest that many would like to still have the ability to use glycine for TURPs as a back up. The complication profile for TURP in the literature used to support the NICE application is interesting.
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> John
>
> John McKnight
> Belfast N.Ireland
>
> Mob [redacted]
>
>
>
> From: [redacted]
> To: [redacted]
> Subject: RE: Endoscopic Distending fluids for the Coroner
> Date: Tue, 26 May 2015 16:41:46 +0000

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>
>
> <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>

Stinson, Emma M

From: Trevor Thompson [redacted]
Sent: 30 May 2015 17:39
To: [redacted]; ODonoghue, JohnP; Haynes, Mark;
Subject: Re: Endoscopic Distending fluids for the Coroner

<font color='black' size='2' face='arial'>John Saline for Prostates. I do v few TURBs but I would use saline for these too.

Aye

TT

-----Original Message-----
From: john mcknight [redacted]
To: Brian Duggan [redacted] fialar [redacted] Sam Gray [redacted] ksureshraman [redacted]
franz.schattka [redacted] colin mulholland [redacted] pauldowney [redacted]
tonyglackin [redacted] aidanpobrien [redacted]
Trevor thompson [redacted]
hugh o' kane [redacted] alex macleod [redacted] ajay pahuja [redacted] p keane [redacted]
david connolly [redacted] chris hagan [redacted]
johnp.odonoghue [redacted] mark.haynes [redacted]
Ali Al-Inizi [redacted]; siobhan woolsey [redacted]
Sent: Thu, 28 May 2015 17:25
Subject: FW: Endoscopic Distending fluids for the Coroner

<style scoped="">#AOLMsgPart_1.2_e2c4c5ce-9d11-4b8d-b186-70c027d240c6 td{color: black;} .aolReplacedBody .hmmessage P { margin:0px; padding:0px } .aolReplacedBody body.hmmessage { font-size: 12pt; font-family:Calibri }</style>

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John

John McKnight

Belfast N.Ireland

Mob Personal Information redacted by the USI

<hr id="stopSpelling">From: <a
Julian Johnston's email address
>

To: <a
Michael Young's email address
John McKnight's email address
Charlie McAllister's email address
Chris Hagan's email address
John Darling's email address
David Morgan's email address
David Glenn's email address
D Glenn's email address
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<style>#AOLMsgPart_1.2_e2c4c5ce-9d11-4b8d-b186-70c027d240c6 td{color: black;} .aolReplacedBody .ExternalClass p.ecxMsoNormal,.aolReplacedBody .ExternalClass li.ecxMsoNormal,.aolReplacedBody .ExternalClass div.ecxMsoNormal { font-size:11.0pt; font-family:"Calibri","sans-serif"; } .aolReplacedBody .ExternalClass a:link,.aolReplacedBody .ExternalClass span.ecxMsoHyperlink { color:blue; text-decoration:underline; } .aolReplacedBody .ExternalClass span.ecxMsoHyperlinkFollowed { color:purple; text-decoration:underline; } .aolReplacedBody .ExternalClass span.ecxEmailStyle17

{ font-family:"Calibri","sans-serif"; color:windowtext; } .aolReplacedBody .ExternalClass span.ecxEmailStyle18 { font-family:"Calibri","sans-serif"; color:#1F497D; } .aolReplacedBody .ExternalClass .ecxMsoChpDefault { font-size:10.0pt; } .aolReplacedBody .ExternalClass div.ecxWordSection1 { }</style>

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BHSCT

<a [redacted]>

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Stinson, Emma M

From: Brian Duggan [redacted]
Sent: 31 May 2015 13:18
To: Trevor Thompson
Cc: [redacted] ODonoghue, JohnP; Haynes, Mark;
Subject: Re: Endoscopic Distending fluids for the Coroner

John,

Happy with saline for prostates, I prefer monopolar for bladder tumours but that's a personal perspective, had an extraperitoneal perforation with bipolar.

Brian

Sent from my iPhone

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John McKnight
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Stinson, Emma M

From: Haynes, Mark [Mark Haynes's email address redacted]
Sent: 15 September 2017 06:57
To: Carroll, Ronan
Subject: RE: Urgent - Medical equipment capital priorities - all divisons to review and update their priorities and list top 5 (showing 1 through 5)

The 'Bipolar sets and pumps' are not optional. There is clear instruction following a regional review that we should not be operating in glycine routinely. We do not have the equipment to offer an alternative and as a urology team and trust are operating at risk every week. If we have a TUR syndrome death (as prompted the regional review when it occurred in a different hospital) our practice will be indefensible.

I was also of the impression (from conversations with Pamela) that a camera stack for theatres was on this list but this does not appear to be the case?

Mark

From: Carroll, Ronan
Sent: 10 September 2017 09:49
To: Nelson, Amie; Corrigan, Martina; Henry, Gillian; Kearney, Emmajane; Kelly, Brigeen; Matthews, Josephine; Murray, Helena; Sharpe, Dorothy; Wilson, Marie; Haynes, Mark; Scullion, Damian; Tariq, S; Weir, Colin
Subject: FW: Urgent - Medical equipment capital priorities - all divisons to review and update their priorities and list top 5 (showing 1 through 5)

Please see Barry's email and request for review of spreadsheet

Ronan Carroll
Assistant Director Acute Services
Anaesthetics & Surgery
Mob [Personal Information redacted by the USI]

From: Conway, Barry
Sent: 06 September 2017 12:35
To: McVey, Anne; Carroll, Ronan; Trouton, Heather; Boyce, Tracey; Carroll, Anita; Gishkori, Esther
Cc: McAlinden, Matthew; Conlon, Noeleen; Livingston, Laura; Lappin, Aideen
Subject: Urgent - Medical equipment capital priorities - all divisons to review and update their priorities and list top 5 (showing 1 through 5)

AD colleagues,

We have been asked to review our medical equipment priority list in anticipation of the next allocation of funding through the Capital Allocations Group.

We have recently had a number of urgent requests received from Divisions whereby equipment had broken down and needed urgently replaced. Some of these items were on the list of priorities albeit not as the top priorities.

In reviewing your current Divisional priorities, could I therefore ask that you also consider any old items of medical equipment that are beyond their expected lifespan and are regular breaking down or no longer fit for purpose. It is important that these items of equipment are considered for replacement as part of your divisional discussions.

I have attached the quarter 2 medical equipment spreadsheet for review.

Could I ask that you urgently review the attached list for your Divisions and send me your updated position by Wednesday 13 September.

Once received I will submit the priority requests to CAG for consideration.

Thanks, Barry.

Mr Barry Conway
Assistant Director – Acute Services
Strategy, Reform and Service Improvement
Southern Health and Social Care Trust
Mobile: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

Stinson, Emma M

From: Carroll, Ronan [redacted]
Sent: 25 October 2017 10:44
To: Kelly, Brigeen; Corrigan, Martina; Murray, Helena; Nelson, Amie; Clayton, Wendy; Haynes, Mark; Scullion, Damian
Subject: FW: capital equipment - list to be prioritised for Acute
Attachments: Medical Equipment 17-18 qtr 3 v3.xlsx

Importance: High

highlighted in yellow are the items to be purchased when Barry gives green light, hopefully very soon
Helena you can swap stacking system for drills

Ronan Carroll
Assistant Director Acute Services
Anaesthetics & Surgery
Mob [redacted]

From: Conway, Barry
Sent: 25 October 2017 10:40
To: Trouton, Heather; Carroll, Ronan; Boyce, Tracey; Carroll, Anita; Carroll, Kay; McVey, Anne
Cc: Gishkori, Esther; Conlon, Noeleen
Subject: RE: capital equipment - list to be prioritised for Acute

Dear all,

Thanks for your time yesterday to review the capital list

All our requests continue to be listed, however based on our discussions yesterday we have highlighted our top 10 – up to a value of 600k. this will help CAG in their allocation of further funding which we hope will be soon.

