Independent Advisory Group (Tayside Breast Cancer)

Report

July 2019

Scottish Government
Riaghaltas na h-Alba
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Contents

Introduction/ Executive Summary

This Independent Advisory Group was appointed in mid-April 2019 with a remit to advise the Chief Medical Officer on how recommendations made in two earlier reports on breast cancer management in NHS Tayside should be implemented.

The aim was to rebuild relationships and maintain public confidence in the safe and effective delivery of cancer medicines within the North Cancer Alliance.

It is important to note what the remit did **not** include. It was not part of the Group's role to comment on the clinical decisions made by medical staff in NHS Tayside, nor to review individual cases. The Group was asked to aim to report in June 2019 and, in conducting this work, the Group acted independently of both the Scottish Government and NHS Scotland.

The membership of the Group included a range of expertise, including cancer specialists, senior pharmacy and service management. Where a need for additional expertise or advice beyond the core membership was identified, it was sought from a range of individuals across NHS Scotland. The Group would like to thank all of those who freely and willingly shared their knowledge and experience. Most of all, the Group would like to thank those patients and family members who met with or wrote to the Group to share their experiences - they were able to provide invaluable insight.

Scotland is a small country, with ambition to deliver high quality health care for all. Patients across Scotland should have access to the same high level of care and treatment, regardless of where they live. Crucially, they must also have the same level of involvement in decision making about their care. The Group is reassured that NHS Tayside is making significant improvements to cancer multi-professional working, but there are lessons to be learned from this occurrence that should be applied across NHS Scotland. It would have been a failing of the Group if it had only considered one health Board in isolation and if a similar scenario later occurred elsewhere.

Therefore the Group considers that the 19 recommendations made in this report, if adopted, will significantly improve cancer care across NHS Scotland by embedding a 'Once for Scotland' approach and facilitating the rapid sharing and adoption of best practice across regional cancer networks and their constituent NHS Boards.

Background

1. An individual in NHS Tayside contacted the Chief Medical Officer for Scotland (CMO), the Chief Pharmaceutical Officer for Scotland (CPO) and the former Cabinet Secretary for Health & Sport to raise concerns relating to a failure in medicines governance in the context of breast cancer treatment in NHS Tayside. The specific allegations related to 'under-dosing' of two oncology medicines included in a type of chemotherapy treatment known as the FEC-T regime at NHS Tayside. The individual further alleged that appropriate patient consent had not been obtained in relation to this variation in practice.

2. These concerns led to the CMO and the CPO commissioning Healthcare Improvement Scotland (HIS) to undertake a fact finding exercise around the lack of consensus on the clinical management of breast cancer in what was then called the North of Scotland Cancer Network (NoSCAN), specifically current practice for the use of systemic anticancer therapy in early breast cancer, and the use of Oncotype DX testing. The HIS visiting panel determined that NHS Tayside practices were at variance with other NHS Boards in Scotland and that improvements in medicines governance arrangements were required. On 1 April 2019, HIS published its report, 'Clinical management of breast cancer in NHS Tayside'. That report made 5 recommendations.

3. Following the publication of the HIS report, an Immediate Review Group (IRG) was commissioned by the CMO and CPO to deliver a clinical risk assessment relating to this variation in clinical practice in NHS Tayside, and its potential impact on patient safety. This risk assessment was focused solely on the content of the HIS Report. The IRG report was subsequently published on 16 April 2019.

4. In April, the CMO also commissioned an Independent Advisory Group to consider both the HIS and IRG reports. This Group was convened to advise the CMO on how recommendations in both the HIS and IRG reports could be implemented to ensure safe and effective delivery of cancer medicines in the recently renamed North Cancer Alliance (NCA – previously known as NoSCAN).

5. The full remit, terms of reference and purpose of this Group can be found at **Annex A** with membership at **Annex B.**

6. Links to key reference documents considered by the Group can be found at **Annex C**.

7. From the outset, the Group was clear that its role and remit was forward looking.

8. The Group did not have access to individual patient records and it was not within the Group's remit to express an opinion on the original clinical decision making processes of the NHS Tayside consultant oncologists, or to undertake any literature review on the evidence underpinning those decisions. In

meeting the terms of reference of the Group, it quickly became apparent that looking at one NHS Board (NHS Tayside) or one network (the NCA) in isolation would not prevent a similar occurrence outwith those geographical boundaries. The national solutions offered in this report, if adopted, will mean that a similar occurrence cannot happen anywhere else in Scotland in the future.

