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RESEARCH ARTICLE

From diagnosis of colorectal cancer to diagnosis of Lynch syndrome: The RM Partners quality improvement project

Laura Monje-Garcia[1] | Timothy Bill[2] | Lindsay Farthing[2] | Nate Hill[2] | Emma Kipps[2] | Angela F. Brady[3] | Zoe Kemp[4] | Katie Snape[5] | Alistair Myers[6] | Muti Abulafi[7] | Kevin Monahan[1]

[1]St Mark's Hospital Centre for Familial Intestinal Cancer, Imperial College London, London, UK

[2]RM Partners West London Cancer Alliance, London, UK

[3]North West Thames Regional Genetics Service, London, UK

[4]The Royal Marsden Hospital Cancer Genetics Unit, London, UK

[5]South West Thames Centre for Genomics, London, UK

[6]Hillingdon Hospitals NHS Foundation Trust, London, UK

[7]Croydon University Hospital, London, UK

Correspondence
Kevin Monahan, St Mark's Hospital Centre for Familial Intestinal Cancer, Imperial College London, London, UK.
Email: k.monahan@imperial.ac.uk

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Abstract

Aim: The UK National Institute for Health and Care Excellence guideline DG27 recommends universal testing for Lynch syndrome (LS) in all newly diagnosed colorectal cancer (CRC) patients. However, DG27 guideline implementation varies significantly by geography. This quality improvement project (QIP) was developed to measure variation and deliver an effective diagnostic pathway from diagnosis of CRC to diagnosis of LS within the RM Partners (RMP) West London cancer alliance.

Method: RM Partners includes a population of 4 million people and incorporates nine CRC multidisciplinary teams (MDTs), overseen by a Pathway Group, and three regional genetic services, managing approximately 1500 new CRC cases annually. A responsible LS champion was nominated within each MDT. A regional project manager and nurse practitioner were appointed to support the LS champions, to develop online training packages and patient consultation workshops. MDTs were supported to develop an 'in-house' mainstreaming service to offer genetic testing in their routine oncology clinics. Baseline data were collected through completion of the LS pathway audit of the testing pathway in 30 consecutive CRC patients from each CRC MDT, with measurement of each step of the testing pathway. Areas for improvement in each MDT were identified, delivered by the local champion and supported by the project team.

Results: Overall, QIP measurables improved following the intervention. The Wilcoxon signed rank test revealed significant differences with strong effect sizes on the percentile of CRC cases undergoing mismatch repair (MMR) testing in endoscopic biopsies ($p = 0.008$), further testing with either methylation or BRAF V600E ($p = 0/03$) and in effective referral for genetic testing (from 10% to 74%; $p = 0.02$). During the QIP new mainstreaming services were developed, alongside the implementation of systematic and robust testing pathways. These pathways were tailored to the needs of each CRC team to ensure that patients with a diagnosis of CRC had access to testing for LS. Online training packages were produced which remain freely accessible for CRC teams across the UK.

Conclusion: The LS project was completed by April 2022. We have implemented a systematic approach with workforce transformation to facilitate identification and 'mainstreamed'

genetic diagnosis of LS. This work has contributed to the development of a National LS Transformation Project in England which recommends local leadership within cancer teams to ensure delivery of diagnosis of LS and integration of genomics into clinical practice.

KEYWORDS
diagnosis, Lynch syndrome, mainstreaming, MMR IHC, quality improvement project

INTRODUCTION

Up to 35% of all cases of colorectal cancer (CRC) in the UK arise due to heritable risk factors and, of these, about 3% are caused by Lynch syndrome (LS). Thus, LS is thought to account for approximately 1200 cases of CRC annually in the UK together with a similar number of extracolonic cancers, especially endometrial cancer in women. In addition, a further 15% of CRCs manifest LS-like tumour features [somatic mismatch repair (MMR)-deficient tumours] due to noninherited causes [1, 2].

Lynch syndrome is the most common cancer predisposition syndrome and the most common form of hereditary CRC. An estimated 200 000 people have LS in the UK, but only 11 000–12 000 affected individuals have been diagnosed [3]. For this reason, in February 2017 the National Institute for Health and Care Excellence (NICE) recommended universal testing for LS for all patients newly diagnosed with CRC (NICE guideline DG27) [4] in the UK. It is thought that 300 lives may be saved annually with full implementation of this guideline, as diagnosis in CRC patients and their relatives provides many opportunities for personalized care and prevention strategies, including surveillance colonoscopy, aspirin as prophylaxis, risk-reducing gynaecological surgery and adaptive oncological therapies. In addition, a diagnosis of deficient MMR (dMMR) can affect cancer treatment options, with certain tumours being more responsive to immune checkpoint inhibitor immunotherapy [5]. It is therefore important that the initial tumour test for MMR status is performed promptly to inform treatment options [2].

