UNIVERSITY OF ABERDEEN

Dr. Mohamed Abdel-fattah, FRCOG

Senior Lecturer/ Consultant Gynaecologist
Sub-specialist in Urogynaecology & Pelvic Floor Reconstruction

Chairman - Scottish Pelvic Floor Network (SPFN)"

Obstetrics & Gynaecology
Division of Applied Health Sciences
School of Medicine & Dentistry
Aberdeen Maternity Hospital
Cornhill Road
Aberdeen AB25 2ZD
Scotland, United Kingdom
Tel: (+44) 01224 438424
Email: m.abdelfattah@abdn.ac.uk

Mr A Neil
Cabinet Secretary for Health and Wellbeing
St. Andrew's House
Regent Road
Edinburgh
EH1 3DG

8TH July: **Meeting of Deputy CMO with Scottish Pelvic Floor Network (SPFN) steering committee; Chairman of Scottish Committee of The Royal College of Obstetricians and Gynaecologists (SCRCOG); Chairman of British Society of Urogynaecologists (BSUG), Vice-president of the International Urogynaecology Association (IUGA) and President of the RCOG.**

Dear Mr Neil

As you will be aware, the above group has met and discussed the background and the potential consequences of the decision to request health boards in Scotland to suspend trans-vaginal mesh (TVM) procedures for treatment of pelvic organ prolapse (POP) and Synthetic Mid-urethral Slings (SMUS) for treatment of stress urinary incontinence (SUI) in women.

I am sure you will recognise that the group represents the highest level of clinical and scientific communities in Urogynaecology in the UK. Our principle interest is in providing the best healthcare treatment options for our patients according to the best available evidence. We also discussed potential implications on clinical services in district hospitals and tertiary units. Furthermore, we discussed implications on the training of tomorrow's consultants and the Scotland-led UK-wide research projects.

The group recognises that your priority must be, like ours, the safety of women. With this in mind we would like to offer you the support from the clinical community through this evidence-based advice:

We wish to reiterate and emphasise the fundamental differences between (a) SMUS used for treatment of SUI and (b) TVM used in POP surgery. Although they are both made of the same synthetic material (Type 1 polypropylene mesh), SMUS differs very considerably from TVM employing a significantly smaller volume of mesh ie a tape. Furthermore, the mode of insertion of SMUS involves minimal tissue dissection and has a very considerable body of supporting evidence for its safety and efficacy.

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The alternative surgical options to SMUS are Burch Colposuspension (BC) and autologous slings (AFS); these are major surgical procedures that require open abdominal surgery, relatively long hospital stay and recovery periods. The current robust medical evidence is provided in the Cochrane review and a number of independent worldwide systematic reviews.[1-3] These reviews showed that, compared to the above alternative surgical procedures, SMUS are associated with (a) significantly lower rate of complications; (b) significantly earlier recovery, hospital discharge and return to normal activities/ work; (c) similar efficacy to BC however superior efficacy to Laparoscopic Colposuspension and AFS. The available evidence was recently appraised (2013) by the National Institute of Clinical Excellence (NICE) Guideline CG171 "The Management of Urinary Incontinence (UI) in Women"[3]. The NICE guideline supports the use of SMUS for the surgical treatment of SUI in women.

Following the CMO letter dated 20th June; most health boards in Scotland have now decided to suspend the use of SMUS in their units, both within clinical and research capacity, until further clarification from your office. The SPFN, SCRCOG and the clinical community in the UK are united in their serious concerns with regards to the potential consequences of the suspension of the use of SMUS in women with SUI. The concerns are several:

Patient Care:

- The decision to suspend SMUS fails to acknowledge the thousands of women over the last 15 years whose lives have been positively transformed following the cure of their SUI by the insertion of a SMUS. The evidence of this is clear in the Austrian and Finnish registries and the recent report of the 17 years follow-up SMUS.
- The decision limits the options for a woman to make her own choice of treatment based on the best evidence available. This is contrary to the principle of the fully informed consent process endorsed and demanded by the GMC.
- The decision compels surgeons and their patients to revert to surgical alternatives, which can be less effective and are associated with higher rates of complications and longer recovery.

Clinical Governance:

- We are very concerned that the clinical community will have to re-introduce operations (e.g. BC & AFS) that have been infrequently performed for over the last decade, undertaken only in tertiary centres and by very few sub-specialist urogynaecologists and urologists. Such operations are not on the routine training curriculum for either gynaecologists or urologists. This undermines all the tenets of clinical governance in terms of safety, effectiveness and patient-centred care.
- There will be a significant "re-learning curve" which can reasonably be expected to be associated with a higher patient morbidity.

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Health Services:

- Health Boards have suspended many operations; this has created a backlog of patients awaiting surgery for much longer than is recommended by Scottish Government. These women are also under a huge degree of uncertainty as to which operation they are going to undergo, if indeed any.
- A number of general hospitals may decide that they are not in a position or do not have the expertise to offer the alternative major surgical options and choose to refer their cases to tertiary centres. Needless to say this will lead to an overwhelming of the tertiary centres and inconvenience for women and their families having to travel long distances. As mentioned the alternative surgery might not have the same outcome as SMUS.