9. The ordering of recommendations does not reflect any prioritisation by the Group, but suggested timescales for implementation and lead responsible body(ies) have been indicated

Process

10. Members of the Group were appointed in late April and were expected to attend each meeting.

11. The Group met 9 times from 26 April, including a meeting with the individual who first raised concerns. Additionally, three separate stand-alone meetings were held between the Chair and Group members with patients, their family members and NHS Tayside consultant oncologists.

12. While it was not possible to meet with all patients or family members involved within the time limits of the Group's work and taking into account the constraints of GDPR (the EU General Data Protection Regulation), all written submissions made were accepted and read by all Group members.

13. Other expertise was sought when required, for example advice was taken from a colleague specialising in NHS Organisational Development and from the two other cancer networks across Scotland (SCAN and WoSCAN).

14. At the first meeting it was agreed that transparency was key and that all tabled Group papers would be published. These can be found online alongside this report. In order to aid transparency for the lay reader a glossary of terms is at **Annex D.**

15. This report has been submitted to the CMO for consideration.

Discussion

1. This section deals with the consideration behind each recommendation listed in **Table 1** below. Recommendations have been grouped into key themes of Governance, Clinical Processes and Patient Informed Consent and are presented in the order that they appear in the body of this report, which does not imply any order of priority.

2. The HIS report expressly excluded coverage of cultural issues within the NHS Tayside breast oncology team and NoSCAN (now the North Cancer Alliance – NCA), which this Group quickly identified as a potential area of concern, and in need of consideration. Key to public trust being regained and relationships rebuilt, will be understanding and addressing the wider issues at play in this area, to avoid a similar situation arising in the future.

3. The Group gave consideration to whether the current organisation of cancer services delivered in Scotland through three regional networks should be replaced with delivery through a single network. On balance it was felt that this would not only present significant logistical problems, but would also diminish access to local knowledge and accountability to local Boards. The Group therefore believes that the optimal arrangement is to maintain the three regional networks, but with improved Governance and better pan-Scotland working across the networks.

4. The Group strongly believes that in a country the size of Scotland, it should be feasible to take a more country wide approach to cancer service delivery. Some pan-Scotland approaches are already in place, e.g. in the case of the cancer Quality Performance Indicators (QPIs) which are developed by the National Cancer Quality Steering Group and then monitored by HIS. The move to a “Once for Scotland” approach is covered in more detail below.

5. In the course of its work, it also became evident to the Group that to look at the NCA in isolation would not provide adequate reassurance that a similar instance could not occur elsewhere in Scotland. It therefore undertook to consider national processes that could be applied across the country.

6. The Group heard evidence of the need for cultural and organisational change (including identification of those with good leadership skills) within NHS Tayside, and more widely across Scotland, to ensure that clinical governance processes are not only explicit, but adhered to in the future. It was noted that in order to deliver a world class service in any clinical area (including cancer), all units and teams need to have the ability to offer self-criticism. The Group believes that this is more likely to happen when the local talent pool is refreshed by external appointments, and/or where team members spend time in different locations.

7. The Group benefitted from discussion with an expert in Organisational Development, and heard about a number of recent actions already underway in NHS Tayside in this area. It was noted that positive leadership is a prerequisite for the development of strong, well-functioning teams. These in

turn are associated with better patient care and outcomes. Leadership is not the same as management, but encompasses any individual who has an influence over others. Work is already underway to improve relationships and trust within NHS Tayside, across the NCA region and across Scotland. NHS Tayside consultants have complied with direction from NHS Tayside to offer the higher dose FEC-T regime to all new breast cancer patients at the start of their treatment, and also to use the Molecular Pathology Evaluation Panel (MPEP) recommended Oncotype DX test to identify which patients with early breast cancer should receive chemotherapy after surgery.

