

Clinical Management of Breast Cancer in NHS Tayside

April 2019

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Published April 2019

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1 Introduction

Regional cancer governance arrangements in Scotland are outlined within MEL 10 (1999)¹. The regional networks contain a number of tumour-specific networks which seek to align evidence-based practice and co-ordinate service delivery and improvement. In order to achieve alignment of practice across a region, clinical management guidelines (CMGs) are developed, which all clinicians within a network agree to follow. CMGs are adopted by the constituent NHS boards within the region.

National guidance for the safe delivery of Systemic Anti-Cancer Therapy (SACT) is set out in CEL 30 (2012)². This includes standards on the clinical governance arrangements for SACT. It states that CMGs are developed and approved by the appropriate disease specific Managed Clinical Network (MCN) and local or regional governance arrangements.

The guidance defines a CMG as a multi-professional document which promotes multi-professional provision of high quality care by detailing appropriate management through all stages of the patient journey including SACT and supportive treatments. CMGs outline best practice and may include a range of agreed treatment options where the evidence supports this.

There are three cancer networks operating across NHSScotland:

- North of Scotland Cancer Network (NOSCAN) made up of five NHS board areas - NHS Highland, NHS Grampian, NHS Tayside, NHS Orkney, NHS Western Isles and NHS Shetland
- West of Scotland Cancer Network (WoSCAN) which includes NHS Greater Glasgow and Clyde, NHS Lanarkshire, NHS Forth Valley and NHS Ayrshire & Arran, and
- South of Scotland Cancer Network (SCAN) which includes NHS Lothian, NHS Borders, NHS Dumfries & Galloway and NHS Fife.

NOSCAN covers three cancer centres whilst the other two networks operate with one cancer centre each.

In June 2017, Healthcare Improvement Scotland published a national external review of progress in NHSScotland with the implementation of national standards to support the safe delivery of SACT³.

The review demonstrated that NHS boards and regional cancer networks have systems in place to support the safe delivery of SACT services, however some areas for improvement were identified and recommendations made³. This included urgent work by NOSCAN and its constituent NHS boards to develop and agree CMGs. Progress against these recommendations has been evidenced through Healthcare Improvement Scotland's monitoring process.

In July 2018, the Chief Medical Officer (CMO) for Scotland and the Chief Pharmaceutical Officer (CPO) for Scotland asked Healthcare Improvement Scotland to carry out fact finding work in relation to the lack of consensus on the clinical management of breast cancer in NOSCAN, specifically around current practice for the use of SACT in the adjuvant and neo-adjuvant setting and the use of Oncotype DX testing.

2 Background

In May 2017, NHS Tayside contacted Healthcare Improvement Scotland about a whistleblowing case the NHS board was managing internally. The individual who raised the concerns remained dissatisfied with the outcome of the local process and continued to pursue their concerns within the organisation. Whilst NHS Tayside asked Healthcare Improvement Scotland to investigate the appropriateness of the whistleblowing process the NHS board had followed, our organisational remit, under the Public Interest Disclosure Act (PIDA), is to seek assurance around any potential quality of care concerns that are raised. This was the focus of Healthcare Improvement Scotland's work at that time.

The outcome of the Healthcare Improvement Scotland PIDA work included a recommendation that NHS Tayside *"...should hold wider discussions to gain agreement and provide assurances that changes to standard practice are supported and due process, which would be in line with national standards CEL30 (2012), is in place and followed."* In the 5 months since the recommendation was made, an agreement within NOSCAN had still not been reached which prompted this further work at the request of the CMO and CPO.

Initially, Healthcare Improvement Scotland staff met with the NOSCAN lead clinician and network manager in order to gain an understanding about the reported lack of consensus encountered during the development of the CMG within the region. During the meeting it was confirmed that:

- there is a lack of consensus within the region on the adjuvant and neo-adjuvant management of breast cancer, specifically relating to the dosage of the FEC-T regimen
- there is a lack of consensus on the role of Oncotype DX testing in the management of breast cancer
- NHS Tayside's practice was at variance with practice in the other NOSCAN NHS boards, and
- NOSCAN had been asked, but declined, to ratify a draft CMG incorporating this variation in dosage. It was reported by the Breast Cancer Managed Clinical Network (MCN) that an agreement could not be reached by clinicians involved within the network.

A review of the published breast cancer CMGs for WoSCAN and SCAN indicated that NHS Tayside's practice is also at variance with the rest of NHSScotland.

This then led to a small, clinically-led panel visiting NHS Tayside in order to talk with colleagues involved in the development of the CMG and clinical delivery of SACT. Terms of Reference were agreed with Scottish Government and shared with NHS Tayside before the visit (Annex A). The following key information was discussed during the panel visit:

- the decision making and evidence base to support the current approach to the oncological management of breast cancer in the adjuvant and neo-adjuvant setting, specifically the dosages and use of growth factor support in the FEC-T regimen (Annex C)
- use of Oncotype DX testing for patients (Annex C)
- consent of patients for adjuvant and neo-adjuvant treatment
- local quality and safety data available to support current practice
- perspectives about the development of the NOSCAN breast cancer CMG, and

- input into regional governance mechanisms.

