The Scottish Parliament
Pàrlamaid na h-Alba

HEALTH AND SPORT COMMITTEE

AGENDA

7th Meeting, 2012 (Session 4)

Tuesday 21 February 2012

The Committee will meet at 10.00 am in Committee Room 2.

1. **Decisions on taking business in private:** The Committee will decide whether to take item 4 in private and whether its consideration of a draft report should be taken in private at future meetings. The Committee will also decide whether its consideration of the approach to the forthcoming Social Care (Self-directed Support) (Scotland) Bill should be taken in private at future meetings.

2. **Subordinate legislation:** The Committee will consider the following negative instruments—

   The National Health Service (General Medical Services Contracts) (Scotland) Amendments Regulations 2012 (SSI 2012/9); and
   The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2012 (SSI 2012/10).

3. **PIP silicone breast implants:** The Committee will consider correspondence received.

4. **Alcohol (Minimum Pricing) (Scotland) Bill:** The Committee will consider a draft Stage 1 report.

Douglas Wands
Clerk to the Health and Sport Committee
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The papers for this meeting are as follows—

Agenda Item 2

Note by the clerk	HS/S4/12/7/1

Agenda Item 3

Correspondence from the Scottish Government	HS/S4/12/7/2
Correspondence from the Independent Healthcare Advisory Services	HS/S4/12/7/3
Correspondence from Rhoda Grant MSP	HS/S4/12/7/4
Note by the clerk	HS/S4/12/7/5

Agenda Item 4

Responses to the Committee's call for views on the pricing mechanism	HS/S4/12/7/6
PRIVATE PAPER	HS/S4/12/7/7 (P)
PRIVATE PAPER	HS/S4/12/7/8 (P)

Subordinate Legislation Briefing

Overview of instruments

1. There are two negative instruments for consideration.

2. A brief explanation of the instruments along with the comments of the Subordinate Legislation Committee is set out below. If members have any queries or points of clarification on the instruments which they wish to have raised with the Scottish Government in advance of the meeting, please could these be passed to the Clerk to the Committee as soon as possible.

Details on the instruments

3. The National Health Service (General Medical Services Contracts) (Scotland) Amendment Regulations 2012 (SSI 2012/9) amend the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004, which set out the framework for general medical services contracts under the National Health Service (Scotland) Act 1978.

4. The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2012 (SSI 2012/10). These Regulations amend the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004, which set out the framework for section 17C agreements under the National Health Service (Scotland) Act 1978.

5. The Subordinate Legislation Committee has not made any comments on the instruments.

6. There has been no motion to annul these instruments.

Dougie Wands

Clerk to the Committee

Deputy First Minister and Cabinet Secretary
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The Scottish Government

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DELIVERING
A GAMES LEGACY FOR SCOTLAND

Our ref: 2012/0003201
February 2012

Thank you for your letter of 25 January seeking further information on PIP silicone breast implants.

NHS Boards have completed checking their patient records and I can confirm that no women have been supplied by NHSScotland with a PIP silicone breast implant. I do not have any additional information on the number of women who may have been supplied with PIP implants by the private healthcare sector.

Where women remain concerned about their PIP silicone breast implant after contacting their private healthcare provider, they should contact initially their GP. I can confirm that the Chief Medical Officer for Scotland has written to GP practices and clinicians outlining the advice and support which GPs are required to offer to women in that situation and have attached a copy of that letter for your information. In addition advice and information is available from NHS Inform's website, www.nhsinform.co.uk or by telephone 0845 22 44 88.

The decision on the treatment to be provided for an individual woman is a clinical one to be taken by the relevant clinician taking into account the woman's clinical history and wishes.

I hope that this reassures the Committee of the support being made available to women in Scotland.

NICOLA STURGEON

Chief Medical Officer, Public Health and Sport Directorate
Chief Medical Officer and Secretariat Division

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The Scottish Government

General Practitioners
Medical Directors
Breast Cancer Surgeons
Plastic Surgeons

DELIVERING
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10 January 2012

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)

Yours sincerely

Harry Burns

SIR HARRY BURNS
Chief Medical Officer

Directorate of Health Workforce and Performance
Access Support Division

The Scottish Government

CEL 27 (2011)
November 2011

Dear Colleague,

Up-dated Adult Exceptional Aesthetic Referral Protocol (June 2011)

Summary

This letter is to provide Boards with the Adult Exceptional Aesthetic Referral Protocol. This protocol supersedes the version distributed with CEL 30 in May 2009.

Background

1. 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.

2. In exceptional circumstances, it is recognised that the procedures contained in the protocol can enhance the lives of patients who fulfil all the criteria. These are set out in the *Adult Exceptional Aesthetic Referral Protocol.*

3. However, in certain circumstances, for example, where there is an underlying disease process, it will be clinically indicated that the patient should receive treatment. In this context the 18 Weeks Referral to Treatment Target will apply.

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

5. NHS Boards should ensure that their Community Health Partnerships pursue an engagement process with General Practitioners to share this approach.

6. NHS Boards should constantly review the effectiveness of their application of the guidance contained in the protocol, and record actual waiting times experienced by patients

Addresses

For action
Chief Executives (NHS Boards)
Medical Directors (NHS Boards)

Chief Executives (Operating Divisions)
Medical Directors (Operating Divisions)

Director (Information Services Division)

For information
Chief Executive (Golden Jubilee National Hospital)

Regional Directors of Planning

Chief Executives (NHS National Services Scotland)

Chief Executive (Healthcare Improvement Scotland)

Chief Executive (NES)

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Yours sincerely

Mike Lyon
Deputy Director, Health and Social Care Directorate

The Adult Exceptional Aesthetic Referral Protocol (AEARP)
September 2011

NHS SCOTLAND

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

Please Note

- Patients should only be referred following a **clinical assessment** where there is a **symptomatic or functional requirement** for surgery.
- All cases will be judged against **agreed criteria on an individual basis**.
- Referral for consideration **does not necessarily mean that surgery will be offered**. This must be communicated to the patient.

The Adult Exceptional Aesthetic Referral Protocol (AEARP)
September 2011

NHS SCOTLAND

Referrer must first assess the following before taking the decision to make a referral under the AEARP.

Patient's Age	If patient is younger than 16 years of age.	AEARP is not applicable. The patient should be managed according to clinical need.
Body Mass Index (BMI)	BMI is a pre-requisite for a number of the procedures covered by the protocol.	Check the specific assessment criteria under the protocol.
Impairment of Function	Where there is a significant functional impairment which can be improved by surgery.	AEARP may not be applicable. Make a referral to a specialty appropriate to symptoms but check relevant section within this document for details.
Psychological Distress	Referral under the protocol may be indicated where the patient has significant and prolonged psychological distress and associated impairment in functioning related to the perceived problem and likely to benefit from aesthetic surgery.	Check the specific assessment criteria under the protocol. Psychology assessment must be by the specialist Clinical Psychologists working with a regional centre.

Contraindications

Significant Major Life Event	If a patient has had a major life event in the previous 12 months e.g. birth, relationship breakdown or a significant bereavement.	Aesthetic Surgery is contra indicated. Consider Significant Major Life Event deferring referral until recovery.

Referral for aesthetic surgery is contra indicated where:

- a patient has had an episode of self harm within the last two years;
- there is a previous diagnosis of body dysmorphic disorder;
- the patient has a disproportionate view of the problem following your examination;
- the patient currently has:
  - a major depressive illness;
  - an active delusional or schizophrenic illness;
  - an eating disorder;
  - obsessive compulsive disorder;
  - substance abuse problem.

