The Regulation and Quality Improvement Authority

The Development of Departmental Cancer Guidelines and Patient Information Leaflets

Northern Ireland Regional Genetics Service

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Assurance, Challenge and Improvement in Health and Social Care

Executive Summary

The Northern Ireland Regional Genetics service (NIRGS) provides diagnosis, cancer risk assessments, genetic testing and risk management advice for individuals and families at risk of hereditary cancer syndromes. Protocols are in place for how this service should be delivered in line with national guidance.

In 2018 it was recognised that existing departmental protocols were poorly organised and inaccessible. There were also gaps in some protocols which required updated information and in some cases, the creation of new protocols. This project aimed to validate and improve the guidelines of the NIRGS Cancer service. By completing this project, we hope to effect long-term change by providing a framework for updating protocols to reflect future changes to clinical practice. The second aim of this project was to improve the consistency and quality of information provided to patients by producing patient information leaflets.

We used online surveys to evaluate baseline practice within our team and to identify any gaps within our existing protocols. We amalgamated existing protocols and updated these using national guidance. We identified gaps in departmental guidance and new protocols were written where needed. These documents were brought together into one comprehensive and version-controlled document. We established a review group with responsibility for overseeing and updating this guidance to reflect current practice.

We produced three patient information leaflets and introduced them into clinical practice. Staff and patient surveys of these leaflets were undertaken. There was a disappointing response rate from patients but the feedback received was positive. We hope to expand this project to produce more leaflets for other conditions and this project has provided a framework for future service development.

Context

The Northern Ireland Regional Genetics Service provides diagnosis and management of conditions with a known or likely genetic basis. Our clinical service is regional; diagnostic and counselling services are provided in a number of hospitals and community health centres across Northern Ireland. Our team provides specialist services for dysmorphology, prenatal genetics, neuromuscular genetics, neuropsychiatric genetics and cancer genetics.

Our cancer genetics service aims to provide individuals and their families with information to aid treatment decisions, promote the early detection of cancer and enhance cancer prevention in relatives. Individuals are given cancer risk estimations based on their family history. Genetic testing can be arranged for cancer predisposition genes and decision making about risk reduction strategies can be facilitated.

We conduct quarterly cancer meetings, which provide a forum for our department and the cancer service within the genetic laboratory to discuss any issues and to develop collective service aims. At one of these meetings in 2018 it was identified that we need consistent and accessible cancer protocols. Historically we had developed multiple cancer protocols. However, these guidelines and agreements were stored in multiple locations and were not regularly updated.

We agreed during this meeting to unite our existing protocols, guidelines and standard operating procedures into one version controlled document with the aim of improving the safety and quality of the cancer genetic service we provide. As a first step, we planned to survey the staff within the department to establish current working practices and to determine which guidelines were being used to guide clinical practice. We also used this exercise to highlight any gaps in our existing protocols, which we needed to rectify.

A second priority identified was to consider how we could best provide information about their cancer genetics appointment to patients. It was felt that developing patient information leaflets would achieve this. Due to the relatively high proportion of breast and ovarian referrals we receive, we decided that leaflets about BRCA gene testing would be a priority. These leaflets would complement patient appointments and our existing clinic summary letters and allow us to provide consistent information to our patients.

We also hoped to make these leaflets available to other health professionals within the Belfast Health and Social Care Trust. There have been ongoing efforts across the UK to “mainstream” cancer genetic testing by offering testing to patients during their routine cancer treatment appointments (1). Local cancer specialists who have started offering this testing have asked for information leaflets that they could provide to their patients. This should also improve the quality and consistency of information given to people who are having genetic testing outside of our department.

Background

The development of departmental Cancer Genetics Guidelines

Historically within the genetics department, we have developed practice guidelines in the form of departmental Standard Operating Procedures (SOPs). These are based on current practice and agreed best practice within the UK genetics community. National guidance such as the National Institute of Health and Care Excellence (NICE) guidance on familial breast cancer (2) and the GUT guidance on managing familial colorectal cancer (3) were also used.

