From the Deputy Chief Medical Officer
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HSS(MD)14 /2015

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For Action:

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

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

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	SAMPLE POLICY	**Reference No:**

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

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

Recommendations

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

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

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

    and with continuous-flow gravity systems,

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

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

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

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

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

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

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

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

1.2 Irrigation fluids used

The irrigation fluid used for these electrosurgical procedures should,

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

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

Recently introduced **bipolar resection equipment** is different to the monopolar type in that it incorporates both active and return poles on the same electrode. This allows a conductive fluid medium (normal saline) to be used for the irrigating fluid instead of a ‘conventional’ nonconductive irrigation fluid (glycine, sorbitol or mannitol).

Irrigating fluids

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

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

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

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

1.3 TUR syndrome[4]

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

It is manifested mainly through a classic triad of,

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

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

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

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

1.4 Purpose

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

1.5 Objectives

To reduce the likelihood of developing the TUR syndrome through,

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

2.0 SCOPE OF THE POLICY

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

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

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

3.0 ROLES/RESPONSIBILITIES

Medical staff to,

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

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

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

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

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

4.0 POLICY PRINCIPLES

4.1 Definitions

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

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

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

Hyponatraemia: Lower sodium concentration than normally found in plasma.

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

4.2 Policy Principles

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

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

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

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

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

4.2.1 Preoperative workup

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

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

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

Urology

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

Gynaecology

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

4.2.2 Selection of surgical technique

Urology

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

One of the most important recent improvements in this field has been the introduction of bipolar electrode technology (B-TURP). This addresses the fundamental flaw of monopolar equipment (M-TURP) by allowing resection in a normal saline irrigation. Therefore, the adoption of bipolar TURP/TURBT allows NS irrigation and permits the removal of glycine and its inherent risks from theatre. The risks of the hyponatraemic and hypo-osmolar aspects of the TUR syndrome are eliminated.

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

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

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

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

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

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

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

They also indicate that,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4.2.3 Identification, control and management of haemorrhage.

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

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

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

Recommendation 4
Increase vigilance when significant haemorrhage is a feature.

4.2.4 Control of the absorption of irrigation fluid

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

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

a. Hyponatraemia

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

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

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

Serum Sodium measurement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

<u>Continuous-flow by gravity</u>

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.

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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.	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