Healthcare Improvement Scotland

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# Familial Breast Cancer Report

June 2014

Evidence

NHS SCOTLAND

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**Implementation of the National Institute for health and Care Excellence (NICE) clinical guideline 164 on 'familial breast cancer' in Scotland**

**Report of the short-life working group**

## Background

The updated National Institute for health and Care Excellence (NICE) guideline 164 on familial breast cancer[1] was published in June 2013 offering several evidence-based recommendations including those regarding genetic testing, surveillance and treatment strategies. Although NICE guidelines have no formal status in Scotland, they are considered by NHSScotland in the absence of Scottish guidance from the Scottish Intercollegiate Guidelines Network (SIGN).

To ensure that breast cancer services for women in Scotland are comparable with those offered elsewhere in the United Kingdom (UK), the Cabinet Secretary for Health and Wellbeing announced on 25 June 2013 that:

> "women who have two or more family members with breast cancer will be offered Tamoxifen for 5 years, where clinically appropriate. Genetic testing will also be offered to women who have a 10% chance of having a faulty gene."

A short-life working group (SLWG), under the Chairmanship of Dr Hilary Dobson, Clinical Lead West of Scotland Cancer Network, was formed to address the applicability of the recommendations from the NICE guideline for the Scottish population and identify and consider any implementation challenges posed. Membership of the group is detailed in Appendix 1 and includes representation from the three Scottish cancer networks and lay representation. The group was supported by Healthcare Improvement Scotland.

The role of the SLWG was to:

- agree which recommendations should be prioritised for implementation in NHSScotland
- identify barriers for implementation of those recommendations and the resources or processes required to overcome the barriers
- produce a draft report for consultation.

The SLWG met on three occasions. Health economists and pharmacy staff from Healthcare Improvement Scotland worked with group members to identify the resource and cost impact of implementing the prioritised recommendations.

## Prioritisation of recommendations

The first task of the SLWG was to identify the recommendations which should be prioritised for implementation. The relevant professional groups and networks will consider the need for implementation of the remaining recommendations over the coming months.

The group reviewed all the recommendations within the NICE guideline and there was strong support within the group to concentrate largely on the recommendations identified within the document as 'key priorities for implementation'. The group prioritised other recommendations that were considered to be important to ensure equity with service provision in other areas of the UK. In some cases, the group agreed minor amendments to

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Familial breast cancer. Classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer. **NICE clinical guideline 164,** June 2013

the wording of the NICE recommendations to reflect the needs of the Scottish population. These are highlighted in bold in the following sections.

## 1. Genetic testing

The group agreed that the following recommendations for some people in families at high risk of breast cancer should be prioritised for implementation:

*Genetic testing for a person with no personal history of breast cancer but with an available affected relative*

1.5.11 and 1.5.13 Offer genetic testing in specialist genetic clinics to a relative with a personal history of breast and/or ovarian cancer **or** a person with breast or ovarian cancer if their combined BRCA1 and BRCA2 mutation carrier probability is 10% or more.

*Genetic testing for a person with no personal history of breast cancer and no available affected relative to test*

1.5.12 Offer genetic testing in specialist genetic clinics to a person with no personal history of breast or ovarian cancer if their combined BRCA1 and BRCA2 mutation carrier probability is 10% or more and an affected relative is unavailable for testing (**that is, the likelihood of a mutation in the family is 20% or more)**.

Definitions of the risk categories are provided in Table 1.

**Table 1: Risk stratification for breast cancer**

| Low risk | Moderate risk | High risk | Very high risk/BRCA gene carrier | Very high risk/TP53 gene carrier |
|---|---|---|---|---|
| • Equates to 17% or less lifetime risk | • Equates to a lifetime risk of breast cancer of greater than 17% but less than 30%,<br>• or a 10-year risk between 40 and 50 years of age which is greater than 3% but less than 8% | • Equates to a lifetime risk of developing breast cancer of 30% or more,<br>• or greater than 8% 10-year risk between 40 and 50 years of age | • Equates to a woman in her thirties whose 10-year risk is greater than 8% as assessed at age 30,<br>• or in her forties and whose 10-year risk is greater than 20% as assessed at age 40,<br>• or 12% where there is a dense mammographic pattern | |
| • Anyone not fulfilling moderate, high or very high risk criteria | • One first-degree* relative with breast cancer diagnosed under the age of 40, or one first-degree relative with male breast cancer diagnosed at any age,<br>• or two first- or one first- and one second-degree relative with breast cancer diagnosed under 60, or ovarian cancer at any age, on the same side of the family,<br>• or three first- or second-degree relatives with breast or ovarian cancer on the same side of the family where one is a first-degree relative of the individual under review or of their father<br><br>*A case of bilateral breast cancer should be treated as the equivalent of 2 affected relatives.* | • Families where one individual has had both breast and ovarian cancer,<br>• or families where there is an estimated 20% likelihood of a BRCA1, BRCA2 or TP53 mutation<br><br>*The individual being assessed should be a first-degree relative of an affected family member or a second-degree relative through an unaffected male.*<br><br>*Affected individuals should be first-degree relatives of each other or related through unaffected males.* | • Carrier of a mutation in BRCA1or BRCA2,<br>• or woman at 30% or greater risk of carrying a mutation in BRCA1 or BRCA2 | • Carrier of a mutation in TP53,<br>• or woman at 30% or greater risk of carrying a mutation in TP53 |

*A first-degree female relative is mother, father, daughter, son, sister or brother. A second-degree female relative is grandmother, grandfather, granddaughter, grandson, aunt, uncle, niece, nephew, half-sister or half-brother.

## 2. Imaging surveillance

The group agreed that the following recommendations should be prioritised for implementation. The group are aware of work being undertaken by the British Society of Breast Radiology to look at imaging recommendations, which may change these in future.

### *Mammographic surveillance*

The group support the current recommended practice in Scotland to:

- offer annual mammographic surveillance to women at moderate- or high-risk of breast cancer (but with a 30% or lower probability of being a BRCA or TP53 carrier), starting from 5 years younger than the youngest affected relative, but not younger than 35 years
- offer annual mammographic surveillance to women aged 30–39 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier, or who have a known BRCA1 or BRCA2 mutation.

With respect to surveillance frequency from age 50 in high-risk cases, the current Scottish recommendation is 18-monthly mammography from 50–70 years of age. Although the NICE recommendation is not evidence based, the group felt that that more frequent screening has potential to detect more tumours early, and thus this recommendation has been included.

1.6.3 Offer annual mammographic surveillance to women:

- aged 40–49 years at moderate risk of breast cancer
- aged 40–59 years at high risk of breast cancer but with a 30% or lower probability of being a BRCA or TP53 carrier
- aged 40–59 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier
- aged 40–69 years with a known BRCA1 or BRCA2 mutation.

1.6.4 Offer mammographic surveillance as part of the population screening programme to women:

- aged 50 years and over who have not had genetic testing but have a greater than 30% probability of being a TP53 carrier
- aged 60 years and over at high risk of breast cancer but with a 30% or lower probability of being a BRCA or TP53 carrier
- **aged 50 years and over at moderate risk of breast cancer**
- aged 60 years and over who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier
- aged 70 years and over with a known BRCA1 or BRCA2 mutation.

1.6.6 Do not offer mammographic surveillance to women:

- aged 29 years and under
- aged 30–49 years who have not had genetic testing but have a greater than 30% probability of being a TP53 carrier
- of any age with a known TP53 mutation.

***Magnetic resonance imaging (MRI) surveillance***

The group agreed that the following recommendations should be prioritised for implementation:

1.6.7 Offer annual MRI surveillance to women:

- aged 30–49 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier
- aged 30–49 years with a known BRCA1 or BRCA2 mutation
- aged 20–49 years who have not had genetic testing but have a greater than 30% probability of being a TP53 carrier
- aged 20–49 years with a known TP53 mutation
- **aged 50–69 years who have not had genetic testing but have a greater than 30% probability of being a BRCA *or a* TP53 carrier, and where mammography has shown a dense breast pattern**
- **aged 50–69 years with a known BRCA1 or BRCA2 mutation, and where mammography has shown a dense breast pattern**
- **under 30 years, only in rare very high risk situations, for example TP53 gene carrier.**

1.6.8 Consider annual MRI surveillance for women aged 50–69 years with a known TP53 mutation.

***Surveillance for women with a personal and family history of breast cancer***

The group recommend that **all women with breast cancer and a family history should receive surveillance according to local protocols, which provide imaging frequency equivalent to that received by those with the same family history but without a personal history of breast cancer**.

***Recommendations for all women having surveillance***

1.6.22 For women under 50 years who are having mammography, use digital mammography at centres providing digital mammography to national breast screening programme standards.

1.6.23 Ensure that individual strategies are developed for all women having mammographic surveillance and that surveillance is:

- to national breast screening programme standards

- audited

- only undertaken after written information is given about risks and benefits.