One of the issues we had experienced with this ad hoc approach was the lack of an agreed system for reviewing and updating these departmental guidelines. Latest practice could be found within these SOPs but also within meeting minutes. This meant that team members missed crucial changes and we found that the same topics were being discussed multiple times. It could also be especially difficult for staff that had been away on a period of leave or for new staff members to find out about current practice.

We were aware that the Clinical Genetics Departments in Manchester had developed a comprehensive booklet of their cancer guidelines and the Royal Marsden had developed a collection of online protocols (4). Therefore we used these models as a template. Our objectives were to:

- Bring together and review all our existing protocols and agreed practice from meeting minutes
- To update this where necessary with current national guidance
- To use work from the clinical genetics departments in Manchester and The Royal Marsden as templates
- To evaluate the current practice and needs of our staff. We hoped to produce guidelines which would be dynamically responsive to changes in practice and new evidence

The development of BRCA patient information leaflets

Research suggests (5,6) that patient information leaflets can help provide information to enable patients to make informed choices and feel supported in their decision making. As genetic testing can have direct implications for a person's relatives we also hoped these leaflets would facilitate information sharing within families. The burden of disseminating genetic results to family members often falls on the first person diagnosed within an extended family. This is acknowledged in clinic by discussing family communication and barriers. Written information can aid this communication (7)

As early as 2003 the need to mainstream genetic advances and take advantage of genetic tools for diagnosis and disease prevention within the NHS has been identified as a priority (1). Following the publication of this white paper the Department of Health for England funded ten 'Mainstreaming Genetics' pilot services The aim was to develop models to help embed genomic services within

the NHS. (8). One of the key findings of these pilots was the importance of regional genetic service in aiding the development of roles and service and providing educational support and the development of education resources (8).

With the advent of genomic medicine it is envisioned that genomic testing will increasingly be offered within mainstream medical practice by non-genetic professionals and be offered by a wide range of specialists. Clinical genetic services will play a key role in supporting integration of testing and specialist knowledge within mainstream medical specialities (9).

The Mainstreaming Cancer Genetics (MCG) survey of current practice and ambitions within regional genetics services and found that the majority of centres (92%) reported increasing demand for testing from non-genetic clinical colleagues. Some of the challenges reported were the limited capacity of current processes and workforce education (10). We felt that by developing leaflets and sharing these with colleagues we could start to build closer working relationships.

Methodology:

<u>The development of departmental guidelines</u>

We completed a trawl of our departmental computer storage drive to identify all existing cancer protocols, which had been previously developed. We also checked the last two years of cancer meeting minutes to identify and include any agreements on best practice. We amalgamated this information into one regulated document and then compared this with national guidance from a range of sources including NICE, GUT and the ICR guidelines. We also used documents and leaflets produced by other clinical genetics departments in Bristol, the Royal Marsden and Manchester as guides for this work to ensure that information we compiled is appropriate, up to date and consistent with National practice.

We used SmartSurvey to develop questionnaires to ascertain current practice within our department. We hoped to identify any gaps within our existing protocols and check whether team members felt that these protocols were easily accessible and useful.

We had 11 responses to the ‘how we practice staff survey” which was a response rate of 73% (11/15). Four consultants and seven genetic counsellors completed the survey. All the respondents felt they were aware of and able to access existing cancer protocols. However, some comments on this survey were:

"*although these need tidied up, put on a Sharepoint/web site, and ratified by the relevant external specialists who will actually be doing the follow-up"*

***"[I] can access these however I feel they could be more concise, I feel pictorial flow/diagrams would be easier to follow than full bodied text*"**

Of the respondents, eight (73%) felt very confident applying the existing departmental guidelines to their clinical practice and three (27%) felt quite confident.

<u>The development of patient information leaflets</u>

Using our agreed departmental information and leaflets previously produced by the Bristol and Guys Genetics departments, we produced two patient information leaflets. These leaflets were designed for patients having predictive and diagnostic testing for the BRCA genes.

