Implementation of the ACE Programme, Wave 2, 2017-18

Realist evaluation

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Executive Summary

The ACE (Accelerate, Co-ordinate, Evaluate) programme was initiated in June 2014 as a set of pilot projects that tested specific interventions and models with the aim of improving cancer diagnosis pathways. It was supported by NHS England, Cancer Research UK (CRUK) and Macmillan Cancer Support and it ran during 2015 and 2016. Subsequently, and in response to the most recent cancer strategy for England (*Achieving World Class Cancer Outcomes (2015)*), a second wave of pilot projects specifically addressed the implementation of Multidisciplinary Diagnostic Centres (MDC). These pilots have been evaluated by the Policy Research Unit for Cancer Screening, Awareness and Early Diagnosis.

This qualitative element of the evaluation used a realist methodology to describe the development and implementation of MDCs a six pilot sites, by considering the contexts, mechanisms and outcomes that operated at each site and then drawing together the key themes that emerged across all six sites. The underlying programme theory for ACE Wave 2 was that pilots would be successfully implemented by being part of a national programme (ACE) that provided support, funding and opportunities for shared learning.

One hundred and twenty-eight interviews were conducted over three rounds between February 2017 and June 2018. All sites successfully implemented their chosen MDC model and the support from the ACE programme was a key factor in enabling this. A transformational style of leadership, together with stable project management were key factors in ensuring a smooth and successful result. MDCs required clinicians and Clinical Nurse Specialists to work in different ways, in particular the CNS role needed to be redefined. The need for a patient navigation function emerged as important in all sites and was explicitly addressed by the appointment of a navigator at some of these.

There remain some concerns about the longer term sustainability of MDCs. In most cases this is due to their success being dependent on one or two highly motivated individuals. It was also apparent that in most cases the MDC had not been fully normalised within the operational systems and staffing capacity of the host Trust, though diagnostic test capacity was not generally a challenge. Further roll-out of MDCs will require comparable resourcing to become established and in all cases Trusts will need to plan in detail the resources required to ensure long-term viability.

1 Background and Introduction

1.0 The ACE programme

The publication in 2011 of *Improving Outcomes: a Strategy for Cancer* (Department of Health, 2011), signalled an increased emphasis on diagnostic testing for GPs, with additional funding to PCTs to enable this. The ACE programme (Accelerate, Coordinate and Evaluate) responded to this desire to accelerate the pace of change towards earlier diagnosis by extending the range of pathways to cancer diagnosis. It was informed in part by developments in cancer diagnostic services in other countries, notably in Denmark (Vested and Olesen, 2015). The ACE programme was initiated in June 2014 as a set of Wave 1 projects that tested specific interventions and models, with, as detailed in *Improving Outcomes: a Strategy for Cancer* (Department of Health, 2011) the aim of 'preventing people from dying prematurely'. Wave 1 projects were supported by NHS England, Cancer Research UK (CRUK) and Macmillan Cancer Support and ran during 2015 and 2016.

The overarching objective of the ACE programme was to develop a national body of evidence and evaluation that informed the operational improvement of early diagnosis cancer pathways through the 2016/17 and 17/18 commissioning rounds.

Sixty projects were identified in Wave 1, nine of which were subject to an in depth qualitative evaluation, three of which focused on the development of Multidisciplinary Diagnostic Centres (MDCs) (Ablett-Spence et al 2016).

The most recent cancer strategy for England (*Achieving World Class Cancer Outcomes (2015)*) also called for the trial and evaluation of MDCs for non-specific symptoms The ACE Wave 2 programme sought to address this by focusing on the development and evaluation of MDCs.

ACE Wave 2 consisted of 5 pilot projects with a total of 10 operational MDC sites, trialling a diagnostic pathway for patients with non-specific but concerning symptoms. These approaches aimed to incorporate a MDC based on a model developed in Denmark in an attempt to improve the pathways to diagnosis. The Policy Research Unit (PRU) for Cancer Awareness, Screening and Early Diagnosis was commissioned to evaluate the ACE Wave 2 programme. Within that commission, at the Primary Care Oncology Group at University of

Newcastle was asked to undertake a qualitative evaluation of the implementation of selected pilot sites.

This report describes the development and implementation process for those pilot sites by considering the contexts, mechanisms and outcomes that operated at each of the six MDC sites. The overarching themes that were common to all the projects are considered in the main text, but each of the six pilots is the subject of a detailed case study and these are provided as appendices.

1.1 The Danish Model of Cancer Diagnosis

The investigation of patients that could indicate cancer can be problematic. For well-defined symptoms clearly linked to a particular cancer, for example a persistent cough possibly indicative of lung cancer, there are pathways in place for the GP to refer urgently, in the case of the NHS this is via a 2 week wait referral. However, there is no equivalent way of referring those with non-specific, vague but worrying symptoms. GPs often have difficulty in identifying the best test and where to send these patients.

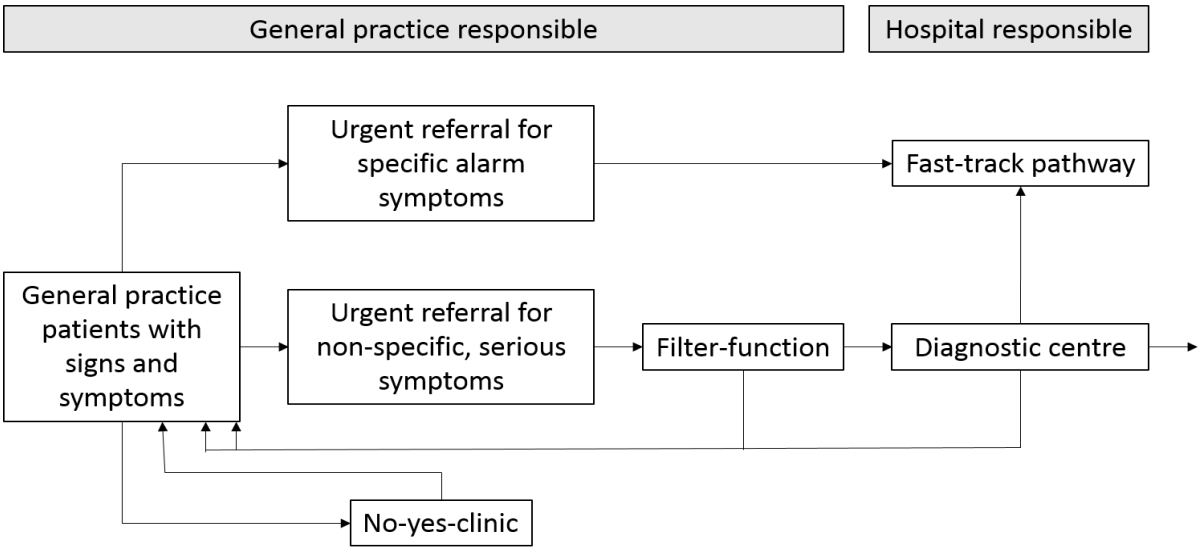
Historically, these patients have often bounced back and forth between the GP and hospital for diagnostic testing until a diagnosis is made. This can in turn delay the diagnosis and subsequent treatment, adversely affecting the outcome for the patient.

Denmark has a similar health service to the UK, where GPs refer patients to hospital facilities for diagnostic tests and specialist opinions, commonly termed the gatekeeper model. Both countries compare poorly to the rest of Europe in terms of cancer survival (Coleman et al, 2011). As a result Denmark implemented a cancer strategy in 2010 that acknowledged the need for diagnostic routes for non-specific but worrying symptoms (the difficult diagnosis) and for low-risk but not no-risk symptoms, to supplement their urgent referral pathway for those with specified alarm symptoms (Vedsted and Olesen, 2015). In doing this, they responded to evidence that many patients with cancer do not present with symptoms that fit the guidelines for urgent referral pathways (Jensen, 2014, Elliss-Brookes 2012). The Danish strategy to support patients with non-specific but worrying symptoms that could signify cancer involved the development of the Multi-Disciplinary Diagnostic Centre (MDC). The MDC pathway consists of a two-step approach with an initial filter performed by the GP and comprising a standard battery of diagnostic investigations (blood

and urine tests and diagnostic imaging), followed by referral to the MDC if the underlying problem remains unclear. (Vedsted and Oleson, 2015)

For the 30-40% of cancer patients who present with vague, “low risk but not no risk” symptoms, Denmark has implemented the “NYC” or No-Yes Clinic (Vedsted and Olesen, 2015). These provide GPs with access to a wider range of diagnostic tests while retaining clinical responsibility. Further evaluation of both these new pathways is ongoing.

Figure 1 The Danish three-legged diagnostic strategy



2. Evaluation Methods

2.1 Realist Evaluation

The ACE (Accelerate, Coordinate, Evaluate) Wave 2 programme identified 5 projects (10 MDC sites, 6 of which participated in this qualitative evaluation) to test out innovative new ways of trying to investigate and diagnose these patients quickly through the development of MDCs.

The qualitative evaluation focused on the following six sites:

North Middlesex University Hospital,

Oxford University Hospitals Trust

Greater Manchester (Manchester University NHS Foundation Trust (Wythenshawe Hospital); The Northern Care Alliance (Royal Oldham Hospital)

St James University Hospital, Leeds

Airedale General Hospital

In order to evaluate the implementation of MDCs, we used the method of realistic evaluation (Pawson and Tilley 1997). This theory-driven approach explores the relationship between the outcomes (intended and unintended consequences), mechanisms and contexts of a programme by mapping out and then testing the 'programme theory'. The underlying programme theory for ACE was that projects already formulated or in development would be enabled to be successfully implemented by being part of a national programme (ACE) that provided support, funding and opportunities for shared learning. A programme theory for each individual site was developed and is detailed in the individual case studies (see appendices B-G). A realistic approach helps to illuminate if and why certain elements of the ACE initiative resulted in particular outcomes. It helps the commissioner of the research to understand 'what worked for whom and in what circumstances' and is increasingly being recognised as a valuable approach to understanding how particular preconditions make intended outcomes more or less likely.

The evaluation was based on detailed case studies of the six selected MDC pilot sites.

The case studies contained the following components:

a. An exploration of the mechanisms that each area had put in place through the ACE Wave 2 programme to develop an understanding of the context in which these mechanisms have been put in place, through one to one interviews with clinicians, managers, commissioners and other key informants in each area.
b. Review of documentation and other material

We used sequential one to one interviews with clinicians, managers, commissioners and other key informants in each project. Potential participants for interviews were identified by the local project lead.

Information sheets and consent forms were emailed to potential participants. They were asked to complete the consent form and return it if they were willing to participate. A convenient interview time was then arranged. Consent was re-confirmed verbally before each interview began.

It was anticipated that participants would each be interviewed up to three times, once early in the implementation stage, once mid-point and finally towards the end of the project.

Interviews lasted up to one hour and were either face to face or via the telephone. The number of interviews per project site differed depending upon the number of key stakeholders per intervention. The first round of interviews was carried out between February and May 2017, with the second round of interviews conducted between September and November 2017 and final interviews between February to June 2018.

All project sites were visited. In total 128 interviews were conducted. In the first round, a total of 46 1:1 interviews were carried out. At each site between three and ten key informants were interviewed at each stage. They came from a range of professional backgrounds and included GP leads, project managers, clinicians, service managers, clinical nurse specialists, support staff and commissioners. Each interview took approximately one hour. In the second round 38 1:1 telephone interviews were carried out. In this round of interviews there were a small number of new informants who had not been interviewed initially, they were introduced due to the fact they had either not been in post at the initial interviews or their role had not been as significant in the initial stages of the project. There were also a slightly larger number of informants who declined to participate in the second round of interviews as they felt they had nothing new to contribute, there were also a small number of participants who were no longer in post. In the final round, 41 1:1 interviews were conducted. Again, some informants felt they had nothing new to contribute and so declined the offer of a final interview.

Table 1 Number of interviews for each case study

	Interview Round			
Cluster/Locations	1	2	3	Total
Airedale	10	9	8	27
Leeds	10	8	9	27
North Middlesex	5	5	6	16
Oldham	5	3	4	13
Wythenshawe	7	6	6	19
Oxford	9	7	8	26

Interviews were recorded, fully transcribed, and analysed using a Framework Analysis approach. Framework analysis is an approach to analysis developed for applied policy

research, which allows the exploration of issues of interest as well as allowing for new issues to emerge (Ritchie and Lewis, 2003). Transcripts were read by two members of the research team in order to identify themes and construct a framework; the framework was then applied to all transcripts systematically. The team then reviewed the transcripts and themes to ensure consistency and agreement of interpretation.

All pilot sites had an opportunity to comment on the accuracy of the completed case-studies and each site responded with comments except for Airedale.

In addition to the interviews, documentary evidence relating to the projects such as project plans and strategies were also reviewed. Attendance by the researchers at ACE Wave 2 meetings along with other material such as meeting notes, local activity data and other documents relating to the projects provided by the sites was valuable in helping the researchers gain a deeper understanding of the contexts, mechanisms and outcomes relating to the whole cluster and also to individual projects within the cluster.

Finally, all pilot sites were asked to provide names of GPs who had and had not used the pathways so that they could also be interviewed. 4 GPs from three sites consented to be interviewed. All 4 had used their local MDC pathway. One was from Airedale, one from Leeds and 2 from Oxford. All had used the pathway at least once, some up to 8 times. The pilot sites were unable to provide us with any GPs who had not used the pathways and who were willing to be interviewed (see Appendix H).

2.2 Normalisation Process Theory

Normalisation Process Theory was used to understand the extent to which projects were successfully implemented and became embedded into routine practices.

Normalisation process theory (NPT) is a sociological theory of the implementation and integration of new technologies and organisational innovations. It proposes that practices become routinely embedded in social contexts as the result of people working, individually and collectively to implement them. It enables us to understand how an intervention, whether it is a technology, procedure or pathway, becomes a routine part of normal practice within a social context (May, 2006) (May and Finch 2009).

The projects reviewed as part of this qualitative evaluation were amenable to analysis using NPT. Innovations may be normalised, i.e. become custom and practice, but other outcomes

are possible. They may become adopted, that is accepted and taken up but not embedded into routine practice, or they may be rejected, where interventions are disregarded or used in a way that subverts the initial purpose of the intervention (May, Finch, Mair et al., 2007).

To understand the embedding of a practice it is necessary to consider what people actually do and how they work. In this context the theory proposes that the work of implementation is operationalised through four generative mechanisms (coherence, cognitive participation, cognitive action, reflexive monitoring). These are affected by factors that promote or inhibit the routine embedding or normalisation of a practice in its social contexts. They form the basis of a framework proposed by May and Finch as a means of applying normalisation process theory and used by us for that purpose (table 2).

Table 2 - Framework for operationalising normalisation process theory

	Coherence What is the work?	Cognitive participation. Who does the work?	Collective action How does the work get done?	Reflexive monitoring How is the work understood?
Systematic explanation of mechanisms and components at work	Factors that promote or inhibit the mobilisation of a practice	Factors that promote or inhibit participation in a practice	Factors that promote or inhibit enacting a practice	Factors that promote or inhibit the appraisal of a practice
Knowledge about the sources and operation of investments at work	Beliefs and behaviours that define and organise objects	Beliefs and behaviours that define and organise actors	Beliefs and behaviours that define and organise work	Beliefs and behaviours that define and organise understanding
Investigation of core questions that could include	How is a practice conceptualised by participants? How does it hold together in action?	How do participants come to engage with a practice? How do they decide on engagement and the purpose it serves?	How do participants enact a practice? How are their activities structured and constrained structured and constrained?	How do participants appraise a practice? What are the effects of appraisal? How are the mediated?

3.0 Overarching Themes

3.1 ACE Programme

The ACE programme is aimed at improving the pathway to cancer diagnosis and thereby improving cancer outcomes. Wave 2 of the ACE programme focuses on the potential for MDC based pathways to support earlier detection of cancers in patients with non-specific symptoms.

The pilot sites selected by the ACE programme developed MDC-based interventions that were designed to integrate with existing local infrastructures. Whilst each MDC had the overall aim of improving cancer diagnosis and ultimately survival, there were distinct differences in the mechanisms used to drive changes in services and the contexts within which mechanisms were implemented.

Six pilot sites were selected for qualitative evaluation of the implementation process. We used realist evaluation as our methodological approach (Pawson and Tilley 1997).

The underlying programme theory for ACE Wave 2 was that pilots would be enabled to be successfully implemented by being part of a national programme (ACE) that provided support, funding and opportunities for shared learning.

Analysis of the interviews resulted in the development of a Contexts, Mechanisms and Outcomes (CM0) model for each pilot (see appendices B-G). The programme theory for each individual pilot differed slightly and each CMO configuration was refined as the interviews progressed, to produce the final CMO model for that case study.

By the end of the qualitative evaluation period, all of the pilot sites had implemented a MDC pathway and tested the associated systems and processes, although the pathways were at different stages of becoming fully incorporated into the working practices of clinicians and organisations (see the methods section 2.0 of this report for further details about Normalisation Process Theory).

In figure 2 we give the CMO model of the ACE Wave 2 programme as a whole, with its overarching contexts, mechanisms and outcomes.

