Meeting of the Breast Cancer Clinical Advisory Group

Tuesday 7th March 2023, 15:30-17:00 via MS Teams

REPORT

Chair: Professor Mark Beresford

NOTES **ACTIONS**

1. Introductions and review of last meeting's notes and actions

Please see the list of attendees and apologies available on the SWAG website here.

There was noted to be a good mix of multi-disciplinary team members plus patient representatives in attendance from across the region.

Breast CAG meet once a year face to face, normally in the Autumn, and have a shorter interim catch up via MS teams, as is the format of the meeting today.

Actions from the previous report are on the agenda.

As there were no amendments requested to the previous report from Tuesday 20th September 2022, the report was accepted as finalised.

2. Clinical Guidelines

Genomic Medicine Service Alliance (GMSA) Update

Presented by Associate Director of Nursing and Midwifery T Miles

The South West GMSA have many positive initiatives underway, including a digital patient empowerment project. This involves production of an information animation that will inform breast cancer patients about the genetic test bundle currently available via the National Genomic Test Directory (and therefore funded by NHSE) which currently includes BRCA 1,2 and 5 other gene alterations.

It will be possible to view the animation in different sections depending on if it is prescribed in Primary or Secondary care. It will bolt on to different Trusts digital platforms to make it possible to counsel and consent patients using the animation, which should be available to share by May 2023.

To further achieve mainstreaming of genomics, counselling and consent training will be provided for every Surgeon, Oncologist and CNS so that BRCA / other gene alteration status is confirmed as early on as possible in the treatment pathway.

All of the surgeons in RUH are routinely counselling and consenting; the CNS team will be trained next.

A peer network will be created for the regional CNS team who are ultimately best placed to provide the counselling/consenting. Backfill of workforce will be required which is currently being negotiated with the Lead Cancer Nurses.

There are a number of CNSs from RUH, NBT and GRH already registered on an upcoming free two-day training course in Bristol, with presentations from Professor Dame Lesley Fallowfield who is an expert in cancer psychology.

Please email any queries about breast cancer and genomics to T Miles: tracy.miles@nhs.net

Eligibility criteria is for any patient under the age of 40, and triple negative under the age of 60.

It is anticipated that additional gene alterations will be added in the near future.

Action: GMSA team will circulate any updates made to the National Genomic Test Directory via H Dunderdale **GMSA Team**

Discussion:

In centres where mainstreaming is already taking place, it has been found that separate requests were required to test for each gene alteration.

This has now been resolved, as all will be included in the one request form, which is also more efficient for the laboratory.

3. Coordination of patient referral pathways

3.1 Breast Pain Referral Pathways in YDH

Presented by Consultant Breast Surgeon C Osborne

YDH is shortly due to merge with SFT.

Over the last 10 years, One Stop Clinics (OSC) have grown by 100% across the nation; breast cancer diagnoses have risen by 14%. By the end of the COVID-19 pandemic, 51% of breast units were failing to see patients within the two week wait target.

Of those attending the clinic, 20-40% of attendees present with breast pain only. This is closer to 20% in YDH. The incidence of breast cancer in women with breast pain and no other symptoms is 0.4%, which is on a par with the breast cancer screening rate of 0.8%; these facts should shape the way that breast pain is managed.

NICE state that breast pain alone is not a symptom of cancer and should not be referred on an urgent cancer referral pathway.

Breast pain clinics are required however, as these women need to be assessed and managed by experienced clinicians who can address the patients' concerns, whereas OSC are to diagnose cancers, referral to which can lead to anxiety, unnecessary imaging, and influence patients' expectations as they may expect a full imaging workup.

Approximately 30% of women with breast pain also have a family history of breast cancer, which may heighten anxiety about the symptom and lead to them seeking advice.

Often, the opportunity to address family history and other breast cancer risk factors are missed in OSC due to the associated time pressures.

In response, a quality improvement project was commenced to set up a breast pain clinic in YDH.

Advice was given to referrers in Primary Care to emphasise that this service was for breast pain only and no other symptoms, and to manage patients' expectations that this was not a suspected cancer two week wait referral.

Additional funding was not required as the recent expansion of clinic spots had left some capacity once the rebound of referrals post-COVID had been managed.

The clinic has been Consultant led, but it is planned to train a specialty doctor and there are Advanced Clinical Practitioners who may also take on the role.

Appropriate paperwork has been designed and reviewed by the MDT.

Appointments are 30 minutes long and include the following:

- Detailed history of the pain
- Medical history
- Menstrual history
- Family history risk assessment using the Qgenome app
- Review of other breast cancer risk factors
- An examination
- Advice on managing symptoms.

A proforma has been developed to collect all of the information, as seen in the presentation.

Outputs may include onward referral to family history clinic if indicated after the risk assessment. Referral for breast imaging only occurs if any red flag signs

emerge. Information on managing breast pain is given, which has a link to a video, as is a personalised summary of the consultation.