A multidisciplinary expert letter published in the *BMJ* in 2017 [6] recommended a national and regional strategy for the management of these patients with the following specific goals:

1. the development of a national LS registry
2. a quality-assured surveillance programme for LS patients
3. a dedicated clinical champion for hereditary CRC within every colorectal multidisciplinary team (MDT).

To embed robust LS diagnostic pathways delivered by CRC MDTs the following LS quality improvement project (QIP) was proposed:

The LS QIP [7] was developed to ensure an effective and fast diagnostic pathway from diagnosis of CRC to diagnosis of LS. The QIP proposed a two-phase solution to ensuring an effective LS diagnostic pathway, which would create a sense of responsibility locally and regionally amongst clinicians. The aims were:

Primary aim: to increase the identification and diagnosis of LS within the RMP cancer alliance geography through successful implementation of the UK NICE DG27 [4] guidelines.

Secondary aims:

- To identify a 'LS champion' within each CRC MDT to coordinate the local diagnostic pathway.
- To develop online and workshop-related training resources to support diagnostic delivery and improve awareness of LS by all CRC MDT clinicians.
- To identify and ensure roles for specific members of each CRC MDT, for example 'reflex' somatic (tumour) testing by histopathologists.
- To ensure effective identification of eligible patients and referral pathways for genetic testing by patient-facing clinicians.
- To offer training in 'mainstreaming' of genetic testing by local CRC MDT clinicians.
- To perform measurement of and reduction in geographical variation in the diagnostic pathway.
- To develop improvements 'tailored' for each CRC MDT.

With this strategy we can maximize opportunities to save the lives of LS patients and those with sporadic dMMR tumours who have a diagnosis of CRC as well as the lives of the asymptomatic LS relatives. This can ensure minimal variability in patient care and appropriate surveillance and implementation of other broader prevention and treatment strategies.

METHOD

Population and project initiation

The RMP West London cancer alliance is one of the 21 cancer alliances established by NHS England to lead on the delivery of cancer care for the population of West London. RMP brings together clinical and managerial leaders within their partner NHS Trusts, primary care partners and other social and health organizations to bring about earlier and faster diagnosis and improve treatment and care for cancer patients within their region. The RMP geography includes a population of 4 million people and incorporates nine CRC MDTs overseen by a Pathway Group (PWG) and three regional genetic services, managing approximately 1500 new CRC cases annually [7].

The QIP was conceived and led by the senior author (KM) from the St Mark's Centre for Familial Intestinal Cancer. The clinical experience and research generated by the department have allowed the team to lead the evidence-based guidelines for the management of patients with inherited CRCs [8]. The centre has international recognition and is one of the national expert centres, providing education and leadership within the field [9]. The LS service provides lifelong care with regular follow-up for patients living with LS and supports other clinical institutions in the UK.

The project was funded by the RMP Cancer Alliance Transformation Fund. The QIP was agreed by the RMP CRC PWG prior to project initiation. The PWG included membership from each CRC MDT, the clinical director and other leadership from the RMP cancer alliance in November 2018. This included an agreement to participate in the index survey, identify LS champions in each MDT, participate in an audit and work with the QIP team to facilitate quality improvement and sustainability. Collaborative working through this forum ensures that each of the organizations has an opportunity to input and agree the outcomes, resulting in improved engagement and support to ensure the project achieves its potential and realizes its benefits.

The project was also agreed with the relevant genomics services in both southwest and northwest London to ensure its objectives align with both services. This allowed consideration to be given to the impact of the project upon these services from the outset, allowing for early risk identification and mitigation. The project commenced in August 2020 with the recruitment of a nurse practitioner (LMG).