3.2 Key Contexts Mechanisms and Outcomes (CMO)

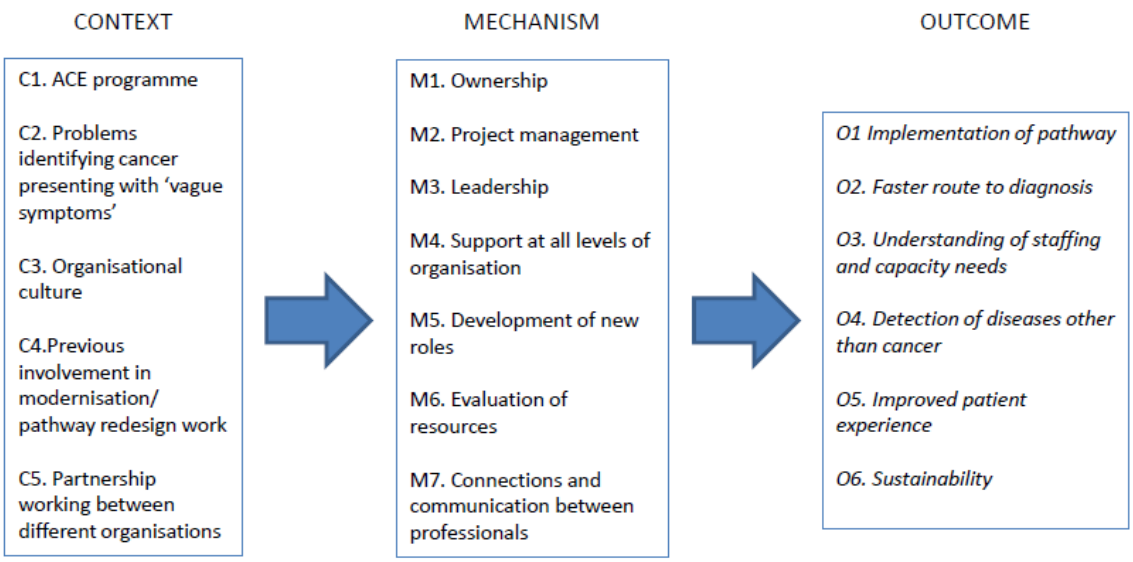


Figure 2 - Overarching CMO model

We identified a number of themes that were common to the majority of projects. These are discussed below:

3.2.1 Contexts

C1 ACE programme

The ACE programme aims to provide funding, one to one support from the programme manager and opportunities for shared learning through an action learning set approach. All of the pilot sites cited being part of the overarching ACE Wave 2 programme as being an important context.

Being part of the ACE Wave 2 programme brought a range of perceived benefits, including additional finance and credibility for the pilot within the host organisation because it was a national initiative with evaluation seen as an integral part. Involvement in the wider programme also provided an opportunity to collaborate and share with others:

"My interest is in finding new ways to investigate cancer in people who go to see their GP. So I found out about the ACE programme and contacted the CCG lead and we talked about whether it was something we should be applying for . . . . . Obviously the funding would be useful and the opportunity to share and learn from the other sites"

Clinical researcher /Macmillan GP

C2 Problems identifying cancers presenting with vague symptoms

In their initial proposals to ACE all of the pilot sites identified that they experienced problems identifying cancer presenting with vague symptoms, this was also reiterated in the interviews:

"So the purpose of the scan pathway is to capture patients that have a low risk but not no risk symptoms and to generate a pathway where they're seen efficiently. So these patients are normally shuttled back and forth from consultant to GP because their symptoms are so vague" Navigator

"It's about GPs having a pathway in to refer patients who have got vague symptoms that they're concerned may be cancer, but don't fit a two-week wait criteria . . . . So it's to enable GPs to refer those patients in for quick assessment to get a prompt diagnosis for the patient or reassurance that there isn't a cancer" Clinical nurse specialist

C3 Organisational culture

Organisational culture varied between pilot sites. Some organisations were able to describe a long history of service improvement, with a proactive approach to developing services and change management:

"The organisation has been very supportive, and this is generally the case, they've let us do what we want, the only issue of concern was where the money was coming from, once they were reassured on that front, they were fine for us to proceed" GP lead

"We have a history of service development and the organisational culture is one which is supportive of moving forward with this project" Project manager

For others the scale and pace of the required change and the number of organisational boundaries that needed to be crossed presented new and different challenges:

"The pace of large scale transformational change is greater than that which we can currently deliver due to pressures on existing services" Lead clinician

One project was hosted by an organisation that due to wider organisational issues was more reactive than proactive and where staff spent a significant amount of time managing problems rather than developing or refining services:

"There are so many pressures, lack of space, issues with consultants and so on, it's a problem finding the time to do this" Lead clinician 2

Organisations where staff felt stable and secure in their roles and where the value of the pilot has been acknowledged appeared to be more effective at implementing change. Conversely, those organisations experiencing structural change, substantial changes in staff and where staff feel their role in the pilot is not valued by the wider organisation were less likely to implement change easily.

C4 Previous involvement in modernisation/pathway redesign work

All of the pilots stated that they had been previously involved in other related modernisation work, and as a result it felt appropriate to get involved in the ACE Wave 2 programme as it built upon previous work:

"It made sense to get involved and apply to ACE to be involved with Wave 2 as it was a logical extension of the work we did with our e consultations in wave 1. . . . . I think the Wave 1 experience made it easier to implement such transformational change" GP lead

The scope of previous redesign work differed between pilots. Some pilots had access to experienced project managers who had been involved in previous initiatives:

"We are lucky in that we have ZZ as a Project Manager and she's been involved in similar initiatives so she brings all that experience and contacts with her. . . . We are also fortunate to work in an organisation where change management is supported" GP lead

"I think this has gone smoothly from my perspective because of all the work we did in Wave 1, That work was invaluable as a basis for us to build up. . . we were already seen as credible by the powers that be and as a result supported at an organisational level" Radiologist

It is difficult to implement such large scale transformational change without having had experience of significant change management initiatives and a supportive organisational culture.

C5 Partnership working between different organisations

All of the pilots claimed to have established robust working relationships between the partner organisations in order to develop and deliver their projects. For some they were building on existing relationships, for others it was about developing completely new

relationships. The most important relationship described by the majority of pilot sites was the one between primary and secondary care.

3.2.2 Mechanisms

M1 Ownership

Ownership involves key stakeholders feeling part of a project, buying in to the vision and taking responsibility delivering their elements of the pilot. Ownership was cited as a key mechanism by the majority of pilots:

"The project is going well we have a proactive steering group, where individuals have taken ownership of their bits of the project. Everyone is really proactive and supportive of the project" Project manager

"Ownership has been key, everyone has run with their bit of the project, for most people it's been additional to their normal workload but they've just got on with it in order to make it work" Project manager

Conversely, lack of ownership was also cited as a problem in projects that had yet to be fully incorporated into clinicians' working practices:

"I think the main challenges have been ownership of the project, the fact that we didn't have a suitable environment for this project, the fact that we didn't have full consultant buy in" Service manager

M2 Project management

Project management is the application of processes, methods, knowledge, skills and expertise to achieve define outputs, outcomes or benefits. The core components of project management include project definition, management planning and progress monitoring, resource allocation and management, risk management and communication. Effective project management was an important mechanism in all projects. None of the pilot sites were able to articulate a specific model of project management, though the model of project management was implicit rather than explicit and differed between pilot sites. Oxford, Leeds, Oldham and South Manchester had project management support from their CCGs, however all the project managers had other responsibilities in addition to supporting the delivery of the ACE Wave 2 pilots:

"I have other responsibilities in relation to ACE and sometimes it's hard to juggle everything"

Project manager

As part of the UCLH Cancer Collaborative a project manager supported 5 sites, one of which was North Middlesex. However the project manager changed early in the project, this initially caused confusion in some regarding the role of the project manager:

"Initially we had XX who was great and I understood what she was doing, then she left and subsequently I lost track of what was going on and whether the role and support we were getting had changed" Service manager

Airedale included a full time project manager in their business case:

"It's great having this resource and means people can focus on their roles whilst the project manager deals with the day to day operational issues" Lead cancer manager

Having a full time project manager worked well until she left mid project and Airedale was unable to replace her immediately:

"Well, we did have plans to replace XX. We had the job advertised and we were all set to interview, and then on the day of the interviews, or the day before the interviews, we didn't have the confirmed funding, so we didn't have clarity from YY (ACE) whether we'd got ongoing funding . . . . . it's probably about 4 weeks since we've had that (confirmation) . . . . So we are in the process of trying to go out for a replacement project manager"

Lead cancer manager

Elements of project management were described by all of the projects. It was evident that the majority of project managers were being required by their employing Trusts to deliver on a range of initiatives, often with minimal or no additional support.

M3 Leadership

Leadership in this context refers to leading a group of people to facilitate change in practice as part of the ACE Wave 2 programme. Leadership came from a variety of sources including GP leads, secondary care clinical leads, commissioning leads, clinical nurse specialists and project managers.

Most of the pilot sites had at least one clearly identifiable person who had clear a vision and communicated it in an articulate manner, though the style of leadership differed between

projects. A transformational style of leadership was apparent in most cases, i.e. a style of leadership where the leader serves as a role model, inspiring and motivating the team, challenging them to be innovative and creative, yet being mindful of the needs and feeling of each individual.

Where the leadership style was weaker or drifted into a laissez faire style of leadership, ownership of the initiative by followers appeared to be less strong.

M4 Support at all levels of the organisation

The most successful pilots in terms of those closest to being normalised, i.e. the MDC pathway becoming routine practice, were those that had support at all levels of the organisation. Successful projects need support at both a service delivery level and at a strategic, senior level. Not all projects had ongoing support at a service delivery level, for example, North Middlesex had had clinicians, managers and a nurse who were very supportive of the pilot at the outset, however as the pilot progressed it became evident that due to other organisational pressures they were unsure about whether they thought it was viable to continue and whether they thought their involvement should continue:

"So, that's a question we don't know the answer to yet. Whether the trust wishes to then employ the same nurse or an alternative individual to carry on, whether there's enough mileage and interest in further funding for the nurse . . . . . Whether the data for the MDC pilot shows that this is sustainable and has a positive effect on patient care, or, actually the current system works as well or better, and we carry on with that?" Lead Clinician 2

"I think the main challenges have been ownership of the project . . . . . the fact that we didn't have full consultant buy in" Service manager

Other projects had support at grass roots level but felt they lacked support at a senior level:

"We've had good support at grass roots level with suitable clinicians expressing an interest in supporting the faculty meeting but unfortunately the Clinical Directors haven't allowed them to be freed up to allow it" Lead clinician 2

Interviewees all reported board level knowledge of the pilots, though often this was as a result of progress updates being filtered upwards. A number of pilots including Leeds,

Wythenshawe, Oldham and Oxford reported increased board level interest in the pilots following the NHS England press release in March 2018.

M5 Development of new roles

A number of new roles were developed to support the development and more particularly the implementation of the MDC pathway. These included administrative, nursing and medical functions and differed from traditional roles.

Nursing roles – all of the pilots, with the exception of Oxford, had a clinical nurse specialist (CNS) who was central to the MDC pathway. However, the skills and responsibilities of the CNS varied significantly between sites.

All CNSs were responsible for supporting patients through the pathway, the unique feature of these CNS roles compared to traditional roles is that patients have access to specialist CNS support before they receive their diagnosis. This is particularly important for this cohort of patients as they all have symptoms which could be indicative of cancer and they are likely to be particularly anxious until they receive a diagnosis.

The level of skill and amount of additional responsibility appeared to vary significantly. Some CNSs carry out a detailed assessment, checking for missing blood and X-ray results, requesting tests if they had been omitted in primary care. CNS involvement in the pathways appears to work well and is appreciated by patients:

"The CNS is very experienced and skilled, the pathway wouldn't work without her" GP lead

"A lot of them (patients) speak highly of KK (the nurse)" MDT co-ordinator

The majority of pilots needed the CNS to become operational quickly in order to get the pathway established. Where the CNS was appointed without the necessary skills and training, delays occurred:

"She (the CNS) has been on a course . . . . . She's just coming to the end of that course, and as part of that, she has learnt how to do the history taking as part of the post"

Lead clinician 1

The majority of CNSs have taken the opportunity to gain clinical assessment skills/advanced skills whilst they have been delivering their pilot service.

A number of the pilot sites (Leeds, Wythenshawe, Oldham and Airedale) are now reviewing the skills of the CNS and how that role complements the MDC clinician. For example, Airedale are currently considering whether the CNS role would be better served by an Advanced Nurse Practitioner (ANP) as they believe it would free up some clinician capacity.

Navigators - Oxford have developed a navigator role that they believe is key to the successful operation of their MDC pilot. At the time of the final set of interviews there were 2 navigators in post, 1 with a nursing background and 1 with a radiology background.

In Oxford the navigator is the first point of contact for patients within secondary care. The navigator with the radiology background checks that the patient is eligible for the ACE SCAN pathway. Both navigators are able to take bloods and book the patient in for their CT scan. The navigator with the radiology background performs the scans for the majority of patients, though other Radiographers within the department are also able to carry them out. If the scan result is suspicious of cancer, the patient is referred to the appropriate site-specific pathway and the GP is informed. If no cancer is identified on the scan, the patient is booked into the MDC for a full clinical assessment and further management as required. Where possible the navigator accompanies the patient to the MDC appointment. Following the MDC the navigator provides feedback to the GP.

The navigator input has worked well in terms of providing continuity for the patient and, anecdotally, patients appear to value the role:

"*XX has been great and the patients and the patients seem to value having some-one who can support them from the point at which they get referred in"* CCG project manager

In Wythenshawe and in Oldham, a navigator role with a more administrative nature has been developed to support the pathway. The navigator is responsible for receiving referrals, liaising with the CNS to arrange clinic appointments, ensuring investigations are ordered and reports are available in clinic. She also meets patients when they arrive for their appointment and takes them to the departments where they are scheduled to have tests such as CT or endoscopy, to ensure that everything gets done in the timescales allotted. The role also involves data collection and tracking the patient. Evidence from the interviews suggest that the project team appear to value the navigator:

"I think we were already establishing that the navigators role was key" Project manager

Administrators – Four of the pilot sites have dedicated administrative support, though the job titles and responsibilities vary. In Leeds an MDC co-ordinator role has been developed to support the pathway. The role is similar to that of the well-established cancer MDT co-ordinator, who has responsibility for the administration of the MDT meetings and tracking patients. The MDC co-ordinator has additional responsibilities, including booking patients for diagnostic tests and clinics, capturing diagnoses, including non-cancer diagnoses and administering patient experience surveys.

There was evidence from the Leeds interviews that the CCG, acute trust and GPs value the role:

"The MDC co-ordinator role is really important to the smooth running of the pathway and allows me to focus on the clinical/nursing issues that I need to" CNS

In response to increased workload the MDC co-ordinator hours were increased as the project progressed and additional administrative support was provided in the form of an extra booking clerk.

In Airedale an ACE administrator role has been developed to support the pathway, the role is a hybrid of a number of existing NHS administrative roles and the post holder(s) have responsibility for liaising with patients and GPs, booking and tracking patients, inputting into the database and typing letters to the GPs:

"They have so many hats to their role, you know, they're appointment clerks, the care coordinator, they're typing up the letters and so on, they are invaluable really" CNS

Clinicians – the skill set of the clinicians delivering the MDC varies significantly across pilot sites, as does the amount of time given to support the MDC.

The Leeds MDC is termed a 'Faculty', comprising the MDC coordinator, a CNS, an oncologist, the physician and on occasions an ITU consultant and a registrar, and meets weekly. The Faculty reviews test and assessment results, make a diagnosis and agree a management plan.

In Airedale the MDC clinician is an oncologist whose role differs from the normal oncologist role:

"I spend a lot of time chasing other specialities for some advice. Some people are very used to it because we go and see them often. Actually they were a bit wary, but now they are

much more open and want to give good advice . . . . Whilst others you're still trying to chase around. Actually if it's really vague and falls between 2, then they'll give you advice but nobody will take ownership" Lead clinician

In Oldham, Wythenshawe and North Middlesex, the MDCs are staffed by gastroenterologists, none of whom reported having concerns about having the requisite skills to deliver the service.

In Oxford the MDC clinical role is filled by geriatricians, who feel that they have the right skill set but that they need to work differently in the context of the MDC pathway as the patients are predominately younger:

"Because I'm a geriatrician we tend to see an older cohort with similar problems of weight loss, non-specific changes in bloods that nobody quite knows what's going on. But obviously it's a bit backwards because we see them in clinic and then organise tests whereas with 9the SCAN pathway) the test is done first, then we see the patient. So they are sort of similar but they are definitely a younger cohort. And, as I see it's a bit tricky sometimes when the scans are identifying abnormalities if you've not met the patient to know how much you should pursue or whether it's appropriate to be organising m*ore tests"* MDC clinician

In addition to actual time spent in clinic/faculty meetings, the majority of clinicians highlighted the amount of time it took to liaise with other specialties. North Middlesex clinicians also commented on the amount of additional time required to triage patients.

These roles seem to be working reasonably well in terms of fidelity to the MDC pathways as they were intended, however there is an acknowledgement that they may need reviewing from a skill and capacity perspective.

M6 Evaluation of resources

All of the pilots experienced some pressure relating to MDC clinician capacity which emerged as the project developed. Many also expressed concern about whether they could meet demand for additional diagnostic capacity such as radiology or endoscopy.

Some pilots undertook capacity modelling to identify the radiology or MDC capacity required. When a shortage of MDC capacity emerged in Wythenshawe and Airedale, the project teams sought to create additional ad hoc capacity by slotting patients into other clinics.

Unexpected issues, such as losing MDC clinicians on a temporary basis in both Airedale and Oxford, created additional problems. Airedale found a locum to cover the MDC clinics, whilst the lead clinician was still available to the steering group meetings and to provide advice to the CNS. Oxford could not get an immediate replacement and as a result patients whose laboratory tests and low dose CT scan were normal were put on a waiting list for the MDC after being informed they did not have cancer by the GP or navigator. Subsequently however, demand for the MDC has exceeded capacity. In an effort to manage the new waiting list an additional 8 slots are being offered at weekends, as a short term measure, by another clinician.

Leeds have experienced difficulty in recruiting the range of clinicians they had hoped for to staff the MDC faculty. They have identified suitable and willing clinicians but at the time of the final interviews these clinicians had not been freed up to attend by their line managers. Interviewees reported that board level support to make this happen had been sought. In the meantime they were suspending their proposed roll out until the matter had been addressed.

