HSE Implementation Plan 2019

This Implementation Plan has been developed by the HSE in response to the Report entitled *The Use of Uro-gynaecological Mesh in Surgical Procedure, Report to the Minister of Health Mr. Simon Harris T.D., from the Chief Medical Officer, 21st November 2018*.

Approved by HSE Leadership Team, April 2019

Abbreviations: NWIHP = National Women and Infants Health Programme, AHD = Acute Hospital Division, HG = Hospital Group, RCSI = Royal College of Surgeons in Ireland, IOG = Institute of Obstetrics & Gynaecology, QAV = Quality Assurance & Verification, SCA = State Claims Agency & HPRA = Health Product Regulation Agency

HSE Implementation Plan in Response to DoH Report entitled *The Use of Uro-gynaecological Mesh in Surgical Procedures*

No	Recommendation	Ref	Specific Actions	Responsible	Additional Resources Implication	Start	End
Patient Information & Consent							
1.	The HSE, working in conjunction with other stakeholders as appropriate, should develop Patient Information & Consent Leaflets on mesh procedures for the treatment of SUI and POP. Information provided should include the benefits and risks of mesh procedures, including risks of failure and complications, as well as describing alternative treatment options, including no treatment.	1.1	Undertake review of literature available internationally regarding patient information and consent for mesh procedures.	HSE-NWIHP	No	Commenced	Completed
		1.2	Develop at national level patient information leaflets on SUI and POP in conjunction with other key stakeholders.	HSE-NWIHP	No	Commenced	April 2019
		1.3	Develop at national level patient consent forms on SUI and POP in conjunction with other key stakeholders.	HSE-NWIHP	No	Commenced	April 2019
		1.4	Circulate final suite of documents directly to hospital groups and relevant clinical sites if/when pause on mesh procedure is lifted by Department of Health.	HSE-NWIHP	No	TBD	TBD
		1.5	Ensure that nationally developed patient information forms and consent forms are utilised in all relevant sites and services.	AHD & HGs	No	TBD	TBD
2.	The HSE, working in conjunction with other stakeholders as appropriate, should develop comprehensive evidence-based information resources about mesh devices and the services in place for the management of mesh related complications for publication on the HSE and other stakeholder websites.	2.1	Complete review of relevant literature and existing examples of evidence-based information resources available to patients internationally in this area.	HSE-NWIHP	No	Commenced	Completed.
		2.2	Create on HSE website a specific section providing information on mesh procedures including potential signs and symptoms of complications, FAQs, contact details for services in each hospital group, national contact details and links to other relevant websites.	HSE-NWIHP	No	Commenced	Completed
		2.3	Maintain and update HSE website on an on-going basis as work in this area progresses.	HSE-NWIHP	No	Commenced	On-going
3.	The HSE should identify a central contact point within the HSE for women who may require assistance to navigate the services and in terms of advice, treatment options, including options to seek a second opinion if necessary.	3.1	Identify national central point of contact and make contact details available on HSE website and communicate existence of same to interested parties.	HSE-NWIHP	No	Commenced	Completed
4.	Put in place a contact point and a referral pathway for women with no treating clinician or with severe complications at every Hospital Group level and a mechanism to communicate same to both women and clinicians.	4.1	Each hospital group to establish a specific and dedicated contact point with associated referral pathway for women with no treating clinician or with severe complications.	HGs	No	Commenced	Completed
		4.2	Specific and dedicated contact point for each hospital group to be communicated via HSE website.	HSE-NWIHP	No	Commenced	Competed
5.	Establish the numbers of women requiring, and likely to require, specialist multidisciplinary services.	5.1	Number of contacts being made to dedicated contact point established in each hospital group and at national level to be centrally collated on a regular basis.	HSE-NWIHP	No	Commenced	On-going
		5.2	Referral numbers to specialist referral centre(s) when established to be routinely recorded locally and centrally collated.	HSE-NWIHP	No	Upon establishment of specialist centre(s)	On-going

6.	Working together with the IOG and RCSI, and having regard to examples of professional good practice elsewhere, to identify and put in place the specialist multidisciplinary services, including specialist diagnostic services, required to meet the specific care needs of women with complex and severe complications and to identify the appropriate locations at which these services will be provided.	6.1	Establish the criteria for a specialist referral centre for women with complex and severe complications.	HSE-NWIHP, RCSI & IOG	No	Commenced	May 2019
		6.2	Identify the required number of centres for Ireland and proposed locations of same.	HSE-NWIHP	No	Commenced	Completed
		6.3	Develop and submit a costed business case to DoH identifying the additional resources required to enable establishment of identified specialist referral centres.	HSE-NWIHP	Yes – Final costs to be quantified	Commenced	May 2019
7.	Pending the full implementation of recommendations 3 – 6, to identify treatment options for women in urgent need of care, including if necessary the sourcing of services from abroad, either through existing mechanisms such as the treatment abroad scheme or through the commissioning of specialist diagnostic and treatment services.	7.1	Engagement to be undertaken with the HSE funded Treatment Abroad Scheme (TAS).	HSE- NWIHP	No	Commenced	Feb 2019
		7.2	Pathway and associated approval processes to be developed to enable women to access clinically recommended diagnostic services overseas under the TAS.	HSE-NWIHP	Yes – will be borne by existing TAS funds.	Commenced	May 2019
Clinical and Professional							
8.	Mesh surgery for the treatment of SUI and POP should only be carried out by appropriately trained surgeons who are on the specialist register and who have undertaken relevant subspecialty training as defined by the IOG and the RCSI. Such specialists will have a declared interest in the treatment of urinary incontinence and/or POP.	8.1	Define professional requirements for surgeons for certification and accreditation in the area of mesh surgery for the treatment of SUI and POP.	RCSI & IOG	No	Commenced	May 19
9.	The HSE should establish and maintain a list or register of persons qualified to undertake SUI and/or POP mesh surgery procedures in HSE funded hospitals on foot of clear guidance from the relevant professional bodies, the IOG and RCSI, re the sub-specialist training and on-going competence requirements for surgeons undertaking these surgeries.	9.1	Process to assess training and experience of surgeons against pre-specified professional requirements to be designed and established.	HSE-NWIHP, RCSI & IOG	Yes	Commenced	June 19
		9.2	Central register to be implemented and maintained on on-going basis	HSE-NWIHP	No	June 19	On-going
10.	Mesh surgery should only be carried out in designated multidisciplinary specialist clinics with the appropriate facilities and with appropriate patient selection and strong clinical governance arrangements in place.	10.1	Establish the criteria for specialist clinics for mesh surgery.	HSE-NWIHP	No	Commenced	May 19