We trialled these leaflets within our clinics and developed a paper and online patient feedback survey. Clinicians in clinics handed out these surveys when a BRCA leaflet was given and could be posted back in the provided freepost envelope or completed using an online weblink. Approximately 30 paper surveys with a link to the electronic survey were distributed to patients by the genetic counselling team during clinic appointments.

We also sent copies of our BRCA leaflets to the Northern Ireland BRCA support group, BRCA link NI. It was hoped that any feedback from patients and their representative groups would help us assess the accessibility and usefulness of leaflets to the patient population. We acknowledged that this method of asking for feedback may only capture the views of those motivated and able to respond. We had hoped to have survey response boxes in the reception areas of our clinic as we identified posting back the surveys or going online as a potential barrier. However due to the suspension of face to face clinics as a result of the COVID 19 pandemic this was not possible.

Finally, we developed an online staff survey using SmartSurvey to determine whether staff had found the leaflet helpful for their practice. It was hoped that this would help us capture whether this had aided in delivering consistent information, whether they had found it useful to explain concepts and whether it had decreased the length of their clinic letters.

Analysis & Interpretation

The Project group arranged an initial meeting to plan the project. We agreed to start by identifying and updating the departmental cancer protocols. We divided into subgroups with responsibility for different disease guidance.

The subgroups trawled the departmental T-drive and meeting minutes for previously agreed protocols. These were evaluated against current national guidance and updated accordingly. A ‘how we practice’ staff survey was developed using SmartSurvey to establish current working practices and areas the team felt were a priority to update.

We drafted two patient leaflets for BRCA diagnostic testing and BRCA predictive testing with comments from the department and sent these to trust corporate communications for review and design development. We then developed patient leaflets surveys for the patient group and staff group. The staff group survey was only electronic. Patient group surveys were available in both paper and electronic formats. BRCA link NI and the oncologists were approached for comment on the patient information leaflets. Finally, we analysed the results of the leaflet surveys and redrafted the diagnostic BRCA leaflet to include panel information.

Challenges encountered during the project

During this project we encountered several challenges. One of the most fundamental was that we struggled to get patient feedback. Due to the Covid 19 pandemic our face-to-face clinic appointments were suspended and routine genetic testing was halted. Therefore very few surveys were distributed to patients. This problem was identified and it was hoped that surveys could instead be posted out to patients along with their letter.

During this project there was also an effort to re-triage some long waiting patients from the consultants’ waiting list to genetic counsellors. Therefore genetic counsellors were seeing more non-cancer patients in their clinics and fewer BRCA patients. This reduced the opportunity to give outpatient surveys. The combination of these factors meant that only a small number of surveys were handed out, much fewer than initially planned.

A change in genetic testing practice during study window meant diagnostic leaflet quickly became outdated for a large group of patients who would now have a wider panel test for several genes instead of just BRCA1 and BRCA2 genes.