Some patients in Oldham experienced delays due to the clinician being unavailable to assess the CT and decide whether they needed to have an OGD. As a result, a protocol for CT assessment was developed and the nurse is now able to perform that function.

Most pilot sites did not report additional pressure on radiology or endoscopy due to the introduction of the MDC pathway, indeed, Leeds believes they can evidence a reduction in imaging as a result of the pathway. However, all sites are aware that expansion of the service could have a future effect on diagnostic services.

M7 Connections and communications between professionals

All of the pilots identified the need to communicate with clinical staff and other stakeholders and this was done in a variety of ways, ranging from one to one discussions to regular steering group meetings, with most pilots opting for a steering group to be the focal point for communication with key stakeholders. Successful communication was based on all parties understanding the purpose of the pilot and their specific role within it. The majority of pilot sites developed communication plans either prior to, or in the early stages of implementation. These included emails and newsletters to GPs, newsletters for secondary

care and GP education events that highlighted the purpose of the pilot and how to refer to the pathway.

A number of projects are now seeking referrer feedback, either in the form of case studies to illustrate the value of the MDC pathway or in the form of referrer experience surveys.

3.2.3 Outcomes

O1. Implementation of pathway

All the pilot sites implemented a MDC pathway. They tested the systems and processes making up the pathway, although they had different challenges and successes. All the sites wish to continue the pathway in some way moving forward although they believe that the pathway will have to change in some way.

O2. Faster route to diagnosis

All pilot sites perceived that prior to the implementation of the project some patients with vague symptoms were managed in primary care for an unnecessary amount of time, because GPs did not have an appropriate referral pathway. These patients were often sent for unnecessary tests or bounced around the referral system, resulting in a delay in diagnosis. Interviewees at all sites except Airedale report that they feel that the MDC is a faster route to diagnosis for both cancer and non-cancer. In Airedale, the clinician feels that in some instances the non-cancer diagnoses are delayed whilst he is seeking advice from other specialties.

O3. Understanding of staffing and capacity needs

All pilot sites have a better understanding of the staffing and capacity needs of the MDC pathway and were able to articulate where staff pressures had become apparent. For example, some MDC clinicians did not have sufficient time to carry out all the duties required for the MDC, such as liaison with other specialities. Pilot sites were also able to identify where there was spare capacity and how it could be utilised. Some sites identified spare CNS capacity (Wythenshawe) which could be used if the service was to be expanded or could be used to support other services such as acute oncology (Oldham). Leeds have already utilised Cancer Transformation Fund monies to increase CNS and administrative support, enabling them to extend access to the MDC model.

Interestingly, diagnostic capacity does not appear to have been under pressure as a result of implementing the MDC pathway. There have been occasional pressures with reporting CT scans, notably where 'hot' reporting (Oldham and Wythenshawe) has been required to support the one stop clinic model. Sites recognise that this could become even more of a pressure as services are expanded.

O4. Detection of diseases other than cancer

All pilot sites report that they have identified a significant number of non-cancer diagnoses requiring ongoing management. This is addressed in more detail in the corresponding quantitative evaluation of the ACE Wave 2 pilots.

O5. Improved patient experience

All sites reported a good patient experience and cited examples of individual case studies. The ACE Patient Experience Survey conducted in parallel with this evaluation showed that patients confirmed high levels of positive experience, notably in relation to the MDC team working together for the patient's benefit, (Howse J and Rubin G, 2018)

O6. Sustainability

The majority of interviewees felt that the continuation of a MDC was a good thing because it was perceived that patients were diagnosed earlier as a result. However, many thought that they were not sustainable in their current configuration. Reasons for this included difficulty in getting sufficient consultant capacity and/or it was perceived as being an expensive resource for a relatively small number of patients, even though the cancer conversion rate was comparable to the two week referral pathway.

GP interviews

Four GPs agreed to be interviewed. The GPs who were interviewed were generally positive, about their MDC, though all four expressed concern regarding the future of the service. They all wanted the service to continue after the current funding ended, as the MDC had provided a valuable alternative pathway for patients who do not fit established 2WW referral criteria but were of concern.

4.0 Discussion

Organisational culture

Organisational culture is a system of shared assumptions, values, and beliefs, which governs how people behave in organisations. These shared values have a strong influence on the people in the organisation and dictate how they act and perform their jobs. The Kings Fund (2016) suggests that a healthy organisational culture is characterised by: leaders who communicate an inspiring vision and values; goal setting at every level; support and compassion for staff; learning and innovation; effective team working; collective leadership.

All the pilot sites described elements of this organisational culture, though they varied in the extent to which these characteristics were evident. The most common characteristics described in the interviews were leaders communicating an ambitious vision, effective team working and continual learning and improvement. For some pilots such as Oxford, collective leadership was also an evident feature. Whilst all the pilots discussed board level awareness of their project, none of the sites described goals being set at board level for frontline staff. Most pilots described support being provided, particularly to the CNS and radiographer navigator roles.

Interviewees from the majority of sites talked positively about their leaders and the perceived effect of the pilot on the quality of care provided.

Previous involvement in modernisation/pathway redesign work

The Kings Fund (2016) describes quality improvement as designing and redesigning work processes and systems to deliver health care with better outcomes and lower cost. It asserts that improvements in the quality of care do not happen by chance; they come from intentional actions by staff who have the skills to enable change. All the pilots were able to describe previous involvement and expertise in pathway redesign work and each site had one or more individuals who had the skills to enable change, they also described motivation and commitment to drive through and support the change process. All the pilot sites were familiar with a range of improvement methodologies, although that knowledge was not necessarily evident in the methods used to implement the MDC pathway.

Project Management

Project management was identified as an important mechanism in the majority of pilots, although no pilot was able to describe in detail the method of project management they were going to use. Although all of the pilots were part of NHS organisations, none referred to using the NHS change model, which might have provided some structure to the projects. Although formal models were not evidenced during the interviews, those pilots with a systematic approach to project management were more effective than those with a more ad hoc approach. Time spent thinking about what the projects wanted to achieve and how they were going to achieve it varied significantly between projects, as did the amount of documentary evidence to support that thinking.

Some pilots were better at anticipating challenges and dealing with problems than others, those who anticipated problems had already developed a range of plans for dealing with them, whilst those projects who were less good at anticipating problems often had a more reactive approach. In some instances, problems had to go back to the steering groups for discussion and resolution. When this happened it sometimes led to delays. This suggests that it would be useful for projects to consider in advance how they will reflect on progress and react to challenges.

All of the projects considered capability and capacity to some extent, they all thought about the clinical skills required to deliver the project and to some extent the need for project management skills, whether they existed within the team or whether additional expertise was needed. Other skills, such as in-depth knowledge of improvement methodologies or change management theory, were considered much less frequently, although nearly all interviewees reported previous experience of improvement work.

Leadership

Transformational leadership was the most prevalent style of leadership described by the interviewees. It works well when trying to implement complex change as it is more appropriate in fast changing situations, where people have high levels of skill and where the leader can afford to get involved in the detail. As well as creating a vision, transformational leaders create opportunities for people to show flair and to take responsibility for new ideas; this style of leadership also empowers people to deal with challenges in a proactive and timely manner which has been a key factor identifiable in the successful projects.

Transformational leadership works well when implementing complex interventions such as the ACE projects because it is not reliant on one individual and it allows individuals to work to their strengths whilst developing new skills. Transformational leaders are often extravert, charismatic and strategic, and in addition to being passionate about quality improvement these traits were identified by interviewees from a number of the successful projects.

The Kings Fund (2018) highlights the importance of local leaders as they have significant impact on the speed of innovation and its spread. Local leadership was evident in many of the pilot sites, conversely, where it was less apparent staff felt less empowered, less able to deal with challenges and less able to become involved with rolling out their project.

Development of new roles and capacity to deliver the service

The Cancer Workforce Plan (2017) addresses the need for the NHS to ensure sufficient numbers of skilled staff to deliver high quality care. It is clear from all the pilot sites that delivering a MDC pathway requires people to work differently. However, it is difficult to ensure sufficient numbers of skilled staff unless some work is undertaken to identify the optimal skill set required, particularly of the clinician and CNS to deliver an effective and efficient MDC pathway.

All CNSs provided a support function for the patient but some were much more proactive in the assessment and ongoing management of patients. This suggests that CNS skill sets are highly variable and lack consistency. Griffiths et al (2013) support this by suggesting that there should be a nationally agreed competency and skills framework for CNSs.

It would appear from the pilots that CNSs who operate at a higher competency level are well suited to working within a MDC pathway environment and have the potential to take a significant amount of pressure off clinicians so long as robust governance arrangements exist. However, it must be recognised that CNSs work alongside medical colleagues and are not autonomous practitioners.

Airedale are actively considering the development of ANP roles. Advanced nurse practitioner roles could bring a different dimension to the delivery of MDC pathways. Health Education England (2017) developed a definition of advanced practice as being delivered by an experienced practitioner whose practice is characterised by a high level of autonomy and complex decision making. Specialist clinical competencies are necessary for advanced

practitioners to manage an episode of care. The autonomous level at which they practise allows for exploration of complex problems and the development of approaches to improve patient experience and outcomes.

Patient navigation is a model of interdisciplinary care which first appeared in the USA in the 1990s. The principle of navigation is to provide active coordination of care that removes barriers to access (Rubin et al, 2015). Navigation programmes seek to provide patients and their families with a map and a guide (the navigator) to overcome system fragmentation. Most studies of navigation in cancer have involved nurses in this role.

Three of the six pilot sites have a navigator role supporting the MDC pathway, the remaining pilot sites have one or more individuals who are working to provide active coordination of care to remove barriers and facilitate a timely diagnosis. In terms of fidelity to the navigation model developed in the USA, none of the pilot sites except Oxford (who had a 0.5wte nurse) and North Middlesex had a nurse in the USA-style navigator role.

In addition to the 0.5wte nurse navigator, Oxford also had a whole time radiographer working as a navigator who in addition to clinical responsibilities are also responsible for coordinating care, giving patients support and providing the administrative function as part of their role.

In contrast, in Wythenshawe and Oldham, the navigator role is essentially an administrative role. Even so it differs from traditional NHS administrative roles in that it is patient rather than task oriented.

The navigator role as implemented in Oldham and Wythenshawe coordinates all elements of the pathway to ensure a timely diagnosis. The navigator is responsible for booking the diagnostic tests and clinic appointments for the patient, liaising with the patient and the clinicians involved to ensure that the patient understands what will happen at each stage of the pathway. Because they provide a “one stop” service in Wythenshawe and Oldham, the navigators at those sites also physically take the patients to the department(s) where they are to undergo investigations and ensure that they are back at the clinic in order to be given their diagnosis.

Leeds has an MDC coordinator role and Airedale have MDC administrators, who provide coordination and work closely with the CNSs attached to the MDC pathway.

North Middlesex does not have a separate navigator role or a specific administrator responsible for coordination of the MDC pathway, instead the responsibility for coordination and guiding the patient through the pathway sits with the CNS.

Clinicians delivering MDCs are also required to operate differently, the skill set required to diagnose patients attending a MDC being more generic, and models differ significantly across pilot sites. However, it appears the more specialised the clinician is, the more concerned they are about missing something potentially serious, whether it be cancer or non-cancer. Furthermore, those less familiar with the patient case mix encountered in the MDC appear to spend a great deal of time liaising with colleagues in order to achieve a diagnosis for the patient.

It may be worthwhile mapping the core clinical competencies required to operate an MDC in order to decide what skill set a clinician should have in order to be most effective in this setting.

Whilst it appears there is scope to develop new roles to specifically support MDCs, Price et al (2015), caution against developing new roles without sufficient forethought: *"Conducting workforce transformation without a solid understanding of need can lead to the new role being underused, existing roles being de-skilled, care becoming fragmented, and financial costs being added to service delivery – all of which can ultimately threaten patient safety and the quality of care"*

It is evident that there is a set of generic functions required to operate an MDC and that the pilot sites have recruited people to fulfil those functions who have different job titles and backgrounds. What is done in one place by a CNS is done in another by an administrator and in a third by a navigator. It is worth considering these generic functions and who might be best placed to deliver them. Certainly a supportive role has emerged in all of the pilots which appears to be a core requirement going forward. This function differs from the traditional administrator role and the traditional cancer CNS role, with patients being supported from the point of receiving the referral through to diagnosis.

Sustainability

All of the pilot sites employed a range of appropriate mechanisms to ensure the delivery of their projects. Our analysis shows that all project sites have tested the systems and

processes which contribute to their respective MDC pathways. Most have delivered the pathway with minimal modifications along the way. The most notable pathway revision was in Airedale, which removed the MDC MDT from the pathway as it was not helpful in dealing with the non-cancer patients, who made up the majority of the patients referred. All of the pilot sites except North Middlesex (where opinions are mixed) see the MDC pathway continuing in some form, though probably evolving from the pilot rather than simply continuing unchanged. There are questions as to whether the models implemented as part of the ACE Wave 2 programme are cost effective and proposed changes involve better utilisation of the CNS and navigator roles and rolling out the MDC methodology to areas such as Upper GI.

It is evident from the interviews with the pilot sites that success in implementation was often due to one or more key individuals driving the project through its development and implementation stages. In the longer term, however, sustainability and spread requires effective teams with a range of skills including; communication, change management, and service improvement and evaluation. These skills were less consistently and universally evident and without them there is a high risk that innovations are not normalised and are unlikely to be sustained.

In terms of roll out to other geographical areas, this is not always straight forward and without challenges. In their case-studies on innovation and on adoption and spread of innovation in the NHS, the Kings Fund (2018) emphasise the challenge and complexity of transferring even simple well-designed innovations from one site to another. Nevertheless, a number of areas have secured funding or are in the process of securing funding to support the continuation and/or roll out of the MDC pathway.

Kaplan et al (2010) identified a set of factors that are associated with success in quality improvement initiatives, many of these factors were also evident in the pilot sites evaluated:

Table 3 Factors reported to be associated with success in quality improvement initiatives

Kaplan et al (2010)	**ACE qualitative evaluation**
Leadership from senior management	This was a key facilitator for pilots and its absence was a barrier, for example, in enabling clinicians to participate in MDCs/MDC faculty meetings.
Supportive organisational culture	Organisations which were open to change were much more likely to be facilitative than those whose who were struggling with change.
Data infrastructure and information systems	Important factors in quality improvement, where information systems are aligned even across organisational boundaries, e.g. the Airedale pilot, it is much easier to exchange information. The other pilot sites operate multiple information systems that are not well integrated. This has resulted in an inordinate amount of time being spent trying to address data infrastructure problems and ironing out data sharing agreements with partner organisations.
Previous involvement in quality improvement	All sites reported previous quality improvement work and existing relationships with some if not all of the partners involved in the ACE Wave 2 pilot. Those developing additional new partnerships reported this as a facilitator as it generated enthusiasm for the projects.
Physician involvement	Consistent leadership irrespective of discipline was identified as an important facilitator in all sites. The most effective pilots were those that had consistent leadership.
Micro-system motivation to change	All sites shared a belief in the value of the ACE Wave 2 programme. They all described patient benefit as a motivating factor resulting from implementing change. Other motivating factors, such as opportunities for personal advancement were also observed. Pilots where this was more limited due to lack of role security or other work pressures taking priority found it harder to support the pilot in the long term.
Resources	Funding from the ACE Wave 2 programme for additional resources in the form of project managers, CNSs, Navigators etc was seen as a major facilitator in enabling the pilots.

Normalisation

All the pilot sites managed to test the systems and processes put in place to deliver their MDC pathway. However, when normalisation process theory was applied to the data, we concluded that none of the pilot sites had completely normalised their initiative (see the NPT tables included within appendices B-G).

All pilot sites had normalised some elements of their initiatives. The majority expressed concern about sustainability in the medium to long term and for most there was recognition that the model as currently operated would not be viable in the future. Ongoing staffing and/or capacity issues in a number of pilots have been a key factor in preventing normalisation. These issues need to be addressed with robust back up plans in place for when problems occur. Without addressing these fundamental issues normalisation cannot occur and initiatives will not be sustained (May C, Finch T, 2009).

5.0 Conclusion

The ACE Wave 2 programme provided resources, expertise and an opportunity for projects to network and learn from each other. In addition, each project can be viewed as a pilot whose evaluation allows others to identify "what worked for whom and in what circumstances" (the detail of the case studies is included in Appendices B – G)

All of the ACE Wave 2 pilot sites evaluated in this study successfully implemented their MDC pathways with minimal changes to their intended model. This success may be explained by the fact that the ACE Wave 2 programme asked for interested parties to apply, so the sites that submitted expressions of interest were already motivated to implement change. All the pilot sites had already identified the issue they proposed to address as one of local and national importance. The involvement of the ACE Wave 2 programme team may have contributed to the successful implementation in a number of ways. Firstly, all pilots received some funding from the ACE Wave 2 programme; many projects used this to fund project managers, CNSs, navigators, and radiographer navigators. 'Hot' reporting of CT scans was also funded from project monies in some pilots. Secondly, some projects found it useful to gain board level support by describing their association with a national policy initiative linked to the national cancer strategy. Thirdly, the support and shared learning that was facilitated by the programme was seen as invaluable by some of the projects.

There have been a number of challenges to implementing the ACE Wave 2 pilots and to ensuring their longer-term sustainability:

5.1 Engaging clinicians and developing clinicians as leaders

Clinical engagement was key to successfully implementing projects. Where clinical leaders are proactive and identified with stakeholders, interviewees reported better engagement. However, leaders do not always have change management skills or knowledge of quality improvement methodologies and there is value in developing that capacity at a local level. There is some merit in projects considering the type of leadership required to ensure that stakeholders maintain their enthusiasm and engagement.

