How to set up an in-house nurse-led colorectal Lynch syndrome clinic

Abstract

The NHS long term plan sets a target that by 2028, 75% of cancers will be diagnosed at an early stage. One of the ways this ambition will be reached is through targeted screening and personalised surveillance of those most at risk of developing cancer, such as those with Lynch syndrome.

This article outlines the essential steps to consider when setting up and managing an in-house nurse-led colorectal Lynch syndrome clinic. It highlights the educational requirements, patient criteria, the importance of thorough planning and the need to liaise-on with key stakeholders.

Filipe Carvalho, Nurse Consultant in Colorectal Disease, Homerton Healthcare NHS Foundation Trust, London; **Anna Koziel**, Nurse Practitioner and Regional Lynch Syndrome Nurse for North Thames GMSA, St Mark's Hospital Centre for Familial Intestinal Cancer, North West London Hospitals NHS Trust, North Thames GMSA, London; **Laura Monje-Garcia**, Nurse Practitioner and Lynch Syndrome Project Lead Nurse, St Mark's Hospital Centre for Familial Intestinal Cancer, Imperial College London, North Thames GMSA, London

filipe.carvalho@nhs.net

Key words

- Bowel cancer
- Colorectal cancer
- Lynch Syndrome
- Nurse-led

This article has been subject to double-blind peer review

Accepted 3 May 2023

Lynch syndrome (LS) is a genetic condition that can significantly increase the risk of developing bowel cancer to up to 80%, and increases the risk of many other cancers such as uterine and ovarian (National Institute for Health and Care Excellence (NICE), 2022). LS is the most common form of hereditary colorectal cancers (CRCs), accounting for about 3.3% of CRCs (NICE, 2017). It is estimated to lead to over 1200 CRCs every year and affect over 175 000 people in the UK, a large proportion of whom will be unaware that they have the condition, and many under the age of 50 (Bowel Cancer UK, 2018; NICE, 2020; NHS England, 2021).

LS is caused by genetic changes (pathogenic variants) in the DNA mismatch repair (MMR) genes (NHS England, 2021). Their main function is to fix mistakes made when DNA is copied during cell division, and normally protects people from developing certain cancers (NHS England, 2021; NICE, 2022. When there is a fault in one of the MMR genes, any mistakes in DNA are not corrected and this can lead to tumour cells developing (NICE, 2020; NHS England, 2021). Cancer patients who have proficient MMR can benefit more from specific chemotherapy regimens, whereas patients with LS (deficient MMR), are usually more responsive to immunotherapy drugs, rather than more conventional chemotherapy treatments (Bowel Cancer UK, 2018; NHS England, 2021). Therefore, MMR status should be established promptly to guide treatment options at the early stages of diagnosis if possible (NICE, 2017).

As LS is a condition inherited in an autosomal dominant manner, there is a 50:50 chance of passing on the condition through generations, so whole families can be devastated by cancer (NHS England, 2021). NICE (2020) estimates that over 300 bowel cancers could be prevented each year in the UK from testing everyone for LS and implementing risk reduction treatments and appropriate surveillance pathways for patients and their at-risk or affected relatives. Implementing nurse-led LS clinics can facilitate the identification of many of these patients, and in doing so, prevent or detect cancers in family members at an earlier stage. Hence all newly diagnosed CRC patients who are identified as likely to have LS should promptly have germline genetic testing promptly (NICE, 2020; NHS England, 2021).

Attaining training requirements

To improve uptake of germline genetic testing for LS, the Genomic Medicine Service Alliance (GMSA) national LS transformation project, developed a training program to assist healthcare professionals (HCPs) through mainstreaming. Mainstreaming refers to shifting genomic testing away from clinical genetics to other clinics and specialities (Hallowell et al, 2019). In the LS testing pathway, this means

that HCPs can now offer genetic counselling and testing in routine oncology clinics. In nursing, this means that this service can now be integrated into in-house nurse-led clinics.