I have tried to ensure each division has a fair share of the top 10 – 3 each for Ronan, Anne and Heather and 1 for Anita.

I will forward this to CAG for their review pending the next allocation of funding.

Barry.

From: Conway, Barry
Sent: 19 October 2017 11:35
To: Trouton, Heather; Carroll, Ronan; Boyce, Tracey; Carroll, Anita; [redacted]
Cc: Gishkori, Esther; Conlon, Noeleen
Subject: capital equipment - list to be prioritised for Acute

AD colleagues,

As agreed at our Acute SMT on Tuesday past, we need to review our capital equipment list and look to give a prioritised list – 1,2,3,4,5, etc..for Acute

At this stage it remains unclear as to how much capital funding we may get for medical equipment for the remainder of the year but I think it would be reasonable for us to assume it may be around 500k to help with our discussions / prioritisation.

We can add more items on to the list above the 500k and if we get more funding, then at least we will be ready to move quickly on these items.

I have attached the latest version of the capital medical equipment list for acute for your information.

Could I suggest we complete this exercise next Tuesday at 1pm in meeting room 1 on the admin floor before Performance SMT?

Noeleen – copying to you for Anne's information on her return. I have also copied to Kay Carroll as she attended the meeting on Tuesday for Anne.

Thanks, Barry.

Mr Barry Conway
Assistant Director – Acute Services
Strategy, Reform and Service Improvement
Southern Health and Social Care Trust
Mobile: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

Pr ority	Directorate	AD	HOS	Descr pt on of Cap tal	H gh eve costs	NHS Cha n YES NO	STA DC or Tender	staggered approach YES NO	Comments update	Date Ordered	Requ s t on Number	Actua Cost £	Expected Date of De very	Date Rece ved	Codes for Eproc
	Acute	Anne McVey	Kay Carroll	Replacement C-Arm Cath Lab CAH	623167	No			**Approved through CAG and in progress**						
	Acute	Ronan Carroll	Marie Wilson	Stacking system and accessories x 1 £152k, Scopes x 3 £120k = Total £272k	196661				**Approved through CAG and in progress**						
	Acute	Heather Trouton	Jeanette Robinson	Slim Linear Endoscope	79000	Hitachi (TBC)			**Approved recently by CAG members (confirmed by A Magwood email 1 Sept 17)**						
	Acute	Tracey Boyce	Tracey Boyce	Medicines Optimisation for Older People capital requirement within IPT for PCs telephone etc	4120				see email 15/9/16 from Barry conway						
7	Acute	Anne McVey	Mary Burke	V60 NIV machine ED DHH	11000				This top priority for DHH ED						
	Acute	Anne McVey	Kay carroll	replacing the haemodialysis machines in DHH	TBC				will require procurement for 35 stations and consumables						
10	Acute	Anne McVey	Louise Devlin	Fibro scanner - gastro team	50000										
	Acute	Anne McVey	Mary Burke	Bladder Scanner for AMU	7500										
	Acute	Anne McVey	Kay Carroll	2 x NIV machines for CAH	22000										
	Acute	Anne McVey	Mary Burke	Slit Lamp CAH ED	7000										
	Acute	Anne McVey	Mary Burke	1 x ECG machine DHH ED	7000				see email 26/1/17						
	Acute	Anne McVey	Mary Burke	ED DHH Slit Lamp	7000				This is second priority for DHH ED						
	Acute	Anne McVey	Mary Burke	ED DHH drager Monitors x 3 (8K each)	24000				see email 26/1/17						
3 (1 echo machine at 80k)	Acute	Anne McVey	Kay Carroll	2 x ECHO machines CAH	160000				K Carroll to confirm cost for ECHO with D Lilburn						
	Acute	Anne McVey	Mary Burke	8 x wall mounted monitors	48000				required for additional cubicle spaces in CAH ED						
	Acute	Anne McVey	Mary Burke	2 NIV machines for CAH ED	22000										
	Acute	Anne McVey	Mary Burke	4 x Trolleys for CAH ED	24000				required for additional cubicle spaces in CAH ED						
	Acute	Anne McVey	Kay Carroll	Vivid E95 4D & EchoPac	136630	yes			For TOE provision on the DHH site for new cardiologist						
	Acute	Anne McVey	Kay carroll	Replacement of Trust Defibulators	450000				business case with options to be prepared						
8	Acute	Ronan Carroll	Marie Wilson	Pain Clinic STH - Generator - radiofrequency ultrasound	17000										
1	Acute	Ronan Carroll	Helena Murray	Camera stack with blue light system	80000				Cah theatres						
5	Acute	Ronan Carroll	Ronan Carroll	10 Bi polar sets which were quoted at £96,000 and 2 pumps which cost £21,000	117000				Linked to Urlogy peer review						
	Acute	Ronan Carroll	Martina Corrigan	Remaining items for Ophthalmology Service in Banbridge	20000	TBC			costs being reviewed by M Corrigan - this needs to be updated						
	Acute	Ronan Carroll	Helena Murray	CD 4 Drill systems for T&O (10 in total)	128000				raised as an urgent need by H Murray						
6	Acute	Heather Trouton	Brian Magee	Tissue processors (2) - CAH labs	70000	yes			This is second priority for Heather's areas						
	Acute	Heather Trouton	Jeanette Robinson	Ultrasound scanner STH - for antenatal scans	70000										
	Acute	Heather Trouton	Joanne McGlade	Colposcope	8000										
	Acute	Heather Trouton	Brian Magee	Blood group analyser for DHH	75000										
	Acute	Heather Trouton	Jeanette Robinson	Mobile x-ray unit for neonatal unit and detector	240000				need to check that there is no central funding for this						
	Acute	Heather Trouton	Brian Magee	Blood Bank Freezer CAH	10850	yes			raised by B Magee - replacement for current freezer in CAH						
9	Acute	Heather Trouton	Patricia McStay	Scanner for treatment room FSW DHH - Voluson S8 BT 16 with two probes	29995	yes			joe smith to confirmed details on email to b conway on 16 August 2017						
	Acute	Heather Trouton	Cathie McIlroy	Humphrey Field Analyser (2)	45475				required to replace equipment in Orthoptics which is now 20 years old						
	Acute	Heather Trouton	Wendy Clarke	Glood Gas Analyser (Delivery Suite CAH)	19000				upgrade required to existing analyser to enable sodium testing for women in labour						
2	Acute	Heather Trouton	Patricia McStay	USS scanners x 4 (midwifery clinics Armagh and STH)	110000										
	Acute	Anita Carroll	Kate Corley	2 Combi Ovens (replacement)	16000										
	Acute	Anita Carroll	Kate Corley	Food Trolleys (ED & Ramone, CAH)	40000										
4	Acute	Anita Carroll	Sandra McLoughlin	SSD test equipment for protein residue	34500										
	Acute	Anita Carroll	Kate Corley	Food Trolleys (Discharge Lounge & Ward 4 Ramone, CAH)	20000										
	Acute	Anita Carroll	Kate Corley	Food Trolleys (ED, DHH)	10000										