The Terms of Reference stated that the fact finding work would not cover:

- cultural and behavioural issues
- team dynamics, and
- multidisciplinary working.

Any issues arising during this fact finding work that could impinge on the quality and safety of care for patients would be considered by the visiting panel and, if appropriate, brought to the immediate attention of NHS Tayside senior management.

3 Summary of key findings and recommendations

NOSCAN has been unable to agree a breast cancer CMG, specifically the FEC-T dosage and the use of Oncotype DX testing because the NHS Tayside breast oncology consultant team has a different opinion from the rest of NOSCAN.

NHS Tayside's practice for FEC-T and the use of Oncotype DX testing is at variance with the other NHS boards that make up NOSCAN, WoSCAN and SCAN.

Current medicines governance structures could support the process of sign-off and implementation of NOSCAN CMGs in NHS Tayside. However, the links between key governance groups and the necessary steps in the NHS Tayside sign-off process are not clear, particularly the formal link with the Area Drug and Therapeutics Committee (ADTC).

NHS Tayside stated that there were no issues identified with the broad approach to consent. However, it appears that NHS Tayside patients are not informed of the difference in practice in relation to other NHS boards within the region and other parts of Scotland.

Recommendations

- A. NOSCAN and all its constituent NHS boards to take account of the findings of this report to complete the implementation of their regional governance processes for cancer CMGs. This should be undertaken **by May 2019** and should include:
 - the engagement and agreement of all NHS boards in NOSCAN to operate regionally and in line with MEL 10 (1999)¹
 - clear structures and processes that define and support the integration of, and linkages between, NHS board and regional medicines governance, and
 - effective multi-professional working in medicines governance, specifically relating to decision making. This should take account of the guidance provided in CEL 30 (2012)².
- B. NOSCAN and all its constituent NHS boards to use the strengthened governance process described above to complete the review, approval and implementation of the NOSCAN breast cancer CMG **by June 2019**. The process should include a robust assessment of the evidence base and national guidance and opportunity for multi-professional peer review and debate.
- C. NHS Tayside to use the strengthened governance processes (recommendations A and B) to confirm appropriate use of Oncotype DX testing by **June 2019**. NOSCAN, if required, should consult with the NHSScotland Molecular Pathology Evaluation Panel (MPEP) if there are still concerns about the evidence base guiding national advice on the use of the test.
- D. Where routine practice is different from that supported by the wider oncology community, patients should be informed of this. This recommendation should be considered and addressed as part of the current national review of consent for SACT led by Healthcare Improvement Scotland.

- E. Although outwith the scope of the fact finding work there appears to be a culture within the team where the multi-professional voice is not being heard. NHS Tayside to consider further work to improve multi-professional team working.

4 Methodology

The purpose of this work was to understand further the situation that currently exists whereby there is no consensus on the clinical management of breast cancer in NOSCAN. In order to do this Healthcare Improvement Scotland convened a panel with external and independent experience, knowledge and skills to undertake a fact finding visit within the parameters of the Terms of Reference. Membership of this panel is included at Annex B. The panel used the following methodology as part of this work.

- Analysis of documentation provided by NOSCAN and NHS Tayside ahead of the visit relating to the issues. This included a large amount of contextual information already available to Healthcare Improvement Scotland through its PIDA work.
- A meeting with the NOSCAN lead clinician and network manager on 29 August 2018 to seek further information and background to this reported lack of consensus.
- A visit to NHS Tayside on 26 October 2018 to meet with key members of staff – this involved a number of structured sessions with invited key staff and an open drop-in session which allowed staff members to attend who had not been formally invited or wanted to attend again.
- A confidential email address to allow NHS Tayside staff to contact Healthcare Improvement Scotland about the issues raised.

The panel spoke with 20 members of NHS Tayside staff during the October visit; an additional member of staff who did not attend the visit provided a written submission. The professional groups included:

- senior medical and pharmacy management
- cancer nurses
- cancer pharmacists
- breast oncologists
- the oncology clinical lead
- the SACT lead clinician
- the breast cancer MCN clinical director, and
- the NOSCAN lead clinician.

After the visit, a survey was conducted which invited the three regional cancer networks to provide details of current prescribing practice in the delivery of SACT for breast cancer in the adjuvant and neo-adjuvant setting.

The panel reviewed the information received and what was heard during the discussions with staff. The panel's findings and recommendations are presented in this report.