1.6.24 Ensure that MRI surveillance includes MRI of both breasts performed to national breast screening programme standards.

## 3. Chemoprevention

The group agreed that the following recommendations should be prioritised for implementation:

**1.7.21 Offer tamoxifen for 5 years to premenopausal women at high risk or greater of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer.**

**1.7.22 Offer tamoxifen for 5 years to postmenopausal women without a uterus and at high risk or greater of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or they have a past history of endometrial cancer.**

**1.7.23 Offer tamoxifen for 5 years to postmenopausal women with a uterus and at high risk or greater of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer.**

## 4. Updated Scottish familial breast cancer surveillance guidance

Table 2 presents draft familial breast cancer guidance updated to reflect the recommendations prioritised in this document.

**Table 2: Scottish surveillance guidelines**

| Low risk | Moderate risk | High risk but less than 30% probability of BRCA1/2 | Gene carrier or very high risk (>30% probability of BRCA1/2) | TP53 gene carrier/>30% probability of TP53 |
|---|---|---|---|---|
| | Surveillance should be offered from the age of 40 years, or 5 years younger than the earliest age of onset of cancer in the family. | Surveillance should start at age 35 years, or 5 years younger than the youngest age of onset in the family. | Surveillance should start from age 30 years, or individualised according to the family. | Surveillance should start from age 20 years, or individualised according to the family. |
| Reassurance.<br>Provision of Information.<br>National Breast Cancer Screening Programme from age 50 years. | Mammography should be 2-yearly below age 40 years, and annually age 40–50 years.<br>Mammography should not usually be commenced before age 35 years, and all women in this group should be offered mammography by the age of 40 years.<br>National Breast Cancer Screening Programme from age 50 years. | Mammography should be 2-yearly below age 40 years, annually age 40–59 years, and subsequently 18 monthly from 60–70 years.<br>Mammography should usually start at age 35 years, and should not be offered under the age of 30 years.<br>Genetic testing should be offered in these families, if a sample is available from an affected relative. If no sample is available, testing an unaffected woman could be considered after careful discussion of the limitations.<br>Where mutation testing cannot be offered, the possibility that the woman may be at sufficiently high risk to be offered MRI (see next column and Table 1) should be considered. | Mammography should be annually from age 30–59 years and 18-monthly from 60–70 years in untested women at very high risk, and annually from 30–69 years in known gene carriers.<br>Breast MRI should be offered in addition to mammography, and should be annually from age 30–49 years, or to 59 years if there is a dense breast pattern on mammography.<br>Breast MRI should only be offered under age 30 years in rare or very high-risk situations.<br>Genetic testing should be offered in these families, if a sample is available from an affected relative. If no sample is available, testing an unaffected woman could be considered after careful discussion of the limitations. | **Do not** offer mammography to women with a known TP53 mutation at any age, or to women with a greater than 30% probability of being a TP53 carrier under age 50 years.<br>Annual breast MRI should be offered from age 20–49 years for women with a greater than 30% probability of being a TP53 gene carrier, and from age 20–69 years for women with a known TP53 mutation. |
| The surveillance programme should be audited as part of the national cancer genetics audit and where possible patients should be recruited into national studies to investigate the efficacy of such surveillance. | | | | |

**Implications for NHSScotland**

The SLWG reviewed the prioritised recommendations to estimate the potential resource requirements for implementation across NHSScotland and the associated cost impact. This included consideration of current practice and the likely numbers of additional genetic screens, imaging, clinic assessments and prescriptions resulting from implementation of the recommendations. Resource requirements and cost impact were only estimated for recommendations where there is a change to current practice.

The recommendations for chemoprevention are supported by a shared-care framework to help ensure consistency and equity of access across NHSScotland and facilitate the approval by Area Drugs and Therapeutics Committees. A shared-care framework is included in Appendix 2. Information detailing advice for patients (Appendix 3) and a template letter for communication between specialist and primary care (Appendix 4) are also included.

Table 3 shows the resource and cost implications of implementing the recommendations. The group recognised that the imaging recommendations will pose significant problems for capacity across NHSScotland. Full details of the cost analysis, including the assumptions made, are provided in Appendix 5.

**Table 3: Annual resource and cost implications of implementing recommendations**

| Recommendations | Description | Resource implications | Estimated additional cost to NHSScotland associated with implementation |
|---|---|---|---|
| 1.5.12 | Genetic testing | • Laboratory tests<br>• Counselling sessions<br>• Supporting infrastructure | £2,974,450 |
| 1.6.3 /7/9/13 | Imaging surveillance | • Increased numbers of mammograms and MRI scans | £871,507 |
| 1.7.21/22/23 | Chemoprevention | • Breast clinics<br>• Prescribing costs<br>• general practitioner (GP) visits | £165,184 (year 1)–<br>£115,188 (steady state) |

**Comment**

It is clear that full implementation of these recommendations may pose some issues for NHSScotland. The group feel that implementation of these recommendations will provide individuals and families in Scotland at risk of breast cancer with service provision comparable with that offered elsewhere in the UK.

In addition to the work of the group, specialty groups will consider, over the coming months, the applicability to NHSScotland of the wider recommendations made in the NICE guideline.

## Appendix 1: Short-life working group membership

| | | |
|---|---|---|
| Hilary Dobson (Chair) | Clinical Director | West of Scotland Cancer Network |
| Ailsa Brown | Lead Health Economist | Scottish Medicines Consortium – Healthcare Improvement Scotland |
| Alison Lanigan | General Surgery Consultant | West of Scotland Cancer Network |
| David Cline | Clinical Priorities Team | Scottish Government |
| Elaine Anderson | Clinical Director | South East Scotland Cancer Network |
| Glyn Neades | Chair of SCAN Breast Group | South East Scotland Cancer Network |
| Helen Gregory | General Practitioner/Associate Specialist in Clinical Genetics | North of Scotland Cancer Network |
| Helen Stevens | Policy Manager – Clinical Priorities Team | Scottish Government |
| Hilda Emengo | Health Services Researcher | Healthcare Improvement Scotland |
| Jackie Dunlop | Macmillan Genetic Counsellor | NHS Tayside |
| Janet Clarke | Consultant Radiographer | South East Scotland Cancer Network |
| Janet Litherland | Consultant Radiologist | West of Scotland Cancer Network |
| Jonathan Berg | Senior Lecturer and Honorary Consultant in Clinical Genetics | North of Scotland Cancer Network NHS Tayside |
| Joy Nicholson | Pharmacist | Healthcare Improvement Scotland |
| Kirsty Macfarlane | Principal Pharmacist | Scottish Medicines Consortium – Healthcare Improvement Scotland |
| Lisa Wilson | Health Economist | Healthcare Improvement Scotland |
| Lucy Hill | Consultant Radiologist | South East Scotland Cancer Network |
| Mary Maclean | Regional Cancer Care Pharmacist | West of Scotland Cancer Network |
| Nick Abbott | Consultant Breast and Oncoplastic Surgeon | North of Scotland Cancer Network |
| Rosemarie Davidson | Consultant in Clinical Genetics | NHS Greater Glasgow and Clyde |
| Sara Twaddle | Director of Evidence (Interim) | Healthcare Improvement Scotland |
| Sarah Vinnicombe | Clinical Senior Lecturer In Cancer Imaging | North of Scotland Cancer Network |
| Sheila Stallard (deputy for Alison Lanigan) | Chair of West of Scotland MCN Family history group | West of Scotland Cancer Network |
| Sinead Power | Team Leader – Clinical Priorities Team | Scottish Government |
| Suzanne Clark | Lay Representative | Glasgow |
| Tanja Gagliardi | Consultant Radiologist | North of Scotland Cancer Network |
| Tom Kane | MCN Manager | West of Scotland Cancer Network |
| Zosia Miedzybrodzka | Honorary Consultant Clinical Geneticist and Service Clinical Director of Genetics | North of Scotland Cancer Network |

## Appendix 2: Tamoxifen shared-care framework

**Clinical indication:** to reduce breast cancer incidence in women who do not have a personal history of breast cancer but who have a high risk of developing breast cancer because of their family history.

This document outlines the shared-care agreement for this medicine and must be used in conjunction with the relevant NHS board policy and procedures for the shared care of medicines.

**Key information on the medicine**

**Background to use of tamoxifen for the given indication**

The NICE clinical guideline '*Familial breast cancer: Classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer', issued: June 2013 (guidance.nice.org.uk/cg164)* concluded that there was high quality evidence that shows tamoxifen is effective in reducing breast cancer incidence when used for chemoprevention in women who do not have a personal history of breast cancer but who have a high risk of developing breast cancer because of their family history.

The recommendations include offering tamoxifen for 5 years to:

- premenopausal women at high risk of breast cancer
- postmenopausal women with or without a uterus at high risk of breast cancer.