Urology Department Governance Meeting Minutes
15th November 2017

1. Minutes of last meeting and matters arising

2. Audits Received
   None
3. Morbidity & Mortality

Health & Care Number	Surname	Date of Death	Consultant on Discharge - Name	Date presented at M&M	Enrolled in Mortality Pathway on NIECR	Status	
Personal Information redacted by the USI	Personal Information	Personal Information redacted by the USI	O'Brien A Mr / McAllister C Dr	19/10/2016	Pre RM&MRS	Awaiting Consultant to complete IMMIX mortality review	Mr O'Brien to forward powerpoint presentation to permit completion of IMMIX
Personal Information redacted by the USI	Personal Information	Personal Information redacted by the USI	O'Brien A Mr		Enrolled on RM&MRS	Awaiting Consultant to complete NIECR mortality review task	Not presented

Personal Information redacted by the USI Personal Information redacted by the USI**: Case referred for review by General Surgery PSM**
Case presentation by Mr Hennessey
Action: Mr Hennessey to obtain notes and prepare draft written response with Mr O'Brien for discussion at next Urology PSM Jan 2018.

4. Complaints & Compliments
   a. None discussed

5. Learning from SAI's, DATIX etc.
   a. Datix Incident Report Number Irrelevant redacted by the USI Mr Glackin (Dr Doherty on call, not present to give her presentation)
      i. Importance of laterality when completing consent.

ii. Importance of operating surgeon reviewing consent and imaging before anaesthesia is commenced

6. Any other Business : Other issues relating to Clinical Governance.

    a. BCG pathway update not presented (Dr Doherty not present)
    b. Handover – broad ranging discussion with the following action points
        i. Improved clinical note entries in keeping with Trust guidelines
        ii. Use of a written daily handover sheet
        iii. Use written handover to and from out of hours team
        iv. Weekend plan to be completed for all Urology in-patients, facilitated by use of a proforma sticker (Dr Hasnain to lead)
        v. Weekly handover preparation on Wednesday afternoon in advance of Thursday Grand Round.

7. Next meetings
    a. Thursday 18th January 2018 at 2pm

Stinson, Emma M

From: Haynes, Mark [redacted]
Sent: 19 November 2017 07:42
To: Gishkori, Esther; Carroll, Ronan
Subject: Saline TUR
Attachments: Trust Action Plan against the Surgical Management of Endoscopic Tissue R....docx; HSS MD 14 2015 - POLICY ON THE SURGIVAL MANAGEMENT OF ENDOSCOPIC TISSUE ....pdf; REVISED Policy on surgery for endoscopic tissue resection V0 5 after PHA....pdf; Letter to Trusts Surgical Policy 17 Sept 15.doc

Morning

With regards recent capital expenditure decisions with respect to saline resectoscopes / infusion pumps, attached is the guidance issued to the region following a patient death and subsequent review. I also attach the trusts response to this guidance including the action plan. You will note the following two standards and the trust response / timelines (I have highlighted the specific actions / timelines).

1. Introduce Bipolar resection equipment. During the switchover to bipolar equipment, limit the use of glycine following careful risk assessment of individual patients. If glycine is still being used, strictly monitor as detailed in recommendation 5.	Within Gynae services bipolar resection equipment is in place within CAH and DHH (with the exception of one Consultant). Glycine is not used at all. The only exception to this is when there is a failure of the bipolar equipment and there is a need to revert back to the monopolar equipment. In the event of this rare occurrence there is strict monitoring of glycine in compliance with recommendation 5.		Ensure robust and monitored control measures are in place for the use of Glycine within urology services	Mrs Mary McGeough (Head of ATICS)	Ongoing
	Within Urology Services a trial of bipolar resection equipment is currently being undertaken by all of the Urology Consultants. Glycine is still in use.		Complete trial of bipolar equipment - There are 4 pieces of equipment being trialled for 6 weeks each to allow the Team to	Mr Young (Lead Consultant Urologist)	31/03/2016

			agree which is the most suitable. Commence procurement process if equipment is deemed suitable	Mrs Mary McGeough (Head of ATICS)	31/03/2016

7. Investigate instilling irrigation fluid by using a pressure controlled pump device and purchasing flow/pressure controllers.	Infusion pumps are used by gynae teams		No action required	-	-

	Infusion pumps are not used by urology teams because at present the pumps are not deemed suitable		Work is currently being carried out by Lead Urology Consultant and equipment supplier to improve the efficiency of the pumps for urology purposes – at present the pumps are not suitable. In the meantime flow is being regulated as per 6(a) and 6 (b) If the equipment is deemed suitable sufficient funding will be required to ensure procurement can proceed	Urology Consultants led by Mr Young Dr Wright Medical Director	31/12/2015 31/03/2016

From a region wide perspective, Southern Trust is the only urological team that are unable to meet this guidance with Saline resection being routine in the other units.

I note Mr Young's recent email regarding this issue. As he states the ST urology team are in a vulnerable position were a TUR syndrome death or significant morbidity to occur where glycine was used as a resection medium.

Given the above information (which I am unsure was reviewed at the time of recent capital expenditure decisions), I wonder whether there is any potential for reconsideration of this issue?

Mark

Received from Mark Haynes on 03/11/2023. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

ACTION PLAN

Reference	HSS (MD) 14/2015
Title of Clinical Guideline / Standard	Policy on the surgical management of endoscopic tissue resection, for example during urological, gynaecological and other relevant surgery
Date of Endorsement and Issue from External Agency:	18/08/2015
Submission Date for Assurance Response / Action Plan to HSCB:	31/10/2015 was the initial deadline date Letter from Dr Little (DHSSPSNI) received 03/11/2015 requesting an update Two week extension given – new deadline for submission 23/11/2015
Directorate/s affected by guideline recommendations	Acute Services
Operational Director	Mrs Esther Gishkori
Identified Change Leader	Mrs Mary McGeough – Head of ATICS Mrs Wendy Clarke – Acting Head of Midwifery & Gynaecology Dr G. McCracken – Clinical Director IMWH Mrs Martina Corrigan – Head of ENT and Urology Mr Young – Lead Consultant Urologist