Essential online training is available through the RM Partners West London cancer alliance website (soon to be moved to E-learning for healthcare), for nurses that wish to set up nurse-led LS clinics. The website involves short videos that provide an overview of all the different stages of the LS pathway. The training also includes a questionnaire, to ensure a correct understanding of the processes and procedures for testing, including how to identify and manage patients likely to have LS. Furthermore, bespoke workshops are also offered, delivered by either an LS nurse specialist or through the local clinical genetics department, to help nurses set up mainstreaming LS clinics, and supplementary online resources and training are accessible via the Health Education England Genomic Education Programme.

Each CRC multidisciplinary team (MDT) should have a designated LS pathway champion, which can be any member of the MDT including surgeons, pathologists and nurses (NHS England, 2021; NICE, 2022); and not necessarily the colorectal nurse specialist. For the purpose of setting up the nurse-led clinic, the colorectal nurse specialist should undergo the online training programme and bespoke workshops, prior to starting to see patients. Ongoing support to improve the delivery of the pathway and ensure continuous growth is provided via a supporting network, which includes the regional LS project team, LS nurse specialists, GMSA, clinical genetics departments and the local cancer alliance (NHS North Thames Genomic Laboratory Hub, 2022a).

Service set-up

During service set-up, a standard operating procedure (SOP) should be agreed on, detailing the delivery of the early diagnostic pathway, from diagnosis of CRC to diagnosis of LS, and outlining the pathway and individual MDT member responsibilities. An example of an appropriate SOP can be found on the RM Partners West London cancer alliance website, which can be easily modified to fit local or regional services.

Communication and thorough planning with key stakeholders is central to creating a successful service (Hatchett, 2008; 2016). Cancer alliances and LS project teams can support communication with key stakeholders in the Trust and provide information about the service set-up. Offering a clear overview to all those who may be affected by the new service, explaining why the service is needed, what the service can provide and what it can offer to the organisation, may facilitate service delivery, help with developmental constraints and mitigate professional and organisational pressures (Hatchett, 2008; 2016). Therefore, liaising with key stakeholders, such as service managers, and obtaining their support, on the proposed nurse-led mainstreaming LS clinic and what is required (for example clinic codes), might help meet specific service needs. Furthermore, as LS falls under transformation, the local cancer alliance might be able to provide funding, leading to cost zero for the organisation.

The LS project team will provide support, guaranteeing that there is a system to order germline LS testing and receive results safely, and a dedicated forum, such as the local genetics MDT meeting, to discuss results, recommendations or any complex cases (NICE, 2020; NHS England, 2021; NHS North Thames Genomic Laboratory Hub, 2022a). Furthermore, the LS project team will support in linking up with the local clinical genetics team, to ensure referrals are actioned and in access to the regional LS network for support and development (NICE, 2017; 2020; NHS England, 2021; NHS North Thames Genomic Laboratory Hub, 2022b).

Identifying patients eligible for genetic testing

All colorectal tumours should be tested for MMR proteins (MLH1, MSH2, MSH6 and PMS2) with either immunohistochemistry or microsatellite instability (MSI), to identify patients in whom the cancer may have occurred because of LS and where further diagnostic tests are indicated (NICE, 2017; 2020; NHS England, 2021). Hence, the LS champion should have a close working rapport with the local histology laboratory, to ensure that every patient with a new diagnosis of CRC, has, if possible, their first available tumour sample tested for MMR and reported in a timely manner. Eligible patients for follow-up at the nurse-led LS clinic are shown in *Table 1* (NICE, 2017; NHS England, 2021).