5 Key findings

5.1 Clinical management guideline (CMG) development and governance

5.1.1 NOSCAN perspective

The governance process for the development of CMGs in NOSCAN is established but currently under review. In the time period the panel considered, the process in place was that the clinical lead for the disease-specific MCN chairs a CMG group to consider guidance and practice in the context of NOSCAN, for example taking into account local geography. After discussion the CMGs would be brought to final draft with approval from the lead. Thereafter, cancer strategy groups within the six constituent NHS boards would be sent the documents for approval which would allow them to be published and used.

When the panel met with NOSCAN in August 2018 they heard that around 40 CMGs had been developed and approved for publication between June 2017 and August 2018. There were a few outstanding CMGs which were expected to be concluded in the near future however the breast cancer CMG was not yet signed off due to a lack of consensus.

During the development of the breast cancer CMG there was key point of variance in relation to the dosing within the FEC-T regimen where a consensus position could not be reached. NHS Tayside would not endorse the CMG with the higher dose, and clinicians in NHS Grampian and NHS Highland would not endorse it without the higher dose being available. A lack of consensus on the use of Oncotype DX testing was also identified.

NOSCAN shared two drafts of the CMG with Healthcare Improvement Scotland: draft 3 which had been reviewed by breast oncologists at a regional meeting in February 2018, and draft 4 which incorporates comments received on draft 3. At the time of the visit, draft 4 had not been shared with the NOSCAN breast cancer CMG group.

Draft 3 specifies fluorouracil 500mg/m²/epirubicin 75 or 100mg/m²/cyclophosphamide 500 mg/m² followed by docetaxel 80 or 100mg/m². The lower dose of docetaxel is given without G-CSF support. The SACT protocol section is prefaced by the following notes:

- *“Doses for some regimens may vary and will depend on, for example, consultant preference, (references 5 and 6), indication and performance status*
- *breast oncologists in NHS Grampian and NHS Highland recommend doses 100mg/m² of epirubicin and docetaxel for patients deemed fit and with specified risk factors*
- *breast oncologists in NHS Tayside recommend 75mg/m² of epirubicin and 80mg/m² of docetaxel.”*

It was noted on the draft 4 version reviewed by the panel that the NHS Tayside breast oncologists had asked for the latter two bullet points to be removed. The document did not provide the rationale for this.

The primary reference sources cited by the different teams to validate their dose preference for the FEC-T regimen are documented in draft 4.

The introduction to draft 4 of the CMG includes the statement:

“Unlike other cancer networks in Scotland, NOSCAN consists of three separate cancer centres. It has therefore not been possible to reach a consensus on certain aspects of the systemic management of breast cancer and this variability is noted within the guideline.”

At our meeting with NOSCAN they outlined the work in progress to streamline and strengthen the NHS board approval process for CMGs. They confirmed that consensus had been achieved for a number of other CMGs. This has been the only guideline to date where geographical variation, due to clinician preference, has become an issue.

A review of the published breast cancer CMGs for WoSCAN and SCAN indicates that NHS Tayside’s practice is also at variance with the rest of NHSScotland. The CMGs for both networks specify doses of FEC 500/100/500 mg/m² and docetaxel 100mg/m². Primary prophylaxis with G-CSF is given as there is a recognised risk of neutropenic sepsis. These dosages can be reduced or an alternative regimen selected dependent on the clinical situation of the patient.

In summary before the visit to NHS Tayside representatives of the panel established the following:

- There is a lack of consensus within NOSCAN on the adjuvant and neo-adjuvant management of breast cancer, specifically regarding the dosage of FEC-T.
- There is a lack of consensus within NOSCAN on the use of Oncotype DX testing.
- In both instances NHS Tayside’s practice is at variance with the other NOSCAN NHS boards. NHS Tayside is also at variance with published guidelines for WoSCAN and SCAN.

5.1.2 NHS Tayside perspective

NHS Tayside breast oncologists and senior medical managers informed the panel that, in the past, NOSCAN encountered significant challenges in the development of CMGs at regional level but it was noted that the regional network was undergoing a number of changes which would now make it more effective. The panel heard from NHS Tayside that there is, in their view, a lack of transparency and openness in NOSCAN. Processes were described as “opaque” and standard operating procedures were required.

Current medicines governance structures could support the process of sign-off and implementation of NOSCAN CMGs in NHS Tayside. However, the links between key governance groups and the necessary steps in the local sign-off process are not clear, particularly the formal link with the Area Drug and Therapeutics Committee.

The NHS Tayside breast oncologists expressed surprise that a lack of consensus had been raised as an issue. In their view they had engaged with the regional process and, while there was no uniformity, a consensus had been reached on a draft with warranted variation. When questioned on their unwillingness to endorse a CMG with the higher dose they were firm in their view that there was no need for this dose to be included.

5.2 Decision making and evidence base for adjuvant and neo-adjuvant treatment of breast cancer

5.2.1 NHS Tayside's medicines governance process

In advance of the Healthcare Improvement Scotland visit, NHS Tayside provided an organogram, relevant policies and procedures, minutes of meetings and annual reports as evidence of the governance structure for medicines within the NHS board.