There is capacity to see up to 200 patients per annum in 5 clinic slots per week. This frees up capacity within the one stop system.

A telephone follow up call to assess the outcomes of any interventions is undertaken 4 weeks later, during which an outcome questionnaire is provided which is collected electronically. All patient records will be reviewed after one year to see if any subsequent cancer diagnoses has occurred or any re-referrals made. Administrative support is available to assist with this as it is a registered quality improvement project.

The project is registered with ASPIRE, a multicentre platform study to evaluate the breast pain pathways which will launch on Wednesday 22nd March 2023.

There have been 39 consultations to date, details of which are within the presentation. Imaging was only arranged for 2 cases, 1 of which was a benign abnormality and 1 to treat anxiety.

At follow up, 74% said that the pain had improved, of which 45% was due to bra fitting, 23% said the pain had gone and 3% said the pain was the same.

Patient Reported Outcomes were overall very positive.

Feedback will be presented to Primary Care and the clinic will continue to be reviewed and adjusted to meet demand.

Discussion:

It is a time intensive service, given that three OSC appointments would be seen in the same time slot, but it is hoped that it will stop referrals from re-presenting, given that the OSC does not meet the needs of these patients.

The service could be delivered in Primary Care, but it would appear that this is no longer happening due to the number of breast pain referrals now sent via the two week wait pathway.

It could be possible to get an interested GP to provide the service.

There has been resistance to set up dedicated breast pain clinics in some of the other centres.

With 12.9% of referrals being made to the family history clinic, the impact on genetic services was questioned. The clinic staff in Taunton had recently expressed concerns about not receiving enough referrals from the Yeovil area. It

is thought that referrals that would have previously been made by Primary Care are now going to be made by the breast pain clinic.

The vast majority of referrals have chest wall or muscular pain.

The benefits from avoiding imaging 37 patients, who would have otherwise gone through the standard OSC process, were highlighted.

Breast Unit Teams are welcome to contact C Osborne for any further information.

4. Service Developments

4.1 NICE Technical Appraisal (TA) update

Presented by M Beresford

Breast CAG plan to have a regular update on the impact of new TA approvals at every meeting; the impact of Abemaciclib on clinic slots was discussed at length in September 2022. Since then, another 3 breast cancer drugs have been approved:

- Alpelisib, is a PI3 Kinase inhibitor approved around September 2022, is placed after CDK46 inhibitor for all patients on palbociclib, abemaciclib and ribociclib who progress that have the PI3 mutation, which is about a third to half of these patients. It is an oral treatment, so the impact on clinics will not be great, as these patients will be receiving chemotherapy as well, but the main toxicity cause is hypoglycaemia, which is a new and complex side effect to manage

- Neoadjuvant pembrolizumab for triple negative cancer was approved in December 2022. Consultant Oncologist T Strawson-Smith is undertaking a national audit of outcomes and implementation of the drug. These patients will be receiving chemotherapy and the immunotherapy will be added alongside it. It improves response rate from 50% to 64%. If well tolerated, it is also given in the adjuvant setting for 9 cycles. This results in a more complicated consent process, longer infusion rates in the neoadjuvant setting, and 9 additional chemotherapy day bed slots required in the adjuvant setting, plus extra toxicity management by the AOS service. When the patient's liver function is affected, it is difficult to know if this is due to the disease, chemotherapy or immunotherapy, each of which would be managed differently. This results in a complex process, requiring an MRI and bloods and multiple different adjustments

- Trastuzumab deruxtecan was approved in the second line setting rather than just the third for HER2 positive disease. Although this has been shown to be more effective that the current second line treatment, there are far more toxicities to manage.

These additional approvals have further stretched the resources of the already stretched oncological services in the 6 months since the last meeting.

Discussion:

Thirty two centres are providing data to the Neoadjuvant pembrolizumab audit, the protocol is in the process of being finalised.

An application for funding from the NIHR has been made by the BHOC for a trial to remove the adjuvant pembrolizumab cycle for those who have had a complete response. The number of participants required is approximately 2,500 and so collaboration with centres in France and other European countries will be essential to prove non-inferiority; results should hopefully free up some day bed slots.

5. Clinical opinion on network issues

5.1 Pan-Alliance Breast Cancer Group update

Presented by M Beresford

The Pan-Alliance Breast Cancer Collaboration has been formed in recognition of the current and projected problems that oncology services are facing. A number of meetings have been held, initially coordinated by Liverpool. The group now includes breast cancer clinical experts and managerial representatives from all Alliances plus from the charity Breast Cancer Now.

A document has been produced for the purpose of escalating the difficulties with providing treatment to the increasing number of metastatic or advanced patients with limited resources, to various people in Government. It is recognition that there are no easy answers, but it does need to be recognised on the Government's agenda.