NHS SCOTLAND

Treatment

Body Contouring

Benign Skin Lesion

Blepharroplasty

Breast Surgery

Breast Augmentation

Mastopexy

Breast Reduction

Breast Implant Complications

Gynaecomastia

Inverted Nipple Correction

Aesthetic Facial Surgery

Hair Transplantation

Pinnaplasty

Rhinoplasty

Tattoo Removal

Thread Veins

Genital Surgery for Functional Indications

NHS SCOTLAND

Body Contouring

Procedures not routinely provided by the NHS

Abdominoplasty, Apronectomy, Liposuction, Thigh/Arm Lift, Excision of Redundant Skin/Fat.
Generally any procedures after significant change in body shape—e.g. massive weight loss, post-bariatric surgery.

Clinical Psychology

All referrals will be seen by a specialist Clinical Psychologist prior to assessment by a surgeon except HIV lipodystrophy cases.
Patients with HIV associated lipodystrophy may be referred for specialist Clinical Psychology assessment if required after surgical assessment.

BMI

BMI ≤27 maintained for one year must be achieved.
In a few, unique cases with significant functional impairment a higher BMI may be considered if this represents a documented weight loss of 50% starting BMI, again sustained for one year.

Special Considerations

Inclusion

Significant psychological impairment (as confirmed by specialist Clinical Psychologist).
Significant physical limitations (significant impaired mobility).
Significant physical signs despite medical intervention (severe, intractable intertrigo).
HIV associated lipodystrophy.

Exclusion

Simple cosmetic requests.

Waiting Times

These procedures are not subject to the 18 Weeks Referral to Treatment Standard.

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

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Benign Skin Lesion

Procedures not routinely provided by the NHS

Excision of clearly benign skin lesions.
Where there is diagnostic doubt or suspicion of malignancy this should be made clear in the referral. In this case referrals are not made under AEARP.
Pre-malignant lesions (e.g. sebaceous naevus) should be referred outside AEARP.

Clinical Psychology

Referral to a specialist Clinical Psychologist is not required.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Inclusions

Issues which may allow consideration of surgical removal include recurrent trauma (e.g. shaving) and recurrent/risk of infection. Please make this clear if this is the reason for referral.
Massive lesions causing functional impairment or disfigurement.

Exclusions

Benign lesions causing no functional impairment or disfigurement will not be removed by NHSScotland as this is purely cosmetic.

Waiting Times

These procedures are not subject to the 18 Weeks Referral to Treatment Standard.
Referrals for suspicion of malignancy or pre-malignant lesions should be made via the appropriate cancer pathway.

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

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Blepharroplasty

Procedures not routinely provided by the NHS

Upper and Lower blepharroplasty—surgery for removal of excess skin and/or 'eye-bags'.

Clinical Psychology

Referral to a specialist Clinical Psychologist may be made at the discretion of the surgical team.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Inclusions

Surgery may be considered where there is restriction of the visual field by the excess skin. Visual field tests to be carried out prior to referral.

Exclusions

Surgery will not be considered where a perception of tiredness or ageing is the primary concern.

Waiting Times

Blepharroplasty for restricted visual fields is subject to 18 Weeks Referral to Treatment Standard.

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

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Breast Surgery

Procedures not routinely provided by the NHS

All procedures to change the appearance of the breast in size, shape or position.
Patients undergoing surgery for breast cancer should be considered under the appropriate pathway.

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 and ≤27.
BMI ≤ 33 may be considered in patients undergoing a planned programme of reconstructive breast surgery.

Special Considerations

Specific to individual procedures, see 'specific procedures' list below for links to relevant sections.
Patients with asymmetry may require one or more of procedures described below.
Photography can be invaluable in assessing referrals. Please include photographs where possible.
Surgery to reverse the normal ageing or post-involutional changes will not be supported.

Specific Procedures

Breast Augmentation
Mastopexy
Breast Reduction
Breast Implant Complications
Gynaecomastia
Inverted Nipple Correction

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

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NHS SCOTLAND

Breast Augmentation

Procedures not routinely provided by the NHS

Breast Augmentation using implants or other techniques e.g. 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 guidelines contained in this protocol.

Return to breast surgery

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Mastopexy

Procedures not routinely provided by the NHS

Surgery performed primarily for breast uplift (with small elements of reduction).

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

Congenital asymmetry > 1 cup size.
Congenital aplasia/hypoplasia.
Chest wall deformity e.g. Poland's Syndrome.
Asymmetry following Breast Cancer treatment.

Exclusions

Simple cosmetic uplift.
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 guidelines contained in this protocol.

Return to breast surgery

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Breast Reduction

Procedures not routinely provided by the NHS

Surgery to reduce breast size

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

Massive disproportion to body habitus.
Intractable intertrigo.
Asymmetry > 1 cup size.
Breast reduction may be appropriate for asymmetry following breast cancer treatment.

Exclusions

Simple cosmetic reduction.
Breast reduction is not a useful primary treatment for breast, back, neck or shoulder pain.
Surgery to reverse the normal ageing or post-involutional changes will not be supported.
Generally inadvisable in patients < 18 years old.

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 guidelines contained in this protocol.

Return to breast surgery

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Breast Implant Complications

Procedures not routinely provided by the NHS

Surgery to correct change in the appearance, size or shape of a breast with a prior history of implant surgery.
Replacement of breast implants will only be performed where the original implant surgery was performed by the NHS.
Patients who have had implant surgery performed privately for reconstruction after breast cancer will be treated as if their implants have been provided by the NHS.
Patients who have had implant surgery performed for cosmetic reasons and present with implant related complications should initially be referred back to the organisation which performed their surgery.
Where this is not possible, investigation and treatment up to the removal of the implant may be performed.

Clinical Psychology

Referral to a specialist Clinical Psychologist may be made at the discretion of the surgical team.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Inclusions

Change in the appearance, size or shape of a breast with a prior history of implant surgery.
Pain related to capsular contracture.

Exclusions

Implants placed privately for cosmetic reasons will not be replaced by NHSScotland. This would establish an ongoing duty of care for the replacement implants.

Waiting Times

These patients are subject to the 18 Weeks Referral to Treatment Standard.
Patients do not require routine follow-up.

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

Return to breast surgery

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Gynaecomastia

Procedures not routinely provided by the NHS

Surgery to change the shape/volume of the male breast.
May include subcutaneous mastectomy or liposuction.

Clinical Psychology

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

BMI

> 20 ≤27.

Special Considerations

Screening for hormone levels should be done prior to referral.
Where indicated referral to Endocrinology should precede referral for surgery.

Inclusions

Clinically significant breast prominence.
Feminised nipple areola complex.
Significant breast asymmetry.
Significant psychological distress.

Exclusions

Where clinical appearance does not match patient perception.

Waiting Times

These patients are not subject to the 18 Weeks Referral to Treatment Standard.

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

Return to breast surgery

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Inverted Nipple Correction

Procedures not routinely provided by the NHS

Surgery to correct inversion of a congenital nipple.
Acquired nipple inversion may be a sign of serious underlying disease and must be investigated and referred via the appropriate protocol.

Clinical Psychology

Referral to a specialist Clinical Psychologist may be made at the discretion of the surgical team, following use of a nipple device for a period of 6 months.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Acquired nipple inversion may be a sign of serious underlying disease and initial referral should be directed to a general surgical breast clinic.
In the absence of significant disease conservative treatment with proprietary suction devices for at least six months should be tried prior to considering referral.
Patients should be made aware prior to referral that surgical correction is likely to render subsequent breast feeding impossible.

