The Independent
MEDICINES & MEDICAL DEVICES
Safety Review

The Independent Medicines and Medical Devices Safety Review

Written Evidence

Professional and Trade Bodies

Published December 2018

Updated January 2019

Contents

WARNING: Please be aware some evidence contains descriptions, pictures and audio of the harm suffered by individuals. Some may find this distressing.

Association of British Neurologists

COI:

None provided

Submission

1. What guidance does the Association provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (or non-intervention)? Please supply copies of relevant guidance, with the dates during which each version was in circulation.

The Association of British Neurologists (ABN) is the professional body of clinical neurologists in the UK. The aim of the Association of British Neurologists is to promote excellent standards of care and champion high-quality education and world-class research in neurology. As such, ABN members have been instrumental in much of the research on the risks of Valproate in pregnancy, disseminating the results in our meetings as well as advising more recently following the recent MHRA statements. Indeed our former President (David Chadwick) was publishing about this topic in 1989 (BMJ. 1989 Nov 4; 299(6708): 1163–1164) and other members, such as Jim Morrow, set up and published registers on epilepsy and pregnancy. This continues and includes our most recent guidance based on the MHRA statements which we have helped in the drafting of (attached as appendix). The MHRA were also invited to address our annual meeting in Birmingham earlier this year.

We are generating additional interpretative guidance that will be a joint effort (with at least RCGP – hopefully also with RCPsych, SRH, ESNA, RCPCH). This guidance is not ready yet, but illustrates the multifaceted aspects that the ABN is working on- largely (but not exclusively) via the ABN Advisory Group for epilepsy.

The ABN is not, however, a medical regulator (the General Medical Council (GMC) is), but we would expect all neurologists, as for any doctor, to follow the guidance on informed consent given by the GMC.

2. How can communication of specific risks to patient groups be improved?

The ABN continues to support ABN members with guidance on the MHRA regulations as outlined in the answer to question 1.

3. What advice do you provide to your members on contraceptive measures for girls on valproate entering puberty?

As neurologists, we do not generally advise our patients on contraception, this is something that would generally happen in primary care. However, neurologists would be expected to advise patients and their GPs on the risks of individual AEDs (anti-epileptic drugs) in pregnancy. We do also give advice on Interactions between AEDs and certain forms of contraception.

As adult neurologists, we generally see patients aged 16 and over so such patients will already have entered puberty- nonetheless the transition of patients with epilepsy from paediatric to adult care is an important time for ensuring appropriate advice has been given. It is important to realise that Valproate would not be a first line agent in a girl entering puberty precisely on account of these risks.

4. Assuming that patient awareness of the risks of valproate use during pregnancy is low, are you taking actions to ensure that your members are complying with the pregnancy prevention plan?

The ABN is not a regulator, but we can and do provide ongoing education on these issues - as outlined in the answer to question 1.

5. What is the prevalence of off-label use of valproate containing medicines for treatment of bipolar disorder, schizoaffective disorder, schizophrenia, migraine and others?

The ABN would not have access on the prevalence of off-label use- this would be only possible to find out from primary care datasets.

Valproate is not on the 'recommended' list of preventatives but is on the list of medication with evidence of efficacy but comes with the full MHRA warning. We include a copy of the draft guidance from BASH (British Association for the Study of Headache) as many of the ABN Advisory Group members on Headache are members of BASH.

6. How have lessons learnt from valproate medications been applied to testing and guidance for newer medications? What advice and actions are taken when prescribing potential teratogens to women of child-bearing age?

For the reasons given to answer 1, this is not really a question that the ABN can address, we continue to present research within our meetings for any new drugs through a rigorous process of peer review. The ABN is not a regulator, but we follow the advice of MHRA and spread guidance as and when new data becomes available.

We have however used data collected eg from the UK epilepsy and pregnancy register to assist in gathering the evidence re Valproate and other drugs.

7. How do we ensure that clinicians respond appropriately to patient concerns?

By following Good Medical Practice and keeping up to date with the field.

8. What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?

Clearly a national electronic prescribing system as is the case in some Scandinavian countries would address much of this, but this would be beyond the remit of this review.

MHRA are already proposing a registry of women of child-bearing age who are on VPA. They have also talked about such a registry for women in this setting who come off VPA. Not sure how this will all be done, there are to be further discussions. In terms of participation, this could be multi-level – when anyone prescribes or dispenses VPA, but would also need to capture specialist recommendations that might not involve prescription or dispensation.

Appendix 1

2018

Spring newsletter:

Valproate: We have known for some time that children born to women who take valproate during pregnancy are at significant risk of birth defects and persistent developmental disorders with a 10% risk of birth defects, an average reduction in IQ estimated at 6-11 points and up to 30-40% risk of developmental disability. The MHRA have just published changes in the licence for Valproate following on from new measures from the European Coordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh). Simply put, the use of valproate in women of child-bearing age will not be allowed unless a pregnancy prevention programme is in place. The ABN epilepsy advisory group, together with input from the ABN council, have looked at this in detail and written the attached editorial published this month in Practical Neurology to help neurologists understand the new rules. We have also updated the advice on the ABN website. We strongly urge all neurologists to familiarise themselves with the new measures and the MHRA will discuss this during a dedicated session in the upcoming Birmingham ABN.

Late June newsletter:

During this year's ABN in Birmingham, the MHRA presented the new regulations which require women of childbearing potential taking valproate to be in a pregnancy prevention programme. There has been much debate about these new regulations before, during and since the meeting but we need to all be aware that these regulations are now in place and need to be adhered to regardless of individual opinions. As neurologists we know that valproate is a serious teratogen but we appreciate that it is also an effective anti-epileptic drug, and for some women with epilepsy, valproate may be the only drug that controls seizures. Until there is an equally effective safer alternative for this group of women we need valproate to remain available. To continue to have valproate available in the future, it is essential we observe the new regulations now. Discussions about its use must be informed. MHRA and ABN have provided information and resources already (links to MHRA, and ABN statements plus a Practical Neurology editorial[1] by Sanjay Sisodiya and the Epilepsy Advisory Group) but we realise that further guidance to deal with this issue for individual patients is needed and the ABN through the epilepsy advisory group will be producing further interpretative guidance over the coming months. The ABN recognises the need for a safe alternative to valproate to be developed and the need to lobby for research to be funded to enable this.

2017

December newsletter:

MHRA's Drug Safety Update team - advice for neurologists.
The December issue of Drug Safety Update is online now

(link contained : Valproate medicines (Epilim▼, Depakote▼): Pregnancy Prevention Programme materials online)

September newsletter:

Use of Sodium Valproate in Epilepsy: Following recent discussions about the risks associated with the use of sodium valproate in pregnancy, we have been asked by the MHRA to remind neurologists that sodium valproate has a license for epilepsy and bipolar disorder only, and we should prescribe it for other reasons (migraine, pain, sensory symptoms) to young women only with great caution, and possibly using a formal pregnancy prevention programme.

Appendix 2

ABN Statement on Sodium Valproate taken in Pregnancy - Feb 2016

https://www.theabn.org/media/Documents/ABN%20publications/ABN%20statement%20on%20valproate%20Feb%202016.pdf

Appendix 3

ABN Statement on Sodium Valproate taken in Pregnancy - Feb 2016 (for general readership)

https://www.theabn.org/media/Documents/ABN%20publications/ABN%20Statement%20on%20Valproate%20for%20general%20read%20Feb%202016.pdf

Association of British Neurologists

Dr June Raine,
Director, Vigilance & Risk Management of Medicines
Medicines & Healthcare Products Regulatory Agency
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ

October 28th 2014

Dear Dr Raine

The Association of British Neurologists is, as the name suggests, the specialist society for neurologists in the UK. We are writing on behalf of our members and have collaborated with the neurologists in the UK Chapter of the International League Against Epilepsy in writing this letter.

We are writing in response to the MHRA press statement of 10th October 2014 following recommendation from the Pharmacovigilance Risk Assessment Committee of the EMA. The press release states:

"It is being recommended that valproate medicines should not be used to treat epilepsy and bipolar disorder in girls, women who can become pregnant or pregnant women unless other treatments are ineffective or not tolerated."

Whilst we welcome further consideration of the risks and benefits of prescribing valproate in women with neurological conditions, we are requesting that this advice is urgently reconsidered and changed with respect to epilepsy, and especially in relation to the idiopathic (genetic) generalized epilepsies (IGE), which affect about 25% of all people with epilepsy. Epilepsy is a serious condition especially when associated with convulsive seizures, often starting in childhood and adolescence, a vital stage in educational and social development, and for some the time when they are first seeking employment. Only a minority will be considering, or be at risk of, pregnancy in the short to medium term, hence our concern about the proposal to withhold an effective treatment. If followed, this advice from EMA/MHRA will expose a significant proportion of girls and women to a period of uncontrolled seizures and associated injury, risk of sudden death (0.5% per year for people with uncontrolled seizures), educational compromise, and social disadvantage.

We have good evidence from randomized controlled trials, valproate is significantly superior at controlling seizures in IGE than the alternatives lamotrigine and topiramate.[1,2] We have insufficient evidence about the effectiveness of levetiracetam in IGE to make a recommendation about its use as a first-line treatment. A recommendation that prevents use of valproate as a first line treatment will result in use of less effective treatments and delay in achieving seizure control.

The teratogenic effects of valproate have been known for some years, including the risks of major malformation and of reduced IQ and cognitive delay and autism. No substantive

primary data has emerged to supersede NICE and SIGN guidance highlighting that these risks should be taken into consideration when making a treatment decision.

Treating epilepsy is a balance of risk versus benefit, and there are not infrequent situations where the benefits of valproate outweigh the risks. Furthermore, current guidelines highlight the principles of informed decision making and the rights of the patient in doing so. If followed, the MHRA guidance would deny female patients that right.

In the UK the diagnosis of epilepsy is made, and treatment is started by neurologists and epilepsy specialists, not by general practitioners or other generalists. Neurologists and epilepsy teams in the UK should be well aware of the risks and benefits associated with sodium valproate, and have experience of discussing these issues with young women and their carers in order to make the most appropriate treatment decision for the individual. They also have considerable experience of counselling women who are considering getting pregnant who might want to change treatment if on valproate.

We would also highlight that the recommendation needs further clarification. What is meant by 'can become pregnant? One interpretation is that this is any premenopausal woman who has not been sterilized. Is this what was intended? Secondly 'unless other treatments are ineffective…' Which treatments did the EMA/MHRA have in mind? Exposing women with IGE to multiple less effective treatments will not be in their best interest.

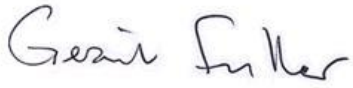
We would also highlight that it is extremely unfortunate that this press release was made without any warning to healthcare professionals via their professional organizations. We are sure that this could have been better communicated and after consultation with appropriate bodies.

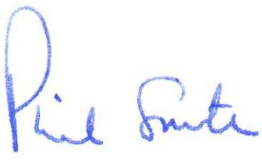
In summary we would wish to see the guidance changed as follows to include the facts that:

1. **For IGE, valproate remains a first line treatment choice**
2. **For other forms of epilepsy, valproate can be used when benefits outweigh risks.**
3. **At diagnosis, any treatment decision must involve a discussion of benefits and harms of treatment options including teratogenicity.**

We look forward to hearing from you.

Yours sincerely,





Geraint Fuller
President, ABN

Phil Smith
President Elect, ABN

1. Marson AG, Al-Kharusi AM, Alwaidh M, et al on behalf of the SANAD Study group. Valproate, lamotrigine or topiramate for generalized and unclassifiable epilepsy: results from the SANAD trial. Lancet 2007;369:1016-1026.

2. Maguire M, Marson AG, Ramaratnam S. Epilepsy (generalised). BMJ Clinical Evidence. 2012

Association of British Neurologists

Women of childbearing potential taking sodium valproate

On 8th February 2016 (World Epilepsy Day), the Medicines and Healthcare products Regulatory Agency (MHRA) launched a communications toolkit (in line with revised European standards) concerning the prescription of sodium valproate to females of childbearing potential (MHRA, 2016). This includes new labelling on boxes of sodium valproate and an additional information sheet for patients, pharmacists, general practitioners and specialists.

Sodium valproate is used mainly for prevention of epilepsy, but also sometimes for treating bipolar disorder and occasionally for migraine prevention. There is now strong evidence that sodium valproate is a potent teratogen, causing major malformations including spina bifida in up to 7% of pregnancies (Morrow et al., 2006), but even more alarming, causing neurodevelopmental delay in the exposed fetus (mean reduction in IQ of 9 points at aged 3 and 6 years) and an increased incidence of autistic spectrum disorder (Meador et al., 2013). Nevertheless, sodium valproate is a very effective antiepileptic medication, and is the proven best drug for controlling genetic (idiopathic) generalised epilepsies (Marson et al., 2007). It is therefore the first choice antiepileptic drug for young men with generalised epilepsies but, owing to the known teratogenic risks, it is used in women only as a last resort. Thus, young women with generalised epilepsies routinely receive second best treatments for their epilepsy. Inevitably, some women, with appropriate discussion and shared decision making, do opt to take sodium valproate for their epilepsy, knowing that they must avoid pregnancy whilst continuing to take this medication.

The new guidance from the MHRA aims to ensure that all women taking sodium valproate are fully informed—and are repeatedly reminded—of the teratogenic risks.

The Association of British Neurologists has represented the Royal College of Physicians at round table discussions on this, chaired by George Freeman MP, Minister for Life Sciences.

The major ongoing challenge is to ensure that, having issued an information sheet and improved the labelling of medication boxes, that women of childbearing potential who still take sodium valproate do actually become fully aware of the risks, if they are to avoid the preventable tragedy of neurodevelopmental damage to their unborn child.

Phil Smith
President, Association of British Neurologists

24 April 2016

Ormond House, 27 Boswell Street, London WC1N 3JZ
Tel: +44 (0)207 405 4060 Fax: +44 (0)207 405 4070 email: info@theabn.org www.abn.org.uk

Registered Charity No. 1077893 Company No. 3816842 Registered Office: Ormond House, 27 Boswell Street, London WC1N 3JZ

References:

MHRA report on sodium valproate, January 2016. **https://www.gov.uk/drug-safety-update/medicines-related-to-valproate-risk-of-abnormal-pregnancy-outcomes**

Marson AG, Al-Kharusi AM, Alwaidh M, Appleton R, Baker GA, Chadwick DW, Cramp C, Cockerell OC, Cooper P, Doughty J, Eaton B, Gamble C, Goulding RP, Howell SJL, Hughes A, Jackson M, Jacoby A, Kellett M, Lawson GR, Leach JP, Nicolaides P, Roberts R, Shackley P, Shen J, Smith DF, Smith PEM, Tudur-Smith C, Vanoli A, Williamson PR. The SANAD study of effectiveness of valproate, lamotrigine, or topiramate for generalised and unclassifiable epilepsy: an unblinded randomised controlled trial. *Lancet* 2007;369:1016–1026.

Meador KJ, Baker GA, Browning N, Cohen MJ, Bromley RL, Clayton-Smith J, Kalayjian LA, Kanner A, Liporace JD, Pennell PB, Privitera M, Loring DW; NEAD Study Group. *Lancet Neurol.* 2013 Mar;12(3):244-52. doi: 10.1016/S1474-4422(12)70323-X. Epub 2013 Jan 23.

Morrow et al. Epilepsy and Pregnancy Register pregnancy: a prospective study from the UK. Malformation risks of antiepileptic drugs in the UK Epilepsy and Pregnancy Register. *J. Neurol. Neurosurg. Psychiatry* 2006;77;193-198.

Association of British Neurologists

Dr. Sarah Mee MB.BS.BScHons
Senior Medical Assessor
Vigilance and Risk Management of Medicines Division(VRMM)
Medicines and Healthcare Products Regulatory Agency (MHRA)
3rd Floor
151 Buckingham Palace Road
London
SW1W 9SZ

9th December 2014

Guidance on the use of sodium valproate

Dear Dr Mee,

Senior members of the Association of British Neurologists drawn from the epilepsy section have looked at the documents forwarded in your email of 4th December. In addition to the comments provided on the attached revised document, the following points are relevant:

- The short deadline for the response is extremely unhelpful and inhibits proper consultation on a very important issue.
- Neurologists are highly experienced in discussing the risks and benefits of various antiepileptic agents. Our experts therefore question whether the use of such forms is appropriate and acceptable to the clinical community, particularly where **a one sided risk is portrayed for valproate, potentially to the detriment of women with epilepsy.** The material should therefore mention the risks of inadequately treated epilepsy.
- There is great concern amongst epilepsy experts that the current wording will be interpreted to mean there is an obligation on the prescriber to try the patient on an alternative medication before valproate, even when it may be the best drug for the individual. **The substitution of patient centred clinical decision making with a rigid prescribing pathway has the potential to lead to significant morbidity and mortality for some women for whom valproate may be the only drug that works**.
- The evidence that valproate is solely responsible for developmental delay remains incomplete and our experts feel that it is presented too strongly as an argument in favour of using alternative agents before valproate.

We trust that these observations will be carefully considered by the Commission on Human Medicines at the meeting on 11th December.
Yours sincerely,

Kevin Talbot
Honorary Secretary

Ormond House, 27 Boswell Street, London WC1N 3JZ
Tel: +44 (0)207 405 4060 Fax: +44 (0)207 405 4070 email: info@theabn.org www.abn.org.uk

Registered Charity No. 1077893 Company No. 3816842 Registered Office: Ormond House, 27 Boswell Street, London WC1N 3JZ

The Association of the British Pharmaceutical Industry
A company limited by guarantee registered in England & Wales number 09826787
Registered office: 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
t +44 (0)207 930 3477 getintouch@abpi.org.uk

Bringing medicines to *life*

Response to Call for Evidence – Medicines & Medical Devices

Introduction

The ABPI represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. We represent companies who supply more than 80 per cent of all branded medicines used by the NHS and who are researching and developing the majority of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome disease.

Globally our industry is researching and developing more than 7,000 new medicines.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.

The Prescription Medicines Code of Practice Authority is a division of the ABPI, with responsibility for operating the Code of Practice, independently from the ABPI. For more information about the PMCPA, please see our response to Question 4 below.

The Office of Health Economics is a subsidiary of the ABPI and provides economic and statistical analyses of critical issues in healthcare. The OHE is supported by research grants and consultancy revenues from the ABPI, commercial clients as well as a number of charitable and other organisations.

The responses provided in response to the Call for Evidence are those of the ABPI and do not necessarily reflect the views of the ABPI's members. In responding to the questions addressed to the ABPI, the ABPI has not withheld any information.

Please see set out below our response to the questions addressed to the ABPI by the Safety Review.

1. **Question 1 -** Please could you provide a timeline outlining your understanding and recognition of risks of valproate containing medicines during pregnancy, and for hormonal pregnancy tests. This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.

   ABPI Response
   The ABPI does not have any information in response to this question.

2. **Question 2 -** With reference to hormonal pregnancy tests, please can you contextualise the relevance of the findings of the McGregor Committee and the PropList. Was the PropList regularly consulted by prescribing clinicians? Would the deletion of an indication usually have been publicised, if so, how? How did the reimbursement of pregnancy tests take place?

   ABPI Response
   The ABPI does not have any information in response to this question.

3. **Question 3 -** Please outline the ABPI position with respect to the Committee for the Safety of Drugs from 1964-1971

ABPI Response
The ABPI understands that the Committee for the Safety of Drugs (the "***Committee***") was established in 1963, that it became operational under the Chairmanship of Professor Sir Derrick Dunlop, in 1964 and that it had a number of functions, specifically:

1. Before a new drug is subjected to trials in patients, to review and assess the evidence on which the manufacturer has concluded that it is reasonably safe to embark on such trials;
2. Before a new drug is released for general use, to review and assess evidence concerning its safety in relation to the purpose for which it is to be used; and

3. To review and assess evidence about adverse effects of the drug in use.

The ABPI's Annual Reports from 1964-1971 refer to the work of the Committee and make reference to consultation with the ABPI with respect to matters falling within the remit of the Committee. We trust that the Review will have access to the historical records of meetings between the ABPI and the Committee, including the minutes of those meetings. The ABPI does not hold any such meeting minutes.

4. **Question 4**
How do you monitor regulatory compliance of your members? What are the outcomes of this monitoring, and what actions are taken, if any? Please make specific reference to:

a. How the PMCPA regulates free samples of prescription medicines;

b. Who holds the responsibility for compliance with changes made to prescription licensing and who is responsible for ensuring compliance with the new regulations?

ABPI Response
The ABPI's Code of Practice covers the promotion of medicines for prescribing to both health professionals and other relevant decision makers. It also includes requirements for interactions with health professionals. In addition it sets standards for the provision of information about prescription only medicines to the public and patients, including patient organisations.

The ABPI expects all companies to adhere to the highest standards of professional conduct, and its Code of Practice reflects and extends beyond UK law. As a self-regulating industry, the ABPI is reliant on members to ensure they are compliant with all clauses of the Code of Practice. It is a condition of membership of the ABPI that companies act in compliance with the Code in carrying out their day to day business activities. Companies that are not members of the ABPI may nevertheless become signatories to the Code and are therefore, also required to comply with the Code.

The Prescription Medicines Code of Practice Authority ("***PMCPA***"), was established by the ABPI in 1993 to operate the industry's Code of Practice independently of the ABPI itself. The PMCPA provides guidance on interpretation of the Code with respect to the activities, advertising and meetings of Code signatories. The PMCPA also operates the complaints procedure set out in the Code, adjudicating when a complaint about a company's materials or activities, is raised. In addition, companies must supply the names and qualifications of their signatories, who are required to certify all promotional material is compliant, to the PMCPA (see Clause 14, Certification).

Complaints about potential breaches may be brought to the PMCPA by anyone, individual or companies – including the PCMPA itself.

If a complaint is upheld, sanctions under the ABPI Code include –

- PMCPA audit of a company's culture and its procedures for complying with the Code.
- requiring promotional material be submitted to the PMCPA to arrange for pre-vetting for a specified period
- requiring the company to take steps to recover items from those to whom they have been distributed
- requiring the company to issue a corrective statement and details of the case are advertised in the medical, nursing and pharmaceutical press
- a public reprimand and details of the case are advertised in the medical, nursing and pharmaceutical press
- publication of detailed case reports
- in every case where a breach is ruled, use of relevant material/activity must cease forthwith
- suspension or expulsion from the ABPI.

Clause 17 of the ABPI Code of Practice relates to the provision of medicines and samples.

Pharmaceutical companies have the responsibility to ensure they are compliant with any changes made to prescription licensing or new regulations, and with any other legislation.

5. **Question 5-** Please outline the process for recommending off-label use of drugs (for example the use of valproate medications for bipolar disorder). How frequently does this occur'? Where does liability for adverse events lie, if a clinician is following NICE Guidelines for off-label use?

ABPI Response
The ABPI does not play any role in determining the appropriate use of specific medicines and does not issue any such recommendations.

It is the role of the MHRA (the Medicines and Healthcare Products Regulatory Agency), in line with the regulatory regime, to determine the circumstances in which off-label use of drugs may be appropriate.

Unlicensed or off-label use of medicines is an appropriate treatment choice for healthcare professionals in meeting the therapeutic needs of an individual patient, where no clinically appropriate licensed medicine is available for that indication. Not all diseases and conditions are currently served by a specific licenced medicine, and prescribers rightly have the flexibility to use treatment alternatives justified by the clinical and therapeutic need of the individual patient.

Off-label and unlicensed use of medicines presents a potentially greater risk to the patient, and therefore any decision to prescribe must carefully assess the risk-benefit for the patient to be treated. The medicine will not have gone through the same degree of regulatory review of the benefits and risks in that indication, nor, for unlicensed medicines, the supportive assessment of the quality, formulation and presentation of the medicine. The responsibility for this additional risk rests with the prescriber.

The decision to prescribe off-label or unlicensed medicines should never be taken on the grounds of cost alone. Preference for off-label or unlicensed use/supply for financial reasons

by healthcare bodies, puts patient safety at risk and undermines the continued robustness of the UK and European regulatory frameworks.

6. **Question 6 -** Assuming patient awareness of the risks of valproate use during pregnancy is low, are you taking actions to ensure that your members are complying with the pregnancy prevention plan? Please explain how the pregnancy prevention plan applies to private prescriptions.

   ABPI Response
   All pharmaceutical companies operating in the United Kingdom are subject to stringent regulatory and legal obligations. Any pharmaceutical company found to be in breach of either its marketing authorisation or any other requirement issued by the MHRA would be subject to sanction by the MHRA.

   The ABPI does not monitor its members with respect to regulatory compliance (other than in respect of the promotion of medicines, as outlined in respect to Question 4 above).

7. **Question 7**
   Do you have any evidence that prescribing behaviour changed, following the renewed guidance on valproate teratogenicity and release of the Valproate toolkit?

   ABPI Response
   The ABPI does not have any information in response to this question.

8. **Question 8**
   Please provide details of valproate prescriptions and pregnancy related adverse event numbers from 1971 to date among your members (if known).

   ABPI Response
   The ABPI does not have any information in response to this question.

9. **Question 9**
   How does the Association ensure that professional achieve, retain and update skills relevant to the medicines available on the market?

   ABPI Response
   With regard to the pharmaceutical industry, Clause 15 of the ABPI Code sets out the standards and behaviour expected of representatives of pharmaceutical companies.

   The ABPI Code also stipulates that medical representatives must take an appropriate examination, at Diploma level, within their first year of employment and pass it within two years; general sales representatives must also take an appropriate examination, in the same time frame, at Certificate level. Details of both qualifications are set out in Clause 16.

   To support professional education, companies may organise scientific meetings and conferences which are attended by health professionals and other relevant decision makers, as long as the benefit provided does not comprise an inducement to prescribe, supply, administer, recommend, buy or sell any medicine (Clause 18). Companies can provide medical and educational goods and services, as long as they are in the interests of patients or benefit the NHS whilst maintaining patient care (Clause 19).

10. **Question 10**
Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are any changes in the types and levels of concerns expressed by patients in relation to particular procedures either in the NHS or private practice?

ABPI Response
Anyone may raise a complaint about the promotion of medicines activities by pharmaceutical companies, the requirements for interactions with health professionals and the provision of information about prescription only medicines to the public and patients, including patient organisations. The complaints can be made about either a member of the ABPI, or a non-member company which has agreed to comply with the Code and accepts the jurisdiction of the PMCPA. These should be submitted to the PMCPA.

The complaints-handling process is set out in the Constitution and Procedure of the PMCPA. Complaints may be anonymous.

Once a complaint has been received, it will be reviewed by a case preparation manager, who will determine whether a case should go before the Code of Practice Panel of the PMCPA. The company concerned is then requested to provide a complete response to the complaint. Where required, the Code of Practice Appeal Board will also consider the complaint, and in exceptional cases, they may report companies to the ABPI Board.

All case reports, which are published on the PMCPA's website, can be searched to identify particular terms. However, if a complaint is anonymous, it will not be possible to say for certain whether or not it came from a patient. Therefore, the accuracy of systematic review of changes in the types and levels of concerns expressed by patients could not be guaranteed.

The ABPI, PMCPA and the MHRA have entered into a Memorandum of Understanding setting out the arrangements for the regulation of the promotion of medicines for prescribing and describes the relationship between self-regulation, effected by the PMCPA, and statutory regulation carried out by the MHRA.

11. **Question 11-** Of the total numbers of complaints received year on year what proportion relate to:
    a. Sodium valproate;
    b. Hormonal pregnancy tests; and
    c. Informed consent?

    How has this changed over time?

    ABPI Response
    The ABPI does not have any information in response to this question.

12. **Question 12 -** If you have had any adverse events concerning the use of hormone pregnancy tests or valprorate containing medicines during pregnancy reported directly to the Association, please provide an anonymised summary, including dates of receipt and indicate what actions were or are being taken in response to these reports.

    ABPI Response
    The ABPI has not received any adverse events reports concerning the matters described above.

13. **Question 13 -** Do you have any indication of use of Yellow Card reporting by your members? For example, have you previously undertaken surveys or encouraged its use and other reporting mechanisms.

ABPI Response
The Yellow Card Scheme is a scheme operated by the MHRA for the reporting of the following:

1. Side effects (Known as adverse events);
2. Medical device adverse incidents;
3. Defective medicines;
4. Counterfeit medicines;
5. Safety concerns for e-cigarettes or refills.

The Yellow Card Scheme is intended for used by healthcare professionals and individuals to report the matters listed above, to the MHRA.

The ABPI does not collect statistics relating the Yellow Card Scheme.

The ABPI has worked with the Royal Pharmaceutical Society ("***RPS***") to support their work in promoting the importance of pharmacovigilance reporting amongst their membership. This includes contributing to a number of Quick Reference Guides published on the website of the RPS.

In 2018, the ABPI worked with the RPS and the MHRA to develop an overview of the Yellow Card Scheme, currently published on the RPS website at this address: https://www.rpharms.com/resources/quick-reference-guides/yellow-card-scheme-advice-for-pharmacists

The ABPI does not collect statistics related to reporting using the Yellow Card Scheme.
The ABPI produces a number of publications that highlight the importance of adverse event reporting, including, *Guidance Notes for Patient Safety & Pharmacovigilance in Patient Support Programmes and Guidelines for Phase 1 Clinical Trials*. In 2018, the ABPI also contributed to *"Guidance Notes on Collecting Adverse Events, Product Complaints and Special Reporting Situations During Market Research,"* a publication by the British Healthcare Business Intelligence Association.

14. **Question 14 -** Where within the healthcare system does your responsibility for disseminating and responding to adverse event reporting as a professional body begin and end vis-a vis- the regulators and manufacturers.

ABPI Response
Pharmaceutical companies have responsibility for putting in place a pharmacovigilance system for the reporting and monitoring of adverse events.

The ABPI does not itself play any role in the reporting or dissemination of adverse event information. In its role as a trade industry body, the ABPI promotes and advocates the importance of adverse event reporting in order to improve patient safety.

15. **Question 15 -** Please can you provide the Review with a summary of how adverse events data, changes in a medicine's status, regulatory interventions (such as the valproate toolkit) have been and are communicated to members.

    ABPI Response
    The ABPI does not communicate this information to its members. This information would be communicated to pharmaceutical companies by the relevant regulatory authority.

16. **Question 16 -** What factors Influence the decision on when to update guidance, and how are adverse events reports weighted in this process given the known level of underreporting?

    ABPI Response
    The ABPI periodically reviews the guidance that it publishes to determine whether the guidance is still applicable or needs updating in the light of new regulations. The ABPI does not provide any guidance on the use of any medicines.

17. **Question 17-**How do you feel the culture of reporting concerns and adverse event by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What, if anything, could be done to improve this?

    ABPI Response
    As indicated in response to other questions, in recent publications, the ABPI has encouraged adverse event reporting when appropriate.

18. **Question 18-** How can we ensure patient outcome reports on treatment interventions reflect subjective patient experiences as well as clinical outcomes?

    ABPI Response
    The ABPI does not have any information in response to this question.

19. **Question 19-** In your view what are the priorities for future research related to the interventions and issues raised by the Review?

    ABPI Response
    The ABPI does not have any information in response to this question.

20. **Question 20-** What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?

    ABPI Response
    The ABPI does not have any information in response to this question.

21. **Question 21-** Part of the Review's remit is to consider wider systems of redress, and we would appreciate any input on redress mechanisms, including the role of insurance.

    ABPI Response
    The ABPI does not have any information in response to this question.

Association of Coloproctology of Great Britain and Ireland – Pelvic Floor Society

COI - Please detail any commercial, financial or legal connection or interest in the pharmaceutical and medical devices industry sector (including subsidiaries) or any other body or organisation of interest to the Review.

The ACPGBI is funded via membership subscription although has heavy industry support for the annual meeting including the major mesh manufacturers, namely Covidien (Medtronic) Cook Ethicon

The PFS is solely funded by industry, all the supporters are declared on our website These also include the mesh manufacturers as above.

In addition some members of the PFS exec conduct both paid and non paid consultancy work for the following

Mr Williams - Cook and Covidien (Medtronic) Mr Mercer Jones - Covidien (Medtronic)

The database and running of the PFS are entirely independent of any industry. Whilst the society is funded by industry, the utilisation of ALL funding is solely at the discretion of the exec committee. At no point has any industry party had involvemnent with the creation, running or data held within the database.

When analysed the data within the database will be available in the public forum, and as such the industry partners will have access to the anonymised data results.

Submission

The Call for Evidence for the Independent Medicines and Medical Devices Safety Review • Synthetic mesh for use in abdominal and vaginal pelvic mesh procedures

Dear review team,

I can provide the response on behalf of the Pelvic Floor Society (Which is a subsection of the Association of Coloproctology of GB and Ireland)

As a Society we have given the issues regarding the safety of the use of mesh in pelvic floor surgery a great deal of thought. This has led to the development of a patient information sheets, enhanced consent forms and a published position statement regarding the use of mesh in the rectal prolapse and constipation surgery. These documents have benefitted greatly from the timely systematic review of all of the published evidence concerning the efficacy of surgery for constipation.

It has also led to the development of an accreditation process for pelvic floor units throughout the UK. The first two units have now achieved accreditation.

We have also previously released the results of a census detailing the use of surgery for pelvic floor disorders (including prolapse and intra rectal intussusception)

All of this information is available on the pelvic floor society website:
www.thepelvicfloorsociety.co.uk

The following key articles are highlighted:

1. Systematic review of the use of surgery for constipation - VMR

Grossi U, Knowles CH, Mason J, Lacy-Colson J, Brown SR; NIHR CapaCiTY working group; Pelvic floor Society. Surgery for constipation: systematic review and practice recommendations: Results II: Hitching procedures for the rectum (rectal suspension). Colorectal Dis. 2017 Sep;19 Suppl 3:37-48. doi: 10.1111/codi.13773. Review. PubMed PMID: 28960927.

http://onlinelibrary.wiley.com/doi/10.1111/codi.13773/full

2. Summary of 5 systematic reviews and consensus document on surgery for chronic constipation:

Knowles CH, Grossi U, Horrocks EJ, Pares D, Vollebregt PF, Chapman M, Brown S, Mercer-Jones M, Williams AB, Yiannakou Y, Hooper RJ, Stevens N, Mason J; NIHR CapaCiTY working group; Pelvic floor Society and; European Society of Coloproctology. Surgery for constipation: systematic review and practice recommendations: Graded practice and future research recommendations. Colorectal Dis. 2017 Sep;19 Suppl 3:101-113. doi: 10.1111/codi.13775. Review. PubMed PMID:28960922.

http://onlinelibrary.wiley.com/doi/10.1111/codi.13775/full

3. Position statement on LVMR from PFS.

Mercer-Jones MA, Brown SR, Knowles CH, Williams AB. Position Statement by The Pelvic Floor Society on behalf of The Association of Coloproctology of Great Britain and Ireland on the use of mesh in ventral mesh rectopexy (VMR). Colorectal Dis. 2017 Sep 19. doi: 10.1111/codi.13893. PubMed PMID: 28926174.

http://thepelvicfloorsociety.co.uk/budcms/includes/kcfinder/upload/files/Mercer-Jones_et_al-2017-Colorectal_Disease.pdf

4. The 2014 ACPGBI census report (linked through the PFS website)

http://thepelvicfloorsociety.co.uk/budcms/includes/kcfinder/upload/files/appendices.pdf

5. The future of pelvic floor services in the UK.

Hainsworth AJ, Schizas AM, Brown S, Williams AB. Colorectal Dis. 2016 Nov;18(11):1087-1093. doi: 10.1111/codi.13341.

6. Most recent published statement regarding the use of mesh in pelvic floor surgery

Can be found here: https://www.acpgbi.org.uk/news/use-of-synthetic-mesh-tape-to-treat-urinary-incontinence-sui-and-urogynaecological-prolapse/

Specifically, in answer to the following questions;

1. We recognise that the majority of patients will not have any follow-up actions providing their implanted device functions well. What is your current understanding of the efficacy and safety of the mesh devices which are currently being used, or which have previously been used, and what advice do you provide your members?

It is expected that all patients after ventral mesh rectopexy (VMR) will be followed up at least once 6 weeks or so post operatively. Many surgeons will follow up for longer (up to 2 years), most rely on primary care to highlight problems further out from the date of surgery. There are clear details of what to look out for regarding mesh related complications on the PFS website and we (I /) direct our patients to this.

2. Please could you provide a timeline outlining your understanding and recognition of risks of synthetic polymer mesh for use in pelvic surgery (abdominal and vaginal). This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.

In the majority of mesh related complications, it is clear that there is a problem within 6 months, although mesh erosions may still occur many years after surgery. Most erosions have become apparent by 48 months after surgery.

3. How do you decide on the content of any information you provide to patients when discussing the risks and benefits of different approaches to stress urinary incontinence and pelvic organ prolapse?

The information has been closely reviewed and standard information leaflets for patients have been developed in conjunction with patient liaison groups. These are available on the PFS website and all members of the PFS are encouraged to use them. The use of clear patient information leaflets and clear communication form one of the pillars of what we consider good clinical practice. As per the press release.

4. How does the Society ensure that professionals achieve, retain, and update skills relevant to the devices available on the market? To what extent are knowledge and skills maintained for non-mesh surgical approaches?

All CPD and training is a matter for an individual surgeon and his/her medical employer / Trust to ensure that practice is up to date and only performed with adequate training. This should be reviewed at the time of annual appraisal. The Society fully supports training and arranges suitable courses (the VMR course is in progress). We are in the process of structuring a modular training scheme, and have already established an animal model for VMR surgery. We anticipate creating a mentorship program for a clinical roll out.

We have also established a system of accreditation of units and their respective MDT set up to ensure that units meet acceptable standards including adequate volume and quality surgery. This is voluntary but accredited units will be publicly available through our website.

5. What advice do you currently give your members regarding management of urinary incontinence and pelvic organ prolapse?

This is encompassed in the Position statement.

6. In your view, what are the priorities for future research related to the interventions and issues raised by the Review?

It is clear from the systematic review on the surgical treatment of constipation that the evidence for surgery in this field is lacking. We had hoped that the PROSPER trial (PROSPER: a randomised comparison of surgical treatments for rectal prolapse.Senapati A, Gray RG, Middleton LJ, Harding J, Hills RK, Armitage NC, Buckley L, Northover JM; PROSPER Collaborative Group. Colorectal Dis. 2013 Jul;15(7):858-68. doi: 10.1111/codi.12177.) would answer some of these questions. This has not been the case.

The PFS (and ACPGBI) are committed to supporting any research that may forward our understanding for this difficult area. At the current time, a phase III randomised trial of LVMR is recruiting patients with high-grade internal prolapse (and chronic constipation). This NIHR-funded study is part of a PGfAR programme called CapaCiTY and the trial is called CapaCiTY III. The position statement made clear our belief that all patients undergoing such surgery should be considered for this study where feasible. Unfortunately, the usual delays in R&D departments are slowing the progress of new centres being able to do so. The study has currently recruited about 20 patients of the 114 required.

A further study of external rectal prolapse has passed the expression of interest stage with the NIHR HTA programme. Called, PROCEED, it is structured as a multicentre (possibly multinational) enhanced cohort study and will aim to recruit approximately 350 patients undergoing any major surgical procedure for external prolapse (including LVMR).

We hope that funders and the UK national research infrastructure will recognise the importance of delivering these two high quality studies.

We await to hear if a planned study to follow the results of surgery for rectal prolapse will be funded through the Department of Health (HTA). This study and the mandatory recruitment to the follow up from the study will be the only way that we will be able to answer these questions moving forward and we hope the government will support such a trial.

7. Please could you provide a timeline outlining your understanding and recognition of risks of valproate containing medicines during pregnancy, and for hormonal pregnancy tests. This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.

NA

8. If you have had any adverse events concerning the use of hormone pregnancy tests or valproate containing medicines during pregnancy reported directly to the Society please provide an anonymised summary, including dates of receipt, and indicate what actions were or are being taken in response to these reports.

NA

9. What guidance does the Society provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (or non-intervention)?

Please supply copies of relevant guidance, with the dates during which each version was in circulation.

We have developed a specific guidance for consent and an enhanced consent checklist for use when consenting a patient for surgery. This will soon be available on the website for general use.

10.Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are changes in the types and levels of concerns expressed by patients in relation to particular procedures either in the NHS or private practice?

It is not possible to measure patient concern, although there has been a reduction in the number of cases performed nationally since the increased public concern. This may reflect public reticence on having mesh implanted, or it may relate to clinician caution and reluctance to perform operations with potentially poor outcomes (however remote the possibility). The likelihood is that both are important factors.

11.Of the total numbers of complaints received year on year what proportion relate to:

a) abdominal/vaginally placed mesh procedures; and b) issues of informed consent?
How has this changed over time?

In UK surgical practice the majority of problems relate to vaginally placed mesh for urinary stress incontinence (USI) and prolapse. The systematic review of published data shows that 1 – 2 % of mesh rectopexy operations (VMRs) lead to mesh related problems, with half of these being an erosion.

Informed consent issues largely relate to an individual surgeon rather than a general trend as far as we are aware.

12.Please describe the Society's role with regard to:

1. a) adverse events reporting;
2. b) patient safety;
3. c) providing a forum for discussion; and
4. d) potential early warning signal detection?

The ACPGBI has no official role in adverse event reporting. The reporting of mesh related problems should be through the “yellow card “process with the MRHA and members are encouraged to do this. Furthermore, this has been reiterated in the recent guidelines and on the website and recent letter to all members.

The PFS provides clear, free information for patients and clinicians to use to advise on how to recognise a mesh related complication and what to do. It also acts as a platform to locate a specialist with the expertise to help resolve problems.

We have also collated a self-nominated list of centres who have the expertise in dealing with mesh complications.

