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The Scottish Government

Chief Executives, NHS Boards
General Practitioners
Medical Directors, NHS Boards
Breast Cancer Surgeons
Plastic Surgeons

DELIVERING
A GAMES LEGACY FOR SCOTLAND

Copy to: Chairs and Directors of Public Health of NHS Boards

6 March 2012

Dear Colleague

PIP SILICONE GEL BREAST IMPLANTS

Following my letter to you of 10 January 2012 I am writing to you with further information on specific issues and to provide guidance on the data collection process to be put in place. All NHS Boards have confirmed that there has been no use of PiP implants in the NHSScotland.

For your convenience, attached is more detailed guidance jointly prepared by the 3 main specialist organisations concerned (**Annex A**).

In the light of the feedback we have received since my first letter, I would like to take the opportunity of highlighting a number of points:

i *Patients of private providers:* if a GP is consulted by a woman who originally received an implant from a private provider, they should encourage them in the first instance to go back to the original provider for advice, scanning if appropriate, and removal or replacement of the implant if desired.

ii However, if the original provider has gone out of business, or is unwilling to help, the GP should carry out a clinical examination and refer onwards to specialist NHS services. They should make clear that the NHS will remove implants implanted privately but not replace them. For patients who received the original implant from a private provider, the criteria for replacement on the NHSScotland is

the same as for a request for primary breast augmentation. **Annex B** contains the link to the Adult Exceptional Aesthetic Referral Protocol – published on 22 November 2011.

iii *Scanning:* scanning by ultrasound or MRI may be useful in helping to confirm whether or not the implant has ruptured. However, if the woman has already decided (after clinical advice) to have the implant removed, scanning is usually unnecessary.

iv *Patients who are not eligible for replacement implants at NHS expense and who offer to pay for replacements as a private transaction:* where the NHSScotland manages a removal of the privately implanted implants due to failure of care by the private provider, the patients may ask whether they can pay for the additional costs of a replacement as part of a single operation in which the NHS pays for the costs of removal. General guidance on this kind of "top up" payment was issued in as a CMO letter "Arrangements for NHS patients receiving healthcare services through private healthcare arrangements" and the link is included in **Annex C**.

v *Information for patients:* an advertisement containing information for patients was published in national newspapers on 14 January, and a copy is attached as **Annex D**. GPs may wish to use this as the basis of a patient information leaflet to give to patients who are concerned about their breast implants. The NHS Inform website also has a series of FAQs. http://www.nhsinform.co.uk/

vi The new data collection method is outlined at **Annex E**. This data will be collected to provide public information and to support the monitoring of the workload on the NHSScotland.

GPs may find it helpful to refer to the attached summary clinical pathways (**Annex F**) or to more specific pathways which have been agreed locally.

I would like to thank you for your continued support with this matter.

Harry Burns

SIR HARRY BURNS

ANNEX A

JOINT SURGICAL STATEMENT ON CLINICAL GUIDANCE FOR PATIENTS, GPs AND SURGEONS

Poly Implant Prothèse (PIP) Breast Implants

Joint Surgical Statement on Clinical Guidance for Patients, GPs and Surgeons

The Association of Breast Surgery, the British Association of Plastic and Reconstructive Aesthetic Surgeons, the British Association of Aesthetic Plastic Surgeons, the Federation of Surgical Speciality Associations and the Royal College of Surgeons participated in the expert group convened by Professor Sir Bruce Keogh to review policy in relation to breast implants from the French company Poly Implant Prothèse (PIP). All organisations have endorsed the findings of the interim report published on 6 January 2012.

These 5 professional surgical organisations are now independently publishing further clinical guidance for GPs and surgeons regarding the care of patients who have received PIP breast implants. The advice below contains updated Scottish & UK guidance.