5.2 Skills

The skills required to deliver these projects are multiple and sometimes diverse. All projects required individuals to have leadership and management skills to ensure their pilot was successfully implemented, they also needed clinicians and CNSs with the technical skills to deliver the MDC pathway. Pilots also needed additional skills such as being able to understand and use quality improvement methodologies and influencing skills. The need for influencing skills was particularly relevant when clinicians were trying to get advice and support from other specialties in order to reach a diagnosis when patients were particularly complex. Individuals fulfilling the navigator function, regardless of discipline also needed good communication skills and a good understanding of the various hospital systems in order to be able to book patients in for investigations and clinics, to track their progress and record outcomes.

5.3 Short–termism

The relatively short-term nature of the ACE Wave 2 pilots meant that some pilots took longer to implement their initiatives than others as they had protracted HR processes and/or difficulty in recruiting and as a result had less data relating to their initiative or had not completed the internal evaluations that they had aspired to.

Despite the relatively short-term nature of the ACE Wave 2 programme a number of pilot sites commented on how they valued the flexible approach from the CRUK ACE programme

staff in allowing them to alter project timescales and in some instances to roll funding forward across financial years.

5.4 Recommendations:

Any sites wishing to introduce an MDC should:

- Ensure organisational commitment and should test receptiveness to change prior to commencing the pilot
- ensure key stakeholders have sufficient time to deliver their responsibilities
- Invest time to develop a robust implementation strategy
- Invest time in developing and maintaining inter/intra organisational relationships
- Build into their plans the capacity to react to challenges as they emerge
- Think about the most appropriate and cost-effective skill set to deliver the initiative and to start building capacity and skills at the earliest opportunity

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Appendix A- Glossary

2WW	2 Week Wait
ACE	Acceleration, Coordination and Evaluation
CCG	Clinical Commissioning Group
CMO	Context Mechanism Outcome
CNS	Clinical Nurse Specialist
CRUK	Cancer Research UK
CT	Computerised Tomography
CUP	Cancer of Unknown Primary
DVT	Deep Vein Thrombosis
FIT	Faecal immunochemical testing
GM	Greater Manchester
GP	General Practitioner
ICBP	International Cancer Benchmarking Partnership
MDC	Multidisciplinary Clinic
MDT	Multidisciplinary Team
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPT	Normalisation Process Theory
NYC	No-Yes Clinic
OGD	Oesophago-gastroduodenoscopy
OUHT	Oxford University Hospital Trust
PRU	Policy Research Unit for Cancer Awareness, Screening and Early Diagnosis
REDCAP	???
SCAN	Suspected Cancer Pathway
UCLH	University College London Hospital

Appendix B – Airedale General Hospital

B.1 Introduction and Background

Airedale, Wharfedale and Craven Clinical Commissioning Group provides services to a large geographical area stretching from Oakworth and Keighley in the south to Settle in the north It serves a population of 158,328, a significant number of which are elderly, particularly within Wharfedale and Craven districts where 9.2% of the population are aged 75+ compared to a national average of 7.5%. There were 644 new cancer diagnoses per 100.00 adults in 2012, higher than the national average (599 per 100,000). Cancer is the leading cause of premature death and the second most frequent cause of all deaths in the area. Airedale, Wharfedale and Craven CCG has a higher than average 2 week wait (2WW) referral activity. In addition, Cancer GP profiles show that there is large variation in activity amongst individual practices.

Following on from the ACE Wave 1 pilot and supported by the Airedale, Wharfedale and Craven (AWC) CCG, Airedale NHS Foundation Trust secured funding to implement an ACE Wave 2 project. The full project team was established in December 2016 with the objective of delivering a new patient pathway via a new Multidisciplinary Diagnostic Centre (MDC) for patients with vague or non-specific but concerning symptoms, or patients who are too unwell to wait for a 2 week wait referral but do not necessarily require hospital admission.

B.1.1 Aims and Objectives

The MDC is designed for patients presenting with vague symptoms who need diagnosis and treatment or referral within a few days of presentation to primary or secondary care.

The MDC project objectives are to:

1. Provide rapid access to patients who are too unwell to wait for 2 week wait referral
2. Specify clinic resources, up skilling booking procedures and outpatient scheduling.
3. Manage the referral process, define criteria that includes worrying but non-specific vague symptoms
4. Enable specialist decision making – a senior oncologist and radiologist will be available daily for advice, CNS arranged triage and direct patient care

5. Well managed (comparative and live) data collection, clear communication and performance monitoring
6. Close links to key departments – MDT coordinators, A&E, ot of hours GP, radiology, endoscopy, acute oncology service, outpatients.

B.1.2 ACE model

MDC Team:

General practice project lead, CCG Senior Design and Delivery Manager, Lead Cancer Manger Airedale NHS Foundation Trust, Patient Service Manager – Cancer Services, Project Manager, Clinical Lead Consultant /Oncologist, Clinical Nurse Specialist, Clinical Director for Diagnostics/Consultant Radiologist, Consultant Radiologist, Consultant in Emergency Medicine, MDC Administrator.

Team engagement:

MDC Project Board meets monthly and the project steering group meets fortnightly, there is also a weekly senior manager meeting.

Communication:

There are internal and external communication plans.

Patients are encouraged to bring a family member with them to their appointment; they are also given a MDC leaflet at the GP consultation, from which they are referred,

There were plans to evaluate patient experience as part of the national evaluation and at a local level.

Referral criteria:

1. Too unwell for a site specific 2 week wait pathway but does not need emergency admission
2. Non-specific but concerning symptoms with a high risk of cancer
3. Unexplained rapid weight loss < 1 month
4. Presenting with significant abdominal pain after primary medical intervention < month
5. Has presented to emergency department with abdominal symptoms
6. Patient must be aged 18 and over

18 practices within AWC CCG are eligible to refer to the MDC.

MDC referrals from primary care are made using the MDC proforma.

Diagnostic pathway:

MDC referrals are triaged by the Clinical Nurse Specialist (CNS) and discussed with the consultant if further advice is required. If all criteria information is complete an MDC Administrator contacts the patient within 24 hours of receiving the referral. The patient is allocated a morning telephone assessment slot with the CNS for the same day or the following morning

The CNS has 30 minutes allocated for the telephone assessment. The CNS decides if it is appropriate for the patient to go to test (typically this will be within 48 hours of telephone assessment). During the telephone assessment the patient is given an outpatient appointment for the next MDC clinic to see the medical oncologist. These are held each week and consist of new and CNS follow up appointment slots.

Prior to being seen in clinic it was anticipated that the patient would be discussed in a MDT Multidisciplinary Team Meeting (MDT), however in the early stages of this pilot this stage was removed from the pathway.

The patient is reviewed face to face at the MDC outpatient clinic; this is supported by information provided by the MDC referral, recent diagnostics and an MDT assessment if one has been done.

The MDC aims to inform the patient of a cancer diagnosis or that cancer has been excluded within 28 working days of the referral. Patients without a cancer diagnosis will have a management plan sent back to referring GP prior to discharge or onward referral on to non-cancer specialist.

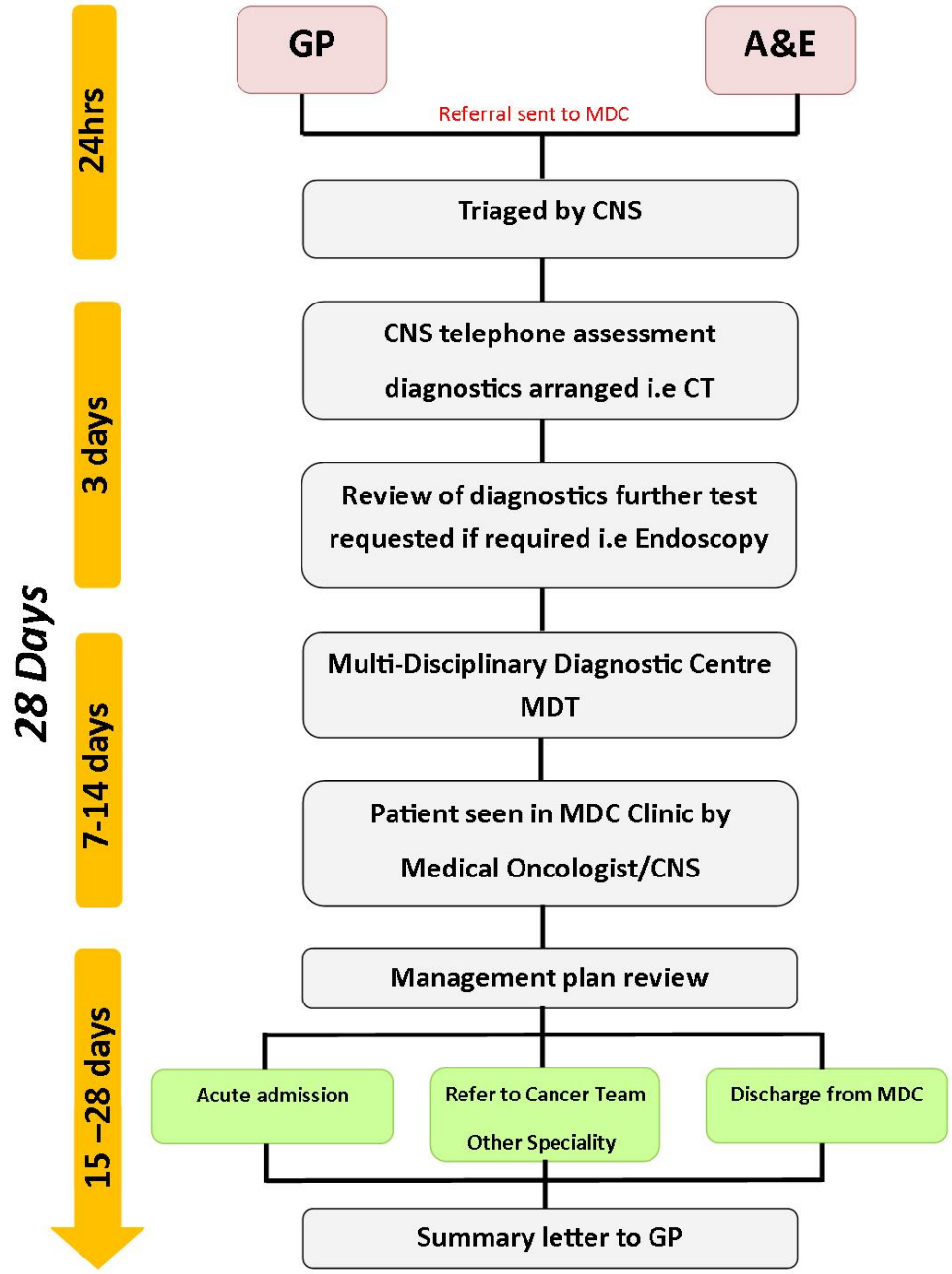

Figure 1 Airedale MDC pathway

N.B. The MDC MDT stage of the pathway no longer happens, following review of diagnostics/further tests patients are seen in MDC.

Patient management plan:

The management plan following MDC assessment is:

- Refer to cancer MDT
- Internally refer to specialist cancer team
- Admit to hospital
- Discharge to primary care

Where cancer is excluded the patient is referred back to primary care with a full detailed clinical summary with diagnosis and MDT outcome. Where the patient requires acute referral for non-cancer this can be done through the MDC.

Should investigations confirm a likely diagnosis of cancer; the medical oncologist discusses the diagnosis and next steps with the patient at their outpatient appointment. The MDC will refer to the specialist MDT so as not to cause delays in the patient's pathway. This is either disease site specific or Cancer Unknown Primary (CUP).

Patient experience:

Patient experience feedback was collected from patients coming through the MDC pathway using the ACE Patient Experience Survey.

It was also planned to send electronic surveys to primary care to help develop the service.

B.2 Evaluation Methodology

The qualitative evaluation of the ACE programme draws on the principles of realist evaluation (Pawson and Tilley, 1997) to develop a contextualised account of the way in which change emerges. See section 2.1 for details of realist methodology.

The underlying programme theory for the site was:

1) If you develop a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes will improve

For the purposes of this case study, a total of 27 1:1 interviews with key informants were carried out.

Analysis of the interviews resulted in the development of a Context, Mechanisms and Outcomes (CMO) model (figure 2).

The CMO model considers the contexts, mechanisms and outcomes that were apparent in the implementation of the initiative. Each of the key mechanisms is considered in turn within the case study.

Normalisation Process Theory (NPT) provides the theoretical basis for understanding how the initiative is understood, implemented and embedded into normal practice. NPT considers four areas; coherence, cognitive participation, collective action, and reflexive monitoring (see section 2.2 for details). Each of these areas are considered in turn in table 1.

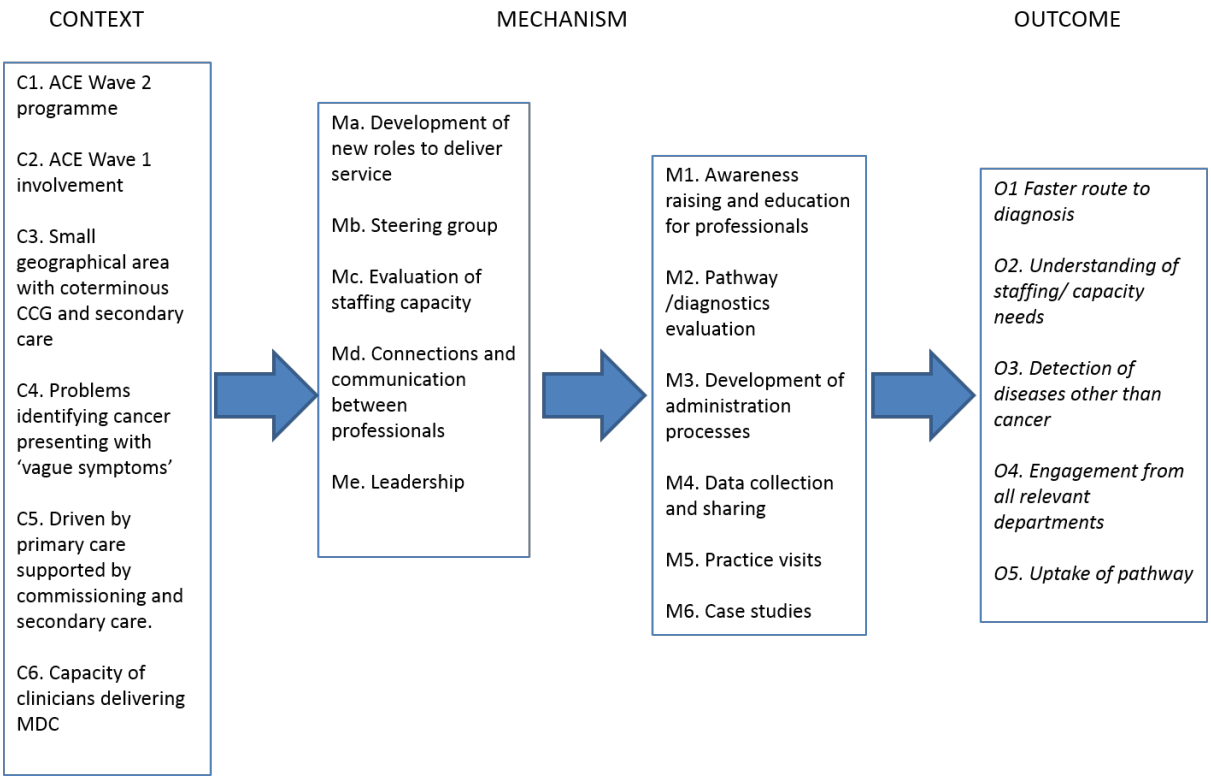

Figure 2 CMO model for Airedale

B.3 Contexts, Mechanisms and Outcomes

B 3.1 Ma Development of new roles to deliver the service

Context and Mechanisms

Airedale identified that patients experiencing vague but concerning symptoms often did not have a smooth pathway leading to diagnosis. They were motivated to develop an MDC pathway because it built upon previous cancer pathway redesign work and more specifically, the work they had done as part of the ACE Wave 1 programme. In addition, the overarching organisational culture was one which was proactive and receptive to change. A

proposed pathway was developed which was informed by the Danish MDC experience as well as their own ACE Wave 1 pilot.

The development of the MDC pathway was actively supported by a project manager appointed with project funding, secondary care managers , a CCG commissioner and led by 2 clinicians; one an oncologist responsible for delivering the MDC, the other a GP lead.

A number of new roles were also developed to support the development and implementation of the pathway, including; the project manager role, an ACE administrator role, a (CNS) role and new remits for clinicians providing the MDC.

Characteristics of mechanisms and outcomes

The project manager role was vital to the delivery of project, she was responsible for the day to day implementation of the pilot. A significant amount of her time was also devoted to liaising with stakeholders, communicating the existence of the pathway to GPs, liaising with them about referrals, coordinating the Project Board and monitoring data. Unfortunately she left relatively early on in the project and other stakeholders reported that this left an important gap:

"*We do miss a project manager. I must admit, because we are quite busy and there's lots of admin for us to do that doesn't include what a project manager would do. And sometimes you can't get the information, reports and things have suffered"* ACE administrator

"I think maybe we underestimated how much she was doing . . . . . she was a quiet character . . . . . maybe we underplayed how much she was actually responsible for achieving"

Lead clinician

"*I think communication with the GPs has suffered not having a project manager, CC (the CNS) still communicates with them regarding specific patients but it's the general communication that has probably suffered".* Patient service manager - Canc

An ACE administrator role was developed to support this pathway, the role is a hybrid of a number of existing NHS administrative roles and the post holder(s) have responsibility for liaising with patients and GPs, booking and tracking patients, inputting into the database and typing letters to the GPs:

"They have so many hats to their role, you know, they're appointment clerks, the care coordinator, they're typing up the letters and so on, they are invaluable really" CNS

The clinical nurse specialist role is key to the success of this model and was developed with the CNS being the first point of contact for patients within secondary care. The CNS triages the patient prior to carrying out an assessment. The CNS also checks for any missing blood or imaging results and requests them if they were not done by primary care. The CNS also plays a key role in supporting the patient and liaising with the clinician who delivers the MDC. She also spends a significant amount of time liaising and advising GPs.

