MESH DOWN UNDER ™

Dedicated to support and information sharing for
New Zealanders injured by surgical mesh.
www.meshdownunder.co.nz

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2 August 2017

Dear Hon Dr Jonathan Coleman,

Thank you for briefly meeting with us on Friday 28th July in Dunedin. You asked us to write to you, once again, to outline our concerns as due to time constraints we were only able to raise two of the discussion points we had previously written to you about.

You also told us that you needed to speak to your advisors in order to respond to our concerns.

At our meeting, we discussed how there was still no specific code for surgical mesh procedures in the current hospital systems or GP IT systems. This results in the inability of doctors to track and monitor patients once implanted with a surgical mesh device and for the health sector to gain a true understanding of how many mesh procedures are happening.

The outcome of this discussion point was that you agreed to check with your advisors about what specific improvements have been made in data extraction since the data analysis was completed by the Ministry of Health in October 2016.

You told us that you would ask your health officials to get back to us with a detailed account showing specific improvements in data capture for surgical mesh procedures.

We gave you a collection of patient stories from mesh injured people, we asked you to read these and you agreed to personally reply with your thoughts after reading them.

We asked if you would consider employing an independent commissioner to take charge of the mesh issue to ensure that the HSC recommendations were implemented with urgency, you mentioned that this was not an option.

After highlighting that there has been a 74% increase in decided claims to ACC for surgical mesh injuries in the last three years, you said that you would discuss the mesh issue with the Director General of Health and respond back to us with feedback about this discussion. We asked if we could attend a meeting (at your invitation) with the Director General of

Health, as this had been suggested to us by the Medical Council – you mentioned that this would not be possible.

The number of mesh related treatment injury claims over the last few years is escalating at an alarming rate. Taking into consideration that surgical mesh complications can be so severe and life changing, this trend needs to be addressed urgently with government lead initiatives beyond the scope of the Select Committee recommendations.

We believe that although you are under the impression that all the Health Select Committee recommendations have been implemented or are in the process of being implemented, our own OIA documents and correspondence with relevant health bodies, suggest that very little has been achieved and very little has changed to provide better patient outcomes.

We spoke how the patient perspective has not been taken into account properly, as the only viewpoint that had been considered by the Min of Health, the government and medical colleges were the petitioners and our colleague Patricia Sullivan. We discussed the need for a public forum so that all patients' experiences could be heard, but you were reluctant or unable to commit to this. We brought to your attention the importance of the 'patients voice' in Australia plus their Senate Inquiry.

We spoke about how the lack of informed consent by doctors regarding the risks associated with mesh procedures is a still a current problem. You thought that this was a medico-legal issue and the onus should rest upon the surgeon and that the patient should complain to the Health and Disability Commissioner.

We emphasised that because this is continuing to happen on such a large scale, that intervention is needed by the Ministry of Health. We brought to your attention that this is one of the HSC recommendations.

Every patient needs to be properly informed about ALL the risks associated with having a surgical mesh implanted, before deciding to have the procedure. As a group, we have met with many health organisations – yet the evidence from new patients that contact us regularly shows that few if any, risk warnings are being discussed during the consenting process.

Our main objective is to halt the trend in rising mesh complications and to ensure that not only patients are able to seek appropriate medical care once they experience complications after undergoing a surgical mesh procedure, but that the GP's also quickly recognise and diagnose this as a potential surgical mesh adverse reaction which will enable better outcomes.

Comments on the HSC recommendations to date:

Recommendation 1. That the Government work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry.
Implementation: The government has lumped this in with the upgrading of the Therapeutic Goods Act, which has been delayed several times. We request further more urgent consideration and discussion amongst the Ministry and colleges to find a much quicker solution to this recommendation.

Recommendation 2. That a registry is informed by the International Urogynaecological Association classification for recording mesh surgery complications.
Implementation: The government has lumped this in with the upgrading of the Therapeutic Goods Act, which has been delayed several times. We request further more urgent consideration and discussion amongst the Ministry and colleges to find a much quicker solution to this recommendation.

Recommendation 3: That the Government suggests that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures.

Communications between relevant health bodies and Medsafe regarding the surgical mesh issue has been inconsistent or do not exist. Documents that we have obtained through the Official Information Act show there has been confusion as to what meetings have or have not taken place and who attended these meetings.