Actions for Trusts					
Recommendation	**Current Control Measures**	**Current level of compliance (%)**	**Action plan**	**Designated Lead**	**Deadline for completion**
1. Preoperative workup **must** be geared towards prevention of the TUR syndrome.	All of these patients are optimised for surgery and as part of the pre-operative work up, the risk factors pertaining to TUR syndrome are identified and managed. Within Urology all patients are provided with a BAUS information Leaflet and at clinic appointment are advised verbally of the risk factors. All patients have standard haematology and electrolyte analysis completed and have careful consideration regarding blood grouping and cross matching.		An audit will be carried out to review the consent process for patients to determine if the patients have been "*truly made aware of the hazards of endoscopic resection using irrigation fluids*". Patients will be identified from Theatre Management System. Recent Investigations aimed at establishment of pathological anatomy and degree of Surgical risk to be scoped Availability of reports of such investigations prior to commencement of surgery to also be scoped	Mrs Mary McGeough (Head of ATICS)	31/12/2015
2. Introduce Bipolar resection equipment. During the switchover to bipolar equipment, limit the use of glycine following careful risk assessment of individual patients. If glycine is still being used, strictly monitor as detailed in recommendation 5.	Within Gynae services bipolar resection equipment is in place within CAH and DHH (with the exception of one Consultant). Glycine is not used at all. The only exception to this is when there is a failure of the bipolar equipment		Ensure robust and monitored control measures are in place for the use of Glycine within urology services	Mrs Mary McGeough (Head of ATICS)	Ongoing

	and there is a need to revert back to the monopolar equipment. In the event of this rare occurrence there is strict monitoring of glycine in compliance with recommendation 5. Within Urology Services a trial of bipolar resection equipment is currently being undertaken by all of the Urology Consultants. Glycine is still in use.		Complete trial of bipolar equipment - There are 4 pieces of equipment being trialled for 6 weeks each to allow the Team to agree which is the most suitable. Commence procurement process if equipment is deemed suitable	Mr Young (Lead Consultant Urologist) Mrs Mary McGeough (Head of ATICS)	31/03/2016 31/03/2016
3. Engineer changes in the type of procedures performed. More secondary procedures for management of heavy menstrual bleeding as per NICE recommendations.	Within gynae secondary procedures are applied but there is skills maintenance of first generation procedures so that the skill base is maintained for abnormal uterine pathology		On-going monitoring and review	All staff working within ATICS, Gynaecology	On-going
4. Increase vigilance when significant haemorrhage is a feature	The need for increased vigilance when significant haemorrhage is a feature is standard practice across all theatre environments. Trust guideline for the management of Blood Loss (2012) is in place and accessible by all staff on the Trust intranet		On-going monitoring and review	All staff working within ATICS, Gynaecology and Urology services	On-going

	Emergency theatre drills carried out on an annual basis and learning from this drill exercise is fed back to the clinical teams and to the Haemovigilence Team for monitoring / action planning				
5. If continue to use glycine, the following **must** be used. a. Measure point-of-care testing (POCT) serum sodium, i. preoperatively. ii. if the surgery is longer than 30 minutes as a routine. iii. intermittently throughout the surgery. iv. if there is a 1000 ml fluid deficit.	Compliant Compliant Compliant Compliant		Ongoing monitoring and review	All staff working within ATICS, Gynaecology	On-going
5b. Dedicated staff for transporting specimens and results.	This recommendation is not complied with. A member of staff who is available when specimens / results from specimens need to be transported will carry out this task. In October 2015 the Trust's Point of Care Committee has just approved the purchase of 5 POCT machines for ATICS – 4 to be used within CAH theatres / DPU and 1 for use within DHH theatres.	N/A	To purchase 5 POCT machines funding of £27k will be required. IPT is currently being completed for review and approval. When the 5 POCT machines are purchased blood results can be obtained within the theatre environment negating the need for a dedicated member of staff to carry out this task	Mrs Mary McGeough Head of ATICS Mr Ronan Carroll AD - CCS	31/03/2016

5c. Surgery, including TURP, TCRE & TCRF must be performed in a 'main' theatre where POCT equipment is immediately available	When the funding is allocated and equipment purchased 1 of the 5 ISTAT machines will be provided to Day Procedure Unit (CAH) to facilitate the carrying out of these surgical procedures		To purchase 5 POCT machines funding of £27k will be required. IPT is currently being completed for review and approval. When the 5 POCT machines are purchased blood results can be obtained within the theatre environment negating the need for a dedicated member of staff to carry out this task	Mrs Mary McGeough Head of ATICS Mr Ronan Carroll AD - CCS	31/03/2016
5d. Accurate fluid input & output measurement and deficit calculation	Within Theatres CAH a dedicated Fluid Balance Nurse has been appointed ATICS have developed their own fluid management documentation sheets and these are currently in use.		The regionally agreed perioperative fluid recording chart is to be implemented within all relevant theatre areas. To be appendiced within the new Standard Operating Procedures for the Management of irrigation fluids for patients undergoing TCRE / TCRF / TURP /TURB/TART	Mary McGeough Head of ATICS Brigeen Kelly Lead Nurse ATICS	31/12/2015

6. For both mono- and bi-polar techniques, limit the distension pressure by, a. maintaining it below the mean arterial pressure (MAP).	A draft Standard Operating Procedure for the Management of irrigation fluids for patients undergoing TCRE / TCRF / TURP /TURB/TART procedures is currently being developed		These draft standard operating procedures need to be reviewed in line with the requirements of the new regional policy, agreed and then implemented within the Trust.	Mary McGeough Head of ATICS Brigeen Kelly Lead Nurse ATICS	31/12/2015
With continuous-flow gravity systems, b. limit the height of the irrigating solution container to 60 cm above the patient and certainly never above 100cm; c. theatre teams must have a procedure for checking and maintaining an agreed height; d. not applying pressure bags to the irrigation fluid bag.	A draft Standard Operating Procedure for the Management of irrigation fluids for patients undergoing TCRE / TCRF / TURP /TURB/TART procedures is currently being developed		The draft standard operating procedures need to be reviewed in line with the requirements of the new regional policy, agreed and then implemented within the Trust.	Mary McGeough Head of ATICS Brigeen Kelly Lead Nurse ATICS	31/12/2015
7. Investigate instilling irrigation fluid by using a pressure controlled pump device and purchasing flow/pressure controllers.	Infusion pumps are used by gynae teams Infusion pumps are not used by urology teams because at present the pumps are not deemed suitable		No action required Work is currently being carried out by Lead Urology Consultant and equipment supplier to improve the efficiency of the pumps for urology purposes – at present the pumps are not suitable. In the meantime flow is being regulated as per 6(a) and 6 (b)	- Urology Consultants led by Mr Young	- 31/12/2015

			If the equipment is deemed suitable sufficient funding will be required to ensure procurement can proceed	Dr Wright Medical Director	31/03/2016
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	Within Theatres CAH a dedicated Fluid Balance Nurse has been appointed ATICS have developed their own fluid management documentation sheets and these are currently in use.		The regionally agreed perioperative fluid recording chart is to be implemented within all relevant theatre areas. To be appendiced within the new Standard Operating Procedures for the Management of irrigation fluids for patients undergoing TCRE / TCRF / TURP /TURB/TART	Mary McGeough Head of ATICS Brigeen Kelly Lead Nurse ATICS	31/12/2015
9. If continue to use glycine, the following **must** be used, throughout the procedure, a. accurate irrigation fluid input & output measurement and deficit calculation	This monitoring process is in place irrespective of whether glycine or saline is being used		On-going monitoring and review of both glycine and saline	All staff involved in this clinical task	On-going
10. Preoperatively, for each individual patient, there **must** be an agreed maximum fluid deficit threshold for action. The surgeon and anaesthetist **must** be informed by the nurse when the threshold is reached.	Within the SHSCT there is no specified individualised threshold. Within the Gynae and Urology teams, the surgeon and anaesthetist must be notified when the maximum fluid deficit threshold		The draft standard operating procedures need to be reviewed to ensure the agreed maximum fluid deficit threshold for notification and stopping surgery is	Mary McGeough Head of ATICS Brigeen Kelly Lead Nurse ATICS	31/12/2015

	is over 500 and then go no further when the maximum fluid deficit threshold is at 1000		specified.		
11. Operations should, if possible, not last longer than 60 minutes, a. Theatre teams **must** have an established mechanism for measuring time and procedures for alerting surgeon and anaesthetist.	The recording of resection time is adhered to. It is also a required field within the ATICS fluid management documentation sheet		The draft standard operating procedures need to be reviewed to ensure this requirement is specified prior to implementation within the Trust.	Mary McGeough Head of ATICS Brigeen Kelly Lead Nurse ATICS	31/12/2015
12. Completion of the standard WHO surgical checklist **must** be adhered to. Adoption of a modified WHO checklist for this kind of procedure should be investigated and piloted	Completion of the standard WHO surgical checklist is adhered to.		The Trust has taken the stance that the WHO checklist will not be modified for this kind of procedure since deviance from the standardised WHO checklist could create its own set of risks for the organisation	Ongoing	Ongoing