The pathway appears to work well with the CNS role being highly valued by the clinician:

"CC is great, she works well with me and because she was an internal appointment she knows just about everyone in the hospital which can be really useful when trying to get advice from other specialisms" Lead clinician

The importance of the CNS role in this pathway is becoming increasingly acknowledged with managers looking at how to further develop the role and the individual post holder:

"I think the advanced practitioner role is a key thing to this that we need to get to grips with within the organisation. You have to have training posts first before you can have advanced practitioner nurses. We've just applied for quite a few of those from an organisation point of view. We're just at the moment seeing if we can have 2 of those posts.

That's what I would say has been the biggest, not surprise to me, but we seem to be going that way. It's probably right because the MDC is like an assessment unit and you need the skills" Patient service manager – Cancer

The MDC clinician role differsto the one normally carried out by an oncologist:

"I spend a lot of time chasing other specialities for some advice. Some people are very used to it because we go and see them often. Actually they were a bit wary, but now they are much more open and want to give good advice . . . . Whilst others you're still trying to chase around. Actually if it's really vague and falls between 2, then they'll give you advice but nobody will take ownership" Lead clinician

Whilst the new roles appear to be working well and patient satisfaction is high, there is some question regarding whether an oncologist has the right skill set for these patients or whether someone with a more generic skill set would be more appropriate:

"They get an oncology team upfront. That's essentially what CC (the CNS) and I are trained in. We can do the cancer, no cancer bits, but then the national team want us to give them a diagnosis. Actually, we're probably not doing that for the bulk of those" Lead clinician

Interpretation

Staff interviewed all seemed appreciative of the new roles. There was evidence from the interviews that there was a shared understanding of the purpose of the ACE MDC pathway and it was viewed as bringing additional value to patients. The pilot has raised the question as to which clinical skills are most appropriate for a clinician to deliver an MDC and whether the role of advanced nurse practitioner could further enhance this pathway.

In terms of normalisation process theory we conclude that the ACE MDC pathway has yet to become completely normalised as there are still issues relating to engaging additional clinicians for advice in making a non-cancer diagnosis.

B.3.2 Mb Project Board/Steering Group

Context and Mechanisms

Airedale was involved in the ACE Wave 1 programme; with their Wave 2 pilot they revised the terms of reference and membership of the existing steering group which then became the Project Board in the planning stages of the Wave 2 pilot.

The project board included key stakeholders from primary care, commissioning and secondary care, it is relevant to note that the area is geographically well defined with a coterminous CCG and secondary care trust, where key stakeholders have a history of working well together.

Characteristics of mechanisms and outcomes

The project was led by the GP cancer lead, supported initially by the project manager (who was a full time appointment but had long term sickness early in the project and subsequently left in December 2017) and by the Project Board.

Monthly project board meetings were held to shape the ACE vague symptoms pathway and how it was to be delivered. Latterly they have focused more on performance management.

The core membership of the project board consisted of the GP cancer lead, senior design and delivery manager from the CCG, consultant medical oncologist/lead clinician, consultant in emergency medicine, consultant radiologist/clinical director for diagnostics, lead cancer manager and cancer patient service manager. As the project was implemented and new postholders, such as the project manager, administrators and the CNS were appointed, they were included on the project board.

The steering group was an operational group which consisted of those directly responsible for the delivery of the pathway and in early stages of implementation met fortnightly to deal with any operational issues. The pilot was also discussed at the weekly senior managers meeting, there is also a mechanism for feeding up to the executive teams in the acute trust and the CCG.

Since the early departure of the project manager and because the pilot has run smoothly, the frequency of project board meetings has more recently reduced and they are more "ad hoc" in nature.

However, due to additional funding received to roll out the ACE methodology to other 2 week wait pathways it is anticipated that the group will start meeting more regularly, redefine membership and terms of reference and become reinvigorated by the new focus:

"Maybe we're looking to see change rather than to roll it out as a standard thing. I think people will rally back round it (the steering group). I think there's definite interest to do that"

Lead clinician

The project board was effective in planning and supporting the implementation of the pilot. The project manager left less than halfway through the implementation stage of the pilot, which could have posed a significant risk to the pilot. However, the pilot remained on track because it was high on everyone's agenda with each member of the board having ownership of the pilot. Key members of the board remained consistently committed.

Interpretation

One reason for the success of the project board was that the membership had a shared vision, members were also close enough for the work to impact on their roles and were

senior enough to be able to take and implement operational decisions. There was also strong leadership and clear lines of accountability.

B.3.3 Mc Evaluation of staffing capacity and other resources

Context and Mechanism

This project was developed following the implementation of a successful Wave1 pilot which involved the implementation of an electronic referral advice pathway with the advice being provided by radiology, this work allowed the team to identify radiology capacity for diagnostics required for patients with vague symptoms who need a quick diagnosis.

In order to get the clinic up and running a room which wasn't really suitable was identified, with a view to it being changed at a later date

Characteristics of mechanisms and outcomes

One radiology slot per day was identified for the pilot, with one endoscopy slot per week also identified. The Clinical Nurse Specialist was able to directly book patients into these slots.

Diagnostic capacity has been sufficient and there have been no issues:

"As far as diagnostics is concerned I have no issues really, everything seems to be working pretty smoothly and it's partly because our numbers are still quite low. So I think we are still able to manage with what capacity we have" Radiologist

Nursing capacity has been sufficient to deliver the pilot in its current configuratio

Finding MDC Clinician capacity has been a challenge at times. Early in the project the MDC clinician was required to fulfil Trust contractual obligations to provide cover in a neighbouring hospital. Backfill was identified to cover the clinic work but time to provide daily advice to the CNS was greatly reduced during this period, which caused some pressure on both the CNS and clinician. This issue had been resolved at the time of the final interviews.

The provision of daily advice was not a problem when the final set of interviews were conducted however there was an acknowledgement that this took up a significant amount of time which was not reflected in the clinician's job plan:

"So having to support Bradford was an issue and caused additional pressure. There was lots of support from the senior team here . . . . . I don't have the leadership things that were happening or being foisted upon me last time (the interviews were conducted)"

Lead clinician

Clinician capacity is a more general issue as there is no recognition of the amount of time it takes to liaise with other specialisms:

"I still don't think he (the clinician) gets enough hours in the week for the job, because I think he only has 1 PA but actually it takes quite a lot of liaison and administration, it's not just about the clinic, it's about the whole working week really" CNS

There are 4 new patient clinic slots and 2 follow up slots per week identified for the MDC, Most of the time interviewees report sufficient clinic capacity to meet demand, on the few occasions where demand has been greater than capacity, they have been able to slot them into free Cancer of Unknown Primary (CUP) clinic slots.

There is sufficient capacity in the system to allow the majority of patients to be seen in the MDC in 7 – 14 days, with the management plan and GP summary letter being sent between 15 – 28 days following referral.

There are plans to extend the role of the CNS in the future to become an Advanced Nurse Practitioner, which would take some of the pressure off the MDC Clinician:

"So AA (the CNS), we're trying to do some development with AA and she's very able to do that. And that will sort itself, but I see that the next step is absolutely going to be CNS delivered and heavily reliant on the CNS teams" Lead cancer manager

Issues with the clinic room remain a challenge:

"The clinic space, the room we use is dreadful. It's got a large ophthalmology machine in one corner and some big fridge. We keep going back to them about it"

Lead clinician

Interpretation

Careful monitoring and the "hands on" approach by everyone involved in the pilot appears to have facilitated a robust understanding of capacity issues.

It is essential for roles and responsibilities to be acknowledged in clinicians' job plans, there also needs to be recognition of support and developmental needs of staff if they are to further develop their roles.

B.3.4 Md Connections and communications between professionals

Context and Mechanism

The project board/steering group and practice visits by the project manager and CNS were key to enabling communication between the professionals involved in the planning, implementation and delivery of the pathway (see Mb for more detail regarding the Project board and steering group).

There is also a proactive, credible GP lead who was responsible for working with commissioners and secondary care colleagues to develop and progress the bid for the Wave 2 work and facilitating education events for the GPs.

Characteristics of mechanisms and outcomes

As previously stated, the project board was effective due to the shared vision of members and the consistent messages given to wider stakeholders such as GPs. The GP visits were also crucial in informing GPs about the existence of the pathway and in giving them specific guidance on how to use it.

Whilst the project manager was in post an ACE newsletter was distributed highlighting achievements and progress and reiterated messages relating to referral criteria.

Education events led by The GP lead were also effective in reiterating messages about the pathway. They were also a useful source of informal feedback.

The departure of the project manager has resulted in some things not being done as thoroughly or as regularly as before. This has included the development of the newsletter, continuing liaison with GPs and the frequency of performance management reports.

Interpretation

The importance of the need for providing repeated, consistent messages in a range of formats is vital if all stakeholders are to be reached and kept engaged.

Sufficient time to liaise with GPs and review data/compile reports needs to be identified as someone's role in the absence of a project manager, particularly if the planned developments using ACE methodology to redesign 2 week wait pathways come to pass.

B.3.5 Me Leadership

Context and Mechanism

Overall pilot leadership came from the GP cancer lead supported by the project manager (employed within secondary care) and key stakeholders including managers, the secondary care lead clinician and the CNS.

The well-defined geographical area with coterminous CCG and secondary care was a key context relating to this mechanism.

Characteristics of mechanisms and outcomes

The GP cancer lead was the same person who led the Wave 1 work in Airedale she is a well-established, credible leader with good communication skills and prior to the implementation of the Wave 2 pilot had established good relationships with key stakeholders:

"I think we've got a fantastic GP, so I think the whole relationship between primary and secondary care has really, through BB (GP Lead) much improved " Lead cancer manager

Within the project board, individuals were tasked with specific responsibilities and leading on specific areas, also for reporting back progress.

Interpretation

This approach to leadership worked well with the pilot being delivered as planned. The successful planning and implementation was heavily dependent on existing relationships and goodwill, which were possibly easier to cultivate in areas where the hospital boundaries and CCG are coterminous and within organisations where structures are less complex and/or where innovations build directly on previous work.

Please see section 4.0 for further discussion about leadership and leadership theory.

B.4 Conclusions

27 1:1 interviews were conducted throughout the evaluation period, generating a significant amount of qualitative data. The CMO configuration presented reflects the key findings resulting from our analysis.

To summarise, the outcomes specified in the CMO table (figure 1) were evidenced in the following ways:

O1. Faster route to diagnosis – there is a perception that prior to the development of the MDC pathway some of these patients were managed in primary care for an unnecessary amount of time because GPs did not have an appropriate pathway to refer them on. In addition, often these patients were sent for unnecessary tests or were bounced around the system, creating a delay in diagnosis.

Informal feedback from GPs indicates that they feel this is a faster route to diagnosis for both cancer and non-cancer patients. To date a small amount of cancers have been detected via this pathway and those that have been detected have been at an advanced stage.

O2. Understanding of staffing/capacity needs – Interviewees state they now understand capacity better in relation to this pathway. There is a need to review the skill set required of any clinician delivering the MDC, and in the meantime reviewing the current occupant's job plan to reflect the time it takes to deliver all of the functions of the MDC pathway being performed.

O3. Detection of diseases other than cancer- Interviewees report that they have identified a significant amount of non-cancers requiring ongoing management and sometimes identifying alternative diagnoses. They have had issues getting advice and support from other clinicians in respect of these patients. In general, these patients are referred back to their GP for further management.

O4, Engagement from all relevant departments - Interviewees report good engagement from the majority of departments.

O5. Uptake of the pathway - At the time of the final set of interviews the majority of GP practices were using the pathway and there is anecdotal evidence they find it useful.

In terms of Airedale's underlying programme theory, they believed that by developing a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes would improve, we have both anecdotal evidence from the interviews and data from the ACE Patient Experience Survey that patient experience is good. However at the

time of writing this case-study it is difficult to evidence whether patient outcomes have improved, though the quantitative evaluation may give further insights into this.

With regards to fidelity to the proposed pathway, initially Airedale had planned to have an MDC MDT tagged on to the end of an existing CUP MDT (see table 1), however this did not work well as the clinicians present were primarily interested in cancer and the vast majority of patients had a non-cancer diagnosis. As a result this stage of the pathway was removed. Other than that, the pathway has remained unchanged.

Applying a Normalisation Process Theory framework to our findings, we conclude that many aspects of the project have been normalised (see section 2.2 for more detail on NPT), these have been analysed using an NPT framework and the results are shown in table 2.

Table 2 Airedale Normalisation Process Theory

	Coherence **What is the work?**	**Cognitive participation.** **Who does the work?**	**Collective action** **How does the work get done?**	**Reflexive monitoring** **How is the work understood?**
Systematic explanation of mechanisms and components at work	Airedale, Wharfedale and Craven CCG, Airedale NHS Foundation Trust and GP practices recognised it as building upon previous cancer pathway redesign work, particularly ACE Wave 1 work. Education events and regular feedback from the Project Manager whilst in post and Lead GP and the, have reinforced the mechanisms of the process	GPs refer patients with concerning vague symptoms. CNS does the assessment, and arranges initial diagnostics. Patients are seen in MDC. GPs informed of results. Where findings require it patient moved to appropriate pathway	Information was provided in relation to the pathway. The CNS was given training and an in-depth induction and ongoing support provided by the Consultant. Protocols for the pathway were also developed	The Project Board met regularly initially and there was a shared understanding amongst stakeholders.
Knowledge about the sources and operation of investments at work	Practices understand the mechanism for referring in and the majority are using the pathway	Value of the intervention was promoted by the Project Manager, GP Lead and Commissioner. There was consensus that the intervention was worthwhile from a patient perspective	GP practices engaged in referring patients to the MDC. CNS responsible for initial assessment Radiology for CT scans. Administrator for booking and following up tests and tracking the patients, also for booking patients into clinic. The Consultant sees the patients in clinic and manages them accordingly, seeking advice, referring on as appropriate or discharging back to the GP.	There is consensus regarding the factors affecting the pathway across key stakeholders.
Core questions	**How is a practice conceptualised by participants?** Viewed positively by CCG, Airedale NHS Trust and General Practice who refer in? In discussions about what	**How do participants come to engage with a practice?** Practices were initially approached by the Lead GP and Project Manager .The project was actively supported by the Project Board. More sustained	**How do participants enact a practice?** Follow protocol. Enlist support from Project Manager when necessary.	**How do participants appraise a practice?** Appraisal and feedback encouraged via weekly the steering group and contact with the Project Manager. Done

	the model will look like going forward	engagement due to education and training of practices and ongoing support is required since the Project Manager left.		informally at a local level
Core questions	**How does it hold together in action?** GP Practices referring to the MDC. The CNS conducting the initial assessment. Radiology coping with demand for the CT scans. Administrator provides administration, booking and tracking functions Consultant sees patients in MDC, seeks further advice from other clinicians and decides most appropriate ongoing management.	**How do they decide on engagement and the purposes that it serves?** Discussions around value to the patient, Consideration of additional workload and subsequent impact on capacity. Project driven by GP Lead and motivated Project Board	**How are their activities structured and constrained?** Practices are responsible for referring the patients to the MDC. The CNS is responsible for assessing the patients (supported by the clinician). Radiology are responsible for CT scans and reporting. The Administrator deals with administrative, booking and patient tracking issues. The Consultant sees patients in clinic and seeks appropriate clinical advice then decides ongoing management, onward referral or discharge back to GP.	**What are its effects of appraisal?** Appraisal has resulted in small changes to the pathway such as discontinuing the MDC MDT as the majority of patients were non-cancer diagnoses

Appendix C – St James University Hospital, Leeds

C.1 Introduction and Background

Leeds Teaching Hospitals NHS Trust is one of the largest teaching hospitals in Europe and a regional and national centre for specialist treatment including cancer, as well as the local hospital for the Leeds communities. At the start of the ACE Wave 2 evaluation Leeds comprised 3 Clinical Commissioning Groups (CCGs); NHS Leeds South and East CCG is made up of 42 local GP practices covering a population of 257,000 people. NHS Leeds North CCG is made up of 26 GP practices in north Leeds covering a population of around 212,000 people. NHS Leeds West CCG is made up of 37 GP practices and covers a population of around 350,000 people. Since April 2018 the CCGs have merged to form a single CCG (NHS Leeds CCG).

The years of life lost from avoidable causes of death is an indicator in the Leeds 2016 Health & Wellbeing Strategy – and is significantly higher than for England. Cancer mortality rates in both male and females are improving but remain worse than the national average. In the affluent areas of Leeds South and East, people can expect to live on average 10 years longer than in the some of the more deprived areas of Leeds.

ACE Wave 2 approved funding for a Leeds MDC project aimed at speeding up diagnosis for people with non-specific but concerning symptoms. The ACE project was a collaboration between Leeds Teaching Hospitals NHS Trust and the Leeds CCGs with project management coming from Leeds West CCG.