Following histology result review in the local CRC MDT meeting and acknowledgement of eligible patients, a proforma letter should be

Table 1. Eligible patients for follow-up at the nurse-led LS clinic

In Immunohistochemistry screening testing
• Loss of MSH2 and/or MSH6 or PMS2 alone • Loss of MLH1 alone, or with any other protein, with no BRAF mutation OR MLH1 methylation not present
If using MSI testing
• Microsatellite Instability high, with no BRAF mutation OR MLH1 methylation not present
Other
• Diagnosis of colorectal cancer under 40 years of age • High-risk family history of colorectal cancer, as per Amsterdam criteria (Monahan et al 2020)

Box 1. LS testing possible results and benefits to patient and family

Pathogenic variant identified

Benefits for patients: personalised therapies (such as immunotherapy and surgery) and surveillance

Implications and benefits for family members: predictive genetic testing and surveillance, referral to specialised genetics centres (cascade testing, family planning, etc)

No pathogenic variant detected

Implications for patients (LS not ruled out): surveillance following Lynch-like syndrome guidelines

Implications for family members: surveillance, referral to specialised genetics centre for further somatic/tumour testing (to clarify if they have LS or not)

Variant of uncertain significance (VUS) identified

Implications for patients (LS not ruled out): surveillance following Lynch-like syndrome guidelines Implications for family members: surveillance, referral to specialised genetics centre for further somatic/tumour testing (to clarify if they have LS or not) and variant of uncertain significance management

sent to the patient's GP, and the patient should be informed, about their upcoming appointment in the CR nurse-led clinic for genetic assessment (NHS England, 2021).

Clinic structure

Prior to the first appointment, patients should be sent information about LS and what the intent of the appointment will consist of (to take a history, explore risks, give information, etc), as well as a family history questionnaire, preferably via post. The latter will allow for the CR nurse specialist to assess the patient's family for LS risk, as accurately as possible, and the patient should be informed that all information given will be held in confidence (NHS England, 2021).

It is recommended for the first appointment to be coded as a new patient, have a duration of 45–60 minutes and be face-to-face. During this appointment, the following should be addressed:

- Discussion of MMR results, what LS is and rationale for attending the clinic
- Discuss the patient's family history and draw up family pedigree (a diagram of the family history that uses standardised symbols and shows relationships between family members)
- Discuss what LS genetic testing is, what it involves and its implications for the patient and relatives. The latter is primarily related to cascade testing, which is the process of informing family members of a genetic condition discovered in the family, followed by family members getting tested for that same condition
- Discuss further management in the clinical genetics department
- Offer genetic counselling and obtain patient consent to undergo genetic testing
- Ensure that the patient understands the three possible results (*Box 1*)
- Obtain a blood sample and send it to the local genetic laboratory
- Make the patient aware of sample turnaround time and how to contact if further information is required
- Direct patient to dedicated patient-specific information resources, for further insight
- Produce a letter summarising the appointment, which should be sent to both patient and the consultant in charge of the patient's care and GP.

Once the nurse specialist receives the germline testing results, and discusses those results and recommendations at the regional specialised genetic forum or MDT, the patient should then be booked for a second appointment, coded as a follow-up, lasting 20–30 minutes, and via telephone or video clinic, pending the patients' preference, where the following should be addressed:

- Results should be given to the patient
- Recommended management discussed
- Recommendations for first-degree family members
- Referral to the local clinical genetics department
- Produce a letter summarising the appointment, enclosing the genetic report, which should be sent to the patient, the referring clinical genetics department, the consultant in charge of the patient and the GP.

The patient can then be discharged from the colorectal nurse-led LS clinic. Good practice

would be to ensure that the local clinical genetics department will action the referral, that a local register of LS patients is maintained (NHS England, 2021), and that patient knows whom to contact if any questions/issues arise (usually the parent cancer team).

Further recommendations

As with any new service, it is important to regularly evaluate quality improvement and ongoing requirements (Hatchett, 2008; 2016). Therefore, auditing and evaluating nurse-led clinics is recommended to provide evidence that they are having a positive impact on patient care and experience, and are meeting patient needs (Hatchett, 2008; 2016). Additionally, the CR nurse specialist should maintain continuing professional development updates to ensure stability, growth, and future developments in the service.

Currently, there is support and training available to set up nurse-led clinics through the GMSA national LS transformation project. In the future, once the project closes, support should be available through the regional LS network, cancer alliances and clinical genetics department.