8. It was further noted that a collegiate approach will be crucial if the NCA (and its constituent NHS Boards) is to operate well in the future. The Group commended NHS Tayside on its approach to offering support to relevant consultant staff and the wider department. A positive working environment is essential, not only for staff morale and welfare, but also because a positive working environment for staff has been shown to improve the patient experience.

9. To support the development of a more collegiate approach across the country, the Group recommends that a separate longer life group be created to ensure implementation of this report's recommendations, particularly those relating to long term changes in organisational culture across cancer networks in NHS Scotland. **(Recommendation 1).** This new group should report directly to the Scottish Cancer Taskforce.

10. The Group has identified a number of recommendations that will require additional resource if this report is to be implemented effectively and in a timely fashion. The Group therefore recommends that sufficient resource is provided to the Regional Cancer Networks to ensure all recommendations in this report are delivered in full. **(Recommendation 2).**

11. It is crucial that patient trust in NHS Tayside and relationships across the NCA continue to improve. While we believe that both the Board and the NCA have made significant efforts in this regard, it was evident from patient and family members that more needs to be done as a priority. Further comment on patient support appears later in this report in paragraphs 27 to 29.

Governance - a "Once for Scotland" approach

12. As stated above, the Group is keen to pursue a "Once for Scotland" approach wherever possible, including the development and implementation of cancer Clinical Management Guidelines (CMGs).

13. The NHS Tayside staff and patients and their families we met were strongly supportive of this during our interactions with them. The Group discussed the new governance arrangements which are now being implemented in the NCA, and the equivalent processes in place in SCAN and WoSCAN. It was agreed that there was scope for aligning these arrangements. The Group therefore recommends that the three regional networks should undertake a mapping

review of the terminology being used in governance structures, with the aim of achieving, where feasible, more consistency across NHS Scotland. **(Recommendation 3).**

14. The Group heard evidence which strongly suggested that the core principles underpinning the establishment of Managed Clinical Networks in NHS Scotland (laid out in MEL (1999) 10) were not being adhered to in NHS Tayside, and possibly more widely across Scotland. The Group therefore recommends that all NHS Scotland staff (particularly clinical staff) be reminded of the requirements of MEL (1999) 10, and the need to engage with the governance arrangements covered in section 8 **(Recommendation 4)**. In the case of consultant staff this would include attendance at relevant advisory groups, e.g. tumour specific meetings. Such attendance should be included in the individual's job plan in consultation with the relevant Medical Director. **(Recommendation 5).** An extract from the relevant section of MEL 1999 (10) can be found in **Annex C1**.

15. The Group also recommends that Scottish Government should consider whether para 1.43 of CEL 30 (2012) (which covers the safe delivery of chemotherapy) requires clarification as to where the balance of governance lies, locally and regionally. The need for revision of the CEL has already been agreed by the Scottish Cancer Taskforce. **(Recommendation 6).** An extract from the relevant section of CEL 30 (2012) can be found in **Annex C2**.

16. The Group reviewed the new NCA processes for the development of CMGs and SACT protocols, and the equivalent processes in SCAN and WoSCAN, including escalation processes through constituent Boards. In the event of lack of clinical consensus around a CMG, the Group believes that Board Medical Directors should be directly involved early in those processes, to facilitate resolution. The Scottish Association of Medical Directors should be used to raise awareness of this report and provide direction and leadership to ensure implementation of the recommendations in this report. **(Recommendation 7).**

17. The Group believes a properly resourced multi-professional National Clinical Management Guidelines Oversight Group should be set up for the development and monitoring of compliance with CMGs, and ensure consistency across NHS Scotland. **(Recommendation 8).** The current regional network CMG development processes would continue, but the new national group would consider any issues of variation between the regional CMGs and would also develop a system to oversee implementation and monitor compliance. The Group accepts that the establishment of the oversight group will take some time and will require sufficient resource (e.g. a national secretariat) to run and maintain its activity. In advance of that happening, it was agreed that regional cancer networks should formalise the process of sharing CMGs across NHS Scotland, in the interests of national consistency, governance and shared learning. **(Recommendation 9).**

