

| Protocol for Referral into the Very High Risk Breast Surveillance Screening Programme in Northern Ireland | |
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| Doc. Ref. No: | Version: 1.0 |
| Author: Dr Catherine Bane | Status: Final |
| Date: 1 December 2021 | Review date: 2 years |

1. Introduction

This document describes the process for referral of women at very high risk of developing breast cancer into the Very High Risk Breast Surveillance Screening Programme (hereafter referred to as the VHR Screening Programme).

Surveillance screening for women at (x8+) risk of developing breast cancer was introduced in Northern Ireland (NI) in 2013. Women in the programme are offered digital X-ray mammography and/or magnetic resonance imaging (MRI) according to protocols published by Public Health England and adopted in NI (see Paragraph 2) and in line with VHR Breast Surveillance Screening Work Instructions and Operational Policy, NHSCT¹.

The service is provided regionally at Antrim Area Hospital, although for women who require mammography screening only, it may be possible to arrange this at their local breast screening unit.

2. Surveillance Protocols & Standards

The VHR Screening Programme in Northern Ireland closely follows protocols and standards published by the NHS Breast Screening Programme/Public Health England in relation to the English VHR Screening Programme.

Protocols for surveillance screening of women at higher risk of developing breast cancer were originally published in 2013². [Updated protocols](#) were published by Public Health England on 8th September 2020. The revised protocols were agreed (with some caveats³) by the NI Co-ordinating Group for the VHR Programme at their

¹ updated January 2021

² Protocols for the surveillance of women at higher risk of developing breast cancer – Version 4 (NHSBSP Publication 74) – originally published in 2013. No longer available.

³ Caveats related to minor deviations in programme management eg: management of women who are breastfeeding; ceasing women post-surgery (NI do not require an opt-out form to be completed as clinicians can view surgery information on NIECR); and also some manual work-arounds in management of the programme as NI does not have BS Select. It is hoped NI will have BS Select by June 2022.

meeting on 2 September 2020, and implemented in NI from October 2020. In line with the 2020 protocols, the programme title was changed from 'The *Higher Risk Breast Surveillance Screening Programme*' to the 'The *Very High Risk Breast Surveillance Screening Programme*'. The title change does not confer any increase in cancer risk for eligible women.

Revised [NHS Breast Screening Programme screening standards](#) were published on 31 March 2021. Five of the standards apply to data collected for the VHR Screening Programme from 1 April 2021.

NICE Guidelines

The [NICE familial breast cancer guidelines](#) categorise women at increased risk of breast cancer as *moderate* or *high*. Only a subset of those defined by NICE as being at *high risk* reach the *very high risk* group threshold used in the NHS BSP. This has previously been set at 8 times the relative risk of women in the general population.

To differentiate between the NICE and NHS BSP guidance, *very high risk* is defined by the NHS BSP as:

- women with a lifetime risk of 40% or greater due to a specific genetic abnormality in the woman or her family
- those receiving radiotherapy to breast tissue during treatment for Hodgkin and non-Hodgkin lymphoma between the ages of 10 and <30 years
- a small number of women who received radiotherapy to breast tissue during treatment for cancers other than lymphoma

Women categorised by the NICE Guidelines as at *moderate* or *high risk* of developing breast cancer, but who do not meet the criteria for the VHR Programme are managed by secondary care (Genetics and Family History Service) in accordance with the NICE Clinical Guideline [\[CG164\]](#).

3. Identification of Eligible Women

An exercise was carried out during the establishment of the VHR Screening Programme in NI in 2013/14 to identify the prevalent pool of women at higher risk of breast cancer (and also any incident cases arising during the year). This involved the Public Health Agency, the Business Services Organisation, the Health & Social Care Trusts, the Regional Medical Genetics Service, the Regional Oncology Service, the Northern Ireland Cancer Registry, Primary Care and the School of Cancer Services in Birmingham. Approximately 300 women were identified for inclusion the programme and invited for surveillance screening. The current figure of annually invited eligible women in NI is 477 (2019/20 programme data).