**Exclusions:** patients with a past or current history or with an increased risk of thromboembolic disease or endometrial cancer, pregnancy and lactation.

Although tamoxifen does not have a UK marketing authorisation for this indication, the NICE guideline development group felt the evidence of benefit was sufficiently strong to outweigh the potential harms of side effects. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's *Good Practice in Prescribing and Managing Medicines and Devices* for further information.

**Dosage and administration**

Tamoxifen 20mg tablet daily for 5 years.

Treatment with tamoxifen should not continue beyond 5 years. Women should be informed that they should stop tamoxifen at least 2 months before trying to conceive and 6 weeks before elective surgery and women of childbearing age should be advised to use a barrier method of contraception.

**Contraindications**

Pregnancy and lactation. Hypersensitivity to tamoxifen or any of its excipients.

Patients with a past or current history or with an increased risk of thromboembolic disease or endometrial cancer.

**Adverse effects**

Tamoxifen is generally well tolerated. Common side effects are hot flushes, fluid retention,

| Key information on the medicine |
| --- |
| mild indigestion and nausea, less common ones include vaginal discharge and bleeding.<br><br>Other side effects include an increased risk of thromboembolic events (including deep vein thrombosis and pulmonary embolism), endometrial cancer, visual disturbances, changes in liver function tests (LFTs) and anaemia.<br><br>Refer to Advice for Patients for further detail (see Appendix 3).<br><br>**Drug interactions**<br><br>Reduced efficacy of tamoxifen has been reported with concomitant use of some selective serotonin re-uptake inhibitor (SSRI) antidepressants (for example, paroxetine, fluoxetine but not citalopram), quinidine, bupropion and rifampicin).<br><br>When tamoxifen is used in combination with coumarin-type anticoagulants, a significant increase in anticoagulant effect may occur. Careful monitoring of the patient is recommended.<br><br>**Monitoring**<br><br>No specific drug monitoring is required other than observation of any adverse effects including early signs and symptoms of visual disturbances, thromboembolic disease and endometrial cancer. |
| **Roles and responsibilities** |
| **Specialist clinics**<br><br>Healthcare professionals working within a family history clinic should discuss and give written information on the risks and benefits of chemoprevention to women at high risk of breast cancer (see Appendix 3). Discussion and information should include the side effects of drugs, the extent of risk reduction, and the risks and benefits of alternative approaches, such as risk-reducing surgery and surveillance.<br><br>Specialist services should obtain informed consent from the patient before transferring prescribing responsibility to primary care (a template letter is provided in Appendix 4)[2].<br><br>**General practitioner**<br><br>The GP will communicate with the specialist services if there is concern regarding poor tolerance to tamoxifen or if there is a change in family history or breast symptoms develop.<br><br>The treatment should be stopped after 5 years based on current evidence. The GP should ensure that there is a mechanism in place to review treatment at that time. |
| **Support and advice for the GP** |
| *Insert as appropriate.* |

[2] [1]NHS Circular No 1992 (GEN) 11 '*Responsibility for Prescribing Between Hospitals and GPs*' states that a consultant should seek the agreement of the GP to share care of a patient. Information regarding dosage, administration and monitoring should be provided by the consultant for the GP.

## Appendix 3: Advice for patients – Tamoxifen and inherited breast cancer risk reduction

### What is tamoxifen and what is it used for?

Tamoxifen is a drug that blocks the effect of the female hormone oestrogen on breast tissue and slows down cell growth and division.

It has been used for 40 years to reduce the risk of breast cancer returning and has been shown in a number of studies to lower the risk of breast cancer occurring in the first place in women at high risk of developing breast cancer. Although it does not have a licence in Europe to be used in this way, recent guidelines have concluded that the evidence of benefit was strong enough to outweigh the potential harms of side effects. Therefore it is recommended to be prescribed to reduce the risk of breast cancer in women who have no personal history of breast cancer but are at high risk of developing breast cancer due to their family history.

### Can tamoxifen reduce my risk of breast cancer?

If you take tamoxifen for 5 years, your risk of breast cancer will reduce by at least a third. For every 10 women at high risk of developing breast cancer, 3 of these women might go on to develop breast cancer. If all 10 of these women took tamoxifen daily for 5 years, only two might go on to develop breast cancer, and one may avoid breast cancer.

For every 1,000 women treated, tamoxifen would prevent 18 breast cancers.

Younger women (aged less than 50 years) are likely to benefit more and experience fewer side effects.

There is as yet no evidence to show that tamoxifen prevents breast cancer deaths in these women.

### How do I take tamoxifen?

Tamoxifen is taken as a tablet or liquid. The recommended dose is 20mg each day for 5 years.

### What are the possible side effects?

Like all medicines, tamoxifen can cause side effects, although not everybody gets them.

### Common side effects

The most common side effects (affecting more than 1 in 10 people) are similar to menopausal symptoms such as:

- hot flushes
- night sweats
- loss of libido (sex drive)
- vaginal dryness
- mild indigestion and nausea.

In most women who have not yet gone through the menopause, taking tamoxifen allows the ovaries to continue to work. When you first start to take tamoxifen, it may stimulate ovulation, making you more fertile. You will be advised not to get pregnant while taking tamoxifen and to use contraception. If you would like to become pregnant, you should discuss this with your doctor as tamoxifen should be stopped at least 2 months before trying to conceive. Breast feeding is not recommended while taking tamoxifen. Tamoxifen also should be stopped 6 weeks before any planned surgery.

Over time, women who have not yet gone through the menopause may find their periods become irregular, lighter or stop completely while taking tamoxifen. If this happens to you, your periods will generally return once you stop taking tamoxifen unless you go through the menopause naturally while taking it.

In women who have gone through the menopause, tamoxifen slows down the natural process of bone loss, reducing the risk of osteoporosis (thinning of the bone). However women who take tamoxifen before going through the menopause may be at increased risk of thinning of the bones.

Other common side effects (affecting between 1 in 10 and 1 in 100 people) include:

- anaemia (condition where there is less than the normal number of red blood cells or less than the normal quantity of haemoglobin in the blood)
- hair thinning
- leg cramps
- joint pains
- headaches.

Changes in vision due to cataracts and changes affecting the retina have also been reported.

**Uncommon or rare side effects**

Uncommon side effects (affecting between 1 in 100 and 1 in 1,000 people) include increase in downy facial hair, weight gain and rare reports of eyesight problems (including corneal changes, optic neuropathy and optic neuritis).

Tamoxifen also causes blood problems (thromboembolic events) such as making you bruise more easily and increases the risk of blood clots. You should report symptoms such as swelling, pain in your leg or shortness of breath straight away. For every 1,000 women treated, tamoxifen would cause 5 thromboembolic events

Tamoxifen can also affect the lining of your womb (endometrium) which may thicken. Occasionally, tamoxifen can cause polyps (growths) or ovarian cysts, and very rarely may cause cancer of the womb (affects between 1 in 1,000 and 1 in 10,000 people). For every 1,000 women treated, tamoxifen would cause 6 endometrial cancers.

If you experience any side effects, talk to your specialist or GP (local doctor) as there may be treatments that can help.

**What if I take other medicines?**

Some medicines may interact with tamoxifen therefore you should inform your doctor of all the medicines you are taking, even those you have bought without prescription. In particular

you should inform your doctor if you are taking paroxetine, fluoxetine (antidepressants), bupropion, quinidine, rifampicin or any blood-thinning medicines such as warfarin.

**References**

Familial breast cancer: Classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer Issued: June 2013 (guidance.nice.org.uk/cg164)

Breast Cancer Care March 2013 http://www.breastcancercare.org.uk/breast-cancer-information/treating-breast-cancer/hormone-therapy/tamoxifen

Clinical Genetics, University Hospitals of Leicester October 2013

http://www2.le.ac.uk/departments/genetics/genie/projects/sfwc/documents/Tamoxifen_Patient_information_leaflet_Oct_2013.pdf

Tamoxifen: Patient Information Leaflet (April 2013) TEVA UK Limited

http://www.tevauk.com/mediafile/id/7040.pdf

**Appendix 4: Template letter for communication between specialist and primary care**

Dear Colleague,

Re your patient:

This lady with no personal history of breast cancer is at high risk of developing breast cancer, due to her family history. She is not at increased risk of thromboembolic disease or of endometrial cancer, and I therefore advise that she takes **tamoxifen 20mg each day for 5 years** to reduce her risk of developing breast cancer.

The use of tamoxifen to reduce the chance of developing breast cancer is not covered in the product licence, but is supported by strong evidence of a level of risk reduction of developing breast cancer in women at high risk due to their family history. The benefits are considered to outweigh the risks associated with treatment, which include an increased chance of developing thromboembolic disease such as deep vein thrombosis and pulmonary embolism and cancer of the lining of the womb (endometrial cancer).

- ☐ I have discussed this with your patient and they have consented to the use of the medication outside the product licence ("off-label use").