18. The NCA have already started a review of all of their extant CMGs, and the Group believes that this should also take place in the other two networks (SCAN and WoSCAN). The process should also ensure associated Systematic Anti-Cancer Therapies (SACT) protocols take into account the existing evidence base (e.g. SMC and SIGN Guidelines) and must include escalation procedures where consensus is not reached. If variation exists, this needs to be explained and justified **(Recommendation 10).**

19. The Group further recommends that the National CMG Oversight Group should hold an annual consensus conference to facilitate and embed a "Once for Scotland" approach that encompasses cancer CMGs. **(Recommendation 11).** Tumour group leads in the three networks should confer prior to these conferences to identify priority areas to be covered and ensure multi-professional attendance. The conference should focus on the development and implementation of CMGs, and any relevant associated issues - for example including, but not limited to - benchmarking, workforce issues, compliance and research which can contribute to the evidence base. The Group felt there would be real benefit in involving patients in the planning and delivery of the national conference.

20. These new arrangements for cancer CMG development and monitoring should be communicated to NHS Scotland through a new CEL. **(Recommendation 12).**

21. The National Cancer Quality Steering Group currently oversees the implementation of the national cancer Quality Performance Indicators (QPI) programme. The QPIs are widely recognised as being a powerful mechanism to improve cancer outcomes by benchmarking of cancer services within NHS Scotland to internationally acceptable standards.

22. Annual review of the QPI data and revision processes are important in driving forward service changes and improving clinical quality and patient outcomes. Each tumour group within the regional network is expected to hold an annual regional meeting to discuss the previous year's results and develop an action plan for the forthcoming year. In addition, each tumour specific QPI is reviewed every 3 years. The Group heard that funding for these meetings can be challenging to identify and that not all Boards send representatives to the meetings. The Group therefore recommends that adequate resource be allocated in each of the networks to hold these meetings and that the networks, along with their constituent Boards, must all be represented at the meetings in order to give proper consideration to the QPI data and complete the audit loop. **(Recommendations 13 and 14).**

23. The opportunities for patient involvement in cancer regional network meetings vary across the country. The Group agreed that the perspective patients can bring to such discussions is important. The Group reflected on the possibility that if patients/lay persons had been involved in the group discussion of the decision to vary practice by the NHS Tayside oncologists, there may have been a different outcome. For clinical governance to be effective, it is crucial

not only to have good governance processes in place, but also to develop systems that are capable of evolving over time, and ensure adherence. In this context, the Group believes that would be mutual benefit if the three networks found ways to observe at first hand the meetings and processes in place in other regions, including levels of patient involvement.

24. The Group therefore recommends that NCA, SCAN and WoSCAN officials take the opportunity to observe at first hand the operation of each other's networks, including patient involvement processes **(Recommendation 15).**

Clinical processes

25. In discussion there was support for the development of a truly national chemotherapy prescribing administration system (CEPAS) capable of identifying the extent of variation in SACT prescribing across the country, in particular the extent of deviation from agreed CMG SACT protocols. Had such a system been in place, the variation in NHS Tayside practice could have been identified quickly. However, this will require resolution of the current complex inter Board clinical governance and contractual arrangements, system administration and technical issues to create a national system from the current five instances of the system in use across the country, (Chemocare®). There is an urgent technical need to upgrade the current instances to the web based version 6 of Chemocare® and work is underway by the cancer networks, with support on contractual issues from National Services Scotland, to deliver this. Work in this area needs to proceed at pace and should be taken forward as a priority.

26. The Group further recommends that the Chief Executives Group and the Scottish Cancer Taskforce have a role in assessing whether sufficient priority is being given to achieving measurable progress in this area. **(Recommendation 16).**

Patient centred consent

27. Informed consent was discussed at some length in the Group, both in relation to the 2015 Supreme Court Judgement on Montgomery, and in relation to the extant 2008 GMC guidance on patient consent (see **Annex C** for references). The Group fully recognises that CMGs are only guidance, and that clinicians are free to deviate from standard practice as defined in the CMG, so long as they are able to justify their decision, follow the due medicines governance process where this is required and record that justification appropriately. The key point in relation to the NHS Tayside breast cancer issue was not that certain medicines were routinely prescribed at lower doses, but that deviation from the practice of other clinicians across the country was not discussed with patients at an individual level. Rather, a "blanket" prescribing policy was applied on a population basis. The Group therefore recommends that, for informed consent to take place, patients must be explicitly informed of any variance from generally accepted standard SACT clinical practice. The risks

of treatment should also be discussed and this discussion recorded in the patient's record. **(Recommendation 17).**