Guidance for Patients

If you have breast implants and do not have details of your implant manufacturer, you are advised to check the details of your implant with the surgeon or surgical provider responsible for your care. The surgeon or provider should have a record of the implants used (including the make and size). We would expect this information to be provided free of charge. If you are unable to access your surgeon or provider you should contact your GP for advice regarding an alternative referral.

We recommend that you discuss your options with your surgeon first of all. The decision on whether a scan will be required will only be made after consultation with a surgeon.

Guidance for GPs

The purpose of this guidance is to ensure patients who seek advice are assessed and managed in an agreed and standardised fashion, and that they have appropriate access to specialist advice.

It is expected that private providers will follow the example of the NHS in England where some NHS patients have PiP implants and call their patients for consultation. The first port of call for all patients who have undergone breast augmentation in the private sector is their original provider.

At present the Scottish Government has decided that private patients referred to the NHS will be entitled to explantation and not routine re-augmentation, following the Adult Exceptional Aesthetic Referral Protocol. Patients planning

re-augmentation soon after explantation should be advised of the increased risk associated with having 2 operations.

GPs are advised that patients should not be referred for scanning (USS/MRI) before receiving a specialist surgical opinion.

GPs consulted by patients with PIP implants are advised to assess the patient for the following signs and symptoms.

Symptoms that may be associated with rupture/gel leak:

- localised pain and discomfort
- axillary pain/discomfort
- persistent burning sensation

Signs of rupture/gel leak:

- lumpiness of the breast
- regional swelling of the lymph nodes/glands (lymphadenopathy) – this may be in the absence of other breast signs/symptoms
- change in the shape of the breast
- hardening or firmness of the breast
- tenderness of the breast
- swelling of the breast

GP referral pathways through the NHS for patients whose private provider is no longer in business:

1. If breast change or lymphadenopathy raises concerns of breast disease requiring urgent investigation:

Patients with significant new breast symptoms or signs should be referred to an NHS Rapid Access Breast Unit. This 'fast track' should ONLY be used when there is a need to exclude serious breast disease. It is not anticipated that this group of patients will be large.

2. If breast lumpiness/lymphadenopathy is felt to be related to problems with implants/gel, but signs or symptoms do NOT raise concerns of breast disease:

In cases where the practitioner has reasonable confidence that the breast lumps or lymphadenopathy are associated with the implant rupture or gel leak, or when patients report changes in shape, size or feel of the breast without raising concerns of breast disease, referral should be made to the regional plastic and reconstructive surgery breast service. These patients do NOT require fast-track referral to the NHS Rapid Access Breast Unit.

3. If there are no signs or symptoms:

For patients without physical signs or symptoms, we feel that there is a duty of care on the part of the original surgical providers to reduce anxieties about the long-term health consequence of these implants. For many women, reassurance and confidence will only be achieved once the implant has been

removed. Where the private provider is no longer in business and this need is identified, referral may be made to the regional plastic and reconstructive surgery breast service.

Guidance for all clinicians regarding scanning

Patients should not be referred for scanning (USS/MRI) before receiving a specialist surgical opinion.

In patients without signs or symptoms of rupture, scanning should only be used to assist decision making where the patient is uncertain of whether to have the implant removed or where rupture is identified. For all patients who have already decided to undergo explantation, scanning is unnecessary.

Caution is urged in interpreting ultrasound or MRI imaging information, owing to the available evidence offering conflicting advice about false positive and negative detection rates for implant rupture and leaks.

Guidance for surgeons

Surgeons and hospital specialists reviewing patients with PIP implants should carefully assess the patient for the possibility of rupture or gel leak.

For patients who have evidence of implant rupture/gel leak -

Patients should be advised of the surgical implications of implant removal/exchange. If it is felt that the risk–benefit ratio favours removal or exchange, then this procedure should be strongly advised.

For patients without symptoms or signs of leak or rupture -

If a patient requests it, removal should be offered in cases where the surgeon considers that the benefits outweigh the risks. If a patient is unable to come to a decision immediately, arrangements should be made for regular review and follow-up. We understand that the current offer to remove and/or replace PIP implants is not time-limited and can be reviewed at future follow-up appointments.