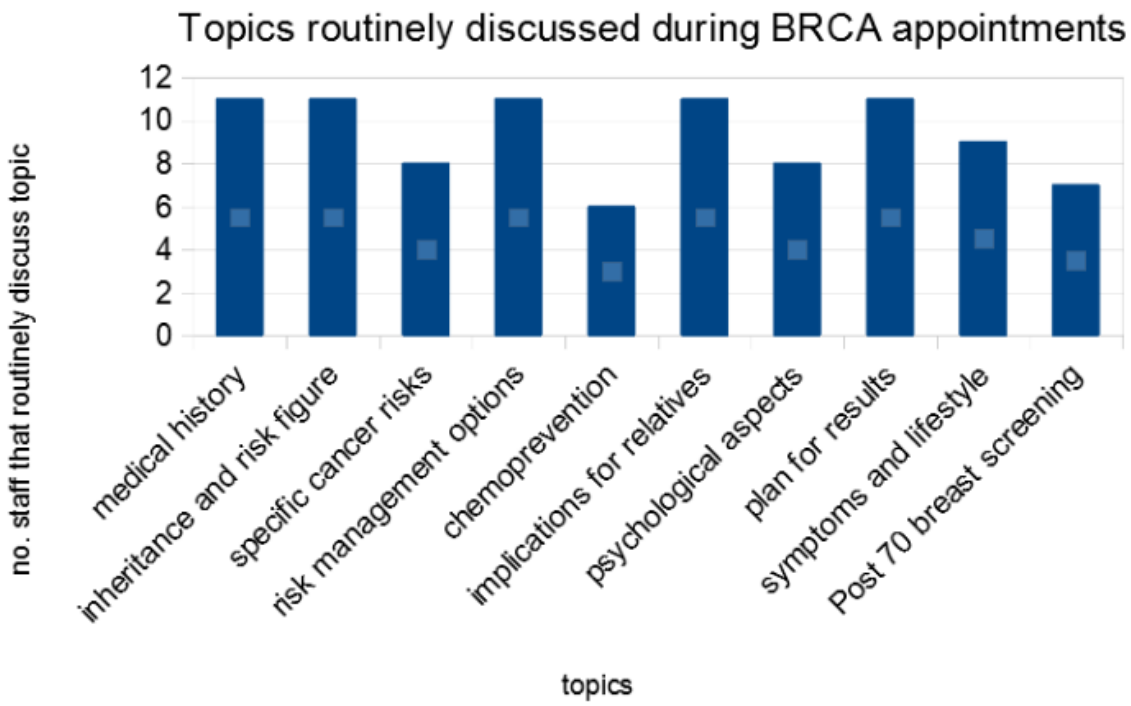
Results

Baseline 'How we Practice' Survey Results

The baseline survey had identified that 80% (8/10) of respondents felt there was some variability in GC practice. 27% (3/11) felt there was high variability between consultants, whilst64% (7/11) felt there was some variability. Therefore it was a priority for us to produce clear and concise departmental guidance which would ensure consistency in the information and advice we are providing to our patients.

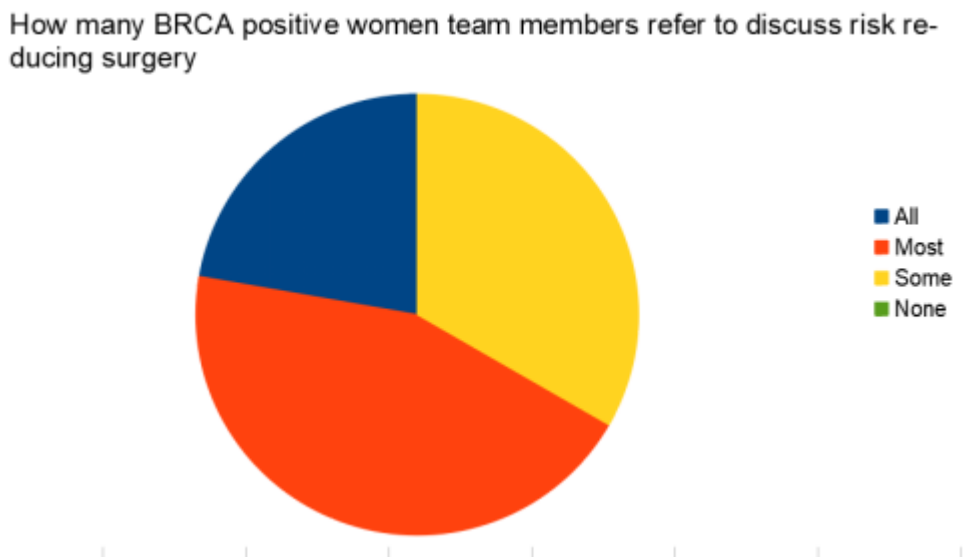
We found that there were some key elements of BRCA testing consultations that were discussed by all 10 staff who responded to this survey question. (Figure 1). Five additional topics were included by the team. Therefore these elements became key areas for us to include in our departmental guidelines and to ensure that we had appropriate information available.