NHS Tayside's ADTC acts as the key strategic and leadership group, assuring and overseeing medicines governance in the NHS board. Part of the role of this group is to: *"advise and support the strategic direction of all aspects of medicines governance and usage in all care settings ensuring inclusion within wider strategic planning carried out by the NHS Tayside Board."* The Terms of Reference for the group describes part of this as: *"supporting the NHS board in the delivery of a comprehensive approach to national policy regarding medicines, linking with regional and national groups where appropriate."*

Reporting into the ADTC are a number of subgroups, including the Oncology and Haematology Medicines Management Group (OHMMG). The Terms of Reference for this group describes its responsibility to: *"review, update and implementation of NHS Tayside, NOSCAN and National Clinical Management Guidelines (CMGs)."* The chair of the OHMMG regularly reports to the ADTC.

The process for approval of both regional and local prescribing cancer guidelines within the NHS board is through these governance groups and it would be typical for such groups to ensure that there is a robust evaluation of current evidence base and opportunity for debate before a decision is made.

5.2.2 FEC-T regimen

The NHS Tayside breast oncology consultant team confirmed that they use lower doses of FEC-T without G-CSF support. The detail of the FEC-T regimen is set out in Annex C. The NHS Tayside breast oncology consultant team advised the visiting panel that the rationale for the lower dosage regimens included:

- the comorbidity related to deprivation within NHS Tayside's catchment area
- it was their perception that, in their patient population, docetaxel 100mg per m² is not well tolerated
- the results of their own audit of their practice found unacceptable rates of neutropenic sepsis with the 100mg per m² docetaxel dose
- a dose reduction was chosen over maintaining dose intensity with primary prophylaxis with G-CSF, as general fatigue and peripheral neuropathy which persisted had a significant impact on patient function and quality of life
- their evaluation of the evidence base supported the decision not to give docetaxel 100mg per m² to any patients, and
- their view is that, although the CMGs in the other two networks specified higher doses, this was not necessarily 'real world' practice, and they asserted that there is warranted variation across Scotland and the UK.

In December 2016, the NHS Tayside breast oncologists made the decision to reduce the dose of docetaxel to 75mg per m² and remove primary prophylaxis with G-CSF from the regimen based on their interpretation of the evidence available to them. The multi-professional team members were then *“informed of planned changes”*. At this point the OHMMG lead pharmacist queried the evidence on which these changes were based. In response, they were advised by email that *“the decision on what chemotherapy and other supportive treatments to give is one for the consultant oncologists.”*

In January 2018, the local NHS Tayside breast cancer guideline was changed again, from 75mg per m² to 80mg per m². This was undertaken following review of the evidence base by the NHS Tayside breast oncologists and was ratified by the OHMMG at that time, although one member chose to abstain. The wider multi-professional team who spoke to the panel noted conflicting interpretation of the available evidence.

NHS Tayside participated in a regional meeting on 26 February 2018 to review a draft of the breast cancer CMG. This draft included both dosage options for FEC-T regimen, however no agreement was reached.

The panel noted that some members of the multi-professional team had taken steps to establish the position in other NHS boards, acknowledging this could differ in practice from CMGs. They noted that practice elsewhere was that patients would receive 100mg per m² as a baseline, with dosages reduced, or an alternative evidence-based regimen used if necessary, to meet individual patients' needs such as in the case of frailty. However, in NHS Tayside, all patients would receive the lower dosage. Some members of the multi-professional team described the situation as a differing interpretation of existing evidence, or selective consideration of the evidence.

Pharmacy and nursing staff indicated that they had felt professionally vulnerable as a result of the change to practice and took steps to seek assurance from their respective senior managers to ensure they had organisational protection to continue delivering the prescribed regimens for neo-adjuvant and adjuvant treatments for breast cancer.

Pharmacy, nursing and the other medical staff we spoke with expressed that they held similar concerns to the individual who first raised concerns, particularly about the lack of discussion and evidence provided to support changes and could not understand why a different conclusion had been reached. They advised that there had been no opportunity for the multi-professional team to reach consensus on this matter or to enter into inclusive discussions about the evidence the decision was based on. This may have been further compounded by a gap in senior pharmacy input into the OHMMG. NHS Tayside senior medical and pharmacy management agreed this had likely led to gaps in pharmacy leadership.

The NHS Tayside breast oncology consultant team confirmed that they use lower doses of FEC-T without G-CSF support. They provided an overview of the evidence base and local informal audit data which informed their practice.

There are firmly held and conflicting views on the FEC-T dosage regimen used in NHS Tayside between professional groups locally and with NOSCAN.

The NHS Tayside breast oncology consultant team are firm in their belief that their practice is in the best interests of patients in NHS Tayside and is warranted variation.

