



Scottish Pelvic Floor Network

Dr. Mohamed Abdel-fattah, FRCOG

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

Chairman - Scottish Pelvic Floor Network (SPFN)"

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Mr. Alex Neil
Health Minister – Scottish Government

Date: 17th June 2014

Dear Mr. Neil

We were surprised to hear from the media, without any prior notification to the Short Life Working group (SLWG) which was convened at your instruction, of the decision to suspend trans-vaginal mesh (TVM) for women having prolapse surgery and mid-urethral synthetic slings (TVT) for urinary incontinence, in Scotland pending an independent review and the European Commission investigation.

Whilst we appreciate that you must have considered this decision carefully, please let us clarify that this decision will have a significant negative impact on medical research in Scotland. Research is the most important tool for improving healthcare in any health service. Scotland is currently leading two large multicentre studies in the UK, funded by NIHR to a total of £4 million and running in over 40 hospitals in UK:

- (A) The SIMS study: comparing the standard TVT procedures for urinary incontinence with a shorter version tape, known as a mini-sling with 50% less mesh volume which is inserted using less invasive surgery;
- (B) The VUE study: investigates the best treatment for uterine (womb) prolapse and whether hysterectomy is required; and the best way of treating vaginal vault prolapse. Some of the procedures require the use of mesh, while in others it is optional.

As in all Scotland-led clinical trials, patient-reported outcomes and experiences, particularly adverse effects, are the primary outcomes assessed in these large clinical trials. These two large and credible research projects will be put at risk from the decision to suspend the use of mesh in Scotland, and consequently we may never be able to answer the clinical dilemmas addressed by these trials. **Hence we ask the health minister to exempt "credible medical research" from the suspension decision.** Credible research can easily be defined as those studies on the NHS portfolio; these studies were subject to rigorous independent review, are ethically approved and are funded by the public NHS money. Moreover, they are regularly monitored by NHS R&D. Women are voluntarily joining these studies after adequate counseling and signing special consent forms approved by Ethics Committees. The need for these two trials was established after consideration of evidence presented to National Institute of Clinical Excellence (NICE) and the NIHR Interventional Procedures Committees.

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The current Scottish government has announced on multiple occasions its support for high quality research and has vowed to support it in the 'Independent Scotland' dossier. The position of Scotland as a leader of medical research for large funding bodies such as NIHR and the Medical Research Council will be jeopardized if we are unable to meet our obligations in leading the above trials. *Hence we ask the health minister to exempt "credible medical research" from the suspension decision and continue to support such research in NHS Scotland.*

We are happy to discuss further if you feel it would be appropriate. We would be happy to present the research projects to you or to the CMO if requested.

Also, on behalf of many concerned colleagues, we invite you to attend the SPFN 6th annual scientific meeting (SPFN-ASM) which will be on Friday 20th June in Crief-hydro hotel – Perth to discuss the clinical implications of the decision with the all the stakeholders present; 124 multidisciplinary clinicians with interest in female pelvic floor function. We will be able to modify the SPFN- ASM program around your availability.

We look forward to hearing from you
Best Wishes

Dr. M. Abdel-fattah
Signed on behalf of the group

Dr Mohamed Abdel-fattah, Chief Investigator SIMS study, Chairman of the Scottish Pelvic Floor Network, and Senior Lecturer/ Consultant Subspecialist Urogynaecologist, [University Of Aberdeen/ NHS Grampian](#)

Professor Cathryn Glazener, Professor of Health Services Research, Chief Investigator VUE study and Associate Specialist in Urogynaecology, [University Of Aberdeen/ NHS Grampian](#)

Professor John Norrie, Director of CHaRT clinical trials unit – [University of Aberdeen/CSO](#)

Professor Suzanne Hagen, Professor of Health Services Research, NMAHP Research Unit, [Glasgow Caledonian University](#)

Professor James N'Dow, Professor of Urology, [University Of Aberdeen/ NHS Grampian](#)

Dr Chris Bain, Consultant Gynaecologist, [NHS Grampian](#)

Dr Kevin Cooper, Co-Chief-investigator HEALTH Study and PREMP study, and Consultant Gynaecologist, [NHS Grampian](#)

Dr. Ian Ramsay, Consultant Urogynaecologist, [Forth Valley NHS](#)

Ms. Ann Gilchrist, Extended Scope Physiotherapy Practitioner in Uro-gynaecology, Team Lead Women's Health, [Forth Valley NHS](#)

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