All CRC patients are eligible for DG27 diagnostic testing [4] at diagnosis. Universal MMR immunohistochemistry (IHC) testing would identify approximately 15%–20% of those with LS or other MMR-deficient CRCs, either by IHC or microsatellite instability (MSI) testing. For those with high MSI or loss of MLH1 staining on IHC, subsequent tumour (somatic) MLH1 promotor hypermethylation and/or BRAF V600E testing, can further define those who should proceed to germline testing. If the results show that the tumour sample does not contain MLH1 promoter hypermethylation or no mutation is identified in BRAF (also called BRAF wild-type), the patient may have LS and should be offered germline genetic testing. On average, germline genetic testing should be performed on approximately 6%–8% of newly diagnosed CRC patients [10].

Evidence from a national survey produced by Bowel Cancer UK [3] presented to the RMP colorectal PWG demonstrated that implementation of testing for patients with CRC is patchy both nationally and within the RMP network.

Implementation of the QIP in two phases

The QIP proposed a two-phase solution to ensuring an effective pathway from diagnosis of CRC to diagnosis of LS, which would create a sense of responsibility locally and regionally amongst clinicians. Phase 1 was essential and included solutions to embed robust and effective LS diagnostic pathways within each MDT.

Phase 1 (essential): implementation of universal testing of CRC following DG27 guidelines

This phase comprises the following components:

- Colorectal MDTs nominate a 'champion' for this pathway.
- Audit of 30 consecutive patients to assess each LS diagnostic pathway at baseline and 1 year later to assess the implementation of the QIP.
- Routine reflex MMR tumour testing for LS, performed preferentially on colonoscopic biopsies.
- Subsequent reflex testing by a pathologist for further somatic tests before germline testing, if required.
- MDTs to identify and refer patients for genetic testing, either to their local clinical genetics service or their trained MDT patient-facing qualified professional.
- Development of a systematic approach for MDTs to refer patients and seek advice from regional genetics services.
- Online training modules for MDT members with relevant continuing profesional development (CPD) and certification for appraisal purposes [7].
- Development of a standard operating procedure for the RMP region approved by the CRC PWG and genomic services [11].
- Making available easily accessible supporting documents (e.g. standard operating procedure, guidelines, quick referral, request forms, consent form, patient information leaflets and website, etc.) [11].

Phase 2 (optional): mainstreaming of germline genetic testing

Phase 2 is optional and includes solutions to streamline germline genetic testing within each MDT so that germline testing can be offered quickly and effectively in routine oncology clinics. It comprises the following components:

- Additional bespoke workshop training and support for MDT members who wish to offer germline genetic testing to their patients in routine oncology clinics.
- Germline testing algorithms to ensure that: (1) carriers of pathogenic MMR variants are referred to specialist clinics, that is, clinical genetics; (2) those patients with negative gene tests or variant of unknown significance results are managed appropriately.
- A system with a forum to safely manage results and offer patients further appointments in specialized genetic services when applicable

Measurables

It was expected to observe an improved LS diagnostic pathway for CRC patients following the intervention in a 1-year period. The key performance indicators (KPIs) for this QIP were collected as part of the QIP audit of 30 consecutive patients to assess each MDT LS