The views heard from the wider NHS Tayside multi-professional team (other medical staff, pharmacy and nursing) are at odds with the NHS Tayside breast oncology consultant team. The NHS Tayside wider multi-professional team also expressed concern that the practice is different to other centres and networks.

5.2.3 Local quality and safety data available to support current practice

The NHS Tayside breast oncology consultant team carried out an internal audit on dose adjustments for people receiving neo-adjuvant treatment with FEC-T100 for the period 2014-2015. The panel was provided with a very brief summary of the results of this audit which included the finding that, of 98 patients treated with 100mg per m² docetaxel, 51 required dose reduction with four stopping treatment. The reason for dose reduction were febrile neutropenia (infection while white blood cells are low) or other side effects. However, the data collection exercise was not repeated to measure the impact of the subsequent change in practice. Also, the audit data had not been widely shared or presented to a multi-professional audience for peer review. Some, but not all of the multi-professional team, were aware of the audit carried out, however none had seen it. Data relating to toxicity is not routinely audited.

Some staff who we spoke with indicated that pharmacy had carried out another small scale audit which seemed to support the position held by the individual who initially raised concerns. This was discounted by the NHS Tayside breast oncologists as, in their view, the methodology was flawed. The results of this audit were not shared with the panel.

In relation to these concerns, the audit cycle was not completed and there was no multi-professional approach to the sharing and presentation of data, audit and evidence to inform decision making.

5.2.4 NHS Tayside's governance review of FEC-T

In the absence of an agreed regional CMG, this change to practice was taken through local governance processes, namely the OHMMG. However, the proposed change in practice was not formally presented at a meeting. OHMMG group members were asked to endorse the change through email and did so. The panel heard from a number of professionals that any debate on this issue was stifled due to the ongoing response to the whistleblower's concerns.

Staff described this situation as a 'lock down' which they found difficult to understand and navigate through. As a result of the lock down situation once the whistleblowing process commenced there was limited communication from the senior medical management to the team on the ground. Staff were left wondering what was happening and left to deliver a treatment that was being questioned but were fearful of raising the topic in case it had a detrimental effect on them. In addition, following an article published in The Times on 11 May 2018, NHS Tayside management staff gave patient information to nursing staff that would allow them to respond to any questions that patients may ask. Nursing staff were concerned this information related only to the NHS Tayside breast oncology consultant team's point of view.

Healthcare Improvement Scotland's fact finding work did not identify any information from NHS Tayside on the impact that this lower dose regimen had on patient tolerability or outcomes. The detail on FEC-T is outlined in Annex C and the practice in other centres and regions is outlined in Section 5.3 below.

In this fact finding work, Healthcare Improvement Scotland did not review the local handling of the whistleblowing process. However, the panel was concerned about the tone and manner in which some senior medical and senior management team members described other staff members involved in the whistleblowing process. The panel believed this indicated a lack of understanding and respect towards their respective professional roles and responsibilities, and suggests a dysfunctional team environment.

The panel was also presented with information on a potential variation in practice in relation to the use of bisphosphonates in early breast cancer. The panel did not undertake a detailed review in this area.

The panel identified that whilst medicines governance structures are in place they were not used appropriately for decision making before or after the areas of concern were raised.

Through the panel discussions and in some of the documentation provided, it was evident that the handling of these concerns has created considerable tension in the local system.

5.3 Current practice in NHSScotland for SACT management of breast cancer in the adjuvant and neo-adjuvant setting

Staff across other disciplines and most of the staff we spoke with from other specialties raised concerns about variance in NHS Tayside compared to practice elsewhere in Scotland. The NHS Tayside breast oncologists asserted that what is prescribed in practice may be different to what is specified in the CMGs. The NHS Tayside breast oncologists and senior medical managers are of the firm view that current practice is 'not egregious' [acceptable practice] and that warranted variation exists across the UK. As this is key to addressing the issue of consent, the panel felt it was important to understand current practice across NHSScotland.

To determine the extent of variation in NHSScotland, NHS boards (through the cancer networks) were surveyed for data on regimens in current use and relative uptake. We received a response from all NHS boards except NHS Borders and NHS Dumfries & Galloway – the returns represent 95% of the Scottish population.

From the responses received we found that, with the exception of NHS Tayside, FEC-T100 with G-CSF prophylaxis is the treatment initiated for the majority of patients requiring neo-adjuvant treatment. In the adjuvant setting, while alternative regimens are used more often than in the neo-adjuvant setting, a significant proportion across NHSScotland are prescribed FEC-T100 with G-CSF prophylaxis.

The survey confirms that FEC-T100 is used in practice across all other NHS boards. It also confirms some people receive alternative regimens or a dose reduction of FEC-T100 in line with regional CMGs.

There is evidence that, in some instances, fluorouracil is being removed from FEC and weekly paclitaxel is being given instead of docetaxel. The toxicity of FEC-T100 is recognised by breast oncologists across the UK and alternative treatments are being implemented or being considered. There is a desire to change routine practice and replace docetaxel with weekly paclitaxel, which is better tolerated.