Figure 1.



We found some areas of high divergence in practice such as whether BRCA positive women were routinely referred for risk reducing breast surgery. Out of the nine team members who answered this question, two discussed this option with all women, four discussed this option with most women and three discussed it with some women (Figure 2).

Figure 2:



The majority of the team felt confident offering testing for all cancer syndromes. However for five of the cancer syndromes (Li Fraumeni, PTEN, MEN2, Birt Hogg Dubé and HLRCC) some of the team did not report feeling confident offering predictive testing for these conditions. This highlights the need for agreed departmental guidelines to support our team.

Two comments on this question were that;

" [I] would be happy to learn more about management of the other conditions so I could advise patients"

"With guidelines I would feel confident in undertaking predictive testing and advising on management of any condition"

The guidelines have recently been completed and disseminated to staff . However, we have not yet been able to repeat our staff survey to determine whether the availability of agreed departmental guidance has improved staff confidence and consistency of information provided to patients.

Leaflets

The leaflets were completed, printed and disseminated to staff to use with their patients. Approximately 30 paper patient surveys were given to patients during their BRCA testing appointment. Unfortunately, this number was much smaller than hoped due to delays in the project and the suspension of face to face clinics during the Covid Pandemic. There was also a reduction in BRCA testing appointments at a critical time due to re-triaging and prioritising of urgent non-cancer referrals.

Of the 30 paper surveys, two were returned in the freepost envelopes provided and only one patient completed the online version of the survey using the provided link. Therefore, we had a response rate of approximately 10% (3/30).

We also received no response to the two emails sent to the Northern Ireland BRCA support group, BRCA Link NI when we asked for feedback on the leaflet.

An electronic staff survey was sent to 13 staff members and 8 responses were received which was a 62% response rate. 100% of the respondents reported that the BRCA patient leaflets had been useful in their practice. 38% (3/11) would like to change something about the leaflets. The proposed changes were expanding the diagnostic BRCA leaflet to reflect that wider genetic testing for BRCA testing is now available:

"The predictive testing leaflet is good but screening leaflet not relevant for most as now do panel test, not just BRCA"

Of the five staff members who had given leaflets to their patients, 100% thought that their patients had found it helpful.

"I gave a patient a leaflet and she later contacted me to ask for more leaflets for her sisters who had also been through the service but not received a leaflet"

"Yes I had patients who had already been passed leaflet by other family members. This is very useful information for patients to have pre-clinic as well".

All six staff who answered the question reported that having the BRCA leaflet had allowed them to decrease the length of their clinic letters.

"Yes- without doubt but also improves consistency in what information is given to patients".

"Very useful. Acts as backup in case I missed anything or in case the patient was bombarded by information during the appointment and instead would be better reading over things later".

All eight staff members felt it would be useful to develop leaflets for other patient groups and the suggestions were for Lynch syndrome, prenatal advice and breast cancer panel testing.

Our three patient responses were from patients who received the diagnostic testing leaflet. They all felt that the leaflets included the right amount of information; it answered their questions and was easy to read. All three patients also responded that they were likely to show the leaflet to family members.

Discussion

As a department, we have made the development of validated protocols for our cancer genetics service a priority. It was hoped that this project would increase the safety and quality of service we provide for our cancer genetics patients as we have agreed guidelines promoting consistent, evidence based practice.

Now that these guidelines have been completed we believe that this project will promote effective working and will provide a higher standard of consistent information to our patients. We plan to repeat the 'how we work' staff survey in six months to measure the effects that these guidelines have had on staff working.

These guidelines will now act as a framework for our cancer practice and will be regularly updated as our protocols or national guidance change. There is now an agreed mechanism for updating these guidelines through the project working group, who will continue to hold ownership and responsibility for this document. Therefore these departmental cancer guidelines should continue to promote best practice, improve quality and safety within the department.