4. Referring Clinicians

Referrals to the programme may be made by one of the following:

- a consultant breast surgeon
- a genetic consultant or genetic counsellor
- an oncologist
- a family history clinician
- a recognised non-medical referrer

Direct referrals from GPs are not accepted. If primary care clinicians are aware of women who may be eligible, they should refer them to the local Family History Clinic.

Consultant Breast Surgeons

Consultant Breast Surgeons should ensure that a family history is taken from all patients presenting in secondary care with breast symptoms or who have concerns about relatives with breast cancer, in accordance with the NICE guideline.⁴ Women should be referred to the Regional Genetics Service as described in this guideline.

Consultant breast surgeons should refer any women known to be at very high risk, who are not already in the VHR Screening Programme. Those awaiting prophylactic bilateral mastectomy should also be referred, given potential long waiting time for surgery.

Regional Genetics Service

Women who are newly identified by the Regional Genetics Service as having a proven germline pathogenic (or likely pathogenic) variant in one of the following should be referred to the VHR Screening Programme at the time of diagnosis – irrespective of their age:

- BRCA1
- BRCA2
- PALB2
- PTEN
- STK11
- CDH1 (E-Cadherin)
- TP53 (Li-Fraumeni Syndrome)
- ATM c.7271T>G (V2424G) variant
- ATM (A-T) homozygotes
- Or another genetic mutation with a similar level of risk
- Or who are not tested but at equivalent very high risk (up to and including the age of 50)

⁴ <https://www.nice.org.uk/guidance/cg164>

If a woman has not been tested, but has a first degree relative with a germline BRCA1, BRCA2 or TP53 pathogenic (or likely pathogenic) variant, she has a 50% chance of carrying this variant. As a result, she will be eligible for VHR screening up to and including the age of 50 (after which she will be returned to the routine Breast Screening Programme). Women in this category under age 50 should be referred by the Family History Clinic to the Regional Genetics Service to confirm their risk.

Regional Clinical Oncology Service

Women who have been treated with radiotherapy for lymphoma to sites involving breast tissue between the ages of 10 and 29 years should be referred by a consultant clinical oncologist to the VHR Surveillance Screening Programme at the time of diagnosis – irrespective of age.

Family History Clinics

Family history clinicians should refer any women known to be at very high risk, who are not already in the VHR Screening Programme e.g. women who were diagnosed outside NI; women who had supradiaphragmatic radiotherapy outside NI and prevalent cases not identified during the exercise in 2013/14.

Women who have not been tested, but have a first degree relative with a germline BRCA1, BRCA2 or TP53 pathogenic variant, have a 50% chance of carrying this variant and should be referred to the Regional Genetics Service, on the understanding that it is to confirm that the familial variant meets criteria for pathogenicity (or likely pathogenicity) and to facilitate onward referral to VHR screening. Please note the individuals are under no obligation to undergo predictive testing.

5. Referral Process

Referring clinicians should request a referral form (Annex A) by emailing the following address: VeryHighRiskBreastScreening@northerntrust.hscni.net. Referral forms should be fully completed and returned to the same email address. Referrals are reviewed by the Lead Consultant Radiologist (or one of the appointed deputies) and managed according to NHSCT Operational Policy, supplemented by multiple work instruction documents which are available on the shared drive at Antrim Area Hospital Breast Screening Unit.

Contact Details for the VHR Breast Screening Unit at Antrim Hospital

Telephone: 028 9442 4426

Email: VeryHighRiskBreastScreening@northerntrust.hscni.net

DOCUMENT CONTROL

Document Location

The source document is held in electronic form in the YPAST shared drive Q:\Cancer SP\General\YPAST Protocols\Breast.