Inclusions

Nipple inversion not responsive to conservative treatment in the absence of significant breast pathology.

Exclusions

Patients not compliant with conservative measures.

Waiting Times

These patients are not subject to the 18 Weeks Referral to Treatment Standard.
Referrals for suspicion of malignancy should be made via the appropriate cancer pathway.

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

Return to breast surgery

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Aesthetic Facial Surgery

Procedures not routinely provided by the NHS

Surgery for lifting one or both sides of the neck, face and brow.
May include all types facelift, brow lift, neck lift.
Indications may include patients with collagen diseases (e.g. cutis laxa) or facial palsy.

Clinical psychology

All referrals for simple age related changes with no underlying cause will be returned.
Referral to a specialist Clinical Psychologist may be made at the discretion of the surgical team.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Inclusions

Where there is a specific, relevant underlying cause, please make this clear in any referral.
Referrals for brow lift may be considered where there is a demonstrable visual field defect. Visual field tests to be carried out prior to referral.

Exclusions

Surgery simply to reverse the normal ageing process will not be supported.

Waiting times

These patients are not subject to the 18 Weeks Referral to Treatment however brow lift for restricted visual fields is subject to the 18 weeks Referral to Treatment Standard.

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

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Hair Transplantation

Procedures not usually provided by the NHS

Grafting or other techniques to restore hair growth to an area of alopecia.

Clinical Psychology

Referral to specialist Clinical Psychologist may be made at the discretion of the surgical team.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Inclusions

Following trauma (including surgery), burns, or rare congenital conditions.

Exclusions

Referrals for normal male pattern baldness will not be considered.

Waiting Times

These patients are not subject to the 18 Weeks Referral to Treatment Standard.

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

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NHS SCOTLAND

Pinnaplasty

Procedures not usually provided by the NHS

Surgery to alter the form of the external ear.

Clinical Psychology

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

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Inclusions

There should be clinically evident significant prominence of the ear(s) and this should be made clear in the referral.
Congenital anomalies will usually have been dealt with in childhood, before the onset of this protocol.

Exclusions

Simple cosmetic pinnaplasty will not be supported.

Waiting Times

These patients are not subject to the 18 Weeks Referral to Treatment Standard.

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

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NHS SCOTLAND

Rhinoplasty

Procedures not usually provided by the NHS

All procedures to alter the form and appearance of the nose.
May include procedures for nasal obstruction.

Clinical Psychology

All referrals where alteration of the form and appearance of the nose is the primary aim will be seen by specialist Clinical Psychologist.
Referrals for nasal obstruction with alteration of the external appearance of the nose will be seen by Clinical Psychology.
Referrals only for nasal obstruction do not require initial specialist Clinical Psychology assessment.
Post-trauma referrals do not need specialist Clinical Psychology assessment if within one year of injury.
Congenital anomalies (e.g. nasal deformity associated with cleft lip) will usually be in a continuing programme of treatment and are not subject to AEARP.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

As a general principle, any procedure performed purely for nasal obstruction does not require psychology assessment and is subject to 18 Weeks Referral to Treatment Standard.
Other procedures will require psychology assessment and will not be subject to 18 Weeks Referral to Treatment Standard.

Inclusions

Procedures to alter the appearance of the nose after trauma within one year will usually be supported.
After one year, post trauma specialist clinical psychology assessment is required.

Exclusions

Procedures performed only for nasal obstruction fall outside this protocol.
Simple cosmetic rhinoplasty will not be supported.

Waiting Times

Procedures for nasal obstruction are subject to the 18 Weeks Referral to Treatment Standard.
Procedures for nasal trauma within 12 months of injury fall are subject to the 18 Weeks Referral to Treatment Standard.
All other indications for rhinoplasty are not subject to the 18 Weeks Referral to Treatment Standard.

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

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Tattoo Removal

Procedures not usually provided by the NHS

Any procedure (surgical or laser) for the purpose of removing or reducing a tattoo.

Clinical Psychology

Referral to a specialist Clinical Psychologist will be at the discretion of the surgical team.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Professional tattoos are usually incompletely removed by laser treatment.
Treatment for post traumatic tattooing will be supported.
Tattoo removal is not usually supported unless the tattoo was gained in the absence of consent.
Tattoo removal other than of face, neck or hands is most unlikely to be supported.

Waiting Times

These patients are not subject to the 18 Weeks Referral to Treatment Standard.

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

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Thread Veins

Procedures not usually provided by the NHS

Laser and microsclerotherapy.

Clinical Psychology

Referral to a specialist Clinical Psychologist will be may at the discretion of the surgical team.

BMI

There are no specific BMI restrictions.
If BMI significantly raised consider carefully whether patient is appropriate for this type of surgery.

Special Considerations

Treatment is only supported for severe thread veins on the face.
Photographs accompanying referrals are invaluable.

Waiting Times

These patients are not subject to the 18 Weeks Referral to Treatment Standard.

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

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Genital Surgery for Functional Indications

Procedures not routinely provided by the NHS

Procedures performed to alter the appearance of the external genitalia.
In the presence of physical dysfunction referral should be made to Gynaecology.
In the presence of psychological/psychosexual dysfunction non-surgical treatment may be more appropriate.

Clinical Psychology

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

BMI

>20–≤27.

Special Considerations

Inclusion

Functional impairment which must be confirmed by an appropriate specialist. This must be a tertiary referral.

Exclusion

Cosmetic genital surgery is not supported by NHSScotland.

Waiting Times

These patients are not subject to the 18 Weeks Referral to Treatment Standard.

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

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6th February 2012

Mr Duncan McNeil MSP
Convener of the Health & Sport Committee
T3.60
The Scottish Parliament
Edinburgh
EH99 1SP

Dear Mr McNeil MSP,

Re: PIP Silicone Breast Implants

Thank you for your letter dated 25 January 2012.

The IHAS represents seven Scottish acute independent healthcare providers, who form a group called the Scottish Independent Hospitals Association (SIHA). I have included the Credentials Document which provides you with more information.

I am aware that the three hospital groups which own these hospitals (BMI Healthcare, Nuffield Health and Spire Healthcare) have responded to you directly. The below collates and adds to the information you have already received.

The SIHA providers that undertook PIP implants are as follows:

BMI Carrick Glen Hospital	Ayr
BMI Kings Park Hospital	Stirling
BMI Albyn Hospital	Aberdeen
BMI Fernbrae Hospital	Dundee
BMI Ross Hall Hospital	Glasgow
Nuffield Health, Glasgow Hospital	Glasgow
Spire Shawfair Park Hospital	Edinburgh
Spire Murrayfield Hospital	Edinburgh

Number of breast procedures carried out where PIP implants were used:

BMI Carrick Glen Hospital	6 (Post 2001 & non-Transform patients)
BMI Kings Park Hospital	7 (Post 2001 & non-Transform patients)
BMI Albyn Hospital	0
BMI Fernbrae Hospital	0
BMI Ross Hall Hospital	5 (Pre 2001 & non-Transform patients)
Nuffield Health, Glasgow Hospital	16
Spire Murrayfield Hospital, Edinburgh Spire Shawfair Park Hospital	'A little over' 800 between the two hospitals.