Identified Limiting Factors for preventing full compliance against guidance recommendations:
1. Required funding for the purchase of 5 new ISTAT point of care machines – cost is estimated at £27k 2. Complete trial of bipolar resection equipment within Urology services to ascertain if it is feasible to remove the need to use glycine – amount of funding required if trial outcomes are favourable is to be determined 3. Ascertain if infusion pumps can be used within urology Services. If deemed suitable for use within Urology Services, funding needs to be prioritised and allocated for the procurement of these devices. Amount of funding required if trial outcomes are favourable is to be determined 4. Finalisation of the Standard Operating Procedure for the Management of Irrigation Fluids for patients undergoing TCRE / TCRF / TURP /TURB/TART procedures 5. Need to replace the existing fluid management documentation with the new regional perioperative fluid recording chart and advise staff of any changes to recording requirements. This new recording chart is to be included within the new standard operating procedure referenced in point (4)

Compliance Scale:

100% Compliance	70-99% Compliance	40-69% Compliance	0-39% Compliance	Pending	Not Applicable

From the Deputy Chief Medical Officer
Dr Paddy Woods

HSS(MD)14 /2015

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

Castle Buildings
Stormont
BELFAST
BT4 3SQ

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

Your Ref:
Our Ref: HSS(MD)14 /2015
Date: 18 August 2015

For Action:

Chief Executives HSC Trusts
Chief Executive HSCB
Chief Executive PHA
Chief Executive RQIA *(for dissemination to independent sector organisations)*

Dear Colleague

POLICY ON THE SURGICAL MANAGEMENT OF ENDOSCOPIC TISSUE RESECTION

ACTION REQUIRED

1. HSC Trusts and independent providers should process this regional policy template for endorsement by the organisational board, or equivalent;

2. HSC Trusts and independent providers should develop action plans to implement the various elements of the endorsed policy;

3. HSC Trusts should work with commissioners to address resource issues arising from these implementation plans in a phased, consistent and timely manner; and

4. the Public Health Agency should report on progress by 30 November 2015.

As a result of the verdict of the Coroner into the cause of death of Mrs Lynn Lewis in October 2013, work was commissioned on ensuring the safe and effective management of procedures involving the use of distending fluids in endoscopic procedures. In recognition of the limited guidance available on the management of these procedures, local work was commissioned, led by Dr Julian Johnston, Assistant Medical Director in Belfast Health and Social Care Trust.

The attached outline policy is the product of that work and we are now commending it for regional implementation.

The policy covers relevant issues including:

- appropriate preparation of patients prior to operation;
- selection of equipment and associated distending medium;
- precautionary measures associated with the distending medium selected;
- necessary measurements prior to, during and after these procedures;
- a good theatre environment in terms of team dynamics; and
- use of the WHO surgical checklist.

We believe this policy covers all aspects of concern raised by the Coroner in light of his findings in this tragic case.

We welcome your full assistance in this matter.

Yours sincerely

Dr Paddy Woods
Deputy Chief Medical Officer

Mrs Charlotte McArdle
Chief Nursing Officer

Cc HSC Trust Medical Directors
HSC Directors of Nursing Services
Chief Executive, BSO
Executive Medical Director/Director of Public Health PHA/HSCB
Dean Medical Faculty, QUB
Dean of Life and Health Sciences, UU
Chief Executive NIPEC
Chief Executive NIMDTA
Director of Safety Forum

This letter is available on the DHSSPS website at
www.dhsspsni.gov.uk/index/phealth/professional/cmo_communications.htm

Insert Trust LOGO

Reference No:

SAMPLE POLICY

Title:	Policy on the surgical management of endoscopic tissue resection, for example during urological, gynaecological and other relevant surgery.			
Author(s)	List name and titles of lead and additional author(s) or group responsible for drafting policy Include contact details			
Ownership:	Insert name of Director / service area / group / directorate			
Approval by:	Insert name of Trust committee / group responsible for approval		**Approval date:**	Insert date each committee approved
Operational Date:	May 2015		**Next Review:**	May 2017
Version No.	V0.5	**Supercedes**	Any legacy policies.	
Key words:	Endoscopic, Resection, Prostatectomy, Myomectomy, TUR syndrome			
Links to other policies				

Date	Version	Author	Comments
20/11/2013	0.1	SE Trust	Initial Draft
03/12/2013	0.2	JR Johnston	Amalgamation of protocols from 5 Trusts.
01/02/2015	0.3	JRJ	Following 3/11/14, 19/01/2015 MLF meetings
20/03/2015	0.4	JRJ	Following regional feedback, NICE publication
August 2015	0.5	PHA	Review by PHA

Recommendations

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

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

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

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

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

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

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

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

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

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

Some of the recommendations can be instituted now and some will depend on purchase of equipment.

1.2 Irrigation fluids used

The irrigation fluid used for these electrosurgical procedures should,

- have neutral visual density so that the surgeon's view is not distorted;
- be non-haemolytic and will not lead to haemolysis if it enters the circulation.

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

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

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

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

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

The most commonly used irrigation fluid has been 1.5 % **glycine solution,** a non-essential amino acid with a low cost and lack of allergic reactions**.** However, it has an osmolality of 200 $mOsm.kg^{-1}$ which is much lower than that of blood [Plasma = 290 $mosmol.kg^{-1}$] and large amounts of this hypotonic irrigation fluid, required to facilitate the procedure, may be absorbed systemically through a vascular bed[2]. This may cause several serious complications known as the **TUR syndrome** which can occur in a variety of surgical disciplines.

Normal saline is used for irrigation with the bipolar resectoscope. It is associated with fewer unfavorable changes in serum sodium and osmolality than is the case when electrolyte-free media are used with monopolar systems[3] e.g. glycine. Its use, however, does not eliminate the need to prevent excess absorption or to closely monitor fluid balance, as overload can occur. Pulmonary oedema is a reported consequence.

1.3 TUR syndrome[4]

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

It is manifested mainly through a classic triad of,

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

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

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

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

1.4 Purpose

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

1.5 Objectives

To reduce the likelihood of developing the TUR syndrome through,

- correct patient selection and preoperative preparation;
- selection of an appropriate surgical technique;
- electing to use surgical equipment which allows the use of irrigation fluid which will not give rise to the TUR syndrome;
- the application of monitoring aimed at detecting the early warning signs of the TUR syndrome;
- establishing a theatre regime based on good theatre practice principles aimed at reducing the development of the TUR syndrome.