Research:

Despite your support in endorsing medical research, a number of the health boards have chosen to ignore this aspect of the CMO letter and suspended the use of SMUS both in clinical and research capacity, possibly due to anxiety about litigation. Three of these boards were originally committed to the SIMS RCT; a Scotland-led, NIHR-funded clinical trial on SMUS. The boards' decision to refuse participation at this stage seriously threatens the study progress.

If this decision is not reversed, and consequently the SIMS trial fails to achieve its recruitment target, the important questions set for this trial will not be answered. In addition we cannot move forward with the evidence regarding the future of SMUS and finally we will have wasted the NIHR funding (£1.8 million) without improving the healthcare of the patients.

I am sure you will acknowledge that a foreseeable consequence would be to face an unfavourable reception from the NIHR when considering funding for future Scotland-led research.

Training:

Specialty trainees in Obstetrics and Gynaecology (O&G) are required to undertake a minimum of two Advanced Training Study Modules (ATSM) in their final two years of training. One of the ATSMs is in Urogynaecology. Across Scotland, five trainees wish to pursue the Urogynaecology ATSM from August 2014 (the number varies each year). A central component of this ATSM is to be surgically competent in the insertion of a SMUS. It will not be possible to offer this ATSM unless the cabinet secretary advice regarding SMUS is at least modified. The consequences of this are;

a. The inability to offer this ATSM will lead to the creation of a cohort of young gynaecologists in Scotland who are unable to perform SMUS. This will negatively

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affect their competitiveness for consultant posts compared to their peers trained in England and Wales.

b. The above will identify training in O&G in Scotland as limited and inferior to that which is available in the remainder of the UK
c. This will potentially create a disincentive for talented young doctors to apply for O&G training in Scotland and to apply elsewhere in the UK. Furthermore, current senior trainees who wish to pursue this training will be forced to seek training opportunities outside Scotland; they may not return.
d. Finally, the senior trainees currently registered for this ATSM, who must complete their full training curriculum, will require to identify training outside of Scotland which may or may not be possible. This has both a reputational and financial consequence for NHS Scotland.

Similar negative consequences apply to the training of doctors in Urology. Urology trainees with an interest in Female Urology and Reconstruction will not choose to apply to Scotland since competency in the insertion of SMUS is an integral requirement of the relevant training module; in fact this is a requirement for them to sit the final professional exit exam.

Recommendations:

We know you appreciate the considerable medical evidence that supports the use of SMUS as a surgical treatment option for curing SUI in women. You will also appreciate the potentially negative consequences of suspending SMUS surgery. We do accept and are sympathetic to the small group of women who have had complications from this operation. However, no surgery is without risk and it is always our aim to reduce such risk. We need to keep all of this in perspective and realise that large numbers of patients have had their lives transformed in a positive manner following SMUS surgery. To deny others this treatment would be unfair.

Therefore we respectfully urge you to issue a clear and unambiguous memo of clarification to the health boards to that effect:

a) Lift any restriction on the use of SMUS as one of the surgical treatment options for women with SUI within the auspices of good clinical practice identified in the NICE guideline CG171 “The Management of Urinary Incontinence (UI) in Women”
b) Reiterate your support for credible clinical trials in the field and strongly encourage health boards to support the introduction and running of the NIHR-funded Scotland-led trials and namely the SIMS & the VUE studies.

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c) Reiterate that your decision to suspend TVM excludes the procedures that involve mesh inserted solely through the abdomen such as abdominal sacrocolpopexy.

d) Instruct health boards to introduce the BSUG/BAUS surgical databases in to their units to facilitate prospective audit and collection of accurate data and to provide clinicians with the required time in their job plans to do so.

In anticipation of your responsiveness, the SPFN and the clinical community confirm their commitment to:

- Work closely with the SLWG and the independent review that you commissioned
- Regularly and prospectively audit the surgical outcomes
- Report all serious complications to the IRA/MRHA

We look forward to hearing from you positively and meeting with you in near future.

Kind Regards

Dr. M. Abdel-fattah, Chairman - Scottish Pelvic Floor Network (SPFN)
Dr. D. Richmond, President - Royal College of Obstetricians and Gynaecologists (RCOG)
Prof. R. Freeman, Vice President – International Urogynaecology Association (IUGA)
Mr. A. Monga, Chairman - British Society Of Urogynaecologists (BSUG)
Dr. P. Owen, Chairman - Scottish Committee RCOG (SCRCOG)
Dr. I. Ramsay, Consultant Urogynaecologist, Steering Committee – SPFN
Dr. P. Granitsiotis, Consultant Urologist, Steering Committee – SPFN
Dr. J. Wilkens, Consultant Urogynaecologist, Steering Committee – SPFN
Dr. M. Allam, Consultant Gynaecologist, Steering Committee – SPFN

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