NHS Tayside’s practice for the SACT management of breast cancer in the adjuvant and neo-adjuvant setting is at variance with current practice in the NHS boards surveyed.

5.4 Oncotype Dx testing

NOSCAN reported that Oncotype DX testing (Annex C) may not be routinely available to the patient cohort within NHS Tayside. The panel reviewed draft 3 of the breast cancer CMG which states: “*If borderline...may benefit from genomic tests (such as Oncotype DX) but this practice is not supported in NHS Tayside.*” It was noted in draft 4 of the CMG that NHS Tayside has asked for this statement to be removed referencing “*no SMC advice*”. There appears to be a lack of awareness of the MPEP and its advice.

The NHS Tayside breast oncology consultant team informed the panel that NHS Predict is their preferred method to stratify risk and that:

- the use of Oncotype DX testing is a ‘current controversy’
- NICE had suspended its guidance and it was no longer to be recommended
- it is not universally used across the UK, and
- the subject was debated at the recent European Society for Medical Oncology (ESMO) conference.

The team noted their perception that the test was marketed in a way which fed on clinical anxiety and a desire by clinicians to have a definitive answer as to whether a patient, within a certain clinical cohort, should receive chemotherapy.

The NHS Tayside breast oncology consultant team confirmed to the panel that Oncotype DX testing was not offered or routinely used in NHS Tayside and this had been the case since 2016. They do not believe it adds value in determining whether someone should receive adjuvant chemotherapy for breast cancer.

In January 2016, the NHSScotland MPEP recommended use of Oncotype DX testing², which is in line with NICE Guidance. Scottish Government policy *Beating Cancer: Ambition and Action* (March 2016) committed to introduce Oncotype DX testing for all women with breast cancer who would clinically benefit from it.

Subsequent to the visit it was apparent that the intelligence on an update of NICE Guidance, used by NHS Tayside to justify their position (January 2018 draft), had since been updated with a second draft April 2018 and was published in December 2018.

The NHS Tayside position on Oncotype DX testing is at variance with the other NHS boards in NOSCAN, the other Scottish networks, MPEP advice and current NICE Diagnostic Guidance 34.

This position taken by the NHS Tayside breast oncologists and the intelligence is supported by senior medical management and appears to have been accepted without a fact check of current national guidance.

5.5 Consent of patients for their treatment

A key concern raised was that patients were not informed of the difference in practice within NHS Tayside. The panel asked all staff groups about the consent process for patients receiving adjuvant and neo-adjuvant treatment for breast cancer.

The panel heard the following:

- NHS Tayside stated that there were no issues identified with the broad approach to consent. The clinical lead reported that they had observed how the NHS Tayside breast oncologists discussed consent with patients and felt their practice was “exemplary”. They noted that specific dosage was not discussed, however did not believe that this would normally form part of the discussion with patients.
- The NHS Tayside breast oncology consultant team confirmed that patients were not informed of dosage or variation in dosage during the consent process. During the course of the day, the panel heard senior medical managers and the NHS Tayside breast oncologists assert that practice is “non egregious” and therefore, in their view, no specific requirement for differences in practice need be communicated.
- Multi-professional staff members raised concerns that patients were not informed of the difference in practice in NHS Tayside in relation to other NHS boards within the region and other regions.
- It was also confirmed that there is no local specific patient information leaflet which explains local practice. Macmillan patient leaflets, which do not contain dosing information, are routinely used.
- It appears that NHS Tayside patients are not informed of the difference in practice in relation to other NHS boards within the region and other parts of Scotland.
- It is unclear to the panel if there was appropriate sharing of information that patients “want or need in order to make decisions” or to “maximise patients’ opportunities, and their ability, to make decisions for themselves.”⁵
- The panel believes that the current practice for consent may not be:
 - truly informed in nature
 - in keeping with current expectations of the General Medical Council (GMC)^{5, 6} or the concept of shared decision making set out by the CMO in *Realistic Medicine*⁷, and
 - in the spirit of current case law.

Where routine practice is different from that supported by the wider oncology community, patients should be informed of this. This recommendation should be considered and addressed as part of the current Healthcare Improvement Scotland led national review of consent for SACT.

6 Recommendations and proposed next steps

Where applicable Healthcare Improvement Scotland will follow up on the agreed recommendations with NOSCAN and NHS Tayside.

External assistance to NOSCAN and NHS Tayside may be required to facilitate the implementation of these recommendations.

These recommendations should inform any broader work that NHS Tayside is undertaking, including the proposed Royal College of Physicians in England Commissioned Review.

Where appropriate, the information gathered throughout this process will be considered as part of Healthcare Improvement Scotland's wider intelligence gathering and sharing process and may be used to inform any future assurance engagement with NOSCAN and NHS Tayside.