2.0 SCOPE OF THE POLICY

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

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

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

3.0 ROLES/RESPONSIBILITIES

Medical staff to,

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

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

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

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

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

4.0 POLICY PRINCIPLES

4.1 Definitions

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

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

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

Hyponatraemia: Lower sodium concentration than normally found in plasma.

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

4.2 Policy Principles

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

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

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

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

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

4.2.1 Preoperative workup

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

- a robust consent process leading to a truly informed patient aware of the hazards of endoscopic resection using irrigation fluids;
- a thorough physiological assessment with attention paid to risk factors such as hypertension, ischaemic heart disease, cardiac failure, anaemia;
- standard haematology and electrolyte analysis - to include a recent haemoglobin, serum sodium;
- careful consideration regarding blood grouping and cross-matching;
- recent investigations aimed at establishing the pathological anatomy and degree of surgical risk especially haemorrhage e.g. ultrasound scan;
- the ready availability of reports of such investigations before surgery commences.

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

Urology

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

Gynaecology

Consideration should be given to the timely commencement of any adjuvant therapy prior to the surgery[3], especially if it helps to reduce the risk of haemorrhage and/or causes a reduction in tumour size.

4.2.2 Selection of surgical technique

Urology

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

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

fundamental flaw of monopolar equipment (M-TURP) by allowing resection in a normal saline irrigation. Therefore, the adoption of bipolar TURP/TURBT allows NS irrigation and permits the removal of glycine and its inherent risks from theatre. The risks of the hyponatraemic and hypo-osmolar aspects of the TUR syndrome are eliminated.

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

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

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

Significantly, the TUR syndrome has not been reported with bipolar equipment[5]. A recent systematic review and meta-analysis[9] comparing traditional monopolar TURP with bipolar TURP established in 22 trials that the TUR syndrome was reported in 35/1375 patients undergoing M-TURP and in none of the 1401 patients undergoing B-TURP. Even taking into account that one study alone was responsible for 17 of the 35 cases, the accompanying editorial states, "*the elimination of TUR syndrome alone has been a worthy consequence of adopting bipolar technology."*

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

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

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

They also indicate that,

- the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate' (or monopolar TURP);
- Healthcare teams may want to use the TURis system instead of monopolar TURP because,
    - there is no risk of a rare complication called transurethral resection syndrome;
    - it is less likely that a blood transfusion after surgery will be needed.

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

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

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

NICE, in February 2015, also issued guidance for the public on this topic. They indicated that, "*the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate'. Healthcare teams may want to use the TURis system instead of monopolar TURP because there is no risk of a rare complication called transurethral resection syndrome and it is less likely that a blood transfusion after surgery will be needed."*

Therefore, the case for moving from a monopolar to bipolar technique for resection of the prostate would appear to be well established as safer with regard to the development of the TUR syndrome. However, it should be remembered that the use of NS is not without risk because there will still be fluid absorption with plasma volume expansion.

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

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

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

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

Their effectiveness in the management of heavy menstrual bleeding (in comparison with hysterectomy - the existing gold standard) has been demonstrated in a number of randomised controlled trials. Although less morbid than hysterectomy, they are associated with a number of complications including uterine perforation, cervical laceration, false passage creation, haemorrhage, sepsis and bowel injury and, importantly, the fluid overload and hyponatraemia associated with the use of 1.5% glycine irrigation fluid resulting in the serious and occasionally fatal consequences discussed above.

However, there are now second generation ablative techniques which do not require the use of electrocautery or the use of glycine or other distension fluids. They avoid the serious risk of hyponatraemia and represent simpler, quicker and potentially more efficient means of treating menorrhagia.

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

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

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

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

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

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

Therefore, this policy recommends that, (as long as they are proven to be safe and effective as judged by the NICE interventional procedure programme,) the use of second generation ablative techniques and bipolar RF systems should be introduced regionally and the use of glycine as a irrigant curtailed, strictly monitored when it is still used and eventually terminated when there ceases to be circumstances when its use is considered the safest.

4.2.3 Identification, control and management of haemorrhage.

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

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

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

Recommendation 4
Increase vigilance when significant haemorrhage is a feature.

4.2.4 Control of the absorption of irrigation fluid

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

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

a. Hyponatraemia

The uptake of 1000 ml of fluid would generally correspond to an acute decrease in the serum sodium concentration of 5-8 mmol/L.[2] Encephalopathy, seizures and even cerebral oedema may develop when the sodium concentration falls below 120mmol.L^{-1}. However, even markedly hyponatraemia patients may show no signs of water intoxication. The crucial physiological derangement of CNS function is not just hyponatraemia *per se*, but also the presence of acute hypo-osmolality[4].

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

Whereas hyponatraemia occurs with equal frequency in men and women, premenopausal women are 25 times more likely to die or have permanent brain damage than men or postmenopausal women, most likely an oestrogen effect[3]. This effect is compounded because fluid absorption is slightly more common during TCRE than during TURP, and especially so with TCFR.

Serum Sodium measurement

Monitoring serum sodium concentration during TURP is common practice and a low value will confirm the diagnosis of hyponatraemia and is effective for assessing intravascular absorption. Significant decreases from a normal preoperative level can occur after just 15 minutes of starting resection. Levels below 120mmol.L^{-1} are invariably symptomatic and a rapid fall is more likely to produce symptoms.

Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care. It brings the test conveniently and immediately to the patient increasing the likelihood that the patient, physician, and care team will receive the results in minutes, enabling diagnosis of hyponatraemia as early as possible and allowing immediate clinical management decisions to be made. They can be used to measure haematocrit, determine haemoglobin and measure serum electrolytes.

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

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

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

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

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

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

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

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

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

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

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

i. Hydrostatic driving pressure of the distending fluid

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

do) and to maintain distending pressure below the mean arterial pressure (MAP).

It is estimated that approximately 40mmHg distending pressure is required to obtain clear vision. At pressures between 40mmHg and approximately 100mmHg (MAP), blood will continue to escape from disrupted capillaries until it is stopped by the tamponade. At this point, when continuous flow is used through the resectoscope, the blood within the cavity will be removed and a clear field of vision will be maintained. Dropping the pressure permits further bleeding. If the pressure is raised above the MAP, the pressure not only prevents the flow of blood out of disrupted vessels but actually forces the distension fluid medium in the reverse direction into the vessels.

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

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

Continuous-flow by gravity

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

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

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

Recommendation 6

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

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

and with continuous-flow gravity systems,

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

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

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

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

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

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

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

While these factors can make volumetric fluid balance measurement an unreliable tool, it is considered a minimum necessity when using fluid filled bag systems that the whole theatre team are aware of the distending fluid

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

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

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

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

Documentation

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

This should be done as a minimum every time a bag (often 3 litre) is hung up and the details clearly expressed verbally to the surgeon and all other theatre staff. These details should be recorded on the dedicated fluid management chart. They might also be displayed on a white marker board in the theatre.

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

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

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

Maximum fluid deficit

Prevention of the TUR syndrome requires that the team have a protocol for responding to any escalating fluid absorption and there must be agreed volume thresholds for action. These thresholds may necessarily vary depending on the,

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

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

The surgeon and anaesthetist must be informed by the nurse when there is a 1000mls glycine deficit. Surgery must be brought to a close unless continuation of surgery is absolutely necessary to control the haemorrhage. The nurse must ensure that the surgeon and anaesthetist acknowledge that they have received this information. This must be documented in the notes along with any action taken.