- ☐ I have advised that patients taking tamoxifen should stop the medication at least 2 months before trying to conceive and at least 6 weeks before planned surgery.

The treatment should be stopped after 5 years based on current evidence. Please ensure you have a mechanism in place to review treatment at this time.

If you have any concerns about sharing responsibility for prescribing of this medication, please contact me to discuss further.

Yours sincerely

Refer to Healthcare Improvement Scotland SLWG report on the implementation of selected recommendations from the NICE CG 164

Enc. Advice for patients – Tamoxifen and inherited breast cancer risk reduction

## Appendix 5: Resource impact and costing report

### Background

A decision was reached by the SLWG that only the new recommendations that do not reflect current practice in Scotland and therefore require considerable change to implement would be prioritised for costing. This section sets out the resource implications and costs of implementing these recommendations across three main headings: genetic testing, imaging surveillance and chemoprevention.

### Methods

The cost impact is estimated by identifying the population affected by the recommendations (eligible population), the current levels of activity and the additional activity required to implement the recommendations. The population estimates for all calculations were taken from the General Register Office for Scotland (2012). For each recommendation the members of the SLWG were therefore asked to provide data or estimates to enable overall resource implications to be calculated. Relevant assumptions are noted throughout the document. The total costs are based on unit costs obtained from the NICE familial breast cancer costing report.

It is acknowledged that there may be additional resource implications associated with implementing some of the other new recommendations within the NICE clinical guideline, for example those recommendations NICE state to 'consider'. However, these are not within the scope of the current report.

#### (A) Genetic testing for a person with no personal history of breast cancer and no available affected relative to test

*Offer genetic testing in specialist genetic clinics to a person with no personal history of breast cancer if their combined BRCA1 and BRCA2 mutation carrier probability is 10% or more and an affected relative is unavailable for testing (NICE recommendation 1.5.12).*

### Key assumptions made

The model is based on annual incidence of breast cancer in women by age group applied to population estimates.

Using data obtained from NHS Greater Glasgow and Clyde, it is assumed that 27% of women with no personal history of breast cancer have no available affected relative to test and therefore are eligible for genetic testing. This percentage has been applied to the estimated annual incidence rates for breast cancer in each age group.

It is also assumed that 1.3% of eligible women are currently offered genetic testing. Around 48% of women are assumed to take up genetic testing (NICE familial breast cancer costing report).

In order to estimate the increase in activity and cost impact of the recommendation, it is assumed that the remaining 98.7% of women eligible will be offered genetic testing with the same 48% uptake.

### Costs of genetic testing

The cost of genetic testing consists of the laboratory cost and the cost of counselling. Counselling involves a risk assessment based on the individual's personal and family history and discussions about the medical implications of a positive or negative result, the psychological risks and benefits of genetic results and the risk of passing a mutation to children. Since an affected relative is not available to test, it is assumed that a full genetic

test is needed to identify whether there is a genetic mutation and the type of mutation. The laboratory costs of genetic testing are estimated to be £700 and it has been assumed that two counselling sessions are required, costing £250 in total (NICE familial breast cancer costing report). It has been assumed that the number of women tested is the same each year. Table A1 presents the estimated 5-year cost and resource impact of implementing the genetic testing recommendation in Scotland.

**Table A1: Estimated 5-year cost and resource impact of implementing the genetic testing recommendation in Scotland**

| Genetic testing | Number of women tested | | Resources | | | | Costs | | Net cost impact of recommendation |
|---|---|---|---|---|---|---|---|---|---|
| | | | Laboratory tests | | Counselling sessions | | | | |
| | Current | Future | Current | Future | Current | Future | Current | Future | |
| **NHS board** | | | | | | | | | |
| NHS Ayrshire and Arran | 0 | 244 | 0 | 244 | 0 | 488 | £0 | £231,800 | **£231,800** |
| NHS Borders | 0 | 85 | 0 | 85 | 0 | 170 | £0 | £80,750 | **£80,750** |
| NHS Dumfries and Galloway | 0 | 109 | 0 | 109 | 0 | 218 | £0 | £103,550 | **£103,550** |
| NHS Fife | 0 | 224 | 0 | 224 | 0 | 448 | £0 | £212,800 | **£212,800** |
| NHS Forth Valley | 0 | 180 | 0 | 180 | 0 | 360 | £0 | £171,000 | **£171,000** |
| NHS Grampian | 0 | 319 | 0 | 319 | 0 | 638 | £0 | £303,050 | **£303,050** |
| NHS Greater Glasgow and Clyde | 2 | 652 | 2 | 652 | 4 | 1,304 | £1,900 | £619,400 | **£617,500** |
| NHS Highland | 0 | 214 | 0 | 214 | 0 | 428 | £0 | £203,300 | **£203,300** |
| NHS Lanarkshire | 0 | 329 | 0 | 329 | 0 | 658 | £0 | £312,550 | **£312,550** |
| NHS Lothian | 1 | 444 | 1 | 444 | 2 | 888 | £950 | £421,800 | **£420,850** |
| NHS Orkney | 0 | 25 | 0 | 25 | 0 | 50 | £0 | £23,750 | **£23,750** |
| NHS Shetland | 0 | 25 | 0 | 25 | 0 | 50 | £0 | £23,750 | **£23,750** |
| NHS Tayside | 0 | 254 | 0 | 254 | 0 | 508 | £0 | £241,300 | **£241,300** |
| NHS Western Isles | 0 | 30 | 0 | 30 | 0 | 60 | £0 | £28,500 | **£28,500** |
| **Scotland** | **3** | **3,134** | **3** | **3,134** | **6** | **6,268** | **£2,850** | **£2,977,300** | **£2,974,450** |

### (B) Imaging surveillance for women with no personal history and women with a personal and family history of breast cancer

Resource implications in relation to imaging are presented in this section of the report according to whether the women have or have not got a personal history of breast cancer.

**Imaging surveillance for women with no personal history of breast cancer**
*Offer annual mammographic surveillance to women:*

- *aged 40–59 years at high risk of breast cancer but with a 30% or lower probability of being a BRCA or TP53 carrier (NICE recommendation 1.6.3).*
- *aged 40–59 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier (NICE recommendation 1.6.3).*
- *aged 40–69 years with a known BRCA1 or BRCA2 mutation (NICE recommendation 1.6.3).*
- *aged 50–69 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier, unless mammography has shown a dense breast pattern (NICE recommendation 1.6.9).*
- *aged 50–69 years with a known BRCA1 or BRCA2 mutation, unless mammography has shown a dense breast pattern (NICE recommendation 1.6.9).*

**MRI surveillance**
*Offer annual MRI surveillance to women:*

- *aged 20–49 years who have not had genetic testing but have a greater than 30% probability of being a TP53 carrier (NICE recommendation 1.6.7).*
- *aged 50–69 years who have not had genetic testing but have a greater than 30% probability of being a BRCA or a TP53 carrier, when mammography has shown a dense breast pattern (NICE recommendation 1.6.9).*
- *aged 50–69 years with a known BRCA1 or BRCA2 mutation, when mammography has shown a dense breast pattern (NICE recommendation 1.6.9).*

**Imaging surveillance for women with a personal and family history of breast cancer**

***Imaging surveillance***

***MRI surveillance***
*Offer annual MRI surveillance to all women aged 30–49 years with a personal history of breast cancer who remain at high risk of breast cancer, including those who have a BRCA1 or BRCA2 mutation (NICE recommendation 1.6.13).*

**Key assumptions made**

With regards to the recommendations for women with no personal history of breast cancer, the eligible population is assumed to be women with high risk and, for some recommendations, a very high risk of breast cancer. Data on the number of women at high risk nd very high risk were available from NHS Grampian, NHS Greater Glasgow and Clyde, and NHS Tayside. To estimate the number of women at risk in each age group for the remainder of the NHS boards, the proportions of women at risk in each age group in NHS Grampian, NHS Greater Glasgow and Clyde, and NHS Tayside, were applied to Scotland population estimates. Regarding the women with a personal and family history of breast cancer, the eligible population is assumed to be high risk and very high risk women with a personal and family history of breast cancer. Data on the number of women were available from NHS Greater Glasgow and Clyde and NHS Tayside and used to estimate the number of women in the remainder of the NHS boards using the same approach.

Using data obtained from NHS Tayside to estimate the women eligible for imaging surveillance, it was assumed that 39.92% of women at high risk have a 30% or lower probability of being a BRCA or TP53 carrier. Also using this data, it was further assumed that 1.98% of women at high risk who have not had genetic testing have a greater than 30% probability of being a BRCA carrier, 7.65% of women at high risk are BRCA1 or BRCA2 mutation carriers and mammography has shown a dense breast pattern for 25% of women.

Based on the discussions among the SLWG members, it is assumed that there are few women in Scotland that are TP53 carriers and thus costs associated with recommendations in relation to these specific groups are not estimated.