13.Please can you provide a brief summary of how adverse events reported to you are collected, processed and investigated? How effective do you think this process is in capturing adverse events data? How do you think this could be improved?

See above

14.Do you have any indication of use of Yellow Card reporting by your members? For example, have you previously undertaken surveys, or encouraged its use and other reporting mechanisms?

Unsure on the uptake rate

15.Where within the healthcare system does your responsibility for disseminating and responding to adverse event reporting as a professional body begin and end vis-a vis the regulators and manufacturers?

The main problem that we face is that membership of the ACPGBI, and therefore the PFS, is voluntary. There is no stipulation that use of the registry / database and guidelines, information leaflets etc is mandatory. As a society we have developed all the tools that we feel are necessary to support members in their professional pelvic floor practice. The census conducted in 2014 however showed that a significant amount of pelvic floor surgery was being performed outside the support of an MDT process and not necessarily by pelvic floor specialists.

16.Please can you provide details of your relevant policies and protocols, if any, for ensuring that information relevant to patient safety, and learning from adverse events is disseminated amongst your members.

None exist, there is a reliance on local governance procedures. The PFS would welcome the mandatory use of the VMR registry.

17.What factors influence the decision on when to update guidance, and how are adverse events reports weighted in this process given the known level of underreporting?

Guidance is updated when new clinical evidence is apparent that reflects on present practice advice. We have increased and accelerated the development of guidance in response to public concerns to support clinicians and patients alike.

18.How can we ensure patient outcome reports on treatment interventions reflect subjective patient experiences as well as clinical outcomes?

Patent reported outcomes in the form of a validated quality of life assessment tool are encouraged within specialist pelvic floor units. The process of accreditation includes the use of these validated quality of life scores for all patients undergoing surgery. Any unit that is badged as accredited will be using such a system. Currently we can only include the use of these tools as one of the quality indicators for an acceptable pelvic floor service and accreditation is a voluntary process. If a mandatory registry were to be supported we could easily incorporate these recognised tools as part

of that registry. Such data will be captured in the CapaCiTY III and PROCEED studies by quantitative and qualitative methods.

19.How do we ensure that clinicians respond appropriately to patient concerns?

This can only be through the usual channels, through the responsible NHS trusts/ GMC

20.How do you feel the culture of reporting concerns and adverse events by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What, if anything, could be done to improve this?

If the reporting of the outcome of surgery for rectal prolapse was mandatory via a nationally run database (this would be achieved with the planned rectal prolapse surgery study (PROCEED)) then we would capture the data in a non-judgemental fashion. ALL results would be captured and so we would have a clear picture of the clinical utility and risks of each operation.

21.What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?

The only way to make a registry work is to have it hosted on the NHS secure site. The entry of data should be mandatory and NHS number linked. This will enable true tracking of cases and then all data on mesh related complications will be captured irrespective of where they present with complications (not necessarily their index hospital). Clearly having the identifiable data of the NHS number will cause GDPR data problems, but these must be overcome if this is to work.

Please let me know if you need clarification on any of these points

Kind regards

Andrew Williams

Chair Pelvic Floor Society

(On behalf of the ACPGBI)

British Association of Urological Surgeons (BAUS)

COI:

None provided

BAUS response to:
The Call for Evidence for the Independent Medicines and Medical Safety Review Reference number: XYSBBG

October 2018

The FNUU (Female, Neurourological and Urodynamic Urology) Section of the British Association of Urological Surgeons (BAUS). In older correspondence the section is referred to as the Section of Female & Reconstructive Urology (SFRU).

As urological surgeons we will only be responding to the review regarding 'Synthetic mesh' as Hormone Pregnancy Tests and sodium valproate do not fall within our remit. This committee represents urologists in the UK who undertake reconstructive urological procedures including managing stress incontinence for women. A small number of our membership undertake female prolapse surgery but as this number is small we will respond only in respect to the use of synthetic mesh for stress incontinence. It is noted that in September 2018 the government issued a ban on the use of synthetic mesh for stress incontinence, pending review this has of course been followed by our members. We have therefore written response as per prior to this ban.

1. **We recognise that the majority of patients will not have any follow-up actions providing their implanted device functions well. What is your current understanding of the efficacy and safety of the mesh devices which are currently being used, or which have previously been used, and what advice do you provide to your members?**

We support the present NICE recommendations for surgical approaches to stress urinary incontinence which are based on high level evidence. These were updated in 2015 and we advise our members to adhere to these. We await the pending NICE review (currently out for consultation) specifically in relation to synthetic mesh.

We advocate surgical approaches recommended by NICE and a follow up appointment within 6 months including vaginal examination. Refer to question 2 and the summary of published evidence at appendix 1 for more detailed information on our current understanding of the efficacy and safety of the mesh devices currently available.

BAUS strongly advocates patients be informed of all conservative and surgical options for stress incontinence with pros and cons discussed for all options. Enclosed in appendix 2 is a BAUS decision making tool to assist patients in making a choice on their surgical options in consultation with their surgeon. Also attached are the BAUS information sheets for the various surgical options. BAUS recommends centres offer surgery for stress incontinence only if they have either the expertise to offer all options or pathways in place for onward regional referrals as needed.

We also recommend that all surgeons undertaking these surgical procedures be active members of an appropriate MDT as specified by NICE and discuss cases as needed in this forum.

2. **Please could you provide a timeline outlining your understanding and recognition of risks of synthetic polymer mesh for use in pelvic surgery (abdominal and vaginal). This may include: initial recognition of the risk, dates of consequential**

and significant research and communication of regulatory and professional guidance to clinicians and patients.

There has been a number of very high profile publications with high levels of evidence published since 2015. Attached at appendix 1 is a summary of these and their conclusions. We feel these support the efficacy and safety of mesh procedures for stress incontinence although we appreciate that there is a small number of patients who have experienced serious side effects.

In terms of BAUS's understanding and recognition of risks, BAUS's initial concern related to the introduction of devices before an adequate body of clinical evidence for efficacy. A timeline and relevant correspondence is attached at appendix 3.

Information from the MHRA was circulated to members in 2013. Links to the MHRA information have been included in the BAUS patient information since 2012. There is currently a page on the patients' area of the BAUS website on vaginal mesh complications which includes links to relevant reports and information from the MHRA.
https://www.baus.org.uk/patients/sui_mesh_complications.aspx

3. How do you decide on the content of any information you provide to patients when discussing the risks and benefits of different approaches to stress urinary incontinence and pelvic organ prolapse?

For the reasons outlined above BAUS has not produced any patient information on POP. In terms of slings for SUI copies of previous BAUS information dating back to 2002/3 are attached at appendix 2.

BAUS have developed a suite of patient information leaflets which have been available on our website since 2012. BAUS leaflets follow a standard template determined by our surgical web editor. The clinical content is determined by the relevant section executive committee, that is an elected group of 8-10 surgeons with a sub-specialty interest, in this case in female urological surgery. The leaflets are regularly reviewed and updated and an oversight group ensure a consistent approach across all leaflets. As can be seen from the 2018 leaflets the recognised complications have not changed significantly but the way in which the information is presented has changed.

A selection of the leaflets were reviewed by the Plain English Campaign. Lessons learnt from this exercise were then applied across all leaflets as it was too costly for BAUS to have all the leaflets (160 plus) reviewed.

BAUS have produced a decision making tool for female stress urinary incontinence, a link to this together with links to the information leaflets for all stress incontinence procedures are at appendix 2. We thought it was important to develop an information sheet which compared all treatments as there are also serious risks and complications associated with other procedures such as autologous sling surgery and colposuspension. Those risks and complications may be less well documented, as compared to tape surgery, but can also be devastating for women.

4. How does the Association ensure that professionals achieve, retain and update skill relevant to the devices available on the market? To what extent are knowledge and skill maintained for non-mesh surgical approaches?

Knowledge attainment and skills maintenance is relevant to all surgical procedures, regardless of speciality, see RCSEngland document "Good Surgical Practice" (2014). It is not the remit of BAUS to regulate urologists or to ensure they stay up to date. BAUS provide resources to help urologists keep up to date in terms of CPD/CME but the responsibility for ensuring surgeons maintain competence rests with each consultant's responsible officer. This occurs via the appraisal and revalidation process for all doctors in keeping with GMC guidance.

In terms of acquisition of new skills, as stated in our 2004 document (included in appendix 3) "if a surgeon undertakes any new class of procedure for which he / she does not have appropriate training then he / she should seek formal training through a process of mentoring."

All urological surgeons have exposure to training in the assessment and management, including surgical management, of stress incontinence in women. However exposure to non mesh surgical options is limited and we identify this as being an issue going forward with the present situation. All members of BAUS performing stress incontinence procedures are expected to enter their data into the BAUS database. However BAUS has no authority to ensure this happens although where BAUS has identified hospitals not complying this has been drawn to the attention of the Medical Directors, generally with very little response.

5. What advice do you give your members regarding management of urinary incontinence and pelvic organ prolapse?

We recommend following the NICE guidelines, using the MDT setting for discussion of cases, as recommended by NICE, and submission of all data on stress incontinence surgery, both mesh and non mesh procedures, to the BAUS database.

6. In your view, what are the priorities for future research related to the interventions and issues raised by the Review?

Particularly in light of the NHS Digital Review 2018 BAUS feels some clarification regarding the decrease in surgery for stress incontinence and what impact this is having on women is much needed. We are concerned that the publicity surrounding mesh procedures has prevented women from seeking help for stress urinary incontinence.

Although the review has captured the surgical removal rate, which has in fact decreased from 10.2 (per 1000) to 7.3 it has not captured the other reported complications such as pain and mobility problems, sexual symptoms or chronic infections and does not capture details of non-mesh surgical procedures for stress urinary incontinence. For women to make an informed choice about undergoing a surgical procedure for stress incontinence and decide what procedure they should have these data are essential.

BAUS would also like to reference the important publication, published online September 2017, 'Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92246 women' Keltie K et al. Nature Scientific Reports 7: *12015* DOI:10.1038/s41598-017-11821-w. They quoted a periprocedural and 30 day complication

of 2.4% for TVT and 1.7% for TOT. The complication rate within 5 years was quoted at around 10% but unfortunately the types of complications have not been reported in detail.

With all of these data available BAUS feels they should be accessed and further interrogated to provide better detail and understanding of the complications recorded. This paper also quoted a 94% re-admission-free and re-operation-free rate following sub-urethral tape insertion for stress incontinence, which highlights the conflicting information currently available to patients and surgeons alike. There is an urgent need for these issues to be clarified as the incidence of surgery for stress incontinence has fallen so sharply and we can only conclude that women are choosing to put up with what is an embarrassing and disabling set of symptoms.

Whilst there appears to be a wealth of publications on midurethral mesh slings, strong evidence on long-term follow-up, complications and standardised approaches to the treatment of mesh complications is lacking. In suggesting this as a research priority, this might help with funding for longer-term follow-up of patients.

7. Please could you provide a timeline outlining your understanding and recognition of risks of valproate containing medicines during pregnancy, and for hormonal pregancy tests. This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.

N/A

8. If you have had any adverse events concerning the use of hormone pregnancy tests or valproate containing medicines during pregnancy reported directly to the Assocation please provide an anonymised summary, including dates of receipt, and indicate what actions were or are being taken in response to these reports.

N/A

9. What guidance does the Association provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (or non-intervention)? Please supply copies of relevant guidance, with the dates during which each version was in circulation.

BAUS itself has not published any guidance on informed consent, we defer to the GMC Guidance on Consent and the Royal College of Surgeons publications Good Surgical Practice (2014) and Consent: Supported Decision-Making (2016).

In 2002/3 BAUS produced a series of procedure specific consent forms which were put on a disk and distributed to members, these included a form on sling procedure for stress urinary incontinence. In addition to the procedure specific forms a copy of the GMC's 1998 guidance on consent and DOH guidance on consent were included. BAUS stopped providing the procedure specific consent forms and started publishing patient information leaflets in 2012.

In order to better support patients in making informed decisions in February 2018 BAUS published on its website a decision-making tool giving a comparison of treatment options for stress urinary incontinence in women. All BAUS leaflets include a publication date and review date.

10. Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are changes in the types and levels of concerns expressed by patients in relation to particular procedures either in the NHS or private practice?

BAUS is a membership organisation and a registered charity (charity no 1127044) whose charitable objective is to promote the highest standard in the practice of urology for the benefit of patients by fostering education, research and clinical excellence.

In practice, the Association promotes and arranges scientific meetings covering every aspect of the practice of urology. These include an Annual Scientific Meeting and various other meetings organised by the sub-specialty sections. The Association supports the education of urologists through activities co-ordinated through the Education Committee. The charity also produces patient information leaflets relating to urological conditions and operations and publishes unit outcomes for a number of surgical procedures. Both activities are intended to provide patients with accurate information about their condition and treatment options and outcomes.

BAUS is not a regulatory body, it does not have the infrastructure or authority to investigate patient complaints. If a patient were to contact BAUS wishing to make a complaint about their treatment or care they would be advised to pursue their complaint via the Trust where they were treated or via the regulator the GMC.

11. Of the total numbers of complaints received year on year what proportion relate to:
a) abdominal/ vaginally place mesh procedures; and
b) issues of informed consent?
How has this changed over time?

Please see answer above.

12. **Please describe the Association's role with regard to:**
a) Adverse events reporting

Any complication could be considered to be an adverse event but in this context we are interpreting an adverse event as being an unexpected adverse incident relating to a medical device. Such incidents or events should be reported to the MHRA and BAUS's role is to promote use of the MHRA reporting system. As shown in the correspondence attached at appendix 3 BAUS issued advice to members in February 2004, again in February 2006 and in 2012. Urological surgeons are advised to report all mesh complications to MHRA however BAUS is not aware of what occurs after this reporting has been done or if any action is taken.

If requested by MHRA BAUS will issue an MHRA alert notice to its members.

In response to reports in the media about patient concerns that they were not being listened to or able to access help when they felt they had problems with mesh inserted for stress incontinence and the NHS England Mesh Oversight Group report, BAUS invited members of the Section of FNUU to identify themselves as centres that had the expertise to evaluate these women and either be able to deal with all mesh issues or have pathways in place with regional centres to deal with the more complex adverse events such as urethral or bladder erosions. Each centre was asked to identify a gynaecologist, urologist, colorectal surgeon and pain management specialist who would be active members of their MDT and deal with the mesh issues with one clinician being named as lead. These centres have not been vetted or accredited. However BAUS is in the process of working with NHS England to both ensure the centres can offer what they say they can and for commissioning purposes.

b) Patient safety

BAUS exists to promote the highest standard in the practice of urology for the benefit of patients. As the correspondence at Appendix 3 shows BAUS was concerned that new devices were being marketed for stress urinary incontinence before there was an adequate body of clinical evidence of efficacy and highlighted that there may be consequent risks to patient safety. BAUS took those concerns to NICE and MHRA. BAUS tried to set up a registry but had limited resource to do this and no authority to enforce it.

In December 2012 the Government had outlined plans to publish surgeon-level outcomes data, taken from national clinical audits, in ten specialty areas which included urology. The Association used this leverage to relaunch an audit of surgery for female SUI and committed to publish surgeon level data on its website, this had the effect of significantly increasing the return rates. Surgeon level data is available at: https://www.baus.org.uk/patients/surgical_outcomes/sui/default.aspx and national reports are accessible at: https://www.baus.org.uk/professionals/baus_business/data_audit.aspx

BAUS remains concerned that new procedures continue to be introduced without adequate safeguards in terms of data collection and registration of devices. It is still the case that new procedures can be introduced to practice without a code, it takes several years to assign a code, so it is impossible to use HES data to monitor the uptake and outcome of new procedures.

c) Providing a forum for discussion

As mentioned above the Association promotes and arranges scientific meetings covering all aspects of urology. Attached at appendix 4 is a summary of the presentations at BAUS concerning SUI and mesh.

d) Potential early warning signal detection

Please see reply at point b above. As demonstrated BAUS is willing to engage with regulators, NICE, MHRA, NHSE in developing appropriate systems but does not have the authority or infrastructure to do this on its own.

13. Please can you provide a brief summary of how adverse events reported to you are collected, processed and investigated? How effective do you think this process is in capturing adverse events data? How do you think this could be improved?

We need to distinguish here between adverse events as defined in 12a above and complications. As described above BAUS does not have a role in collecting, processing or investigating adverse events. The BAUS audit does collect data on surgical complications and a paper for the last 3 years has just been published (Cashman S, Biers S, Greenwell T, Harding C, Morley R, Fowler S, ThiruchelvamN; BAUS Section of Female Neurological and Urodynamic Urology. Results of the British Association of Urological Surgeons Female stress urinary incontinence procedures outcomes audit 2014-2017. BJU Int. 2018 Sep 17. doi:10.1111/bju.14541. [Epub ahead of print])

However there are shortcomings:

1. BAUS has no mandate to ensure all urologists performing this procedure enter their data.
2. The database is self-reporting by surgeons who often get little or no support to do so
3. The database does not collect complications after 3 months and follow up data is very poorly completed.

BAUS would expect adverse events relating to a device, such as mesh complications to be reported to the MHRA. In the context of our audit there is no mechanism to report other longer term outcomes and complications (pain etc) outside the follow up period of 3 months. This is also the case for all surgical procedures regardless of speciality. As far as BAUS is aware there is no linkage or attempt to triangulate information collected by MHRA / HES/ BAUS & BSUG.

14. Do you have any indication of use of Yellow Card reporting by your members? For example have you previously undertaken surveys, or encouraged its use and other reporting mechanisms?

There is a link on the BAUS website and members are encouraged to use it, see 12a above, but BAUS does not police this or receive any feedback on it. Although MHRA emailed BAUS in April 2017 about a potential survey and we indicated our willingness to circulate information to our members they never actually came back to us with one.

15. Where within the healthcare system does your responsibility for disseminating and responding to adverse event reporting as a professional body begin and end vis-a-vis the regulators and manufacturers?

BAUS will disseminate information to members if requested to do so by one of the regulatory bodies and is willing to engage constructively with regulators and manufacturers but BAUS does not have the authority to direct these bodies to act as demonstrated by the correspondence at appendix 3.

16. Please can you provide details of your relevant policies and protocols if any, for ensuring that information relevant to patient safety, and learning from adverse events is disseminated amongst your members.

If a device alert was received from MHRA it would be disseminated to members. More generally notices about publications such as NICE Guidelines or the mesh reports, such as

those listed on our website, would be circulated to members. Hot topics and updates would also be routinely included in the meeting programmes and updates on our own audit, with any learning points from it, are regularly included in the annual meeting.

17. What factors influence the decision on when to update guidance and how are adverse events reports weighted in this process given the known level of underreporting.

There is no mechanism by which BAUS routinely receives adverse event reports.

In terms of the complications data which BAUS collects this is reviewed on an annual basis. When updating our patient information leaflets where data exists this would be used to inform the risks quoted, if information is not available from BAUS data then figures from the published literature would be used.

The principal clinical guidance document for female stress urinary incontinence is the NICE Guideline and NICE publish on their site their protocols for updates.

18. **How can we ensure patient outcome reports on treatment interventions reflect subjective patient experiences as well as clinical outcomes.**

Although the BAUS SUI database includes some patient reported measures (ICIQ-UI short form questionnaire which patients complete prior to surgery and at 3 months) completion rates are quite poor and responsibility for administering the PROM and entering the data rests with the surgeon which is not ideal. Ideally you need to properly resource a PROMS programme such as the NHS funded programme which is in place for hip and knee replacement.

19. How do we ensure that clinicians respond appropriately to patient concerns?

Ensure engagement with database and mesh centres. We would also advocate that further data collection tools are devised with patient concerns at the forefront to ensure these issues are being identified and that there are commissioned pathways for mesh centres.

In terms of learning lessons when new devices or techniques are introduced there should be national data collection and follow-up so that data can be aggregated and analysed in a timely manner. Make comparative data available to clinicians, this would make it easier to pick up any problems and take remedial action whether that is in terms of units and individuals or nationally.

20. How do you feel the culture of reporting concerns and adverse events by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What if anything could be done to improve this?

It is important to set this question in the context of changes that have taken place in the culture of the NHS and the relationship between healthcare professionals and patients.

The conduct of doctors is regulated by the GMC. All doctors are required to adhere to Good Medical Practice published by the GMC and are held to account via annual appraisal and 5 yearly revalidation across each of the domains - including safety and quality. However, the number of doctors being referred to the GMC and the costs of litigation in the NHS have been steadily increasing. These include a number of high profile court cases.

Clinicians, and particularly surgeons, are consequently being put under pressure with increasing patient expectations but diminishing resources on the ground including support from nurses and junior doctors. Doctors are reporting higher levels of burnout[1] and it is important to understand this and the impact it may have on the culture of open disclosure.

In the era of social media where all events are immediately available to be highlighted and judged by the general public without an understanding of often complex medical issues, there needs to be a robust framework that supports the accurate reporting of clinical data - including outcomes. Funding also needs to be provided to set up a robust framework to report on outcomes of new procedures so that any potential issues can be identified as early as possible.

The BAUS audit publications and the recently published GIRFT (Getting it Right First Time) report demonstrate that urologists are keen to engage in constructive scrutiny of their practise. BAUS would like to see greater use of HES data as a resource for monitoring care and outcomes and in terms of new procedures and implants:

1. Fully funded mandated registry
2. Automatic PROM at 12/12
3. No new procedure introduced without a code being in place to facilitate monitoring uptake using HES.
4. Coding for revision procedures for any new procedure is very important.

This would all require a more joined up approach between the relevant agencies including NHSE, NHS Digital, NICE Interventional Procedures Programme and the MHRA together with professional organisations such as BAUS.

21. What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?

1 a data base that is run independently (not necessarily by BAUS)
2 submission of data to be mandated by NHS England (this cannot be policed by BAUS)
3 support for data entry - ideally it should not be done by the operating surgeon
4 recognition for surgeons that work with high risk patients and complex situations that might skew their data

To encourage healthcare professionals to use a registry there needs to be good clinical engagement at all stages and it needs to generate timely, accurate feedback including appropriate risk adjustment.

Please explain the basis for the evidence you are submitting to the Review, how that evidence was selected, the extent to which any relevant material has been withheld and the reasons why.

The clinical evidence has been selected based on the level of evidence. BAUS has not knowingly withheld any relevant material.

1. Rates of self-reported "burnout" and causative factors amongst urologists in Ireland and the UK: a comparative cross-sectional study.
F O'Kelly, R P Manecksha, DM Quinlan, A Reid, A Joyce, K O'Flynn, M Speakman, J Thornhill
https://doi.org/10.1111/bju.13218

Appendix 1

BAUS Summary of Evidence for Synthetic mid urethral slings for the treatment of Stress Urinary Incontinence in Females September 2018

1 Cochrane 2015 mid urethral sling for stress urinary incontinence

Authors' conclusions

Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI. With the exception of groin pain, fewer adverse events occur with employment of a transobturator approach. When comparing transobturator techniques of a medial-to-lateral versus a lateral-to-medial insertion, there is no evidence to support the use of one approach over the other. However, a bottom-to-top route was more effective than top-to-bottom route for retropubic tapes.

2 Nature Review 2015

Safety consideration for synthetic sling surgery; Blaivas JG, Purohit S, Benedon MS et al, Nature Reviews Urology 12. 481-500 (2015)

Authors conclusions

- The effectiveness of synthetic mid urethral slings (SMUS) is comparable to the time honoured gold standards- the autologous fascial sling and Burch colposuspension
- At least 15% of women with SMUS experience serious adverse outcome and/or recurrent sphincteric incontinence
- A subset of women sustain refractory lifestyle altering complications that are unique to women with a SMUS
- SMUS associated complications are under-reported
- The overall quality of published evidence is currently low with respect to assessing SMUS safety and SMUS-associated complications

3 The Scottish Independent Review of the Use Safety and Efficacy of Transvaginal Mesh Implants for Stress Urinary Incontinence and Pelvic Organ Prolapse in women: interim report October 2015

Authors Conclusions

- No significant differences were found in the risk of adverse effects between retropubic and transobturator, mid-urethral mesh tape procedures.
- Mid-urethral mesh tape procedures were not found to be associated with greater risk of adverse outcomes than laparoscopic colposuspension, though long-term, data was not collected.

- Mid-urethral mesh tape procedures were associated with lower complication rates than traditional suburethral sling operations.
- The clinical importance of these adverse outcomes does differ: bladder perforation (more common in retropubic procedures) is of little or no clinical importance, whilst groin pain (more common for transobturator procedures) is of greater importance clinically.

Recommendations were made these are extensive

4 Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR): 'Opinion on the safety of surgical meshes used in urogynaecological surgery December 2015

Authors Conclusions:
In sling surgery, there is evidence that absorbable biological materials have a high `failure rate while sling surgery with non-absorbable synthetic mesh was effective with an approximately mesh exposure rate of 4% (Brubaker et al., 2011). Autologous slings are a more invasive alternative (because of the need to harvest native tissue), but they also can be inserted using a minimally invasive approach. The traditional surgical approach of colposuspension is associated with greater morbidity compared to sling surgery with mesh.
However, synthetic sling SUI surgery is an accepted procedure with proven efficacy and safety in the majority of patients with moderate to severe SUI, when used by an experienced and appropriately trained surgeon. Therefore, the SCENHIR supports continuing synthetic sling use for SUI, but emphasises the importance of appropriately trained surgeons and detailed counselling of patients about the associated risk/benefits.

5 Lancet publication 2017

Adverse Events after first, single mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997-2016: a population-based cohort study; Morling JR, McAllister DA, Agur W et al, The Lancet, 389, No. 10069, 629-640, Feb 2017

Authors Conclusion:
For stress urinary incontinence in routine clinical practice, mesh surgery was associated with a lower risk of immediate complications and subsequent prolapse surgery than the main alternative non-mesh open surgical procedure (colposuspension), and a similar risk of later complications and further incontinence surgery.

6 Cochrane review of retropubic colposuspension 2016

Authors Conclusion
55 trials involving a total of 5417 women.
Overall cure rates were 68.9% to 88.0% for open retropubic colposuspension (ORC).

Evidence from 22 trials in comparison with suburethral slings (traditional slings or trans-vaginal tape or transobturator tape) found no overall significant difference in incontinence rates in all time periods evaluated.
Subgroup analysis of studies comparing traditional slings and open colposuspension showed better effectiveness with traditional slings in the medium and long term (RR 1.35; 95% CI 1.11 to 1.64 from one to five years follow up).

7 BJOG Long term outcomes of TOT in women with stress urinary incontinence 2017

Long term outcomes of tranobturator tapes in women with stress urinary incontinence; E-TOT randomised control trial; Karmaker DK, Mostafa A, Abdel-Fattah M, BJOG; DOI: 10.1111/1471-0528. 14561

Authors Conclusions:
This is the largest and longest follow-up randomised trial of TO-TVT. TO-TVT is associated with 71.6% patient-reported success rate, 4% groin pain/discomfort, and 8% continence re-operation rate at a median of 9 years follow-up. The success rate is almost stable after 3 years.

8 The Scottish Independent Review of the Use Safety and Efficacy of Transvaginal Mesh Implants for Stress Urinary Incontinence and Pelvic Organ Prolapse in women: final report: March 2017

Authors Conclusion:
In light of the totality of these findings, the members of the IR who perform surgery for SUI are of the view that:

- the retropubic mesh tape is a valid option to be offered routinely to women considering surgical treatment for SUI;
- colposuspension and autologous fascial pubo-vaginal sling are both appropriate alternatives for women who wish to avoid the use of a permanent implant, provided they accept the increased associated short-term morbidities and longer recovery, and increased long-term risk of prolapse following colposuspension;
- women may wish to consider urethral injection therapy; they should be made aware that the efficacy is less than with other interventions, and decreases over time; hence the risk of re-admission for complications or re-operation for SUI is very much higher
- small numbers of colposuspension and autologous fascial pubo-vaginal sling procedures have been undertaken in Scotland in recent years (see chapter 4); if a procedure cannot be provided locally, by appropriately skilled and experienced staff, the option of referral to alternative units should be discussed with the patient.

In the case of surgical treatment for SUI, a review of the different sources of evidence has led us to recommend that women must be offered all appropriate treatments (mesh and non-mesh) as well as the information to make informed choices. Management of patients must follow agreed care pathways and the importance of multidisciplinary assessment is emphasised.

When surgery involving polypropylene or other synthetic mesh tape is contemplated, a retropubic approach is recommended. The Expert Group must develop appropriate pathways, including one for management of those suffering complications. Work

with Medical Directors and Planners will be required to ensure their smooth implementation.

9 Nature Scientific Reports September 2017

Keltie K et al. Nature Scientific Reports 7: *12015* DOI:10.1038/s41598-017-11821-w.

Authors Conclusions:
Complications of surgical mesh procedures have led to legal cases against manufacturers worldwide and to national inquiries about their safety. The aim of this study was to investigate the rate of adverse events of these procedures for stress urinary incontinence in England over 8 years.

This was a retrospective cohort study of first-time tension-free vaginal tape (TVT), trans-obturator tape (TOT) or suprapubic sling (SS) surgical mesh procedures between April 2007 and March 2015.

Cases were identified from the Hospital Episode Statistics database. Outcomes included number and type of procedures, including those potentially confounded by concomitant procedures, and frequency, nature and timing of complications.

92,246 first-time surgical mesh procedures (56,648 TVT, 34,704 TOT, 834 SS and 60 combinations) were identified, including 68,002 unconfounded procedures. Peri-procedural and 30-day complication rates in the unconfounded cohort were 2.4 [2.3–2.5]% and 1.7 [1.6–1.8]% respectively; 5.9 [5.7–6.1]% were readmitted at least once within 5 years for further mesh intervention or symptoms of complications, the highest risk being within the first 2 years. Complication rates were higher in the potentially confounded cohort. The complication rate within 5 years of the mesh procedure **was 9.8 [9.6:10.0]% This evidence can inform future decision-making on this procedure.**

10 NHS Digital review April 2018

100,516 patients reviewed
Readmission for removal 1.2-1.7 per 1000
Removal post 30 days 10.2 per 1000 but dropping to 7.2
Outpatient to Trauma and orthopaedics assuming that this captures emergency attendances 34-44 per 100 in the non tape group 44-29

Unfortunately the type of complications have not been reported in detail. With all of these data available BAUS feels they should be accessed and further interrogated to provide better detail and understanding of the complications recorded. There is an urgent need for these issues to be clarified as the incidence of surgery for stress incontinence has fallen so sharply and we can only conclude that women are choosing to put up with what is an embarrassing and disabling set of symptoms.

11 Meta analysis 2018

The efficacy and safety comparison of surgical treatments for stress urinary incontinence: A network meta-analysis. Song P, Wen Y, Huang C et al Neurourol Urodyn. 2018 Apr;37(4):1199-1211.

Authors Conclusion

- There were 44 studies which reported objective cure rate (7117 patients). Compared to TVT, TOT (and Adjust) had no significant difference in objective cure rate (whist TVTO and TVT-S had lower objective cure rates)
- There were 18 studies that described subjective cure rate (2490 patients). There were no significant differences between TVT, TOT, and TVT-O.
- There were 20 studies (3200 patients) reporting the number of postoperative complication. Results from NMA suggested that there were no statistically significant differences existed between TVT and TOT (TVTO, Adjust and TVT-S)
- A total of 16 studies had described the adverse event of the bladder perforation. TOT (TVTO and TVT-S) had a statistically lower bladder perforation rate compared with TVT.
- 13 studies reported the adverse event of tape erosion - there were no significant differences between TVT and TOT (Adjust, TVT-S and TVTO).
- In total of 22 studies were analyzed the postoperative urinary retention. The method of TVT-O appeared to exhibit a less postoperative retention compared with TVT (TVT-O: OR = 0.35, 95%CI [0.16, 0.74]). The other surgeries of TVT-S, TOT, and Ajust had no significant difference with each other.
- There were 22 studies describing postoperative pain. No significant difference was observed concerning TVT and TOT. (TVT-S had the lowest pain risk)

TOT had a superior efficacy and ranking the first place in both objective cure rate and subjective cure rate.

Appendix 2

Stress Urinary Incontinence – BAUS patient information

2002/2003	BAUS consent forms, produced on disk and made available to all members, included DOH Guidelines to Consent and 1998 GMC Guidelines on consent, attached.
	Sling for SUI procedure specific consent form attached.
2012	BAUS patient information leaflets put on BAUS website, SUI leaflet attached together with MHRA leaflet which was also added to the BAUS website.
2014	leaflets updated after review by plain English campaign/society
2016	Leaflets reviewed, minimal change, copy attached.

Leaflets reviewed and updated 2017/18, the latest versions are those currently on the BAUS website:

Synthetic mid-urethral taps for stress urinary incontinence (female)

Link to MHRA summary of the evidence on the benefits and risks of vaginal mesh implants

Comparison of treatment options for stress urinary incontinence in women

Urethral bulking injections for stress urinary incontinence

Autologous sling procedures for stress urinary incontinence

Colposuspension for stress urinary incontinence

Insertion of an artificial urinary sphincter (AUS) in Women

Formation of an ileal conduit

General information for patients on incontinence of urine

Information for patients on vaginal mesh complications

General Medical Council Guidelines on consent Seeking patients' consent: the ethical considerations November 1998

Contents

Guidance to doctors

Being registered with the General Medical Council gives you rights and privileges. In return, you must meet the standards of competence, care and conduct set by the GMC.

This booklet sets out the principles of good practice which all registered doctors are expected to follow when seeking patients' informed consent to investigations, treatment, screening or research. It enlarges on the general principles set out in paragraph 12 of our booklet Good Medical Practice.

Introduction

1. Successful relationships between doctors and patients depend on trust. To establish that trust you must respect patients' autonomy - their right to decide whether or not to undergo any medical intervention even where a refusal may result in harm to themselves or in their own death1. Patients must be given sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.

2. This right is protected in law, and you are expected to be aware of the legal principles set by relevant case law in this area2. Existing case law gives a guide to what can be considered minimum requirements of good practice in seeking informed consent from patients.

3. Effective communication is the key to enabling patients to make informed decisions. You must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. Open, helpful dialogue of this kind with patients leads to clarity of objectives and understanding, and strengthens the quality of the doctor/patient relationship. It provides an agreed framework within which the doctor can respond effectively to the individual needs of the patient. Additionally, patients who have been able to make properly informed decisions are more likely to cooperate fully with the agreed management of their conditions.

Consent to investigation and treatment

Providing sufficient information

4. Patients have a right to information about their condition and the treatment options available to them. The amount of information you give each patient will vary, according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patients may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life3.

5. The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, may include:

details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated; uncertainties about the diagnosis including options for further investigation prior to treatment; options for treatment or management of the condition, including the option not to treat; the purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure;and details of what the patient might experience during or after the procedure including common and serious side effects; for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment;
advice about whether a proposed treatment is experimental; how and when the patient's condition and any side effects will be monitored or re-assessed; the name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;
whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment;
a reminder that patients can change their minds about a decision at any time; a reminder that patients have a right to seek a second opinion; where applicable, details of costs or charges which the patient may have to meet.

6. When providing information you must do your best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. You should not make assumptions about patients' views, but discuss these matters with them, and ask them whether they have any concerns about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision.

7. You must not exceed the scope of the authority given by a patient, except in an emergency4. Therefore, if you are the doctor providing treatment or undertaking an investigation, you must give the patient a clear explanation of the scope of consent being sought. This will apply particularly where:

treatment will be provided in stages with the possibility of later adjustments;
different doctors (or other health care workers) provide particular elements of an investigation or treatment (for example anaesthesia in surgery);

a number of different investigations or treatments are involved; uncertainty about the diagnosis, or about the appropriate range of options for treatment, may be resolved only in the light of findings once investigation or treatment is underway, and when the patient may be unable to participate in decision making.
In such cases, you should explain how decisions would be made about whether or when to move from one stage or one form of treatment to another. There should be a clear agreement about whether the patient consents to all or only parts of the proposed plan of investigation or treatment, and whether further consent will have to be sought at a later stage.

8. You should raise with patients the possibility of additional problems coming to light during a procedure when the patient is unconscious or otherwise unable to make a decision. You should seek consent to treat any problems which you think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought to before you proceed. You must abide by patients' decisions on these issues. If in exceptional circumstances you decide, while the patient is unconscious, to treat a condition which falls outside the scope of the patient's consent, your decision may be challenged in the courts, or be the subject of a complaint to your employing authority or the GMC. You should therefore seek the views of an experienced colleague, wherever possible, before providing the treatment. And you must be prepared to explain and justify your decision. You must tell the patient what you have done and why, as soon as the patient is sufficiently recovered to understand.

Responding to questions

9. You must respond honestly to any questions the patient raises and, as far as possible, answer as fully as the patient wishes. In some cases, a patient may ask about other treatments that are unproven or ineffective. Some patients may want to know whether any of the risks or benefits of treatment are affected by the choice of institution or doctor providing the care. You must answer such questions as fully, accurately and objectively as possible.

Withholding information

10. You should not withhold information necessary for decision making unless you judge that disclosure of some relevant information would cause the patient serious harm. In this context serious harm does not mean the patient would become upset, or decide to refuse treatment.

11. No-one may make decisions on behalf of a competent adult. If patients ask you to withhold information and make decisions on their behalf, or nominate a relative or third party to make decisions for them, you should explain the importance of them knowing the options open to them, and what the treatment they may receive will involve. If they insist they do not want to know in detail about their condition and its treatment, you should still provide basic information about the treatment. If a relative asks you to withhold information, you must seek the views of the patient. Again, you should not withhold relevant information unless you judge that this would cause the patient serious harm.

12. In any case where you withhold relevant information from the patient you must record this, and the reason for doing so, in the patient's medical records and you must be prepared to explain and justify your decision.

Presenting information to patients

13. Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between you and your patients which keeps them abreast of changes in their condition and the treatment or investigation you propose. Whenever possible, you should discuss treatment options at a time when the patient is best able to understand and retain the information. To be sure that your patient understands, you should give clear explanations and give the patient time to ask questions. In particular, you should:

use up-to-date written material, visual and other aids to explain complex aspects of the investigation, diagnosis or treatment where appropriate and/or practicable;
make arrangements, wherever possible, to meet particular language and communication needs, for example through translations, independent interpreters, signers, or the patient's representative; where appropriate, discuss with patients the possibility of bringing a relative or friend, or making a tape recording of the consultation;
explain the probabilities of success, or the risk of failure of, or harm associated with options for treatment, using accurate data; ensure that information which patients may find distressing is given to them in a considerate way. Provide patients with information about counselling services and patient support groups, where appropriate;
allow patients sufficient time to reflect, before and after making a decision, especially where the information is complex or the severity of the risks is great. Where patients have difficulty understanding information, or there is a lot of information to absorb, it may be appropriate to provide it in manageable amounts, with appropriate written or other back-up material, over a period of time, or to repeat it;
involve nursing or other members of the health care team in discussions with the patient, where appropriate. They may have valuable knowledge of the patient's background or particular concerns, for example in identifying what risks the patient should be told about; ensure that, where treatment is not to start until some time after consent has been obtained, the patient is given a clear route for reviewing their decision with the person providing the treatment. Who obtains consent

14. If you are the doctor providing treatment or undertaking an investigation, it is your responsibility to discuss it with the patient and obtain consent, as you will have a comprehensive understanding of the procedure or treatment, how it is carried out, and the risks attached to it. Where this is not practicable, you may delegate these tasks provided you ensure that the person to whom you delegate:

is suitably trained and qualified; has sufficient knowledge of the proposed investigation or treatment, and understandsthe risks involved; acts in accordance with the guidance in this booklet.
You will remain responsible for ensuring that, before you start any treatment, the patient has been given sufficient time and information to make an informed decision, and has given consent to the procedure or investigation.

Ensuring voluntary decision making

15. It is for the patient, not the doctor, to determine what is in the patient's own best interests. Nonetheless, you may wish to recommend a treatment or a course of action to patients, but you must not put pressure on patients to accept your advice. In discussions with patients, you should:

give a balanced view of the options; explain
the need for informed consent.
You must declare any potential conflicts of interest, for example where you or your organisation benefit financially from use of a particular drug or treatment, or treatment at a particular institution.

16. Pressure may be put on patients by employers, insurance companies or others to undergo particular tests or accept treatment. You should do your best to ensure that patients have considered the options and reached their own decision. You should take appropriate action if you believe patients are being offered inappropriate or unlawful financial or other rewards.

17. Patients who are detained by the police or immigration services, or are in prison, and those detained under the provisions of any mental health legislation may be particularly vulnerable. Where such patients have a right to decline treatment you should do your best to ensure that they know this, and are able to exercise this right.

Emergencies

18. In an emergency, where consent cannot be obtained, you may provide medical treatment to anyone who needs it, provided the treatment is limited to what is immediately necessary to save life or avoid significant deterioration in the patient's health. However, you must still respect the terms of any valid advance refusal which you know about, or is drawn to your attention. You should tell the patient what has been done, and why, as soon as the patient is sufficiently recovered to understand.

Establishing capacity to make decisions

19. You must work on the presumption that every adult has the capacity to decide whether to consent to, or refuse, proposed medical intervention, unless it is shown that they cannot understand information presented in a clear way5. If a patient's choice appears irrational, or does not accord with your view of what is in the patient's best interests, that is not evidence in itself that the patient lacks competence. In such circumstances it may be appropriate to review with the patient whether all reasonable steps have been taken to identify and meet their information needs (see paragraphs 5-17). Where you need to assess a patient's capacity to make a decision, you should consult the guidance issued by professional bodies6.