Discussions have taken place with NICE to ask that they undertake service impact assessments as part of the NICE TA approval process. Attempts are made to assess this by local centres, which is difficult with limited resources. It would make more sense if this could be organised to look at the national impact, then centres could divide results by the local population served, assess the number of clinic slots etc. required, and easily create a business case for additional resources.

6. Patient experience

6.1 Presented by Patient Representative J Chambers

A SWAG Patient Community has recently been established to bring together all SWAG Patient Representatives from each of the CAG meetings, Cancer Alliance Working Groups and Charity / Community Groups to make sure that there is as wide a representation of patient voices as possible. This will aim to improve the contributions that representatives can make, rather than just providing individual experiences. A number of different projects are going to be undertaken by the group.

Breast CAG can contact the group via H Dunderdale if any help is needed to co-produce patient information.

7. Quality indicators, audits and data collection

7.1 National Cancer Treatment Variations Project

The Cancer Alliance have asked Breast CAG to respond to the request from National Treatment Variation Team who have stated that 'breast cancer surgical teams should examine their reoperation rates after breast conservation surgery to identify areas where reoperation rates can be reduced, whilst supporting safe breast conservation'.

This is based on data sourced from the National Audit of Breast Cancer in Older Patients (2022) collected between 2014-2019, with data completeness that is said to be variable.

Feedback from RUH:

A national margin re-excision audit, run by St. Georges, is underway to look at margins in detail. It is thought that most centres will be involved.

RUH have an ongoing prospective audit for all re-excisions which has been undertaken since 2017 and is discussed on a biannual basis.

Feedback from YDH:

- Reoperation rates are looked at on a monthly basis as per previous Peer Review guidelines.

Information gathered prior to the meeting:

Feedback from NBT:

Reoperation rates are routinely examined with the following factors considered in addition to margins:

- Cosmesis
- Weights of samples removed
- Grade of surgeon (SpR vs Consultant)
- Mode of localisation
- Degree of calc on MMG vs actual microscopic size of DCIS
- Oncoplastic procedure vs standard wle
- What is an acceptable margin (no cancer at the inked edge, vs 1mm vs 2mm) etc.

Feedback from SFT:

- Excision data is collated every year as SFT are always outliers within screening.
- Margins of 2mm are accepted on DCIS and 1mm on invasive disease
- SFT have investigated at length how to improve this; nothing has been identified-for last 14 years.

Reasons:

Uncalcified DCIS so not seen on preoperative imaging
Cancers bigger than identified on preoperative imaging – do not have resources to MRI every single breast cancer patient pre operatively when there is no disconcordance or standard imaging clear cut**.**

Breast CAG therefore already comply with the request from the National Treatment Variation Team. Centres are encouraged to participate in the national re-excision audit.

Breast Cancer Response to Treatment Variation

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8. Research

8.1 Clinical Research Network update

Please see the presentation and Excel spreadsheet of open trials and trials in set up uploaded to the SWAG website

Presented by C Matthews

Research Delivery Manager C Matthews manages the cancer portfolio for West of England CRN.

National clinical trial recruitment from April 2022- March 2023 shows that recruitment to breast cancer trials has doubled in comparison with 2021/22. A comparison between national and regional recruitment levels shows this reflected across the SWAG region. Everyone involved was thanked for their efforts in increasing research activity.

The Question 58 in the National Cancer Patient Experience Survey 'Cancer research opportunities were discussed with the patient' scored below average across SWAG (42%) in comparison with the national average. Breast CAG are asked how to increase conversations about research.

42% was considered quite high when thinking about the number of patients who are eligible for trials.

Patient Representative feedback is to let the patient know that research trials have been considered, even if the outcome is that there is no eligible trial available.

The way a trial is promoted also needs to be considered; a trial previously offered to Patient Representative J Chambers at an earlier stage in the treatment pathway had been rejected due to the quality of the patient information leaflet.

An NIHR 6-month Associate Principal Investigator (PI) role is open to any interested clinician who doesn't have research in their current role. It allows associates to work alongside current PIs on studies (as documented in the presentation) signed up to the scheme.

An Associate PI, who is a Consultant Radiographer, has been appointed in YDH to focus on the ATNEC study.

SFT have appointed an Associate PI to assist with SMR.

Any PI interested in getting help from an associate while helping their personal development is to get in touch.

NIHR website links and team contact details are available within the presentation.

Discussion:

There are ongoing issues with capturing all the trials open across the region.

There are a number of trials open that will support patients to travel to other centres by helping with travel expenses and childcare costs.

Further information on the trials available across the region needs to be shared to enable cross-referrals. Consultant Oncologist R Bowen manages this for Gynae by updating the list of trials directly from investigators.

Action: To send H Dunderdale contact details for research updates

Date of next meeting: A Doodle Poll will be circulated to find the next optimal date in Autumn/Winter.

Consultant Oncologists