Approvals

Contents Approved By

Name – Dr Adrian Mairs
(obo the Co-ordinating Group for the VHR Programme)

Signature



Date - 1 December 2021

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Related Documents

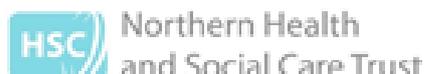
| Title | Date | Location | Author | Description |
|---|--------------------------------|---|-----------------------|--|
| Protocols for surveillance of women at very high risk of developing breast cancer | 08/09/20 (Updated 26/07/21) | https://www.gov.uk/government/publications/breast-screening-higher-risk-women-surveillance-protocols/protocols-for-surveillance-of-women-at-higher-risk-of-developing-breast-cancer | Public Health England | Guidance aimed at BSP providers, commissioner, organisations and individuals who refer women into the VHR programme. |

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| NHS Breast Screening Programme screening standards valid for data collected from 1 April 2021 | Updated 31/03/21 | https://www.gov.uk/government/publications/breast-screening-consolidated-programme-standards/nhs-breast-screening-programme-screening-standards-valid-for-data-collected-from-1-april-2021 | Public Health England | Screening standards for the NHS breast screening programme (BSP). |
| Breast screening: using MRI with higher risk women | 01/12/12 | https://www.gov.uk/government/publications/nhs-breast-screening-using-mri-with-higher-risk-women | Public Health England | Technical guidelines for healthcare professionals screening women at a higher risk of developing breast cancer. |
| Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer | 25/06/13 (Last updated: 20/11/19) | https://www.nice.org.uk/guidance/cg164 | National Institute for Health & Care Excellence | This guideline covers care for people with a family history of breast, ovarian or another related (prostate or pancreatic) cancer. |

Revision History / Document History

| Date | Version | Author | Description of Change |
|------|---------|--------|-----------------------|
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Annex A – Referral Form



Referral / Notification of Very High Risk Patient

| Patients Details | | | | |
|---|---------------------------------|---------------------------|--|---------------------------|
| Name: | Click here to enter text. | | Health & Care No: | Click here to enter text. |
| Address: | Click here to enter text. | | Date of Birth: | Click here to enter text. |
| | | | Tel Home: | Click here to enter text. |
| Postcode: | | | Tel Mobile: | Click here to enter text. |
| Referrer / Notifier | | GP Details | | |
| Title: | Click here to enter text. | | Name: | Click here to enter text. |
| Name: | Click here to enter text. | | Practice: | Click here to enter text. |
| Address: | Click here to enter text. | | Address: | Click here to enter text. |
| | | | Postcode: | |
| Postcode: | | | Previous Screening | |
| Select one of the following: | Consultant Breast Surgeon | <input type="checkbox"/> | Previous MRI/ Mammogram Date & Location | Click here to enter text. |
| | Genetic Consultant | <input type="checkbox"/> | Any other Relevant Information | |
| | Genetic Counsellor | <input type="checkbox"/> | Any Other Relevant Information | Click here to enter text. |
| | Oncologist | <input type="checkbox"/> | | |
| | Family History Clinician | <input type="checkbox"/> | | |
| | Recognised Non Medical Referrer | <input type="checkbox"/> | | |
| Familial Breast Clinic: | Referral Made | <input type="checkbox"/> | Clinic Location | Click here to enter text. |
| | Already Attending | <input type="checkbox"/> | | |
| Risk (Please Tick) | | | | |
| BRCA 1 | <input type="checkbox"/> | | TP53 (Li-Fraumeni) | <input type="checkbox"/> |
| BRCA 2 | <input type="checkbox"/> | | A-T HOMOZYGOTE | <input type="checkbox"/> |
| BRCA Not Tested | <input type="checkbox"/> | | A-T HETEROZYGOTE | <input type="checkbox"/> |
| BRCA Risk Equivalent Please State: | <input type="checkbox"/> | | Supradiaphragmatic Radiotherapy: Age 10 – 30 (Please state patient's age at time of treatment) | <input type="checkbox"/> |
| | | Click here to enter text. | | |
| PALB2 | <input type="checkbox"/> | | Any Other Relevant information | <input type="checkbox"/> |
| PTEN | <input type="checkbox"/> | | | |
| STK11 | <input type="checkbox"/> | | | |
| CDH1(E-Cadherin) | <input type="checkbox"/> | | | |
| To Be completed by BSU | | | | |
| Referral Accepted for Very High Risk Screening <input type="checkbox"/> | | | Other: Click here to enter text. | |
| Referral Rejected for Very High Risk Screening <input type="checkbox"/> | | | | |
| Radiologist Name: Click here to enter text. | | | Signature: | |
| Date: | Click here to enter text. | | | |

Email Address: VeryHighRiskBreastScreening@northerntrust.hsc.ni.net