Fluctuating capacity

20. Where patients have difficulty retaining information, or are only intermittently competent to make a decision, you should provide any assistance they might need to reach an informed decision. You should record any decision made while the patients were competent, including the key elements of the consultation. You should review any decision made whilst they were competent, at appropriate intervals before treatment starts, to establish that their views are consistently held and can be relied on.

Mentally incapacitated patients

21. No-one can give or withhold consent to treatment on behalf of a mentally incapacitated patient7. You must first assess the patient's capacity to make an informed decision about the treatment. If patients lack capacity to decide, provided they comply, you may carry out an investigation or treatment, which may include treatment for any mental disorder8, that you judge to be in their best interests. However, if they do not comply, you may compulsorily treat them for any mental disorder only within the safeguards laid down by the Mental Health Act 19839, and any physical disorder arising from that mental disorder, in line with the guidance in the Code of Practice of the Mental Health Commission10. You should seek the courts' approval for any non-therapeutic or controversial treatments which are not directed at their mental disorder.

Advance statements

22. If you are treating a patient who has lost capacity to consent to or refuse treatment, for example through onset or progress of a mental disorder or other disability, you should try to find out whether the patient has previously indicated preferences in an advance statement ('advance directives' or 'living wills'). You must respect any refusal of treatment given when the patient was competent, provided the decision in the advance statement is clearly applicable to the present circumstances, and there is no reason to believe that the patient has changed his/her mind. Where an advance statement of this kind is not available, the patient's known wishes should be taken into account - see paragraph 25 on the 'best interests' principle.

Children

23. You must assess a child's capacity to decide whether to consent to or refuse proposed investigation or treatment before you provide it. In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment. Your assessment must take account of the relevant laws or legal precedents in this area11. You should bear in mind that:

at age 16 a young person can be treated as an adult and can be presumed to have capacity to decide; under age 16 children may have capacity to decide, depending on their ability to understand what is involved12; where a competent child refuses treatment, a person with parental responsibility or the court may authorise investigation or treatment which is in the child's best interests. The position is different in Scotland, where those with parental responsibility cannot authorise procedures a competent child has refused. Legal advice may be helpful on how to deal with such cases.

24. Where a child under 16 years old is not competent to give or withhold their informed consent, a person with parental responsibility may authorise investigations or treatment which are in the child's best interests13. This person may also refuse any intervention, where they consider that refusal to be in the child's best interests, but you are not bound by such a refusal and may seek a ruling from the court. In an emergency where you consider that it is in the child's best interests to proceed, you may treat the child, provided it is limited to that treatment which is reasonably required in that emergency.

'Best interests' principle

25. In deciding what options may be reasonably considered as being in the best interests of a patient who lacks capacity to decide, you should take into account:

options for treatment or investigation which are clinically indicated; any evidence of the patient's previously expressed preferences, including an advance statement; your own and the health care team's knowledge of the patient's background, such as cultural, religious, or employment considerations; views about the patient's preferences given by a third party who may have other knowledge of the patient, for example the patient's partner, family, carer, tutor-dative (Scotland), or a person with parental responsibility; which option least restricts the patient's future choices, where more than one option (including nontreatment) seems reasonable in the patient's best interest.

Applying to the court

26. Where a patient's capacity to consent is in doubt, or where differences of opinion about his or her best interests cannot be resolved satisfactorily, you should consult more experienced colleagues and, where appropriate, seek legal advice on whether it is necessary to apply to the court for a ruling. You should seek the court's approval where a patient lacks capacity to consent to a medical intervention which is non-therapeutic or controversial, for example contraceptive sterilisation, organ donation, withdrawal of life support from a patient in a persistent vegetative state. Where you decide to apply to a court you should, as soon as possible, inform the patient and his or her representative of your decision and of his or her right to be represented at the hearing.

Forms of consent

27. To determine whether patients have given informed consent to any proposed investigation or treatment, you must consider how well they have understood the details and implications of what is proposed, and not simply the form in which their consent has been expressed or recorded.

Express consent

28. Patients can indicate their informed consent either orally or in writing. In some cases, the nature of the risks to which the patient might be exposed make it important that a written record is available of the patient's consent and other wishes in relation to the proposed investigation and treatment. This helps to ensure later understanding between you, the patient, and anyone else involved in carrying out the procedure or providing care. Except in an emergency, where the patient has capacity to give consent you should obtain written consent in cases where:

the treatment or procedure is complex, or involves significant risks and/or side effects; providing clinical care is not the primary purpose of the investigation or examination; there may be significant consequences for the patient's employment, social or personal life; the treatment is part of a research programme.

29. You must use the patient's case notes and/or a consent form to detail the key elements of the discussion with the patient, including the nature of information provided, specific requests by the patient, details of the scope of the consent given.

Statutory requirements

30. Some statutes require written consent to be obtained for particular treatments (for example some fertility treatments). You must follow the law in these areas.

Implied consent

31. You should be careful about relying on a patient's apparent compliance with a procedure as a form of consent. For example, the fact that a patient lies down on an examination couch does not in itself indicate that the patient has understood what you propose to do and why.

Reviewing consent

32. A signed consent form is not sufficient evidence that a patient has given, or still gives, informed consent to the proposed treatment in all its aspects. You, or a member of the team, must review the patient's decision close to the time of treatment, and especially where:

significant time has elapsed between obtaining consent and the start of treatment;
there have been material changes in the patient's condition, or in any aspects of the proposed treatment plan, which might invalidate the patient's existing consent; new, potentially relevant information has become available, for example about the risks of the treatment, or about other treatment options.

Consent to screening

33. Screening (which may involve testing) healthy or asymptomatic people to detect genetic predispositions or early signs of debilitating or life threatening conditions can be an important tool in providing effective care. But the uncertainties involved in screening may be great, for example the risk of false positive or false negative results. Some findings may potentially have serious medical, social or financial consequences not only for the individuals, but for their relatives. In some cases the fact of having been screened may itself have serious implications.

34. You must ensure that anyone considering whether to consent to screening can make a properly informed decision. As far as possible, you should ensure that screening would not be contrary to the individual's interest. You must pay particular attention to ensuring that the information the person wants or ought to have is identified and provided. You should be careful to explain clearly:

the purpose of the screening;
the likelihood of positive/negative findings and possibility of false positive/negative results; the uncertainties and risks attached to the screening process;
any significant medical, social or financial implications of screening for the particular condition or predisposition; follow up plans, including availability of counselling and support services.

If you are considering the possibility of screening children, or adults who are not able to decide for themselves, you should refer to the guidance at paragraphs 19-25. In appropriate cases, you should take account of the guidance issued by bodies such as the Advisory Committee on Genetic Testing 14.

Consent to research

35. Research involving clinical trials of drugs or treatments, and research into the causes of, or possible treatment for, a particular condition, is important in increasing doctors' ability to provide effective care for present and future patients. The benefits of the research may, however, be uncertain and may not be experienced by the person participating in the research. In addition, the risk involved for research participants may be difficult to identify or to assess in advance. If you carry out or participate in research involving patients or volunteers, it is particularly important that you ensure:

as far as you are able, that the research is not contrary to the individual's interests; that participants understand that it is research and that the results are not predictable.

36. You must take particular care to be sure that anyone you ask to consider taking part in research is given the fullest possible information, presented in terms and a form that they can understand. This must include any information about possible benefits and risks; evidence that a research ethics committee has given approval; and advice that they can withdraw at any time. You should ensure that participants have the opportunity to read and consider the research information leaflet. You must allow them sufficient time to reflect on the implications of participating in the study. You must not put pressure on anyone to take part in research. You must obtain the person's consent in writing. Before starting any research you must always obtain approval from a properly constituted research ethics committee.

37. You should seek further advice where your research will involve adults who are not able to make decisions for themselves, or children. You should be aware that in these cases the legal position is complex or unclear, and there is currently no general consensus on how to balance the possible risks and benefits to such vulnerable individuals against the public interest in conducting research. (A number of public consultation exercises are under way.) You should consult the guidance issued by bodies such as the Medical Research Council and the medical royal colleges16 to keep up to date. You should also seek advice from the relevant research ethics committee where appropriate.

Notes

1 This right to decide applies equally to pregnant women as to other patients, and includes the right to refuse treatment where the treatment is intended to benefit the unborn child. See St George's Healthcare
NHS Trust v S [1998] Fam Law 526 and 662, and MB (an adult: medical treatment) [1997] 2 FCR 541,CA

2 Advice can be obtained from medical defence bodies such as the Medical Defence Union, Medical Protection Society, the Medical and Dental Defence Union of Scotland, or professional associations such as the BMA., or your employing organisation.

3 Our booklet 'Serious Communicable Diseases' gives specific guidance on seeking consent to testing for conditions like HIV, Hepatitis B and C.

4 Guidance on treating patients in emergencies is included in paragraph 18.

5 A patient will be competent if he or she can: comprehend information, it having been presented to them in a clear way; believe it; and retain it long enough to weigh it up and make a decision. From Re C (Adult: Refusal of Medical Treatment) [1994] 1 All ER 819. But seek legal advice, in case of doubt.

6 For example the BMA/Law Society publication, "Assessment of Mental Capacity: Guidance for Doctors and Lawyers" available from the BMA.

7 Except in Scotland where a 'tutor-dative' with appropriate authority may make medical decisions on behalf of the patient. Seek legal advice, in case of doubt.

8 Legal advice should be obtained in case of doubt. A relevant precedent is the case of Regina v Bournewood Community and Mental Health NHS Trust ex parte L [1998] 3 All ER, 289 HL.

9 And similar legislation in Scotland and Northern Ireland

10 Code of Practice Dec 1998 Pursuant to S118 of the Mental Health Act 1983

11 You should consult your medical defence body or professional association for up to date advice. Appendix A lists some of the relevant key legislation.

12 Age of Legal Capacity (Scotland) Act 1991 (Section 2.4); Gillick v West Norfolk and Wisbech AHA ALL ER [1985], 3 ALL ER 402

13 This also applies to young people between 16 and 18 years old, except in Scotland.

14 ACGT can be contacted at: ACGT Secretariat, Department of Health, Room 401, Wellington House, 133-135 Waterloo Road, London, SE1 8UG. Telephone: 020 7972 4017

15 Consult your medical defence body, a professional association such as the BMA, or your employing organisation.

16 Appendix B gives an indicative list of published guidance. The GMC plans to publish further guidance on research.

APPENDIX A

Children and Consent to Treatment and Testing: Some Key Legislation

England & Wales

Family Law Reform Act 1969
Gillick v West Norfolk and Wisbech AHA [1985], 3 AER 402
Children Act 1989
Scotland

Age of Legal Capacity (Scotland) Act 1991 Children
Act (Scotland) 1995, Section 6, Part 1.
Northern Ireland

Age of Majority Act 1969, Section 4.
APPENDIX B
Other Guidance on Research: Indicative List of Relevant Publications

'Good Medical Practice', paragraphs 55-56. The General Medical Council, 178-202 Great Portland Street, London, W1W 5JE. 1998.

'The Ethical Conduct of Research on Children'. MRC Ethics Series. The Medical Research Council, 20 Park Crescent, London, W1N 4AL. 1991 and 1993.

'Responsibility in Investigations on Human Participants and Materials and on Personal Information'. MRC Ethics Series. The Medical Research Council. 1992.

'The Ethical Conduct of Research on the Mentally Incapacitated'. MRC Ethics series. The Medical Research Council. 1991 and 1993.

'Research Involving Patients'. The Royal College of Physicians of London, 11 St Andrew's Place, London, NW1 4LE. January 1990.

'Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects'. Second Edition. The Royal College of Physicians of London, 11 St Andrew's Place, London, NW1 4LE. January 1990.

'Local Research Ethics Committees' (HSG(91)5). Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS. 1991.

'Multi-Centre Research Committees' (HSG(97)23). Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS. 1997.

'ABPI Guidance Note. Patient Information and Consents for Clinical Trials'. Association of British Pharmaceutical Industry, 12 Whitehall, London, SW1A 2DY. May 1997.

'International Ethical Guidelines for Biomedical Research Involving Human Subjects'. Council for International Organisations of Medical Sciences (CIOMS), c/o World Health Organisation, Avenue Appia, 1211 Geneva 27, Switzerland.

'Charter for Ethical Research in Maternity Care.'1997. National Childbirth Trust, Alexandra House, Oldham Terrace, Acton, London W3 6NH.

'Human Tissue: Ethical and Legal Issues 'Nuffield Council on Bioethics, 28 Bedord Square, London WC1B 3EG April 1995.

Department of Health

Good practice in consent implementation guide:

consent to examination or treatment

Good practice in consent implementation guide:

consent to examination or treatment

Contents

Introduction to this Implementation Guide

This *Good practice in consent implementation guide* contains a model consent policy and four consent forms, together with an accompanying information leaflet *About the consent form.* This model documentation has been developed as part of the Department of Health's 'good practice in consent' initiative, as promised in the *NHS Plan,* with the aim of assisting NHS organisations to promote good practice in the way patients are asked to give their consent to treatment, care or research. An electronic version of this documentation can be downloaded from www.doh.gov.uk/consent.

The four forms are designed to meet the needs of different groups of patients at different times:

- consent form 1 for patients able to consent for themselves
- consent form 2 for those with parental responsibility, consenting on behalf of a child/young person
- consent form 3 both for patients able to consent for themselves and for those with parental responsibility consenting on behalf of a child/young person, where the procedure does not involve any impairment of consciousness. This form is shorter than the others, as the fact that the patient is expected to remain alert during the procedure makes some of the information covered in forms 1 and 2 unnecessary. The use of this form is optional.
- consent form 4 for adults who lack capacity to consent to a particular treatment. As no-one else can give consent on behalf of such a patient, they may only be treated if that treatment is believed to be in their 'best interests'. This form requires health professionals to document both how they have come to the conclusion that the patient lacks the capacity to make this particular healthcare decision, and why the proposed treatment would be in the patient's best interests. It also allows the involvement of those close to the patient in making this healthcare decision to be documented.

Whatever the format used, a copy of the page documenting the details of the treatment should be offered to the patient, for example through the use of 'no carbon required' (NCR) copies.

The text for patients 'About the consent form' should be made available to patients in advance of their being asked to sign a consent form, and may be published in any appropriate format. Text should only be omitted if it will never be relevant (for example the section on anaesthesia could be omitted if the organisation involved would never be seeking consent for anaesthesia).

Consent policy

The model policy has been designed to encourage the addition of local information where indicated. If it is felt to be helpful to extend the scope of the model policy, this should be done by means of a separate schedule so that it does not affect the existing layout of the rest of the policy. This will enable staff moving between NHS organisations to know exactly where to look for particular information in their new organisation's policy.

Implementation

The required time-scales for implementing the model consent documentation are set out in circular HSC 2001/023. The Clinical Negligence Scheme for Trusts will be revising its consent to treatment standard to reflect the new requirements from the Department of Health and will ensure that Trusts are aware of when they will be assessed against that new standard.

Guidance on consent

The Department has published a range of guidance documents on consent, which are freely available from the NHS Response Line (08701 555 455) or from www.doh.gov.uk/consent. These are listed below:

- *Reference guide to consent for examination or treatment*, March 2001
- *12 key points on consent: the law in England*, March 2001
- *Consent – what you have a right to expect*, July 2001 (leaflet for patients, with versions for adults, children/young people, people with learning disabilities, parents and relatives/carers)

- *Seeking consent: working with children*, November 2001
- *Seeking consent: working with older people*, November 2001
- *Seeking consent: working with people with learning disabilities*, November 2001

Model policy for consent to examination or treatment

1 Introduction

Why consent is crucial

1. Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

This policy

2. The Department of Health has issued a range of guidance documents on consent (see overleaf), and these should be consulted for details of the law and good practice requirements on consent. This policy sets out the standards and procedures in this [Trust/PCT/PCG/practice] which aim to ensure that health professionals are able to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

What consent is – and isn't

3. "Consent" is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:

    - be competent to take the particular decision;
    - have received sufficient information to take it; and
    - not be acting under duress.

4. The context of consent can take many different forms, ranging from the active request by a patient of a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional's advice. In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the

patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. In many cases, 'seeking consent' is better described as 'joint decision-making': the patient and health professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge.

5. Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, **no-one else can give consent on their behalf**. However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance directive. For further details on advance directives see the Department of Health's *Reference guide to consent for examination or treatment* (chapter 1, paragraph 19).

Guidance on consent

6. The Department of Health has issued a number of guidance documents on consent, and these should be consulted for advice on the current law and good practice requirements in seeking consent. Health professionals must also be aware of any guidance on consent issued by their own regulatory bodies.

   - *Reference guide to consent for examination or treatment* provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies are available [insert local access details] and may also be accessed on the internet at www.doh.gov.uk/consent.

   - *12 key points on consent: the law in England* has been distributed widely to health professionals working in England. This one-page document summarises those aspects of the law on consent which arise on a daily basis and is attached at Appendix A. Further copies are available from www.doh.gov.uk/consent.

   - Specific guidance, incorporating both the law and good practice advice, is available for health professionals working with children, with people with learning disabilities and with older people. Copies of these booklets are available [insert local details] and on the internet at www.doh.gov.uk/consent.

II Documentation

1. For significant procedures, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient's notes if necessary), or through documenting in the patient's notes that they have given oral consent.

Written consent

2. Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is *evidence* that the patient has given consent, but is not *proof* of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

3. It is rarely a legal requirement to seek written consent,[1] but it is good practice to do so if any of the following circumstances apply:

   - the treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications')
   - the procedure involves general/regional anaesthesia or sedation
   - providing clinical care is not the primary purpose of the procedure
   - there may be significant consequences for the patient's employment, social or personal life

[1] The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances.

- the treatment is part of a project or programme of research approved by this [Trust/PCT/PCG]

[Individual Trusts/PCTs/PCGs may choose to list in an Annex whether written/oral/non-verbal consent is appropriate for specified procedures.]

4. Completed forms should be kept with the patient's notes. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional.

5. It will not usually be necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about, similar care in the past), it would be helpful to do so.

Procedures to follow when patients lack capacity to give or withhold consent

6. Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented in form 4 (form for adults who are unable to consent to investigation or treatment), along with the assessment of the patient's capacity, why the health professional believes the treatment to be in the patient's best interests, and the involvement of people close to the patient. The standard consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient's notes.

7. An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. You should involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient's situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

8. Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Where the consequences of having, or not having, the treatment are potentially serious, a court declaration may be sought. See Appendix D for details of how to do this.

Availability of forms

9. Standard consent forms and forms for adults who are unable to consent for themselves are reproduced in Appendix B and are available from [local details]. There are three versions of the standard consent form: **form 1** for adults or competent children, **form 2** for parental consent for a child or young person and **form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary.

III When should consent be sought?

1. When a patient formally gives their consent to a particular intervention, this is only the *endpoint* of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

Single stage process

2. In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given orally.

3. If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

Two or more stage process

4. In most cases where *written* consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

5. Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure, and should have received a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patients arrive for treatment, however, a member of the healthcare team **must** check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?"

6. While administrative arrangements will vary, it should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse, or change their mind. It will rarely be appropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment (for example, by changing into a hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

Seeking consent for anaesthesia

7. Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's notes or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (eg where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

8. In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility.

Emergencies

9. Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

Treatment of young children

10. When babies or young children are being cared for in hospital, it will not usually seem practicable to seek their parents' consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, you should remember that, in law, such consent is required. Where a child is admitted, you should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, you must do so, unless the delay involved in contacting them would put the child's health at risk.

11. Only people with 'parental responsibility' are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.

IV Provision of information

1. The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where to go, how long they will be in hospital, how they will feel afterwards and so on.

2. Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the *presumption* must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

3. The following sources of patient information are available in this [Trust/PCT/PCG]:

    - [Insert local details, including advice on accessibility/readability for those developing such materials. Also include what specific provision is made for those who, for reasons of disability or otherwise, would not find printed information particularly accessible (tapes, pictorial materials etc) together with details of local independent advocacy groups where these exist. Some Trusts have developed 'patient passports' determining what information is needed at which points in a patient's 'journey' through healthcare. Others have made provision for patients to receive tape-recordings of consultations so that they have a permanent record of what was discussed.]

Provision for patients whose first language is not English

4. This [Trust/PCT/PCG] is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English.

   - [Insert local details of how to access translation and interpreting service, what materials are available in which languages etc. Reference other relevant local policies or guidance eg on use of interpreting. Helpful guidance is found in the toolkit *Bridging the Gap* produced by Sheffield Health Authority and the Commission for Racial Equality.[2]]

Access to more detailed or specialist information

5. Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. This [Trust/PCT/PCG] has made the following arrangements to assist patients to obtain such information:

   - [Insert local details eg help via PALS, access on site to NHS Direct Online and the National Electronic Library for Health, links with local medical libraries. In hospitals, this policy can be adapted at Directorate level to include more specific information here.]

Access to health professionals between formal appointments

6. After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they take their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice). [Insert local details of what systems are in place at GP practice/ Directorate level eg GP surgeries which have a defined hour in the day for phone calls, space in consent form for contact number of appropriate health professional, such as specialist nurse.]

---

2. Contact David Codner (Senior Manager Black and Minority Ethnic Health Issues) at Sheffield Health Authority for details

Open access clinics

7. Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. You should ensure that they have the information they need before proceeding with an investigation or treatment. [Insert local details of relevant arrangements, such as provision of information through primary care.]

V Who is responsible for seeking consent?

1. The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.

2. Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, team work is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

Completing consent forms

3. The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

4. If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves.

   [Insert local details, where appropriate at Directorate level, covering:

   - what training is available for health professionals who do not themselves carry out specific procedures, but could potentially provide the information patients need in coming to a decision.

- what procedures are in place to ensure that the health professionals 'confirming' the patient's consent have genuine access to appropriate colleagues where they are personally not able to answer any remaining questions.]

Responsibility of health professionals

5. It is a health professional's own responsibility:

   - to ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so; and

   - to work within their own competence and not to agree to perform tasks which exceed that competence.

   If you feel that you are being pressurised to seek consent when you do not feel competent to do so [insert local details of whom to contact, such as clinical governance lead.]

VI Refusal of treatment

1. If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the *Mental Health Act 1983*. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail. The following paragraphs apply primarily to adults.

2. If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this on the form.

3. Where a patient has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

4. If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

VII Tissue

1. The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues and is currently under review. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all. At present, this [Trust/PCT/PCG] requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes. [Insert local details of how this should be done. The system must be well-publicised and transparent, making provision for patients to record their consent or objection to the use of such tissue and for this to be notified to the laboratory. Patients must also be able to record any objections to particular uses or use of particular tissues.]

2. Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply. [Insert local details.]

3. Pending the outcome of the review of the law governing the use of human organs and tissue, the Department of Health believes that tissue samples may be used for quality assurance purposes without requiring specific patient consent *provided* there is an active policy of informing patients of such use. This is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised. [Insert local details of policy.]

VIII Clinical photography and conventional or digital video recordings

1. Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

2. Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

3. Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.

4. If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

5. The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

6. If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of some-one close to the patient. You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

IX Training

[Insert details of training available on consent in this organisation, covering both basic training on the law of consent, and training on any specific procedures used in this organisation.]

Dated:
Person responsible for policy:
Policy approved by:
Policy to be reviewed by [date]:

Appendix A

12 key points on consent: the law in England

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.

2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.

3. Patients may be competent to make some health care decisions, even if they are not competent to make others.

4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent **cannot** over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent?

6. It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusal of treatment

10. Competent adult patients are entitled to refuse treatment, even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the fetus.

Adults who are not competent to give consent

11. **No-one** can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

12. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'advance refusal'), and those circumstances arise, you must abide by that refusal.

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment*, available from the NHS Response Line 08701 555 455 and at www.doh.gov.uk/consent.

Appendix B

Current forms in use in this organisation

Appendix C

Useful contact details

[eg risk managers, training managers, clinical governance leads, clinical ethics committees]

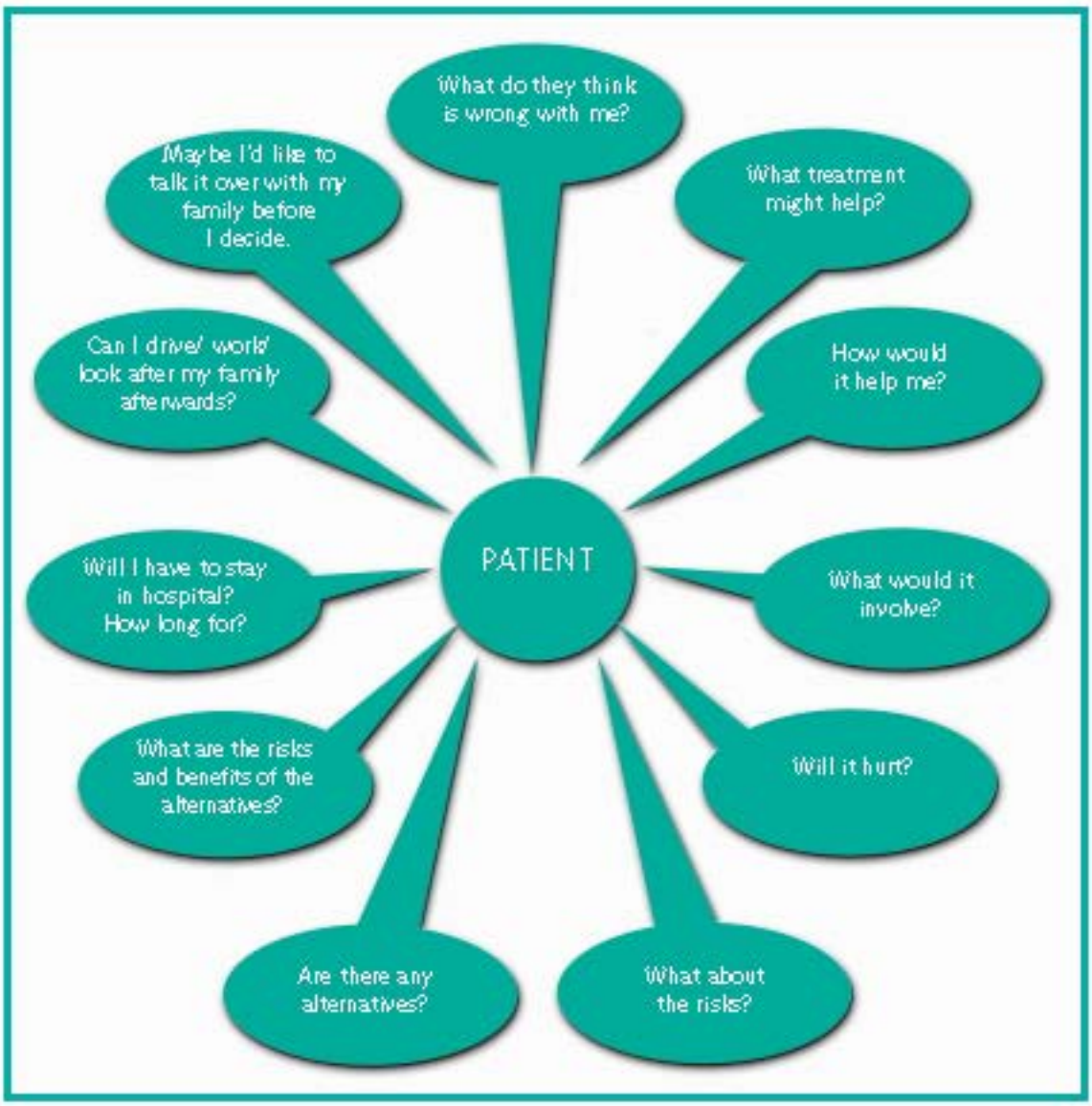
Appendix D

How to seek a court declaration

[eg details of how to contact the organisation's legal services, what information they will require etc]

Appendix E

Seeking consent: remembering the patient's perspective



[NHS organisation name]

consent form 1

Patient agreement to investigation or treatment

Patient details (or pre-printed label)

Patient's surname/family name _____

Patient's first names _____

Date of birth _____

Responsible health professional _____

Job title _____

NHS number (or other identifier) _____

☐ Male ☐ Female

Special requirements _____
(eg other language/other communication method)

To be retained in patient's notes

Patient identifier/label

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear) _____

_____

_____

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits _____

_____

_____

Serious or frequently occurring risks _____

_____

_____

Any extra procedures which may become necessary during the procedure

☐ blood transfusion _____

☐ other procedure (please specify) _____

_____

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

☐ The following leaflet/tape has been provided _____

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

Signed _____ Date _____

Name (PRINT) _____ Job title _____

Contact details (if patient wishes to discuss options later) _____

Statement of interpreter (where appropriate)

I have interpreted the information above to the best of my ability and in a way in which I believe s/he can understand.

Signed _____ Date _____

Name (PRINT) _____

Top copy accepted by patient: yes/no (please ring)

Patient identifier/label

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

_____

_____

_____

Patient's signature _____ Date _____

Name (PRINT) _____

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signed _____ Date _____

Name (PRINT) _____

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed _____ Date _____

Name (PRINT) _____ Job title _____

Important notes: (tick if applicable)

☐ See also advance directive/living will (eg Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign/date here) _____

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for

This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoire to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the Department of Health's *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

- they are unable to comprehend and retain information material to the decision and/or
- they are unable to weigh and use this information in coming to a decision.

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 2 of the form or in the patient's notes.

[NHS organisation name]

consent form 2

Parental agreement to investigation or treatment for a child or young person

Patient details (or pre-printed label)

Patient's surname/family name _____

Patient's first names _____

Date of birth _____

Age _____

Responsible health professional _____

Job title _____

NHS number (or other identifier) _____

☐ Male ☐ Female

Special requirements _____
(eg other language/other communication method)

To be retained in patient's notes

Patient identifier/label

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear) _____

_____

_____

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the child and his or her parent(s). In particular, I have explained:

The intended benefits _____

_____

_____

Serious or frequently occurring risks _____

_____

_____

Any extra procedures which may become necessary during the procedure

☐ blood transfusion _____

☐ other procedure (please specify) _____

_____

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient and his or her parents.

☐ The following leaflet/tape has been provided _____

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

Signed _____ Date _____

Name (PRINT) _____ Job title _____

Contact details (if child/parent wish to discuss options later) _____

Statement of interpreter (where appropriate)

I have interpreted the information above to the child and his or her parents to the best of my ability and in a way in which I believe they can understand.

Signed _____ Date _____

Name (PRINT) _____

Top copy accepted by patient/parent: yes/no (please ring)

Patient identifier/label

Statement of parent

Please read this form carefully. If the procedure has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form and **I confirm** that I have 'parental responsibility' for this child.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that my child and I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of the situation prevents this. (This only applies to children having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save the life of my child or to prevent serious harm to his or her health.

I have been told about additional procedures which may become necessary during my child's treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

_____

_____

_____

Signature_____ Date _____

Name (PRINT) _____ Relationship to child _____

Child's agreement to treatment (if child wishes to sign)

I agree to have the treatment I have been told about.

Name_____ Signature _____

Date_____

Confirmation of consent (to be completed by a health professional when the child is admitted for the procedure, if the parent/child have signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the child and his or her parent(s) that they have no further questions and wish the procedure to go ahead.

Signed_____ Date_____

Name (PRINT) _____ Job title _____

Important notes: (tick if applicable)

☐ See also advance directive/living will (eg Jehovah's Witness form)

☐ Parent has withdrawn consent (ask parent to sign/date here) _____

Guidance to health professionals (to be read in conjunction with consent policy)

This form

This form should be used to document consent to a child's treatment, where that consent is being given by a person with parental responsibility for the child. The term 'parent' has been used in this form as a shorthand for 'person with parental responsibility'. Where children are legally competent to consent for themselves (see below), they may sign the standard 'adult' consent form (form 1). There is space on that form for a parent to countersign if a competent child wishes them to do so.

Who can give consent?

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. The courts have stated that if a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. If children are not able to give consent for themselves, some-one with parental responsibility may do so on their behalf.

Although children acquire rights to give consent for themselves as they grow older, people with 'parental responsibility' for a child retain the right to give consent on the child's behalf until the child reaches the age of 18. Therefore, for a number of years, both the child and a person with parental responsibility have the right to give consent to the child's treatment. In law, health professionals only need the consent of one appropriate person before providing treatment. This means that in theory it is lawful to provide treatment to a child under 18 which a person with parental responsibility has authorised, even if the child refuses. As a matter of good practice, however, you should always seek a competent child's consent before providing treatment unless any delay involved in doing so would put the child's life or health at risk. Younger children should also be as involved as possible in decisions about their healthcare. Further advice is given in the Department's guidance *Seeking consent: working with children.* Any differences of opinion between the child and their parents, or between parents, should be clearly documented in the patient's notes.

Parental responsibility

The person(s) with parental responsibility will usually, but not invariably, be the child's birth parents. People with parental responsibility for a child include: the child's mother; the child's father if married to the mother at the child's conception, birth or later; a legally appointed guardian; the local authority if the child is on a care order; or a person named in a residence order in respect of the child. Fathers who have never been married to the child's mother will only have parental responsibility if they have acquired it through a court order or parental responsibility agreement (although this may change in the future).

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for children and their parents when making up their minds about treatment. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly.

Guidance on the law on consent

See the Department of Health publications *Reference guide to consent for examination or treatment* and *Seeking consent: working with children* for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

Patient identifier/label

[NHS organisation name] consent form 3

Patient/parental agreement to investigation or treatment

(procedures where consciousness not impaired)

Name of procedure

(include brief explanation if medical term not clear) _____

_____

_____

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient/parent. In particular, I have explained:
The intended benefits _____

_____

_____

Serious or frequently occurring risks _____

_____

_____

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of those involved.

☐ The following leaflet/tape has been provided _____

Signed _____ Date _____

Name (PRINT) _____ Job title _____

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe s/he/they can understand.

Signed _____ Date _____ Name (PRINT) _____

Statement of patient/person with parental responsibility for patient

I agree to the procedure described above.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that the procedure will/will not involve local anaesthesia.

Signature _____ Date _____

Name (PRINT) _____ Relationship to patient _____

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient/parent has signed the form in advance)

I have confirmed that the patient/parent has no further questions and wishes the procedure to go ahead.

Signature _____ Date _____

Name (PRINT) _____ Job title _____

Top copy accepted by patient/parent: yes/no (please ring)

Guidance to health professionals (to be read in conjunction with consent policy)

This form

This form documents the patient's agreement (or that of a person with parental responsibility for the patient) to go ahead with the investigation or treatment you have proposed. **It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care: for example for drug therapy where written consent is deemed appropriate.** In other circumstances you should use either form 1 (for adults/competent children) or form 2 (parental consent for children/young people) as appropriate.

Consent forms are not legal waivers – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients also have every right to change their mind after signing the form.

Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, if they wish. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form (see also 'This form' above)

If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

- they are unable to comprehend and retain information material to the decision and/or
- they are unable to weigh and use this information in coming to a decision.

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds about treatment. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this overleaf or in the patient's notes.

The law on consent

See the Department of Health's *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

[NHS organisation name]

consent form 4

Form for adults who are unable to consent to investigation or treatment

Patient details (or pre-printed label)

Patient's surname/family name _____

Patient's first names _____

Date of birth _____

Responsible health professional _____

Job title _____

NHS number (or other identifier) _____

☐ Male ☐ Female

Special requirements _____
(eg other language/other communication method)

To be retained in patient's notes

Patient identifier/label

All sections to be completed by health professional proposing the procedure

A Details of procedure or course of treatment proposed

(NB see guidance to health professionals overleaf for details of situations where court approval must first be sought)

B Assessment of patient's capacity

I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment because:

☐ the patient is unable to comprehend and retain information material to the decision; and/or
☐ the patient is unable to use and weigh this information in the decision-making process; or
☐ the patient is unconscious

Further details (excluding where patient unconscious): for example how above judgements reached; which colleagues consulted; what attempts made to assist the patient make his or her own decision and why these were not successful.

C Assessment of patient's best interests

To the best of my knowledge, the patient has not refused this procedure in a valid advance directive. Where possible and appropriate, I have consulted with colleagues and those close to the patient, and I believe the procedure to be in the patient's best interests because:

(Where incapacity is likely to be temporary, for example if patient unconscious, or where patient has fluctuating capacity)

The treatment cannot wait until the patient recovers capacity because:

D Involvement of the patient's family and others close to the patient

The final responsibility for determining whether a procedure is in an incapacitated patient's best interests lies with the health professional performing the procedure. However, it is good practice to consult with those close to the patient (eg spouse/partner, family and friends, carer, supporter or advocate) unless you have good reason to believe that the patient would not have wished particular individuals to be consulted, or unless the urgency of their situation prevents this. "Best interests" go far wider than "best medical interests", and include factors such as the patient's wishes and beliefs when competent, their current wishes, their general well-being and their spiritual and religious welfare.

(to be signed by a person or persons close to the patient, if they wish)

I/We have been involved in a discussion with the relevant health professionals over the treatment of (patient's name). I/We understand that he/she is unable to give his/her own consent, based on the criteria set out in this form. I/We also understand that treatment can lawfully be provided if it is in his/her best interests to receive it.

Any other comments (including any concerns about decision)

Name _____ Relationship to patient _____

Address (if not the same as patient) _____

_____

_____

Signature _____ Date _____

If a person close to the patient was not available in person, has this matter been discussed in any other way (eg over the telephone?)

☐ Yes ☐ No

Details:

Signature of health professional proposing treatment

The above procedure is, in my clinical judgement, in the best interests of the patient, who lacks capacity to consent for himself or herself. Where possible and appropriate I have discussed the patient's condition with those close to him or her, and taken their knowledge of the patient's views and beliefs into account in determining his or her best interests.

I have/have not sought a second opinion.

Signature _____ Date _____

Name (PRINT) _____ Job title _____

Where second opinion sought, s/he should sign below to confirm agreement:

Signature _____ Date _____

Name (PRINT) _____ Job title _____

Guidance to health professionals (to be read in conjunction with consent policy)

This form should only be used where it would be usual to seek written consent but an adult patient (18 or over) lacks capacity to give or withhold consent to treatment. If an adult **has** capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the *Mental Health Act 1983,* different legal provisions apply and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form as well). If the adult now lacks capacity, but has clearly refused particular treatment in advance of their loss of capacity (for example in an advance directive or 'living will'), then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the law on consent, see the Department of Health's *Reference guide to consent for examination or treatment* (www.doh.gov.uk/consent).

When treatment can be given to a patient who is unable to consent

For treatment to be given to a patient who is unable to consent, the following **must** apply:

- the patient must lack the capacity ('competence') to give or withhold consent to this procedure AND
- the procedure must be in the patient's best interests.

Capacity

A patient will lack capacity to consent to a particular intervention if he or she is:

- unable to comprehend and retain information material to the decision, especially as to the consequences of having, or not having, the intervention in question; and/or
- unable to use and weigh this information in the decision-making process.

Before making a judgement that a patient lacks capacity you must take all steps reasonable in the circumstances to assist the patient in taking their own decisions (this will clearly not apply if the patient is unconscious). This may involve explaining what is involved in very simple language, using pictures and communication and decision-aids as appropriate. People close to the patient (spouse/partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates or supporters.

Capacity is 'decision-specific': a patient may lack capacity to take a particular complex decision, but be quite able to take other more straight-forward decisions or parts of decisions.

Best interests

A patient's best interests are not limited to their best medical interests. Other factors which form part of the best interests decision include:

- the wishes and beliefs of the patient when competent
- their current wishes
- their general well-being
- their spiritual and religious welfare

Two incapacitated patients, whose *physical* condition is identical, may therefore have different best interests.

Unless the patient has clearly indicated that particular individuals should not be involved in their care, or unless the urgency of their situation prevents it, you should attempt to involve people close to the patient (spouse/partner, family and friends, carer, supporter or advocate) in the decision-making process. Those close to the patient cannot require you to provide particular treatment which you do not believe to be clinically appropriate. However they will know the patient much better than you do, and therefore are likely to be able to provide valuable information about the patient's wishes and values.

Second opinions and court involvement

Where treatment is complex and/or people close to the patient express doubts about the proposed treatment, a second opinion should be sought, unless the urgency of the patient's condition prevents this. Donation of regenerative tissue such as bone marrow, sterilisation for contraceptive purposes and withdrawal of artificial nutrition or hydration from a patient in PVS must never be undertaken without prior High Court approval. High Court approval can also be sought where there are doubts about the patient's capacity or best interests.