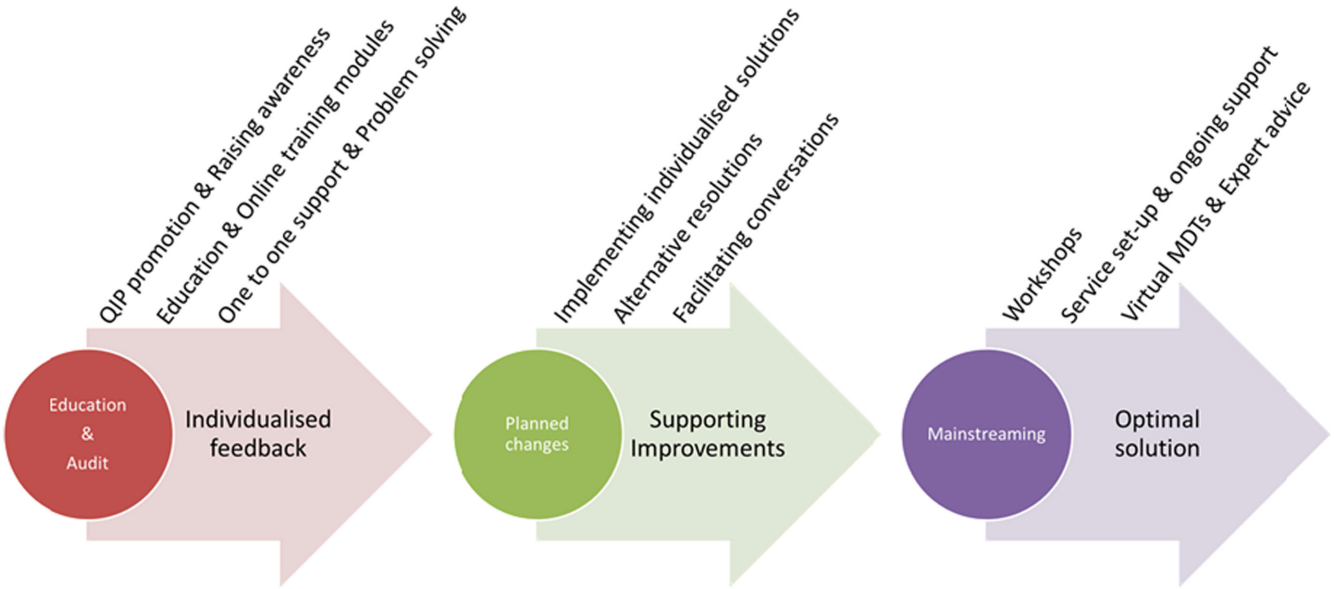

FIGURE 1 Quality improvement project (QIP) intervention model (MDTs, multidisciplinary teams).

diagnostic pathway. The audit was performed at baseline to assess the pathway for each MDT. The audit was repeated 1 year later, postintervention, to assess the success of the intervention.

KPIs and gold standard targets

1. Total MMR IHC performed: it was expected that, by the end of the QIP, MMR IHC testing would be performed automatically in at least 97% of all newly diagnosed CRC cases. The 3% gap accounts for the cases for which a tumour sample will not be available (i.e. emergency bowel obstruction).
2. Total MMR IHC performed in biopsies: it was expected that at a minimum of 60% of the patients would have a colonoscopic biopsy available for testing. Testing of biopsies provides superior orientation for analysis, and ensures that results can be used for treatment planning.
3. Further testing with either methylation or BRAF when indicated: it was expected that 100% of eligible cases should have further somatic testing.
4. MDT discussion: it was expected that 100% of MMR results would be discussed during the MDT meeting.
5. Referral for germline genetic testing: it was expected that 100% of eligible cases would be referred to their local genetics centre or 'mainstreamed' locally by a trained cancer MDT clinician.

Intervention

A regional project manager and nurse practitioner were appointed to support the LS champions, to develop online training packages, tutorials, easily accessible supporting documents, germline genetic testing consultation workshops and a public and patient involvement (PPI) group [7, 11]. A responsible LS champion was nominated within each of the nine MDTs prior the commencement of the project. KM, project lead, presented the project plan to the RMP PWG, which included representation from each CRC MDT. This facilitated collection of the baseline QIP pathway audit. The baseline audit was key to assessing the LS diagnostic pathway in each MDT, identify gaps with the LS champion, problem-solving and finding solutions. These discussions needed to be followed up by the QIP team with the LS champion to assess if the changes were implemented and manage any barriers encountered. Solutions were individualized and negotiated locally and with the cancer alliance.

Delivery of the project incorporated individual CRC MDT negotiations, agreement of action plans, education and regular performance feedback. MDTs that wished to complete the LS diagnostic pathway by setting up a clinic to offer germline genetic testing were supported to develop an 'in-house' mainstreaming service [1].

Overall baseline audit results were later presented by KM in the RMP PWG, and separately to each of the nine regional CRC MDTs with a comprehensive explanation of general issues, discussion of how barriers and 'bottlenecks' were assessed and provision of the opportunity to address any questions from the MDT members who were not LS champions (Figure 1).

Re-auditing of the LS pathway and completion of this project through the CRC RMP geography took place in April 2022.

MATERIALS

Phase 1 training: online training and resources

A series of QIP resources [1, 2] was developed which included discrete and relevant online CPD-accredited online training modules [7] to help members of the CRC MDTs understand LS, the diagnostic

pathway, genetic counselling and LS management. An associated supporting documents webpage [11] was created with flowcharts, guidelines, consent and request forms necessary to support the LS diagnostic pathway. A standard operating procedure was developed in collaboration with the PWG and genomic services within the RMP region. The team also developed patient resources, such as a patient information leaflet and a website with PPI review and support (Figures 2 and 3).