Surgical procedure

Surgeons removing an implant should do so using conventional techniques. Where possible the implant should be removed or exchanged through the original incision.

In cases with a soft 'quiet' capsule without evidence of silicone impregnation/local inflammation or contracture the capsule and immediate pericapsular tissues should be biopsied, but a capsulectomy will usually be unnecessary.

In cases of extensive capsular thickening/inflammation/contracture a complete capsulectomy should be performed. The capsule and biopsies from areas of pericapsular thickening should be sent for histology.

In patients with breast cancer who have undergone implant-based breast reconstruction, any suggestion of capsular thickening should prompt consideration of full capsulectomy and excision biopsy of areas of thickening. All specimens must be sent for histology.

Patients with extensive lymphadenopathy or extensive parenchymal swelling and lumpiness should be discussed in a breast multi-disciplinary meeting. Where lymph node removal may be clinically indicated, it should only be carried out in patients who are fully informed about the risks of additional axillary surgery.

Specific Considerations for PIP-related Explantation

Reports have suggested that in cases of PIP implant rupture/leak the inflammatory reaction may be more intense than usual, making a conventional capsulectomy more difficult. Washing or wiping the cavity with diluted aqueous povidone-iodine (PVPI) topical antiseptic solution or aqueous chlorhexidine appears to help dislodge and remove residues of the silicone gel from the surface of the cavity. In cases of extreme contamination where re-augmentation had been planned, a decision to defer replacement should be considered. Surgeons are advised to discuss this possibility with patients in advance.

Dealing with the Implant

A ruptured implant should be discarded unless arrangements for examination have been made with the Medicines and Healthcare products Regulatory Agency.

We would advise surgeons to collect all available data at the time of consultation and surgery. Recent advice from the MHRA includes a form to capture specific data. This has been circulated to consultants in NHSScotland. Once the form is completed as applicable, it should be returned to Dr Susanne Ludgate at the MHRA (susanne.ludgate@mhra.gsi.gov.uk)

Implant Replacement

Patients from the private sector who have been unable to secure help from their original provider will be eligible for help from the NHS. The Scottish Government has offered implant removal but implants will not be replaced routinely in these patients in line with the Adult Exceptional Aesthetic Referral Protocol. Surgeons are advised to make this clear at the initial consultation.

We would encourage all surgeons and surgical providers responsible for breast augmentations using PIP implants to undertake replacement surgery without making a charge to the patients.

Professional Conduct

It is expected that all surgeons will offer advice and care based on these guidelines. We hope and expect that a compassionate and caring attitude will be shown to all patients.

Future Monitoring

Patients who have undergone explantation following rupture/gel leak of PIP implants should be advised to attend annual follow-up for at least 2 years. Patients who underwent a 'clean' explantation or re-implantation should be advised about normal follow-up procedures.

Where a patient decides, after consultation with specialist, not to have their PIP implants removed, they should be followed up on an annual basis. Where a GP has seen a patient with a PiP related issue who chooses not to be seen by a specialist, an annual review to check for any clinical change would be good practice.

In the case of private patients should be followed up by the surgeon or provider responsible for the original implantation. Patients with PIP implants should be made aware of the signs and symptoms of implant rupture and gel bleed. **This guidance may change after consultation with relevant parties.**

CRITERIA FOR BREAST IMPLANTATION IN NHSSCOTLAND

CEL 27 (2011) Updated Adult Exceptional Aesthetic Referral Protocol [PDF - 296Kb]

The Adult Exceptional Aesthetic Referral Protocol contains a series of aesthetic procedures, which, as they are not treating an underlying disease process, are not routinely available on the NHS, and can only be provided on an exceptional basis where there is clear evidence of benefit to the patient.