Due to the interdependent elements of each of the imaging surveillance recommendations, it has not been possible to obtain data on current activity levels within NHS Scotland. In order to estimate current activity it has been assumed that 10% of all eligible women are currently being treated according to each recommendation, other than in NHS Highland where 70% of all eligible women are currently receiving annual mammograms (Personal Communication, Nick Abbott). However, all women aged 50–59 years currently receive 18-monthly mammograms; therefore it has been assumed that a 50% increase is required. In order to estimate the increase in activity and cost impact of each of the recommendations, it is assumed that the remaining 90% of eligible women will be treated according to each recommendation (other than in NHS Highland).

Due to the considerable uncertainty around current and future activity levels, sensitivity analysis showing the cost impact at a range of current activity levels has been provided. This is provided in Appendix 5A. The annual number of eligible women has been estimated for 5 years. In doing so, it has been assumed that the same numbers of women are eligible each year. In addition, an estimate has been made of the number of women reaching an age at which they are eligible for screening and similarly, the number of women reaching an age at which they no longer require screening, in accordance with the age ranges specified for each recommendation. These numbers are expected to be small. Due to data on current activity levels being available for NHS Highland, sensitivity analysis has not been provided for this NHS board.

Tables A2 and A3 below, show the estimated current and 5-year cost and resource impact of implementing the imaging surveillance recommendations in Scotland, for women with no personal history of breast cancer and women with a personal and family history of breast cancer, respectively. Table A4 then provides the overall net cost of implementing the imaging surveillance recommendations in Scotland. Given the assumptions described that have been used to derive the numbers of women eligible for each of the recommendations (for example proportions applied), and the small unit costs, the numbers presented in the tables are relatively low.

**Table A2: Estimated current and 5-year cost and resource impact of implementing the imaging surveillance recommendations in Scotland, for women with no personal history of breast cancer**

| Imaging surveillance | Women with no personal history of breast cancer | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of mammograms | | | | | Number of MRIs | | | | | Net cost impact of recommendations |
| NHS board | Current | Cost | Future | Cost | Net cost impact | Current | Cost | Future | Cost | Net cost impact | |
| NHS Ayrshire and Arran | 44 | £2,332 | 526 | £27,878 | £25,546 | 0 | £0 | 39 | £9,750 | £9,750 | £35,296 |
| NHS Borders | 12 | £636 | 172 | £9,116 | £8,480 | 0 | £0 | 14 | £3,500 | £3,500 | £11,980 |
| NHS Dumfries and Galloway | 17 | £901 | 222 | £11,766 | £10,865 | 0 | £0 | 18 | £4,500 | £4,500 | £15,365 |
| NHS Fife | 41 | £2,173 | 495 | £26,235 | £24,062 | 0 | £0 | 35 | £8,750 | £8,750 | £32,812 |
| NHS Forth Valley | 32 | £1,696 | 415 | £21,995 | £20,299 | 0 | £0 | 32 | £8,000 | £8,000 | £28,299 |
| NHS Grampian | 88 | £4,664 | 826 | £43,778 | £39,114 | 0 | £0 | 59 | £14,750 | £14,750 | £53,864 |
| NHS Greater Glasgow and Clyde | 111 | £5,883 | 1,315 | £69,695 | £63,812 | 1 | £250 | 78 | £19,500 | £19,250 | £83,062 |
| NHS Highland | 117 | £6,201 | 727 | £38,531 | £32,330 | 0 | £0 | 30 | £7,500 | £7,500 | £39,830 |
| NHS Lanarkshire | 66 | £3,498 | 790 | £41,870 | £38,372 | 0 | £0 | 53 | £13,250 | £13,250 | £51,622 |
| NHS Lothian | 87 | £4,611 | 1,057 | £56,021 | £51,410 | 0 | £0 | 69 | £17,250 | £17,250 | £68,660 |
| NHS Orkney | 1 | £53 | 45 | £2,385 | £2,332 | 0 | £0 | 12 | £3,000 | £3,000 | £5,332 |
| NHS Shetland | 1 | £53 | 45 | £2,385 | £2,332 | 0 | £0 | 12 | £3,000 | £3,000 | £5,332 |
| NHS Tayside | 314 | £16,656 | 1,556 | £82,468 | £65,812 | 2 | £500 | 106 | £26,500 | £26,000 | £91,812 |
| NHS Western Isles | 2 | £106 | 49 | £2,597 | £2,491 | 0 | £0 | 12 | £3,000 | £3,000 | £5,491 |
| **Scotland** | **933** | **£49,463** | **8,240** | **£436,720** | **£387,257** | **3** | **£750** | **569** | **£142,250** | **£141,500** | **£528,757** |

**Table A3: Estimated current and 5-year cost and resource impact of implementing the imaging surveillance recommendations in Scotland, for women with a personal and family history of breast cancer**

| Imaging surveillance | Women with a personal and family history of breast cancer | | | | |
|---|---|---|---|---|---|
| | Number of MRIs | | | | |
| NHS board | Current | Cost | Future | Cost | Net cost impact |
| NHS Ayrshire and Arran | 2 | £500 | 99 | £24,750 | £24,250 |
| NHS Borders | 0 | £0 | 30 | £7,500 | £7,500 |
| NHS Dumfries and Galloway | 0 | £0 | 40 | £10,000 | £10,000 |
| NHS Fife | 2 | £500 | 94 | £23,500 | £23,000 |
| NHS Forth Valley | 1 | £250 | 84 | £21,000 | £20,750 |
| NHS Grampian | 3 | £750 | 145 | £36,250 | £35,500 |
| NHS Greater Glasgow and Clyde | 8 | £2,000 | 372 | £93,000 | £91,000 |
| NHS Highland | 1 | £250 | 84 | £21,000 | £20,750 |
| NHS Lanarkshire | 3 | £750 | 154 | £38,500 | £37,750 |
| NHS Lothian | 4 | £1,000 | 218 | £54,500 | £53,500 |
| NHS Orkney | 0 | £0 | 9 | £2,250 | £2,250 |
| NHS Shetland | 0 | £0 | 9 | £2,250 | £2,250 |
| NHS Tayside | 1 | £250 | 49 | £12,250 | £12,000 |
| NHS Western Isles | 0 | £0 | 9 | £2,250 | £2,250 |
| **Scotland** | **25** | **£6,250** | **1,396** | **£349,000** | **£342,750** |

**Table A4: Total 5-year cost and resource impact of implementing the imaging surveillance recommendations in Scotland**

| NHS board | Women with no personal history of breast cancer | Women with a person and family history of breast cancer | Net cost impact |
|---|---|---|---|
| NHS Ayrshire and Arran | £35,296 | £24,250 | **£59,546** |
| NHS Borders | £11,980 | £7,500 | **£19,480** |
| NHS Dumfries and Galloway | £15,365 | £10,000 | **£25,365** |
| NHS Fife | £32,812 | £23,000 | **£55,812** |
| NHS Forth Valley | £28,299 | £20,750 | **£49,049** |
| NHS Grampian | £53,864 | £35,500 | **£89,364** |
| NHS Greater Glasgow and Clyde | £83,062 | £91,000 | **£174,062** |
| NHS Highland | £39,830 | £20,750 | **£60,580** |
| NHS Lanarkshire | £51,622 | £37,750 | **£89,372** |
| NHS Lothian | £68,660 | £53,500 | **£122,160** |
| NHS Orkney | £5,332 | £2,250 | **£7,582** |
| NHS Shetland | £5,332 | £2,250 | **£7,582** |
| NHS Tayside | £91,812 | £12,000 | **£103,812** |
| NHS Western Isles | £5,491 | £2,250 | **£7,741** |
| **Scotland** | **£528,757** | **£342,750** | **£871,507** |

It should be noted that the following recommendations were also contained in the NICE report and identified by the group as being important to recognise within all the imaging resource implications for NHS Scotland:

*For women less than 50 years who are having mammography, use digital mammography at centres providing digital mammography to national breast screening programme standards (NICE recommendation 1.6.22).*

*Ensure that individual strategies are developed for all women having mammographic surveillance and that surveillance is:*

- *to national breast screening programme standards*
- *audited*
- *only undertaken after written information is given about risks and benefits (NICE recommendation 1.6.23).*

*Ensure that MRI surveillance includes MRI of both breasts performed to national breast screening programme standards (NICE recommendation 1.6.24).*

Data were not available to allow an estimate of the costs associated with implementing these recommendations.

### (C) Chemoprevention for women with no personal history of breast cancer

*Offer tamoxifen for 5 years to premenopausal women at high risk or greater of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer (NICE recommendation 1.7.21).*

*Offer tamoxifen for 5 years to postmenopausal women without a uterus and at high risk or greater of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or they have a past history of endometrial cancer (NICE recommendation 1.7.22).*

*Offer either tamoxifen for 5 years to postmenopausal women with a uterus and at high risk or greater of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer (NICE recommendation 1.7.23).*

**Key assumptions made**

It is assumed that chemoprevention is not current practice in NHSScotland for women with no personal history of breast cancer.