SIHA providers that **will** remove and replace PIP implants free of charge:

BMI Healthcare	BMI Healthcare will provide the required diagnostic imaging, removal and replacement to all patients who paid BMI Healthcare for their surgery and PIP implant from 2001 onwards at no cost to the patient.
Nuffield Health	Nuffield Health have promised to review, and remove and/or replace the implants in those patients who have a clinical need. This includes those patients who express a desire to have them removed regardless of whether they are experiencing difficulty or have damaged implants, provided they are fully informed.
Spire Healthcare	Spire Healthcare is offering any Spire patient with such implants a free consultation with a consultant surgeon, and where recommended, a free scan (MRI or ultrasound). Where the surgeon feels it reasonable and the patient wishes to do so, Spire is offering free ex-plantation or exchange of implants on a like-for-like basis. Where patients do not wish a procedure, Spire is offering a free follow-up scan in two years time to check on the state of their implants.

Instances where SIHA providers **will not** remove and replace PIP implants free of charge:

BMI Healthcare	For any patients who have had PIP implants inserted at a BMI hospital but paid a third party such as the Harley Medical Group, i.e. did not pay BMI, or who had surgery in another provider's hospital, BMI will remove and replace these at a discounted procedure price, to be paid either by the third party or the patient.

For your information, Nuffield Health (Glasgow Hospital) has broken down its data into organsations that also use Nuffield; i.e. Surgicare and Transform:

Company	No. of PIP patients who have had implants inserted	No. of PIPs seen for OPD review in past 2 weeks	No. of PIPs scheduled to be seen for OPD review in next 2 weeks	No. who have had PIPs replaced at Nuffield Glasgow Hospital	No. scheduled to have PIPs removed/replaced
Surgicare	16	10	3	1	9
Transform	8	0	0	0	0
Nuffield	1	0	0	0	0
Other	0	0	0	1	0

Transform and the Harley Medical Group also operate in Scotland:

The Harley Medical Group	Glasgow clinic opened in October 2012. No PIP implants used since 2010.
Transform	460-470 patients in Scotland. All operations performed in Scottish Hospitals in the period 2004/05. Transform is offering free consultation, free scan, free removal. For removal and re-augmentation, a non-profit fee of £2500 is being charged. All surgery to be carried out in Scottish hospitals.

I trust this information will be all that you require. Please do contact me if you require any further information.

Yours sincerely,

Sally Taber
Director

HS/S4/12/7/4

Duncan McNeil
Convener
Health and Sport Committee
The Scottish Parliament
EDINBURGH
EH99 1SP

Please quote Ref: 01095298/C12/KT

2 February 2012

Dear Duncan

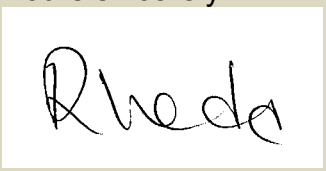
PE1378

I recently had discussions with Mairi Johnston with regard to PIP breast implants which you will no doubt have been following in the press. While this coverage is in regard to breast implants that did not contain medical grade silicone. However, Ms Johnston and I believe that there are problems with medical grade implants which are not recognised and therefore treatment for conditions caused by ruptures are not available.

In light of recent incidents I wonder if the Health and Sport committee would consider re-opening the petition or holding an enquiry into the wider issues surround implants and their safety.

Best wishes

Yours sincerely



Rhoda Grant, MSP

Rhoda Grant
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PIP silicone breast implants

Purpose

1. The Committee is invited to consider correspondence received from private healthcare providers and the Scottish Government regarding PIP silicone breast implants.

2. The Committee is also invited to consider correspondence from Rhoda Grant MSP asking the Committee to consider holding an inquiry into the wider issues surrounding implants and their safety.

Background

3. A SPICe briefing note is attached as an annexe to this paper. It provides background information concerning breast implants supplied by the French Company Poly Implant Prothese (PIP), together with an outline of the actions taken by the authorities in Scotland, the UK and the EU.

4. The Committee is asked to note that the current PIP case is unrelated to the more general issues raised by petitioner Mairi Johnston, whose petition was closed by the Committee on 13 December 2011.

Private providers

5. On 8 February 2012, in response to a request for information, the Committee received correspondence from the Independent Healthcare Advisory Service (IHAS) which represents seven Scottish acute independent healthcare providers, who form a group called the Scottish Independent Hospitals Association (SIHA). A copy of the letter has been circulated as a separate paper.

6. IHAS has provided data about the number of breast procedures carried out in SIHA hospitals where PIP implants were used. It also sets out the position of the various private providers on removal and replacement of PIP implants for patients in Scotland.

Scottish Government position

7. The Scottish Government has accepted the advice of the UK Expert Group and adopted the approach taken by the UK Department of Health. In correspondence to the Committee dated 8 February 2012, the Cabinet Secretary for Health and Wellbeing confirmed that no women have been supplied by NHSScotland with a PIP silicone breast implant.

8. The Cabinet Secretary also provided a copy of correspondence issued by the Chief medical Officer for Scotland to all GP practices and clinicians outlining the advice and support which GPs are required to offer to women. In terms of replacement of PIP implants, the letter states that this would not happen routinely and refers clinicians to the Adult Exceptional Aesthetic Referral Protocol, which should be used in such cases. This states that—

"Replacement of breast implants will only be performed where the original implant surgery was performed by the NHS."

9. A copy of the letter and attachments has been circulated as a separate paper.

Correspondence from Rhoda Grant MSP

10. The Committee has also received correspondence from Rhoda Grant MSP inviting it to consider re-opening Petition PE1378 from Mairi Johnston, or holding an inquiry into the wider issues surrounding implants and their safety.

11. The Committee is asked to note that there is no provision in Standing Orders allowing a petition to be re-opened. However, the Committee can decide to hold an inquiry into any matter which falls within its remit.

Committee options

12. In light of the continuing concerns about the safety of PIP silicone breast implants, the Committee could consider taking further action to obtain additional information.

13. If the Committee wishes to take further action, it is invited to consider the following options—

a) Invite the Cabinet Secretary for Health, Wellbeing and Cities Strategy to attend the Committee to confirm the support available from the NHS in Scotland for women with PIP implants

b) Invite oral evidence from representatives of SIHA

c) Launch a wider inquiry into the safety of silicone breast implants and treatment for conditions caused by ruptures.

14. If the Committee wishes to take oral evidence in the immediate future, this could be accommodated at its next meeting on Tuesday 28 February 2012.

15. The Committee is invited to decide what action, if any, it wishes to take at this time.

Dougie Wands

Clerk to the Committee

HEALTH AND SPORT COMMITTEE

THE SAFETY OF PIP BREAST IMPLANTS: UPDATE BRIEFING

INTRODUCTION

Members will recall the SPICe briefing that was produced for the Committee Meeting on 24 January 2012. At that meeting Members agreed to seek additional information from the Scottish Government and the Independent Healthcare Advisory Services (IHAS).

This briefing provides an update on current work being undertaken by the UK Government, Scottish Government and the EU in regard to PIP implants, together with a summary of the actions being taken by private operators who are members of the Scottish Independent Hospitals Association.

UK GOVERNMENT ACTION

Guidance

Following the report of the Expert Review Group and the UK Government's announcement of the offer that would be made to women who had PIP implants, the Chief Medical Officer for England issued a letter[1] to clinicians on 6 January 2012. This encouraged GPs and others to make sure that patients were made aware that all breast implants carry risk of rupture and of the risks associated with surgery in having implants removed. It reiterated the decision of the UK Government as to the circumstances under which PIP breast implants would be removed and replaced on the NHS, including that a decision to remove implants should be informed by "an assessment of clinical need, risk or the impact of unresolved concerns". It also restated the position concerning patients who had PIP implants provided through the private sector. In circumstances where a clinic no longer exists or refuses to support the patient, then they could have them removed by the NHS (based on an assessment of clinical need) but that this service would not include replacement.