Print this Document

Before completing consent please read "Guidance For Health Professionals" for consent form 1 provided on the CD

Click here to read Guidelines (under the section called New Department of Health "Guidelines to Consent" page 40)

CONSENT FORM

for

UROLOGICAL SURGERY

(Designed in compliance with DH Department of Health consent form 1)

PATIENT AGREEMENT TO INVESTIGATION OR TREATMENT

Patient Details or pre-printed label

Patient's NHS Number or Hospital number	
Patient's surname/family name	
Patient's first names	
Date of birth	
Sex	
Responsible health professional	
Job Title	
Special requirements *e.g. other language/other communication method*	

To be retained in patient's notes

Patient identifier/label

Name of proposed procedure (Include brief explanation if medical term not clear)	ANAESTHETIC
SLING PROCEDURE FOR URINARY STRESS INCONTINENCE (SYNTHETIC OR NATURAL) THIS OPERATION INVOLVES THE CREATION OF A SUPPORTING HAMMOCK BY PLACING A TAPE UNDER THE URETHRA FOR SUPPORT. THIS WILL INCLUDE A CYSTOSCOPIC EXAMINATION OF THE BLADDER AND A SMALL INCISION IN THE VAGINA. YOUR SURGEON WILL TELL YOU THE TYPE OF MATERIAL (DONOR TISSUE, NATURAL OR SYNTHETIC) THEY WILL USE, AND THE TYPE OF INCISION REQUIRED (VAGINAL OR ABDOMINAL)	- **GENERAL/REGIONAL** - **LOCAL** - **SEDATION**

Statement of health professional

(To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy) I have explained the procedure to the patient. In particular, I have explained:

The intended benefits

TO TREAT URINARY STRESS INCONTINENCE

Serious or frequently occurring risks including any extra procedures, which may become necessary during the procedure. I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient. Please tick the box once explained to patient

COMMON
- ❑ TEMPORARY INSERTION OF A CATHETER (sometimes via a small incision in the skin) AND WOUND DRAIN

OCCASIONAL
- ❑ FAILURE TO IMPROVE URINARY INCONTINENCE
- ❑ RECURRENCE OF URINARY INCONTINENCE AT LATER TIME
- ❑ RECURRING BLADDER INFECTIONS DUE TO POOR EMPTYING OF BLADDER
- ❑ INFECTION OF INCISION REQUIRING FURTHER TREATMENT

RARE
- ❑ WORSENING OF FREQUENCY AND URGENCY OF URINATION
- ❑ RETENTION OF URINE REQUIRING PROLONGED CATHETERISATION OR SELF-CATHETERISATION
- ❑ DISCOMFORT FROM SLING IN VAGINA OR FROM SUTURES HOLDING THE SLING
- ❑ REACTION TO SLING MATERIAL (INFLAMMATION, INFECTION OR ALLERGIC) REQUIRING REMOVAL
- ❑ IF SEXUALLY ACTIVE DISCOMFORT WITH SEXUAL INTERCOURSE
- ❑ PERFORATION OF THE BLADDER REQUIRING PROLONGED CATHETER OR SURGICAL REPAIR
- ❑ EROSION OF THE SLING INTO THE URETHRA REQUIRING FURTHER SURGERY

ALTERNATIVE THERAPY: OBSERVATION, PHYSIOTHERAPY, PADS, INJECTION THERAPY, COLPOSUSPENSION

A blood transfusion may be necessary during procedure and patient agrees **YES or NO (Ring)**

Signature of Health Professional	**Job Title**
Printed Name	**Date**

The following leaflet/tape has been provided

Contact details (if patient wishes to discuss options later) _____

Statement of interpreter (where appropriate) I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signature of interpreter: **Print name:** **Date:**

Copy (i.e. page 3) accepted by patient: yes/no (please ring)

Patient identifier/label

Patient Copy

Name of proposed procedure (Include brief explanation if medical term not clear)	ANAESTHETIC
SLING PROCEDURE FOR URINARY STRESS INCONTINENCE (SYNTHETIC OR NATURAL) THIS OPERATION INVOLVES THE CREATION OF A SUPPORTING HAMMOCK BY PLACING A TAPE UNDER THE URETHRA FOR SUPPORT. THIS WILL INCLUDE A CYSTOSCOPIC EXAMINATION OF THE BLADDER AND A SMALL INCISION IN THE VAGINA. YOUR SURGEON WILL TELL YOU THE TYPE OF MATERIAL (DONOR TISSUE, NATURAL OR SYNTHETIC) THEY WILL USE, AND THE TYPE OF INCISION REQUIRED (VAGINAL OR ABDOMINAL)	- **GENERAL/REGIONAL** - **LOCAL** - **SEDATION**

Statement of health professional (To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy) I have explained the procedure to the patient. In particular, I have explained:

The intended benefits TO TREAT URINARY STRESS INCONTINENCE

Serious or frequently occurring risks including any extra procedures, which may become necessary during the procedure. I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient. Please tick the box once explained to patient

COMMON
- ❑ TEMPORARY INSERTION OF A CATHETER (sometimes via a small incision in the skin) AND WOUND DRAIN

OCCASIONAL
- ❑ FAILURE TO IMPROVE URINARY INCONTINENCE
- ❑ RECURRENCE OF URINARY INCONTINENCE AT LATER TIME
- ❑ RECURRING BLADDER INFECTIONS DUE TO POOR EMPTYING OF BLADDER
- ❑ INFECTION OF INCISION REQUIRING FURTHER TREATMENT

RARE
- ❑ WORSENING OF FREQUENCY AND URGENCY OF URINATION
- ❑ RETENTION OF URINE REQUIRING PROLONGED CATHETERISATION OR SELF-CATHETERISATION
- ❑ DISCOMFORT FROM SLING IN VAGINA OR FROM SUTURES HOLDING THE SLING
- ❑ REACTION TO SLING MATERIAL (INFLAMMATION, INFECTION OR ALLERGIC) REQUIRING REMOVAL
- ❑ IF SEXUALLY ACTIVE DISCOMFORT WITH SEXUAL INTERCOURSE
- ❑ PERFORATION OF THE BLADDER REQUIRING PROLONGED CATHETER OR SURGICAL REPAIR
- ❑ EROSION OF THE SLING INTO THE URETHRA REQUIRING FURTHER SURGERY

ALTERNATIVE THERAPY: OBSERVATION, PHYSIOTHERAPY, PADS, INJECTION THERAPY, COLPOSUSPENSION

A blood transfusion may be necessary during procedure and patient agrees **YES or NO (Ring)**

Signature of Health Professional	**Job Title**
Printed Name	**Date**

The following leaflet/tape has been provided

Contact details (if patient wishes to discuss options later) _____

Statement of interpreter (where appropriate) I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signature of interpreter:	**Print name:**	**Date:**

Patient identifier/label

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree

- to the procedure or course of treatment described on this form.
- to a blood transfusion if necessary
- That any tissue that is normally removed in this procedure could be stored and used for medical research (after the pathologist has examined it) rather than simply discarded. PLEASE TICK IF YOU AGREE ☐

I understand

- that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)
- that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told

- about additional procedures which may become necessary during my treatment. I have listed below any procedures which **I do not wish to be carried out** without further discussion.

_____

_____

Signature of Patient:		**Print please:**	**Date:**

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here. (See DOH guidelines).

Signed_____
Date_____
Name (PRINT) _____

Confirmation of consent

(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance). On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature of Health Professional	**Job Title**
Printed Name	**Date**

Important notes: (tick if applicable)

☐ See also advance directive/living will (eg Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign/date here) ...../.....

THE BRITISH ASSOCIATION OF UROLOGICAL SURGEONS

35-43 Lincoln's Inn Fields
London
WC2A 3PE

Telephone +44 (0)20 7869 6950
Facsimile +44 (0)20 7404 5048
Internet www.baus.org.uk
Email admin@baus.org.uk

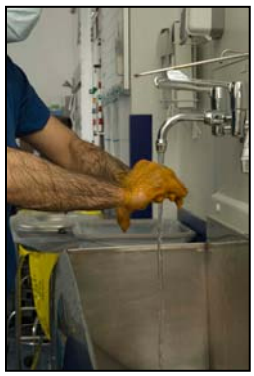
SYNTHETIC VAGINAL TAPES FOR STRESS INCONTINENCE

PROCEDURE-SPECIFIC INFORMATION FOR PATIENTS

What is the evidence base for this information?

This publication includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and evidence-based sources. It is, therefore, a reflection of best urological practice in the UK. It is intended to supplement any advice you may already have been given by your GP or other healthcare professionals. Alternative treatments are outlined below and can be discussed in more detail with your Urologist or Specialist Nurse.

What does the procedure involve?



Vaginal tapes are implanted to treat stress incontinence (leakage of urine when you exercise, sneeze or strain). The tape is placed under the urethra like a sling or hammock to support the urethra (water pipe) and keep it in the correct position.

Synthetic tapes are made from a plastic material, and the majority are made from a non-absorbable polypropylene mesh, which is usually well-accepted by the body. This means that the tape will remain in the body forever.

The first tape of this kind was introduced 15 years ago and is called the tension-free vaginal tape (TVT); many other manufacturers now sell similar tapes. An alternative to the TVT is the trans-obturator tape (TOT); this itape s introduced in a slightly different way. The TOT operation has been carried out in the UK for the last 5 years.

The TVT & TOT are now the most commonly performed operations for stress incontinence in the UK.

Both procedures are relatively quick, taking around 30 minutes to perform, either under general or local anaesthetic. The operations are often performed as a day case, meaning that you can go home on the same day.

The results of TVT and TOT are roughly equal. About 2 out of 3 women will be completely dry after the operation and 1 out of 3 will have some degree of leakage. However, most of those who still have some leakage are much better following surgery. The overall success can also be expressed as the satisfaction rate and approximately 9 out of 10 women are satisfied with the result after either a TVT or a TOT.

What are the alternatives to this procedure?

The previous most common operation that was done for stress incontinence is called the Burch colposuspension. However, this is a much more invasive procedure and involves making a cut in the lower abdomen, above the pubic bone, in order to support the neck of the bladder.

Injection treatment is done sometimes but, although less invasive, is less likely to be successful than either TVT or TOT.

Other alternatives include observation, physiotherapy and usage of pads.

Questions for your surgeon

Here are some questions you could ask your surgeon, prior to surgery, if you are thinking of having a vaginal tape inserted for incontinence:

- Can you give me a full description of what the treatment involves?
- Is this type of treatment right for me?
- What are the different tapes available?
- What are the pros and cons of the different tapes?
- What are the alternative surgical or non-surgical treatments?
- What are the possible side-effects or adverse events associated with the treatment?
- What happens if this particular treatment does not work?
- Do you follow NICE guidelines for the use of tapes?
- Do you perform at least 20 of these procedures a year, as recommended by NICE?
- Have you (the surgeon) looked at your results for the operation?
- If so, what is the success rate and risk of complications?

What should I expect before the procedure?

A pre-operative visit will be arranged by the hospital to check on your fitness for anaesthesia and surgery, at which:

- Blood tests, heart tracing (ECG) and chest X-ray may be performed to ensure that you are in optimal health
- You may be given oral or vaginal oestrogen (hormone) if you are near or already menopausal. It is important to comply with this medication because it thickens your vaginal tissues for easier surgery and faster healing
- All your medications and medical conditions, if any, must be made known to the doctor and must be optimally controlled
- If you are taking Aspirin or other blood thinning drugs, please let us know. You may have to stop taking them a week prior to surgery
- You will be advised when and what you can eat or drink before surgery
- Culture swabs will be taken for MRSA

You will usually be admitted on the same day as your surgery. After admission, you will be seen by members of the medical team which may include the Consultant, Specialist Registrar, House Officer and your named nurse.

You may be given an injection of a blood thinning agent before surgery, and afterwards until you are adequately mobilised. You may also be given a preparation to clear your bowels. You may be given intravenous antibiotics at the time the anaesthetic is given, and possibly after surgery too.

You may be given a pre-medication by the anaesthetist which will make you dry-mouthed and pleasantly sleepy.

Please be sure to inform your surgeon in advance of your surgery if you have any of the following:

- an artificial heart valve
- a coronary artery stent
- a heart pacemaker or defibrillator
- an artificial joint
- an artificial blood vessel graft
- a neurosurgical shunt
- any other implanted foreign body
- a regular prescription for Warfarin, Aspirin or Clopidogrel (Plavix®)
- a previous or current MRSA infection
- a high risk of variant-CJD (if you have received a corneal transplant, a neurosurgical dural transplant or previous injections of human-derived growth hormone)

At some stage during the admission process, you will be asked to sign the second part of the consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you wish to proceed. Make sure that you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.

Fact File 1 • The NHS Constitution
Same-Sex Accommodation

As a result of the new NHS constitution, the NHS is committed to providing same-sex accommodation in hospitals by April 2010. This is because feedback from patients has shown that being in mixed-sex accommodation can compromise their privacy. The NHS pledges that:

- sleeping and washing areas for men and women will be provided
- the facilities will be easy to get to and not too far from patients' beds

To help accomplish this, the Department of Health has announced specific measures designed to "all but eliminate mixed-sex accommodation" by 2010. These include:

- more money for improvements in hospital accommodation
- providing help and information to hospital staff, patients and the public
- sending improvement teams to hospitals that need extra support
- introducing measures so that the Department can see how hospitals are progressing

What happens during the procedure?

TVT / TOT continence surgery is usually performed either under local anaesthetic (when you will be awake) or under general anaesthetic (when you will be asleep throughout the operation). All methods minimise pain; your anaesthetist and surgeon will explain the pros and cons of each type of anaesthetic to you.

The TVT operation involves two small incisions (each 0.5cm long) in the lower part of your abdomen (below the pubic hairline) and a 1.5cm incision in the front wall of the vagina. The TVT tape is inserted from the vagina, then up to the small incisions in your abdomen. The tape lies between the vaginal skin and your urethra (water pipe).

The TOT operation is similar except that it is done by making a small incision at the top of each of your thighs, on the inner side, just below the groin. The tape is brought out through these incisions.

For both TVT and TOT, the tape is cut off level with the skin, so it is not sticking out at the end of the operation; a stitch is used to close the incisions.

At the end of the procedure, a urinary catheter may be inserted into your bladder to allow free urine flow and a vaginal pack may also be inserted.

What happens immediately after the procedure?

In general terms, you should expect to be told how the procedure went and you should:

- ask if what was planned to be done was achieved
- let the medical staff know if you are in any discomfort
- ask what you can and cannot do
- feel free to ask any questions or discuss any concerns with the ward staff and members of the surgical team
- ensure that you are clear about what has been done and what is the next move

You may experience nausea and occasional vomiting (you should rest and medications will be given to relieve these symptoms)
Pain from the wound – this is usually mild and you will be given painkillers to use as required.

If you are given a regional anaesthetic, a 6-hour period of rest is recommended before you are allowed to get out of bed; after that, you are encouraged to move around.

You will be allowed to eat and drink on the same day as the operation.

The vaginal pack, if used, will be removed before you go home (or arrangements made to have it removed later).

If a urinary catheter has been inserted, it is usually removed on the same day as the operation or arrangements may be made for you to have it removed later. You will be encouraged to pass urine on your own and the volume of the remaining urine will be measured.

The average hospital stay is 1 day.

Are there any side-effects?

Most procedures have a potential for side-effects. You should be reassured that, although all these complications are well-recognised, the majority of patients do not suffer any problems after a urological procedure.

Common (greater than 1 in 10)

- Need to go to the toilet frequently, due to a feeling of having to rush to the bathroom (urgency) and, sometimes, with urine leakage due to urgency. Usually, you will have had this before the operation too
- Failure, so that you still have bad leakage. Some women still have mild leakage
- Inability to empty the bladder completely so that you need either to keep a catheter in all the time or you may have to use a catheter several times a day to empty the bladder (intermittent self-catheterisation)
- Infection

- Slow urine flow
- Recurrence of stress incontinence; this can happen years after the tape has been inserted even if it cured your symptoms originally
- Pain; you will get some discomfort/pain for a while, usually where the skin was cut during the operation. TOT can cause thigh or groin pain. This can be relieved by simple painkillers in most cases but there are occasions when more powerful painkillers (neuropathic analgesics) powerful drugs may be required

Occasional (between 1 in 10 and 1 in 50)

- Injury to the bladder during the TVT operation; the risk is much less for TOT surgery
- Misplacement of the tape; this should be discovered at the time of surgery and the tape re-positioned correctly
- Bleeding
- Injury to surrounding tissues (e.g. bladder, rectum and blood vessels)
- Erosion of the tape into the vagina, bladder or urethra; we know that this can occur years after the operation. The risk has been estimated to occur in 5 out of every 100 operations
- Migration of the tape into the vagina, bladder or urethra; this can happen several years after the tape was inserted. Symptoms such as recurrent urinary infection, change in urinary symptoms, vaginal discharge and discomfort during intercourse may occur

Rare (less than 1 in 50)

- None

Hospital-acquired infection

- Colonisation with MRSA (0.9% - 1 in 110)
- Clostridium difficile bowel infection (0.01% - 1 in 10,000)
- MRSA bloodstream infection (0.02% - 1 in 5000)

The rates for hospital-acquired infection may be greater in high-risk patients e.g. with long-term drainage tubes, after removal of the bladder for cancer, after previous infections, after prolonged hospitalisation or after multiple admissions.

What should I expect when I get home?

By the time of your discharge from hospital, you should:

- be given advice about your recovery at home
- ask when to resume normal activities such as work, exercise, driving, housework and sexual intimacy
- ask for a contact number if you have any concerns once you return home
- ask when your follow-up will be and who will do this (the hospital or your GP)
- ensure that you know when you will be told the results of any tests done on tissues or organs which have been removed

When you leave hospital, you will be given a “draft” discharge summary of your admission. This holds important information about your inpatient stay and your operation. If you need to call your GP for any reason or to attend another hospital,

please take this summary with you to allow the doctors to see details of your treatment. This is particularly important if you need to consult another doctor within a few days of your discharge.

You may require pain-killing tablets at home for several days and it may take a week at home to become comfortably mobile.

You are advised:

- Not to drive for at least one week after surgery (you should be confident that you can perform an emergency stop
- Not to douche your vagina or engage in sexual activity for at least a month after surgery
- To avoid carrying heavy weights (of more than 5kg) whenever possible for a month.
- To have at least two weeks off work after discharge from hospital, unless you and your surgeon agree something different. If you have an infection or other complications(s), your recovery is likely to take longer.

What else should I look out for?

You should seek help from your doctor (or from the surgeon / department / ward that looked after you) if you experience:

- Severe vaginal bleeding
- Severe abdominal pain or swelling
- Foul-smelling discharge from the wound
- High fever (you should take your temperature if you suspect this)
- Pain when passing urine
- Difficulty in passing urine
- Pain or swelling of the calves

Are there any other important points?

Different hospitals have different policies for reviewing women after sling surgery. Some like to see all their patients, usually 3-6 months after the operation, whilst others will arrange a routine telephone follow-up at a similar time. All hospitals, however, would wish to see you again if you have any problems or there is anything you are worried about.

Make sure you keep a record of the name of your Consultant, the ward you were on, the date of your operation and the telephone number of the hospital and the ward you were on.

If you would like further information, please look up the documents listed below:

Abrams P et al. Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe. European Urology (2011). Available on the **European Urology website**

Further guidance of the use of incontinence tapes on the NICE (National Institute for Health and Clinical Excellence) website - **Urinary incontinence: the management of urinary incontinence in women**

NICE also provides advice for patients contemplating this procedure – **Urinary incontinence: understanding NICE guidance**

The MHRA is still gathering information about the use and complications of these devices and would encourage reporting of adverse events - **Reporting a safety problem with a device**

Driving after surgery

It is your responsibility to ensure that you are fit to drive following your surgery. You do not normally need to notify the DVLA unless you have a medical condition that will last for longer than 3 months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to provide you with advice on request.

Is there any research being carried out in this area?

Before your operation, your surgeon or Specialist Nurse will inform you about any relevant research studies taking place, and, in particular, if any surgically-removed tissue may be stored for future study. If this is the case, you will be asked if you wish to participate and, if you agree, to sign a special form to consent to this.

All surgical procedures, even those not currently the subject of active research, are subjected to rigorous clinical audit so that we can analyse our results and compare them with those of other surgeons. In this way, we can learn how to improve our techniques and our results; this means that our patients will get the best treatment available.

What should I do with this information?

Thank you for taking the trouble to read this publication. If you wish to sign it and retain a copy for your own records, please do so below.

If you would like a copy of this publication to be filed in your hospital records for future reference, please let your Urologist or Specialist Nurse know. However, if you do agree to proceed with the scheduled procedure, you will be asked to sign a separate consent form that will be filed in your hospital. You will, if you wish, be provided with a copy of the consent form.

I have read this publication and I accept the information it provides.

Signature..... Date.....

How can I get information in alternative formats?

Please ask your local NHS Trust or PALS network if you require this information in other languages, large print, Braille or audio format.

Most hospitals are smoke-free. Smoking increases the severity of some urological conditions and increases the risk of post-operative complications. For advice on quitting, contact your GP or the **NHS Smoking Helpline** free on **0800 169 0 169**

Disclaimer

While every effort has been made to ensure the accuracy of the information contained in this publication, no guarantee can be given that all errors and omissions have been excluded. No responsibility for loss occasioned by any person acting or refraining from action as a result of the material in this publication can be accepted by the British Association of Urological Surgeons Limited.

Fact File 2 • The NHS Constitution

Patients' Rights & Responsibilities

The constitution, as a result of extensive discussions with staff and the public, sets out new rights for patients which will help improve their experience within the NHS. These new rights include:

- a right to choice and a right to information that will help them make that choice
- a right to drugs and treatments approved by NICE when it is considered clinically appropriate
- a right to certain services such as an NHS dentist and access to recommended vaccinations
- the right that any official complaint will be properly and efficiently investigated, and that they be told the outcome of the investigations
- the right to compensation and an apology if they have been harmed by poor treatment

The constitution also lists patient responsibilities, including:

- providing accurate information about their health
- taking positive action to keep themselves and their family healthy
- trying to keep appointments
- treating NHS staff and other patients with respect
- following the course of treatment that they are given
- giving feedback, both positive and negative, after treatment

Synthetic vaginal tapes for stress incontinence

INFORMATION FOR PATIENTS

What does the procedure involve?
Vaginal tapes are implanted to treat stress incontinence. Stress incontinence is leakage of urine when you exercise or cough or sneeze.

The tape is placed under the urethra like a sling or hammock to support and keep the urethra in the correct position. The urethra is the tube that leaves the bladder, through which you pass urine.

Synthetic tapes are made out of a plastic material and the majority are made from a non-absorbable polypropylene mesh, which is usually well accepted by the body. This means that the tape will remain in the body forever.

The first tape of this kind was introduced 15 years ago and is called the TVT (**T**ension free **V**aginal **T**ape). Many other manufacturers now sell tapes similar to the TVT.

An alternative to the TVT is the TOT, which is the abbreviation for **T**rans **O**bturator **T**ape. This tape is introduced in a slightly different way to the TVT. The TOT operation has been carried out for the last 5 years in the UK.

The TVT and the TOT are now the most frequently performed operations for stress incontinence in the UK.

Both the TVT and the TOT are operations that are relatively quick, taking around 30 minutes to perform, either under a general anaesthetic or under local anaesthetic. These operations can be done as a day case, meaning that you go home on the same day.

The results of the TVT and TOT are roughly equal. About 2 out of 3 of women will be completely dry after the operation and 1 out of 3 will still have some degree of leakage. However most of those who still have some leakage are much better following surgery. The overall success can also be expressed as the satisfaction rate and approximately nine out of ten women are satisfied with the result after either a TVT or a TOT.

What are the alternatives to this procedure?

The previous most common operation that was done for stress incontinence was called the Burch colposuspension. However this is a much more invasive procedure and involves making a cut in the lower part of the abdomen, above the pubic bone, in order to support the neck of the bladder. Injection treatment is done sometimes and, although less invasive, is less likely to be successful than either the TVT or the TOT.

Other alternatives include observation, physiotherapy and usage of pads.

What should I expect before the procedure?

A pre-op visit will be arranged by the hospital to check on your fitness for anaesthesia and surgery, at which:

- Blood tests, heart tracing (ECG) and chest X-ray may be done to ensure that you are in optimal health.
- You may be given oral or vaginal oestrogen (hormone) if you are near or already menopausal. It is important to comply with this medication as it thickens your vaginal tissues for easier surgery and faster healing.
- All your medications and medical conditions, if any, must be made known to the doctor and must be optimally controlled.
- If you are on aspirin or other blood-thinning drugs, please let us know. You may have to stop taking it a week prior to the surgery.
- You will **be advised when and what you can eat and drink before surgery**
- You will probably be admitted on the same morning of surgery.
- You may be given preparation to clear your bowels.

What happens during the procedure?

The TVT / TOT continence surgery is usually done, either under local anaesthetic (when you will be awake), or general anaesthetic (when you will be asleep throughout the operation). You may discuss it with your surgeon and the anaesthetist.

The TVT operation involves two small incisions, each 0.5 cm long, on your lower abdomen below your pubic hairline and a 1.5 cm incision on the front wall of the vagina. The TVT tape is inserted from the vagina and then up to the small cuts in your abdomen. The tape lies between the vaginal skin and your urethra.

The TOT operation is similar to the TVT except that it is done by making a small cut at the top of each of your thighs, on the inner side of the thigh just below the groin. The tape is brought out through these incisions.

For both TVT and TOT, the tape is cut off level with the skin, so it is not sticking out at the end of the operation. A stitch will be used to close the cuts.

At the end of the surgery, a urinary catheter may be inserted into your bladder to allow free urine flow. A vaginal pack may be inserted as well.

What happens immediately after the procedure?

After the operation, you may experience:

- Nausea and occasional vomiting - You should rest and medication will be given to relieve these symptoms.
- Pain from the wound - This is usually mild and you will be given painkillers to use as required.

Post-operative care - You should rest and gradually increase your movement.

If you are given regional anaesthesia (e.g. an epidural anaesthetic which numbs the lower half of your body), a 6-hour period of rest is recommended before you are allowed to get out of bed. After that, you are encouraged to move around.
You will be allowed to drink and eat on the same day of operation.

The vaginal pack, if any, will be removed before you go home, or arrangements made to have it removed later.

If a urinary catheter is used, it will be removed later on the same day or, arrangements made to have it removed later.

You will be encouraged to pass urine on your own. The volume of the remaining urine may be measured.

Are there any side effects?

The TVT / TOT operation is generally a safe procedure. However, like all operations, complications may occur occasionally.

Common complications (greater than 1 in 10):

- Need to go to the toilet frequently due to a feeling of needing to rush to the bathroom (urgency) and sometimes with urine leakage due to urgency. Usually you will have had this before the operation too.
- Failure, so that you still have bad leakage. Some women will still have mild leakage.
- Inability to empty the bladder completely, so that you need either to keep a catheter in all the time, or you may have to use a catheter several times a day to empty the bladder (intermittent self catheterisation).
- Infection
- Slow urine flow
- Recurrence of stress incontinence may occur. This can happen years after the tape has been inserted which cured your symptoms.
- Pain, you will get some discomfort/pain for a while, usually where the skin was cut during the operation. TOT can cause thigh or groin pain. Simple analgesia relieve the pain in most cases, there are occasions when neuropathic analgesics may be required.

Occasional (between 1 in 10 and 1 in 50)

- Injury to the bladder during the TVT operation; the risk is much less for TOT surgery
- Misplacement of the tape: this should be discovered at operation and the tape repositioned correctly
- Bleeding
- Injury to surrounding tissues (e.g. bladder, rectum and blood vessels)
- Erosion of the tape into the bladder, urethra, or vagina. We know that this can occur years after the operation. The risk has been estimated to occur in 5 out of every hundred operations.
- The tape can migrate into the vagina, bladder or urethra. This can happen several years after the tape was inserted. Symptoms such as recurrent urinary infection, change in urinary symptoms, vaginal discharge and discomfort with intercourse may occur.

What should I expect when I get home?

You are advised:

- Not to drive for at least one week after surgery (you should be confident you could perform an emergency stop procedure)
- Not to douche your vagina or engage in sexual activity for a month after surgery.
- To avoid carrying heavy weights (of more than 5 kg) wherever possible for a month.
- To have at least two weeks off work after discharge, unless you and your surgeon agree something different. If you have any infection or other complications your recovery is likely to take longer.

- You should call or visit your GP or call the surgeon/department/ward that looked after you if you have the following symptoms:
    - Severe vaginal bleeding
    - Severe abdominal swelling or pain
    - Foul smelling discharge from the wound
    - High fever (temperature, which you should measure)
    - Pain when passing urine
    - Difficulty in passing urine
    - Pain or swelling of the calves

Are there any other important points?

1. Will you need to be seen in the hospital after the operation?

Different hospitals have different policies. Some hospitals like to see all their patients; usually 3 to 6 months after the operation, whilst others will arrange a routine telephone follow up at a similar time. All hospitals would want to see you if there were any problems or anything you were worried about.

Make sure you keep a record of the name of your consultant, the ward you were on, the dates of your operation and the telephone number of the hospital and the ward you were on.

2. Further Information

If you want further information then you could look up the documents listed below

- An article that summarises these discussions will be published in the journal European Urology
- Abrams P, et al. Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe. Eur Urol (2011)
- It is available on the European Urology website (external link)
- Further guidance on the use of incontinence tapes can be found on the NICE (National Institute for Health and Clinical Excellence) website: Urinary incontinence: the management of urinary incontinence in women (external link)
- NICE also provides advice for patients contemplating this procedure: Urinary incontinence: understanding NICE guidance (external link)
- The MHRA is still gathering information on the use and complications associated with these devices and would encourage reporting of adverse events to us. Reporting a safety problem with a device

The British Association of Urological Surgeons

35-43 Lincoln's Inn Fields
London
WC2A 3PE

Phone: +44 (0)20 7869 6950
Fax: +44 (0)20 7404 5048
Website: www.baus.org.uk
E-mail: admin@baus.org.uk

SYNTHETIC VAGINAL TAPES FOR STRESS INCONTINENCE

INFORMATION FOR PATIENTS

What evidence is this information based on?

This booklet includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and other sources. As such, it is a reflection of best urological practice in the UK. You should read this booklet with any advice your GP or other healthcare professional may already have given you. We have outlined alternative treatments below that you can discuss in more detail with your urologist or specialist nurse.

What does the procedure involve?

Vaginal tapes are implanted to treat **stress incontinence** (leakage of urine when you exercise, sneeze or strain). The tape is placed under the urethra (water pipe) like a hammock to support it and keep it in the correct position.

Synthetic tapes are made from a plastic material, mostly from a non-absorbable polypropylene mesh, which is usually well-accepted by the body. This means that the tape will remain in the body forever.

The first tape of this kind, introduced 15 years ago, is called the **tension-free vaginal tape** (TVT); many other manufacturers now sell similar tapes. An alternative to the TVT is the **trans-obturator tape** (TOT). The TOT operation has been carried out in the UK for the last 5 years. The TVT & TOT are now the most commonly performed operations for stress incontinence in the UK.

Both procedures are relatively quick, taking around 30 minutes to perform, either under general or local anaesthetic. The operations are usually performed as a day case, meaning that you can go home on the same day.

The results of TVT and TOT are roughly equal. About 2 out of 3 women will be completely dry after the operation and 1 out of 3 will have some degree of leakage. Most of those who still have some leakage are much better following surgery. The overall success can also be expressed as the *satisfaction rate*. Approximately 9 out of 10 women are satisfied with the result after either a TVT or a TOT.

What are the alternatives to this procedure?

The most common operation done for stress incontinence is called the **Burch colposuspension**. This is a more invasive procedure and involves making an cut in the lower abdomen to support the neck of the bladder. Injection treatment is done sometimes but is less likely to be successful than either TVT or TOT. Other alternatives to the procedure include observation, physiotherapy and usage of pads.

Questions for your surgeon

Here are some questions you should ask your surgeon, prior to surgery, if you are thinking of having a vaginal tape inserted for incontinence:

- Can you give me a full description of what the treatment involves?
- Is this type of treatment right for me?
- What are the different tapes available?
- What are the pros and cons of the different tapes?
- What are the alternative surgical or non-surgical treatments?
- What are the possible side-effects or adverse events associated with the treatment?
- What happens if this particular treatment does not work?
- Do you follow NICE guidelines for the use of tapes?
- Do you perform at least 20 of these procedures a year, as recommended by NICE?
- Have you (as the surgeon) looked at your results for the operation? and
- If so, what is the success rate and risk of complications?

What should I expect before the procedure?

A pre-operative visit will be arranged by the hospital to check on your fitness for anaesthesia and surgery, at which:

- You may have blood tests, a heart tracing (ECG) and a chest X-ray to check that you are in good health;
- You may be given oral or vaginal oestrogen (hormone) if you are near the menopause (or have already reached it). This thickens your vaginal tissues for easier surgery and faster healing;
- You must tell your surgeon about all the drugs you are taking;
- If you are taking warfarin, aspirin or clopidogrel, please let us know because you may have to stop taking them before surgery;
- We will advise you about starving before surgery;
- Culture swabs will be taken for MRSA.

You will usually be admitted to hospital on the same day as your surgery. Once you have been admitted, you will be seen by members of the medical team which may include the consultant, specialist registrar, house officer and your named nurse.

You will be given an injection of a drug called Clexane under your skin. Together with elasticated stockings provided by the ward, this will help to prevent venous thrombosis (clots in your legs). You may also be given a mild laxative to clear your bowels.

You may be given intravenous antibiotics at the time the anaesthetic is given, and possibly after surgery too.

You will be asked not to eat and drink for six hours before surgery. Immediately before the operation, the anaesthetist may give you a pre-medication which will make you dry-mouthed and pleasantly sleepy.

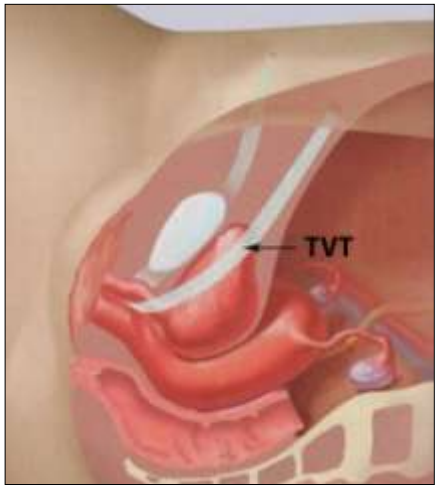
Please tell your surgeon (before your surgery) if you have any of the following:

- An artificial heart valve
- A coronary artery stent
- A heart pacemaker or defibrillator
- An artificial joint
- An artificial blood-vessel graft
- A neurosurgical shunt
- Any other implanted foreign body
- A regular prescription for warfarin, aspirin or clopidogrel (Plavix®)
- A previous or current MRSA infection
- A high risk of variant-CJD (if you have had a corneal transplant, a neurosurgical dural transplant or injections of human-derived growth hormone).

When you are admitted to hospital, you will be asked to sign the second part of your operation consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you want to go ahead. Make sure that you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.

What happens during the procedure?

TVT/TOT continence surgery is usually performed either under local anaesthetic (when you will be awake) or under general anaesthetic (when you are asleep). All methods reduce the leve of pain afterwards. Your anaesthetist will explain the pros and cons of each type of anaesthetic to you.



In the TVT operation (pictured) you will have two small cuts (each 0.5cm long) in the lower part of your tummy (below the pubic hairline) and a 1.5cm cut in the front wall of the vagina. The TVT tape is inserted from the vagina up to the small incisions in your tummy. The tape lies between the vaginal skin and your urethra (water pipe).

The TOT operation is similar except that a small incision at the top of each of your thighs, on the inner side, just below the groin and the tape is brought out through these incisions.

For both procedures, the tape is cut off level with the skin and “buried” under the skin with a stitch to close the incisions.

At the end of the procedure, a bladder catheter may be put in to allow free urine flow and a vaginal pack is often used.

What happens immediately after the procedure?

You should be told how the procedure went and you should:

- ask the surgeon if it went as planned;
- let the medical staff know if you are in any discomfort;
- ask what you can and cannot do;
- feel free to ask any questions or discuss any concerns with the ward staff and members of the surgical team; and
- make sure that you are clear about what has been done and what happens next.

You may experience sickness and occasional vomiting but we will give you drugs to relieve these symptoms. Pain from the wound is usually mild and you will be given painkillers to use as required.

If you have had a spinal anaesthetic, a six-hour period of rest is recommended before you can get out of bed; after that, we will encourage you to move around. You will be allowed to eat and drink on the same day as the operation.

Your vaginal pack, if oput in, will be removed before you go home (or arrangements made to have it removed later). If you have had a bladder catheter, we usually remove it the same day as the operation but arrangements may be made for you to have it removed later. You will be encouraged to pass urine on your own and we will measure how well you empty your bladder.

The average hospital stay is one day.

Are there any side-effects?

Most procedures have possible side-effects. But, although the complications listed below are well-recognised, most patients do not suffer any problems.

Common (greater than 1 in 10)

- Need to go to the toilet frequently, due to a feeling of having to rush to the bathroom (urgency) and, sometimes, with urine leakage due to urgency; you will have had this before the operation.
- Failure, so that you still have bad leakage. Some women still have mild leakage.
- Inability to empty the bladder completely so that you need either to keep a catheter in all the time or insert a catheter several times a day (intermittent self-catheterisation).
- Infection.
- Slow urine flow.
- Recurrence of stress incontinence can happen years after the tape has been inserted, even your symptoms were cured at first.
- You will get some discomfort/pain for a while, usually where the skin was cut during the operation. TOT can cause thigh or groin pain but this can be

relieved by simple painkillers in most patients. There are occasions when more powerful painkillers may be needed.

Occasional (between 1 in 10 and 1 in 50)

- Injury to the bladder during the TVT operation; the risk is much less for TOT surgery.
- Misplacement of the tape (which should be discovered at the time of surgery and the tape re-positioned).
- Bleeding.
- Injury to surrounding tissues (e.g. bladder, rectum and blood vessels).
- Erosion of the tape into the vagina, bladder or urethra; we know that this can occur years after the operation. The estimated risk is in 5 out of every 100 operations .
- Migration of the tape into the vagina, bladder or urethra which can happen several years after the tape was inserted. Symptoms such as recurrent urinary infection, change in urinary symptoms, vaginal discharge and discomfort during intercourse may occur.

Rare (less than 1 in 50)

- None.

Hospital-acquired infection

- Colonisation with MRSA (0.9% - 1 in 110).
- MRSA bloodstream infection (0.02% - 1 in 5000).
- Clostridium difficile bowel infection (0.01% - 1 in 10,000).

The rates for hospital-acquired infection may be greater in high-risk patients, for example those patients

- with long-term drainage tubes;
- who have had their bladder removed due to cancer;
- who have had a long stay in hospital; or
- who have been admitted to hospital many times.

What should I expect when I get home?

When you are discharged from hospital, you should:

- be given advice about your recovery at home;
- ask when you can begin normal activities again, such as work, exercise, driving, housework and sex;
- ask for a contact number if you have any concerns once you return home;
- ask when your follow-up will be and who will do this (the hospital or your GP); and
- be sure that you know when you get the results of any tests done on tissues or organs that have been removed.

When you leave hospital, you will be given a “draft” discharge summary. This contains important information about your stay in hospital and your operation. If you need to call your GP or if you need to go to another hospital, please take this summary with you so the staff can see the details of your treatment. This is

important if you need to consult another doctor within a few days of being discharged.

You may require pain-killing tablets at home for several days and it may take a week or more at home to become comfortably mobile.

You are advised:

- Not to drive for at least one week after surgery (you should be confident that you can perform an emergency stop);
- Not to douche your vagina or have sex for at least a month after surgery;
- Not to carry weights of more than 5kg for a month; and
- To take at least two weeks off work after, unless you and your surgeon agree something different. If you have an infection or other complications(s), your recovery is likely to take longer.

What else should I look out for?

You should seek help from your doctor or your surgeon if you experience:

- Severe vaginal bleeding;
- Severe abdominal pain or swelling;
- Foul-smelling discharge from the wound;
- High fever (you should take your temperature if you suspect this);
- Pain on passing urine;
- Difficulty passing urine; or
- Pain or swelling of the calves.

Are there any other important points?

Different hospitals have different policies for reviewing women after sling surgery. Some like to see all their patients three to six months after the operation; others simply arrange telephone follow-up. All hospitals, however, would wish to see you again if you have any problems or there is anything you are worried about.

Make sure you keep a record of the name of your consultant, the ward you were on, the date of your operation, the telephone number of the hospital and the ward you were on.

If you would like further information, please use the links below to look up the documents listed:

Abrams P, Chapple CR, Drake M, El-Neil S, Ludgate S, Smith ARB. Synthetic vaginal tapes for stress incontinence: proposals for improved regulation of new devices in Europe. European Urology (2011); 60(6): 1207 - 1211. (**N.B.** *Only accessible to those with a user login to the journal*).

Further guidance of the use of incontinence tapes on the National Institute for Health and Clinical Excellence (NICE) website. http://guidance.nice.org.uk/CG40.

The MHRA is still gathering information about the use and complications of these devices and would encourage careful reporting of any adverse events.
http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.htm.

Driving after surgery

It is your responsibility to make sure you are fit to drive following your surgery. You do not normally need to tell the DVLA that you have had surgery, unless you have a medical condition that will last for longer than three months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to give you advice on this.

Is any research being carried out in this area?

Before your operation, your surgeon or specialist nurse will tell you about any relevant research studies taking place. In particular, they will tell you if any tissue that is removed during your surgery will be stored for future study. If you agree to this research, you will be asked to sign a special form giving your consent.

All surgical procedures, even those not currently undergoing research, are audited so that we can analyse our results and compare them with those of other surgeons. In this way, we learn how to improve our techniques and results; this means that our patients will then get the best treatment available.

What should I do with this information?

Thank you for taking the trouble to read this booklet. If you want to keep a copy for your own records, please sign below. If you would like a copy of this booklet filed in your hospital records for future reference, please let your urologist or specialist nurse know. However, if you do agree to go ahead with the scheduled procedure, you will be asked to sign a separate consent form that will be filed in your hospital records; we can give you a copy of this consent form if you ask.

I have read this booklet and I accept the information it provides.

Signature..... Date.....

How can I get information in alternative formats?

Please ask your local NHS Trust or PALS network if you require this information in other languages, large print, Braille or audio format.

Most hospitals are smoke-free. Smoking can make some urological conditions worse and increases the risk of complications after surgery. For advice on stopping, contact your GP or the free **NHS Smoking Helpline** on **0800 169 0 169**

Disclaimer

While we have made every effort to be sure the information in this booklet is accurate, we cannot guarantee there are no errors or omissions. We cannot accept responsibility for any loss resulting from something that anyone has, or has not, done as a result of the information in this booklet.