This protocol applies to all specialties and clinicians undertaking procedures contained in the protocol and should be adhered to in all circumstances.

This protocol supersedes the version distributed with CEL 30 in May 2009.

Breast Augmentation

Procedures not routinely provided by the NHS

Breast Augmentation using implants or other techniques eg fat transfer.

Clinical Psychology

All referrals will be seen by a specialist Clinical Psychologist prior to assessment by a surgeon.

Patients undergoing reconstructive surgery may not require psychological assessment. This decision will be at the discretion of the surgical team.

BMI

>20 -≤27.

BMI ≤ 33 may be considered in patients undergoing a planned programme of reconstructive surgery.

Special Considerations

Inclusions

- Significant psychological distress combined with physical symptoms (as confirmed by a specialist Clinical Psychologist).
- Congenital asymmetry > 1 cup size.
- Congenital aplasia/hypoplasia (inc tuberous breast).
- Congenital chest wall deformity (e.g. Poland's Syndrome).
- Implant surgery may be appropriate for asymmetry following breast cancer treatment.

Exclusions

- Simple cosmetic augmentation.
- Surgery to reverse the normal ageing or post-involutional changes will not be supported.

Waiting Times

- These patients are not subject to the 18 Weeks Referral to Treatment Standard.
- Some patients may be subject to guarantee times within other pathways.

Aesthetic surgery is not routinely offered by the NHS and can only be provided on an exceptional case basis in line with the guidance.

GUIDANCE ON ARRANGEMENT FOR NHS PATIENTS RECEIVING HEALTHCARE SERVICES THROUGH PRIVATE HEALTHCARE ARRANGEMENTS

http://www.scotland.gov.uk/Publications/2009/03/25112155/0

The guidance provides a framework to support local decisions concerning the possible combination of elements of NHS and private care for individual patients. Decisions regarding the provision of NHS services remain matters for NHS Boards; and clinicians remain responsible for clinical decisions regarding the care of individual patients.

Key Principles and Requirements for NHS Boards

This guidance takes full account of the core principles of the NHS as set out below:

- the NHS provides a comprehensive service, available to all
- access to its services is based on clinical need not an individual's ability to pay
- the NHS aspires to high standards of excellence and professionalism
- NHS services must reflect the needs and preferences of patients, their families and their carers
- the NHS works across organisational boundaries with other organisations in the interests of patients, communities and the wider population
- the NHS is committed to providing the best value for taxpayers' money, making the most effective and fair use of finite resources
- the NHS is accountable to the public, communities and patients that it serves

The following key requirements should apply:

- the primary purpose of any NHS organisation is to provide NHS care;
- NHS and private care should be delivered separately and there should be clear separation in legal status, liability and accountability between NHS and private care provision;
- in all cases the discrete elements of NHS and private care must be understood by all parties;
- the NHS should never subsidise private care with public money, which would breach core NHS principles;
- any arrangements to combine NHS and private care must be lawful;
- any arrangements to combine NHS and private care must not compromise the legal, professional or ethical standards required of NHS clinicians;
- on the basis that the private and NHS elements of care can be fully delineated they should be capable of being delivered independently at a different time and place from each other. This could include the facilities of a private healthcare provider, or part of an NHS organisation which has been designated for private care, including amenity beds;
- the NHS must not offer a two-tier service: the NHS provides treatment free at the point of access. Unless legislation allows, the NHS cannot charge patients for NHS care.

GUIDANCE FOR PATIENTS

May be freely adapted for local use as a patient information leaflet.

THE NHS WILL SUPPORT WOMEN WITH PIP BREAST IMPLANTS

The latest advice from the NHS and plastic surgery experts is that women with PiP breast implants do not need to have them removed unless they have symptoms such as pain and tenderness.

There is no link to cancer and there is no clear evidence of an increased risk of harm compared to other brands of breast implants.