28. The Group noted that a national review of SACT consent is currently underway, aiming to standardise the various documentation currently in use, develop guidance on SACT consent and move to a "Once for Scotland" approach. The Group recommends that all Boards must adopt the standardised approach to SACT consent once guidance is available, to ensure national consistency in documentation of informed consent across Scotland. **(Recommendation 18).**

29. The Group also feel it is important to acknowledge the work underway in NHS Tayside to support both patients and their family members. This is through a new offer of continued support for their wellbeing, and extended health monitoring, including the offer of independent medical advice from outside NHS Tayside which emerged during the course of the work of this Group. We recommend that NHS Tayside should continue to pursue and prioritise the actions to deliver this **(Recommendation 19).**

Conclusion

30. A summary of all recommendations appears as **Table 1** below**.**

31. The Group applauds the work already in hand in the NCA to ensure consistency around the development of cancer CMGs (in particular SACT protocols), and believe that it bodes well for a national, "Once for Scotland" approach to cancer service delivery. The Group believes that the 19 recommendations outlined above, if adopted, will ensure a more consistent approach to cancer patient management across the country, to the benefit not only of patients, but also clinicians and other staff. The Group hopes that others will support implementation of this report's recommendations, with the result that patients and families have confidence that a repeat of the NHS Tayside situation can be avoided in the future, across the entirety of NHS Scotland.

Summary of recommendations **Table 1**

A summary of all 19 recommendations appears below. The preceding discussion section explains the reasoning behind each.

Number	Recommendation	Timescale	Lead Responsibility
1	A separate longer life group should be created to ensure the implementation of this report's recommendations, particularly those relating to long term changes in organisational culture across cancer networks in NHS Scotland. This new group should report to the Scottish Cancer Taskforce.	Short term	Scottish Government
2	Sufficient resource should be provided to the Regional Cancer Networks to ensure that this report's recommendations are delivered in full.	Short term	NHS Boards
3	The three Regional Cancer Networks should undertake a mapping review of the terminology being used in governance structures, with the aim of achieving, where feasible, more consistency across NHS Scotland.	Medium term	Regional Cancer Networks
4	All NHS Scotland staff (particularly clinical staff) should be reminded of the requirements of MEL (1999) 10, and the need to engage with the governance arrangements covered in section 8. See **Annex C1** for the relevant extract.	Short term	Scottish Government
5	In the case of consultant staff, delivery of Recommendation 4 includes attendance at relevant advisory groups e.g. tumour specific meetings. Such attendance should be included in the individual's job plan, in consultation with the relevant Medical Director.	Short term	NHS Boards/Regional Cancer Networks
6	Consideration should be given to whether para 1.43 of CEL 30 (2012) requires clarification regarding where the balance of governance lies, locally and regionally. The need for revision of the CEL has already been agreed by the Scottish Cancer Taskforce. See **Annex C2** for the relevant extract.	Short term	Scottish Government
7	The Scottish Association of Medical Directors should be used to raise awareness of this report and provide direction and leadership to ensure implementation of the recommendations in this report.	Short term	Medical Directors
8	To ensure consistency across NHS Scotland, a properly resourced multi-professional National Clinical Management Guidelines (CMG) Oversight Group should be set up for the development of and monitoring of compliance with cancer CMGs.	Medium term	Scottish Government
9	The Regional Cancer Networks should formalise the current informal process of sharing CMGs across NHS Scotland in the interests of national consistency and shared learning.	Short term	Regional Cancer Networks