11.	The HSE should identify surgical locations meeting this requirement, for (i) SUI procedures and (ii) POP procedures, on foot of clear guidance from the relevant professional bodies, the IOG and RCSI, re the recommended multidisciplinary expertise and technical facilities required at units where each type of surgery takes place.	11.1	Process to assess suitability of surgical locations for mesh surgery against pre-specified criteria for specialist clinics to be designed and established.	HSE-NWIHP	Yes – Final costs to be quantified	Commenced	May 19
12.	National clinical guidance to inform the development of evidence based care pathways for the assessment and management of women with (i) incontinence and (ii) prolapse should be developed as a priority by the HSE in accordance with the NCEC standards for clinical practice guidelines. Guidance should encompass the entire pathway of care for both conditions, including the full range of treatment options, both surgical and non-surgical.	12.1	Establish group with required clinical expertise.	HSE-NWIHP, IOG, RCSI	No	May 19	May 19
		12.2	Draft and complete national clinical guidelines for the assessment and management of women guided by NCEC standards.	HSE-NWIHP, IOG, RCSI	No	May 19	July 19
13.	There are concerns about the rate of complications associated with the use of transvaginally placed mesh implant devices in the management of POP. Transvaginal mesh should not be offered as a first line treatment in the management of POP.	13.1	Recommendation will be incorporated into delivery of recommendation 12.	HSE-NWIHP	No		
14.	To ensure that patient health, wellbeing and safety are paramount in all treatment decisions, the use of transvaginally placed mesh implant devices in the management of complex POP cases, where other treatment options have failed or are not appropriate, should only be offered following assessment and discussion at MDT settings, and after detailed discussion with the patient about the associated risks and benefits.	14.1	Recommendation will be incorporated into delivery of recommendation 12.		No		
15.	The HSE, on foot of clear guidance from the relevant professional training bodies, the IOG and RCSI, should develop agreed protocols for the use of transvaginally placed mesh implant devices in the management of complex POP cases where other treatment options have failed or are not appropriate, which clarify MDT structures at regional and/or national level where such cases should be discussed.	15.1	Recommendation will be incorporated into delivery of recommendation 12.		No		

Information Requirements							
16.	The HSE should develop a data collection system to ensure that basic information about the numbers, locations and types of uro-gynaecological mesh procedures carried out in HSE-funded hospitals, including mesh revisions and removals, is routinely collected and centrally collated.	16.1	Minimum data set to be collected on an on-going basis to be identified.	HSE-NWIHP	No	Commenced	Completed
		16.2	Process for on-going collection of data at national level to be designed.	HSE-NWIHP	No	Commenced	Completed
		16.3	Active deployment of data collection system as and when MESH related surgery recommences in Ireland.	HSE-NWIHP, clinical sites	Yes – Final costs to be quantified	TBD	TBD
17.	The business case for the establishment of a national register of implants used in the treatment of SUI and POP, with mandatory registration of implants (based on the existing model of the register of orthopaedic implants established by NOCA) and with scope for research and audit should be examined by the IOG, the RCSI and the HSE.	17.1	Engagement with NOCA in relation to review existing register models and methodologies underpinning same.	HSE-NWIHP	No	Commenced	Completed
		17.2	Examination of business case for establishment of national register to be undertaken by HSE.	HSE-NWIHP	No	Commenced	June 19
18.	Information collection and adverse event reporting systems must be strengthened to ensure that the long-term safety of these devices is appropriately monitored.	18.1	Engagement with State Claims Agency to actively review NIMS and its capacity to capture incidents involving mesh devices to be undertaken.	HSE National QAV, SCA	No	Commenced	April19
		18.2	Engagement with HPRA to review and identify any improvements that could be made to current systems of reporting to be undertaken.	HSE National Medical Devices, HPRA	No	Commenced	April 19
		18.3	Exploration with HPRA & SCA of potential methodologies that would enable NIMS and HPRA to capture and share incidents relating to Mesh implant devices.	HSE (National Medical Devices &, QAV), HPRA	No	Commenced	Jun 19
19.	Existing guidance and governance mechanisms in relation to adverse event reporting should be reviewed by the HSE in conjunction with the HPRA and the SCA to ensure appropriate reporting of device-related adverse outcomes to both the HPRA and the NIMS, with mandatory reporting of serious adverse events.	19.1	Review of current guidance provided to acute system so as to support increased level of reporting of Mesh related incidents to be undertaken.	HSE QAV, Hospital Groups	No	Commenced	April 19
		19.3	Engagement with HPRA and hospital groups to review existing mechanisms relating to the reporting of incidents to HPRA.	HSE National Medical Devices, HPRA, Hospital Groups.	No	Commenced	April 19