RECOMMENDATIONS:

- A. NOSCAN and all its constituent NHS boards to take account of the findings of this report to complete the implementation of their regional governance processes for cancer CMGs. This should be undertaken **by May 2019** and should include:
 - the engagement and agreement of all NHS boards in NOSCAN to operate regionally and in line with MEL 10 (1999)¹
 - clear structures and processes that define and support the integration of and linkages between board and regional medicines governance, and
 - effective multi-professional working in medicines governance, specifically with regard to decision making. This should take account of the guidance provided in CEL 30 (2012)².
- B. NOSCAN and all its constituent NHS boards to use the strengthened governance process described above to complete the review, approval and implementation of the NOSCAN CMG for breast cancer **by June 2019**. The process should include a robust assessment of the evidence base and national guidance and opportunity for multi-professional peer review and debate.
- C. NHS Tayside to use the strengthened governance processes (recommendation A and B), to confirm appropriate use of Oncotype DX **by June 2019**. NOSCAN, if required, should consult with MPEP if there are still concerns about the evidence base guiding national advice on its use.
- D. Where routine practice is different from that supported by the wider oncology community, patients should be informed of this. This recommendation should be considered and addressed as part of the current national review of consent for SACT led by Healthcare Improvement Scotland.

- E. Although outwith scope of the review there appears to be a culture within the team where the multi-professional voice is not being heard. NHS Tayside to consider further work to improve multi-professional team working.

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ANNEX A: Terms of Reference

Healthcare Improvement Scotland

Terms of Reference:

Clinical Management of Breast Cancer in NHS Tayside

September 2018

Introduction

In July 2018 The Chief Medical Officer (CMO) for Scotland and the Chief Pharmaceutical Officer (CPO) for Scotland have asked that Healthcare Improvement Scotland fact find in relation to the situation that currently exists whereby there is no consensus on the clinical management of breast cancer in North of Scotland Cancer Network (NoSCAN), specifically current practice for the use of systemic anticancer therapy (SACT) in the adjuvant and neo-adjuvant setting and the use of Oncotype Dx testing.

In response, Healthcare Improvement Scotland met with representatives from NoSCAN in August 2018. Information available to date suggests that NHS Tayside practice is at variance with the rest of the NoSCAN region, the South East Scotland Cancer Network (SCAN) and West of Scotland Cancer Network (WoSCAN). We believe that this has been a known local issue since at least the summer of 2016 and has been previously raised with Healthcare Improvement Scotland through our Public Interest Disclosure Act (PIDA) role in May 2017. A key conclusion of the Healthcare Improvement Scotland PIDA work was that the NHS Board should hold wider discussions in order to gain agreement around standard practice and provide assurances that due process is being followed. NoSCAN informed Healthcare Improvement Scotland that a consensus could not be reached.

In September 2018, NHS Tayside asked the Royal College of Physicians (London) (RCPL) to undertake a service review. It is understood that this work will not commence until after the Healthcare Improvement Scotland work is completed. In order to avoid duplication and to potentially inform the college review the Healthcare Improvement Scotland findings will be shared with the RCPL on completion.

Remit

The purpose of this work is to fact find from NHS Tayside. The key information to be discussed will be:

- The decision making and evidence base to support the current approach to the oncological management of breast cancer in the adjuvant and neo-adjuvant setting, specifically the dosages and use of growth factor support in the FEC-T regimen
- Use of Oncotype DX testing for patients
- Consent of patients for adjuvant and neo-adjuvant treatment
- Local quality and safety data available to support current practice

- Perspective regarding development of the NoSCAN Clinical Management Guideline for Breast Cancer
- Input into regional governance mechanisms

This work will not cover:

- Cultural and behavioural issues
- Team Dynamics
- Multidisciplinary working

Should any issues arise during this work that could impinge on the quality and safety of care for patients, they will be considered by the panel and if appropriate brought to the immediate attention of NHS Tayside senior management.

Method

A small team with external and independent experience, knowledge and skills has been established to represent Healthcare Improvement Scotland.

In conjunction with colleagues in NHS Tayside the Healthcare Improvement Scotland team will arrange a visit, ideally on a single day to minimise disruption, in order to speak with key staff. Documentation may be requested to support this work as required.

Visit team

The visiting team will comprise of the individuals listed below. If required, additional advice/expertise will be sought.

- Mrs Belinda Henshaw – Senior Reviewer, Healthcare Improvement Scotland
- Ms Mary Maclean – National Clinical Lead – Cancer Medicines, Healthcare Improvement Scotland
- Dr Nadeem Siddiqui – Consultant Gynaecological Oncologist, NHS Greater Glasgow & Clyde

Timescales and reporting

The actual visit date is still to be determined but will be in October 2018.