Number	Recommendation	Timescale	Lead Responsibility
10	A review of all existing CMGs and associated Systemic Anti-Cancer Therapy (SACT) protocols against extant central reference material e.g. relevant Scottish Medicines Consortium (SMC) guidelines and Scottish Intercollegiate Guidelines Network (SIGN) guidelines, should be undertaken in all three regions. The process must include escalation procedures where consensus is not reached. If variation exists, this needs to be explained and justified.	Long term	Regional Cancer Networks
11	The National CMG Oversight Group should hold an annual consensus conference to facilitate and embed a "Once for Scotland" approach that encompasses cancer CMGs. There would be benefit in involving patients in the planning and delivery of the national conference.	Medium term	Scottish Government
12	New arrangements for cancer CMG development and monitoring should be communicated to NHS Scotland through a new CEL.	Medium term	Scottish Government
13	Regional Cancer Networks along with constituent Board representatives should attend regional tumour specific meetings to consider Quality Performance Indicators (QPI) data.	Short term	Regional Cancer Networks
14	Adequate resources should be allocated to the Regional Networks from Boards to hold regional tumour group meetings to consider QPI data and complete the audit loop.	Medium term	NHS Boards
15	Officials in all 3 Regional Cancer Networks (NCA, SCAN and WoSCAN) should take the opportunity to observe the operation of each other's networks, including patient involvement processes.	Short term	Regional Cancer Networks
16	The current upgrade of Chemocare ®should be delivered as quickly as is safely possible, to ensure resilience of the service and allow the development and delivery of national reports capable of monitoring prescribing practice. The Chief Executives Group and the Scottish Cancer Taskforce have a role in assessing whether sufficient priority is being given to achieving measurable progress in this area.	Medium term	NSS/Regional Networks/Chief Executives/ Scottish Cancer Taskforce
17	Patients must be explicitly informed of any variance from generally accepted standard SACT clinical practice, for informed consent to take place. The risks of treatment should also be discussed and this discussion recorded in the patient's record.	Short term	NHS Boards
18	All Boards must adopt the standardised approach to SACT consent once guidance is available to ensure national consistency in documentation of informed consent across Scotland.	Short term	NHS Boards
19	NHS Tayside should continue to offer extended support for patients & families including wellbeing support and the offer of enhanced health monitoring to affected patients.	Short term	NHS Tayside

Annex A

Independent Advisory Group (NHS Tayside Breast cancer)

Remit

To carefully consider the individual recommendations made in the Healthcare Improvement Scotland report " Clinical Management of Breast Cancer in NHS Tayside" and the "Clinical Risk Assessment" of that report produced by the Immediate Review Group. To advise the Chief Medical Officer on how these recommendations can be implemented to ensure safe and effective delivery of cancer medicines in the North Cancer Alliance (NCA – previously known as NoSCAN). The group will aim to produce this advice to CMO in June 2019.

Terms of Reference

The CMO has commissioned Professor Aileen Keel CBE, Director of Innovative Healthcare Delivery Programme and Chair of the Scottish Cancer Taskforce to independently consider the findings of both the HIS report "Clinical Management of Breast Cancer in NHS Tayside published on 1 April 2019 and the Clinical Risk Assessment of the Healthcare Improvement Scotland Report "Clinical Management of Breast Cancer in NHS Tayside" published by the CMO/CPO appointed Immediate Review Group on 16 April 2019.

Purpose

This independent group will advise the CMO on the implementation of the recommendations in the HIS report and Clinical Risk Assessment. The group will make further recommendations aimed at rebuilding relationships and maintaining public confidence in the safe and effective delivery of cancer medicines in the North Cancer Alliance and consider whether responsibilities need clarification, with a particular focus on:

- Current cancer medicines governance processes in the NCA, including the development of Cancer Management Guidelines (CMGs), and the processes for achieving clinical consensus in this context across the network.
- Escalation procedures when consensus is not achieved.
- Consideration of how effective and meaningful executive engagement from constituent boards within the NCA can be developed and maintained
- Any further actions that need to be taken in relation to the wider operations of the NCA, to ensure full engagement of its constituent Boards, as well as consideration of how best to incorporate the views of patients into its work.

In undertaking this work the Chair will meet with affected patients to consider the impact on them. Where appropriate the Group will seek external advice, expertise or evidence on specific matters.