Phase 2 training: mainstreaming germline genetic testing bespoke workshops

For teams prepared to mainstream germline genetic testing for LS, additional support was provided with educational workshops, support and advice on how to set up their service. These bespoke workshops or tutorials aimed to provide the training needed to support the practical aspects of obtaining informed consent, and genetic counselling and testing for LS. They addressed key challenges for mainstreaming and examined practical examples of how these challenges can be overcome [12]. The training was delivered in 2-h sessions every 2 weeks. Generally, teams required between four and six workshops to complete the mainstreaming training.

The bespoke mainstreaming workshops were developed and delivered by LMG. Training was aligned to the Health Education England Genomic Education Programme's competency frameworks: (a) facilitating genomic testing; a competency framework [13]; (b) communicating germline genomics results: a competency framework [14]. Figure 4 illustrates some of the specific aspects of germline genetic testing for LS.

Mainstreaming teams were also supported to set up their clinics and speak to key stakeholders. Following set-up, the nurse practitioner continued providing advice, coaching and creating a support network for the mainstreaming teams. A crucial part of the support network was providing access to the weekly St Mark's virtual hereditary cancer MDT. This provides a forum for discussing genetic results and complex cases and providing reassurance and a safety net. Any genomic test directory updates, CPD, etc. were discussed in this forum and reinforced by the nurse practitioner on an ad hoc basics.

RESULTS

Descriptive statistics

Percentiles are used for descriptive statistics and analysis. Inspection of the overall percentile results in Table 1 indicates improvements across all measurables. The table uses a traffic light system to illustrate three degrees of improvement. Green illustrates the ideal target as defined in the KPIs and gold standard box. Orange illustrates intermediate improvement and red a lower level of performance. In the baseline audit, MMR IHC was performed in under 90% of 292 CRC cases. This improved to over 95% of patients at the 1-year follow-up. IHC testing in colonoscopic biopsies improved from 54% to 77% of cases. Only 37.5% of eligible patients underwent methylation/BRAF E600 testing at baseline; this improved to 75% at follow-up. Lastly, the

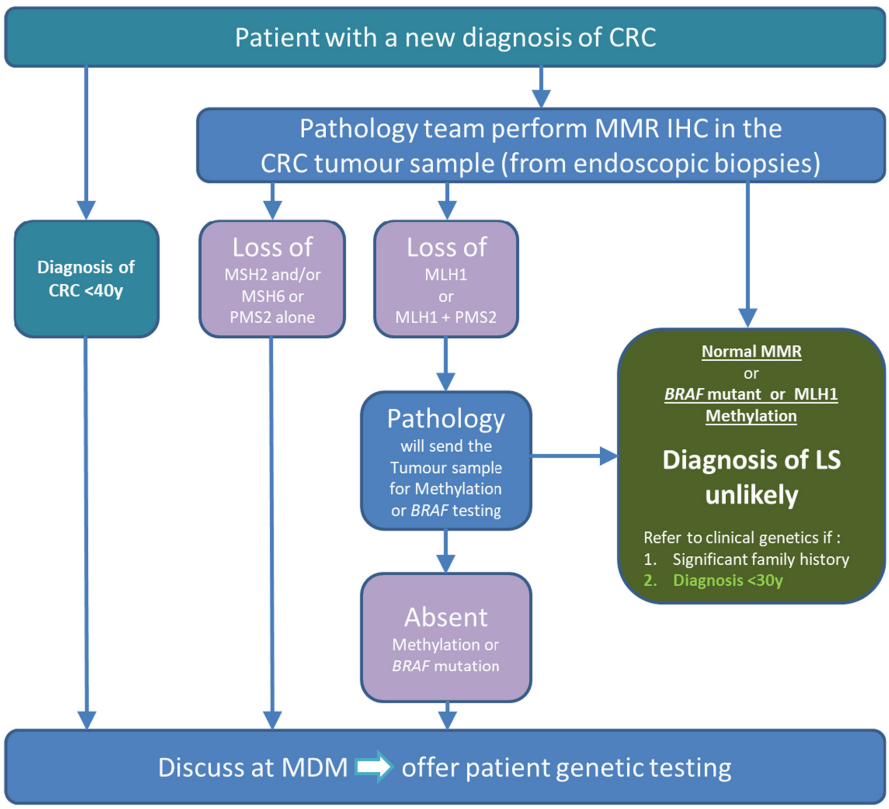

FIGURE 2 Flow diagram showing tumour testing to identify patients eligible for genetic testing for Lynch syndrome (LS) (CRC, colorectal cancer; MDM, multidisciplinary [team] meeting; MMR, mismatch repair).