The eligible population is assumed to be women with a high risk and very high risk of breast cancer (based on data from NHS Greater Glasgow and Clyde). Data on the number of women at high risk and very high risk were available from NHS Greater Glasgow and Clyde, NHS Tayside and NHS Grampian. To estimate the number of women at risk in each age group for the remainder of the NHS boards, the proportions of women at risk in each age group in NHS Greater Glasgow and Clyde were applied to Scotland population estimates. The age of premenopausal women is assumed to be 20–49 years and the age of postmenopausal women is assumed to be from age 50 years onwards (NICE familial breast cancer costing report).

It is assumed that 25% of eligible women may take up chemoprevention based on discussions among the SLWG members.

Chemoprevention may not always work or may cause side effects and therefore treatment may be stopped after 1 year; it was therefore assumed that 40% of women stop chemoprevention (NICE familial breast cancer costing report).

It is assumed that all women will be treated with tamoxifen since tamoxifen studies have looked specifically at breast cancer whereas raloxifene studies have not.

Using data obtained from NHS Tayside to estimate the number of new women eligible for chemoprevention in years 2–5, a value of 3% was assumed and applied to estimate the number of women in the remainder of the NHS boards.

**Cost of chemoprevention**

The annual cost of tamoxifen is £36 (electronic drugs tariff 2012/2013). In addition to drug costs, a 6-monthly GP visit is assumed to be required to monitor treatment and for women to receive a repeat prescription.

Table A5 shows the estimated cost and resource impact of implementing the chemoprevention recommendations in Scotland for 5 years. The estimated costs at year 5 are considered to represent steady-state costs.

**Table A5: Estimated 5-years resource and cost impact of implementing the chemoprevention recommendations in Scotland**

| Chemoprevention | Year 1 | | | | | Year 2 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | GP visits | | | | | GP visits | | | |
| | Number of women | Number | Cost | Drug cost | Total cost impact | Number of women | Number | Cost | Drug cost | Total cost impact |
| **NHS board** | | | | | | | | | | |
| NHS Ayrshire and Arran | 105 | 210 | £8,400 | £3,780 | £12,180 | 67 | 134 | £5,360 | £2,412 | £7,772 |
| NHS Borders | 33 | 66 | £2,640 | £1,188 | £3,828 | 21 | 42 | £1,680 | £756 | £2,436 |
| NHS Dumfries and Galloway | 43 | 86 | £3,440 | £1,548 | £4,988 | 28 | 56 | £2,240 | £1,008 | £3,248 |
| NHS Fife | 99 | 198 | £7,920 | £3,564 | £11,484 | 63 | 126 | £5,040 | £2,268 | £7,308 |
| NHS Forth Valley | 81 | 162 | £6,480 | £2,916 | £9,396 | 51 | 102 | £4,080 | £1,836 | £5,916 |
| NHS Grampian | 185 | 370 | £14,800 | £6,660 | £21,460 | 117 | 234 | £9,360 | £4,212 | £13,572 |
| NHS Greater Glasgow and Clyde | 269 | 538 | £21,520 | £9,684 | £31,204 | 170 | 340 | £13,600 | £6,120 | £19,720 |
| NHS Highland | 89 | 178 | £7,120 | £3,204 | £10,324 | 57 | 114 | £4,560 | £2,052 | £6,612 |
| NHS Lanarkshire | 155 | 310 | £12,400 | £5,580 | £17,980 | 98 | 196 | £7,840 | £3,528 | £11,368 |
| NHS Lothian | 217 | 434 | £17,360 | £7,812 | £25,172 | 137 | 274 | £10,960 | £4,932 | £15,892 |
| NHS Orkney | 7 | 14 | £560 | £252 | £812 | 5 | 10 | £400 | £180 | £580 |
| NHS Shetland | 7 | 14 | £560 | £252 | £812 | 5 | 10 | £400 | £180 | £580 |
| NHS Tayside | 126 | 252 | £10,080 | £4,536 | £14,616 | 80 | 160 | £6,400 | £2,880 | £9,280 |
| NHS Western Isles | 8 | 16 | £640 | £288 | £928 | 6 | 12 | £480 | £216 | £696 |
| **Scotland** | **1,424** | **2,848** | **£113,920** | **£51,264** | **£165,184** | **905** | **1,810** | **£72,400** | **£32,580** | **£104,980** |

**Table A5: Estimated 5-years resource and cost impact of implementing the chemoprevention recommendations in Scotland**

| Chemoprevention | Year 3 | | | | | Year 4 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | GP visits | | | | | GP visits | | | |
| | Number of women | Number | Cost | Drug cost | Total cost impact | Number of women | Number | Cost | Drug cost | Total cost impact |
| **NHS board** | | | | | | | | | | |
| NHS Ayrshire and Arran | 69 | 138 | £5,520 | £2,484 | £8,004 | 71 | 142 | £5,680 | £2,556 | £8,236 |
| NHS Borders | 22 | 44 | £1,760 | £792 | £2,552 | 23 | 46 | £1,840 | £828 | £2,668 |
| NHS Dumfries and Galloway | 29 | 58 | £2,320 | £1,044 | £3,364 | 30 | 60 | £2,400 | £1,080 | £3,480 |
| NHS Fife | 66 | 132 | £5,280 | £2,376 | £7,656 | 67 | 134 | £5,360 | £2,412 | £7,772 |
| NHS Forth Valley | 54 | 108 | £4,320 | £1,944 | £6,264 | 56 | 112 | £4,480 | £2,016 | £6,496 |
| NHS Grampian | 121 | 242 | £9,680 | £4,356 | £14,036 | 125 | 250 | £10,000 | £4,500 | £14,500 |
| NHS Greater Glasgow and Clyde | 176 | 352 | £14,080 | £6,336 | £20,416 | 181 | 362 | £14,480 | £6,516 | £20,996 |
| NHS Highland | 58 | 116 | £4,640 | £2,088 | £6,728 | 60 | 120 | £4,800 | £2,160 | £6,960 |
| NHS Lanarkshire | 101 | 202 | £8,080 | £3,636 | £11,716 | 104 | 208 | £8,320 | £3,744 | £12,064 |
| NHS Lothian | 142 | 284 | £11,360 | £5,112 | £16,472 | 146 | 292 | £11,680 | £5,256 | £16,936 |
| NHS Orkney | 6 | 12 | £480 | £216 | £696 | 6 | 12 | £480 | £216 | £696 |
| NHS Shetland | 6 | 12 | £480 | £216 | £696 | 6 | 12 | £480 | £216 | £696 |
| NHS Tayside | 82 | 164 | £6,560 | £2,952 | £9,512 | 85 | 170 | £6,800 | £3,060 | £9,860 |
| NHS Western Isles | 6 | 12 | £480 | £216 | £696 | 6 | 12 | £480 | £216 | £696 |
| **Scotland** | **938** | **1,876** | **£75,040** | **£33,768** | **£108,808** | **966** | **1,932** | **£77,280** | **£34,776** | **£112,056** |

**Table A5: Estimated 5-years resource and cost impact of implementing the chemoprevention recommendations in Scotland**

| Chemoprevention | Year 5 | | | | |
|---|---|---|---|---|---|
| | | GP visits | | | |
| | Number of women | Number | Cost | Drug cost | Total cost impact |
| **NHS board** | | | | | |
| NHS Ayrshire and Arran | 73 | 146 | £5,840 | £2,628 | £8,468 |
| NHS Borders | 24 | 48 | £1,920 | £864 | £2,784 |
| NHS Dumfries and Galloway | 30 | 60 | £2,400 | £1,080 | £3,480 |
| NHS Fife | 69 | 138 | £5,520 | £2,484 | £8,004 |
| NHS Forth Valley | 57 | 114 | £4,560 | £2,052 | £6,612 |
| NHS Grampian | 129 | 258 | £10,320 | £4,644 | £14,964 |
| NHS Greater Glasgow and Clyde | 186 | 372 | £14,880 | £6,696 | £21,576 |
| NHS Highland | 62 | 124 | £4,960 | £2,232 | £7,192 |
| NHS Lanarkshire | 107 | 214 | £8,560 | £3,852 | £12,412 |
| NHS Lothian | 151 | 302 | £12,080 | £5,436 | £17,516 |
| NHS Orkney | 6 | 12 | £480 | £216 | £696 |
| NHS Shetland | 6 | 12 | £480 | £216 | £696 |
| NHS Tayside | 87 | 174 | £6,960 | £3,132 | £10,092 |
| NHS Western Isles | 6 | 12 | £480 | £216 | £696 |
| **Scotland** | **993** | **1,986** | **£79,440** | **£35,748** | **£115,188** |

**Overall cost impact of implementing the genetic testing, imaging surveillance and chemoprevention recommendations in NHSScotland**

The total costs of implementing the key recommendations in Scotland and each NHS board are shown in Table A6.