Annex B

Membership

Name	Representing
Aileen Keel	Chair
Alan Rodger	Retired Former Medical Director, Beatson West of Scotland Cancer Centre
David Dunlop	Scottish Government Clinical Advisor
Grant Archibald	Chief Executive, NHS Tayside
Lorraine Cowie	NCA Manager NHS Grampian
Boyd Peters	Highland NHS Board (representing Chief Executive)
Aileen Muir	Lead Pharmacist for Governance NHS GG&C
James Mandor	SCAN Clinical lead
David Cameron	Deputy Chair Clinical Director, Edinburgh University Cancer Centre
Ian Rudd	Director of Pharmacy, NHS Highland
Laura McIver	Chief Pharmacist, Healthcare Improvement Scotland
Amanda Croft	Chief Executive, NHS Grampian

Secretariat was led by Marianne Barker of The Scottish Government.

Members received no remuneration.

Annex C

References

General Background

Clinical management of breast cancer in NHS Tayside (HIS Report) published 1 April 2019

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/programme_resources/nhs_tayside_breast_cancer.aspx

Clinical management of breast cancer in NHS Tayside: risk assessment of the Healthcare Improvement Scotland report, published 16 April 2019

https://www.gov.scot/publications/clinical-risk-assessment-healthcare-improvement-scotland-report-clinical-management-breast-cancer-nhs-tayside-april-2019/

MEL 1999/10- 9 Feb 1999 - Introduction Of Managed Clinical Networks Within The NHS In Scotland – see **Annex C1** for extract

https://www.sehd.scot.nhs.uk/mels/1999_10.htm

CEL 30 2012- July 2012 - [Revised] Guidance For the Safe Delivery of Systemic Anti-Cancer Therapy – See **Annex C2** for extract

https://www.sehd.scot.nhs.uk/mels/CEL2012_30.pdf

Patient consent

The full Supreme Court judgement on Montgomery vs Lanarkshire Health Board (11 March 2015)

https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf

GMC guidance on consent (2 June 2008, currently under review)

https://www.gmc-uk.org/-/media/documents/consent---english-0617_pdf-48903482.pdf

Occupational Development documents

Values Based Recruitment

https://www.sehd.scot.nhs.uk/dl/DL(2018)10.pdf

Compassionate Leadership

https://www.kingsfund.org.uk/publications/caring-change

NHS Scotland Staff Governance Standard

https://www.staffgovernance.scot.nhs.uk/what-is-staff-governance/staff-governance-standard/

NHS Scotland iMatter process

https://www.staffgovernance.scot.nhs.uk/monitoring-employee-experience/imatter/

Annex C1

Extract from MEL 1999/10- 9 Feb 1999 - Introduction Of Managed Clinical Networks Within The NHS In Scotland.

(Note- Paragraph numbering is as appears in original document)

8. In considering whether or not to confer such recognition, Boards, Trusts and the ME must take into account the degree to which the arrangements proposed satisfy the following core principles and are consistent with the policies in Designed to Care and the report of the Acute Services Review:

8.1 each Network must have clarity about Network management arrangements, including the appointment of a person who is recognised as having overall responsibility for the operation of the Network, whether a lead clinician, a clinical manager or otherwise. Each Network should produce a written annual report to the appropriate Health Board or Trust, which would also be available to the public;

8.2 each Network must have a defined structure which sets out the points at which the service is to be delivered, and the connections between them;

8.3 each Network must have a clear statement of the specific clinical and service improvements which patients could expect as a result of the establishment of the Network;

8.4 each Network must use a documented evidence base, such as SIGN guidelines where these are available, and must be committed to expansion of the evidence base through appropriate R & D;

8.5 each Network must be truly multi-disciplinary/multi-professional and should include representation from patients' organisations in its management arrangements;

8.6 each Network must have a clear policy on the dissemination of information to patients, and the nature of that information, bearing in mind the role of primary care in helping to lead the patient through the system;

8.7 all the health professionals who would make up the Network must indicate their willingness to practice in accordance with the evidence base and with the general principles governing Networks;

8.8 an integral part of each Network must be a quality assurance programme acceptable to the Clinical Standards Board for Scotland, which also has a role in ensuring consistency of standards and quality of treatment across all Managed Clinical Networks;