Clinical implications

The literature supporting the role of nurse-led clinics is growing. Studies have shown that nurse-led clinics can improve patient experience and demonstrate nurses' ability to run a measurably effective service.

Creating a nurse-led LS clinic can benefit patients by providing a more consistent patient pathway for earlier identification of undiagnosed patients with LS This can lead to cascade genetic testing of family members, who, if also positive for LS, can be prompted to undergo early cancer screening and surveillance diagnostic tests, such as colonoscopy to detect CRC, and preventive treatments, such as aspirin. In addition, reassurance can be offered to patients and relatives when testing rules out a diagnosis of LS. **GN**

Declaration of interest *None*

Box 2. Key points when establishing a colorectal nurse-led LS clinic

1. Identify the CRS LS pathway champion
2. Complete the recommended national LS project online training and further bespoke workshops
3. Link with the regional GMSA LS project team and cancer alliance for guidance and support
4. Link with key stakeholders for support and consider funding sources
5. Set out clinic format, structure and resources needed
6. Liaise with the local histology laboratory to guarantee MMR testing and timely reporting
7. Acknowledge eligible patients for genetic counselling at the CR Nurse-Led LS clinic
8. Link with local genetic laboratory, for genetic testing ordering and access to results
9. Join the local genetics MDT meeting for results discussion and recommended genetic management
10. Liaise with local genetics clinic for referral for cascade testing, further tumour testing, family planning, etc
11. Join regional LS network meetings, if available, for support and development

Bowel Cancer UK. It's time to test for Lynch syndrome. 2018. https://bowelcancerorguk.s3.amazonaws.com/Campaigns/LYNCH%20SYNDROME%20REPORT%20FINAL.pdf (accessed 9 January 2023)

Hallowell N, Wright S, Stirling D et al. Moving into the mainstream: healthcare professionals' views of implementing treatment focussed genetic testing in breast cancer care. Fam Cancer. 2019;18(3):293–301. https://doi.org/10.1007/s10689-019-00122-y

Hatchett R. Nurse-led clinics: 10 essential steps to setting up a service. Nurs Times. 2008;104(47):62–64

Hatchett R. How to set up a nurse-led clinic. Nurs Stand. 2016;30(37):64–65. https://doi.org/10.7748/ns.30.37.64.s45

Monahan KJ, Bradshaw N, Dolwani S et al. Guidelines for the management of hereditary colorectal cancer from the British Society of Gastroenterology (BSG)/Association of Coloproctology of Great Britain and Ireland (ACPGBI)/United Kingdom Cancer Genetics Group (UKCGG). Gut. 2020;69(3):411–444. https://doi.org/10.1136/gutjnl-2019-319915

National Institute for Health and Care Excellence. DG27: Molecular testing strategies for Lynch syndrome in people with colorectal cancer. 2017. https://www.nice.org.uk/guidance/dg27 (accessed 9 January 2023)

National Institute for Health and Care Excellence. NG151: colorectal cancer. 2020. https://www.nice.org.uk/guidance/ng151/resources/colorectal-cancer-pdf-66141835244485 (accessed 9 January 2023)

National Institute for Health and Care Excellence. QS20: colorectal cancer. 2022. https://www.nice.org.uk/Guidance/QS20 (accessed 8 January 2023)

NHS England. Implementing Lynch syndrome testing and surveillance pathways. 2021. https://www.england.nhs.uk/wp-content/uploads/2021/07/B0622-implementing-lynch-syndrome-testing-and-surveillance-pathways.pdf (accessed 8 January 2023)

NHS North Thames Genomic Laboratory Hub. National GMSA transformation project: Lynch syndrome. 2022a. https://www.norththamesglh.nhs.uk/national-gmsa-transformation-project-lynch-syndrome/ (accessed 8 January 2023)

NHS North Thames Genomic Laboratory Hub. Regional Lynch Syndrome expert networks in development. 2022b. https://www.norththamesglh.nhs.uk/new-regional-lynch-syndrome-expert-networks-in-development/