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

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

iii. The length of the surgical procedure.

Estimates of the amount of fluid absorbed range from 10 – 30 mls per minute of resection time; over a 45 – 60 minute case that could equate to 1 – 1.8 litres.

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

Recommendation 11
Operations should, if possible, not last longer than 60 minutes. Theatre teams **must** have an established mechanism for measuring time and procedures for alerting surgeon and anaesthetist.

4.2.5 Theatre environment

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

- Theatre staff must always be aware of the potential hazards of, and equipment used, for any surgical procedure before it is performed.
- One core member of the theatre team must be assigned to the duty of gathering together the information needed to ensure the whole theatre team are aware of the distending fluid input & output and the deficit. They will need to be proficient and practiced in this technique and must not have other duties to perform while monitoring fluid balance. It would not be expected that the surgeon should have to operate and also supervise this function at the same time. They should remain in theatre for the duration of the procedure, in the same fashion as the surgeon.
- Medical staff must always have situational knowledge of the theatre environment that they are working in and the availability (or non-availability) of any theatre equipment they consider necessary. They must be informed, in good time, of any equipment that is not working.
- Nursing staff should have a working knowledge of any equipment being used in their theatre or have the immediate presence of technical staff who do have that knowledge.

4.2.6 WHO checklist

Completion of the WHO surgical checklist with the sign in, time out and sign out must be adhered to. This will allow a surgical, anaesthetic and theatre team brief at the beginning for the whole theatre team and an opportunity to check that everything is in place to perform the biochemical and volumetric monitoring, to agree fluid absorption volume limits and should include any discussion of limiting intravenous fluids intraoperatively.

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

Recommendation 12
Completion of the standard WHO surgical checklist **must** be adhered to. Adoption of a modified WHO checklist for this kind of procedure should be investigated and piloted.

5.0 IMPLEMENTATION OF POLICY

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

5.1 Resources

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

6.0 MONITORING

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

7.0 EVIDENCE BASE / REFERENCES

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8.0 CONSULTATION PROCESS

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

9.0 APPENDICES / ATTACHMENTS

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

10.0 EQUALITY STATEMENT

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

Major impact ☐

Minor impact ☐

No impact. ☐

SIGNATORIES

_____ **Date:** _____

Author

_____ **Date:** _____

Author

_____ **Date:** _____

Director

Insert Trust LOGO

Peri-operative fluid recording chart

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

Addressograph Label

Fluid recorder: _____ Operation: _____

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

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

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

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

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

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

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

Insert Trust LOGO

Continued.

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

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

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

Public Health Agency

Public Health Agency
12-22 Linenhall Street
Belfast
BT2 8BS

Tel 0300 555 0114
Fax : 02890 553682
www.publichealth.hscni.net

HSC Trust Medical Directors:-
Belfast Health and Social Care Trust
South Eastern Health and Social Care Trust
Southern Health and Social Care Trust
Northern Health and Social Care Trust
Western Health and Social Care Trust

17th September 2015

Dear Colleagues

Re: Progress on HSS(MD) 14/2015
Policy on the Surgical Management of Endoscopic Tissue Reaction

The DHSSPS wrote to your Trust (letter attached for ease of reference) requiring that :-

- The Trust should endorse the policy
- The Trust should develop action plans to implement the policy

I would ask that you provide an update on progress within your Trust by 31st October 2015.

This will facilitate progressing any issues which require input from HSCB/PHA and to enable the PHA to report to the DHSSPS by 30th November 2015.

Yours sincerely

Dr Janet Little

Assistant Director of Service Development & Screening

CC Lynn Charlton, Margaret McNally

Improving Your Health and Wellbeing

Stinson, Emma M

From: Haynes, Mark <[redacted]>
Sent: 07 March 2017 10:28
To: England, Susan; Young, Michael; Glackin, Anthony; ODonoghue, JohnP
Cc: Johnston, Pamela
Subject: RE: Demo Bipolar Sets

Thanks Susan

My view is that we shouldn't take up this offer.

We need to move to bipolar resection. We also need to move to the kit that came out top through the tender process (not an inferior piece of kit that didn't come out top but has been reduced in the sales). Buying different pieces of kit will continue our current situation with multiple pieces of equipment from different suppliers which are not compatible with each other.

Does anyone have any idea why has no money been found for an equipment change that has been mandated through a regional review of a SUI?

Mark

From: England, Susan
Sent: 07 March 2017 09:53
To: Haynes, Mark; Young, Michael; Glackin, Anthony; ODonoghue, JohnP
Cc: Johnston, Pamela
Subject: RE: Demo Bipolar Sets

Hi Mark,

That`s correct but there has been no funding to date.

Just wanted to run the offer past you as we are short on trays and would be in dire straights without the on loan sets,

Thanks,

Susan

From: Haynes, Mark
Sent: 07 March 2017 09:47
To: England, Susan; Young, Michael; Glackin, Anthony; ODonoghue, JohnP
Cc: Johnston, Pamela
Subject: RE: Demo Bipolar Sets

I thought we had been through a formal process for the purchase of the bipolar kit and a decision had been made to purchase (and the final decision wasn't Tontarra)?

From: England, Susan
Sent: 07 March 2017 09:45
To: Young, Michael; Glackin, Anthony; Haynes, Mark; ODonoghue, JohnP
Cc: Johnston, Pamela
Subject: FW: Demo Bipolar Sets

Dear all,

David Haslett has allowed us to borrow 2 Tontarra Bi polar Resectocope sets while we have several of our Monopolar working elements out for repair/replacement.

The on loan sets have only been used by ourselves during the trial last year and he has sent an email below offering a discounted price if we would like to buy them.

What do you think?

Thanks,

Susan

From: David Haslett [Personal Information redacted by the USI]
Sent: 06 March 2017 14:30
To: England, Susan
Subject: Demo Bipolar Sets

Dear Susan,

Please find attached quotation for 2 x demo sets (already in use in Craigavon), as discussed. These were supplied new to you in January 16, and have not been used elsewhere. I have discounted these to £5000 for both sets.

Many thanks.

Kind Regards
David Haslett

Mob: [Personal Information redacted by the USI]
Email: [Personal Information redacted by the USI]

Operating Room Systems Ltd
Unit B2
22 Heron Road
Belfast
N. Ireland
BT3 9LE
TEL: +44 28 9073 9198
FAX: +44 28 9046 9859
WEB: www.operatingroomsystems.com

Stinson, Emma M

From: Young, Michael [redacted]
Sent: 07 March 2017 21:34
To: Carroll, Ronan; England, Susan; Haynes, Mark; Johnston, Pamela; Murray, Helena
Cc: Corrigan, Martina
Subject: RE: Bipolar resection kit

Ok All
Just coming in on this at end of day and on-call – not full team included, but most of top level having had full discussion.
Several points.
1/ this issue has been concluded with the Storz quote being agreed by the CAH urology review, after due care and consideration of all factors.
2/ ANother company, not meeting the agreement, has tried an underhand approach
3/ this review of the care of patients requiring resection of urological tissue has been carefully reviewed by the CAH team and has gone beyond the use of saline /glycine. Ie not just the switch between the choice of irrigation fluid. We have considered the complete package.
4/ before progressing I had suggested a review of our current equipment.
5/ frankly it appears our current equipment is out-dated and last reviewed more than a decade ago.
6/ I would suggest a fresh start in view of the planned change to the approach on how we deal with this clinical entity
7/ TUR resection, laser prostate surgery and urolift are all going to be introduced – correct tools for each
8/ I have had this discussion with Sister England over the past free months and although a review of current equipment was trying to define the current stock quality, we agreed that this was not productive.
9/ My personal view on this is that the DoH have had a dictate on this issue. We have given due care and attention and come to a conclusion to conform. Our analysis is that X number of scope systems are required and if they wish use to provide the service then X number need purchased.
10/ Sister England and I feel, after due consideration and experience in this arena, that 10 resectoscope sets are needs to provide this service for saline TURP. Other equipment governing fluid management in general should be regarded as equally important and will be included in the quote for providing the service.