8.9 the educational and training potential for Networks should be used to the full, through exchanges between those working in the community and primary care and those working in hospitals/specialist centres. Networks' potential to contribute to the development of the intermediate specialist concept should also be kept in mind, and Networks should develop appropriate affiliations to universities, the Colleges and SCPMDE;

8.10 all health professionals in the Network must produce audit data to required standards and participate in open review of results;

8.11 all Networks must include arrangements to circulate staff in ways which improve patient access, and enable professional skills to be maintained. Each Network should have an appropriate programme of continuous professional development in place for every member of the Network, as well as a mechanism for ensuring the programme is being followed;

8.12 there must be evidence that the potential for Networks to generate better value for money has been explored**.**

Annex C2

Extract from CEL 30 2012- July 2012 - [Revised] Guidance For the Safe Delivery of Systemic Anti-Cancer Therapy

(Note- Paragraph numbering is as appears in original document)

1.4 Clinical Management Guidelines

1.4.1 A Clinical Management Guideline (CMG), as defined in the glossary, is in place for all common cancers. In paediatric cancer care, an approved clinical trial protocol may replace a CMG.

1.4.2 In rarer cancers, where there is no CMG, a SACT protocol is in place.

1.4.3 All CMGs or SACT protocols are approved by the appropriate, disease specific Managed Clinical Network (MCN) and local or regional governance arrangements.

1.4.4 An approved clinical trial protocol may be used in the absence of a SACT protocol.

1.4.5 Policies and procedures are in place to manage off-protocol requests for SACT, ensuring compliance with CEL (17) 2010.

Annex D

Glossary and abbreviations

Cancer Networks – there are 3 cancer networks in Scotland, SCAN, NCA and WoSCAN each responsible for delivery of cancer services within defined geographic boundaries

CEL – Chief Executive Letter - A circular issued by Scottish Government to inform NHS Scotland and other agencies of changes in Government policy, recent legislation or other information.

CEPAS – Chemotherapy Electronic Prescribing and Administration System An electronic system used for prescribing and administration of chemotherapy and all SACT, supports safe use of SACT and is capable of monitoring prescribing practice.

Chemocare® is the CEPAS software product currently used across NHS Scotland.

CMG – Clinical Management Guideline - a document that sets out information on the diagnosis and management of diseases or conditions, including cancer.

CMO - Chief Medical Officer.

CPO - Chief Pharmaceutical Officer.

FEC-T – A type of chemotherapy used to treat breast cancer

HIS - Healthcare Improvement Scotland – an organisation that is part of NHS Scotland with the aim of implementing better quality health and social care for everyone in Scotland.

IRG – Immediate Response Group.

MEL – Management Executive Letter. Now known as CEL.

MPEP - Molecular Pathology Evaluation Panel (https://www.mpep.scot.nhs.uk/)

NoSCAN - now known as NCA (Northern Cancer Alliance).

NCA – Northern Cancer Alliance (was NoSCAN) One of the 3 cancer networks in Scotland. Provides cancer care across 6 NHS Boards – Grampian, Highland, Orkney, Tayside, Shetland and Western Isles https://www.nrhcc.scot/nca. The other networks are SCAN and WoSCAN.

NSS – National Services Scotland.

Oncotype DX- a genomic test that predicts how likely breast cancer is to recur after surgery, and the likely benefit of chemotherapy.

QPI – Quality Performance Indicator. A measure of performance, used to evaluate success.

SACT - Systemic Anti-Cancer Therapy- the treatment of cancer with medicines. Chemotherapy is a type of SACT.

Scottish Cancer Taskforce – A Scottish Government Group that provides oversight on all aspects of cancer policy in Scotland.

SCAN - South East Scotland Cancer Network. One of the 3 cancer networks in Scotland. Provides cancer care across 4 NHS Boards-Borders, Dumfries and Galloway, Fife and Lothian https://www.scan.scot.nhs.uk/Pages/default.aspx

WoSCAN – West of Scotland Cancer Network. One of the 3 cancer networks in Scotland. Provides cancer care across 4 NHS Boards- Ayrshire and Arran, Forth Valley, Greater Glasgow and Lanarkshire. https://www.woscan.scot.nhs.uk/

This publication is available at **www.gov.scot**

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