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

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To: NHS medical directors

Copies for information to:
Chief Executives of Cluster SHAs
Chief Executives of PCT clusters
Chief Executives of NHS Trusts
Chief Executives of NHS Foundation Trusts
Chief Executive Monitor

Dear colleague

PIP SILICONE BREAST IMPLANTS: FINAL REPORT OF THE EXPERT GROUP

I attach for your information a link 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). You will find the report at http://www.dh.gov.uk/health/2012/06/pip-report/ .

2. Since our interim report in January, the group has assessed the results of further chemical and toxicological analysis carried out in the UK and elsewhere, and a wide range of data on ruptures and clinical findings at explantation for PIP and other implants, including analysis of a major collection of data on explantations over the period 2001 to 2011. The key points which we draw out of the available information are as follows:

i rigorous world-wide chemical and toxicological analyses of a wide variety of PIP implants have not shown any evidence of potential harm to human health;

ii 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;

iii PIP implants are significantly more likely to rupture or leak silicone than other implants;

iv 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 .

3. In the light of this evidence, we are reiterating and amplifying our earlier advice that

- all providers of breast implant surgery should contact any woman who has or may have PIP implants– if they have not already done so – and offer her a clinical examination and any appropriate investigation to determine if the implants are still intact;

- if the original provider is unable or unwilling to do this, she should seek referral through their GP to an appropriate specialist;
- if there is any sign or reasonable suspicion of rupture, she should be offered an explantation;
- if the implants appear to be intact she should be offered the opportunity to discuss with her specialist the best way forward, taking account of the points at Annex A;
- 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 respect her decision and remove her implants. Where her original provider is unable or unwilling to help, the NHS will remove but not normally replace the implant, unless there are good clinical, rather than cosmetic reasons, to do so;
- If a woman decides not to seek early explantation, she should be offered annual follow up in line with the advice of the surgical associations published in January[1]. 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 armpits, which may indicate a rupture. At the first signs of a possible rupture, they should be offered removal of the implants.

4. The model of care which we have asked the NHS to offer to its patients, and to patients of private providers who approach the NHS for help, remains as described in the letter of 6 January from the NHS Chief Executive, a copy of which is attached at Annex B. We are looking to commissioners and providers to continue to work together to operationalise and resource this model. It is particularly important that GPs should respect the understandable anxiety of women with PIP implants and should refer them on for specialist assessment and advice, 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 C.

5. Please could you ask your trust board to consider how you would wish to communicate with women who have received PIP implants from the trust, in the light of this new information.

Yours sincerely

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

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[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 A: POSSIBLE POINTS TO CONSIDER IN DISCUSSION BETWEEN A WOMAN AND HER SPECIALIST

- There is a risk of morbidity and mortality associated with any surgery, even for this generally healthy population;
- The available evidence from the Allergan and Mentor core studies suggests that the risks of complications are greater for subsequent breast augmentation procedures than for a primary breast augmentation;
- All breast implants have a finite risk of failure; if a woman decides not to seek early removal of her PIP implants there is still a 15-30% chance that she will develop a rupture which may need surgery at some stage within 10 years of implantation, compared with an estimated 10-14% for other leading brands of silicone breast implant. The available data suggests that the risk of failure of PIP implants in any 12-month period is more or less constant from 3 years after implantation onwards;
- The more significant adverse consequences of rupture or leakage of PIP implants appear to occur primarily in cases where the signs are already apparent on clinical examination, rather than for “silent” ruptures;
- Breast cancer patients who develop enlarged axillary lymph nodes following implant-based breast reconstruction require full investigation by the multidisciplinary breast team with responsibility for their care. Other women with ruptured implants who develop enlarged axillary lymph nodes require appropriate investigation (which may include image-guided lymph node biopsy) to determine if the additional complications associated with axillary surgery at the time of explantation would be justified;
- If a woman decides not to seek an explantation at this time, a policy of annual review with explantation at the earliest sign of rupture will forestall at least a proportion of the cases in which a rupture or leakage of silicone gel might result in significant clinical problems;
- Despite extensive testing in the UK and internationally, there is to date no evidence implicating PIP implants (or other silicone breast implants) in other forms of longer term damage to health.

ANNEX B: CHIEF EXECUTIVE LETTER OF 6 JANUARY

To: Chief Executives of all Strategic Health Authority Clusters
Chief Executives of all Primary Care Trust Clusters,
Chief Executives of all NHS Trusts,
Chief Executives of all NHS Foundation Trusts,
Chief Executive of Monitor.

Dear Colleague

Re: PIP SILICONE GEL BREAST IMPLANTS

The Secretary of State recently asked the NHS Medical Director, Sir Bruce Keogh to lead an Expert Advisory Group to review the available data in light of the concerns about PIP Breast Implants. The Expert Group have today reported and I am writing to inform you of their conclusions and to set out what, therefore, our expectations are for the care of NHS patients who have had these implants. The Chief Medical Officer has also written to General Practice and relevant health professionals. A copy of this letter can be found at http://www.dh.gov.uk

The Expert Group's Report

In summary, the group has concluded that the advice given by the MHRA still stands and that there is not enough evidence to recommend routine explantation of these breast implants. The group also agrees there is no link with cancer.

However, the group also acknowledges that many of the implants are made up of non-medical grade silicone and should not have been implanted in women in the first place and as such recognises that this is a worrying time for women with PiP implants and that they need to be properly supported by those who performed the implantations. The full report can be found online at http://www.dh.gov.uk

This is therefore a worrying time for patients who have had breast implants, both those who know they have had a PIP implant and those that could be concerned their implant might be a PIP.

What this means for NHS Patients

In any situation like this we have a duty of care to NHS patients and as such we need to ensure that they receive the support they can expect from the NHS. That support should include the following model of care:

- All women who have received a PIP implant from the NHS will be contacted to inform them that they have a PIP implant and to provide relevant information and advice. If in the meantime NHS patients seek information about the make of their implant then this will be provided free of charge;

- Women who wish to will be able to seek a consultation with their GP, or with the surgical team who carried out the original implant, to seek clinical advice on the best way forward;
- If the woman chooses, this could include an examination by imaging to see if there is any evidence that the implant has ruptured;
- The NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk or the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS.

We want the private sector to offer the same service to its patients as the NHS is offering and we are working with them to best ensure an equivalent model of care is provided. If a clinic that implanted PIP implants no longer exists or refuses to care for their patient - where that patient is entitled to NHS services, the NHS will support the removal of PiP implants in line with the guidance above. Any NHS service in that respect would not include the replacement of private cosmetic implants.

I know that commissioners and providers will work together locally to ensure that the model of care set out above is operationalised and resourced appropriately.

Thank you for your support in doing so.

Yours sincerely,

Sir David Nicholson KCB CBE
NHS Chief Executive

ANNEX C: CLINICAL GUIDANCE FROM THE EXPERT GROUP

[Originally Annex E of *Poly Implant Prostheses (PIP) breast implants: interim report of the expert group* (DH 2011), 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.