**Table A6: Net cost impact of implementing the genetic testing, imaging surveillance and chemoprevention recommendations in NHSScotland**

| Net costs to implement the key recommendations | Genetic testing | Imaging surveillance* | Chemoprevention** | Total |
|---|---|---|---|---|
| NHS Ayrshire and Arran | £231,800 | £59,546 | £8,468 | **£299,814** |
| NHS Borders | £80,750 | £19,480 | £2,784 | **£103,014** |
| NHS Dumfries and Galloway | £103,550 | £25,365 | £3,480 | **£132,395** |
| NHS Fife | £212,800 | £55,812 | £8,004 | **£276,616** |
| NHS Forth Valley | £171,000 | £49,049 | £6,612 | **£226,661** |
| NHS Grampian | £303,050 | £89,364 | £14,964 | **£407,378** |
| NHS Greater Glasgow and Clyde | £617,500 | £174,062 | £21,576 | **£813,138** |
| NHS Highland | £203,300 | £60,580 | £7,192 | **£271,072** |
| NHS Lanarkshire | £312,550 | £89,372 | £12,412 | **£414,334** |
| NHS Lothian | £420,850 | £122,160 | £17,516 | **£560,526** |
| NHS Orkney | £23,750 | £7,582 | £696 | **£32,028** |
| NHS Shetland | £23,750 | £7,582 | £696 | **£32,028** |
| NHS Tayside | £241,300 | £103,812 | £10,092 | **£355,204** |
| NHS Western Isles | £28,500 | £7,741 | £696 | **£36,937** |
| **Scotland** | **£2,974,450** | **£871,507** | **£115,188** | **£3,961,145** |

* The figures presented are the costs for 5 years.
** The figures presented are the costs for year 5, as these are considered to represent steady-state costs.

**References**

Familial breast cancer: Costing report Issued: June 2013 http://guidance.nice.org.uk/CG164

**Appendix 5A: Sensitivity analysis**

**Table A7: Annual costs and resource impact of imaging surveillance recommendations for women with no personal history of breast cancer, when current activity levels are 20% (base case 10%)**

| Imaging surveillance | Women with no personal history of breast cancer | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of mammograms | | | | | Number of MRIs | | | | | Net cost impact of recommendations |
| NHS board | Current | Cost | Future | Cost | Net cost impact | Current | Cost | Future | Cost | Net cost impact | |
| NHS Ayrshire and Arran | 48 | £2,544 | 520 | £27,560 | £25,016 | 0 | £0 | 39 | £9,750 | £9,750 | £34,766 |
| NHS Borders | 14 | £742 | 170 | £9,010 | £8,268 | 0 | £0 | 14 | £3,500 | £3,500 | £11,768 |
| NHS Dumfries and Galloway | 19 | £1,007 | 219 | £11,607 | £10,600 | 0 | £0 | 18 | £4,500 | £4,500 | £15,100 |
| NHS Fife | 45 | £2,385 | 489 | £25,917 | £23,532 | 0 | £0 | 35 | £8,750 | £8,750 | £32,282 |
| NHS Forth Valley | 36 | £1,908 | 411 | £21,783 | £19,875 | 0 | £0 | 32 | £8,000 | £8,000 | £27,875 |
| NHS Grampian | 95 | £5,035 | 820 | £43,460 | £38,425 | 1 | £250 | 57 | £14,250 | £14,000 | £52,425 |
| NHS Greater Glasgow and Clyde | 125 | £6,625 | 1,301 | £68,953 | £62,328 | 3 | £750 | 77 | £19,250 | £18,500 | £80,828 |
| NHS Highland* | 117 | £6,201 | 727 | £38,531 | £32,330 | 0 | £0 | 30 | £7,500 | £7,500 | £39,830 |
| NHS Lanarkshire | 73 | £3,869 | 783 | £41,499 | £37,630 | 0 | £0 | 53 | £13,250 | £13,250 | £50,880 |
| NHS Lothian | 99 | £5,247 | 1,045 | £55,385 | £50,138 | 2 | £500 | 67 | £16,750 | £16,250 | £66,388 |
| NHS Orkney | 1 | £53 | 45 | £2,385 | £2,332 | 0 | £0 | 12 | £3,000 | £3,000 | £5,332 |
| NHS Shetland | 1 | £53 | 45 | £2,385 | £2,332 | 0 | £0 | 12 | £3,000 | £3,000 | £5,332 |
| NHS Tayside | 316 | £16,771 | 1,554 | £82,362 | £65,591 | 4 | £1,000 | 104 | £26,000 | £25,000 | £90,591 |
| NHS Western Isles | 2 | £106 | 48 | £2,544 | £2,438 | 0 | £0 | 12 | £3,000 | £3,000 | £5,438 |
| **Scotland** | **991** | **£52,546** | **8,177** | **£433,381** | **£380,835** | **10** | **£2,500** | **562** | **£140,500** | **£138,000** | **£518,835** |

* Due to data on current practice being available, sensitivity analysis has not been provided; therefore these figures are the same as those for the base case.

**Table A8: Annual costs and resource impact of imaging surveillance recommendations for women with a personal and family history of breast cancer, when current activity levels are 20% (base case 10%)**

| Imaging surveillance | Women with a personal and family history of breast cancer | | | | |
|---|---|---|---|---|---|
| | Number of MRIs | | | | |
| **NHS board** | **Current** | **Cost** | **Future** | **Cost** | **Net cost impact** |
| NHS Ayrshire and Arran | 4 | £1,000 | 97 | £24,250 | £23,250 |
| NHS Borders | 1 | £250 | 30 | £7,500 | £7,250 |
| NHS Dumfries and Galloway | 1 | £250 | 39 | £9,750 | £9,500 |
| NHS Fife | 4 | £1,000 | 92 | £23,000 | £22,000 |
| NHS Forth Valley | 3 | £750 | 82 | £20,500 | £19,750 |
| NHS Grampian | 6 | £1,500 | 141 | £35,250 | £33,750 |
| NHS Greater Glasgow and Clyde | 16 | £4,000 | 364 | £91,000 | £87,000 |
| NHS Highland* | 3 | £750 | 82 | £20,500 | £19,750 |
| NHS Lanarkshire | 6 | £1,500 | 151 | £37,750 | £36,250 |
| NHS Lothian | 9 | £2,250 | 214 | £53,500 | £51,250 |
| NHS Orkney | 0 | £0 | 8 | £2,000 | £2,000 |
| NHS Shetland | 0 | £0 | 8 | £2,000 | £2,000 |
| NHS Tayside | 2 | £500 | 48 | £12,000 | £11,500 |
| NHS Western Isles | 0 | £0 | 9 | £2,250 | £2,250 |
| **Scotland** | **55** | **£13,750** | **1,365** | **£341,250** | **£327,500** |

* Due to data on current practice being available, sensitivity analysis has not been provided; therefore these figures are the same as those for the base case.

**Table A9: Annual costs and resource impact of implementing the imaging surveillance recommendations in Scotland, when current activity levels are 20% (base case 10%)**

| NHS board | Women with no personal history of breast cancer | Women with a personal and family history of breast cancer | Net cost impact |
|---|---|---|---|
| NHS Ayrshire and Arran | £34,766 | £23,250 | **58,016** |
| NHS Borders | £11,768 | £7,250 | **19,018** |
| NHS Dumfries and Galloway | £15,100 | £9,500 | **24,600** |
| NHS Fife | £32,282 | £22,000 | **54,282** |
| NHS Forth Valley | £27,875 | £19,750 | **47,625** |
| NHS Grampian | £52,425 | £33,750 | **86,175** |
| NHS Greater Glasgow and Clyde | £80,828 | £87,000 | **167,828** |
| NHS Highland* | £39,830 | £19,750 | **59,580** |
| NHS Lanarkshire | £50,880 | £36,250 | **87,130** |
| NHS Lothian | £66,388 | £51,250 | **117,638** |
| NHS Orkney | £5,332 | £2,000 | **7,332** |
| NHS Shetland | £5,332 | £2,000 | **7,332** |
| NHS Tayside | £90,591 | £11,500 | **102,091** |
| NHS Western Isles | £5,438 | £2,250 | **7,688** |
| **Scotland** | **£518,835** | **£327,500** | **£846,335** |

* Due to data on current practice being available, sensitivity analysis has not been provided; therefore these figures are the same as those for the base case.