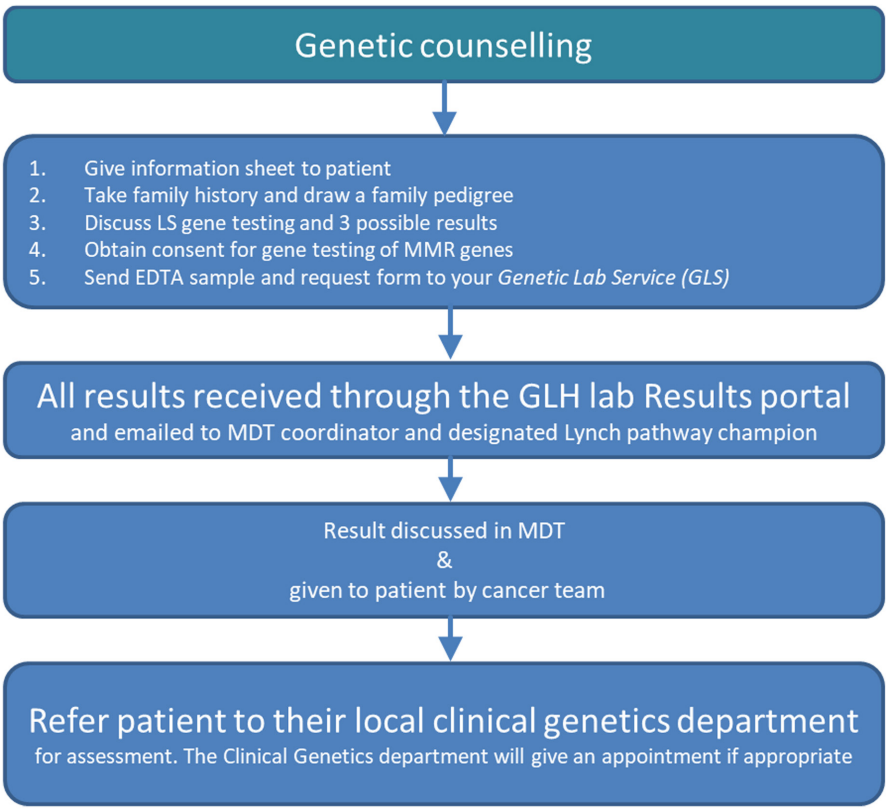

FIGURE 3 Flow diagram showing steps to follow to offer genetic counselling: consenting patients for genetic testing for Lynch syndrome (LS) and giving results (EDTA, ethylenediaminetetraacetic acid; GLH, genomic laboratory hub; MDT, multidisciplinary team; MMR, mismatch repair).