However, if you are concerned, you should:

- **Find out** if you have PiP implants by checking your medical notes.
- **Speak** to your specialist or your clinic if you had them done privately.
- **Agree what's best for you** Get advice on whether or not you need a scan then discuss appropriate action with your doctor.

The following organisations have said they will replace PiP implants for free if clinically necessary: Holly House, Highgate Hospitals, Make Yourself Amazing, Ramsay Health Care, Spire Healthcare, BMI Healthcare, Nuffield Healthcare and HCA International.

If your private clinic no longer exists or refuses to remove your PiP implants, speak to your GP. The NHS will remove your implants if your doctor agrees, but the NHS will not replace implants unless it is clinically necessary.

For further information visit http://www.nhsinform.co.uk/

DATA COLLECTION GUIDANCE

Coverage

Data will be required from the plastic surgery and breast surgery centres in Scotland located in Grampian, Greater Glasgow & Clyde, Lothian and Tayside. This will relate to all patients referred to these centres due to concerns relating to PiP implants.

Timescale

Data will be required on a fortnightly basis. The data collection will be kept under review and any decisions on the duration of the collection will be relayed to the centres.

Data will relate to the 14 day period from Monday to Sunday. Submissions are required by midday on the Wednesday following the end of the reporting period and this will be published centrally by ISD the following Tuesday. The first reporting period will be from Monday 27 February to Sunday 11 March 2012 inclusive. Centres should also include the total number of referrals since Friday 6 January 2012.

Data Requirements

The data required to be submitted on a fortnightly basis will be the total number of referrals to the reporting centre relating to concerns about PiP implants. This includes referral by GP, self-referral or referral by any other route.

The return should include all patients referred with concerns due to PiP implants. If the manufacturer of the implant is unknown the patient should be included in the fortnightly data. The template for submission allows referrals to be coded as either “PiP Implants” or “Unknown Implants”. Fortnightly data should identify those where the implant is known to be a PiP implant where possible and as unknown implant otherwise. When the manufacturer has been identified the total since January 2012 can be revised to take this into account. This would mean keeping records of the number of patients with unknown manufacturer to date and updating the “Total since 6 January” on a fortnightly basis by moving any patients which were previously counted as unknown into the “PiP Implants” category.

Nil returns are required where there has been no activity relating to PiP implants during the fortnight in question.

Data Submission

Due to the emergent nature of this collection the plan is to publish the total number of referrals at this stage. The template below also allows centres to supply further data on the referrals which will be useful for monitoring service level pressures relating to PiP implants. This includes data on referrals and additions to inpatient/daycase lists and also data on activity: the number of new outpatient appointments, the number of scans (MRI/ultrasound) and the number of surgeries performed.

However, long-term monitoring may require the submission of patient level data. It is required that for any patient reported as per the definitions above (with PiP implant), arrangements are made locally to record patient details to allow identification retrospectively. This may be needed to monitor the services required to meet the needs of these patients and to allow for follow-up should guidance change on the care required for these patients.

The template supplied to centres should be completed and returned to the ISD named contact: elaine.parry@nhs.net, by midday on the Wednesday following the reporting period.

Data Submission Template

	Reporting Centre				Within the last fortnight		Total since 6 January 2012	
					PiP Implants	Unknown Implants	PiP Implants	Unknown Implants
Referrals and additions to list	Number of referrals	GP	Self - referral	Other				
	Number of Outpatients added to Inpatient / Daycase waiting list for explant							
Activity	Number of new Outpatient appointments							
	Number of scans	MRI	Ultrasound	Other				
	Number of explants completed	Procedure - Insertion						
		Procedure - Removal						

Publication

This data will be collated and validated by ISD. The data collection will be reviewed and this will inform plans to publish the data. Plans for data collection and publication will then be published on Tuesday 6 March 2012.

OUTLINE PRIMARY CARE CLINICAL PATHWAY: ORIGINAL IMPLANT PRIVATE