Reviews

With the publication of the report of the Expert Review Group, it was also announced there would be two further reviews to look at different aspects of

[1] Chief Medical Officer for England. (6 January 2012) *PIP Silicone Gel Breast Implants*. Available at: http://www.nhs.uk/news/2012/01January/Documents/CMO_letter_PIPImplants_060112.pdf

the PIP case. The terms of reference for these were published[2] on 24 January 2012.

The first review, led by Lord Howe the UK Minister for Quality, aims to establish what happened in the UK when the Medicines and Healthcare products Regulatory Agency (MHRA)and the UK Department of Health learnt about the situation with PIP implants. Specifically, it is considering:

- what information about PIP implants was available from routine adverse reporting systems
- what external concerns about PIP implants were brought to the attention of the MHRA or the wider Department of Health, and when
- how these concerns and any related information were handled
- what advice was sought and from whom
- what information was shared between MHRA and its counterparts in other countries in the EU and elsewhere
- how decisions were taken, and who was involved in this process
- what action was taken to safeguard and advise patients
- whether action was sufficiently prompt and appropriate

Lord Howe is to submit a report to the UK Secretary of State for Health at the end of March 2012.

The second review is being led by Prof Sir Bruce Keogh, the Medical Director for the NHS in England, and will look at whether the cosmetic surgery industry needs to be more effectively regulated, and specifically:

- whether the regulation of the products used in cosmetic interventions is appropriate
- how best to assure patients and consumers that the people who carry out procedures have the skills to do so
- how to ensure that the organisations which deliver such procedures have the clinical governance systems to assure the care and welfare of people who use their services
- how to ensure that people considering such interventions are given the information, advice and time for reflection to make an informed choice
- whether there should be a statutory requirement for such organisations to offer redress in the event of harm, and if so how this could be funded
- what improvements are needed in systems for reporting patient outcomes, including adverse events, for central analysis and surveillance

[2] UK Department of Health (24 January 2012) *Department of Health sets out scope of PIP implant and cosmetic surgery reviews*. Available at: http://mediacentre.dh.gov.uk/2012/01/24/department-of-health-sets-out-scope-of-pip-implant-and-cosmetic-surgery-reviews/

This review will be more complex and thus the expectation is that a report will be presented to the Secretary of State by March 2013.

SCOTTISH GOVERNMENT ACTION

Following the publication of the Expert review Group the Scottish Government adopted the position taken by the UK Government. The following sections provide an update on a number of issues since that point.

PIP implants on the NHS in Scotland

Following a review by NHS Boards the Cabinet Secretary has now confirmed that there were no PIP implants used by the NHS in Scotland[3].

The offer to women who received PIP implants privately

In terms of those women who had received PIP implants from private clinics, on 9 January 2012 the First Minister reiterated the point that the NHS would step in if clinic no longer existed or was not willing to remove the implants, but also stated[4]:

> "The presumption will be that that will cover only removal of implants, but if the clinical opinion is that replacement is required and that is what the woman wants, that would also be covered by our national health service."

On 10 January, the Chief Medical Officer (CMO) for Scotland wrote to clinicians on similar lines to the CMO for England (see above). Again, this reiterates the situation for women who had PIP implants provided through a private clinic. In terms of replacement, this states this would not happen routinely. The letter makes reference to, and attaches a copy of the updated Adult Exceptional Aesthetic Referral Protocol, which should be used in such cases. This states that replacement of breast implants which were implanted at a private clinic would only take place on the NHS in exceptional circumstances (see protocol on Breast Implant Complications). Pages 1 and 2 of the protocol describe the matters that must be considered to determine whether such a procedure would be an exceptional case.

The numbers of women in Scotland who have PIP implants

As regards the numbers of women affected in Scotland, the figure of 4,000 has been consistently used by the Scottish Government, though the First Minister has stated[4] that the estimate is between 2,500 and 4,000. Given, as noted above, that there are no NHS cases this means this figure relates to

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[3] Scottish Government (9 February 2012) Letter from the Cabinet Secretary for Health, Wellbeing and Cities Strategy to the Convener of the Health and Sport Committee. Available at: http://www.scottish.parliament.uk/S4_HealthandSportCommittee/General%20Documents/20120209Cab_Sec_to_DM.pdf

[4] Scottish Parliament (12 January 2012) Official Report: col 5252-5253. Available at: http://www.scottish.parliament.uk/parliamentarybusiness/28862.aspx?r=6658&mode=html#iob_60660

private sector implantation. The Committee has received data from the Scottish Independent Hospitals Association, which shows that there were around 1,300 PIP cases recorded by its membership and by the company Transform[5]. The Scottish Government has advised that the 4,000 figure was arrived at based on MHRA data on the total number of sales of PIP implants that had been made in the UK. It does not take account of those cases where a woman may have gone abroad for treatment.

Calls for a public inquiry

There have been calls for an inquiry to be undertaken into the PIP case in Scotland. However, in answer to a recent Parliamentary Question[6], the Cabinet Secretary noted that the regulation of medical devices was reserved, but also stated that officials would be liaising with the UK Department of Health in relation to the two reviews being carried out by the UK Department of Health (see above).

EU LEVEL ACTION

Members will recall that the regulation of all medical devices is dealt with under EU regulations. At the time of the original SPICe briefing it was being reported that the European Commission had been asked by a number of Member States to review what had happened in the PIP case. On 9 February 2012, the European Health and Consumer Policy Commissioner called[7] for Member States to ensure they were fully implementing the current legislation on medical devices. He announced a joint plan of immediate actions to include the following:

- verify the designations of notified bodies to ensure that they are designated only for the assessment of medical devices and technologies that correspond to their proven expertise and competence
- ensure that all notified bodies make full use of their powers given to them under the current legislation which including the powers to conduct unannounced inspections
- reinforce market surveillance by national authorities**,** in particular spot checks in respect of certain types of devices
- improve the traceability of medical devices

In addition, the Commissioner called for improvements in the functioning of the vigilance system for medical devices. These include giving systematic

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[5] Independent Healthcare Advisory Service (6 February 2012) *PIP Silicone Breast Implants*. Available at: http://www.scottish.parliament.uk/S4_HealthandSportCommittee/General%20Documents/20120208_IHAS_to_DM.pdf

[6] Scottish Parliament (9 February 2012) Official Report: col 6286-6287. Available at: http://www.scottish.parliament.uk/parliamentarybusiness/28862.aspx?r=6823&mode=pdf

[7] Europa (9 February 2012) *Medical devices: European Commission calls for immediate actions - tighten controls, increase surveillance, restore confidence*. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/119&format=HTML&aged=0&language=EN&guiLanguage=en

access for notified bodies to reports of adverse events, and encouraging healthcare professionals and empowering patients to report adverse events.

This announcement also disclosed what other actions the European Commission was undertaking. Firstly, the Commission's Scientific Committee on Emerging and Newly Identified Health Risks[8] was asked to carry out a more in-depth investigation on the potential health impact of faulty PIP silicone breast implants, based on data from investigations by Member States. Secondly, is the continuation of the revision of the Medical Devices legislation**,** which will take account of the results of a 'stress test' that is identifying the shortcomings that have come to light as a result of the PIP case.