Following the visit, a short report will be compiled detailing the findings as agreed by the visit team members. This report will be presented to CMO/CPO to help form a decision on the next steps. This report will be provided to the CMO/CPO by Wednesday 31 October 2018 (with agreement then extended to 30 November 2018).

END

ANNEX B: Visiting panel and internal reference group membership

Visiting panel

Ms Belinda Henshaw, Senior Inspector/Reviewer, Healthcare Improvement Scotland

Ms Mary Maclean, National Clinical Lead – Cancer Medicines, Healthcare Improvement Scotland

Dr Nadeem Siddiqui, Consultant Gynaecological Oncologist, NHS Greater Glasgow and Clyde

Ms Tammy Nicol, Project Officer, Healthcare Improvement Scotland

Internal reference group

Dr George Fernie, Senior Medical Reviewer, Healthcare Improvement Scotland

Ms Ann Gow, NMAHP Director, Healthcare Improvement Scotland

Dr Brian Robson, Medical Director, Healthcare Improvement Scotland

Mr Mark Aggleton, Head of Service Review, Healthcare Improvement Scotland

Ms Laura McIver, Chief Pharmacist, Healthcare Improvement Scotland

ANNEX C: FEC-T and Oncotype DX - background information

FEC-T with G-CSF

The FEC-T regimen is used in the treatment of breast cancer and comprises of:

- fluorouracil
- epirubicin
- cyclophosphamide, and
- docetaxel (Taxotere).

Fluorouracil, epirubicin and cyclophosphamide (FEC) are given in combination for 3-4 cycles followed by 3-4 cycles of docetaxel (T). A key factor driving the lack of consensus on the breast cancer CMG in NOSCAN is the dosage of docetaxel in this regimen.

Having chemotherapy for cancer can affect the bone marrow, reducing the ability to make new white blood cells. This is called neutropenia and can increase your risk of infection. To help strengthen the immune system, clinicians may prescribe a treatment called granulocyte-colony stimulating factor (G-CSF). This helps the body to make more white blood cells which helps to reduce the risk of infection and allows chemotherapy treatments to be given on time and at the planned dose.

G-CSF can be given at the outset of treatment if it is known the risk of infection is high with certain regimens. The risk of neutropenia and infection with FEC-T100 is known to be high so it is normal practice in NHSScotland to give G-CSF routinely with this regimen.

FEC-T100 will not be suitable for all people requiring treatment. In certain cases it will be appropriate to reduce the dose of docetaxel or use an alternative regimen.

The toxicity of FEC-T100 is recognised by breast oncologists across UK and there is evidence of alternative treatments being implemented or under consideration. The fluorouracil component of FEC is being removed and there is a desire to move to weekly paclitaxel which is better tolerated.

Oncotype DX testing

Oncotype DX is a gene expression profiling test that can provide information on the biological features of an individual's breast cancer which can predict the course of the disease and help guide treatment decisions.

In 2013, NICE issued Diagnostic Guidance 10: *Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat*. This guidance includes the recommendation that:

Oncotype DX is recommended as an option for guiding adjuvant chemotherapy decisions for people with oestrogen receptor positive (ER+), lymph node negative (LN-) and human epidermal growth factor receptor 2 negative (HER2-) early breast cancer if:

- *the person is assessed as being at intermediate risk **and***
- *help in predicting the course of the disease and would therefore help when making the decision about prescribing chemotherapy **and***
- *the manufacturer provides Oncotype DX to NHS organisations according to the confidential arrangement agreed with NICE.*

NICE Guidance has no status in NHSScotland, however may be used by NHS boards as a source of evidence of best practice.

In January 2016, the NHSScotland MPEP recommended use of Oncotype DX ([link](#)) which is in line with NICE Guidance. Scottish Government policy *Beating Cancer: Ambition and Action* (March 2016) committed to introduce Oncotype DX testing for all women with breast cancer who would clinically benefit from it.

A review of NICE DG10 was initiated in 2017 with initial stakeholder consultation in January 2018. Oncotype DX was no longer recommended at this stage, however following extensive stakeholder feedback the second consultation, in April 2018, recommended it as an option. The final published NICE Guidance - *Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer* (DG34, December 2018) - includes the recommendation that:

*EndoPredict (EPclin score), **Oncotype DX Breast Recurrence Score** and Prosigna are recommended as options for guiding adjuvant chemotherapy decisions for people with oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative and lymph node (LN)-negative (including micrometastatic disease) early breast cancer, only if:*

- *they have an intermediate risk of distant recurrence using a validated tool such as PREDICT or the Nottingham Prognostic Index*
- *information provided by the test would help them choose, with their clinician, whether or not to have adjuvant chemotherapy taking into account their preference*
- *the companies provide the tests to the NHS with the discounts agreed in the access proposals and*
- *clinicians and companies make timely, complete and linkable record-level test data available to the National Cancer Registration and Analysis Service as described in the data collection arrangements agreed with NICE.*

Published April 2019

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