**Table A10: Annual costs and resource impact of imaging surveillance recommendations for women with no personal history of breast cancer, when current activity levels are 30% (base case 10%)**

| Imaging surveillance | Women with no personal history of breast cancer | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of mammograms | | | | | Number of MRIs | | | | | Net cost impact of recommendations |
| NHS board | Current | Cost | Future | Cost | Net cost impact | Current | Cost | Future | Cost | Net cost impact | |
| NHS Ayrshire and Arran | 54 | £2,862 | 514 | £27,242 | £24,380 | 0 | £0 | 38 | £9,500 | £9,500 | £33,880 |
| NHS Borders | 16 | £848 | 168 | £8,904 | £8,056 | 0 | £0 | 14 | £3,500 | £3,500 | £11,556 |
| NHS Dumfries and Galloway | 21 | £1,113 | 218 | £11,554 | £10,441 | 0 | £0 | 17 | £4,250 | £4,250 | £14,691 |
| NHS Fife | 50 | £2,650 | 485 | £25,705 | £23,055 | 0 | £0 | 33 | £8,250 | £8,250 | £31,305 |
| NHS Forth Valley | 40 | £2,120 | 407 | £21,571 | £19,451 | 0 | £0 | 32 | £8,000 | £8,000 | £27,451 |
| NHS Grampian | 101 | £5,353 | 815 | £43,195 | £37,842 | 2 | £500 | 56 | £14,000 | £13,500 | £51,342 |
| NHS Greater Glasgow and Clyde | 138 | £7,314 | 1,287 | £68,211 | £60,897 | 4 | £1,000 | 76 | £19,000 | £18,000 | £78,897 |
| NHS Highland* | 117 | £6,201 | 727 | £38,531 | £32,330 | 0 | £0 | 29 | £7,250 | £7,250 | £39,580 |
| NHS Lanarkshire | 81 | £4,293 | 773 | £40,969 | £36,676 | 2 | £500 | 51 | £12,750 | £12,250 | £48,926 |
| NHS Lothian | 111 | £5,883 | 1,034 | £54,802 | £48,919 | 2 | £500 | 66 | £16,500 | £16,000 | £64,919 |
| NHS Orkney | 2 | £106 | 45 | £2,385 | £2,279 | 0 | £0 | 12 | £3,000 | £3,000 | £5,279 |
| NHS Shetland | 2 | £106 | 45 | £2,385 | £2,279 | 0 | £0 | 12 | £3,000 | £3,000 | £5,279 |
| NHS Tayside | 318 | £16,833 | 1,554 | £82,362 | £65,529 | 5 | £1,250 | 103 | £25,750 | £24,500 | £90,029 |
| NHS Western Isles | 2 | £106 | 48 | £2,544 | £2,438 | 0 | £0 | 12 | £3,000 | £3,000 | £5,438 |
| **Scotland** | **1,053** | **£55,788** | **8,120** | **£430,360** | **£374,572** | **15** | **£3,750** | **551** | **£137,750** | **£134,000** | **£508,572** |

* Due to data on current practice being available, sensitivity analysis has not been provided; therefore these figures are the same as those for the base case.

**Table A11: Annual costs and resource impact of imaging surveillance recommendations for women with a personal and family history of breast cancer, when current activity levels are 30% (base case 10%)**

| Imaging surveillance | Women with a personal and family history of breast cancer | | | | |
|---|---|---|---|---|---|
| | Number of MRIs | | | | |
| **NHS board** | **Current** | **Cost** | **Future** | **Cost** | **Net cost impact** |
| NHS Ayrshire and Arran | 6 | £1,500 | 95 | £23,750 | £22,250 |
| NHS Borders | 1 | £250 | 29 | £7,250 | £7,000 |
| NHS Dumfries and Galloway | 2 | £500 | 38 | £9,500 | £9,000 |
| NHS Fife | 6 | £1,500 | 90 | £22,500 | £21,000 |
| NHS Forth Valley | 5 | £1,250 | 81 | £20,250 | £19,000 |
| NHS Grampian | 9 | £2,250 | 138 | £34,500 | £32,250 |
| NHS Greater Glasgow and Clyde | 24 | £6,000 | 356 | £89,000 | £83,000 |
| NHS Highland* | 5 | £1,250 | 81 | £20,250 | £19,000 |
| NHS Lanarkshire | 9 | £2,250 | 148 | £37,000 | £34,750 |
| NHS Lothian | 13 | £3,250 | 209 | £52,250 | £49,000 |
| NHS Orkney | 0 | £0 | 8 | £2,000 | £2,000 |
| NHS Shetland | 0 | £0 | 8 | £2,000 | £2,000 |
| NHS Tayside | 3 | £750 | 47 | £11,750 | £11,000 |
| NHS Western Isles | 0 | £0 | 8 | £2,000 | £2,000 |
| **Scotland** | **83** | **£20,750** | **1,336** | **£334,000** | **£313,250** |

* Due to data on current practice being available, sensitivity analysis has not been provided; therefore these figures are the same as those for the base case.

**Table A12: Annual costs and resource impact of implementing the imaging surveillance recommendations in Scotland, when current activity levels are 30% (base case 10%)**

| NHS board | Women with no personal history of breast cancer | Women with a personal and family history of breast cancer | Net cost impact |
|---|---|---|---|
| NHS Ayrshire and Arran | £33,880 | £22,250 | **£56,130** |
| NHS Borders | £11,556 | £7,000 | **£18,556** |
| NHS Dumfries and Galloway | £14,691 | £9,000 | **£23,691** |
| NHS Fife | £31,305 | £21,000 | **£52,305** |
| NHS Forth Valley | £27,451 | £19,000 | **£46,451** |
| NHS Grampian | £51,342 | £32,250 | **£83,592** |
| NHS Greater Glasgow and Clyde | £78,897 | £83,000 | **£161,897** |
| NHS Highland* | £39,580 | £19,000 | **£58,580** |
| NHS Lanarkshire | £48,926 | £34,750 | **£83,676** |
| NHS Lothian | £64,919 | £49,000 | **£113,919** |
| NHS Orkney | £5,279 | £2,000 | **£7,279** |
| NHS Shetland | £5,279 | £2,000 | **£7,279** |
| NHS Tayside | £90,029 | £11,000 | **£101,029** |
| NHS Western Isles | £5,438 | £2,000 | **£7,438** |
| **Scotland** | **£508,572** | **£313,250** | **£821,822** |

* Due to data on current practice being available, sensitivity analysis has not been provided; therefore these figures are the same as those for the base case.

**Appendix 5B: Key assumptions and unit costs**

**Table A13: Key assumptions**

| Assumptions | Value | Source |
|---|---|---|
| **Genetic testing** | | |
| Proportion of women eligible for genetic testing (with no available relative to test) | 27% | NHS Greater Glasgow and Clyde |
| Uptake | 48% | NICE Familial breast cancer costing report |
| Proportion of women currently offered genetic testing | 1.3% | NHS Greater Glasgow and Clyde |
| Proportion of women not currently offered genetic testing | 98.7% | |
| **Imaging surveillance** | | |
| Current test frequency for women aged 50–59 years | 67% | |
| Percentage of women at high risk with a ≤30% probability of being a BRCA carrier (women at high risk) | 39.92% | Ninewells Hospital Dundee |
| Percentage of women untested but >30% probability of being a BRCA carrier (women at high risk) | 1.98% | Ninewells Hospital Dundee |
| Estimated proportion of women with a dense breast pattern | 25% | NHS Tayside |
| Percentage of women who are BRCA1/2 carriers | 7.65% | Ninewells Hospital Dundee |
| Current number of women offered annual mammographic surveillance | 10% | |
| Current number of women offered annual MRI | 10% | |
| **Chemoprevention** | | |
| Estimated percentage who take up chemoprevention | 25% | NICE |
| Proportion who stop chemoprevention after 1 year | 40% | NICE Familial breast cancer costing report |
| Proportion who receive chemoprevention for 5 years | 60% | NICE Familial breast cancer costing report |
| Annual increase in the number of women offered tamoxifen | 3% | NHS Tayside |

**Table A14: Unit costs**

| **Genetic testing** | | | |
|---|---|---|---|
| | **Unit cost £** | **Number of tests or sessions** | **Cost £** |
| Laboratory cost | £700 | 1 | £700 |
| Counselling cost per hour | £125 | 2 | £250 |
| **Total** | | | **£950** |

| **Surveillance tests** | |
|---|---|
| | **Unit cost £** |
| Digital mammography | £53 |
| MRI, Payment by results 2013-14 tariff, HRG code RA05Z | £250 |

| **Chemoprevention** | | |
|---|---|---|
| | **Annual cost £** | **5-year cost £** |
| Tamoxifen (electronic drug tariff) 20 mg daily - £2.91 for 30-tablet pack<br>20 mg daily – £2.91 for 30-tablet pack | £36 | £180 |

| **Monitoring visits to GP or clinic** | **Unit cost £** | **Visits** | **Annual cost £** |
|---|---|---|---|
| Number of visits per year (6 monthly for prescription) | £40 | 2 | £80 |
| 5-year cost | | | £400 |

Healthcare Improvement Scotland

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