PRIVATE SECTOR ACTIONS

The Committee has received a letter[9] from the Independent Healthcare Advisory service on behalf of the Scottish Independent Hospitals Association. As noted above, this details the numbers of women who have received PIP implants from its members. However, it also provides a summary of the actions that each of its member organisations have agreed to take in relation to the removal and replacement of PIP implants.

There are three providers who are SIHA members – BMI Healthcare, Nuffield Health and Spire Healthcare – all of which have agreed to remove and replace PIP implants free of charge.

However, the letter also notes that BMI Healthcare will not remove and replace PIP implants in cases where:

- the patients had PIP implants inserted in a BMI hospital but paid a third party
- patients had surgery in another provider's hospital

In such circumstances BMI will remove and replace the implants at a discounted price to be paid by the patient or the third party.

Jude Payne
SPICe Research
15 February 2012

Note: Committee briefing papers are provided by SPICe for the use of Scottish Parliament committees and clerking staff. They provide focused information or respond to specific questions or areas of interest to committees and are not intended to offer comprehensive coverage of a subject area.

[8] *Scientific Committee on Emerging and Newly Identified Health Risks* [Online]. Available at: http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm

[9] Independent Healthcare Advisory Service (6 February 2012) *PIP Silicone Breast Implants*. Available at: http://www.scottish.parliament.uk/S4_HealthandSportCommittee/General%20Documents/20120208_IHAS_to_DM.pdf

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Professor Jonathan Chick

Thank you for asking my view.

In my view 'affordability' is the chief factor. However, calculating fluctuations in affordability of alcoholic beverages would require dedicated work, and there are sometime differing views on how to calculate this.

The mechanism needs to be simple, and one that can take effect without, each time, some dispute.

Therefore I favour the argument that Tim Stockwell sent you - that the minimum price should be follow some already used and accepted general price index/cost of living index.

Once enacted, it is fairer to the industry, in that their commercial forecasts can be based on a slightly more certain basis, and one they may already use (though this is outside my expertise).

Yours sincerely

Jonathan Chick

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Dr Jan Gill

I feel that my area of expertise precludes me from commenting authoritatively on this topic.

A personal opinion would be that regular appraisal of the price which permitted e.g. annual re-adjustment might gain acceptance and therefore be 'low key' in terms of media coverage. It could thereby possibly deter stock piling/panic buying and also permit a more realistic appraisal of the impact of Minimum Unit pricing on the various measures of alcohol –related harm.

How the various influential factors which inform price at present, will react and adjust post the introduction of MUP are perhaps poorly modelled at present . A relatively speedy review of the MUP may be required.

Jan Gill

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Law Society of Scotland

I refer to the above, to your e.mail dated 7 February 2012 and am now in receipt of the following comments from both the Law Society of Scotland's Licensing Law and Competition Law Sub-Committees for your information.

The Society agrees that index-linking the minimum unit price is not appropriate for the reasons set out in the paper under "disadvantages".

The Society believes that information on minimum unit pricing should be collected regularly in order that the ability of the legislation to deliver that which it was conceived to deliver can be measured against actual rather than model data.

The Society anticipates that this type of exercise would be one of the European Commission's key conditions and, even if this is not the case, the Scottish Government should in any event consider this as a necessary undertaking.

The resetting of minimum unit price could therefore be part of a process of regular review of the efficacy of the legislation. The Society appreciates that initially, modelling would be used but as actual data emerges, this data would come to be used in place of modelling.

The decisions about what data to collect and about when and how to use modelling and introduce actual data, as well as the content and frequency of reviews should in themselves be evidence based.

The Society believes that the point about cost is a valid one and that some sort of cost benefit analysis requires to be undertaken.

The Society takes the view that if the Scottish Government does not collect such data and use same in order to conduct a review process, then such an exercise may be conducted by other interested parties and statistics gained there from may be advanced in order to argue that the legislation was simply an experiment that had not delivered the results expected and as a consequence of this, the balance of the proportionality argument on which the EU legality of the measure has been set against, had demonstrated that this was in fact a disproportionate measure.

In all the circumstances, any proposed mechanism for fixing minimum unit pricing requires to be fair, understandable and proportionate.

Also, from a practical point of view, the Society notes that it would be difficult for premises licence holders to keep abreast of quarterly reviews as prices are set in advance. Accordingly, any minimum unit pricing mechanism employed would require to have a realistic run-in time.

I trust that these comments on your paper on minimum unit pricing mechanisms are of assistance to you.

Should you, however, wish to discuss further, please do not hesitate to contact me.

Kind regards

Alan McCreadie

Deputy Director of Law Reform

Law Society of Scotland

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Andrew Leicester

Thank you for this email and the opportunity to respond on uprating mechanisms.

Once a minimum price is implemented, the issue of how it is uprated is clearly important. Even assuming inflation at 2.5% per year, a minimum price introduced at 45p in 2012 would, in real terms, be worth 35p per unit just a decade later, by 2022.

In the early phase of introduction, it may be that the minimum price is adjusted within the first year or two based on evidence from further modelling and ex post evidence on the impact of the policy. Once a settled 'appropriate' minimum price is established, it would seem less important to rely on regular re-modelling exercises in determining the new price each year. It may be that periodic assessment is made on the appropriateness of the current minimum price based on new data and new modelling of the impact but this need not be an annual occurrence.

Unless there is clear evidence that the rate is substantially 'wrong' it would not seem necessary to adjust the minimum price more than once per year. This is typically the approach taken towards tax thresholds, benefit levels, excise taxes and so on. It is not obvious what the advantage of quarterly adjustments would be.

The question is then against what benchmark the uprating should take place. There appear to be four main options:

1. Inflation as measured by the Retail Prices Index (RPI)

2. Inflation as measured by the Consumer Prices Index (CPI)

3. Some measure of inflation specific to alcohol prices

4. Some measure of income, earnings or other factors which might determine 'affordability'

Since region-specific inflation measures are not routinely published by the Office for National Statistics, any choice from options 1-3 would have to depend on UK-wide inflation estimates rather than Scottish-specific inflation rates. It may be possible to obtain estimates of the Scottish inflation rate or alcohol price inflation rate from ONS but it is not obvious that there is any reason to expect inflation trends in Scotland over the medium run to differ substantially from the rest of the UK.

At present, UK excise duties are uprated annually, typically at the Budget, based on a forward-looking measure of the RPI. In particular, the 'default' position is that the excise duty is uprated in line with the year-on-year RPI rate as expected in the third quarter of the year following the Budget. The Chancellor has discretion to set duty rates at any level, however, and it is my understanding that this default is not statutory in that if the Chancellor made no announcement on duty rates then they would not change in cash terms. In other words, the 'default' has to be confirmed as an active policy decision.

For excise duties on motor fuel in particular there has been a recent trend towards pre-announcing future changes several years in advance, with these announcements later changed. This is not a helpful way of making policy leading to considerable uncertainty. A more sensible approach would be to pre-commit to a mechanism by which the price is uprated each year according to some measure of inflation, and perhaps spelling out that the rate is subject to periodic review every few years (perhaps every 5 years) at which point there may be a more substantial revision. This would generate relative medium-run certainty about future pricing whilst leaving open a way in which the price could be updated to take account of wider social trends. Of course, flexibility is desirable, so leaving open the option of changing the price outside of this mechanism is important but the option should be exercised only in extreme circumstances (where, for example, there is strong evidence that the price is no longer appropriate).