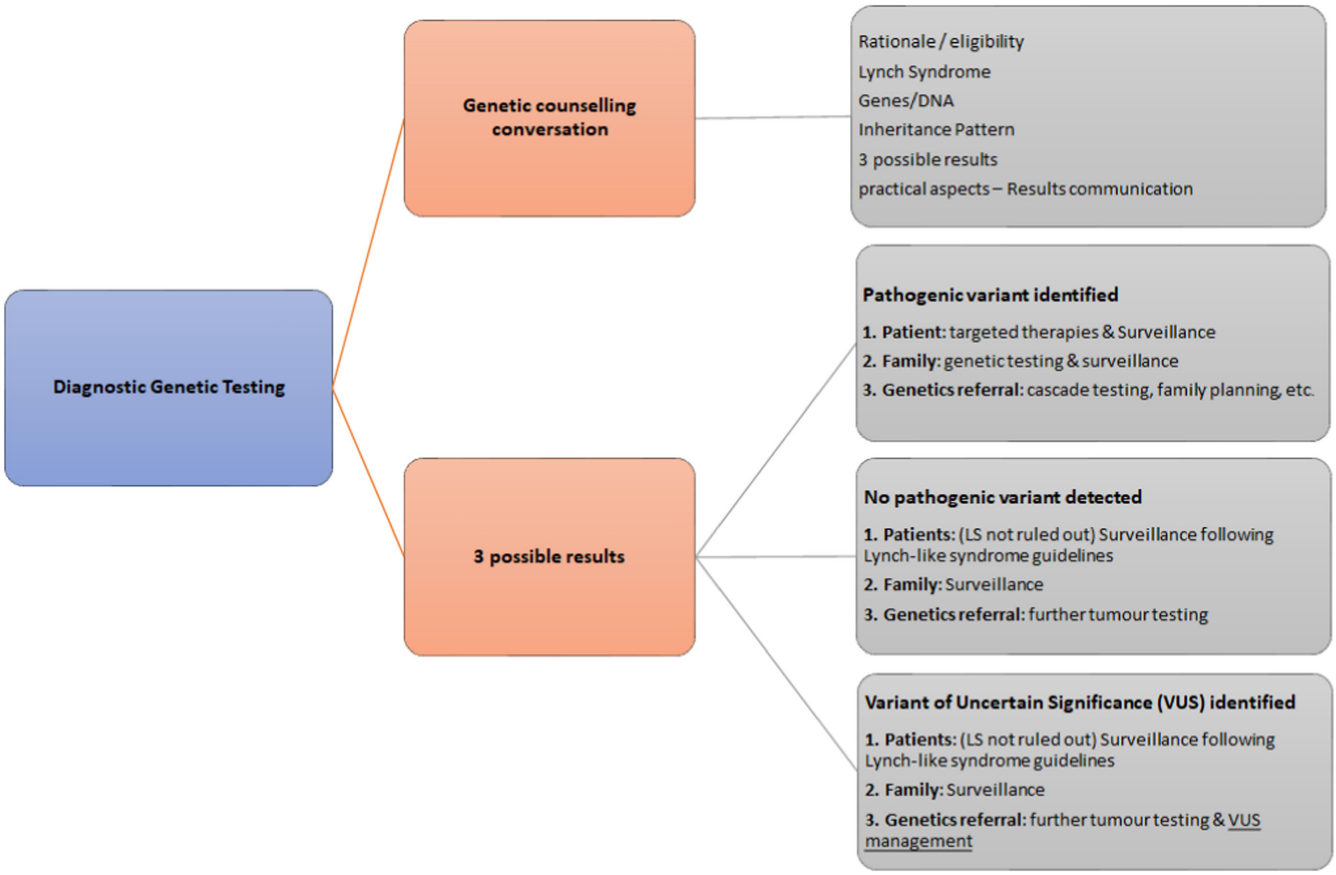

FIGURE 4 The specific aspects of germline genetic testing for Lynch syndrome (LS) which complement the Higher Education England Genomic Education Programme's competency frameworks.

TABLE 1 Audit results for the nine CRC MDTs in the RM Partners region at baseline and follow-up in percentiles. The table shows degrees of improvement using a traffic light system. The ideal targets in green are defined in the key performance indicators and gold standard targets box. Significant results with the Wilcoxon signed rank test are marked with an asterisk (*$p < 0.05$).

Measurables	Green	Orange	Red	Total baseline	Total follow-up	*p*-value (Wilcoxon signed rank test)
Mismatch repair immunohistochemistry	>97%	>85%	<85%	89.72%	95.10%	0.16
Endoscopic biopsy	>60%	>50%	<50%	54.45%	77.60%	*0.008
MLH1 methylation/BRAF	100%	>60%	<60%	37.50%	75.68%	*0.03
MDT discussion	>97%	>80%	<80%	68.15%	90%	0.94
Referral for germline genetic testing	100%	>70%	<70%	10.34%	74%	*0.02

biggest improvement was seen in the number of successful referrals for germline genetic testing which improved from 10% to 74%.

Analysis

The Wilcoxon signed rank test revealed improved measurables postintervention. Significant differences with a strong effect size [15] were demonstrated for the percentile of CRC cases having IHC in endoscopic biopsies, further testing with either methylation or BRAF and in referrals of eligible patients for genetic testing.

The percentile of CRC cases that had MMR IHC performed was nonsignificantly higher postintervention (Median (Mdn) = 100%, $n = 9$) compared with baseline (Mdn = 87%, $n = 9$; Table 1; $p = 0.16$, $r = 0.36$). However, the percentile of CRC cases that had MMR testing on diagnostic biopsies (as opposed to postsurgical resection tissue) was significantly higher postintervention (Mdn = 80%, $n = 8$) compared with baseline (Mdn = 61.67%, $n = 9$; $p = 0.008$, with a strong effect size $r = 0.61$).