The NHS Constitution
Patients' Rights & Responsibilities

Following extensive discussions with staff and the public, the NHS Constitution has set out new rights for patients that will help improve your experience within the NHS. These rights include:

- a right to choice and a right to information that will help you make that choice;
- a right to drugs and treatments approved by NICE when it is considered clinically appropriate;
- a right to certain services such as an NHS dentist and access to recommended vaccinations;
- the right that any official complaint will be properly and efficiently investigated, and that patients will be told the outcome of the investigations; and
- the right to compensation and an apology if you have been harmed by poor treatment.

The constitution also lists patients' responsibilities, including:

- providing accurate information about their health;
- taking positive action to keep yourself and your family healthy.
- trying to keep appointments;
- treating NHS staff and other patients with respect;
- following the course of treatment that you are given; and
- giving feedback (both positive and negative) after treatment.

Published: March 2014
Due for review: March 2015

The British Association of Urological Surgeons

35-43 Lincoln's Inn Fields
London
WC2A 3PE

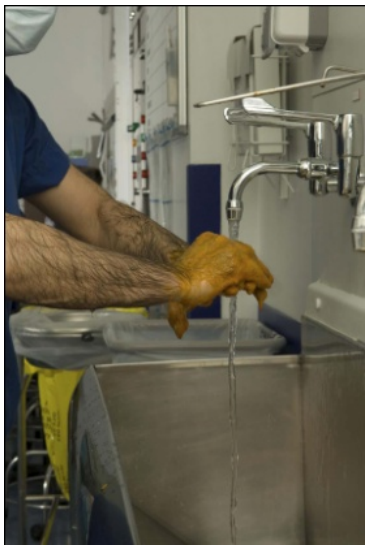
Phone: +44 (0)20 7869 6950
Fax: +44 (0)20 7404 5048
Website: www.baus.org.uk
E-mail: admin@baus.org.uk

SYNTHETIC VAGINAL TAPES FOR STRESS INCONTINENCE

INFORMATION FOR PATIENTS

What evidence is this information based on?

This booklet includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and other sources. As such, it is a reflection of best urological practice in the UK. You should read this booklet with any advice your GP or other healthcare professional may already have given you. We have outlined alternative treatments below that you can discuss in more detail with your urologist or specialist nurse.



What does the procedure involve?

Vaginal tapes are implanted to treat **stress incontinence** (leakage of urine when you exercise, sneeze or strain). The tape is placed under the urethra (water pipe) like a hammock to support it and keep it in the correct position.

Synthetic tapes are made from a plastic material, mostly from a non-absorbable polypropylene mesh, which is usually well-accepted by the body. This means that the tape will remain in the body forever.

The first tape of this kind, introduced 15 years ago, is called the **tension-free vaginal tape** (TVT); many manufacturers now sell similar tapes. An alternative to the TVT is the **trans-obturator tape** (TOT). The TOT operation has been carried out in the UK for the last 5 years. The TVT & TOT are now the most commonly performed operations for stress incontinence in the UK.

Both procedures are relatively quick, taking around 30 minutes to perform, either under general or local anaesthetic. The operations are usually performed as a day case, meaning that you can go home on the same day.

The results of TVT and TOT are roughly equal. About 2 out of 3 women will be completely dry after the operation and 1 out of 3 will have some degree of leakage. Most of those who still have some leakage are much better following surgery.

The overall success can also be expressed as the **satisfaction rate**. Approximately 9 out of 10 women are satisfied with the result after either a TVT or a TOT.

What are the alternatives to this procedure?

The most common operation done for stress incontinence is called the **Burch colposuspension**. This is a more invasive procedure and involves making a cut in the lower abdomen to support the neck of the bladder. Injection treatment is sometimes done but is less likely to be successful than either TVT or TOT. Other alternatives to the procedure include observation, physiotherapy and usage of pads.

Questions for your surgeon

Here are some questions you should ask your surgeon, prior to surgery, if you are thinking of having a vaginal tape inserted for incontinence:

- Can you give me a full description of what the treatment involves?
- Is this type of treatment right for me?
- What are the different tapes available?
- What are the pros and cons of the different tapes?
- What are the alternative surgical or non-surgical treatments?
- What are the possible side-effects or adverse events associated with the treatment?
- What happens if this particular treatment does not work?
- Do you follow NICE guidelines for the use of tapes?
- Do you perform at least 20 of these procedures a year, as recommended by NICE?
- Have you (as the surgeon) looked at your results for the operation? and
- If so, what is the success rate and risk of complications?

What should I expect before the procedure?

A pre-operative visit will be arranged by the hospital to check on your fitness for anaesthesia and surgery, at which:

- You may have blood tests, a heart tracing (ECG) and a chest X-ray to check that you are in good health;
- You may be given oral or vaginal oestrogen (hormone) if you are near the menopause (or have already reached it). This thickens your vaginal tissues for easier surgery and faster healing;
- You must tell your surgeon about all the drugs you are taking;
- If you are taking warfarin, aspirin or clopidogrel, please let us know because you may have to stop taking them before surgery;
- We will advise you about starving before surgery;
- Culture swabs will be taken for MRSA.

You will usually be admitted to hospital on the same day as your surgery. Once you have been admitted, you will be seen by members of the medical team which may include the consultant, specialist registrar, house officer and your named nurse.

You will be given an injection of a drug called Clexane under your skin. Together with elasticated stockings provided by the ward, this will help to prevent venous thrombosis (clots in your legs). You may also be given a mild laxative to clear your bowels.

You may be given intravenous antibiotics at the time the anaesthetic is given, and possibly after surgery too.

You will be asked not to eat and drink for six hours before surgery. Immediately before the operation, the anaesthetist may give you a pre-medication which will make you dry-mouthed and pleasantly sleepy.

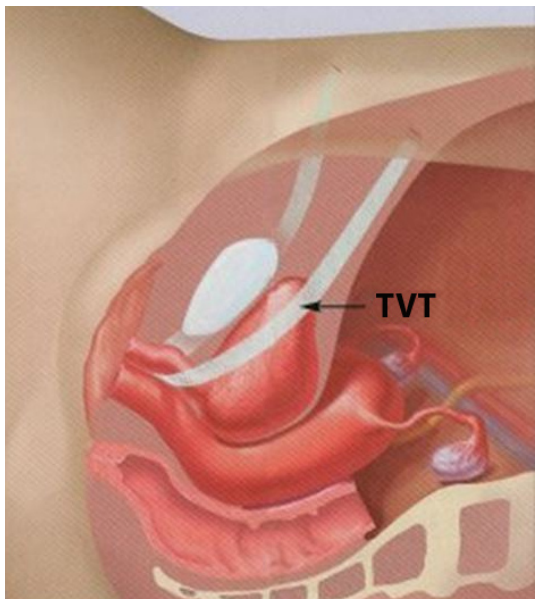
Please tell your surgeon (before your surgery) if you have any of the following:

- An artificial heart valve
- A coronary artery stent
- A heart pacemaker or defibrillator
- An artificial joint
- An artificial blood-vessel graft
- A neurosurgical shunt
- Any other implanted foreign body
- A regular prescription for a blood thinning agent such as warfarin, aspirin, clopidogrel (Plavix®), rivaroxaban, prasugrel or dabigatran
- A previous or current MRSA infection
- A high risk of variant-CJD (if you have had a corneal transplant, a neurosurgical dural transplant or injections of human-derived growth hormone).

When you are admitted to hospital, you will be asked to sign the second part of your operation consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you want to go ahead. Make sure that you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.

What happens during the procedure?

TVT/TOT continence surgery is usually performed either under local anaesthetic (when you will be awake) or under general anaesthetic (when you are asleep). All methods reduce the leve of pain afterwards. Your anaesthetist will explain the pros and cons of each type of anaesthetic to you.



In the TVT operation (pictured) you will have two small cuts (each 0.5cm long) in the lower part of your tummy (below the pubic hairline) and a 1.5cm cut in the front wall of the vagina. The TVT tape is inserted from the vagina up to the small incisions in your tummy. The tape lies between the vaginal skin and your urethra (water pipe).

The TOT operation is similar except that a small incision at the top of each of your thighs, on the inner side, just below the groin and the tape is brought out through these incisions.

For both procedures, the tape is cut off level with the skin and "buried" under the skin with a stitch to close the incisions.

At the end of the procedure, a bladder catheter may be put in to allow free urine flow and a vaginal pack is often used.

What happens immediately after the procedure?

You should be told how the procedure went and you should:

- ask the surgeon if it went as planned;
- let the medical staff know if you are in any discomfort;
- ask what you can and cannot do;
- feel free to ask any questions or discuss any concerns with the ward staff and members of the surgical team; and
- make sure that you are clear about what has been done and what happens next.

You may experience sickness and occasional vomiting but we will give you drugs to relieve these symptoms. Pain from the wound is usually mild and you will be given painkillers to use as required.

If you have had a spinal anaesthetic, a six-hour period of rest is recommended before you can get out of bed; after that, we will encourage you to move around. You will be allowed to eat and drink on the same day as the operation.

Your vaginal pack, if oput in, will be removed before you go home (or arrangements made to have it removed later). If you have had a bladder catheter, we usually remove it the same day as the operation but arrangements may be made for you to have it removed later. You will be encouraged to pass urine on your own and we will measure how well you empty your bladder.

The average hospital stay is one day.

Are there any side-effects?

Most procedures have possible side-effects. But, although the complications listed below are well-recognised, most patients do not suffer any problems.

Common (greater than 1 in 10)

- Need to go to the toilet frequently, due to a feeling of having to rush to the bathroom (urgency) and, sometimes, with urine leakage due to urgency, especially if you had this before the operation.
- Failure, so that you still have bad leakage. Some women still have mild leakage.
- Inability to empty the bladder completely so that you need either to keep a catheter in all the time or insert a catheter several times a day (intermittent self-catheterisation).
- Infection.

- Slow urine flow.
- Recurrence of stress incontinence can happen years after the tape has been inserted, even your symptoms were cured at first.
- You will get some discomfort/pain for a while, usually where the skin was cut during the operation. TOT can cause thigh or groin pain but this can be relieved by simple painkillers in most patients. There are occasions when more powerful painkillers may be needed.

Occasional (between 1 in 10 and 1 in 50)

- Injury to the bladder during the TVT operation; the risk is much less for TOT surgery.
- Misplacement of the tape (which should be discovered at the time of surgery and the tape re-positioned).
- Bleeding.
- Injury to surrounding tissues (e.g. bladder, rectum and blood vessels).
- Erosion of the tape into the vagina, bladder or urethra; we know that this can occur years after the operation. The estimated risk is in 5 out of every 100 operations.
- Migration of the tape into the vagina, bladder or urethra which can happen several years after the tape was inserted. Symptoms such as recurrent urinary infection, change in urinary symptoms, vaginal discharge and discomfort during intercourse may occur.

Rare (less than 1 in 50)

- None.

Hospital-acquired infection

- Colonisation with MRSA (0.9% - 1 in 110).
- MRSA bloodstream infection (0.02% - 1 in 5000).
- Clostridium difficile bowel infection (0.01% - 1 in 10,000).

Please note: The rates for hospital-acquired infection may be greater in "high-risk" patients. This group includes, for example, patients with long-term drainage tubes, patients who have had their bladder removed due to cancer, patients who have had a long stay in hospital or patients who have been admitted to hospital many times.

What should I expect when I get home?

When you are discharged from hospital, you should:

- be given advice about your recovery at home;
- ask when you can begin normal activities again, such as work, exercise, driving, housework and sex;
- ask for a contact number if you have any concerns once you return home;
- ask when your follow-up will be and who will do this (the hospital or your GP); and
- be sure that you know when you get the results of any tests done on tissues or organs that have been removed.

When you leave hospital, you will be given a "draft" discharge summary. This contains important information about your stay in hospital and your operation. If you need to call your GP or if you need to go to another hospital, please take this summary with you so the staff can see the details of your treatment. This is important if you need to consult another doctor within a few days of being discharged.

You may require pain-killing tablets at home for several days and it may take a week or more at home to become comfortably mobile.

You are advised:

- Not to drive for at least one week after surgery (you should be confident that you can perform an emergency stop);
- Not to douche your vagina or have sex for at least a month after surgery;
- Not to carry weights of more than 5kg for a month; and
- To take at least two weeks off work after, unless you and your surgeon agree something different. If you have an infection or other complications(s), your recovery is likely to take longer.

What else should I look out for?

You should seek help from your doctor or your surgeon if you experience:

- Severe vaginal bleeding;
- Severe abdominal pain or swelling;
- Foul-smelling discharge from the wound;
- High fever (you should take your temperature if you suspect this);
- Pain on passing urine;
- Difficulty passing urine; or
- Pain or swelling of the calves.

Are there any other important points?

Different hospitals have different policies for reviewing women after sling surgery. Some like to see all their patients three to six months after the operation; others simply arrange telephone follow-up. All hospitals, however, would wish to see you again if you have any problems or there is anything you are worried about.

Make sure you keep a record of the name of your consultant, the ward you were on, the date of your operation, the telephone number of the hospital and the ward you were on.

If you would like further information, please use the links below to look up the documents listed:

Abrams P, Chapple CR, Drake M, El-Neil S, Ludgate S, Smith ARB. Synthetic vaginal tapes for stress incontinence: proposals for improved regulation of new devices in Europe. European Urology (2011); 60(6): 1207 - 1211. (**N.B.** *Only accessible to those with a user login to the journal*).

Further guidance of the use of incontinence tapes on the National Institute for Health and Clinical Excellence (NICE) website.
http://guidance.nice.org.uk/CG40.

The MHRA is still gathering information about the use and complications of these devices and would encourage careful reporting of any adverse events.
http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.htm.

Driving after surgery

It is your responsibility to make sure you are fit to drive following your surgery. You do not normally need to tell the DVLA that you have had surgery, unless you have a medical condition that will last for longer than three months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to give you advice on this.

Is any research being carried out in this area?

Before your operation, your surgeon or specialist nurse will tell you about any relevant research studies taking place. In particular, they will tell you if any tissue that is removed during your surgery will be stored for future study. If you agree to this research, you will be asked to sign a special form giving your consent.

All surgical procedures, even those not currently undergoing research, are audited so that we can analyse our results and compare them with those of other surgeons. In this way, we learn how to improve our techniques and results; this means that our patients will then get the best treatment available.

What should I do with this information?

Thank you for taking the trouble to read this booklet. If you want to keep a copy for your own records, please sign below. If you would like a copy of this booklet filed in your hospital records for future reference, please let your urologist or specialist nurse know. However, if you do agree to go ahead with the scheduled procedure, you will be asked to sign a separate consent form that will be filed in your hospital records; we can give you a copy of this consent form if you ask.

I have read this booklet and I accept the information it provides.

Signature..... Date.....

How can I get information in alternative formats?

Please ask your local NHS Trust or PALS network if you require this information in other languages, large print, Braille or audio format.

Most hospitals are smoke-free. Smoking can make some urological conditions worse and increases the risk of complications after surgery. For advice on stopping, contact your GP or the free **NHS Smoking Helpline** on **0800 169 0 169**

Disclaimer

While we have made every effort to be sure the information in this booklet is accurate, we cannot guarantee there are no errors or omissions. We cannot accept responsibility for any loss resulting from something that anyone has, or has not, done as a result of the information in this booklet.

The NHS Constitution
Patients' Rights & Responsibilities

Following extensive discussions with staff and the public, the NHS Constitution has set out new rights for patients that will help improve your experience within the NHS. These rights include:

- a right to choice and a right to information that will help you make that choice;
- a right to drugs and treatments approved by NICE when it is considered clinically appropriate;
- a right to certain services such as an NHS dentist and access to recommended vaccinations;
- the right that any official complaint will be properly and efficiently investigated, and that patients will be told the outcome of the investigations; and
- the right to compensation and an apology if you have been harmed by poor treatment.

The constitution also lists patients' responsibilities, including:

- providing accurate information about their health;
- taking positive action to keep yourself and your family healthy.
- trying to keep appointments;
- treating NHS staff and other patients with respect;
- following the course of treatment that you are given; and
- giving feedback (both positive and negative) after treatment.

Published: March 2016. **Due for review:** March 2018

Appendix 3

BAUS timeline re mesh

2 December 2003	Letter to Section members from Paul Abrams, Chairman, reporting on meeting with NICE and MHRA to discuss BAUS's concerns about devices being marketed before an adequate body of clinical evidence of efficacy and the consequent risks to patient safety. (Attached)
February 2004	Good clinical practice for new procedures letter sent to section members. Copy attached.
19 March 2004	Members of BAUS SFRU exec and BSUG met in Bournemouth. Records of the meeting indicate that the problem of new devices / procedures being introduced with little or no supporting evidence was discussed. Attached minutes of the meeting and Malcolm Lucas's notes of the meeting.
January 2005	Section commenting on draft scope of NICE urinary incontinence guidelines.
July 2005	Section Exec Committee minutes "NICE Guidelines – There will be a formal reappraisal of all synthetic slings. Current advice on techniques other than TVT was that the procedure should be performed within the constraints of clinical governance. Urologists should follow the good practice guidelines on the SFRU website when undertaking new procedures. "
13 February 2006	Good Practice Guidelines for Urogynaecological and Female Pelvic Reconstructive surgery with particular reference to the introduction of new procedures by BAUS SFRU and BSUG. Copy attached
October 2006	NICE Guideline issued
July 2007	BAUS SFRU & BSUG guidance on implementation of NICE Guideline issued.
October 2010	Section Exec Committee minutes record: "[redacted] reported that [redacted], clinical director of MHRA, had written to him expressing concerns relating to tape surgery. He said they were convening a meeting, chaired by [redacted] and including [redacted] and [redacted], to look at the issues." No further information or notes of such a meeting in BAUS records.
June 2011	BAUS response to consultation on urinary incontinence update: "Women with persistent or recurrent SUI and women with tape complications should be treated in a specialist centre that sees an adequate number of complex cases to ensure that patients are treated effectively."

Appendix 3

BAUS timeline re mesh

March 2012	Section Executive committee minutes record: **MHRA request for notice to membership re. vaginal slings** Chris Chapple outlined his recent discussions with the MHRA, where concerns had been raised about tape erosion. Members agreed that collecting data on this would be relevant at this time as there was not good data available on long term erosion rates. Unless there was a registry of all implants and data entry was mandatory, then it was impossible to get good base line data. Any registry would have to be financed, it was noted the national hip register was financed by the inclusion of a charge for the national registry being added to the tariff for all hip implants. It was thought a similar system should apply for all implants.

	Discussions about implant registries would be taken forward with MHRA."
20 September 2012	Letter from Adrian Joyce, then President of BAUS, to Professor Sir Bruce Keogh regarding patient complications relating to the use of mesh implants for prolapse and incontinence surgery (attached).

Appendix 3

BAUS timeline re mesh

November 2012	Section Executive minutes record: **Slings and complications of mid-urethral tapes data** It was reported that this had been launched at BAUS 2012 following some changes to the dataset. There had been 63 returns from 13 centres, but it was noted only 50% had completed the Quality of Life form from patients. As revalidation comes on stream people would be required to enter data in compliance with audits for revalidation." BAUS audit of SUI launched in June 2012, BAUS members advised that data collected in 2014 would be published in 2015 as part of the consultants' outcome project. In November 2012 DH published a press notice to coincide with the publication of the York report in which they announced The Department of Health, the NHS Commissioning Board, NHS surgeons (urologists and gynaecologists), and the Medicines and Healthcare products Regulatory Agency (MHRA) were taking action to help reduce the side effects after surgery using vaginal tape for stress incontinence and vaginal meshes for pelvic organ prolapse. They included an outline action plan to address the issues raised by the report. The key elements were: • To develop proposals for a single registry of vaginal implants, building on the existing registries maintained by the professional associations; • To develop and issue professional guidance for surgery using vaginal meshes, complementing existing NICE guidance, on aspects such as selection of patients, choice of device, and processes for informed patient consent; • To develop and issue guidance to commissioners to enable them to commission services from providers which maintain high standards of training and clinical audit; • To develop and issue professional guidance on those centres competent to carry out surgery for women with recurrent problems from incontinence or prolapse, or women needing further surgery as a result of complications. There had been a rush to pull this together but following publication BAUS heard nothing further from NHS England until it received an email on 5 August 2013 inviting BAUS to take part in a teleconference on 24 September 2013. The teleconference on 24 September was chaired by Catherine Calderwood, then National Clinical Director, Maternity and Women's Health, it was agreed there needed to be further discussion
	with the professional societies regarding databases. BAUS never received any notes of the teleconference. This was subsequently overtaken by the Willett's review.

Appendix 3

BAUS timeline re mesh

December 2013	Letter from Bruce Keogh sent to the Health Service, BAUS President was a cosignatory. BAUS drew this to the attention of all members, updated information on website and included link to MHRA. Although this letter refers to centres for removal of mesh which are recognized by Commissioners or via Specialised Commissioning processes, it would be fair to say that these processes are still in development in 2018. Following this letter BAUS wrote to members inviting centres to self-nominate and subsequently published a list of centres, jointly with BSUG, each organisation included the list on it's website, see: https://www.baus.org.uk/patients/sui_mesh_complications.aspx
4 June 2014	BAUS invited to join NHS England working group chaired by Professor Keith Willett. It is assumed the Independent Medicines & Medical Safety Review have access to the subsequent reports produced by the Working Group, although links are included on the web page referred to above.

BAUS
Section of
Female
Urology

The British Association of Urological Surgeons
Section of Female and Reconstructive Urology

35-43 Lincoln's Inn Fields
London WC2A 3PE
Telephone: 020 7869 6850 Facsimile: 020 7404 5048
Email: femaleurology@baus.org.uk

2 December 2003

Dear Friends

Meeting between the National Institute for Clinical Excellence (NICE), the Medicines and Healthcare products Regulatory Agency (MHRA) and the BAUS Section of Female and Reconstructive Urology

Malcolm Lucas, Roland Morley, Mark Speakman and myself met [redacted] and [redacted] from NICE and Susanne Ludgate MHRA, (a recent merger between the Medical Devices Agency and the Medicine Controls Agency) on Thursday 16th October 2003. We are grateful to them for agreeing to meet us to hear our concerns.

We discussed the problem of new devices being marketed before an adequate body of clinical evidence of efficacy and the consequent risks to patient safety. Dr Ludgate sketched out the process by which new devices are licensed, obtain a CE marking and become, therefore, freely available on the European Market. In the EU, unlike drugs which are licensed by a government regulatory agency, devices have their CE mark checked by one of a number of Notified bodies, of which there are 9 in the UK and over 60 in the EU.

These are commercial organisations, the relevant Notified Body carries out a conformity assessment procedure in order to allow the CE marking to be affixed. This means that the Notified Body checks that the manufacturer has demonstrated compliance with all the relevant essential requirements, in essence has demonstrated that the device performs as claimed, will not compromise the clinical condition or safety of the patient and that any risks which may be associated with the use of the device constitute acceptable risks when weighed against the benefits to the patient. For many devices, particularly those of high risk, compliance with the relevant essential requirements can only be demonstrated by clinical data.

This clinical data can be generated in one of three ways, namely by a compilation and analysis of existing scientific data currently available on the device in question; a compilation of the literature on an equivalent CE marked device, where equivalence can be demonstrated in all relevant areas including design, critical performance, conditions of use, principles of operation, biological safety; or if compliance cannot be adequately demonstrated by either of these, data generated from a specifically designed clinical investigation will be required. Such a clinical investigation must be authorized by the Competent Authority.

It should be noted that the Regulations require performance and not efficacy to be demonstrated (Dr Ludgate has written a paper on this topic for the European Commission). MEDDEV 2.7 (04-2003, link: http:/europa.eu.int/comm./enterprise/medical_devices/guidelines/baseguidelines.htm)

Points from the meeting:

Changing the process? We feel that the process has significant shortcomings and should be changed. Paul Abrams is in contact with his MP who is a member of the Select Committee on Health and will write again to him

Protecting patients – a number of steps are likely to help:

1 Our registry of trials (Co-ordinator: Roland Morley)

2. Our National audit of incontinence procedures (Co-ordinator: Malcolm Lucas). We are hoping that this will become a collaborative project with the British Society of Urogynaecology.

3. Writing to urologists and gynaecologists expressing our believe that no device should be used unless there is adewquate evidence of efficacy for that device and requesting such evidence from manufacturers.

4. Writing to companies offering to take part in good quality clinical trials

5. Informing MHRA of adverse events

6. Asking the NICE Interventional Procedures Advisory Committee (IPAC) to evaluate certain procedures. We plan to ask them to evaluate:

    - Transobdurator fossa procedures for stress urinary incontinence
    - Intramural urethral bulking for stress urinary incontinence
    - Adjustable intramural urethral implants for stress urinary incontinence
    - Allograph/xenograph slings for stress urinary incontinence

Please let me have any thoughts you have on these matters

With best wishes

Professor Paul Abrams
Chairman
BAUS Section of Female and Reconstructive Urology

BAUS
Section of
Female
Urology

The British Association of Urological Surgeons
Section of Female and Reconstructive Urology

35-43 Lincoln's Inn Fields
London WC2A 3PE
Telephone: 020 7869 6950 Facsimile: 020 7404 5048
Email: femaleurology@baus.org.uk

24 February 2004

Dear Member

New techniques and devices for urinary incontinence

As you know, the Section of Female and Reconstructive Urology has been concerned about the proliferation of new techniques and devices for the treatment of urinary incontinence and pelvic floor defects, often with little data to support their use.

The European CE mark constitutes no more than recognition that the product is "fit for purpose" and it is possible for products to become registered with no clinical data at all, simply by claiming equivalence to other notified devices. For us to bring about a change in the system of notification is unlikely because it is a European standard. Neither can clinical practice be regulated by a body like BAUS - which has no statutory authority.

We propose, however, that members of SFRU should adhere to a "Code of Good Practice", the draft content of which appears below. This matter will be discussed at the forthcoming AGM of the Section and your views are invited either then or in advance by email either to: [redacted] or myself at [redacted].

With best wishes

Yours sincerely

Malcolm Lucas

BAUS
Section of
Female
Urology

The British Association of Urological Surgeons
Section of Female and Reconstructive Urology

35-43 Lincoln's Inn Fields
London WC2A 3PE
Telephone: 020 7869 6950 Facsimile: 020 7404 5318
Email: femaleurology@baus.org.uk

Proposed Code of Good Practice for SFRU Members

1. Surgeons should participate in national audit and submit data on all continence and pelvic floor procedures that they carry out.

2. If a surgeon undertakes any new class of procedure for which he / she does not have appropriate training then he / she should seek formal training through a process of mentoring.

3. When undertaking new procedures surgeons must notify their trust's clinical governance committee.

4. When utilising new materials or devices in previously established procedures the trust's clinical governance committee should be informed.

5. Any intention to undertake a formal evaluation of a new technique should be registered with the clinical trials database at SFRU.

6. Formal evaluations involving new procedures should receive appropriate local ethical approval.

7. Companies promoting new procedures or devices should be directed to the SFRU to liase with potential "trialists" before a surgeon agrees to participate in a company driven evaluation.

8. A surgeon who encounters a serious adverse event related to the use of a device or implant in the treatment of incontinence should notify the MHRA through its SAE reporting process.

9. New procedures / classes of procedure should be notified to IPAC (NICE) through the NICE website.

February 2004

Female Urology/Executive Committee/Joint Meetings with BSUG

Joint Committee meeting BSUG/BAUS
19th March 2004, (Bournemouth)

Present

[redacted]

Apologies received from [redacted]

1. **New technologies**
BAUS have met with NICE and MHRA to discuss regulation of new procedures. NICE have stated that they're unable to alter the European law on registration. BAUS have written to its members recommending a code of practice (appended below).

This 'code of practice' will be sent to the BSUG membership and discussed at the AGM in July. BAUS are meeting with its membership in April.

The aim was not to 'stifle' practice or new procedures, but to ensure adequate and appropriate regulation.

BAUS (via [redacted]) will contact all commercial companies requesting them to liaise with Specialist Societies to fund proper evaluation of the new procedure e.g. that BAUS and BSUG design and perform the clinical trials. This will be discussed further. Already American Medical Systems and Q-Med have expressed an interest with regards to transobturator tape and Zuidex bulking agent.

2. **Audit database**
BAUS have developed a database similar to that for Urological Oncology. The aim is to use the data to develop clinical trials. In particular BAUS wish to know 'who is doing what, where and on whom'. Outcomes are being assessed at this stage.

It was agreed that a copy of this database would be obtained from the BAUS website for BSUG. BAUS have managed to ensure that identity of the surgeon remains anonymous. It was agreed that [redacted] would work with BAUS on this issue.

It was hoped that there could be one uniform database on Urinary Incontinence with separate fields for Prolapse, Urological Procedures etc. Where possible, uniformity could be obtained in pre-Op Assessment, urodynamics and surgical procedure.

Notes on meeting between BAUS Section of Female and Reconstructive Urology and British Society of Urogynaecologists, Bournemouth International Convention Centre, Friday 19th March 2004.

Present

[redacted]

Apologies received from [redacted]

Introduction of new devices	Action
The problem of new devices / procedures being introduced with little or no supporting evidence was discussed. SFRU have met with MHRA and NICE and it is clear there is nothing that we can do to alter European law on registration. A provisional code of conduct has been circulated to SFRU members to be discussed at next AGM. BSUG agreed to circulate to their members too with the aim of introducing this as a joint code after discussion at their meeting in ?July. Simon Harrison has written a letter to companies exhorting them to work with SFRU to develop the evidence base for new procedures – preferably by setting up appropriate RCTs. The logistical limitations of this were acknowledged. BSUG are keen to make this a joint letter. The draft will be circulated (through [redacted] and [redacted]@rcog.org.uk) to their committee and agreed format then sent out by [redacted]@baus.org.uk Two companies have already expressed an interest in supporting RCTs. QMed and AMS. The former would compare Zuidex with another bulking	[redacted] [redacted]

product. AMS are interested in an RCT to compare Sparc with Monarc and have asked SFRU and BSUG to provide list of potential collaborators. MGL to write draft protocol	[redacted]
Database SFRU have developed an access based database for registration of all incontinence surgery by their members. [redacted], a freelance database expert who works for BAUS, has set this up within the framework of the BAUS oncology database which has been running for several years. BSUG also have a draft database, purely for stress incontinence surgery, with more detail of preoperative assessment and some outceom assessment. All agreed that these databases should be brought together as much as possible. [redacted] and [redacted] to communicate and bring together common data fields. BSUG also have a freelance programmer ([redacted]) who should be asked to liaise with [redacted]. SFRU must add QOL – this could be a choice – eg; Kings, BFLUTS, IIQ and UDI	[redacted], and [redacted]
Joint Training Discussion about provision of cross over experience in each specialty. BSUG have 13 specialist training posts (12 in England one in Wales unfilled) but Urology do not yet have established posts. Still waiting for decisions from SAC / government about subspecialist training years in urology. RCOG have regular meeting of section chairs with council which proves to be a very useful forum for discussing specialist traiing needs. [redacted] made point that these posts must be tied in to expected consultant vacancies / the level of need for subspecialists and we do not know what these numbers are. [redacted], [redacted] and [redacted] will compare the contents of each subspecialist training document and discuss how an agreed cross over programme could be developed.	[redacted]
Definition of a Subspecialist Not discussed in detail. [redacted] to send copy of our definitions to [redacted] and vice versa	JM. RF
Integrated Continence Services We still know little of the extent to which continence services have been integrated around the UK. [redacted] (Royal College of Nursing) has been gathering data on this. A survey has also been done by SFRU but the results not known yet. [redacted] to chase [redacted]	

BAUS
Section of
Female
Urology

The British Association of Urological Surgeons
Section of Female and Reconstructive Urology

35-43 Lincoln's Inn Fields
London WC2A 3PE
Telephone: 020 7869 6950 Facsimile: 020 7404 5048
Email: femaleurology@baus.org.uk

13 February 2006

Dear Colleague

GOOD PRACTICE GUIDELINES FOR UROGYNAECOLOGICAL AND FEMALE PELVIC RECONSTRUCTIVE SURGERY

Please find attached a first draft of Good practice guidelines for urogynaecological and female pelvic reconstructive surgery with particular reference to the introduction of new procedures. I would be grateful if you could have a look through them and let me have any comments or amendments you would like to make.

Professor Paul Abrams recently initiated some correspondence between BSUG, SFRU and ICS regarding the good practice code that the Section drew up in 2004 with a view to trying to reach a consensus statement that could be more widely adopted as a minimum standard.

BSUG and ICS had come back to the Executive Committee with some initial comments on the 2004 draft and Malcolm Lucas (BSFRU Chairman) and Tony Smith drew up the attached updated draft document to take into account all of the feedback received.

Please could you have a look through the attached document and let me have any comments by Friday 20th February. If I don't hear from you by the 20th, I shall assume that you are happy with the document.

I look forward to hearing from you

With best wishes

Jane Morrison
Sections Administrator

BAUS
Section of
Female
Urology

The British Association of Urological Surgeons
Section of Female and Reconstructive Urology

35-43 Lincoln's Inn Fields
London WC2A 3PE
Telephone: 020 7869 6950 Facsimile: 020 7404 5408
Email: femaleurology@baus.org.uk

Good Practice Guidelines for Urogynaecological and Female Pelvic Reconstructive Surgery with particular reference to the introduction of new procedures

by

The British Association of Urological Surgeons Section of Female and Reconstructive Surgery and The British Society of Urogynaecology

General Principles

- Surgeons should participate in national audit and are encouraged to submit their data on all continence and pelvic floor procedures that they carry out to SFRU or BSUG databases. Any intention to undertake a formal evaluation of a new procedure should be registered with the relevant clinical trials database such as that held at SFRU / BSUG.

- If a surgeon undertakes any new class of procedure for which he / she does not have appropriate training then he / she should seek formal training through a process of mentoring. This includes appropriate training of the surgical team.
  This training should be documented.

- When proposing to perform new procedures surgeons must notify their trust's clinical governance committee.

- When proposing to utilise new materials or devices in previously established procedures the trust's clinical governance committee should be informed.

- Formal evaluations involving the development of new techniques (see below) should receive appropriate local ethical approval.

- Companies promoting new procedures or devices should be directed to the SFRU and/or to BSUG or other to liaise with potential "triallists" before a surgeon agrees to participate in a company driven evaluation.

- A surgeon who encounters a serious adverse event related to the use of a device or implant in the treatment of incontinence should notify the MHRA through its SAE reporting process. (x ref to web link)

- New procedures / classes of procedure should be notified to IPAC (NICE) through the NICE website. (x ref to web link)

BAUS
Section of
Female
Urology

The British Association of Urological Surgeons
Section of Female and Reconstructive Urology

35-43 Lincoln's Inn Fields
London WC2A 3PE
Telephone: 020 7869 6950 Facsimile: 020 7404 5318
Email: femaleurology@baus.org.uk

New Procedures

These are defined by NICE **(DOH HSC 2003/011 – 13/11/03)** as one where " a doctor no longer in a training post is using it for the first time in his or her NHS clinical practice" Such a procedure should include not only whole procedures but also modifications to existing procedures.

Here the fundamental principles should be

- Approval of the Trust Clinical Governance Committee whose responsibilities are clearly defined by the above HSC document
- Participation in Audit to allow accurate representation of own outcomes and comparison with other's outcomes for same procedure. BSUG and SFRU databases should be used for this purpose.
- Appropriate training / mentoring of the surgeon and their team.
- Registration of all serious adverse events associated with the use of devices with MHRA through its SAE reporting process (x ref web link)

Many surgical procedures are currently performed without level 1 / 2 evidence of their value but their continued use can be justified as part of common custom and practice.

Substantial modifications to such procedures, or those with existing level 1 / 2 evidence should be considered to be "New procedures" for the purposes of this code of practice. Their incorporation into clinical practice should meet the standards laid out above.

For example, the TVT has Level 1 / 2 evidence of its value but alternative methods of introducing a sub-urethral tape (through the retro-pubic space or the obturator foramen) could be defined as new since they have not yet been subjected to robust analysis by RCT against TVT or other procedures. Another example is the anterior vaginal fascial repair which has for the past century been performed for repair of anterior vaginal wall prolapse. Supplementation of an anterior repair with graft material should be regarded as a new procedure because the risks and benefits of supplementation have not been studied comprehensively for any of the numerous materials available.

Development of New Procedures

All of the following situations should be classified as clinical research. Consent should be obtained from a local research ethical committee and the Trust's own Research and Development advisory committee who will assess the scientific quality of the study. These committees should ensure that the research concept is sound and that the study is appropriately constructed to answer the questions raised.

- When a procedure applies a surgical principle which is neither of proven safety or efficacy nor in common surgical use (referred to as a "new class" in the discussion paper
- When a procedure applies an established surgical principle in a previously untried situation or a situation of unproven efficacy or safety.
- When a procedure involves implantation of a device or material which has not been previously used or is of unproven safety or efficacy

BAUS
Section of
Female
Urology

The British Association of Urological Surgeons
Section of Female and Reconstructive Urology

35-43 Lincoln's Inn Fields
London WC2A 3PE
Telephone: 020 7869 6950 Facsimile: 020 7404 5948
Email: femaleurology@baus.org.uk

- When a procedure involves the implantation of a previously established device or material but in a situation which is of unproven safety or efficacy
- When a procedure involves an established surgical procedure which is being carried out using previously untested methods of access, the use of devices or technology which in themselves are of unproven safety or efficacy in that situation.

New Devices

New devices or materials can only be employed if they have a European CE mark. This CE mark (issued not by Government but by commercial organisations) does not give any endorsement of efficacy or value in clinical practice but simply ensures that a device is "fit for purpose" – more of a retailing concept than a clinical one. Any new device employed in a procedure should result in adherence to the standards for introducing new techniques through proper clinical research as defined above.

Questions surgeons should ask themselves before proceeding with a new procedure.

- Is there sufficient clinical evidence supporting use of this procedure?
- Do the Trust know that I am performing this procedure?
- Have I been fully trained to perform this procedure?
- Are other staff appropriately trained to assist use of the procedure?
- Is there a robust system for documenting details of the procedure and the outcome including complications:
    - locally
    - nationally

January 2006

THE BRITISH ASSOCIATION OF UROLOGICAL SURGEONS

35-43 Lincoln's Inn Fields
London
WC2A 3PE

Tet: 020 7869 6950
Fax: 020 7404 5048
Email: admin@baus.org.uk

20 September 2012

Professor Sir Bruce Keogh
Room 504
Richmond House
79 Whitehall
SWIA 2NS

Email [redacted]

Dear Sir Bruce

Re: Patient Complications relating to the use of mesh implants for Prolapse and Incontinence Surgery

I have recently received a copy of a letter that was sent to you by David Richmond from the RCOG and Tony Smith, Chair of the British Society of Urogynaecologists. I am sure it will come as no surprise to you to learn that urologists also share their concerns about the potential adverse effects of vaginal tapes, slings and meshes for stress urinary incontinence and prolapse. This is becoming an increasing issue for patients and raises serious issues in relation to training, patient consent and who is best suited to helping these patients when complications do arise.

I know some of the wider issues thrown up by this matter such as medical device regulation and the possibility of establishing a national implant registry fall within the terms of your current review of the regulation of cosmetic interventions. However we still think there would be merit in meeting with you, the RCOG, BSUG and MHRA at the earliest opportunity to discuss this specific matter, as at the moment there is the real concern that each organisation is, or is about to, run its own national registry for such interventions.

As you are no doubt aware the MHRA commissioned an independent review of all current and up-todate evidence on the use and potential problems associated with tapes and meshes. Our understanding is that this Wilf be published in the near future. All of our organisations are likely to face questions when this is published and it would be helpful if we have had the opportunity to sit round a table and review all the issues and implications with the aim of developing a constructive outcome for patients in advance of publication of this report.

I look forward to hearing from you.
With kind regards

Yours sincerely

British Society of Urogynaecology (BSUG)

COI:

As a small Charity BSUG does not currently receive any financial sponsorship/support from the pharmaceutical industry or medical devices industry sector or any other body or organisation of Interest to the Review. We run Conferences which are organised by the RCOG. Exhibitors pay for stands at these conferences.

BSUG have also provided to the Review declarations of interest from the Chair, Vice Chair and Trustees of BSUG:

Jonathan Duckett (Chair)	Nil
Swati Jha (Vice Chair)	Fulwood Health Care
Maya Basu (Trustee)	Nil
Jennifer Davies	Lecture fee from Centura for Regional Meeting.
Andrew Hextall (Trustee)	Minor shareholding (<0.1%) of Spire Healthcare
Azar Khunda	Nil
Christian Phillips (Trustee)	Fotona Laser Health Academy – Research and Training in UK (No honoraria but training and research collaborator. No shares. No pecuniary interests)
Ashish Pradhan (Trustee)	Shareholder in CMR Surgical, Cambridge
Dudley Robinson (Trustee)	Nil
Gans Thiagamoorthy	Dr Gans Ltd.
Karen Ward (Trustee)	Vice-Chair UKCS (Non financial) Clinical Lead Nice Guideline Committee (Non financial) Trustee Birth-Aid (Non financial)

Submission:

Thank you for inviting BSUG to comment on the IMMD Safety review into the use of Synthetic mesh in abdominal and vaginal pelvic mesh procedures. We would like to highlight that a vaginal mesh for prolapse is very different to a vaginal mesh for incontinence both in terms of the success and complication profile.

The mesh inserted for stress incontinence surgery has been shown to be highly effective with a low incidence of side effects compared to mesh inserted vaginally to reinforce prolapse surgery. Research has suggested a risk of mesh related complications in prolapse surgery of around 10% with no added benefit over non mesh surgery. Following the NICE guidance on Transvaginal mesh repair for Anterior and Posterior vaginal wall repair (IPG 599), vaginal mesh for prolapse should only be performed in the context of research. BSUG is supportive of this decision.

For the purposes of the responses below we would like to clarify that unless otherwise stated we are referring to mesh used to treat incontinence.