There does not appear to be a strong case for uprating the minimum price according to alcohol-specific inflation measures. In the short-term, alcohol inflation rates will be strongly influenced by the introduction of a minimum price or wider alcohol policy such as duty rates. If alcohol prices are rising more rapidly than general inflation, then a minimum price uprated according to general inflation will have steadily less 'bite' but presumably the higher alcohol price would be the desired outcome in any case. Again, having a periodic review of the price leaves open the possibility of using evidence about differential price rises for cheaper and more expensive alcohol in determining an appropriate minimum price level.

The question of whether to use the RPI or CPI is not clear cut. There is a growing trend towards basing uprating decisions on the CPI but for the moment the RPI remains the inflation measure used for alcohol and other excise taxes. The RPI includes housing costs and is arguably a 'better' measure of inflation as experienced by households, though the method by which the CPI is calculated may make it a better reflection of how higher prices affect the cost of living since it allows (in a particular way) for the possibility that households substitute when relative prices change. A simple discussion is at http://www.ifs.org.uk/publications/5301 (and links therein).

It is also not really clear why excise duties are uprated according to forecasts of the RPI in the future whereas benefit uprating depends on outturn inflation from the previous September. Over the long run it probably makes little difference, but it may be more credible to base the uprating on observed outturn inflation measures rather than forecasts.

I hope this is helpful. I should stress these are personal thoughts and not those of the IFS.

Thanks

Andrew Leicester

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Professor Anne Ludbrook

Thank you for the opportunity to comment on this issue. The principle of maintaining the real value of the minimum price is an important one and the erosion that has taken place over time in duty rates points to the need to have a mechanism in place.

I am not sure that defining an automatic uprating mechanism is quite the way to go, however. There are some practical issues, such as the data available for a Scottish affordability index as indicated in recent Health Scotland work, and it may be that these can be improved upon over time. There is also the experience with the 'automatic' fuel duty escalator which has failed to remove the political aspect from the uprating process.

Perhaps the model which could be followed, albeit in a less resource intensive way, would be the uprating of the minimum wage. The recommendations are made by the Low Pay Commission - a mix of academic economists, union representatives and business representatives - based on evidence on a range of relevant factors. This means that concerns about jobs, for example, can be balanced with maintaining the real value of the minimum wage. These recommendations require to be approved - I think by the relevant Secretary of State - but I don't think they have to go to vote in Parliament. The researchers supporting the LPC can also undertake analysis of particular market issues as required.

Uprating MUP is not going to have such widespread impact on the economy as the minimum wage and a lighter touch may be appropriate. I would anticipate that much of the underpinning data can be provided through existing organisations, such as Health Scotland and ISD, with perhaps some more in depth analysis carried out as and when needed. The data would be assessed by an independent panel to make the recommendation on uprating. If such an independent panel were established then perhaps their first remit might be to determine the optimum interval for uprating. I don't think this is quite the same as uprating duty - which applies to all alcohol - and personally would not want to make a decision on this until after the implementation of MUP when data will be available on how other prices have changed in response. It is still unclear whether producers and retailers will maintain differentials or cross subsidise prices above MUP and these reactions could lead to quite different conclusions about uprating.

Hope this is helpful

Regards

Professor Anne Ludbrook

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

National Association of Cider Makers

I have no comments to offer on this.

Kind regards

Bob Price

Policy Adviser

National Association of Cider Makers

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Dr Peter Rice

Thank you for asking for my views on this crucial issue.

My preference is for an index linked type of approach, with a frequent adjustment linked to affordability. A formula which came up with an automatic adjustment figure while allowing for a secondary correction based on the examination of other data. The automatic adjustment could happen twice a year, with the correction annually, for instance.

- The key relationships are between affordability and consumption and harm. Affordability is the result of price and income changes. Much of the increase in alcohol affordability in the 80s and 90s was due to rising incomes, rather than falling alcohol price. A formula based on price alone would not have been sufficient over that period. There is some academic debate at present on how best to measure affordability, but this should be able to be resolved.
- For the "correction" process, there needs to be a examination of real time trends in consumption and sales patterns. Health Scotland's Price Band report from 2010 (link below) was a good piece of work and this data would be very important to be regularly updated and this, together with data from retailers (see below) could form the basis for an annual "tweak". This correction process could include a full blown Sheffield type analysis at a less frequent interval.

  http://www.scotpho.org.uk/downloads/scotphoreports/scotpho100721_alcoholofftrade2009_rep.pdf
- Alcohol producers and retailers are an important source of data. For instance, the fascinating data on low alcohol sales given by Emma Reynolds of Tesco at the 17th Jan committee session had not been available before. Similarly, the data from ASDA on patterns in their Northern Ireland outlet was of interest. There needs to be a mechanism to access this information in the interests of public health. The New Zealand government has announced its intention to establish this.

  http://www.parliament.nz/enNZ/PB/Debates/Debates/f/7/4/49HansD_20110913_00000627-Alcohol-Reform-Bill-Second-Reading.htm
- I would suggest that the model that should not be followed is the Westminster one. While we have seen significant duty increases since 2008, which the RCPsych has welcomed, prior to that duty changes were limited and seemed to become a central part of the politics of the Budget process, to the detriment of public health. The IFS report (Fig 2.7 on p13) shows how excise duty rates fell in real terms from 1982.

Thanks again for the request.

Peter Rice

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Scotch Whisky Association

We thank the Committee for allowing us the opportunity to submit comments on this paper. While we welcome the invitation to comment on the questions posed, our submission does not imply that we accept the principle or legality of minimum pricing.

The Scotch Whisky Association remains opposed to minimum pricing. It is untested, has not been introduced anywhere else and therefore claims as to its effectiveness are without substance. It is essential that if introduced, the minimum unit price that is set should be given sufficient time to demonstrate its impact, if any, including any unintended consequences. Its effectiveness, or lack thereof, would require to be measured against transparent and objectively evidenced criteria.

The relationship between producers and the off-trade retail sector over the sale and pricing of alcohol is highly complex. Contract terms vary hugely and are affected by the rates of excise duty and VAT; they also depend on a wide variety of issues including discounts for volume, meeting sales targets, listing charges and shelf positioning. Contracts can be long or short term. Regular changes in the minimum unit price would distort the contractual relationship between the producer, with the retailer wishing to pass the additional and unforeseen costs on to the producer/wholesaler.

Should minimum pricing be introduced, details on how the legislation will be implemented, inspected and enforced and the process by which Ministers effect any change should therefore be well understood and allow the licensed trade /industry a reasonable period of notice to implement any changes.

On this basis, and for the deficiencies highlighted in the paper circulated, inflation based changes are NOT appropriate. It should be remembered that any minimum price, including any changes, would need to overcome the legal barrier that a minimum pricing regime must be a proportionate measure. To date, no government has done so.

Proportionality may alter over time following changes in consumption, harm, the level of the minimum price, external issues such as tax, unintended consequences and the impact on different products depending upon the price set. An automatic mechanism for changing any minimum unit price cannot take account of these elements, each must be properly assessed before any change might be contemplated. Thus, only a full review can be considered as a review mechanism.

The frequency assumes that minimum pricing overcomes initial and ongoing existing legal obstacles.

We would also note the paper only set out two options, there may be more. We would hope the Scottish Government would hold a full consultation prior to coming to any decision on determining the mechanism for amending the MUP.

Scotch Whisky Association

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Scottish Beer and Pub Association

Thank you for giving my Association the opportunity to further comment on the Committee's deliberations around the Alcohol (Minimum Pricing) (Scotland) Bill in relation to the "Mechanisms for Changing the Minimum Price" Paper.

I would make the following comments in respect of the Paper.