The percentile of CRC cases that had either methylation or BRAF testing when there was loss of MLH1 protein in MMR IHC increased from baseline (Mdn = 20%, $n = 9$) to 1-year follow-up (Mdn = 100%, $n = 9$; $p = 0.03$, with a strong effect size $r = 0.52$).

The percentile of eligible CRC patients who were offered germline genetic testing by either being referred to a specialized genomic centre or offered testing in-house increased from baseline (Mdn = 0%, $n = 9$) to 1-year follow up (Mdn = 100%, $n = 9$; $Z = -2.41$, $p = 0.02$, with a strong effect size $r = 0.57$).

CONCLUSIONS

Overall, we have implemented a systematic approach with workforce transformation to facilitate identification and 'mainstreamed' genetic diagnosis of LS. The intervention showed improvements across all stages of the LS diagnostic pathway, and this has led to a large increase in the referral rate of eligible patients for germline genetic testing.

We learnt that to embed and maintain the LS diagnostic pathway the role of the LS champion is essential and should be maintained. As a result, this work contributed to the development of the new NICE standard QS20 [16] in England, which recommends local leadership within cancer teams to ensure delivery of diagnosis of LS.

Overall, there were improvements across all measurables, as shown by the traffic light system used, which demonstrates one-colour improvement in nearly all measurables. However, some optimal targets were not met, reflecting that the pathway is complex and further support and reinforcement is required.

During the QIP we developed new mainstreaming services and demonstrated implementation of systematic and robust testing pathways across the RMP cancer alliance. Although each cancer MDT improved performance, the biggest improvement was observed in one MDT that established a mainstreaming service. LS champions within this team were motivated and undertook extended mainstreaming training and workshops. They also took advantage of the support offered by the virtual hereditary cancer MDT; this illustrates why mainstreaming is the optimal solution and the benefits that having a local genomics clinic and skilled professionals can bring to the CRC MDT.

There are limitations of QIPs that depend in large part on goodwill amongst clinical colleagues who are overstretched and whether or not there is not specific funding to support this activity. To move to a 'business-as-usual' model, specific funding and long-term support needs to be provided to ensure sustainability. However, by demonstrating patient benefit using our structured approach we hope to encourage reproduction within other geographies and health systems in the UK and elsewhere. Testing by local cancer teams also requires support from regional and national expert centres to ensure ongoing support for testing as technology and pathways evolve and management of complexity in subsequent lifelong care of people with LS.

This programme model has now evolved into the NHS England LS genomics transformational project [17], integrating genomics into clinical practice. The national project also includes the endometrial cancer pathway and gynaecological cancer MDTs; we recommend that work focuses on supporting the national project initiatives and gynaecological cancer MDTs.

AUTHOR CONTRIBUTIONS

Laura Monje-Garcia: Conceptualization; methodology; validation; investigation; formal analysis; supervision; project administration; resources; writing – original draft; data curation; visualization. **Timothy Bill:** Conceptualization; investigation; supervision; funding

acquisition; project administration; resources; visualization; validation. **Lindsay Farthing:** Conceptualization; validation; supervision; funding acquisition; project administration; resources; visualization. **Nate Hill:** Conceptualization; investigation; funding acquisition; project administration; resources; validation; visualization. **Emma Kipps:** Conceptualization; visualization; supervision; validation. **Angela F. Brady:** Conceptualization; visualization; supervision; validation. **Zoe Kemp:** Conceptualization; visualization; supervision; validation. **Katie Snape:** Conceptualization; visualization; supervision; validation. **Alistair Myers:** Conceptualization; visualization; supervision; validation. **Muti Abulafi:** Conceptualization; visualization; supervision; validation. **Kevin Monahan:** Conceptualization; methodology; data curation; investigation; validation; formal analysis; supervision; funding acquisition; visualization; project administration; resources.

FUNDING INFORMATION

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare. All coauthors have seen and agree with the contents of the manuscript and there is no financial interest to report. We certify that the submission is original work and is not under review at any other publication.

DATA AVAILABILITY STATEMENT

All the materials mentioned in this manuscript are referenced and were produced by the study team.

ETHICS STATEMENT

This was a quality improvement project assessing existing testing pathways, which used no patient identifiable data, therefore ethical approval was not required.

ORCID

Laura Monje-Garcia https://orcid.org/0000-0002-4000-2241
Muti Abulafi https://orcid.org/0000-0001-7088-4292
Kevin Monahan https://orcid.org/0000-0002-7918-4003

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