C.1.1 Aims and Objectives

The primary aim of this pilot was to design and develop a pathway to '*Improve patient experience and outcomes by getting the quickest, most accurate diagnosis for people with non-specific, concerning symptoms, with GP suspicion of cancer.'*

Objectives include:

Better clinical outcomes:

- Reduction in proportion of emergency diagnoses
- Increase in numbers of patients with diagnostic concern referred at appropriate stage

- Reduction in patients presenting advanced stage cancers and other serious progressed diseases
- Reduction in numbers of separate imaging events per patient

Improved patient experience and more effective use of resources:

- Reduction in numbers of appointments
- Reduction in numbers of separate imaging events per patient
- Reduction in numbers of investigations to definitive diagnosis
- Reduction in numbers of patients being reviewed at more than 1 MDT
- Reduction in numbers of patients being referred on multiple 2ww pathways
- Patients more involved in decision making/ an increased understanding of why they have been referred

C.1.2 Leeds ACE model

MDC Team

Clinical Leads x 2, Clinical Nurse Specialist, Cancer Information Specialist, MDC Co-ordinator, GP Leads x 2, Project Manager, Lead Cancer Centre Manager.

Team Engagement:

The MDC project group meets monthly, and the MDC faculty meeting (comprising of the 2 lead clinicians, the clinical nurse specialist and the MDC co-ordinator) meets weekly, although there are plans to expand the numbers of specialists involved and the frequency of meetings.

Communication:

There were internal and external communication plans.

Patients are encouraged to bring a family member with them to their appointment

There are plans to evaluate patient experience as part of the national evaluation.

Referral criteria:

The Leeds non-specific symptoms pathway includes a broad range of non-specific but concerning symptoms in line with ACE guidance, which form the referral criteria for patients, including:

- Weight loss, unexplained/ significant

- Abdominal Pain, progressive, recurrent, unexplained
- Change in bowel habit to loose stools with upper abdominal pain, persistent, unexplained
- General condition (GP gut feeling) clinical intuition
- Nausea/ Appetite loss
- Anaemia

Respiratory symptoms were not included in the non-specific symptoms pathway as there was already a direct access chest x-ray pathway in Leeds. Fatigue was also not included as it was considered to be too subjective and would present difficulty in measuring and therefore quantifying change.

Diagnostic pathway:

The design of the Leeds ACE pathway focuses on a rapid evaluation of current symptoms and medical co-morbidity through a nurse led assessment alongside an initial range of diagnostic blood tests and chest x-ray requested by the GP. This evaluation is available to clinicians prior to their first clinical contact with the patient in order to best inform further investigative testing and onward referral. This pathway focuses on reaching a diagnosis for all patients, providing an explanation of symptoms, and has not solely been developed as a cancer exclusion pathway.

Referral process and pathway:

- Patients presents at GP with a range of non –specific symptoms
- GP requests ACE Blood test battery through OrderComms (including Chest X-ray)
- GP acts on results and makes referral (if appropriate) to ACE pathway
- Patient is booked in for nurse led assessment
- Comorbidity evaluation / Psychological screening/ Dietetic screen
- Drugs review (including compliance)
- Baseline physiology (observations, body composition, ECG, PFT/spirometry, TUG, shuttle-runs, stair climb,)
- MDC meeting / MDC patient management plan

- Diagnosis – findings functional and not organic – refer back to GP with plan
- Patient booked for further tests
- Diagnosis and referral therapeutic services

- Communication to GPs / Patient and others

Patient experience:

Patient experience feedback was sought 2or all patients coming through the MDC using the ACE Patient Experience Survey.

C.2 Evaluation Methodology

The qualitative evaluation of the ACE programme draws on the principles of realist evaluation (Pawson and Tilley, 1997) to develop a contextualised account of the way in which change emerges. See section 2.1 for details of realist methodology.

The underlying programme theory for the site was:

If you develop a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes will improve

A MDC pathway will facilitate a more effective use of resources (imaging etc.)

For the purposes of this case study, a total of 27 1:1 interviews with key informants were carried out.

Analysis of the interviews resulted in the development of a Context, Mechanisms and Outcomes (CMO) model (figure 1)

The CMO model considers the contexts, mechanisms and outcomes that were apparent in the implementation of the initiative. Each of the key mechanisms is considered in turn within the case study.

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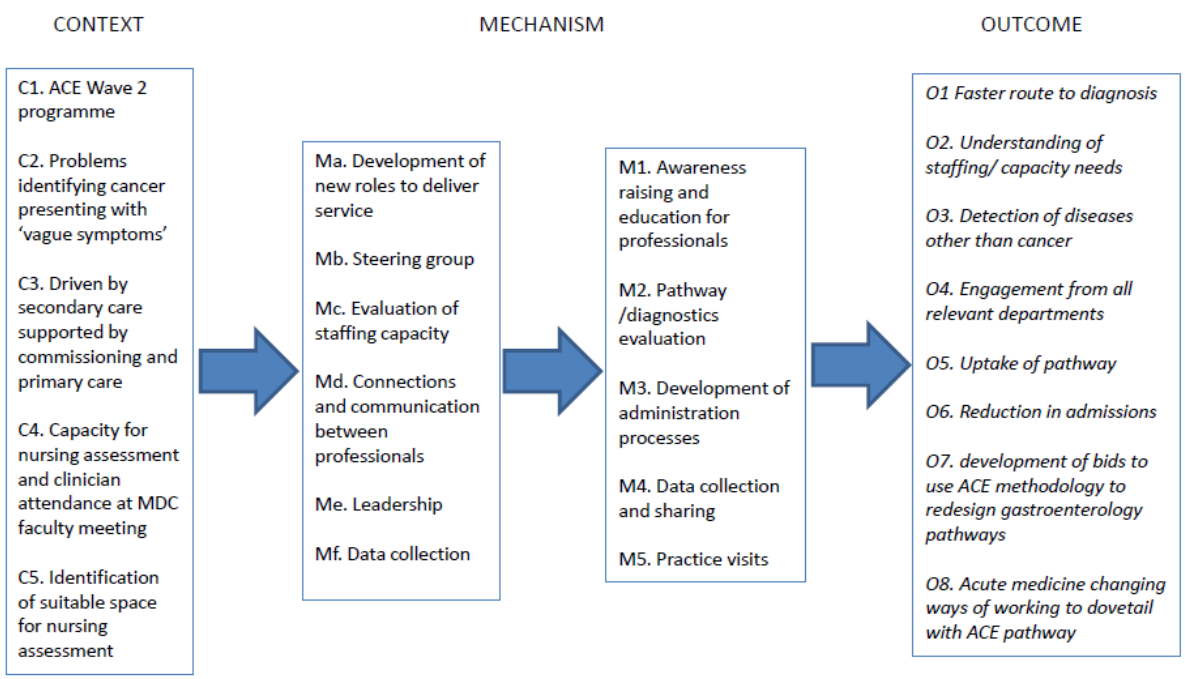


Figure 2 CMO model for Leeds

C.3 Contexts, Mechanisms and Outcomes

C.3.1 Ma Development of new roles to deliver the ACE MDC pathway

Context and Mechanism

Leeds identified that patients experiencing vague but concerning symptoms often did not have a smooth pathway leading to diagnosis. They were motivated to develop an MDC pathway because it built upon previous cancer pathway redesign work and the overarching organisational culture was one which was proactive and receptive to change. A proposed pathway was developed which was informed by the Danish MDC experience.

The development of the MDC pathway was actively supported by a project manager from the CCG and led by 2 clinicians within secondary care; one physician and one oncologist. Support was also provided by primary care cancer leads and the cancer services manager within the Trust.

A number of new roles were also developed to support the development and implementation of the pathway, including; a MDC co-ordinator role, a Clinical Nurse Specialist (CNS) role and clinicians providing MDC faculty meeting support

Characteristics of mechanisms and Outcomes

An ACE MDC coordinator role has been developed to support this pathway, the role is similar to the well-established Cancer MDT (Multidisciplinary Team) coordinator roles, who have responsibility for the administration of MDT meetings and tracking cancer patients. The ACE MDC coordinator has additional responsibilities including booking patients in for diagnostic tests and clinics, capturing diagnoses, including non-cancer diagnoses, and administering patient experience surveys.

There is evidence from the interviews that the organisation values the role of the MDC coordinator:

"The MDC Coordinator role is really important to the smooth running of the pathway and allows me to focus on the clinical/nursing issues that I need to"

Clinical nurse specialist

The contracted hours of the MDC co-ordinator post have increased incrementally throughout the evaluation period, initially it was a 7.5 hour post, which increased to 18.75 hours as the number of referrals and associated work load increased, at the time of the final interviews the role had been increased to 37.5 hours per week. In addition to this an additional 18.75 hours of a booking clerk and 37.5 hours of administrative support have also been provided to support the MDC coordinator role.

The clinical nurse specialist role is key to the success of this model, which was developed with the CNS being the first point of contact for patients within secondary care. The CNS carries out a detailed assessment which includes an in-depth psychological assessment. She checks for any missing blood or imaging results and requests them if they were not done in primary care. The CNS also plays a key role in presenting the patient at the MDC faculty meeting where the clinicians discuss the individual patient and make decisions relating to the next steps i.e. further investigations, referral elsewhere, review or discharge. Following the MDC Faculty meeting the CNS telephones the patient to let them know the results of any investigations and any further tests or appointments that they will need.

The pathway appears to work well with the CNS role being highly valued by the clinicians:

"*The CNS role is key to making the whole thing work, she is the first point of contact with secondary care, without her input the pathway simply wouldn't, couldn't work*"

Lead clinician 2

There is also anecdotal evidence that the role is valued by patients:

"Verbal feedback I've had from two patients – the support was great and they've asked why more of this isn't happening" Lead clinician 2

"A lot of them (patients) speak highly of XX the nurse. I think one of them said we were better than BUPA, which we are thinking about as having as our tag line" MDT co-ordinator

In response to feedback about the key role the CNS plays in the MDC pathway and the increasing number of patients being referred, the Trust has increased the CNS input into the pilot and increased her hours from 18.75 to 37.5 per week. Initially there was no back-fill to cover for annual leave for this post, this has recently also been resolved.

The Trust has also recently been successful in securing funding from the Cancer Transformation Fund, a proportion of which will be used to fund additional CNS capacity to assist in the longer term role out of this pathway:

"This additional funding is enabling us, now, to plan for that city-wide roll out. Part of the will involve more CNSs to work in community venues" Initial project manager

The MDC faculty functions in a similar way to that of a cancer MDT, where each clinician brings specific expertise to individual patient discussions to assist in making a diagnosis and agreeing a management plan. At the time of the final set of interviews the MDC faculty meeting was held once a week, its composition being the MDC coordinator, the CNS, the oncologist, the physician and on occasions an ITU consultant and a registrar. There are plans to increase the frequency of meetings in response to increased referrals and as they recruit more clinicians (please see section Mc for more detail). However it must be noted that to date it has proved difficult to get additional clinician support due to competing clinical priorities and bed pressures.

Interpretation

Staff interviewed all seemed appreciative of the new roles. There was evidence from the interviews that there was a shared understanding of the purpose of the ACE MDC pathway

and it was viewed as bringing additional value to patients and in some instances (such as reducing the amount of unnecessary imaging) to the organisation.

In terms of normalisation process theory we conclude that the ACE MDC pathway has yet to become completely normalised as there are still issues relating to engaging additional clinicians in the MDC faculty meeting; this has been a challenge since the inception of the project. There are ambitious plans to roll out the pathway to community venues and the ACE methodology internally to other specialities. However at the time of the final interviews the lead clinician reported that these plans were on hold until such time as they had recruited more clinicians to the faculty meeting and were in a position to increase the number of meetings accordingly.

C3.2 Mb Steering group

Context and Mechanisms

In order to deliver the project within the ACE timeframe a steering group including; managers, commissioners, clinicians and support services was established in the planning stages of the project. The formation of the steering group made up of key individuals required to plan and implement the pathway also helped to ensure that they were "bought into" and supportive of the project.

Characteristics of mechanisms and outcomes

The steering group continues to meet regularly. Initially it met to map existing pathways, to develop the new ACE MDC pathway and to agree evaluation metrics. As the pathway became operational the focus changed to more operational issues and became a forum for monitoring and reviewing progress.

The steering group was viewed as being effective by those interviewed:

"I think it's been really useful, a place to discuss operational issues, review the pathway and develop our thinking about how best to roll out the ACE methodology."

Cancer services manager

Membership of the Steering group is largely unchanged with all key individuals remaining involved, more recently the focus of the group has changed since they were successful in securing additional funding from the Cancer Transformation Fund. They are now working at an organisational level to strengthen the presence of primary care on the steering group

and roll out the MDC pathway to other locations and the methodology to other specialities. There are reports that this has consolidated the steering group further:

"*We still have all the key people attending the steering group and they are still proactive, in fact since we have secured additional funding to help with the roll out that's reinvigorated the steering group"* CCG project manager

Interpretation

One of the reasons the steering group was effective was that it was formed during the early planning stages of the pilot, which ensured that the majority of members had a clear understanding of the purpose of the MDC pathway and enabled them to contribute to the design of the pathway, ensuring they had ownership of the initiative.

Leeds is a large and complex organisation and a number of interviewees commented that many individuals/teams operate in silos. This project has proved to be different, bringing together individuals who would not normally work together which has had the unanticipated benefit of fostering a better understanding of each other's roles and the professional pressures affecting them.

C3.3 Mc Evaluation of staffing/space capacity

Context and Mechanisms

As discussed in section Ma, CNS and MDC coordinator/ administrative support capacity was regularly reviewed. In addition, the clinical leads sought to attract other clinicians to participate in the MDC faculty meeting.

Finding clinic space in St James' Hospital has been a challenge. Initially the CNS was using a ward nursing office to do initial patient assessments; this was not ideal as it was not a designated clinical area.

Insufficient radiology and endoscopy capacity has not been an issue whilst the project has been running and both departments are very supportive of the initiative.

Characteristics of Mechanisms and Outcomes

Hours for the CNS and MDC coordinator/ administrative support roles were increased in response to service demand.

The lead clinicians had limited success in recruiting additional clinicians to attend the MDC faculty meeting and this remained an issue each time they were interviewed as part of the evaluation. They had recruited 2 other clinicians to the MDC at the time of the final interviews but had reached an impasse due to the fact that although they had identified clinicians with the right skills and willingness to participate, their clinical directors were unable to release them to take up this activity because of other pressures. The time-limited funding which was available to support this initiative did not facilitate such major job planning revisions:

"Although we've secured a considerable number of clinical PA's, the funding for them, getting clinicians released into the project is proving to be very, very difficult"

Lead clinician 2

The executive team at the Trust is highly supportive of this initiative and the project team are hopeful that this support will help resolve the situation.

Clinic space for the CNS was identified by the time the final interviews were conducted and further space in community venues has been identified in preparation for the planned roll out of the MDC pathway.

Clinicians report that there has been a decrease in the number of investigations required for patients on this pathway and are currently collating data to support that:

"We have reduced the numbers of investigations. We've got a scan rate of 40% which means 60% of patients don't get a CT, so don't need a Radiologist. We've got an upper GI scope rate of 10% and a lower GI scope rate of 5%" Lead clinician 2

Interpretation

Capacity issues can occur when staff are required to take on roles in addition to their day to day responsibilities such as in the case of the clinicians. Reviewing job plans and having clear job descriptions prior to commencing the project may have alleviated some of the frustrations resulting from difficulty in freeing up people up to attend MDC faculty meetings.

C3.4 Md Connections and communication between professionals

Context and Mechanisms

There was agreement across a range of stakeholders including primary and secondary care that there were problems identifying cancer presenting with vague symptoms and that it would be appropriate to design a pathway to *"improve patient experience and outcomes by getting the quickest, most accurate diagnosis for people with non-specific, concerning symptoms with a GP suspicion of cancer".*

Characteristics of mechanisms and outcomes

Both internal and external communication plans exist. A significant amount of communication occurred within the steering group with members of the group being expected to relay consistent information to their own constituencies. Interviewees reported good communication existed which provided consistent messages in addition to a wide variety of other formats being used to reinforce messages and update on progress:

"We had a robust communication plan, we used a range of ways to get messages out to GPs and internally within the trust, these included, emails, newsletters, meetings with GPs and feedback at a range of strategic and operational meetings" Cancer services manager

The pathway and referral criteria were also sent to GPs and there is some anecdotal evidence that this combined with discussions with practices helped raise awareness of the project:

"Practices got information and some had a visit too, this certainly seemed to help in making them aware of the pathway. GP lead

Interpretation

The importance of the need for providing consistent messages in a range of formats across directorates/stakeholder organisations is evident if all stakeholders are to be kept informed and engaged.

C3.5 Me Leadership

Context and Mechanisms

There were clinical leaders from both primary and secondary care supported by managers from the CCG and secondary care who were responsible for designing and implementing the MDC pathway

Characteristics of Mechanisms and Outcomes

This devolved style of leadership has enabled the team to effectively implement the MDC pathway and test the systems and processes they have developed as part of it. The leader with the most appropriate skill set has taken responsibility for addressing those leadership issues most appropriate for them. However, both of the clinical leads have reflected on the amount of time the leadership function takes and implications for the pathway moving forward:

"It's taken a considerable amount of (leadership) time . . . . . the fact that we're scaling numbers up means we will need to run through the meetings 3 times a week minimum. Which means that's a much bigger ask of clinical time which means we need more people, more leadership is required to coordinate it all and until we've got the people and it's all set up we can't increase the numbers" Lead clinician 2

"Time is always an issue . . . . . If I could go back and do something differently I'd have said to my clinical director and my general manager "Right I don't need 3 hours or 4 hours, I need a whole day." They would not have given me that" Lead clinician 1

Interpretation

Consistent credible leadership is vital for a project to succeed. Where a model of joint leadership is employed it is essential for the leaders to have a clear, shared vision and implementation plan to work to. Leaders also need protected time included in their job plans to enable them to lead effectively.

C4.0 Conclusions

27 1:1 interviews were conducted throughout the evaluation period, generating a significant amount of qualitative data. The CMO configuration presented reflects the key findings resulting from our analysis.