***Q 1**. We recognise that the majority of patients will not have any follow-up actions providing their implanted device functions well. What is your current understanding of the efficacy and safety of the mesh devices which are currently being used, or which have previously been used, and what advice do you provide your members?*

Response: The majority of patients will have follow up after continence mesh surgery and this is collected in the BSUG database. This is routine and standard clinical practice for all women having an incontinence mesh inserted. The timing of this follow up ranges from 6 weeks to 12 months. We also routinely collect data on intraoperative events and complications happening distant from the insertion. If the device is functioning well however no further action or intervention will be required.

There are a huge amount of data on the safety and efficacy of these procedures. The BSUG database has 120,000 cases with around 40,000 mesh continence procedures. We have produced National Reports looking at the outcomes of all continence procedures including incontinence meshes and the results of these are attached as **Appendix 1**. On the basis of this, 92.3% of women describe themselves as much better or very much better. 96.3% reported no complications. 1.9% of patients reported pain that persisted for more than 30 days.

The largest dataset of continence surgery following mesh insertions for stress urinary incontinence in due to be published in JAMA. Of 100,000 women undergoing a continence sling, 3% of women had a removal procedure, 5% had a reoperation for SUI and 7% had any reoperation (mesh removal and/or reoperation for stress urinary incontinence) in a nine year period after their surgery. These rates are in line with other studies from England and Scotland but are lower than some reported by the media (**Appendix 2 and 2A** – currently embargoed till publication) and provides data on the outcome of mesh continence procedures and has been published (**Appendix 2**). To summarise 3.3% of patients will have had the mesh removed 9 years after the original insertion leaving 96.7% without mesh removal.

We also attach population based surveys from other countries including Denmark (Appendix 3), Netherlands (Appendix 4), France (Appendix 5) and Norway (Appendix 6) on outcomes following incontinence meshes. All of these large studies demonstrate evidence of benefit following the use of synthetic mesh for incontinence.

Our members are encouraged to use the NHSE information written by the NHSE mesh review team which included representatives from patients and BSUG amongst others.

Q 2. *Please could you provide a timeline outlining your understanding and recognition of risks of synthetic polymer mesh for use in pelvic surgery (abdominal and vaginal). This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.*

Response: Between 1985 and 1995, several surgical meshes, including Trelex Natural Mesh (Boston Scientific, Marlborough, MA), Supple Peri-Guard (Synovis, St Paul, MN), GORE-TEX Soft Tissue Patch (GORE, Flagstaff, AZ), Mersilene mesh (Ethicon, Somerville, NJ) and Marlex mesh (C. R. Bard, Inc., Murray Hill, NJ), were cleared by the FDA for uses including hernia repair; however, none were cleared for use as vaginal meshes. In 1996, Boston Scientific's ProteGen mesh, the first vaginal mesh for the surgical treatment of SUI, was approved under the FDA 510(k) premarket notification process. The 510(k) ruling allows manufacturers to bring a new product to market without rigorous testing if it is deemed to be 'substantially equivalent' and 'at least as safe and effective' to a legally marketed device.

ProtoGen 510K (K963226) was predicated on mesh devices previously approved for hernia repair (Gore-tex, Marlex and Mersilene) and no further testing was deemed necessary, despite a lack of clinical safety trials for transvaginal placement. The chain of events demonstrating how the 510 (k)

pathway led to approval of mesh use in surgery for pelvic organ prolapse (POP) is shown in Appendix 7.

Individual clinicians and BSUG regularly contribute to the scientific papers produced on these subjects and we keep ourselves abreast of developments. Many of us had significant concerns regarding the introduction and commercialisation of the TVT procedure when it was first introduced in the UK in 1998. Many surgeons did not feel that the procedure was proven to be safe and effective at the initial time that it was introduced. The TVT/Colposuspension (**Appendix 8**) trial was developed and run to address concerns from urogynaecologists in the UK. Many individuals were unhappy with the scientific evidence regarding safety and efficacy and did not immediately introduce the technique. BSUG was only formed in 2001 after the introduction of the TVT procedure. One of the main reasons for the introduction of the BSUG database was to study the safety and efficacy of the TVT procedure.

Q 3. *How do you decide on the content of any information you provide to patients when discussing the risks and benefits of different approaches to stress urinary incontinence and pelvic organ prolapse?*

Response: The BSUG has an Information Committee which has responsibility for developing Patient Information leaflets and information pertaining to Consent of various surgical procedures. The committee takes key information from clinical guidance on a particular topic, and develops a first draft information leaflet based on this. Members of the committee are tasked with writing this in a way that is understandable to people who do not have a medical background. These are reviewed every three years or sooner as clinically indicated. Following on from the pause on use of vaginal mesh, the BSUG website has highlighted which procedures are part of the pause and the leaflets not relevant have been removed from the website.

BSUG also works with the RCOG in developing information leaflets. The process involves testing the information before it is published by asking both the public and healthcare professionals for comments on the draft. The process for developing RCOG patient information is accredited by the NHS Information Standard to ensure it is clear, accurate, evidence-based, up-to-date and easy to use. The BSUG information committee are currently developing a Patient Decision Aid in collaboration with the RCOG and this is going to public and peer consultation before being presented to the RCOG Clinical Quality Board before being introduced into practice. This Patient Decision Aid allows patients to consider all options for Stress Incontinence surgery before reaching a decision about their own personal choice. The current version which has gone out to consultation is attached as Appendix 9.

BSUG and the RCOG also worked with NHSE and patient groups to produce the current NHSE information sheet for midurethral sling (TVT type) procedures and prolapse operations. BSUG have adopted the NHSE leaflets rather than developing separate ones.

Q 4. *How does the Society ensure that professionals achieve, retain, and update skills relevant to the devices available on the market? To what extent are knowledge and skills maintained for non-mesh surgical approaches?*

Response: This is out with the remit of the British Society of Urogynaeocology. The maintenance and assessment of competence and skills is part of the appraisal process. We support members through education and training but these are of a generic nature and generally not related to specific products. We also provide governance guidelines and expect members to adhere to these however the statutory obligations to do so rest with the clinicians.

BSUG does however have a system of unit Accreditation to maintain Standards for Service Provision in Urogynaecology Units. The standards provide a framework that will help urogynaecology units to improve patient care, encourage multidisciplinary working, and enhance prospects for individuals units to grow and develop. These standards are measurable, comparable and identify those units which deliver best practice. They are designed to provide a robust mechanism for ensuring quality control in units practising clinical urogynaecology, which will be of value to service users, commissioners and providers.

BSUG are a small charity affiliated to the RCOG and our objects are:
- to relieve sickness promote good health and advance education for the public benefit in particular but not exclusively by:
- encouraging the study and management of female pelvic dysfunction including, but not limited to, urinary incontinence, pelvic organ prolapse and faecal incontinence;
- raising and setting standards, including of training, in urogynaecology including but not limited to, the provision of a network of support through discussion, study and communication;
- aiding an effective clinical network of care for urogynaecology patients throughout the United Kingdom and Republic of Ireland; and
- by providing a forum for practitioners with an interest in urogynaecology throughout the United Kingdom and Republic of Ireland.

Q 5. *What advice do you currently give your members regarding management of urinary incontinence and pelvic organ prolapse?*

Response: BSUG is affiliated to IUGA (International Urogynaecology Association) and EUGA (European Urogynaecology Association) and together these organisations provide up to date evidence based guidelines on the management of urinary incontinence and pelvic organ prolapse. We also advise members to follow Guidelines issued by NICE relevant to these conditions.

The BSUG runs courses on all aspects of Urogynaecology practice. Training and education are provided through lectures and conferences. BSUG is also responsible for working with the RCOG and the GMC to provide a syllabus for subspecialty training and Advanced Training Special Skills modules (ATSM). This training is delivered by members of BSUG.

Following the recent mesh pause BSUG has developed a training module for native tissue continence surgery to allow Consultant members to acquire the skills necessary to fulfil the requirements of the high vigilance scrutiny.

Q 6*. In your view, what are the priorities for future research related to the interventions and issues raised by the Review?*

Response: BSUG believe that the main focus for future research should be aimed at reducing risk from interventions. BSUG is committed to providing high quality safe and effective care to the women of the UK. Research clearly suggests that synthetic sling continence procedures are relatively safe and effective procedure which are superior to other options with overall fewer complications. However, we are aware some patients have suffered devastating consequences where mesh implants have gone wrong. We would like to understand the problems from a patient perspective and to be able to talk to patients in a non-confrontational way so that we can understand how their care could have been different. We are also keen to collect further data relating to complications and success rates with alternative surgical procedures.

We note that **Questions 7** and **8** are not pertinent to the use of synthetic meshes and neither do they relate to urogynaecological conditions and therefore have not been addressed as they are outside the remit of BSUG.

***Q 9**. What guidance does the Society provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (or non-intervention)? Please supply copies of relevant guidance, with the dates during which each version was in circulation.*

Response: BSUG provides clinicians guidance on informed consent through the patient information leaflets. These are prepared by the Information committee which is a new committee of the BSUG and is only 3 years old. All leaflets can be accessed on the following website (https://bsug.org.uk/pages.php/information-forpatients/111?id=111).

In the BSUG leaflets risk are referred to as common, rare etc. or an approximate level of risk may be given. Further information about risk is explained in a leaflet published by the Royal College of Obstetricians and Gynaecologists "Understanding how risk is discussed in healthcare".

https://www.rcog.org.uk/globalassets/documents/patients/patient-informationleaflets/pi-understanding-risk.pdf

We use the following table to communicate risks and complications of interventions in our leaflets:

Risk table		
Verbal description[a]	Risk	Risk description[b]
Very common	1 in 1 to 1 in 10	A person in family
Common	1 in 10 to 1 in 100	A person in street
Uncommon	1 in 100 to 1 in 1000	A person in village
Rare	1 in 1000 to 1 in 10000	A person in small town
Very rare	Less than 1 in 10000	A person in large town

***Q 10**. Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are changes in the types and levels of concerns expressed by patients in relation to particular procedures either in the NHS or private practice?*
Response: This is out with the remit of the BSUG. When patients or clinicians report complaints to the Society, we encourage them to resolve this locally through the local complaints process. As the BSUG does not have the authority to provide mediation, or remedial measures where required. This responsibility would fall within the individual employing trusts/hospitals.

***Q 11**. Of the total numbers of complaints received year on year what proportion relate to:*
a) abdominal/ vaginally place mesh procedures; and
b) issues of informed consent?
How has this changed over time?

Response: See response to Q 10.

***Q 12.** Please describe the Society's role with regard to:*
a) adverse events reporting;
b) patient safety;
c) providing a forum for discussion; and
d) potential early warning signal detection?

Response: The BSUG strives to promote and ensure patient safety.

a) We have always encouraged adverse event reporting through the MHRA since this was first introduced in 2015. In 2017, and to support adverse reporting by members we added a link on the BSUG database to achieve this. This link allows direct entry of adverse events onto the MHRA website.
b) Patient safety is mandated under the duties of a doctor described by the GMC. Hence all doctors have a responsibility to ensure patient safety. We also collect data relating to surgical complications on the database.
c) Our educational courses provide a forum for discussion.
d) BSUG have reacted proactively to early warning signs.

***Q 13**. Please can you provide a brief summary of how adverse events reported to you are collected, processed and investigated? How effective do you think this process is in capturing adverse events data? How do you think this could be improved?*

Response: Adverse events are collected through the BSUG database and submitted to the MHRA. They are responsible for collecting, processing and investigating these adverse events. In addition this data is anonymised and investigations are performed by individual Trusts not by BSUG. The process of capturing adverse events data is not fully effective as this is currently voluntary.

Mandatory reporting would be a good outcome from this review as we have not been able to achieve this in the past despite asking for compulsory registration of all urogynaecology procedures. The purchaser provider relationship for health provision has meant that NHSE has been unable to stipulate regulations for delivery of care.

***Q 14**. Do you have any indication of use of Yellow Card reporting by your members? For example, have you previously undertaken surveys, or encouraged its use and other reporting mechanisms?*

Response: We have recently undertaken a survey of our membership which shows that 70% of all members use the Yellow Card reporting through the BSUG database. The overall usage of the database was by 75.84% of the members. We attach the results of this survey (**Appendix 10**).

The BSUG have encouraged the use of the Yellow card reporting and for ease of use introduced a tab on the BSUG database to allow direct reporting to the MHRA. Members are encouraged to use the database and record all adverse events.

***Q 15**. Where within the healthcare system does your responsibility for disseminating and responding to adverse event reporting as a professional body begin and end visa vis the regulators and manufacturers?*

Response: Adverse event reporting is primarily via reports to the MHRA. BSUG encourages adverse event reporting. The MHRA will notify manufacturers of adverse events reported under the yellow card system. Individual clinicians have been responsible for identifying different benefits and risks from running large high quality trials.

The BSUG has this year produced a National report looking at adverse events from all continence procedures including but not limited to meshes. This will be made available to the public and will go a long way to dissemination of adverse events and allows a comparison of the various incontinence procedures (**Appendix 1**).

Q 16. *Please can you provide details of your relevant policies and protocols, if any, for ensuring that information relevant to patient safety, and learning from adverse events is disseminated amongst your members.*

Response: This is not the remit of BSUG. Adverse events will be reported in clinical trials and fed back to our members through education.

Q 17. *What factors influence the decision on when to update guidance, and how are adverse events reports weighted in this process given the known level of underreporting?*

Response: Guidance is updated every 3 years under a rolling programme. Information sheets are updated with the latest scientific evidence. Where National/International guidance is published which impacts on existing guidance, this will be updated sooner.

Adverse event reporting is something that our members do as individuals but we do not have access to the results of this reporting. This is the remit of the MHRA who receive the adverse event reports.

Q 18*. How can we ensure patient outcome reports on treatment interventions reflect subjective patient experiences as well as clinical outcomes?*

Response: The BSUG database records both PROM (Patient reported outcomes) and clinical outcomes. This is by a patient Global impression of improvement which is a 7 point scale which records data on improvement through to deterioration of health as reported by patients. Clinical outcomes are reported separately for each individual patient but these do not impact on PROM.

Q 19*. How do we ensure that clinicians respond appropriately to patient concerns?*

Response: Clinicians have a duty of care to their patients and responding to patient concerns is enshrined in the GMC guidance on Good Medical Practice. This document lays out the key responsibilities of a doctor.

Q 20. *How do you feel the culture of reporting concerns and adverse events by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What, if anything, could be done to improve this?*

Response: We feel there is more open reporting of concerns and adverse events by clinicians and others within the healthcare system. This is a change for the better. BSUG have been very proactive in encouraging the reporting of adverse events.

The yellow card system has been improved to make is accessible and easy to complete. Only a few years ago it was a paper system but is now electronic and on line with a direct link from the BSUG database. We do not believe that clinicians are a barrier to reporting. Clinicians need to understand their responsibility in reporting adverse events and any mandating of this process would be welcome. The NHSE mesh review tried to encourage reporting through the appraisal process.

Q 21*. What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?*

Response: In setting up a Registry it is important to articulate the purpose of the registry and identify key stakeholders. It is essential to have a clearly defined purpose which helps clarify the need for

certain data. In addition, having a clear sense of how the data may be used will avoid burdensome data collection.

The defining features of an effective registry would include the following:
-building a registry team
-establish a governance and oversight plan
-define the scope and rigor needed
-define the data set, patient outcomes, and target population
-develop a study plan or protocol
-develop a project plan
-periodic critical evaluations of the registry should be undertaken by key stakeholders to ensure that the objectives are being met

Many of these key features are already present in the BSUG database and the data collected through the database could be used to populate this Registry which could be an off shoot from the BSUG database.

The hosting of the registry should be by an independent body and this could be any of the following
-DoH
-HQIP
-MHRA
-RCOG.

Healthcare professionals can be encouraged to use the registry by making this mandatory for certain specific procedures.

All evidence which forms the basis of this response is attached as appendices. No evidence has been withheld and we have answered the questions honestly and to the best of our ability.

We have no commercial interests relating to this review although both Professor Jonathan Duckett and Miss Swati Jha have published widely on the subject of mesh.

We would like to suggest the following potential questions to ask of others who may be giving evidence to the Review:

1. Has the opinion of mesh patients who have not suffered an adverse outcome been sought? BSUG have a list of such patients who would be willing to be contacted should the review board wish to speak to them.
2. How many women have suffered complications of chronic pain as a result of non-mesh procedures? Have the complications of non-mesh procedures been evaluated by the Review panel?
3. We would suggest an independent evaluation of women with problems to see if they have predisposing factors eg fibromyalgia. This may assist in identifying patients more likely to have problems and help with patient selection in the future.
4. We would like to suggest a random survey by an independent organisation i.e. HQIP of 10,000 patients to see what their outcomes have been after incontinence surgery.

We confirm that we give permission for this evidence to be used for the purposes of the Review.

Yours sincerely

Professor Jonathan Duckett Chair BSUG
Miss Swati Jha Vice Chair BSUG

APPENDIX 1

BSUG Audit and Database Committee 2018. 1st National Report on Stress Urinary Incontinence Surgery in the UK

https://bsug.org.uk/budcms/includes/kcfinder/upload/files/BSUG%20National%20Report%20-%20Stress%20%20Incontinence%20Surgery%20in%20the%20UK%20(2008-2017).pdf

APPENDIX 2 and 2A

Article and supplementary content:

Gurol-Urganci I, Geary RS, Mamza JB, et al. (2018) Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women With Stress Urinary Incontinence. *JAMA.* 320(16):1659–1669. doi:10.1001/jama.2018.14997

APPENDIX 3

Article:

Hansen, MF (2018) Surgical treatment for urinary incontinence in women – Danish nationwide cohort studies. Danish Medical Journal 65(2): B5447

http://ugeskriftet.dk/dmj/surgical-treatment-urinary-incontinence-women-danish-nationwide-cohort-studies

APPENDIX 4

Article:

Schraffordt Koops, S. E., Bisseling, T. M., Heintz, A. P. and Vervest, H. A. (2006), Urogynaecology: Quality of life before and after TVT, a prospective multicentre cohort study, results from the Netherlands TVT database. BJOG: An International Journal of Obstetrics & Gynaecology, 113: 26-29. doi:10.1111/j.1471-0528.2005.00809.x

APPENDIX 5

Article:

Collinet, P., et al. (2008) The safety of the inside-out transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. International Urogynecology Journal 19(5):711-5. doi:10.1007/s00192-007-0514-6

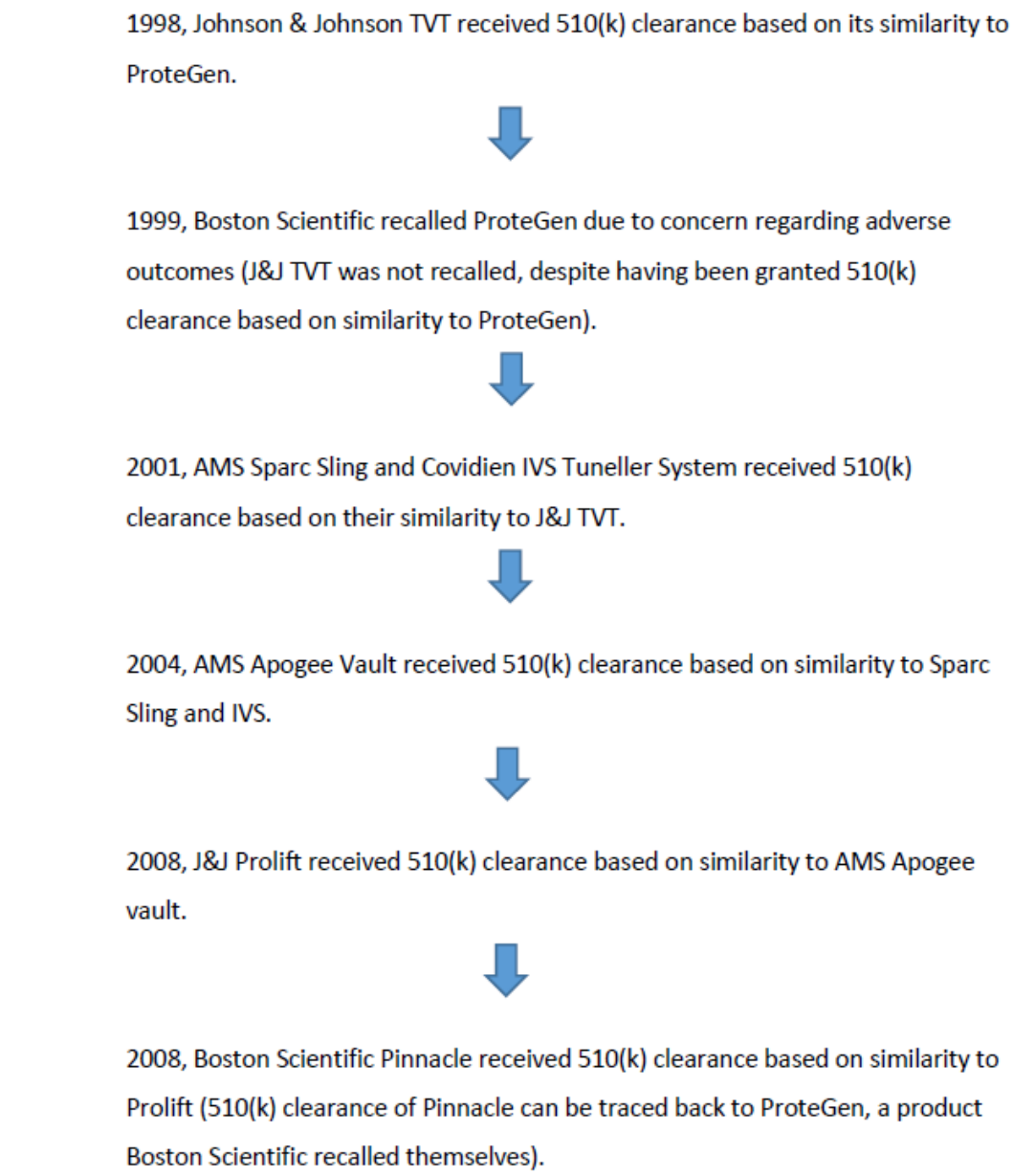
APPENDIX 6

Article:

Dyrkorn, O.A., Kulseng-Hanssen, S. & Sandvik, L. (2010) TVT compared with TVT-O and TOT: results from the Norwegian National Incontinence Registry. International Urogynecology Journal 21: 1321. https://doi.org/10.1007/s00192-010-1195-0

APPENDIX 7

Figure 1 Cascade of events leading to Transvaginal mesh approval in practice



APPENDIX 8

Article:

Ward Karen, Hilton Paul (2002) Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence BMJ 325 :67 doi:/10.1136/bmj.325.7355.67

APPENDIX 9

RCOG vs 4 PDA

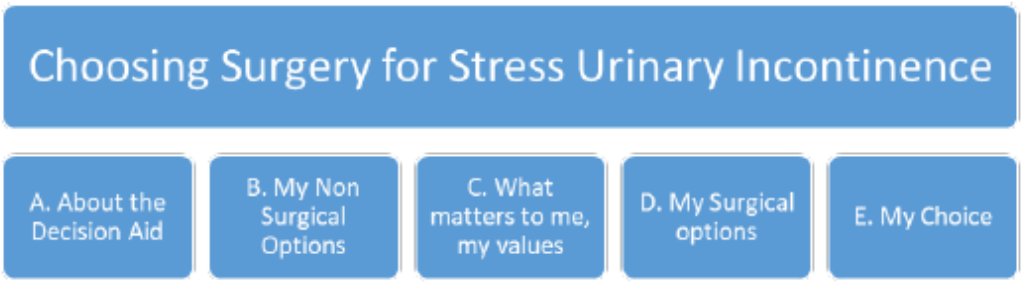
Patient
Label

BSUG
British Society of Urogynaecology

Patient Decision Aid (PDA): Choosing Surgery for Stress Urinary Incontinence

Shared-Decision Making Tool

PLEASE COMPLETE SECTIONS C and E AND HANDBACK THIS FORM TO A MEMBER OF STAFF OR PUT IN THE POST



RCOG vs 4 PDA

A) About this decision aid

This decision aid aims to help you make a choice when you are considering treatment for stress urinary incontinence. It is important that the treatment option chosen is personalised for you. As well as being as safe and effective as possible, the type of treatment chosen will focus on your individual needs and preferences as much as possible.

By finding out more about you we can improve shared-decision making and subsequently the overall outcome of treatment. One way to make this better is for your healthcare professional to find out what is important to you. During decision-making, it is important to establish *'what matters to you'*.

Once you have read this document you will be able to complete sections C and E with support from your health care professional.

Completed forms should be handed back to the team looking after you.

What happens after I complete this form?

Your choices will be discussed at our dedicated meeting (multidisciplinary team or MDT meeting) to help plan your care. You will be informed of the outcome of the discussions, including any recommendations for you to consider.

What if I do not want to give the information?

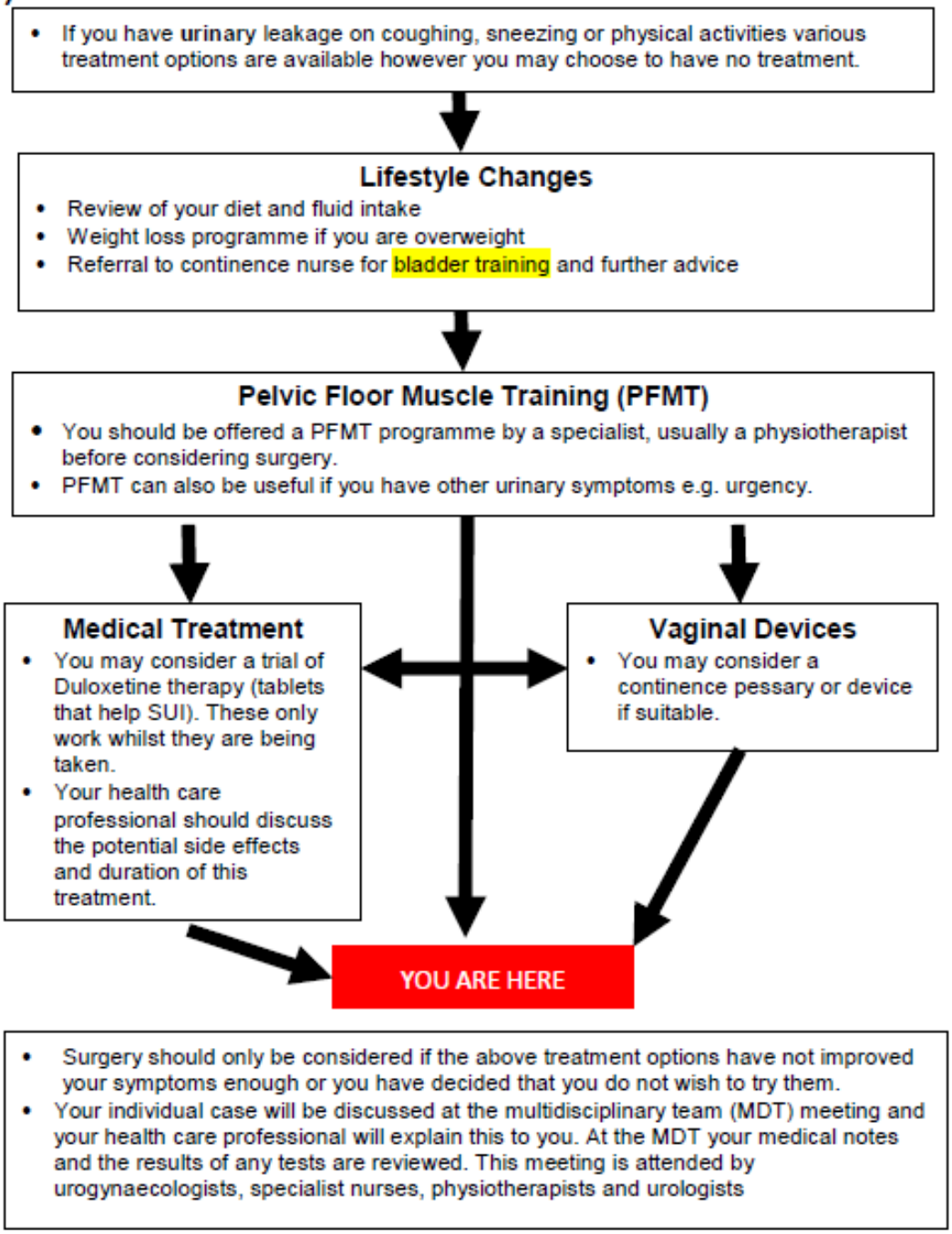
You do not need to share any information that you do not want to.
We will be happy to help you with any concerns you may have at any stage

Can I change the information once I have completed it?

Yes, we recognise that *what matters to you* may change during the decision-making process. You can change your information and decision at any time.

RCOG vs 4 PDA

B) What are the non-surgical options for treatment of my Stress Urinary Incontinence (SUI)?



Please ask your health care professional for the leaflet about the specific surgical procedure(s) you are considering.
Referral to a different clinician (or a different hospital) may be required, depending on availability of expertise at your local hospital.

C) What matters to me? (PLEASE COMPLETE)

- Please let us know what is important to you from the list below.
- Some things that matter to you may be physical, psychological, emotional or social.
- There are no "right or wrong" answers as it is about you.
- A member of staff can help you to complete it and provide additional information.

Please rate from 0 to 10 (0 low priority, 10 high priority) next to each of the following items:

What matters to you	Importance out of 10	Top 3 (Please tick)
• Cure of leakage	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Using fewer continence pads	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding a hospital stay	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Shorter hospital stay	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Quick recovery and return to normal activities	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding major abdominal surgery	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding repeat surgery in the future	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Whether you have plans for a pregnancy in the future	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Less pain after surgery	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding a synthetic mesh tape and its complications	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding self-catheterisation	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding general anaesthesia	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Avoiding local anaesthesia	**0** 1 2 3 4 5 6 7 8 9 **10**	
• Others (what are they)		

E) My Choice (PLEASE COMPLETE THIS TABLE)

Procedure	I will choose this option because…	I will NOT choose this option because…
Colposuspension		
Synthetic Vaginal Mesh Tape		
Natural Tissue Sling		
Urethral bulking agent injection		

Your signature: …… Your Name: …… Date:……

Please write any further comments here:

FOR OFFICE USE ONLY

Procedure	Outcome of MDT Discussion Date:	Outcome of further patient consultation if necessary. Date:
Colposuspension		
Synthetic Vaginal Mesh Tape		
Natural Tissue Sling		
Urethral bulking agent injection		

Clinician's signature: ……Clinician's Name: ……GMC No: ……: Date:……

APPENDIX 10

Midurethral Sling (MUS) Pause (BSUG Membership)

SUMMARY → DESIGN SURVEY → PREVIEW & SCORE → COLLECT RESPONSES → ANALYZE RESULTS → PRESENT RESULTS NEW!

CURRENT VIEW

+ FILTER + COMPARE + SHOW

SAVED VIEWS (1)

EXPORTS (1)

PDF: Responses_All_181004.pdf

+ New Export

SHARED DATA

RESPONDENTS: 269 of 269

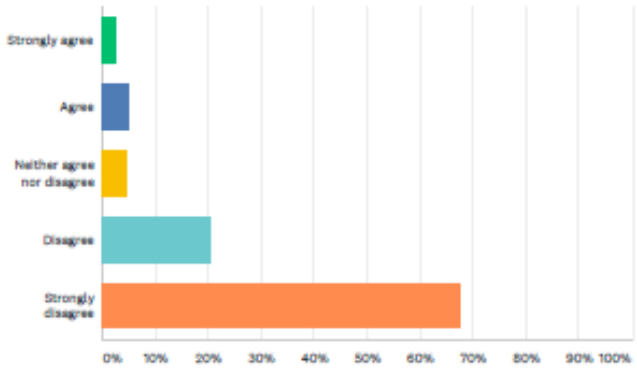
QUESTION SUMMARIES DATA TRENDS INDIVIDUAL RESPONSES

Page 1

Q1

Do you agree with the ban on tapes for SUI?

Answered: 269 Skipped: 0

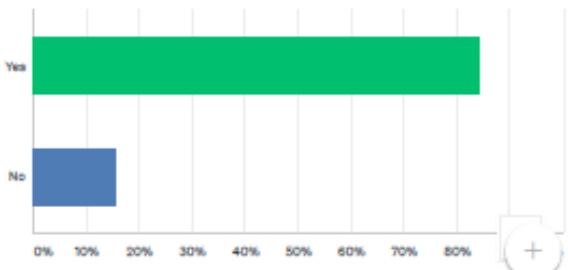


ANSWER CHOICES	RESPONSES
Strongly agree	2.60%
Agree	4.83%
Neither agree nor disagree	4.46%
Disagree	20.45%
Strongly disagree	67.66%
TOTAL	

Q2

Do you take all MUS procedures through an MDT?

Answered: 269 Skipped: 0

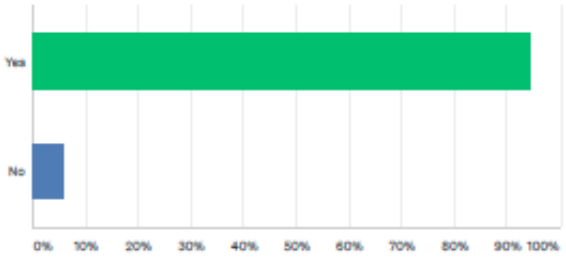


ANSWER CHOICES	RESPONSES
Yes	84.39%
No	15.61%
TOTAL	

Q3

Do you document full Montgomery criteria consent (options of nc and all alternatives)?

Answered: 268 Skipped: 1

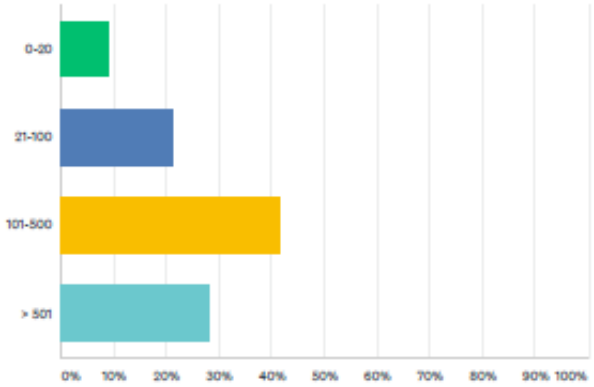


ANSWER CHOICES	RESPONSES
Yes	94.40%
No	5.60%
TOTAL	

Q4

How many MUS have you done?

Answered: 269 Skipped: 0



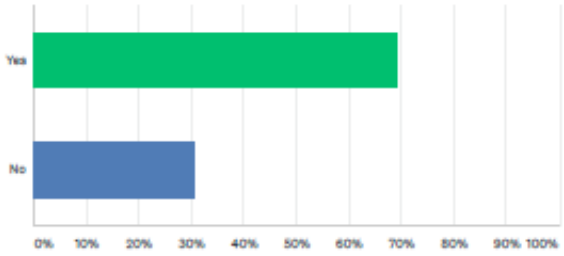
ANSWER CHOICES	RESPONSES
0-20	8.92%
21-100	21.19%
101-500	41.64%
> 501	28.25%
TOTAL	

Q5

Custo

Do you supervise/teach trainees to do MUS ?

Answered: 289 Skipped: 0



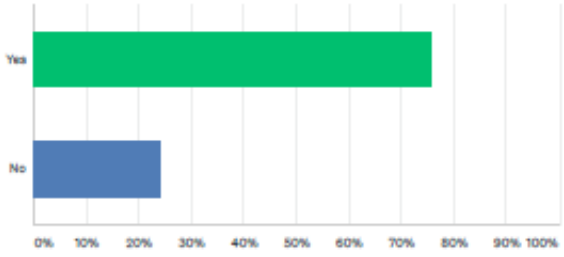
ANSWER CHOICES	RESPONSES
Yes	69.14%
No	30.86%
TOTAL	

Q6

Custo

Do you routinely consecutively record your NHS patients undergo on the BSUG/BAUS database?

Answered: 289 Skipped: 0



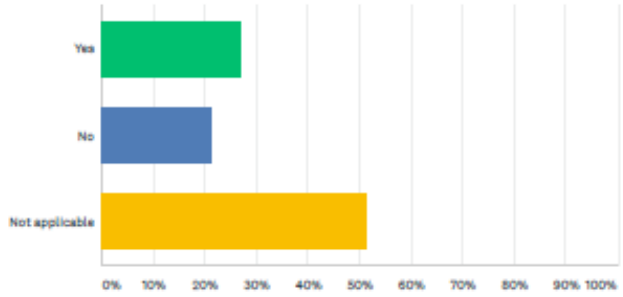
ANSWER CHOICES	RESPONSES
Yes	75.84%
No	24.16%
TOTAL	

Q7

Custo

Do you routinely consecutively record your private patients unde MUS on the BSUG/BAUS database?

Answered: 286 Skipped: 3

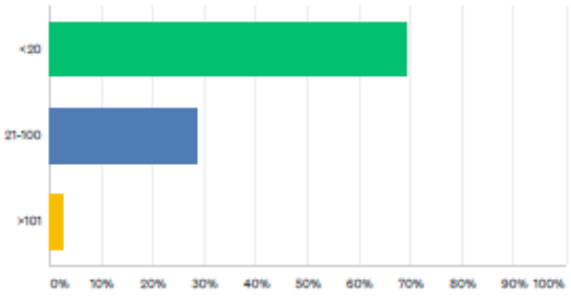


ANSWER CHOICES	RESPONSES
Yes	27.07%
No	21.43%
Not applicable	51.50%
TOTAL	

Q8

How many tape complications have you dealt with?

Answered: 268 Skipped: 1

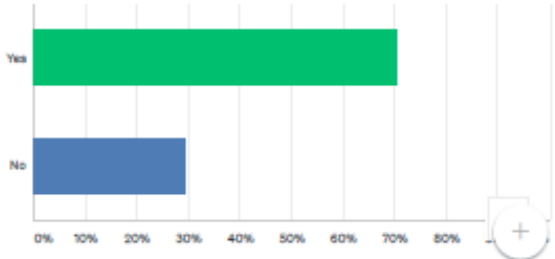


ANSWER CHOICES	RESPONSES
<20	69.03%
21-100	28.36%
>101	2.61%
TOTAL	

Q9

Do you routinely report complications to the MHRA?

Answered: 268 Skipped: 1

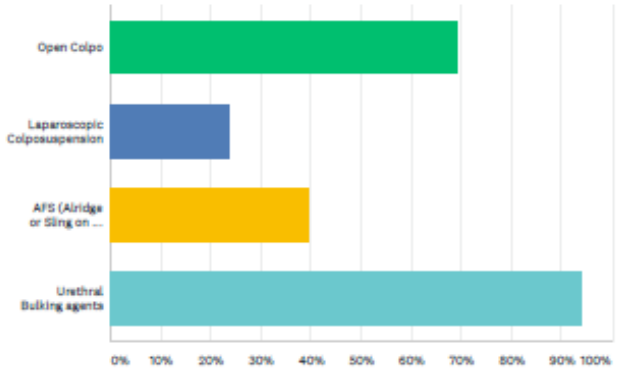


ANSWER CHOICES	RESPONSES
Yes	70.52%
No	29.48%
TOTAL	

Q10

What alternatives are you happy to offer?

Answered: 266 Skipped: 3



ANSWER CHOICES	RESPONSES
Open Colpo	69.17%
Laparoscopic Colposuspension	23.68%
AFS (Alridge or Sling on a String)	39.47%
Urethral Bulking agents	93.98%
Total Respondents: 266	

Prescription Medicines Code of Practice Authority

COI Statement:

The PMCPA administers the pharmaceutical industry's system of self regulation. The PMCPA is a division of the ABPI. The PMCPA income comes from pharmaceutical companies and others. Details are given on the PMCPA website (www.pmcpa.org.uk) and in the PMCPA annual report.

Submission:

How does the Prescription Medicines Code of Practice Authority regulate free samples of prescription medicines?

The ABPI Code of Practice for the Pharmaceutical Industry was first established in 1958. The ABPI Code is administered by the PMCPA. The pharmaceutical industry is committed to self-regulation and this is supported by the Medicines and Healthcare products Regulatory Agency (MHRA) which is responsible for UK law.

The ABPI Code includes requirements for the promotion of medicines for prescribing to health professionals. It reflects and extends beyond UK law. It also covers other areas including the provision of information about prescription only medicines to the general public. A copy of the ABPI Code is available on the PMCPA website.

The provision of medicines and samples is covered in Clause 17 of the ABPI Code. The supply of samples is limited to health professionals qualified to prescribe that medicine and may only be supplied in response to written requests which are signed and dated. Samples are limited in size, must be marked 'free medical sample – not for resale' or similar and no more than four samples of a particular medicine can be supplied to an individual health professional during the course of one year. Samples may be provided for no longer than two years after a health professional first requests a sample of that medicine. Companies are required to have adequate systems of control and accountability for samples. Systems must clearly establish, for each health professional, the number of samples provided.

How do you monitor compliance?

Anyone with concerns about the conduct of a pharmaceutical company is encouraged to submit a complaint to the PMCPA. The complaints system is set out in the PMCPA Constitution and Procedure and full details of completed cases are published on the PMCPA website. In the first instance, all cases are considered by the Code of Practice Panel. The Panel rulings can be appealed to the Code of Practice Appeal Board. The Appeal Board is chaired by a legally qualified chairman and includes independent members from outside the industry. The independent members must be in a majority.

Please explain the basis for the evidence you are submitting to the Review, how that evidence was selected, the extent to which any relevant material has been withheld and the reasons why.