This conversation should involve the Leads within the departments involved, THUGS, hospital management and DoH. I do believe that if the DoH have an issue then they should contribute to the bill.

I agree that our time of assessment has concluded.
A date for a switch to the principle of using saline should be made (exceptions accepted).
This date needs to be defined.
Trust and DoH needs to accept.
If delayed, then such procedures suspended.

MY

This email has not been circulated beyond initial list, other than including our Urology Administrative Lead.

From: Carroll, Ronan
Sent: 07 March 2017 20:28
To: England, Susan; Haynes, Mark; Johnston, Pamela; Murray, Helena; Young, Michael
Subject: RE: Bipolar resection kit

Bargain!!

Ronan Carroll
Assistant Director Acute Services
ATICs/Surgery & Elective Care

Personal Information redacted by the USI

From: England, Susan
Sent: 07 March 2017 18:05
To: Carroll, Ronan; Haynes, Mark; Johnston, Pamela; Murray, Helena; Young, Michael
Subject: RE: Bipolar resection kit

Dear Ronan,

The quotes we received are from last year.

We require 10 Bi polar sets which were quoted at £96,000 and 2 pumps which cost £21,000, Total £117,000.

Thanks,

Susan

From: Carroll, Ronan
Sent: 07 March 2017 17:37
To: Haynes, Mark; England, Susan; Johnston, Pamela; Murray, Helena; Young, Michael
Subject: RE: Bipolar resection kit

Mark
Tks – Susan can you determine what is required interms of scopes etc & the price pls
Ronan

Ronan Carroll
Assistant Director Acute Services
Anaesthetics & Surgery
Personal Information redacted by the USI

From: Haynes, Mark
Sent: 07 March 2017 15:55
To: Carroll, Ronan; England, Susan; Johnston, Pamela; Murray, Helena; Young, Michael
Subject: Bipolar resection kit

Afternoon

Just following up on the discussions I have had with some of you today. You will all be aware of the review of endoscopic resection in Northern Ireland with respect to the use of Glycine and risk of TUR syndrome associated with this (which followed the death of a patient as a result of TUR syndrome following a TCER in glycine). As you will recall the review recommended switching to Bipolar resection in saline from existing practice of monopolar resection in glycine.

In order to do this we trailed bipolar resection instruments from a number of companies and following these trials identified the preferred equipment according to the trial criteria.

Unfortunately we appear to be stalled in terms of progressing this. In order to comply with the review recommendations a significant equipment purchase is required. To add to this the equipment we currently have is old and regularly in need of repair meaning that we are spending money repairing monopolar resection kit which we should have replaced with the new kit.

Can we look into progressing this as a matter of urgency. Until we have obtained the necessary equipment I suggest we will need to identify our non-compliance with the recommendations of the review on the trust risk register as each of us Urologists, and the Trust, will be open to criticism if we have a significant TUR syndrome while we continue to offer only monopolar resection in Glycine.

Mark

Stinson, Emma M

From: Corrigan, Martina [redacted]
Sent: 17 November 2017 06:43
To: Haynes, Mark
Subject: RE: urgent - update from CAG meeting this morning..

I know and in fairness Ronan did put all three forward as being priority one but it appears to have been graded by someone else as a 2!!

Regards

Martina

From: Haynes, Mark
Sent: 17 November 2017 06:40
To: Corrigan, Martina
Subject: RE: urgent - update from CAG meeting this morning..

How was it ever priority 2? I was clear when we discussed that 3 items needed to be 1 – spare stack for theatre, Orthpaedic sets and the bipolar resectoscopes?

From: Corrigan, Martina
Sent: 17 November 2017 06:36
To: Haynes, Mark
Subject: FW: urgent - update from CAG meeting this morning..

Morning

Email trail showing that the bi polar were not being considered – will send the S&G through when I find it in my archives

Regards

Martina

From: Carroll, Ronan
Sent: 16 November 2017 13:57
To: Conway, Barry
Cc: Murray, Helena; Corrigan, Martina; Gishkori, Esther
Subject: FW: urgent - update from CAG meeting this morning..

Barry
The Blue light camera stack & this are together. So need to oder both or something else. The consequence is that all TURPS will cease in Jan

5	10 Bi polar sets which were quoted at £96,000 and 2 pumps which cost £21,000 Priority 2

Ronan Carroll
Assistant Director Acute Services
ATICs/SEC
[redacted]

From: Conway, Barry
Sent: 14 November 2017 11:01
To: Carroll, Ronan
Subject: RE: urgent - update from CAG meeting this morning..

Ronan,

No. the only thing approved at this stage is the blue light camera stack. That's why I was raising the alert. Nothing else approved.

Barry.

From: Carroll, Ronan
Sent: 14 November 2017 11:00
To: Conway, Barry
Subject: RE: urgent - update from CAG meeting this morning..

Can I move on the top 3

Ronan Carroll
Assistant Director Acute Services
ATICs/SEC
Personal Information redacted by the USI

From: Conway, Barry
Sent: 14 November 2017 10:54
To: Gishkori, Esther; Carroll, Ronan; McVey, Anne; Trouton, Heather; Boyce, Tracey; Carroll, Anita; Walker, Helen
Cc: Stinson, Emma M
Subject: urgent - update from CAG meeting this morning..

Dear all,

I attended Capital Allocations Group this morning.

The Trusts have just received an additional 806k for general capital (to be spread across medical equipment, estates, ICT and Transport).

To date approx. 200k has been allocated from the 806K across all areas – this morning it has been confirmed that the blue light camera stack for CAH theatres has been approved (80k).

Apparently this 806k for general capital is the last allocation for this year.

I have expressed significant concern on behalf of acute RE pending medical equipment requests which is currently in the system (£2.1 m). Our prioritised list of 10 items across acute divisions (600k) was deemed to be the minimum that we needed for this year. We already know we need to replace the defibs across the Trust next year (approx. 450k) and replace the renal stations (approx. 650k). This morning we have been told that some laundry machinery which may need to be replaced next year will also have to go on the medical equipment list.

I have asked that our concerns are logged in the minutes from today's meeting and advised that I would brief Esther as well. At this stage I think we need to escalate the situation to SMT for further discussion RE best way forward as its clear the funding being allocated is insufficient to meet existing demand, and this will be further impacted next year.

Barry.

Mr Barry Conway

Assistant Director – Acute Services
Strategy, Reform and Service Improvement
Southern Health and Social Care Trust
Mobile: Personal Information redacted by the USI
Email: Personal Information redacted by the USI