Leaflets

During this project we have developed three patient information leaflets. At the beginning of the project, we only planned to produce two leaflets on predictive and diagnostic genetic testing. These patient leaflets were agreed by the department and developed in conjunction with the Belfast Health and Social Care Trust corporate communications team.

We introduced these leaflets into clinical practice in August 2019. It was hoped that these leaflets would improve the quality and consistency of information given to

patients and facilitate information-sharing within families. Unfortunately, despite developing a patient survey in paper and electronic formats we received only one patient feedback in time to include within this report.

Significantly fewer surveys than hoped were passed out to patients in clinics (25) and we had no response to requests for feedback to the local BRCA support group, BRCAlink NI. Part of the reason may be due to the suspension of clinic appointments and the replacement with virtual clinics due to the Covid 19 pandemic. We also had a reduction in cancer cases in clinics due to a re-triaging of the waiting list to include general patients in genetic counsellor clinics. As a department we recognise the importance of patient input into these leaflets and we will continue to hand out the surveys by post during virtual clinics and send copies of the electronic survey link.

During the Covid 19 pandemic we predominantly moved to telephone clinics. However video clinics have been trialled and a move towards electronic communications has been necessary. This may present an opportunity to send patient survey links by email which could facilitate a higher response rate on the electronic survey.

The BRCA leaflets were shared with the oncologists who were satisfied with the content of these and thought they would be helpful in their clinics. One further aspect that has come out of this project has been the awareness that closer working with cancer specialists is desirable to further embed mainstreaming of genetic testing and the lessons learned from the 100,000 genomes project in mainstream practice.

We recorded high levels of staff satisfaction with the leaflets and anecdotal evidence of patient satisfaction. During the project, we received feedback from staff that the diagnostic testing leaflet was no longer ideal for a large group of these patients due to a change in testing practice. Belfast Genetics laboratory developed three new gene panels for breast cancer only patients, breast and ovarian cancer patients and ovarian cancer patients. These panels included more genes now and our leaflets which only included the BRCA1 and BRCA2 genes were no longer relevant when these tests were ordered.

In response to this feedback, we developed a new leaflet aimed at patients having breast or ovarian cancer gene panel tests. These leaflets will be introduced into clinical practice soon and we will also aim to record patient views and review these when it is available.

Conclusion

At the completion of this project, we have developed agreed protocols for the diagnosis and management of individuals with various inherited cancer syndromes. These have been agreed and collated into one document. We have also implemented a review system which will ensure that this document remains up to date and integral to practice within our team.

We have also developed three patient information leaflets which we believe has improved the consistency and quality of information we offer to our patients and the patients that will be offered genetic testing outside of the genetics clinic as part of their cancer treatment.

A key limitation of this project was the lack of patient engagement and survey responses. This is partially due to very few surveys being handed out due to various reasons including Covid19 pandemic but we would also like to make providing feedback easier for our patients and will explore sending the electronic survey by email.

The fact that one leaflet became obsolete to a large group of patients during the project highlights how quickly guidelines and testing practices can change within medical genetics. Especially during the current climate of a move to genomic testing and the huge investments made in the area worldwide. The development of the first two leaflets has given us a framework for presenting information and also the contacts within the trust to produce these in a patient-friendly format. Therefore it was relatively easy to adapt to these changes and produce a new leaflet for panel testing.

This project has given us solid foundations to build upon within the genetic team. There has also recently been a shakeup in clinical structures and we now have a consultant lead for the cancer service.

Staff engagement has been high and there is interest in expanding the project to provide leaflets for other patient groups, specifically people with a family history of colorectal cancer or Lynch syndrome.

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Project Team
Dr Tabib Dabir, Clinical director and Consultant Clinical Geneticist Mrs Sianan MacParland, Lead Genetic Counsellor Mrs Aoife Bradley, Genetic Counsellor Dr Gillian Rea, Consultant Clinical Geneticist Dr Deirdre Donnelly, Consultant Clinical Geneticist

The **Regulation** and
Quality Improvement
Authority

The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
@RQIANews