Firstly, the Association still supports the position as outlined in our initial response to the Committee, namely:

"Process

In the event that the Scottish Government is successful in passing the Alcohol (Minimum Pricing) Bill, the Association would suggest that the processes for reviewing and adjusting any minimum pricing level need to be made more transparent and explicit. We believe that the Scottish Government has said that any proposal to adjust the minimum pricing level would be subject to an affirmative vote by the Scottish Parliament.

"SBPA would suggest that this needs to go further in that the Parliament, in advance of any vote on these matters, should have to take evidence on these matters and produce a report commenting on any Scottish Government proposals to adjust minimum pricing levels. This exercise should perhaps be advised by an independent advisory group with a wide membership reflecting the lack of industry involvement.

"Again we would suggest this detail needs to be included on the face of the Bill itself and not left to Regulations which are subject to much lower levels of parliamentary scrutiny than the legislation itself." [SBPA Submission to the Scottish Parliament Health and Sport Committee's Inquiry Into the Alcohol (Minimum Pricing) (Scotland) Bill]

Secondly, given these comments we would not support there being some form of automatic uprating in the minimum unit price for alcohol linked to either CPI or indeed RPI.

Thirdly, as stated in our previous response, and in the Committee's Paper, we would agree that regular uprating on an Index-Linked basis *"may lead to instability in the contracts negotiated between retailers and manufacturers and lead to logistical problems for retailers in terms of things like price labelling."*

Fourthly, in terms of the two options set out in the paper, we would be more inclined to support the second option, specifically that any change to the minimum unit price is linked to a biennial methodological study to evaluate effectiveness of the policy. This impact assessment should be wider than just whether minimum pricing and should also consider the impact on moderate consumers, lower demographics, black market and different types of businesses. We believe it will take a minimum of two years for consumer behaviour to settle down; trying to analyse changes earlier than this will not produce meaningful analysis. This method of evaluation will also allow a greater understand any compensating behaviour by consumers which is currently not foreseen. Any research will need to be based on pre-defined

parameters as to what will constitute success for the policy in order for it to be meaningfully evaluated.

However, we would suggest that the use of this mechanism should not have an automatic effect, i.e. that any analysis generated by this methodology should still be subject to detailed inquiry by the relevant Scottish Parliament Committees and to a formal decision by the Scottish Parliament. This would allow an additional safeguard to be put in place prior to any adjustment in the minimum unit price being allowed to take place.

This is in line with the comments made in our original response as above.

I trust that our comments are of use and we will be willing to supply any further information or comment to the Committee should that be required.

Yours sincerely

Patrick Browne

Chief Executive

Scottish Beer and Pub Association

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Scottish Youth Parliament

The Scottish Youth Parliament does not have a position on which of the pricing mechanisms would be preferable. If you have any other queries or would like further information please do not hesitate to contact us.

Kind regards

Rob Gowans

Policy and Research Officer

Scottish Youth Parliament

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Professor Tim Stockwell

Thank you for asking for further input into this important matter. In the great scale of things the most important issue is introducing the minimum price policy in the first place. As years go by it will also be important to ensure there is no major slippage in these minimum prices. Canada used to automatically adjust alcohol excise taxes every year until the late 1980s and then it was agreed to only adjust it through periodic legislation - the result is two updates in 25 years and then only to compensate for reductions in GST i.e. no real increase in tax overall. Australia adjusts its beer and spirits excise taxes quarterly with the CPI along with tobacco and petrol and no one complains. In BC minimum prices are only occasionally adjusted for most products and slightly more regularly for spirits - when they do so it makes front-page news along the lines "another government tax grab on our alcohol". It is well-known that some US states have not adjusted their beer excise taxes for over 50 years, some even retaining the derisory rates of "a penny a gallon". The more complex the calculation and process the more uncertainty and the greater the ease with which another government of a different persuasion could simply halt indexation. Furthermore, the more elaborate the calculation the more uncertainty for those involved in the industry. CPI adjustments would not allow for every swing in alcohol consumption or household income but they are well understood and reasonably predictable. I strongly recommend that the bill stipulates quarterly CPI adjustments to the minimum price. This would be a very small piece of uncertainty for producers and retailers to factor in the their financial planning.

Finally, however excellent the Sheffield Model is and however useful it has been to developing the policy I think it would be a mistake to make it the mechanism for indexing the minimum price. It would be an unnecessarily cumbersome approach and allow too many variables to potentially influence the outcome.

On affordability indexes, I think this would introduce more variability in prices over time and that the CPI anyway captures some of the boom and bust cycle of the economy. As long as there is indexation I think the main worry is to make sure the mechanism is a simple and resilient to change as possible.

With best wishes

Tim Stockwell

Alcohol (Minimum Pricing) (Scotland) Bill

Pricing mechanism

Wine and Spirit Trade Association

We welcome the opportunity to comment on the proposals discussed during the oral evidence to the Health & Sport Committee on the Alcohol (Minimum Pricing) (Scotland) Bill about the mechanisms that could be used to change the minimum unit price should the Bill be passed.

Our response to this paper should not be viewed as implicit support for minimum unit pricing. We continue to remain opposed to the policy on the grounds that there is no evidence to support its effectiveness and that it will prove to be illegal under EU law.

Implementation

As with all legislation we would urge the Scottish Government to allow a suitable time period between implementation and review, to ensure that the impact on consumer behaviour can be properly assessed. Allowing a period of at least 2 years from implementation will ensure that a meaningful analysis of the changes can be made and will also allow for a better understanding of any compensating behaviour by consumers.

Parameters for evaluation

Clear parameters of success must be set out before any decision can be reached on the review mechanism for the minimum unit price. It will be important that the evaluation considers better the impact of the policy on consumption and its impact on levels of alcohol harm. It is difficult to assess the effectiveness of a policy if the criteria against which its success will be measured are not clearly set out. For instance, will success be measured against the outcomes predicted to be achieved by the most recent version of the Sheffield Modelling or will new targets be set against which the relative success of minimum unit pricing will be measured?

The evaluation should also consider the policy's impact on moderate consumers, low income groups, illicit trade and cross-border trade and on different types of business (retailers, producers, online etc). In order to demonstrate proportionality under EU law the policy will have to take into account its impact on a range of factors.

The UK government has announced that it will be reviewing the methods used to measure alcohol related hospital admissions. The Scottish Government should ensure that any evaluation acknowledges the impact that the changes to the methodology could have on the perceived impact of the policy. For instance, if a change to the methodology at UK level leads to a reduction in the number of hospital admissions captured by the data the evaluation should recognise this as a methodological change and not a reduction as a result of the policy.

Index-linked mechanism

We do not support an index-linked mechanism for reviewing the price. As outlined above any review should take into account a wide range of factors and an index-linked mechanism would not consider the impact the policy is

having on reducing levels of alcohol harm. Index-linking the price mechanism would cause significant problems with contracts negotiated between retailers and manufacturers and would make budgeting, planning and pricing exceptionally difficult for retailers who could have thousands of products to deal with.

Re-run the Sheffield modelling

Of the two options outlined in the paper we would favour a review at 2 year intervals based upon a methodological study to evaluate the effectiveness of the policy. This would provide a greater degree of stability for businesses operating in Scotland and could take into account a wider range of factors as outlined above.

The review mechanism for minimum unit pricing requires considerable attention and detailed consideration. We would therefore urge the Scottish Government to hold a full consultation prior to reaching any decision to ensure that views from all interested parties are taken into account.

Wine and Spirit Trade Association