

*From Sir Bruce Keogh KBE, DSc, FRCS, FRCP
NHS Medical Director for England*



Gateway reference: 17744
18 June 2012

To: General medical practitioners

Copies for information to:
Chief Executives of Cluster SHAs
Chief Executives of PCT clusters

Dear colleague

PIP SILICONE BREAST IMPLANTS: FINAL REPORT OF THE EXPERT GROUP

I am writing to draw your attention to the final report of the expert group which I chaired to consider the possible health impacts of the silicone breast implants manufactured by the company Poly Implant Prothèse (PIP). The group's summary and recommendations are attached at Annex A, and the full report can be seen on the DH website at <http://www.dh.gov.uk/health/2012/06/pip-report/>.

Our essential recommendation remains the same: that any woman with PIP implants who is anxious about the implications for her health should have the opportunity of a specialist consultation and, in the light of this consultation, should decide in her individual circumstances whether she wants the implants removed.

Patients originally treated in the NHS have already been contacted and offered an outpatient appointment. We have asked private providers to offer the same care to their patients. However, we know that a number of private providers have gone out of business, and others are unable or unwilling to offer the care which they owe. In these circumstances patients may come to you seeking advice or access to NHS specialist services, including imaging.

I am sure that you will respect the very understandable anxiety of women in this situation. I would therefore be very grateful if you could refer them on for specialist assessment and advice as needed, particularly if clinical examination shows signs and symptoms which suggest a possible rupture. Guidance on criteria for referral was included in our interim report and a further copy is attached for your convenience at Annex B.

Yours sincerely

A handwritten signature in black ink that reads 'Bruce Keogh'. The signature is written in a cursive style and is underlined with a single horizontal line.

**Sir Bruce Keogh KBE, DSc, FRCS, FRCP
NHS Medical Director**

ANNEX A: SUMMARY AND RECOMMENDATIONS FROM THE EXPERT GROUP

We have carefully reviewed the available evidence on breast implants from the company Poly Implant Prothèse (PIP), including the results of additional studies commissioned since our interim report in January. We have concluded that

- rigorous world-wide chemical and toxicological analyses of a wide variety of PIP implants have not shown any evidence of significant risk to human health;
- there is no reason to believe that further testing will change this conclusion, given the results of the chemical analysis and the number of batches that have now been tested world-wide, which have all reached a similar conclusion;
- PIP implants are significantly more likely to rupture or leak silicone than other implants, by a factor of around 2-6, and this difference is detectable within 5 years of implantation;
- in a proportion of cases, failure of the PIP implant results in local reactions but these are readily detected by outward clinical signs – “silent” ruptures (ruptures which come to light only on explantation) are not generally associated with these local reactions.

In sum, PIP implants are clearly substandard although there is no evidence of a significant increased risk of clinical problems in the absence of rupture.

In the light of these conclusions we reiterate and amplify our previous advice that:

- all providers of breast implant surgery should contact any women who have or may have PIP implants– if they have not already done so – and offer them a specialist consultation and any appropriate investigation to determine if the implants are still intact;
- if the original provider is unable or unwilling to do this, a woman should seek referral through her GP to an appropriate specialist;
- if there is any sign of rupture, she should be offered an explantation;
- if the implants still appear to be intact she should be offered the opportunity to discuss with her specialist the best way forward, taking into account the factors listed in paragraph 33 of the report;
- if in the light of this advice a woman decides with her specialist that, in her individual circumstances, she wishes to have her implants removed her healthcare provider should support her in carrying out this surgery. Where her original provider is unable or unwilling to help, the NHS will remove but not normally replace the implant;
- if a woman decides not to seek early explantation, she should be offered annual follow up in line with the advice issued by the specialty surgical associations in January 2012¹. Women who make this choice should be encouraged to consult their doctor if they notice any signs of tenderness or pain, or swollen lymph glands in or around their breasts or armpits, which may indicate a rupture. At the first signs of rupture, they should be offered removal of the implants.

¹ Association of Breast Surgery, British Association of Plastic and Reconstructive Aesthetic Surgeons, British Association of Aesthetic Plastic Surgeons, Federation of Surgical Speciality Associations and Royal College of Surgeons *PIP breast implants: joint surgical statement on clinical guidance for patients, GPs and surgeons* (Royal College of Surgeons of England, January 2012 updated June 2012) at <http://www.rcseng.ac.uk/publications/docs/pip-statement/>

ANNEX B: CLINICAL GUIDANCE FROM THE EXPERT GROUP

[Originally Annex E of *Poly Implant Protheses (PIP) breast implants: interim report of the expert group* (DH 2012), slightly reordered for greater clarity.]

Patients

1. Any patient with breast implants is advised to check the details of their implant with their surgeon or clinic.

GPs

2. GPs consulted by patients with PIP implants should explore the patient symptoms and examine the breast and locoregional lymph nodes.
3. Patients with local signs and symptoms should be referred for a specialist opinion.
4. Signs will include
 - Lumpiness of the breast
 - Lumpiness/ swelling of the regional lymph nodes
 - Change in shape of the breast
 - Deflation of the breast
 - Redness
 - Tenderness of the breast
 - Swelling of the breast
5. Symptoms may include
 - Pain
 - Hyperaesthesia

Guidance for GPs for NHS specialist referrals

6. **Patients with PIP implants who experience lumpiness within the breast and lymph nodes** : In cases where there is concern regarding the nature of the lumpiness, referral should be made to a rapid access breast service. In cases where the practitioner is happy that the lumps are associated with the implant or gel, referral should be made to the regional reconstructive breast surgery department.
7. **Patients with changes in shape or feel of the breast**, for instance discomfort, deflation or asymmetry should be referred to their regional breast reconstructive unit. These patients do not require fast track referral.

Guidance for GP referrals for private patients

8. General Practitioners may be approached by patients who underwent their surgery in the private sector. These patients should be advised to contact their original provider. It is expected by the expert group and the professional bodies represented on it that these providers will offer the same service as the NHS without cost to the patient.

Surgeons

9. Surgeons and hospital specialists reviewing patients with PIP implants should carefully assess the patient for the possibility of rupture or leak. Those patients who have evidence of implant rupture should be advised regarding the implications of implant removal/ exchange. If it is felt that the risk benefit ratio favours explantation/ exchange then this procedure should be advised. For NHS patients the patient may be offered re-implantation. For patients from the private sector who have been unable to secure help from their original provider, the NHS will offer implant removal where it is felt to be clinically appropriate, but no re-implantation will be offered.

Ongoing review

10. Where a patient decides, after consultation with her GP or specialist, not to have an explantation, she should be followed up on an annual basis. This review would normally be carried out by the GP (for NHS patients) or by the clinic which carried out the original implant (for private patients).

Possible updates to guidance

11. This guidance may change after consultation with relevant parties.