We have, for example, discovered that "Discussed at the Council of Medical Colleges Board Meeting on 8 December 2016" in fact referred to Dr Simpson advising that he will be setting up meetings in the New Year. OIA documents provided to us show that these meetings were not arranged, nor did they occur.

To our knowledge, the government, Min of Health and relevant health bodies have made no effort (to date) to contact and survey all mesh injured patients to get a proper understanding of mesh injuries and the difficulties they face in seeking treatment.

Patient literature that is given to patients still does not contain accurate and consistent information or include all the potential associated risks of having a surgical mesh procedure.

For Example, the patient information leaflet recommended by RANZCOG for MUS states that the complication of mesh exposure occurs ‘very occasionally’, yet a similar patient information document provided in the UK by the NHS state that mesh exposure is ‘common’.

http://c.ymcdn.com/sites/www.iuga.org/resource/resmgr/leaflet/Mid-Urethral_Slings.pdf

http://bsug.org.uk/budcms/includes/kcfinder/upload/files/SUI%20Mesh%20Tapes%20Leaflet%20Version%2024_160517.pdf

We are still regularly hearing from patients that they are not being given proper informed consent about the associated risks of undergoing a surgical mesh procedure.
We direct these patients to the HDC but usually find that HDC ‘believe’ that the surgeon ‘did discuss’ the potential risks. It almost always comes down to a patient’s word against the surgeons. Consequently, much more robust documentation for use pre-surgery needs to be created and its use made mandatory. This cannot happen effectively without funding from the ministry.

Medsafe needs to provide accessible and up to date information regarding potential surgical mesh complications on the Medsafe Website. This should include information pertaining to the reclassification of surgical mesh devices.

Medsafe needs to update their position statement surrounding transvaginal mesh for POP to reflect the current recommendations of the RANZCOG.

Medsafe relies on manufacturers of medical devices and sponsors who sell surgical mesh to alert doctors when products are withdrawn due to safety reasons. This should be the responsibility of Medsafe and this information needs to be given in an appropriate timeframe to all medical colleges and relevant health clinicians. This information needs to be readily accessible and easily obtained from the Medsafe website by the public.

Recommendation 4: That the Government encourages health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored.

There have been few improvements in data collection from using existing hospital coding systems- referring to hospital data statistics information we discussed during our meeting.

Implementing a ‘red flag’ in the GP system is essential to identify when surgical mesh has been used, to enable early diagnosis of potential mesh complications and to ensure that patients can be monitored closely after implantation.

Concern: There is currently still no code for surgical mesh and very little evidence to support that there has been a significant improvement after subsequent analysis by the Ministry of Health. There is still no way for patients with mesh complications to be tracked and monitored.

Recommendation 5: That the Government encourages utilisation of the adverse events reporting system as applicable to medical devices.

The Ministry of Health needs to provide funding for education and guidance for all health professionals about what specifically needs to be reported in regards to surgical mesh complications.

We are meeting with ACC on August 15th to identify improvements made in the ACC and Medsafe reporting systems.

Concern: Due to the sharp rise in claims made to ACC for surgical mesh injuries in such a short time, and the severity of surgical mesh complications, we believe that there is a risk to the public. We believe that it is essential for the reporting of surgical mesh adverse events to be made mandatory by all health professionals.

Recommendation 6: That the Government endorses the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery.

The Medsafe website suggests that this has been completed within the scope of two meetings.

There is a need for the provision of funding by the MOH to enable specialist surgical training specifically in mesh removal. RANZCOG has declined to take up the opportunity for their surgeons to learn from expert international removal specialists and instead considers it acceptable for surgeons in NZ to learn from each other. Whilst peer review is important, we believe this is insufficient as most admit that they are unable or unwilling to fully remove the surgical mesh. This leads to patients having to undergo several surgical procedures, whilst surgeons take a piecemeal approach to removing this permanent implant. This is both traumatic for patients and can result in further harm. Surgeons are learning on patients.
Anchor

There is a need for the provision of funding by the MOH to enable surgical training for non-mesh repair options, particularly for a non-acute inguinal hernia.

We look forward to hearing from you shortly in regards to the information that you said that you would provide during our meeting, your personal response to the patient experience letters we gave you and of the concerns out lined above.

Kind regards
Charlotte Korte
Patricia Sullivan
Carmel Berry