The evidence provided was selected to answer the specific questions. There is extensive information about the PMCPA and its work in the public domain**.**

Royal College of Anaesthetists

COI:

The College receives no sponsorship or funds from commercial organisations (other than occasional sponsorship of individual events through our events department).

Further information can be found in the section headed Guidance on the Register of Interests: https://www.rcoa.ac.uk/president-and-council/council-code-of-conduct

Part IX, section 4.1 of The Faculty of Pain Medicine regulations document, https://www.ficm.ac.uk/sites/default/files/ficm_regulations_-_v4.pdf describes the responsibilities and conduct of board members in regards to conflicts of interests.

Royal College of Anaesthetists

16th October 2018

Written submissions by the Royal College of Anaesthetists and the Faculty of Pain Medicine to the

Independent Review of Medical Devices, 2018

About the Royal College of Anaesthetists (RCoA)

- Sixteen per cent of all hospital consultants are anaesthetists making anaesthesia the single largest hospital specialty in the UK[1,2,3]
- Anaesthetists play a critical role in the care of two-thirds of all hospital patients[4] and 99% of patients would recommend their hospital's anaesthesia service to family and friends[5]
- With a combined membership of 22,000 fellows and members, representing the three specialties of anaesthesia, intensive care and pain medicine, we are the third largest Medical Royal College by UK membership.

Should you have any questions on this submission, please contact [redacted] at [redacted].

About the Faculty of Pain Medicine

The Faculty of Pain Medicine is the professional body responsible for the training, assessment, practice and continuing professional development of specialist medical practitioners in the management of pain in the UK. It supports a multi-disciplinary approach to pain management informed by evidence-based practice and research.

General Comments

From the anaesthetic perspective we have no specific evidence to submit around the three medicines/medical devices listed. However, we do wish to submit general observations around the regulation and monitoring of medical devices, where were we have considerable experience.

The specialty as long been concerned that medical devices used in anaesthetic practice, especially those used in airway management, are not subjected to any clinical trial of efficacy (that leads to a freely accessible published, peer-reviewed paper) before they are CE marked. We remain disappointed that 'clinical testing' required to obtain a CE mark remains rudimentary.

This shortcoming is coupled with very poor support for post-marketing surveillance of the functioning of devices across the NHS. Each individual Trust is free to choose its own devices, based on very little prior clinical evidence, and if any audits are conducted, their outputs remains held locally and there are few formal routes to share this information. Clinicians are often not supported by their Trusts – eg, through Supporting Professional Activity in their contracts and job plans – to conduct this essential audit work. This is because Trusts regard these audits at scale as something beyond the narrow remit of 'individual patient care' which is the general focus of job plans.

These concerns – and some potential solutions – have been aired in several key, highly cited publications in the literature[6,7], that we also submit as evidence.

Both the Royal College and Association of Anaesthetists have extensive experience in conducting national-level audits on key questions concerning patients (see: https://www.nationalauditprojects.org.uk/). However these have been funded wholly from within the specialty and capacity to do more can only be increased by increased external funding support. The dissemination of recommendations from these national audits is extremely effective and contributes to preventing adverse incidents.

Based on these experiences, we make the following suggestions to prevent they type of adverse incidents in the list above:

Royal College of Anaesthetists

16th October 2018

1. Make it a requirement for medical devices to demonstrate clinical efficacy before they are marketed, as evidenced by a publication of a suitably powered clinical trial in a peerreviewed journal. This may require amendment of the Medical Devices Directive
2. Support clinicians to undertake audits in area beyond their own immediate clinical practice, so as to detect wider range of adverse events (eg, through explicit recognition in job plans)
3. Support, with funding, the collection of data from individual Trusts at national level, by way of post-marketing surveillance of adverse events, or national audits
4. Create funding streams to support specialty-led national audits across all specialties.

Faculty of Pain Medicine comments about synthetic mesh for use in abdominal and vaginal pelvic mesh procedures

The Faculty of Pain Medicine of the Royal College of Anaesthetists acknowledges that those patients with pelvic pain, from any cause, greatly suffer with quality of life being significantly impacted. There is a rise in the numbers of patients with vaginal mesh who are being referred to pain clinics. Management of these patients is not straightforward and surgical removal does not necessarily cure the problem in all cases. We are not aware of the incidence of complications or the benefits of these procedures to other patients, as they do not present to pain clinics. Having an understanding of benefits and risks (including number of procedures undertaken) will help guide how to best manage complications. If the incidence of complications is low this does not underestimate the impact they have on individuals but will influence how services are organised to provide optimal care for those patients whether their treatment is straightforward with surgical solutions or more complex where there is no cure with high levels of pain and quality of life significantly impacted.

As the nature of pain in these patients tends to be complex, it will require specialist pain management input and for some patients this will need to be in units that have an expertise in pelvic pain. Co-ordination between specialist services is required to optimise the patient pathway and improve patient access to appropriate services. This will need formal working often with multidisciplinary input between the parent specialty (Urogynaecology, Neurogyanacology) or centres recognised to undertake vaginal mesh procedures and their specialist pain management services.

The Faculty of Pain Medicine of the Royal College of Anaesthetists has published 'Core Standards for Pain Management Services in the UK'[8] and is responsible for pain training and continuing professional development of specialist medical practioners in the management of pain in the UK.

[1] NHS Digital. *NHS Hospital & Community Health Service (HCHS) monthly workforce statistics - Provisional Statistics*. July 2017.
[2] Stats Wales. *Medical and dental staff by specialty and year.* March 2017.
[3] Information Services Division Scotland. *HSHS Medical and Dental Staff by Specialty*. December 2016.
[4] Audit Commission. *Anaesthesia under examination: The efficiency and effectiveness of anaesthesia and pain relief services in England and Wales*, National report, 1998.
[5] EMK Walker, M Bell, TM Cook, MPW Grocott, and SR Moonesinghe for the SNAP-1 investigators. Patient reported outcome of adult perioperative anaesthesia in the United Kingdom: a cross-sectional observational study. British Journal of Anaesthesia 2016 [6] Cook TM. Novel airway devices: spoilt for choice? Anaesthesia 2003; 58: 107–10.

[7] Pandit JJ et al. The Difficult Airway Society 'ADEPT' guidance on selecting airway devices: the basis of a strategy for equipment evaluation. Anaesthesia. 2011 Aug;66(8):726-37

[8] Faculty of Pain Medicine. *Core Standards for Pain Management Services in the UK*. 2015

RCGP

COI Statement:

The RCGP receives sponsorship from industry for its various projects and a copy of the relevant sponsorship policy can be found here:

http://www.rcgpac.org.uk/wp-content/uploads/2018/03/RCGP-Sponsorship-Policy.pdf

In addition, the Code of Business Conduct Policy sets out guidance on Conflicts of Interest, voluntary and consultancy work.

Royal College of General Practitioners

24 October 2018

Dr Victoria Tzortziou Brown FRCGP, MFSEM, PhD, MSc, Joint Honorary Secretary of Council

For enquiries please contact:

Dr Victoria Tzortziou Brown
Royal College of General Practitioners
30 Euston Square
London NW1 2FB

[redacted]

Dear Dr Brasse

Re: RCGP Response to the Call for Evidence for the Independent Medicines and Medical Devices Safety Review - Reference number LQBWWH

The Royal College of General Practitioners (RCGP) welcomes the opportunity to respond to the call for evidence for the Independent Medicines and Medical Devices Safety Review and gives permission for this evidence to be used for the purposes of the Review.

The RCGP is the largest membership organisation in the United Kingdom solely for GPs. Founded in 1952, it has over 52,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline. RCGP is an independent professional body with expertise in patient-centred generalist clinical care.

Executive summary

- The RCGP is committed to promoting patient safety and high standards of care and working with other relevant organisations, including MHRA and other Royal Colleges, to ensure the effective dissemination of relevant and important information to our members. The RCGP is not however a regulatory body, does not have a monitoring, investigatory or regulatory function and therefore is not in a position to assess compliance with standards and best practice.
- The RCGP has a long history of developing resources and training for our 52,000 GP members and other healthcare professionals: from shaping the curriculum to the development of over 700 quality assured and peer reviewed online learning modules, maintaining educational libraries and providing education accreditation. Our bespoke Online Learning Community has a total of 160,000 users and 103 Online learning opportunities outside of formal modules that aim to provide bitesize, rapid learning opportunities, including podcasts, screencasts and online learning videos. As part of this we have produced learning resources on sodium valproate and the use of mesh.

- The RCGP is also committed to raising awareness amongst members on important issues as they arise via the Chair`s weekly messages to members, the RCGP`s news webpage, via social media as well as by taking part in media discussions. We have used these methods to raise awareness on the risks associated with the prescribing of sodium valproate.

Answers to the Review questions

1. *Please could you provide a timeline outlining your understanding and recognition of risks of the interventions under Review. This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.*

   Primodos: Primodos was discontinued by the manufacturer in 1978. The RCGP was approached by Sky News in January 2017 and subsequently conducted a review of the information held in our archives relating to hormone pregnancy tests, including Primodos. This included published and unpublished research studies, and correspondence between researchers, dating from the 1960s - 1980s. The RCGP followed due process by advising the regulator at the time (the Committee on the Safety of Medicines) and can provide further information on this if required.

   Sodium Valproate: Since December 2015 when the MHRA updated their prescribing guidance following the outcome of a European Medicines Agency review, the RCGP has included notifications of any changes to MHRA guidance and any publication of MHRA resources and patient safety alerts relating to prescribing sodium valproate in its weekly message to members. The most recent notification was May 2018. In May 2017, the RCGP published a blog on its online learning platform relating to prescribing sodium valproate to women of childbearing age, linking to relevant e-learning modules. In September 2017, the RCGP cooperated with the BBC into an investigation into sodium valproate prescribing. The College's statement is included in the Appendix, has been published on the website's news pages, and RCGP Chair Helen Stokes-Lampard conducted a number of media interviews, including on BBC Radio 4's Today programme.

   MESH: The NHS report about complications of Mesh implants was cascaded to GP practices mainly via CCGs in the late summer of 2017. RCGP Wales Chair, Dr Rebecca Payne, conducted an interview on BBC Radio Wales in August 2017. We have had requests for comment on hernia mesh implants and in August 2017 we issued a statement to the BBC Victoria Derbyshire show about this (which is included in the Appendix). The RCGP subsequently wrote a joint GP factsheet with the RCOG which was published in May 2018, promoted in the Chair's blog and since then has been on the RCGP website in the Women's Health library.

2. *What is the awareness of your membership of 'Fetal Valproate Spectrum Disorders'? How do you advise, or otherwise provide support to your members with regard to rare syndromes and disorders?*
   The RCGP has incorporated relevant online resources for members within the perinatal mental health toolkit http://www.rcgp.org.uk/clinical-and-research/resources/toolkits/perinatal-mental-health-toolkit.aspx and http://www.rcgp.org.uk/clinical-and-research/resources/a-to-z-clinical-resources/epilepsy.aspx which include the relevant MHRA toolkit and video) and an e-learning module on antiepileptic drugs and hormonal contraception (http://elearning.rcgp.org.uk/blog/index.php?entryid=13). Because of the breadth of General Practice, GPs cannot be expected to know the detail on rare disorders or syndromes but are taught to seek expert help when they exceed their scope of practice.

3. *How was the MHRA Valproate Toolkit disseminated in your network?*
   Please see answer to the question above. The online material incorporates the relevant MHRA Valproate Toolkit. This also went out via the Chair's weekly message to members.

4. *Assuming patient awareness of the risks of valproate use during pregnancy is low, are you taking actions to ensure that your members are complying with the pregnancy prevention plan?*
   The RCGP is not a regulatory body and therefore is not in a position to ensure compliance with the pregnancy prevention plan.

5. *How are you advising your members on contraceptive measures for girls on valproate entering puberty?*
   In addition to the above-mentioned online resources, one of the RCGP`s Online Essential Knowledge Updates (Essential knowledge update 17) provides advice for GPs on this topic.

6. *What actions would your members take with regard to those affected by in utero exposure to pharmaceuticals? Do your members report to congenital malformations registries?*
   Health care professionals (including GPs) are advised to report to the Yellow Card Scheme any suspected adverse reactions associated with medicines taken during pregnancy experienced by women or the baby or child. Congenital malformations are not usually diagnosed by GPs and therefore usually hospital specialists notify the congenital malformations register.

7. *Please describe the data collection process for Prescription Event Monitoring for drugs, including: study length, cohort size, and whether the information requested can be modified to include pregnancy complications and/or teratogenic effects.*
   Not relevant. GPs use the Yellow Card reporting scheme and reports can also be made by patients.

8. *What advice do you give members with regard to non-surgical management of urinary incontinence and pelvic organ prolapse?*
   The RCGP has produced relevant advice on the non-surgical management of urinary incontinence and pelvic organ prolapse under the Online Women's Health Library section: http://elearning.rcgp.org.uk.

9. *Are there existing care pathways for the management of post-operative care for pelvic mesh surgery, including complications?*
   The RCGP and Royal College of Obstetricians & Gynaecologists (RCOG) created a factsheet for GPs to help with the diagnosis and management of women who are presenting with potential complications or anxieties related to their surgery. This has been published within our e-learning resources: http://elearning.rcgp.org.uk/mod/page/view.php?id=8254 and http://elearning.rcgp.org.uk/mod/page/view.php?id=6884 .

10. *What advice do you give members when dealing with women who have suffered adverse events arising from mesh surgery?*
    The relevant advice has been incorporated in the above-mentioned factsheet for GPs.

11. *How does the College ensure that professionals achieve, retain, and update skills relevant to the medicines and devices available on the market?*
    The RCGP produces Regular Essential Knowledge Updates quarterly which focus on recent new guidelines and important research. These are available free of charge to all members. In addition, the RCGP has been developing a new initiative on Rapid Updates which aims to provide information to members in response to significant changes in practice.

The Mesh factsheet was an example of this new service. The RCGP has no regulatory role though and therefore cannot provide assurance that GPs achieve, retain and update their skills on all medicines and devices available on the market.

12. *What guidance does the College provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (or non-intervention)? Please supply copies of relevant guidance, with the dates during which each version was in circulation.*
    It is the responsibility of the operating clinician to communicate risks/benefits of surgical procedures to patients and obtaining informed consent on such procedures. This is a part of the consent process regulated by the GMC. Regarding drug treatments, GPs must conform to GMC guidance on informed consent and shared decision making with patients.

13. *How can communication of specific risks to patient groups be improved?*
    The use of decision aids for patients can enhance patient understanding of the risks and potential benefits of interventions. NICE has done some work developing these as have various academic institutions. However, it can be time consuming to develop such tools and they are only as accurate as the available evidence is incorporated and they need constant updating/revision. The advancement of technology may have an important role to play in this area.

14. *Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are changes in the types and levels of concerns expressed by patients in relation to particular procedures either in the NHS or private practice?*
    There are many different avenues through which patients can raise a complaint. These are summarised on the NHS website (www.nhs.uk). Patients can raise a complaint via their GP practices, another NHS provider, via their local Clinical Commissioning Group or NHS England for example. There is no robust mechanism at present to systematically collect information on these complaints in order to analyse them and identify patterns.
    The RCGP responds to complaints about the RCGP itself, its educational outputs or its public statements but not to individual complaints about a doctor's clinical practice – the latter is properly the function of other organisations such as the Doctor's individual Practice or the Medical Defence bodies. The RCGP is not a regulatory authority nor does it have management responsibilities for its members.

15. *Of the total numbers of complaints received year on year what proportion relate to: a) abdominal/vaginally place mesh procedures; b) sodium valproate and hormonal pregnancy tests; and c) informed consent? How has this changed over time?*
    We do not have access to this information.

16. *If you have had any adverse events concerning the use of hormone pregnancy tests, valproate containing medicines during pregnancy, or pelvic mesh, reported directly to the College please provide an anonymised summary, including dates of receipt, and indicate what actions were or are being taken in response to these reports.*
    As mentioned above, the RCGP does not have a monitoring or regulatory function and therefore does not keep a log of such events but would direct any such reports to the relevant bodies so that they can be logged and investigated.

17. *How do you see the College's role with regard to: a) adverse events reporting; b) patient safety; c) providing a forum for discussion; and d) potential early warning signal detection?*
    The RCGP is committed to promoting patient safety and high standards of care and working with other relevant organisations, including MHRA and other Royal College Colleges, to ensure the effective dissemination of relevant important information to our members. Our Continuous Professional Development (CPD) resources have a strong focus on safety and we

will soon be able to provide an opportunity for forum discussions within our RCGP Online Libraries. The RCGP is not a regulatory body though and is not in a position to investigate individual cases. When individual cases are brought to the attention of the RCGP, we advise on the relevant routes for formally reporting these.

18. *Please can you provide a brief summary of how adverse events reported to you are collected, processed and investigated? How effective do you think this process is in capturing adverse events data? How do you think this could be improved?*
    This question has been covered in the question above. Individual adverse events are not normally reported to the College and the RCGP does not collect, process or investigate such events. Individual cases are directed to the relevant bodies for investigation.

19. *Do you have any indication of use of Yellow Card reporting by your members? For example, have you previously undertaken surveys, or encouraged its use and other reporting mechanisms?*
    We do not have any relevant information on this.

20. *Where within the healthcare system does your responsibility for disseminating and responding to adverse event reporting as a professional body begin and end vis-a-vis the regulators and manufacturers?*
    The RCGP works with relevant organisations (e.g. MHRA) to raise members` awareness on potential adverse events but is not responsible for the dissemination of all adverse events and for collating and responding to information on adverse events. In March 2010, the National Patient Safety Agency published the National framework for Reporting and Learning from Serious Incidents Requiring Investigation. http://www.nrls.npsa.nhs.uk/resources/?entryid45=75173 . This framework details how all organisations providing NHS funded care should report, investigate and monitor serious incidents. The National Framework has been subsequently updated by NHS England Serious Incident Framework 2013 to take into consideration the new NHS architecture and should be read in conjunction with the National Framework. http://www.england.nhs.uk/ourwork/patientsafety/. In addition, NHS providers report adverse incidents via the Yellow Card Scheme which helps MHRA to monitor the safety of all healthcare products in the UK. MHRA has a role of cascading information about side effects directly to practices via Clinical Commissioning Groups.

21. *Please can you provide details of your relevant policies and protocols, if any, for ensuring that information relevant to patient safety, and learning from adverse events is disseminated amongst your members.*
    We do not have relevant policies or protocols in place. The RCGP works with other relevant organisations (e.g. MHRA, NICE) to disseminate information on patient safety via our on-line resources for members (e.g. Essential knowledge updates and Rapid Responses), via the Chair`s blog, the RCGP news page on our website and via social media.

22. *What factors influence the decision on when to update guidance, and how are adverse events reports weighted in this process given the known level of underreporting?*
    The RCGP does not collate or analyse information on adverse events. Relevant guidance incorporating information on adverse events is usually produced by other bodies such as NICE, SIGN, MHRA etc. The RCGP sees its role as incorporating the latest guidance in its educational resources for members and assisting with the dissemination of such guidance.

23. *How do we ensure that clinicians respond appropriately to patient concerns?*
    Responding to patient concerns is part of the GP training. The CQC provides assurance that GP practices have the systems in place for adequately responding to patient concerns and complaints. The appraisal process incorporates the reporting and reflection on complaints and significant events by individual GPs.

24. *How do you feel the culture of reporting concerns and adverse events by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What, if anything, could be done to improve this?*
    As mentioned above, practices need to have systems in place for adequately responding to patient concerns and complaints. They also need to report adverse events via the available channels (e.g. NRLS, Yellow Card Scheme). Individual GPs report and reflect on significant events and complaints via the appraisal process. The culture of reporting concerns and adverse events by clinicians and others could be improved by a greater emphasis on learning rather than blaming, by greater assurances that reported cases will be analysed so that patterns can be identified, and system-wide learning is enabled and by ensuring that the tools and resources for systematic reporting and reflection are available to all clinicians.

25. *How can we ensure patient outcome reports on treatment interventions reflect subjective patient experiences as well as clinical outcomes?*
    Regarding adverse events, patients can report these themselves via the Yellow Card Scheme but there may be a need for disseminating this message widely. With regards to collecting data reflecting more general patient experiences following treatment interventions, there is a need for relevant tools to be developed. Such tools need to be co-produced with patients.

26. *In your view, what are the priorities for future research related to the interventions and issues raised by the Review?*
    One research priority could be exploring the role of technology in improving patient safety, enhancing shared and informed decision making and collecting patient information on adverse events and patient experience. The role of GP IT systems have matured over the last 20 years and application programme interfaces such as prescribing decision support systems, recommended by Clinical Commissioning Groups (CCGs) now assist drug prescribers in primary care. NIHR researchers have also worked together as experts across regions to develop a patient safety toolkit (http://www.rcgp.org.uk/clinical-and-research/resources/toolkits/patient-safety.aspx) working with the RCGP Clinical Innovation and Research centre (CIRC) funded by the NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre.
    Another research opportunity presents by utilising big data provided by GP practices in Clinical Practice Research Datalink (CPRD), RCGP Research Surveillance Centre (RSC), Q-Research, the THIN Database, Research One and the SAIL Databank in Wales and Scotland's SPIRE database as well as the NHS Business Authority GP Prescribing data which can provide practice-based data including Northern Ireland and regional based databases from GP records includes those being set up as part of Clinical Effectiveness Programmes.
    Post marketing drug surveillance is a crucial aspect of the clinical research activities in pharmacovigilance and pharmacoepidemiology. (Pharmaceutical companies are also obliged to produce risk management plans for drugs). One such mechanism includes the European Medicines Agency (EMA) and their ongoing pharmacovigilance studies and surveillance of black triangle labelled drugs.
    Successful utilisation of available Electronic Health Record (EHR) data can complement and strengthen post marketing safety studies. In terms of the secondary use of EHRs, access and analysis of patient data across different domains are a critical factor. For example, the RCGP supports the UK wide national dataset, the RCGP Surveillance Centre. The RCGP Research and Surveillance Centre (RSC) is one of Europe's oldest sentinel systems >50years surveillance with focus on data quality and cases of disease, close collaboration with Public Health England.

Another exemplar is, for 30 years, research using CPRD data which has produced over 2,000 peer reviewed publications with focus on drug safety and pharmacoepidemiology. The RCGP collaborates with the CPRD. Q-Risk is embedded in GP IT systems and allows risk stratification across diseases for example for cardiovascular health.

Both the RCGP RSC and CPRD provide unique opportunities for researchers to harness the power of large multi-linked observational datasets, while protecting patient confidentiality:

- All data are anonymised;
- Both RCGP RSC and CPRD collect fully-coded patient electronic health records from GP practices across the UK;
- Both are representative of the UK population with respect to age, gender and ethnicity;
- Linkage to secondary care and registry data is available.

For a summary of GP datasets please see: http://www.farrinstitute.org/wp-content/uploads/2017/10/Datasets-that-may-be-of-interest-to-Primary-Care-Researchers-in-the-UK-May-2016.pdf.

These datasets are a result of hard work by GPs and primary care staff coding their clinical encounters. Additional resources in developing training for coding and support for practices will improve the quality of GP datasets.

The Drug Research Safety Unit (DRSU) epidemiologists have experience of working with CPRD data. The DSRU describes itself as a NHS observational data service, based in the UK. However, the addition of GP researchers and GP input to the DRSU would improve pharmacovigilance with additional pragmatic trials such as the DECIDE trial are likely to improve early notification of adverse events with new medication and devices. In addition, artificial intelligence should be trialled for pharmacovigilance.

At present, there are multiple systems in primary care to record safety issues which include the Yellow Card scheme, Datix, Riddor, Information Governance, CQC, Mortality review such as LeDeR etc. Research could look at a single front end system linked to the notes that auto-populates clinical details to reduce data entry time for front-line clinicians. The system could then send the appropriate report to the appropriate organisation. The ability to print medical certificate of the cause of death directly from GP systems as can occur in Scotland would also improve mortality data in the clinical records rather than rely on data linkage with separate systems and improve pharmacovigilance for Severe Adverse Events.

The use of prescribing indicators such as those in the RCGP patient safety toolkit are to be encouraged and assessed.

In Wales, National prescribing indicators reinforce patient safety when prescribing:

'The National Prescribing Indicators for 2018–2019 have been prepared by a multi-professional collaborative group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and subsequently endorsed by the All Wales Medicines Strategy Group (AWMSG)'. (http://www.cpwales.org.uk/The-Health-Landscape/National-Prescribing-Indicators.aspx).

27. *What governance arrangements are in place for clinicians participating in post-marketing studies, and how have these changed over time? Please include details of: a) how post-marketing studies were and are carried out; b) limitations on free samples; c) details of what compensation or gifts clinicians can accept; d) the number of studies a clinician can be involved in; and e) how informed consent of the patient is obtained.*

All non-commercial and commercial research in primary care is regulated by the Health Research Authority. Most research is part of the National Institute of Healthcare Research (NIHR) portfolio and easily identifiable by the clinical research networks (CRN) but there continues to be some commercial research where the pharmaceutical organisations or Clinical Research organisations (CRO) directly approach GP practices. The consequence of this is that the local CRNs are not aware of this activity.

The General Medical Council published updated guidance on the financial and commercial arrangements and conflicts of interest for doctors in 2013.

The guidance helps GPs to recognise when conflicts of interest arise, how to avoid them wherever possible, and requirements for declaring and managing them.
There is advice about accepting gifts, sponsorship, incentives, commissioning services, and relationships with the pharmaceutical industry. It helps GPs to make decisions in a way that maintains public trust in the profession.
GPs have a professional and ethical duty to prescribe drugs and recommend treatments based on their judgment of a patient's clinical needs and the effectiveness of the treatment. This means that GPs cannot allow themselves to be influenced by incentives to prescribe one drug or treatment over another. To do so would undermine the trust patients place in GPs. GPs cannot allow gifts or inducements from pharmaceutical firms or anyone else to bias their clinical judgment. In Good Medical Practice the GMC states: 'You must be open and honest in financial and commercial dealings with employers, insurers and other organisations or individuals.'
It continues: 'You must act in your patients' best interests when making referrals and when providing or arranging treatment or care. You must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat, or refer patients.'
Under the provisions of the Medicines (Advertising) Regulations 1994, GPs may be subject to summary conviction if they accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship that is prohibited by the regulations. This was consolidated with other regulations to form The Haman Medicines Regulation 2012 (http://www.legislation.gov.uk/uksi/2012/1916/contents/made).
In 2016 the Association of the British Pharmaceutical Industry’s Disclosure UK database (www. disclosureuk.org.uk) was launched and in 2017 it found 55% of doctors and other healthcare professionals are allowing their names to appear alongside the fees and expenses they receive from drug companies. Without statutory declarations of financial conflicts of interest, this voluntary register contains significant gaps. The RCGP would strongly urge doctors involved in the pharmaceutical sector to participate fully in this scheme to ensure patients’ confidence in the profession is maintained
Under the terms of the NHS England GMS contracts regulations, GPs in England are obliged to declare any gift worth more than £100. GP practices must keep a register of all gifts made by patients, relatives or any person who provides or wishes to provide services for either the contractor, or its patients. The rules apply to all GPs in a practice, their employees or locums and extends to the spouses or partners of those people. Regulations do not apply to gifts worth less than £100 or gifts that are unconnected with services provided (or to be provided in the future) by the GP.
The RCGP would advise GP practices to apply the regulations widely to avoid future criticism and include in the register any hospitality offered by and accepted from pharmaceutical representatives.
The RCGP supports research in general practice. This includes collaboration with the MHRA Clinical Practice Research Datalink and the RSCP Research Surveillance Centre. In addition, the RCGP has worked with NIHR to design Research Ready which is a quality assurance programme for all research-active UK GP practices. It is designed in line with the UK Research Governance Framework’s legal, ethical, professional, and patient safety requirements. The programme serves to provide information, support and guidance to accredited practices in research; both to assist with meeting the requirements above, and with considering and conducting research.
The programme is split between two levels of accreditation: Research Ready® Universal and Research Ready® Advanced.
Research Ready® Universal gives access to training and support for the whole practice team to upskill them to engage with research. It can be used by all practice staff, both clinical and non-clinical (GPs, nurses, practice management, administrators).
Research Ready® Advanced acts as a quality mark for practices to demonstrate their capability and experience in performing complex research.

It can be used by general practices who have excelled at, and have demonstrable experience of, successfully undertaking at least 2 Clinical Trials involving Investigational Medicinal Products (CTIMPs) in the last 2 years, where a clinician within the practice has acted as a Principal Investigator (PI) in one or more of Pharmaceutical-industry sponsored CTIMPs or Non-industry or NHS CTIMPs. In order to become Research Ready® Advanced, the practice must have an active and valid Research Ready® Universal accreditation.

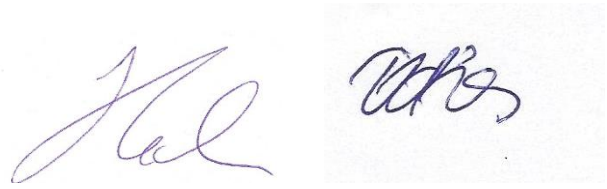
The RCGP strongly promotes informed consent as one of the founding principles of research ethics. Patients should enter research freely (voluntarily) with full information about what it means for them to take part, and that they give consent before they enter the research. Consent should be obtained before the patient enters the research (prospectively). The minimum requirements for consent to be informed are that the patient understands what the research is and what they are consenting to. There are two distinct stages to a standard consent process for competent adults: Stage 1 (giving information): the person reflects on the information given usually in a patient information leaflet; they are under no pressure to respond to the researcher immediately. Stage 2 (obtaining consent): the researcher reiterates the terms of the research; the patient agrees to each term (giving explicit consent) before agreeing to take part in the project as a whole. Signed written consent should be obtained. Researchers in general practice must ensure that they comply with the General Data Protection Regulation (GDPR) during and after the consent process.

28. *What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?*
An effective clinical registry will need to be held centrally, GPs and patients need to be aware of it, should connect with other relevant schemes (e.g. Yellow cards), should be easy to use, should give feedback to users and result in useful summaries that can guide clinical improvements.

The responses to the above questions have been provided following discussion with the Clinical Innovation and Research Centre (CIRC), Communications and Policy and Professional Development teams within the RCGP. The responses have also drawn upon information from relevant past correspondence between the RCGP and other stakeholders on the issues. The responses focused mainly on answering the questions in this review document. There is additional material which can be made available if there are any additional queries or points that need clarification. The RCGP would be willing to send representatives to the oral evidence gathering sessions as required.

The RCGP receives sponsorship from industry for its various projects and a copy of the relevant sponsorship policy is available on request.

Yours Sincerely



Dr Jonathan Leach and Dr Victoria Tzortziou Brown
RCGP Joint Honorary Secretaries of Council

Appendix

STATEMENTS

Sodium Valproate (response to BBC investigation in Sept 2017):

"The dangers associated with sodium valproate, particularly for treating pregnant women, are widely known in general practice – indeed throughout the NHS. There have been various awareness-raising campaigns and GPs should discuss these concerns with patients before considering valproate as a treatment, particularly for women with epilepsy who are of childbearing age.
"Concerns around valproate are longstanding - and as more supporting evidence has come to the fore about the drug's effect on pregnant women and unborn foetuses, warnings from the Medicines and Healthcare Regulatory Authority (MHRA) for both healthcare professionals and patients have been strengthened.
"These warnings have been incorporated into the Quality Outcomes Framework (QOF) that underpins the way in which GPs practise – and warnings are now clearly stated in patient information leaflets, and on the medication packets.
"The RCGP, along with the Royal Pharmaceutical Society, has also endorsed resources from the MHRA, which we have cascaded to our members using various channels available to us.
"Prescribing is a core skill in general practice, and GPs will always prescribe in the best interests of the patient in front of them, in conversation about the risks and benefits of different treatment options, and in line with current guidance.
"The College's curriculum – which all new GPs must demonstrate competency of before practising independently as a GP – states that trainees should: 'Counsel patients appropriately regarding epilepsy medication including drug interactions, side effects and contraceptive and pregnancy advice'.
"Any incidences in which valproate has been prescribed with pregnant women are a cause for concern. We call on all agencies to redouble efforts to ensure that the most up to date warnings are widely distributed to all healthcare professionals and patients - and the RCGP will continue to play our part in ensuring we achieve this.
"We would support the MHRA's advice that any patients who are currently taking sodium valproate, should not stop without seeking medical advice.
"Patients should never hesitate to raise any concerns they have about valproate, or any other medication, with their GP or other health professional."

Hernia mesh (response to BBC Victoria Derbyshire investigation in Aug 2017):

“It’s always distressing to hear that a patient is in pain because of a treatment, or surgical operation, they have received.
“Whilst most aftercare following an operation will be delivered by the surgical team, GPs do often become involved, especially if side-effects might not obviously be linked to the surgery – so it’s important that we are made aware of emerging issues with certain treatments and operations, so we know to consider them as possibilities when our patients come to us with a problem.
“It’s also important that our patients are made aware of all potential side-effects before undergoing an operation, so that if those side-effects do present, they will have a good idea that it might be because of the surgery.
“Different patients will react differently to treatments – and many hernia mesh procedures go ahead without patients experiencing problems. But all patients must be made aware of all the risks, and the different treatment options available to them, so that they can make an informed choice about whether to undergo an operation, or not.”

Royal College of Obstetricians and Gynaecologists

COI Statement

The RCOG welcomes financial or other material support from a variety of sectors. Sponsorship by industry may enable the RCOG to fund meetings or events, professional development, guidelines and patient information leaflets or other educational materials, research and other activities. If a company offers financial support, the RCOG will seek to be clear about the company's expectations and ensure that these are in line with the RCOG's charitable objects.

Any collaboration must clearly support the RCOG's strategic aims and objectives, promote the work of the RCOG and accord with RCOG values. Before seeking or accepting financial contributions from industry, the RCOG will ensure it has a thorough understanding of the company through a duediligence process. Where financial support is offered, the RCOG will seek to be clear about the company's expectations, ensuring that these are in line with the RCOG's charitable objects. The RCOG name, logo and any of its materials may not be used by industry without our written agreement and the RCOG maintains editorial control over any content that refers to the relationship.

Any direct collaboration with industry or direct funding of a project that is carried out by industry will be subject to a clear agreement and terms and conditions that will identify requirements and expectations, particularly around intellectual property, publications and exploitation.

For more information on how the RCOG works with industry, please visit:
https://www.rcog.org.uk/en/about-us/policies/advertising-and-sponsorship-policy/

Ethicon

The RCOG currently receives financial support from Ethicon, which supports the RCOG to offer some of its awards to medical students and doctors to develop their skills and knowledge in the field of obstetrics and gynaecology.

Ethicon also exhibit at RCOG events, such as the RCOG Congress, courses and congresses. All funds raised by the College are used to support our charitable activities in education, clinical quality and advocacy. Since 2015, Ethicon has spent £37,158 on exhibiting with the RCOG.

Ethicon is not involved in the selection of prize winners and the RCOG remains entirely independent.

Which RCOG prizes do Ethicon fund?

The RCOG has an endowment fund used for travelling fellowship/scholarship awards which was originally established in 1983 with funds from Ethicon. The current balance of the fund is £138,287.

An amount of £20,500 has been awarded to students, members and trainees over the past five years. Ethicon is not involved in the selection of prize winners and the RCOG remains entirely independent. The prize money focuses on topics within obstetrics and gynaecology. None of the projects focus on urogynaecology – the specialist medical field that involves the treatment of stress urinary incontinence and pelvic organ prolapse, including mesh surgical procedures.

What are the prizes awarded?

Ethicon Student Elective Award: Six prizes of up to £500 per annum are awarded to approved student medical electives in obstetrics and gynaecology. An elective is a period of time taken away from medical school to explore a particular area of medicine, to undertake research or to teach. Electives can be undertaken in the UK but can also provide the opportunity to travel overseas, allowing students to experience a different culture, health system and encounter a range of medical conditions seldom seen in the UK and Europe. Countries visited include Mauritius, Samoa, The Gambia, Jamaica, India and South Africa.

Ethicon Travel Award: One prize of up to £2,000 per annum is awarded to a member or trainee to develop their skills and knowledge whilst taking part in an overseas placement and to advance the practice and development of obstetrics and gynaecology globally. Areas of practice have included:

- Placement as a volunteer in Sierra Leone offering clinical support, training of local staff and to effect improvements to achieve sustainable development
- Advanced Techniques in Operative Gynaecological Endoscopy in France
- Exposure to advanced surgical training to treat ovarian, endometrial and cervical cancer
- The provision of obstetric care at a large public maternity hospital in Namibia and to run a quality improvement and safety course

How much are these prizes worth? How many have been awarded?

Six prizes of up to £500 per annum are awarded to approved student medical electives in obstetrics and gynaecology. Twenty five student electives have been supported by Ethicon over the past five years, amounting to £12,500 in funding support.

One prize of up to £2,000 per annum is awarded to a member or trainee to develop their skills and knowledge whilst taking part in an overseas placement and to advance the practice and development of obstetrics and gynaecology globally. Four travel awards have been supported by Ethicon over the past five years amounting to £8,000 in funding support.

Exhibitors at RCOG World Congresses and Urogynaecology related meetings:

2018

Annual Scientific Update in Urogyanecology 2018:

- Albyn Medical
- BK Medical
- Boston Scientific
- Consilient Health
- Cynosure
- Genesis Medical
- iMEDicare
- Mediplus
- Contura
- June Medical
- Allergan

- Hospital Services Limited
- BSUG

Understanding Urogyanecology 2018:

- Albyn Medical

Surgical Masterclass in Urogyanecology 2018:

- Contura Ltd
- Eurosurgical Ltd June Medical
- Boston Scientific

2017

Annual Scientific Update in Urogyanecology 2017:

- Yes Yes
- Albyn Medical
- Allergan
- Astellas
- BK Medical
- Boston Scientific
- Cogentix
- Cynosure
- European Specialty Pharma
- Genesis
- Kebomed
- Laborie
- Mediplus Ltd June Medical
- Medtronic

Understanding Urogyanecology 2017:

- Genesis
- Mediplus Ltd

Female Sexual Dysfunction 2017:

Yes Yes

- W12 Conferences
- Thermi
- Mediplus Ltd

Laparoscopic Urogynaecology 2017:

- Kebomed

Childbirth and the Pelvic floor 2017:

- June Medical
- BK Medical

2016

Annual Scientific Update in Urogyanecology 2016:

- Specialty European Pharma
- Kebomed
- Karl Storz
- Boston Scientific
- Astellas
- Allergan
- Medtronic
- Genesis Medical
- June Medical
- BK Medical
- Cynosure Mediplus
- Cogentix Medical
- Albyn Medical
- Laborie

Understanding Urogyanecology 2016:

- Astellas
- Medi Plus
- Genesis

Surgical Masterclass in Urogyanecology 2016:

- Astellas
- Boston Scientific
- Cynosure
- Karl Storz Kebomed
- Richard Wolf
- Specialty European Pharma
- Mediplus
- Albyn Medical
- June Medical

RCOG World Congresses

2018 Singapore Congress:

- Johnson and Johnson
- Cook Medical

2017 Cape Town Congress:

- Johnson and Johnson
- Medtronic

2016 Birmingham Congress:

- Cook Medical

Please let us know if you would like information going further back or any more detail.

Ref No: QXNMBW

Ms Valerie Brasse
Review Secretary
Independent Medicines and Medical Devices Safety Review
Rm 3.25b Shepherd's House,
King's College London,
London
SE1 1UL

Dear Ms Brasse,

Thank you for inviting the Royal College of Obstetricians and Gynaecologists (RCOG) to comment on the IMMD Safety Review into the use of synthetic mesh in abdominal and vaginal pelvic mesh procedures, sodium valproate and Primodos.

Royal College of Obstetricians and Gynaecologists (RCOG): The RCOG works to improve women's health care across the world. Founded in 1929, we now have over 16,000 members worldwide and work with a range of partners both in the UK and globally to improve the standard of care delivered to women, encourage the study of obstetrics and gynaecology (O&G), and advance the science and practice of O&G. The British Society of Urogynaecology (BSUG) is a specialist society of the RCOG; specialist societies are independent organisations that represent various specialist areas of practice within O&G[1]. BSUG is submitting an independent response to the Review.

The RCOG believes that it is paramount that women with pelvic organ prolapse and stress urinary incontinence are made aware of all the treatment options available, and empowered with information about the risks associated with any procedures, to enable them to make an informed decision about the right treatment for their condition. Specialist training, surgical experience and appropriate patient selection are all crucial factors in ensuring current and future patients receive the highest quality care.

For the purposes of the responses below we would like to clarify that unless otherwise stated we are referring to mesh used to treat urinary incontinence.

Lastly, our response refers to the roles of other bodies, including statutory agencies where applicable.

Q 1. We recognise that the majority of patients will not have any follow-up actions providing their implanted device functions well. What is your current understanding of the efficacy and safety of the mesh devices which are currently being used, or which have previously been used, and what advice do you provide your members?

Response: It is routine and standard clinical practice for all women having an incontinence mesh inserted to receive follow up after surgery with a majority of patients supported in this way. The timing of this follow-up ranges from 6 weeks to 12 months. This is currently collected in the BSUG voluntary database. The BSUG database also collects data on intraoperative events and complications happening

[1] http://bsug.org.uk/

distant from the insertion. If the device is functioning well, however, no further action or intervention is usually required.

The RCOG has provided the appended (appendix 1) clinical advice to its Members and Fellows in response to the implementation of a high vigilance restriction period regarding vaginal mesh for incontinence[2]: Additionally, the RCOG has a mesh webpage, which links to the full details of the scope and processes for the high vigilance period set out by NHS Improvement and NHS England[3].

