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General Practitioners
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Dear Colleague

PiP Breast Implants

I am writing to update you on the situation in Scotland following the emergence of concerns around PiP breast implants and the press information released 6/1/12 by the Health Secretary Nicola Sturgeon <http://www.scotland.gov.uk/News/Releases/2012/01/06190058>.

Ensuring the health and well being of women in Scotland who have had breast implants remains our priority within this update.

I can confirm that the UK expert advisory group published their report on 6 January 2012 – the report can be accessed at <http://www.dh.gov.uk>.

In summary the group have reviewed the available data and concluded that there is no clear evidence at present that patients with a PiP implant are at greater risk of harm than those with other implants, but that the available evidence is subject to considerable uncertainty. Accordingly they are recommending the collection of additional data. In addition the group supports the MHRA (Medicines and Healthcare Regulatory Agency) advice that does not recommend routine removal of implants at present. The group also agree there is no evidence to link the implants with cancer.

Patients can access both the expert report at <http://www.dh.gov.uk/health/2012/01/pip-implants-interim-report/> and MHRA guidance and other useful information at the NHS Inform weblink on <http://www.nhsinform.co.uk>.

In Scotland we believe that no surgical procedures using implants from this manufacturer have been carried out within the NHS but there could be a significant number of women with these implants that have been inserted in the private sector. NHS Boards are continuing to check their records to identify if there are any women with PiP implants that have been inserted under NHS care and will contact any identified women directly and offer a consultation and, if clinically necessary, removal and replacement.

It is expected within Scotland that private surgery providers will take responsibility for their patients and offer the same service as the NHS. If, however, the private provider is no longer operating or is unable to offer appropriate care the NHS will support the removal of the implant if clinically appropriate, but will not routinely support replacement as per the exceptional aesthetic protocol (attached as separate pdf). In this situation it is expected that the patient will contact their GP in the first instance to access further assessment.

When counselling patients with these or other implants clinicians should be aware of the following issues:

1. All breast implants carry a risk of rupture, increasing over time, and many require removal within 10 years. Please refer to the Expert Advisory Group report which provides data from the FDA on implant removal rate, and the 8 and 10 year rupture rate which has been found in 2 studies of other makes of implants

2. It is important that patients are also made aware of the other risks of surgery when considering implant removal. This is a major procedure and like all operations carries associated risks including anaesthetic risks and risks of infection. The Royal College of Anaesthetists has published that the risk of death from anaesthesia is approximately 1/100,000. There are clearly other less severe risks - please refer to the Royal College of Anaesthetists Risk Information Leaflet (<http://www.rcoa.ac.uk/index.asp?pageID=1209>)



Updated Adult
Exceptional Aesthetic

Yours sincerely

Harry Burns

SIR HARRY BURNS
Chief Medical Officer