To summarise, the outcomes specified in the CMO table (figure 1) were evidenced in the following ways:

O1. Faster route to diagnosis – there is a perception that prior to the development of the MDC pathway some of these patients were managed in primary care for an unnecessary amount of time because GPs did not have an appropriate pathway to refer them on. In addition, often these patients were sent for unnecessary tests or were bounced around the system, creating a delay in diagnosis.

Informal feedback from GPs indicates that they feel this is a faster route to diagnosis for both cancer and non-cancer patients. To date a small amount of cancers have been detected via this pathway and those that have been detected have been at an advanced stage.

O2. Understanding of staffing/capacity needs – Interviewees state they understand capacity better in relation to this pathway. Initially, fluctuating demand proved to be frustrating, particularly for the clinicians. More recently demand for the service has been high and nursing and administrative support has been increased in order to meet the additional demand. Some of the increase was built into the original business case, however funding for the expansion of the service has come from a successful bid to the Cancer Transformation Fund. There is still a need to increase clinician capacity into the MDC Faculty meeting/increase the number of faculty meetings. This has been an issue since commencement of the project and remains work in progress despite Chief Executive support.

O3. Detection of diseases other than cancer - Interviewees report that they have identified a significant amount of non-cancers requiring ongoing management. They have had issues relating to the coding of new non-malignant diagnoses, this is being addressed and they will be able to provide appropriate data in due course.

O4. Engagement from all relevant departments – Interviewees report good engagement from the majority of departments. The main remaining challenge is getting Clinical Directors to agree to free up clinicians to participate in MDC faculty meeting(s).

O5. Uptake of pathway – At the time of the final set of interviews the majority of GP practices were using the pathway, there is anecdotal evidence they find it useful. Demand has increased and as a result of good feedback from both GPs and patients, they aim to roll out their pilot across the whole of Leeds.

O6. Development of bids to use ACE methodology to redesign gastroenterology pathways – A successful bid was made to the Cancer Transformation Fund to secure funding to use the ACE methodology to redesign gastroenterology pathways and continue rolling out and testing the ACE pilot. The additional funding is intended to test out the delivery of ACE in different settings such as primary care though the detail currently requires more work.

In terms of fidelity to their proposed model, Leeds have delivered the specified pathway in the way that they envisaged except for the fact that the faculty meeting has not involved the range of specialisms that they had originally aspired to.

Anecdotally, Leeds believe they have delivered on a number of quantitative outcomes including reducing the number of appointments and reducing the numbers of imaging requests and requests for other investigations. We are unable to comment on this but it is the focus of a separate quantitative evaluation by the Policy Research Unit for Cancer Awareness, Screening and Early Diagnosis.

In terms of underlying programme theory for the Leeds pilot, they believed that by developing a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes would improve. We have both anecdotal evidence from the interviews and data from the ACE Patient Experience Survey that patient experience is good. However at the time of writing, it is difficult to evidence whether patient outcomes have improved, though the quantitative evaluation may provide further insights.

Leeds also believed that an MDC pathway would facilitate a more effective use of resources (imaging etc.), interviewees report that this has been the case and that they have data to support this.

Applying a Normalisation Process Theory (NPT) framework to our findings, we conclude that the pilot has tested systems and processes and many elements of the pathway have become normalised (see section 2.2 for detail on Normalisation Process Theory), these have been analysed using a NPT framework and the results are shown in table 1.

Table 1 Leeds Normalisation Process

	Coherence **What is the work?**	**Cognitive participation.** **Who does the work?**	**Collective action** **How does the work get done?**	**Reflexive monitoring** **How is the work understood?**
Systematic explanation of mechanisms and components at work	Leeds teaching hospitals NHS Trust, local CCGs and GP practices recognised it as building upon previous cancer pathway redesign work. Education events and regular feedback from the CCG Project Manager and Lead GPs have reinforced the mechanisms of the process	GPs refer patients with concerning vague symptoms. CNS does the assessment,and arranges initial diagnostics. Patients are discussed in the MDC faculty meeting and seen/referred on as appropriate. GPs informed of results.	Information was provided in relation to the pathway. The CNS was supported by the Consultants. The MDC Pathway Coordinator was also given training and provided with ongoing support. Detailed protocols for the pathway were also developed.	Membership of the steering group helped appraisal of systems and processes by stakeholders
Knowledge about the sources and operation of investments at work	Not all practices understand the mechanism for referring patients and how it linked with the pathway. Education aimed at the GPs seemed to address these issues.	Value of the intervention was promoted by the proponents of the service from the CCG. There was consensus that the intervention was worthwhile from a patient perspective	GP practices engaged in referring patients to the MDC. CNS responsible for initial assessment Radiology for CT scans. MDC Pathway Coordinator for booking and following up tests and tracking the patients, also for Coordination and follow up from MDC Faculty meeting. The Consultants see appropriate patients in clinic and manage them accordingly, referring on as appropriate or discharging back to the GP.	There is good understanding of the factors affecting the pathway across key stakeholders, with the steering group proactively managing issues and continuing to shape and develop the service as it rolls out and as they get an opportunity to scrutinise data.
Core questions	**How is a practice conceptualised by participants?** Viewed positively by CCG, General Practice and Leeds Teaching Hospitals NHS Trust.	**How do participants come to engage with a practice?** Practices were initially approached by the Lead GPs and CCG Project Manager. The project was actively supported by the local Trust and CCG boards. More sustained engagement due to education and training of practices and ongoing support	**How do participants enact a practice?** Follow protocol. Enlist support from Steering group when necessary.	**How do participants appraise a practice?** Appraisal and feedback encouraged via the steering group. Appraisal has resulted in small changes to the pathway and has also led to the steering group putting together a successful bid for Cancer Transformation Fund monies to support the role out of the pathway to other venues

		provided to GPs by CNS and CCG Project Manager.		and to roll out the ACE methodologies to other specialities.
Core questions	**How does it hold together in action?** Most GP Practices are referring to the MDC. The CNS conducts the initial assessment. Radiology coping with demand for the CT scans. MDC Pathway Coordinator provides administration, booking and tracking functions Consultants discuss patients in faculty in faculty meeting, seeing patients if necessary, also decides most appropriate ongoing management.	**How do they decide on engagement and the purposes that it serves?** Discussions around value to the patient, Consideration of additional workload and subsequent impact on capacity. Project driven by Leeds Teaching Hospital Trust, Leeds CCG, engages GP Leads and an engaged steering group	**How are their activities structured and constrained?** Practices are responsible for referring the patients to the MDC. The CNS is responsible for assessing the patients (supported by the clinician). Radiology are responsible for CT scans and reporting. The MDC pathway coordinator deals with administrative, booking and patient tracking issues. The Consultants discuss patients in faculty meeting and where appropriate sees patients in clinic then decides ongoing management, onward referral or discharge back to GP.	**What are its effects of appraisal?** Appraisal has resulted in small changes to the pathway and has also led to the steering group putting together a successful bid for Cancer Transformation Fund monies to support the role out of the pathway to other venues and to roll out the ACE methodologies to other specialities.

Appendix D – North Middlesex University Hospital

D.1 Introduction and Background

NHS Haringey CCG and NHS Enfield CCG are both served by the North Middlesex University Hospital.

Haringey CCG HAS 40 GP practices serving a population of 267,540. It is ranked the 29th most deprived out of 209 CCGs in England. The percentage of the population who are 65 years or over in Haringey is 9.6% which is lower than the England average of 17.1%. Around 870 patients are diagnosed with cancer per year and there are around 340 cancer deaths per year in Haringey.

There are 48 GP practices in Enfield serving a population of 328,000. It is ranked the 56th most deprived out of 209 CCGs. The percentage of the population who are 65 years or over in Enfield is 13% which is lower than the England average of 17.1%. Around 1,300 patients are diagnosed with cancer per year and there are around 560 cancer deaths per year in Enfield.

Both areas are ethnically diverse with over 10 different languages in common use.

The MDC based at North Middlesex University Hospital is designed to help provide a timely diagnosis for patients with a broad range of vague but concerning general and abdominal symptoms including new abdominal pains, weight loss and persistent nausea and GP suspicion of gastrointestinal cancer. These are referred to as non-specific cancer symptoms (NSCS).

D.1.1 Aims and Objectives

The overarching aim of the project is to improve patient survival, experience, and costs associated with cancer presenting with NSCS through the following objectives:

1. Shorten interval from presentation to diagnosis
2. Decrease use of inpatient beds during cancer diagnosis
3. Reduce the number of Accident & Emergency (A&E) or GP visits before a cancer diagnosis
4. Improve patient experience on the cancer diagnostic pathway

5. Develop a system to improve diagnostic stage and survival in abdominal cancer

D.1.2 ACE model

MDC team:

Project Manager – University College London Hospital (UCLH) Cancer Collaborative, Clinical Lead/ Gastroenterologist, Lead Clinician/Gastroenterologist, GP Lead, Service Manager., Clinical Nurse Specialist (CNS)

Communication:

Monthly steering group - UCLH Cancer Collaborative

Lead consultant and CNS meet regularly review patient database (provided by ACE Programme) and address problems.

Referral criteria:

The MDC is appropriate for patients that have symptoms with a high risk of cancer AND either

a. Have non-specific but concerning symptoms, with no clear site-specific 2WW pathway, OR
b. Are too unwell for a site-specific 2WW pathway but do not need admission.

Non-specific but concerning symptoms should have the following characteristics:

1. The symptoms are unexplained and unexpected
2. Significant clinical concern that the patient might have cancer
3. Symptom duration between 3/52 and 6/12 unless very serious or urgent
4. Patient >40 or IF<40 the reason for the referral must be clearly specified
5. Patient will benefit from a rapid diagnosis and is able to attend within 5 working days

Specific indications for MDC Referral:

New unexplained abdominal pain

- A new persistent symptom OR
- Significant abdominal pain presenting at least twice in previous month
- Pre-existing condition in same area but with different symptoms. Specify___

Unexplained weight loss

- Weight loss causing serious concern – specify weight and amount___

New and persistent unexplained nausea / loss of appetite

- Must describe the reason for suspicion ___

GP Gut feeling / Persistent patient or family concern

- Must describe the reason for suspicion

Painless jaundice

- Bilirubin > 50 mmol/l
- No likely benign cause

Referrals from primary care are made using the MDC EMIS referral form which is emailed to the MDC email account. All referrals include formal assessment of patient self-reported symptoms, which provides immediate additional clinical information and may contribute in future to the development of decision support tools. Referrals from A&E will also be directed to the CNS. Where the patient is not a match for the pathway, clinicians decide on the most appropriate alternative pathway.

Diagnostic pathway:

The intention was that all MDC electronic referrals should be triaged by the CNS, and discussed with the consultant as needed, preferably after a telephone assessment by the CNS has been carried out. Out-patient administrative staff then contact the patient to arrange the first appointment; ideally this is within 1-2 working days.

Clinical decisions are made by CNS/senior specialist consultant at the point of assessing the referral and when reviewing the patient in person. This is supported by information provided in the electronic GP referral. The MDC aims to inform patients of a cancer diagnosis, or that cancer has been excluded, within 28 working days of the referral. Patients without a cancer diagnosis have a management plan in place prior to discharge.

Once the appropriate investigation pathway has been identified, the CNS tracks patients throughout their diagnostic journey, and takes appropriate action, escalating if necessary any delays with the relevant clinician, directorate management teams and cancer services management to prevent delays in patient care.

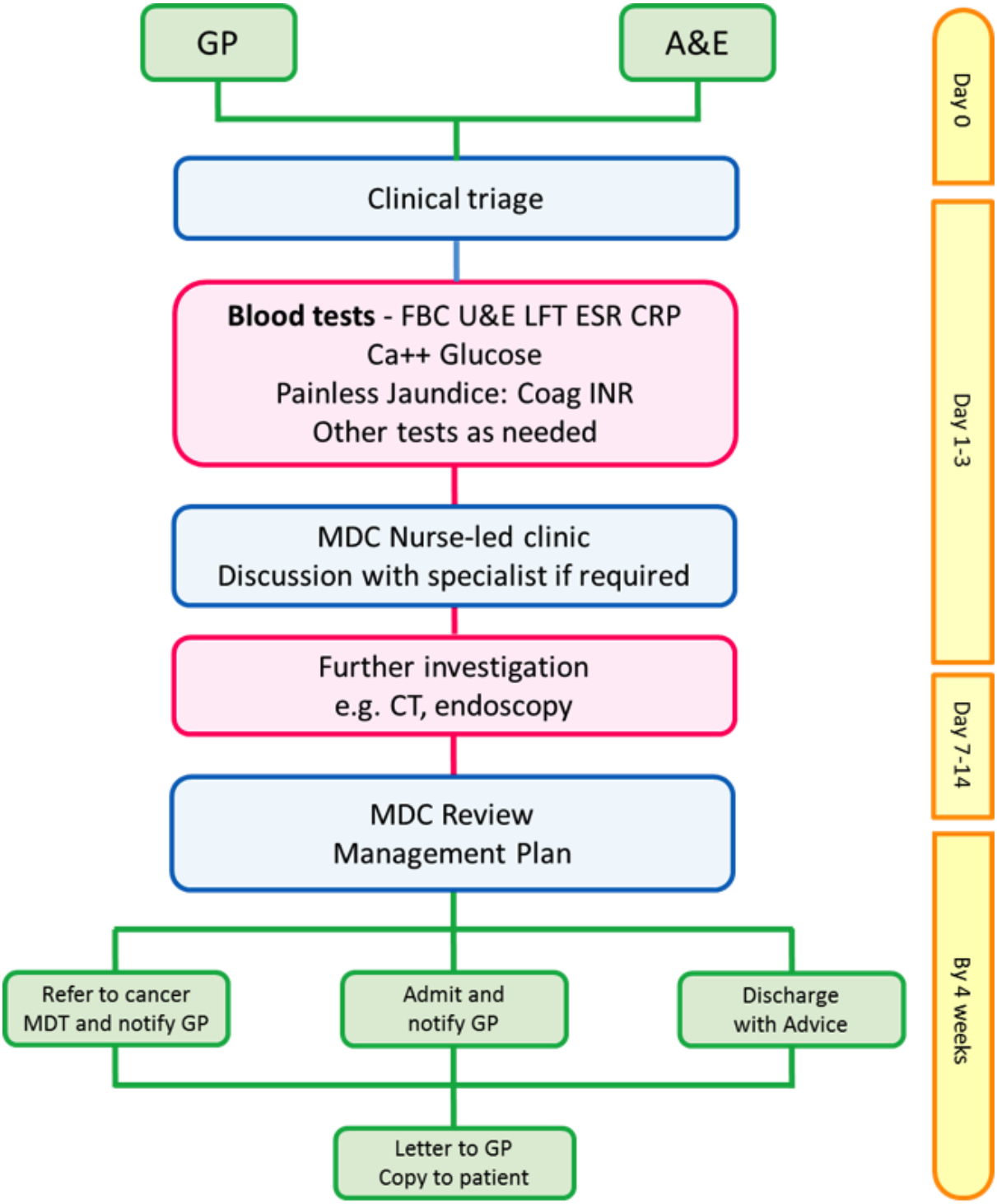


Figure 1 North Middlesex Pathway

Patient management plan:

The MDC will provide a definitive diagnosis for patients wherever possible. The management plan following the specialist assessment is as follows:

- Refer to Cancer MDT
- Admit to hospital
- Discharge to Primary Care with advice

The CNS ensures clear and timely communication from the MDC to GP as follows:

- Email to primary care, confirming that patient has attended the appointment, and the next steps (e.g. endoscopy appointment)
- Clinic letter after the patient has been reviewed with results.

Patient experience:

Patient experience feedback was collected from patients on the pathways using the ACE patient experience survey.

D.2 Evaluation Methodology

The qualitative evaluation of the ACE programme draws on the principles of realist evaluation (Pawson and Tilley, 1997) to develop a contextualised account of the way in which change emerges. See section 2.1 for details of realist methodology.

The underlying programme theory for the site was:

2) If you develop a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes will improve
3) Improve patient experience by providing CNS support to patient

For the purposes of this case study, a total of 16 1:1 interviews with key informants were carried out.

Analysis of the interviews resulted in the development of a Context, Mechanisms and Outcomes (CMO) model (figure 2)

The CMO model considers the contexts, mechanisms and outcomes that were apparent in the implementation of the initiative. Each of the key mechanisms is considered in turn within the case study.

Normalisation Process Theory (NPT) provides the theoretical basis for understanding how the initiative is understood, implemented and embedded into normal practice. NPT considers four areas; coherence, cognitive participation, collective action, and reflexive monitoring (see section 2.2 for details). Each of these areas are considered in turn in table 1.