The RCOG has communicated the clinical advice and the mesh webpage to its Members and Fellows through a number of channels, including our website, a safety alert email and our monthly enewsletter, encouraging them to use the information provided by NHS Improvement and NHS England.

Prior to the high vigilance period being set, the College communicated to its Members and Fellows via the below methods:

- The RCOG mesh webpage which brings together all relevant guidance.
- A now archived Scientific Impact Paper on The Use of Mesh in Gynaecological Surgery. This was shared via a dedicated email to our Members when first published.
- Lastly, we have commented publically on various mesh reports over a number of years[4].

Q 2. Please could you provide a timeline outlining your understanding and recognition of risks of synthetic polymer mesh for use in pelvic surgery (abdominal and vaginal). This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.

Please see BSUG's response to this question in appendix 2 and the answer to Q.10.

Q 3. How do you decide on the content of any information you provide to patients when discussing the risks and benefits of different approaches to stress urinary incontinence and pelvic organ prolapse? **Response:**

As part of its work, the RCOG produces clinical guidelines and parallel information for the public on the treatment and care of women [5].

The RCOG aims to support women in understanding what they can expect of their health care and the options available to them to make informed decisions based on evidence-based, accessible information. It produces parallel information for the public which is designed to be:

- Web-based but able to download and print
- Used and adapted by each unit within the UK and Ireland as needed
- Readily available
- Easy to understand
- Reliable

[2] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/mesh-safety-alert/
[3] https://www.rcog.org.uk/en/guidelines-research-services/patient-safety/mesh/
[4] https://www.rcog.org.uk/en/search-results/?q=mesh&type=News+Article
[5] https://www.rcog.org.uk/en/patients/patient-leaflets/

- Up-to-date

Our Green-top Guidelines are accredited by NICE, and our patient information leaflets have Information Standard accreditation.

Please find further information about our patient information and guidance in appendix 3.

Q 4. How does the College ensure that professionals achieve, retain, and update skills relevant to the devices available on the market? To what extent are knowledge and skills maintained for nonmesh surgical approaches?

Response:

The RCOG has strong and clear governance structures and takes patient safety very seriously[6]. The College has an Education Board, which is responsible for the RCOG curriculum and any changes made to the curriculum, and a Clinical Quality Board, which is responsible for issues of patient safety. Both Boards report to the College's Council. RCOG Council is responsible for furthering the College's mission and for setting its long-term priorities and goals. Council establishes and oversees the clinical, educational, professional, academic and ethical activities of the College. It is chaired by the President and meets 6 times a year.

Whilst the College is not a regulator, if the safety concern is immediate, the RCOG advises its members to raise the concern(s) with the appropriate regulator: the Medicines and Healthcare products Regulatory Agency (MHRA), the Care Quality Commission (CQC) and the General Medical Council (GMC).

The RCOG supports its Fellows and Members through education and training but these are generally not related to specific products. Doctors in training develop certain areas of practice in their final two years in the training programme, either by completing Advanced Training Skills Modules (ATSM) which allow some degree of specialisation within a general O&G post, or by completing subspecialist training that enables them to develop high-level skills in their specialist area of interest. For example, trainees who want to practise some urogynaecology within a generalist O&G consultant role would undertake the College's ATSM in urogynaecology and vaginal surgery, while those who wish to practise as specialist urogynaecologists would complete the College's subspecialist training programme in urogynaecology.

The College has recently revised its advanced training programmes in urogynaecology to reflect the pause on mesh procedures.

The College, alongside BSUG and the General Medical Council (GMC), provides the syllabus, logbook and assessment for ATSM and subspecialty training in urogynaecology.

The curriculum and logbook for this training were revised in October 2018. These revisions were approved by the GMC.

The revisions include:

[6] https://www.rcog.org.uk/en/about-us/governance/

- The introduction of a standardised logbook, which means that it is now mandatory for trainees to keep a surgical log of all procedures, which is then assessed.
- 'Urethrotomy' and 'Stapled transanal resection procedure' have been removed from the curriculum.
- A module on laparoscopic urogynaeoclogy is now a mandatory component of the curriculum.

All trainees registered for subspecialty training in urogynaecology must complete the generic subspecialty curriculum, which applies to all subspecialties. The generic subspecialty curriculum covers non-clinical skills including communication, team working, leadership and clinical governance.

Additionally, the College is also supporting BSUG in developing a module for consultants who need to train (or re-train) in non-mesh procedures.

The RCOG also advises its members to follow guidelines issued by NICE relevant to these conditions. We also provide governance guidelines and expect members to adhere to these; however, the statutory obligations to do so rest with the clinicians.

Also, the maintenance and assessment of competence and skills is part of the appraisal process.

Lastly, the College has a continuing professional development (CPD) programme (CPD), which encourages lifelong learning, supported by eLearning and courses/conferences [7]. Urogynaecologists can use learning skills, relating to relevant devices, for CPD purposes. However, the programme does not prescribe specific skills.

Q 5. What advice do you currently give your members regarding management of urinary incontinence and pelvic organ prolapse?

The RCOG has a mesh webpage which brings together the available information about mesh, including NICE guidelines relevant to mesh and information provided by other bodies and organisations[8]. The mesh webpage has been signposted to our members via our monthly enewsletter and other communications channels with members.

Q 6. In your view, what are the priorities for future research related to the interventions and issues raised by the Review?

Response: The RCOG is committed to patient safety and is constantly assessing how it can improve care to make it safer and reduce the risks associated. We believe that future research should be underpinned by evidence-based guidelines, ideally NICE guidance, and should focus on reducing risk from interventions and providing safe and effective care for women across the UK.

Furthermore, future research should focus on data relating to complications and success rates with alternative surgical procedures.

Most importantly, any future research should widely involve patients and patient groups.

[7] https://www.rcog.org.uk/en/cpd-revalidation/cpd-programme/
[8] https://www.rcog.org.uk/en/guidelines-research-services/patient-safety/mesh/

Q 7. Please could you provide a timeline outlining your understanding and recognition of risks of valproate containing medicines during pregnancy, and for hormonal pregnancy tests. This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.

On 24 April 2018 The Medicines and Healthcare products Regulatory Agency (MHRA) announced that valproate medicines – used to treat epilepsy and bipolar disorder – must no longer be prescribed to women of child bearing age unless she is on a pregnancy prevention programme (PPP).

In response to this announcement, the College issued the below statement and safety alert by email to all of our UK members:

The Medicines and Healthcare products Regulatory Agency (MHRA) has today announced that valproate medicines – used to treat epilepsy and bipolar disorder – must no longer be prescribed to women of child bearing age unless she is on a pregnancy prevention programme (PPP).

The medication significantly increases the risk of birth defects and developmental disorders in children born to women who take it during pregnancy. Up to 4 in 10 babies are at risk of developmental disorders, and around 1 in 10 are at risk of birth defects.

Healthcare professionals who prescribe valproate must ensure sure the women is enrolled in a PPP, which includes the completion of a signed risk acknowledgement form and seeing a specialist at least every year.

These new regulatory measures are being supported across the NHS with other authorities also making changes – such as new GP system computer alerts – to ensure changes in prescribing behaviour take place promptly. Women who are prescribed valproate are encouraged to contact their GP and arrange to have their treatment reviewed. Women should not stop taking valproate without medical advice.

In June 2016, the College published its clinical guideline (Green-top Guideline) on the management of epilepsy in pregnancy. This guidance recommends that exposure to sodium valproate and other anti-epileptic drugs should be minimised by changing the medication prior to conception, as recommended by an epilepsy specialist after a careful evaluation of the potential risks and benefits.

It is also notes that women should be advised to seek advice from their GP and/or specialist team before conception or as soon as they are aware that they are pregnant. For women with epilepsy, the lowest effective dose of the most appropriate anti-epileptic drug should be prescribed and they should be looked after by a specialist team throughout pregnancy[9].

The guideline was highlighted to all members in a bespoke email, via the College's e-newsletter, our website and social media.

Q 8. If you have had any adverse events concerning the use of hormone pregnancy tests or valproate containing medicines during pregnancy reported directly to the College please provide an anonymised summary, including dates of receipt, and indicate what actions were or are being taken in response to these reports.

Response: The College is not aware of receiving any reports of adverse events.

[9] https://www.rcog.org.uk/globalassets/documents/guidelines/green-topguidelines/gtg68_epilepsy.pdf

Q 9. What guidance do you give your members for advising families on the management of congenital malformations as the result of in utero exposure to medicines, including valproate containing medicines?

Response: The College has a Green-top Guideline on Epilepsy in Pregnancy and accompanying patient information [10]. However, neither gives guidance on the management of congenital malformation as the result of in utero exposure to valproate.

Q 10. What guidance does the College provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (non-intervention)? Please supply copies of relevant guidance, with the dates during which each version was in circulation.

Response: The RCOG believes that consent is a fundamental part of clinical practice.

Since 2004, the College has produced an 'Obtaining Valid Consent' guideline, which has been updated three times, most recently in 2015 [11]. The purpose of the advice is to provide a good practice framework for obtaining valid consent in obstetrics and gynaecology. The College also has a Consent Advice series, which promotes good practice in this area focusi9ng on specific procedures[12]. The aim is to ensure that all patients are given consistent and adequate information for consent. The documents follow the structure of the Department of Health/Welsh Assembly Government Consent Forms. We advise that the Consent Advice series is read in conjunction with the RCOG Clinical Governance Advice No. 6: Obtaining Valid Consent[131415].

All of this information is brought together on our consent hub, setting out how to apply these resources and also referencing the Montgomery ruling[114151617]. These resources have been highlighted to our members on a number of occasions via our regular member communications.

Furthermore, the experiences of women and the issues raised in reports, parliamentary questions and debates, and the media stress the importance of ensuring consent and an understanding of risk are central to issues of patient safety.

The College has ensured that its members are supported regarding consent and communicating risk[18].

The RCOG has a dedicated page on its website bringing together resources for healthcare professionals and women/the public on mesh, to support evidence-based care and shared, informed decision making[19].

---

[10] https://www.rcog.org.uk/globalassets/documents/patients/patient-informationleaflets/pregnancy/pi-epilepsy-in-pregnancy.pdf
[11] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/clinical-governance-advice6/
[12] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/?q=&subject=&type=Consent+Advice&orderby=title
[13] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/clinical-governance-advice-
[14] /
[15] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/clinical-governance-advice7/
[16] https://www.rcog.org.uk/en/patients/patient-leaflets/understanding-how-risk-is-discussed-inhealthcare/
[17] https://www.rcog.org.uk/en/guidelines-research-services/consent/
[18] https://www.rcog.org.uk/en/guidelines-research-services/consent/
[19] https://www.rcog.org.uk/en/guidelines-research-services/patient-safety/mesh/

Additionally, the College provides patient facing information to ensure that women receive consistent, high quality information about risk [19]. The College has a patient information leaflet on pelvic organ pro[20]lapse, which is currently being updated [21]. We are also working with BSUG to coproduce a Shared Decision Aid for stress urinary incontinence. The aid will help women to consider their surgical options after non-surgical options have been exhausted, guiding their thinking around the outcomes that are important to them to help make decisions.

Lastly, the College had input into NHS England's patient information leaflets on mesh via a clinical representative [22].

Q 11. Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are changes in the types and levels of concerns expressed by patients in relation to particular procedures either in the NHS or private practice?

Response: The RCOG is not a regulator and has no statutory role in complaints handling. We do however receive a small number of concerns or complaints from both clinicians and members of the public. If the safety concern is immediate, the RCOG advises its members to raise the concern(s) with the appropriate regulator: the Medicines and Healthcare products Regulatory Agency (MHRA), the Care Quality Commission (CQC) and the General Medical Council (GMC). We also pass any complaints we receive to the appropriate regulator.

When the College receives complaints from patients, depending on the issue, we will provide them with any patient information available that is relevant to their complaint and sign-post them to the appropriate organisation/body.

Q 12. Of the total numbers of complaints received year on year what proportion relate to: a) abdominal/ vaginally place mesh procedures; and
b) issues of informed consent? How has this changed over time?

Please see answer to Q.11.

Q 13. Please describe the College's role with regard to: a) adverse events reporting;
b) patient safety;
c) providing a forum for discussion; and
d) potential early warning signal detection?

Response:

a. Adverse events reporting: The RCOG's mesh webpage clearly states that all complications must be reported via the MHRA Yellow Card Scheme. Patient safety drives the RCOG's

[20] https://www.rcog.org.uk/en/patients/patient-leaflets/understanding-how-risk-is-discussed-in-healthcare/
[21] https://www.rcog.org.uk/en/patients/patient-leaflets/pelvic-organ-prolapse/
[22] https://www.england.nhs.uk/mesh/

guidelines and training/education and is core to the recommendations we make. The College encourages all adverse events to be reported in line with the NHS Improvement incident reporting framework[23]. The College does not have a reporting system as the RCOG has no statutory role in adverse events reporting. Members of BSUG are encouraged to use the BSUG database to record all surgical cases.

b. Patient safety: Patient safety drives the RCOG's guidelines, training and education. It is core to the recommendations we make. The College has a number of patient safety initiatives, such as our Each Baby Counts programme and our Clinical Indicators Programme[2425]. The College's Clinical Indicators Programme forms a large part of the College's work on patient safety and consists of a number of projects aiming to develop clinically relevant, methodologically robust performance indicators for obstetric and gynaecological care using currently available data. The RCOG Clinical Indicators Programme has successfully led the way for improvements in obstetrics, with the development of the National Maternity and Perinatal Audit (NMPA), and is now expanding this work into gynaecology with the recent publication of a report into the development of benign gynaecology indicators[2627].

   The RCOG has a joint standing committee for patient safety which meets quarterly to discuss all O&G patient safety related issues. This committee reports to the Clinical Quality Board. The College also hosts a number of events relating to patient safety and quality improvement in the specialty including Improving the Quality of Women's Health Care, a national patient safety conference with over 200 attendees, which was held in October 2017 [27].

c. Providing a forum for discussion; and: The RCOG has a clear governance structure, which enables its members to contribute to and take part in the College's work, including decision making. The RCOG's elected Council is responsible for furthering the College's mission and for setting its long-term priorities and goals. The elected Council establishes and oversees the clinical, educational, professional, academic and ethical activities of the College. The College also has a number of boards and committees who are responsible for various aspects of the College's work, and whose membership primarily comprises our Fellows, Members and Trainees as well as other relevant stakeholders. Importantly, the lay voice is represented on all of our committees via our Women's Network, while our Women's Voices Involvement Panel enables wider lay engagement in our work [2829]. For the full list of Committees, please visit the College's website [30].

---

[23] https://improvement.nhs.uk/resources/serious-incident-framework/
[24] https://www.rcog.org.uk/eachbabycounts
[25] https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinicalindicators-programme/
[26] http://www.maternityaudit.org.uk/pages/home
[27] https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinicalindicators-programme/benign-gynaecological-care/benign-gynaecology-report-2015-16/ [27] https://www.rcog.org.uk/en/departmental-catalog/Departments/postgraduate-and-scientificmeetings/womens-health-patient-safety-day/
[28] https://www.rcog.org.uk/en/patients/rcog-womens-network/
[29] https://www.rcog.org.uk/en/patients/womens-voices-involvement-panel/
[30] https://www.rcog.org.uk/en/about-us/governance/ [31] https://www.rcog.org.uk/en/guidelines-

d. Potential early warning signal detection: The RCOG has no formal, statutory role in this area. Should concerns be raised with the College, we sign-post to the relevant body. If the VicePresident for Clinical Quality agrees that something needs to be communicated to the RCOG membership, the College will issue a safety alert to all Fellows and Members via email [31].

Q 14. Please can you provide a brief summary of how adverse events reported to you are collected, processed and investigated? How effective do you think this process is in capturing adverse events data? How do you think this could be improved?

Response: The College does not have a role in collecting/processing and investigating adverse events as we are not a regulator – any such reports are either passed to the relevant regulator or we signpost to the relevant regulator. For example, the MHRA, CQC or GMC.

Q 15. Do you have any indication of use of Yellow Card reporting by your members? For example, have you previously undertaken surveys, or encouraged its use and other reporting mechanisms?

Response: The College does not have any indication of the use of the MHRA's Yellow Card Scheme by its members. Nevertheless, the College encourages its members to report via the Yellow Card Scheme. The College's website provides information on how to report mesh complications and also directs members and patients to BSUG's website. BSUG's website also has information on how to report mesh complications.

Q16. Where within the healthcare system does your responsibility for disseminating and responding to adverse event reporting as a professional body begin and end vis-a vis the regulators and manufacturers?

Response: The RCOG encourages its members to report adverse events, primarily through the MHRA. The MHRA will notify manufacturers of adverse events reported under the Yellow Card Scheme.

BSUG has this year produced a national report looking at adverse events from all continence procedures including but not limited to meshes. This will be made available to the public and allows a comparison of the various incontinence procedures**. Please see BSUG's response to this question.**

Q 17. Please can you provide details of your relevant policies and protocols, if any, for ensuring that information relevant to patient safety, and learning from adverse events is disseminated amongst your members.

Response: The RCOG disseminates key third-party reports to its membership, together with RCOG comment where this is deemed appropriate, via a number of communications channels, including our monthly e-newsletter and triannual membership magazine.

Each time the RCOG publishes a new or updated piece of guidance (such as Green-top Guidelines or Scientific Impact Papers), this is disseminated to the membership via a bespoke email in addition to our standard membership communications channels. The same process applies to any reports or position statements produced by the College in relation to patient safety issues.

---

researchservices/guidelines/?q=&subject=&type=Patient+safety+alert

There is also a dedicated patient safety page on the RCOG website [31].

Q 18. What factors influence the decision on when to update guidance, and how are adverse events reports weighted in this process given the known level of underreporting?

Response: The RCOG's Green-top Guidelines and Scientific Impact Papers are reviewed by the Guidelines Committee and Scientific Advisory Committee respectively every 3 years to assess whether an update is needed. Where sufficient new evidence has been published in that time, a new edition of the guidance will be developed. If the Guidelines Committee or Scientific Advisory Committee do not believe there is enough new evidence, they will not update the guideline that year. If the guideline or paper is not updated, it is reviewed every subsequent year.

Adverse event reporting is something that our members do as individuals but we do not have access to the results of this reporting. This is the remit of the MHRA who receive the adverse event reports.

Q 19. How can we ensure patient outcome reports on treatment interventions reflect subjective patient experiences as well as clinical outcomes?

Response: The RCOG believes the development of patient related outcomes (PROMs) and patient reported experience (PREMs) is vitally important in order that long term patient reported outcomes and experience can be captured. This can be achieved by ensuring lay involvement in the development of research and audit protocols. This allows evidence to be gathered around outcome and experience that are important to the patient rather than only the clinical outcome, which can support patient decision making in the future.

This would give more accurate information regarding outcomes, including both success and complication rates, and provide comprehensive data to inform women and healthcare professionals about the benefits and risks of all urogynaecological procedure.

Patient outcome reports with only clinical data cannot provide insight into the nature and severity of urinary incontinence and the problems women face following treatment with mesh.

Please also see response to Q22.

Q 20. How do we ensure that clinicians respond appropriately to patient concerns?

Response: Clinicians have a duty of care to their patients and responding to patient concerns is enshrined in the GMC guidance on Good Medical Practice [32]. This document lays out the key responsibilities of a doctor.

Q 21. How do you feel the culture of reporting concerns and adverse events by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What, if anything, could be done to improve this?

[31] https://www.rcog.org.uk/en/guidelines-research-services/patient-safety/
[32] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

Response: The RCOG believes that there is more open reporting of concerns and adverse events by clinicians and others within the healthcare system. The College proactively encourages its Fellows and Members to report adverse events.

The MHRA's Yellow Card system has been improved to make it accessible and easy to complete. It has only recently become an online system.

We do not believe that clinicians are a barrier to reporting. Clinicians need to understand their responsibility in reporting adverse events and any mandating of this process would be welcome. The NHSE mesh review tried to encourage reporting through the appraisal process.

Q 22. What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?

Response:

The RCOG continues to call for a mandatory prospective register, collecting outcome data for all urogynaecological procedures, including mesh. This would give more accurate information regarding outcomes, including both success and complication rates, and provide comprehensive data to inform women and healthcare professionals about the benefits and risks of all urogynaecological procedure.

A mesh registry should be designed in such a way that:

- it captures women's concerns and therefore collects data reported by women themselves
- it is able to produce some relevant outcomes in a relatively short time
- it can achieve (near-)complete case ascertainment and a high level of data completeness
  - the burden of data collection on clinical staff is kept to a minimum
- it does not rely on clinician-reported complications, adverse events and outcomes, to avoid the possibility of 'gaming' of clinical data
- it is managed in such a way that it is demonstrably independent of any clinical or commercial interest and that it can benefit from the input of all relevant stakeholders, including patients (in the case of mesh, representing those who had mesh tape insertions as well as those who had alternative treatments), clinicians, and academics with relevant methodological background.

Lastly, and it is difficult to overstate its importance, there is a need for patient-reported outcomes and experiences. A register with only clinical data cannot provide insight into the nature and severity of urinary incontinence and the problems women face following treatment with mesh. A national registry should always collect data reported by women themselves, before and after treatment, and including mesh and non-mesh treatment options. These patient-reported data can be combined with the registry data through data linkage and analysed together.

An example of a current 'effective registry' can be seen in the National Joint Registry which captures data on patients who undergo a hip or knee replacement in English NHS. The registry fulfils the following criteria:

- Clinical data is entered by the surgeons in the National Joint Registry for the 1.8million patients who undergo joint replacement each year. This combination of information for all patients (now more than 1.8million) means we can measure how well different implants perform over time.

- It includes data on clinical history and comorbidities, as well as data on further treatments (revision surgery; of removals and reoperations in case of mesh) is derived from data linkage with the Hospital Episode Statistics (HES).
- Includes data on the impact of the joint replacement on patients' hip or knee function and quality of life via linkages with the NHS Patient-Reported Outcome Measures programme, collecting patient-reported outcome and experience data just before surgery and six months post-surgery.

The RCOG believes that a registry should be hosted by an independent body.

Healthcare professionals can be encouraged to use the registry by making this mandatory for certain specific procedures.

All evidence which forms the basis of this response is referenced. No evidence has been withheld and we have answered the questions honestly and to the best of our ability.

We would like to suggest the following potential questions to ask of others who may be giving evidence to the Review:

- Has the opinion of mesh patients who have not suffered an adverse outcome been sought?

- How many women have suffered complications of chronic pain as a result of non-mesh procedures? Have the complications of non-mesh procedures been evaluated by the Review panel?

- We would suggest an independent evaluation of women with problems to see if they have predisposing factors e.g. fibromyalgia. This may assist in identifying patients more likely to have problems and help with patient selection in the future.

- We would like to suggest a random survey by an independent organisation i.e. HQIP of 10,000 patients to see what their outcomes have been after incontinence surgery.

We confirm that we give permission for this evidence to be used for the purposes of the Review.

The RCOG is committed to improving care for girls and women across the globe. We will do everything we can to work with patients, clinicians and other organisations to ensure women with incontinence and prolapse receive high-quality and safe care, and the tools and information they need to make informed choices about their health.

Appendix 1

RCOG guidance for clinical care related to vaginal mesh:

Guidance for clinical care

For the majority of patients, mesh surgery should not be performed during this period of high vigilance restriction.

For some patients, mesh procedures may be the only viable treatment option. This includes cases where clinicians judge there is clinical urgency to carry out the procedure and no suitable alternative exists, and/or where delay would risk harm to the patient. However, this treatment should only be used in carefully selected patients who understand the risks and have given fully informed consent. For this group of patients, the period of high vigilance restriction will include:

- *strict adherence to the recently published IPGs (Interventional Procedure Guidance) published by NICE for these procedures*
- *multidisciplinary team assurance at trust levels to support the necessity of the procedure without delay*
- *fully supported patient choice and sign off in advance of that process*
- *evidence of the competence of the surgeon*

NHS Improvement and NHS England set up a Clinical Advisory Group to:

- *define procedures and scope for the high vigilance restriction*
- *advise on appropriate confirmation process to ensure appropriateness of any mesh procedures intended*

- *recommend a process for provider trust Medical Director sign off of the surgeon's competence for those mesh procedures required and any alternate operations*
- *advise on best options to ensure patient information and consenting processes are in place in a trust*

Appendix 2

Between 1985 and 1995, several surgical meshes, including Trelex Natural Mesh (Boston Scientific, Marlborough, MA), Supple Peri-Guard (Synovis, St Paul, MN), GORE-TEX Soft Tissue Patch (GORE, Flagstaff, AZ), Mersilene mesh (Ethicon, Somerville, NJ) and Marlex mesh (C. R. Bard, Inc., Murray Hill, NJ), were cleared by the FDA for uses including hernia repair; however, none were cleared for use as vaginal meshes. In 1996, Boston Scientific's ProteGen mesh, the first vaginal mesh for the surgical treatment of SUI, was approved under the FDA 510(k) premarket notification process. The 510(k) ruling allows manufacturers to bring a new product to market without rigorous testing if it is deemed to be 'substantially equivalent' and 'at least as safe and effective' to a legally marketed device. ProtoGen 510K (K963226) was predicated on mesh devices previously approved for hernia repair (Gore-tex, Marlex and Mersilene) and no further testing was deemed necessary, despite a lack of clinical safety trials for transvaginal placement. The chain of events demonstrating how the 510 (k) pathway led to approval of mesh use in surgery for pelvic organ prolapse (POP) is shown in Appendix 7.

Individual clinicians and BSUG regularly contribute to the scientific papers produced on these subjects and we keep ourselves abreast of developments. Many of us had significant concerns regarding the introduction and commercialisation of the TVT procedure when it was first introduced in the UK in 1998. Many surgeons did not feel that the procedure was proven to be safe and effective at the initial time that it was introduced. The TVT/Colposuspension (Appendix 8) trial was developed and run to address concerns from urogynaecologists in the UK. Many individuals were unhappy with the scientific evidence regarding safety and efficacy and did not immediately introduce the technique. BSUG was only formed in 2001 after the introduction of the TVT procedure. One of the main reasons for the introduction of the BSUG database was to study the safety and efficacy of the TVT procedure.

Appendix 3

What does information for the public include?

Information for the public usually covers, in non-medical language, the recommendations made in the equivalent guideline. It also includes:

- a series of questions and answers women are most likely to want to know. Examples of these questions might include:
  - What is this intervention/condition?
  - What could it mean for me?
  - What could it mean for my baby (where relevant)?
  - What treatment options are available?
  - What are the risks and benefits of interventions/treatments?
  - Further information and support available

- a link to the equivalent guideline or statement
- the date of publication

How is information for the public produced?

Information, based on RCOG guidelines, is developed by the RCOG's Patient Information Committee. This group includes consumer representatives from the College's Women's Network, obstetricians and gynaecologists, midwives and nurses.

When a guideline is in production, the Patient Information Committee begins to develop parallel information based on this and prepares a first draft. This is discussed and revised by the Patient Information Committee.

Peer review

Draft guidelines, as well as parallel information for the public, go through a number of revisions before publication. This process is known as peer review. It helps to ensure that the RCOG draft:

- guideline is evidence-based and practical
- information for the public accurately reflects the guideline in an accessible way.

The draft guideline document is circulated to expert health professionals (obstetricians, gynaecologists, midwives).

The draft information for the public is circulated to:

- relevant clinicians (including RCOG Members and Fellows)
- the RCOG Women's Network, which has 15 lay members.
- the RCOG Women's Voices Involvement Panel, which has a membership of 500.
- consumer representatives
- relevant voluntary sector organisations
- identified outpatient clinics for women who are attending to comment.

As part of the peer review process, draft documents are also posted on the public section of the RCOG website (under Guidelines – Consultation documents: www.rcog.org.uk/en/guidelinesresearchservices/guidelines/consultation-documents). This means that everyone who wishes to comment has an opportunity to do so. The review is also highlighted on social media to invite public comments.

The drafts go through a number of revisions, based on reviewers' comments. Members of the Guidelines Committee and the Patient Information Committee consider peer reviewers' comments and then agree all changes necessary.

Final approval

Before publication, the final version of the guideline and patient information must be approved by the following RCOG committees:

- Clinical Quality Assurance Group
- Clinical Quality Board

Informing healthcare professionals and the public

After publication, all Members and Fellows of the RCOG receive an email informing them of the published guideline. This means that a copy goes to every obstetrician and gynaecologist in the UK who is a Member or Fellow of the RCOG. New guidelines and associated patient information are also highlighted in our monthly membership e-newsletter and tri-annual membership magazine. The information is also publicised to relevant patient support organisations and the wider public through social media.

Both the guideline and parallel patient information are available on the public section of the RCOG website.

Keeping information up-to-date

Guidelines are reviewed three years after publication. They are either:

- updated – if new evidence has emerged that needs to be included; or
- withdrawn – if the guideline is no longer relevant or if external evidence-based information has been published by a third party (e.g. NICE) since the original edition of the guideline

If new evidence emerges with important implications for practice, then a guideline may need to be reviewed within three years of publication.

Parallel information for the public is also reviewed. As a minimum, the information is updated whenever the equivalent guideline is revised.

Royal College of Psychiatrists

COI:

Members of the Psychopharmacology Committee (Chair: Professor David Baldwin) provide full declarations of interest which are available on the College website. The College provides clear guidance regarding potential conflicts of interest: 'Good Psychiatric Practice: relationships with pharmaceutical and other related organisations' (CR202, March 2017) and 'Competing interests: guidance for psychiatrists' (PS01/2017, March 2017).

Submission:

1. *Please could you provide a timeline outlining your understanding and recognition of risks of valproate containing medicines during pregnancy. This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients*. College members are medical practitioners registered with the General Medical Council and so would receive information regarding risks of valproate containing medicines at the same time as that information is circulated to all other medical practitioners. The GMC should be able to provide details of when warnings regrading valproate had been circulated throughout the medical profession.

2. *What is the prevalence of off-label use of valproate containing medicines for treatment of bipolar disorder, schizoaffective disorder, schizophrenia and other uses?* Valproic acid (as the semisodium salt) and sodium valproate are used within licence (i.e. not 'off-label') for treatment of manic episodes associated with bipolar disorder: they must be started and supervised by a specialist experienced in managing bipolar disorder. Valproate-containing medicines (valproic acid and sodium valproate) are also used for prophylaxis (long-term treatment) in patients with bipolar disorder, to reduce the likelihood of further episodes. Use of medicines for other indications (schizophrenia and schizoaffective disorder) is outside the terms of the authorisation (i.e. 'off-label') although it should be noted that bipolar disorder and schizoaffective disorder are closely related conditions. Valproate-containing medicines are also often prescribed to patients with learning disability and epilepsy, many of whom receive care within mental health services.

A recent clinical audit (Paton et al., BMJ Open 2018 Apr 12;8(4):e020450) of prescribing practice across 55 mental health Trusts in female patients of child bearing potential and with the diagnosis of bipolar disorder (conducted by the Prescribing Observatory for Mental Health of the College) found that 24% of women aged younger than 50 years were prescribed valproate-containing medicines: in only half of such women was there documented evidence that information had been provided on the risks for the unborn child and the need for adequate contraception. The current prevalence of 'off-label' use of valproate in patients with schizophrenia or schizoaffective disorder within mental health services is uncertain, but the findings of previous prevalence studies conducted in other countries (Israel, United States and multiple Asian countries) suggest that between 14.1 and 35.2% of patients might be prescribed valproate-containing medicines, typically combined with antipsychotic medication.

3. *Assuming that patient awareness of the risks of valproate use during pregnancy is low, are you taking actions to ensure that your members are complying with the pregnancy prevention plan?* The College guidance regarding valproate-containing medicines is at an advanced stage of preparation: the penultimate draft will be discussed during a meeting with Lord O'Shaugnessy (Department of Health and Social Care) on Thursday 15th November. The final version of the guidance to College members should be complete by the end of that month, and anticipate that we can make that

guidance available to the Review for its meetings in late November. The College will expedite publication of the guidance and its dissemination throughout the membership. The College itself does not have a role in ensuring that its members comply with pregnancy prevention plans or other provisions relating to prescribing valproate-containing medicines: this is a matter of clinical governance so is within the responsibilities of individual clinicians and their employing mental health service providers (NHS Trust and private providers).

4. *What advice do you provide to your members on contraceptive measures for girls on valproate entering puberty?* The College has not issued specific advice about prescription of valproate-containing medicines to girls entering puberty but a statement about this will be included within our imminent published guidance.

5. *How have lessons learnt from valproate medications been applied to testing and guidance for newer medications?* The College is not involved in the testing of newer medications. Guidance regarding new medicines is provided by the MHRA and NICE (and the particular pharmaceutical companies): College members will become aware of the identified benefits and risks of new medicines through a range of mechanisms (educational events, journal publications, Trust drugs and therapeutics committees, etc.).

6. *How does the College ensure that professionals achieve, retain, and update skills relevant to the medicines available on the market?* The College hosts an International Congress each year, which includes a psychopharmacology 'stream' of sessions (usually the most well attended of all sessions) in which internationally regarded speakers describe the balance of risk and benefit with established and novel medicines. Our 2018 Congress included two sessions which provided guidance on valproate-containing medicines (S35: valproate prescribing – evidence of benefit and harm; S46: prescribing medication during pregnancy), both of which were attended by very large numbers of clinicians. The College also hosts Faculty and Divisional events which typically include talks relating to risk and benefit in psychopharmacology.

7. *What guidance does the College provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (or non-intervention)? Please supply copies of relevant guidance, with the dates during which each version was in circulation.* College members have been provided with the statement 'Informed consent – the new law', based on legislation arising from the case of Montgomery v. Lanarkshire Health Board (2015). Current guidance on the College website stipulates: the legal obligation upon clinicians to provide information to patients about their treatment; information must be understood by the patient; and documentation must confirm that the patient understands the seriousness of their condition, anticipated benefits and risks of treatment, and any reasonable alternatives to treatment.

8. *How can communication of specific risks to patient groups be improved?* College members are experienced in assessing, communicating and managing risks associated with specific patient groups (for example, those with intellectual disability, cognitive impairment, diminished insight) and particular aspects of practice (for example, involuntary admission and treatment, working with families and multi-disciplinary teams). Our members are encouraged to refine their overall communications skills, and specific skills in risk assessment and management, by undertaking continuous professional development activities agreed with peer groups and approved by clinical managers.

9. *Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are changes in the types and*

levels of concerns *expressed by patients in relation to particular procedures either in the NHS or private practice*? The professional regulator of psychiatrists is the GMC, so it is their (and local Trust) procedures which would deal with these professional practice matters.

10. *Of the total numbers of complaints received year on year what proportion relate to: a) Sodium valproate;*

b) issues of informed consent? How has this changed over time? See above, the College would not routinely receive such complaints, so does not hold such data.

11. *If you have had any adverse events concerning the use of valproate containing medicines during pregnancy reported directly to the College please provide an anonymised summary, including dates of receipt, and indicate what actions were or are being taken in response to these reports.* The College does not have a role in gathering, synthesising or reporting adverse events associated with specific medicines. However, its Quality Improvement Initiatives (for example, the Prescribing Observatory for Mental Health, and the separate National Clinical Audits of Psychosis, Dementia and Anxiety and Depression) together gather considerable data from participating mental health trusts on many hundreds of patients - for example, the recent anxiety-depression audit includes data on 4128 'cases' - and prescribing patterns and reports of adverse events are included within these national audits.

12. *How do you see the College's role with regard to: a) adverse events reporting; b) patient safety; c) providing a forum for discussion; and d) potential early warning signal detection?* As stated above, the College does not have a role in gathering, synthesising or reporting adverse events associated with specific medicines. The College produces and updates guidance on particular aspects of prescribing practice, which typically include detailed consideration of patient safety: for example the December 2017 guidance on unlicensed applications of licensed drugs in psychiatric practice (College Report 210) describes the steps which should be considered before and during the prescription of a drug outside the terms of its licence. Through its regular national and regional meetings, the College provides a forum for discussing all aspects of psychiatric practice, including the use of potentially hazardous medicines in vulnerable patient groups.

13. *Please can you provide a brief summary of how adverse events reported to you are collected, processed and investigated? How effective do you think this process is in capturing adverse events data? How do you think this could be improved?* As stated above, the College does not have a role in gathering, synthesising or reporting adverse events associated with specific medicines.

14. *Do you have any indication of use of Yellow Card reporting by your members? For example, have you previously undertaken surveys, or encouraged its use and other reporting mechanisms?* The College has not gathered data on the use of Yellow Card reporting by its members.

15. *Where within the healthcare system does your responsibility for disseminating and responding to adverse event reporting as a professional body begin and end vis-a-vis the regulators and manufacturers?*

16. *Please can you provide details of your relevant policies and protocols, if any, for ensuring that information relevant to patient safety, and learning from adverse events is disseminated amongst your members.* We use a range of mechanisms to do this such as International Congress; CPD Online; Leaflets; Podcasts and College Reports and Position Statements . A recent example is the College has published a paper for its members which is relevant to responding to adverse events and serious incidents: 'Principles for full investigation of serious incidents involving patients under the care of

mental health and intellectual disability provider organisations' (OP104, March 2018). We will also be issuing guidance to psychiatrists on sodium valproate in the near future.

17. *What factors influence the decision on when to update guidance, and how are adverse events reports weighted in this process given the known level of underreporting?* The College periodically addresses areas of particular concern relating to psychotropic drug prescribing by disseminating guidance to its members – for example CR2015 (Person-centred care: implications for training in psychiatry, September 2018), CR 210 (mentioned above), CR209 (Good Psychiatric Practice: Confidentiality and Information Sharing, November 2017), and CR206 (Prescribing anti-epileptic drugs for people with epilepsy and intellectual disability, October 2017) are all relevant to concerns regarding valproate-containing medicines. Publication and dissemination of our imminent guidance regarding valproate will be a high priority for the College.

18. *How do we ensure that clinicians respond appropriately to patient concerns?* Our trainees and members are encouraged to sensitively address patient concerns in each consultation (and stations focused on communication skills in challenging situations are included in our CASC membership examination). The College also encourages its members to gather, submit and discuss anonymised patient feedback whilst preparing for and during their annual appraisal and revalidation.

19. *How do you feel the culture of reporting concerns and adverse events by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What, if anything, could be done to improve this?* Reporting of concerns and adverse events may be difficult for certain patient groups in psychiatric practice – for example, in those with impaired insight, a learning disability, cognitive impairment, self-neglect, and pervasive communication difficulties – so particular attention to potential problems is necessary in these groups. Mental health pharmacists can occupy an important position in identifying and managing concerns during psychotropic drug treatment, as some patients may find it easier to describe their concerns to a pharmacist than to the doctor: the College supports the proposals for joint working within the recent statement from the Royal Pharmaceutical Society (*No health without mental health: How can pharmacy support people with mental health problems?, June 2018*).

20. *How can we ensure patient outcome reports on treatment interventions reflect subjective patient experiences as well as clinical outcomes?* Many mental health services use patient rated outcome measures routinely – for example 'improving access to psychological services' teams employ the PHQ-9 and GAD-7 patient-completed scales as part of usual practice – but assessment of adverse events in psychiatric practice is hindered by the lack of reliable, valid, sensitive, patient-completed scales which are both comprehensive and feasible to use in routine clinical practice. It seems more realistic to encourage an atmosphere of open reporting, in which patients and clinicians work together to assess the nature, incidence, intensity, duration and need for intervention for reported adverse events.

21. *In your view, what are the priorities for future research related to the interventions and issues raised by the Review?* The College Prescribing Observatory for Mental Health is well placed to conduct further clinical audits of prescribing practice relating to valproate-containing medicines: there also seems some scope for qualitative research examining why people choose to prescribe valproate-containing medicines in women of child-bearing potential, when alternative pharmacological treatments are available.

22. *What would you consider to be the defining features of an effective registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?* One of

the challenges in establishing an effective registry relating to valproate-containing medicines in patients in psychiatric practice is the episodic nature of bipolar disorder: agreements reached with a patient in a settled euthymic mental state may be refuted when that patient experiences the elation and altered judgement of an acute manic episode or ignored whilst experiencing the despondency and self-neglect of a depressive episode.

Please explain the basis for the evidence you are submitting to the Review, how that evidence was selected, the extent to which any relevant material has been withheld and the reasons why. This statement was drafted by the Chair of the Psychopharmacology Committee, working with representatives from relevant College Faculties. It has been approved by the senior officers of the College. No material has been withheld.

Please detail any commercial, financial or legal connection or interest in the pharmaceutical and medical devices industry sector (including subsidiaries) or any other body or organisation of interest to the Review. Members of the Psychopharmacology Committee (Chair: Professor David Baldwin) provide full declarations of interest which are available on the College website. The College provides clear guidance regarding potential conflicts of interest: 'Good Psychiatric Practice: relationships with pharmaceutical and other related organisations' (CR202, March 2017) and 'Competing interests: guidance for psychiatrists' (PS01/2017, March 2017).

The College is happy for this statement to be included for the purposes of the Review.

Professor David Baldwin, Chair of the Psychopharmacology Committee

On behalf of The Royal College of Psychiatrists

October 2018

Please note, the guidance on prescription of valproate-containing medicines can now be found on the website of the Royal College of Psychiatrists (December 2018):

https://www.rcpsych.ac.uk/docs/default-source/improving-care/better-mh-policy/position-statements/ps04_18.pdf?sfvrsn=799e58b4_2

Royal Pharmaceutical Society

COI: None declared.

Comment:
The Royal Pharmaceutical Society welcomes this independent medicines and medical devices safety review and believes it is important to understand how scientific evidence regarding teratogenicity and its dissemination impacts on pharmaceutical licensing decisions. We are actively supportive of the recently introduced pregnancy prevention programme as a safety mechanism and develop resources, campaigns to support pharmacy teams to support patients.