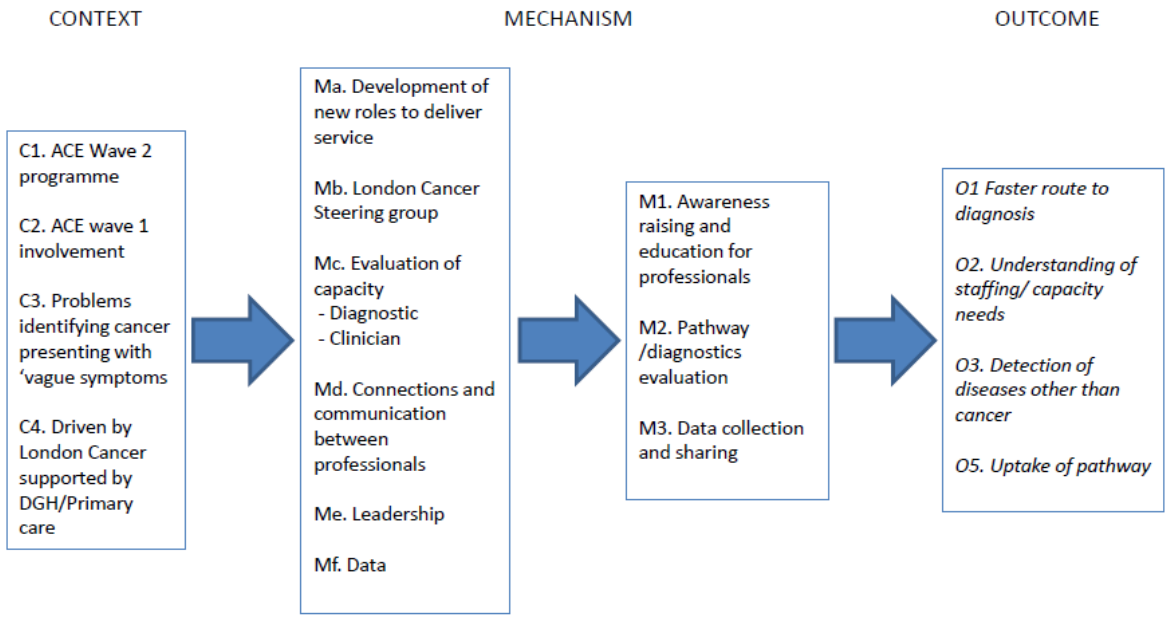


Figure 2 CMO model for North Middlesex

D3 Context, Mechanisms and Outcomes

D.3.1 Ma Development of new roles to deliver the service

Contexts and mechanisms

London cancer had previously identified problems in diagnosing cancer presenting with vague symptoms and piloted 2 MDCs for vague abdominal symptoms in the ACE Wave 1 programme; at UCLH and Queens Hospital, Romford. The model developed at UCLH was effective from a system and process perspective and at the time of the final wave 1 evaluation interviews was on the way to becoming normalised. As a result the UCLH Cancer Collaborative decided to roll the model out as part of the ACE Wave 2 programme to other sites including North Middlesex University Hospital.

This work was supported by a project manager from UCLH Cancer Collaborative and led locally by 2 gastroenterologists, one of whom was also the lead at the UCLH Cancer Collaborative.

A clinical nurse specialist (CNS) role was also developed to support the delivery of the service.

Characteristics of mechanisms and outcomes

A CNS role is key to the successful implementation of this pathway, being responsible for triaging referrals and liaising with the consultant as necessary. The clinical decisions are made by the CNS and consultant at the point of assessing the referral. Prior to the appointment of the CNS it was anticipated that the triage would be carried out by the CNS who would seek additional clinical advice as an exception, however this has not really happened and one of the clinicians reported working with the nurse to triage patients. At the final interview, the second clinician reported that due to additional training the role of the CNS was now developing in the way they had originally anticipated:

"We now have a formalised process by which the CNS does the telephone interview . . . . . she has been on a course at the Royal Marsden to gain her clinical assessment skills, she's just coming to the end of that course, and as part of that, she has learnt how to do the history taking as part of the post. So, she's now doing that successfully and recording it, and the letters are getting into the notes, and then we're seeing the patients" Lead clinician 1

The CNS is also responsible for being a point of contact for patients, ordering investigations, chasing results, booking patients into MDC slots, tracking patients through their diagnostic journey and communicating the outcome to the GP.

Interpretation

Learning needs assessment at the time of appointment is important given the novel nature of roles in the MDC. It may have resulted in an earlier referral for the additional training that the CNS required to deliver the key responsibilities of the role.

D.3.2 Mb UCLH Partners Steering Group

Context and mechanisms

Because the roll out of the MDC was a UCLH Cancer Collaborative initiative, the steering group was a London wide group with representation from each site.

Characteristics of mechanisms and outcomes

The steering group is held regularly in London and whilst there is representation from each site, North Middlesex was only represented on a regular basis by the lead clinician who also worked with the UCLH Cancer Collaborative. The venue meant that the service manager, the other lead clinician, GP representative and sometimes the CNS could not attend due to busy workloads and the time it took to travel to and from the meeting:

I always found it difficult to get to off-site meetings for the MDC" Service manager

"*The steering group was off-site, it was managed by DD and then she left . . . . I wasn't necessarily involved"* Lead clinician 2

It is evident from some of the interviews that this arrangement has not always been effective, and interviewees do not always see the relevance of the meetings:

"Due to all of my other commitments I haven't been able to attend the steering groups, to travel takes too much time out of my day and in any case when we've had issues we've had to try to come up with local solutions" Service manager

"So we weren't directly linked and that's what I think needs to be. If it's within the trust it should be trust led, with those people coming in and providing support . . . . This was pushed more as a cancer network project that just happens here" Lead clinician 2

Interpretation

The lack of attendance at the steering group reflects a lack of ownership in terms of the overarching UCLH Cancer Collaborative initiative. This could have been mitigated against by rotating the venues of the steering group meetings or the replacement project manager feeding back to a local operational/sub group.

D.3.3 Mc Evaluation of capacity

Context and mechanisms

Prior to commencing the pilot North Middlesex University Hospital had a number of capacity issues, particularly in relation to the number of gastroenterologists and diagnostic capacity.

The pilot was not given additional administrative support by the Trust.

Characteristics of mechanisms and outcomes

North Middlesex University Hospital has had a significant turnover of consultant staff and have experienced difficulties in recruitment, this is a problem common to some other UK gastroenterology departments:

"I think we've had significant turnover of consultant staff, we continue to carry consultant vacancies. This is very much additional work for the two clinicians, I think they're finding that quite difficult" Service manager

In order to pilot systems and processes relating to the MDC pathway, the clinicians agreed to see patients on an ad hoc basis. Initially they were added to existing gastrointestinal clinics held in endoscopy:

"So (initially) we agreed that we were going to see patients on an ad hoc basis to start with, with a clear knowledge that once the number of referrals built up, we would then create a specific clinic for those patients . . . . . And that's exactly what we need to do. So we're still in the process of discussing how to do that. The process has not been enabled by the fact that we're essentially 3 consultants down in our provision" Lead clinician 1

"We continue not to have ring-fenced clinic slots for these patients. They're always seen as add ons, and that's not ideal" Service manager

Interviewees reported that endoscopy waiting lists had also been a long standing issue, however the consensus was this was not an issue for the MDC pathway patients.

The lack of administrative support has also had an impact, as the CNS has had to pick up those responsibilities at a time when she had to deliver a service and also had to address development needs in order to fulfil her role effectively.

Interpretation

Due to the pressures on consultant capacity it is unlikely that this pilot would have got underway without the goodwill and commitment of the 3 clinicians involved. Shortly after the MDC was implemented and whilst referrals were building, one of the three MDC consultants left the Trust, putting additional pressure on the service. Due to the continued capacity issue and no additional consultant recruitment looking likely in the short term, sustainability of this service is likely to become an issue.

D.3.4 Md Connections and communication between professionals

Context and mechanisms

There was consensus across a range of stakeholders at the UCLH Cancer Collaborative and locally within both primary and secondary care that there were problems in identifying cancers presenting with vague symptoms. It was considered appropriate to implement a pathway previously piloted at UCLH that would provide a quick diagnosis for those presenting with vague symptoms, and which they hoped would improve patient experience and outcomes.

Characteristics of mechanisms and outcomes

There appears to have been a robust communication plan at UCLH Cancer Collaborative level but a clear communication plan was less apparent at a local level, although a significant amount of effort was reported in trying to educate and engage the GPs:

"We've had several teaching sessions, training sessions with the GPs at their Protected Learning Time events. We've put out a lot of data to the CCGs about the service"

Lead clinician 1

The local GP Lead is committed to and engaged with the pilot and promotes it regularly to GP colleagues, however at the time of the final interviews she had not been given an update on GP referrals into the service:

"My feeling is that it (the pathway) was being used very well within the hospital but maybe not as well from a primary care point of view. . . . . I think it's a slow burner and as the GPs get used to it they'll value it. I think at the moment the uptake isn't that good . . . . . so for instance, it's something I have as a rolling item on the cancer board, and regularly promote to GPs . . . . My feeling is, it's probably not being utilised as well as it could be in primary care" GP lead

To support communication about the MDC to primary care, the GP Lead has plans for the local CRUK facilitator to promote the pilot:

"She will be doing practice visits and the MDC is highlighted as something for her to be promoting, so we could target that a little bit more accurately if we knew the practices who weren't using it" GP lead

Despite the communication to date and plans for future reinforcement of messages, there was a view that GPs need more information regarding referral criteria and how to use the pathway:

" I've just vetted a handful (of referrals) this morning and we've got patients who are aged 90 plus, are old, frail, elderly with various symptoms, or clinical concerns being ticked. Now that's absolutely fine. Having never met the patient it would be cruel and maybe inappropriate to send them through some invasive tests without having met them. I think you just get the feeling that this is now seen as a quick way to get the patient into the system. I mean I've had some corkers of inappropriate referrals, patients with clear gynae symptoms sent to MDC. I say "we can do gastro, hepatology but gynae is not our forte" and actually probably causes delays . . . . . We had one 2 weeks ago and the referral merely said "I've organised a MRI test, and needs neurosurgical intervention. Please see and refer to neurosurgery" Now that's completely inappropriate" Lead clinician 2

Although perceptions seem to differ about how much and how appropriately GPs are using the pathway, there is no doubt that the pathway is being used and that many of the referrals are appropriate:

"A lot of GPs are referring patients in. It's dipped just slightly but it's probably about 5 to 6, up to 10 per week. I think we probably just need to do a reappraisal of the GPs or recommunication with the GPs to let them know about the service, but there's no doubt that they find it helpful and it's one of the ways to get patients in" Lead clinician 1

Interpretation

A clear local communication plan was not evident at the time of the final interviews. Whilst everyone interviewed appeared to be supportive of the pilot, it is notable that they all have slightly differing perceptions of progress and challenges and for some team members there is a definite disconnect with the work that is going on through the UCLH Cancer Collaborative. A locally owned steering/operational group with membership from the collaborative might have helped the team members to come to a shared understanding of the issues and to develop strategies to address them that drew on the wider experience of the Cancer Collaborative.

D.3.5 Me Leadership

Context and mechanisms

One of the Lead Clinicians at North Middlesex was also a clinical lead at the UCLH Cancer Collaborative, which influenced the Trust's decision to pilot an MDC pathway. Initially, there was positive feedback from clinicians and managers at North Middlesex and they were supported by the project manager from the UCLH Cancer Collaborative.

The project manager left to take up another post during the very early stages of the pilot and was replaced by a new post holder.

Characteristics of mechanisms and outcomes

Both clinicians provided leadership for the pilot at a local level, though it is apparent that they have each identified different challenges and have different perspectives on the progress and success of the project.

The replacement Project Manager also had a different style to the initial post holder and there was a resulting lack of clarity relating to the Project Manager role:

"When DD was here she was actively involved and supportive of what we were doing, some of her help was quite practical when we needed it. I'm less involved with the project manager now, partly because I have a new role and partly because the project manager is more hands off and I'm not sure what she is responsible for" Service manager

Interpretation

There was uncertainty around the project manager's role and responsibilities that could have been more effectively addressed.

D.3.6. Mf Data

Context and Mechanism

A significant amount of data collection was planned as part of this project. In order to collect this, a REDCAP database was installed.

Characteristics of mechanisms and outcomes

The CNS was responsible for maintaining the database on behalf of the pilot. Initially she did not have the IT skills to do this and as a result required a significant amount of training and

support to be able to use the system. This was an additional pressure at a time when the she was also trying to get the pathway established and see patients.

UCLH Cancer Collaborative did provide some support to help the CNS learn how to use the database.

Interpretation

A learning needs assessment prior to appointment may have identified the initial IT skills deficit and might have facilitated an earlier referral for the additional training. However, these are not core skills for a CNS and it might have been a viable alternative to recruit and administrative assistant with IT skills. who was able to fulfil this function.

D.4 Conclusions

16 1:1 interviews were conducted throughout the evaluation period, generating a significant amount of qualitative data. The CMO configuration presented reflects the key findings resulting from our analysis.

To summarise, the outcomes specified in the CMO table (figure 2) were evidenced in the following ways:

O1.Faster route to diagnosis – there is a perception that prior to the development of the MDC pathway some patients were managed in primary care for an unnecessary amount of time because GPs did not have an appropriate pathway to refer them on or alternatively they were bounced around the system, creating unnecessary delays in diagnosis. Informal feedback from the GP Lead indicates that this has been a faster route to diagnosis for cancer patients who do not fit a traditional 2 week wait pathway and for non-cancer patients.
O2.Understanding of staffing/capacity needs – Interviewees state they understand capacity better in relation to the MDC pathway. There are mixed views as to whether the model is sustainable and also whether it needs a designated clinic rather than continue providing the current slots within existing clinics and an endoscopy setting.
O3.Detection of diseases other than cancer- Interviewees report that they have identified a significant amount of non-cancers requiring ongoing management.
O4.Uptake of the pathway – the pathway is being utilised, although it is unclear whether it is being utilised by all GP practices and some referrals may not be appropriate.

In terms of North Middlesex's underlying programme theory, they believed that by developing a pathway enabling a quick diagnosis for patients with vague symptoms, patient experience and outcomes would improve. We have some anecdotal evidence from the interviews which indicates that patient experience is good.

North Middlesex also believed that the role of the clinical nurse specialist would enhance the patient experience by supporting people prior to diagnosis. The team at North Middlesex believe that patients feel better supported at a particularly stressful time whilst they are waiting for a diagnosis although no evidence was presented to support this.

Applying a Normalisation Process Theory (NPT) framework to our findings, we conclude that while the pilot has tested systems and process, we cannot conclude that the pathway has become normalised (see section 2.2 for detail on Normalisation Process Theory) (table 1).

Table 1 North Middlesex normalisation process

	Coherence **What is the work?**	**Cognitive participation.** **Who does the work?**	**Collective action** **How does the work get done?**	Reflexive monitoring How is the work understood?
Systematic explanation of mechanisms and components at work	North Middlesex University Hospital, UCLH Cancer Collaborative, local CCGs, and GP practices recognised it as building upon previous cancer pathway redesign work. Education events and regular feedback from the Lead GP and the, have reinforced the mechanisms of the process	GPs refer patients with concerning abdominal symptoms. CNS/Clinician does the assessment, and arranges initial diagnostics. Scans and endoscopies done within secondary care. Patients are seen in a GI clinic. GPs informed of results. Where findings require it, the patient is moved to appropriate pathway	Information was provided in relation to the pathway. The CNS was given training and an in-depth induction and ongoing support for provided by the Consultants. Detailed protocols for the pathway were also developed	The steering group meets at Cancer Collaborative level but there is no local arrangement. The work and challenges at a local level are perceived differently by different individuals.
Knowledge about the sources and operation of investments at work	Not all practices understood the mechanism of referring patients and how it linked with the pathway.	Value of the intervention was promoted by North Middlesex University Hospital, UCLH Cancer Collaborative, and local CCGs. There was consensus that the intervention was worthwhile from a patient perspective.	GP practices engaged in referring patients to the MDC. CNS/Clinician responsible for initial assessment and ordering investigations. Radiology for CT scans. CNS for booking and following up tests and tracking the patients, also for booking patients into clinic. The consultants see the patients in clinic and manage	There is mixed understanding of factors affecting the pathway across the small number of key stakeholders. Some issues lack consensus.

			them accordingly, refer on as appropriate or discharge back to the GP.	
Core questions	**How is a practice conceptualised by participants?** Viewed positively by UCLH Cancer Collaborative and General Practices who use the pathway. Mixed perceptions regarding the progress of the pilot and potential benefits amongst secondary care stakeholders.	**How do participants come to engage with a practice?** Practices were initially approached by the Lead GP and UCLH Cancer Collaborative Project Manager The project was actively supported by the UCLH Cancer Collaborative. More sustained engagement through education and training of practices and ongoing support is required	**How do participants enact a practice?** Follow protocol. Enlist support from Project Manager when necessary.	**How do participants appraise a practice?** Appraisal and feedback encouraged via the weekly steering group and contact with the Project Manager. Done informally at a local level
Core questions	**How does it hold together in action?** Some GP Practices referring to the MDC. The Clinician/CNS conducting the initial assessment and arranging investigations. Radiology coping with demand for the CT scans. CNS provides administration and tracking function. Consultant sees patients in existing GI clinic and decides most appropriate ongoing management. There is not a consensus relating to whether this is sustainable or not.	**How do they decide on engagement and the purposes that it serves?** Discussions around value to the patient, Consideration of additional workload and subsequent impact on capacity. Project driven by UCLH Cancer Collaborative supported by a motivated engaged Lead Clinician.	**How are their activities structured and constrained?** Practices are responsible for referring the patients to the MDC. The CNS is responsible for assessing the patients (supported by the clinician) and referring them for investigations. Radiology are responsible for CT scans and reporting. The CNS deals with administrative and patient tracking issues. Consultants see patients in clinic and decide ongoing management, onward referral or discharge back to GP.	**What are its effects of appraisal?** Appraisal has resulted in small changes to the pathway. Formal appraisal is not happening at a local level.

Appendix E – The Northern Care Alliance (Royal Oldham Hospital)

E.1 Introduction and Background

Greater Manchester has some of the worst cancer outcomes in England, with high cancer incidence and high cancer related mortality rates which are associated with low uptake of screening programmes and late stage diagnosis. However, despite having some of the highest rates of premature deaths due to cancer, Greater Manchester has made significant improvements in recent years, bringing one year survival rates and patient experience in some areas in line or ahead of all other areas in England.

Across Greater Manchester (GM) there was consensus that although significant progress had been made, in order to further improve clinical outcomes, focused action was required to support primary care colleagues in identifying and referring patients at an earlier stage. The objective of the GM ACE Wave 2 project was to develop appropriate referral pathways for patients in whom the GP has a clinical suspicion of cancer, but who do not necessarily meet the criteria for existing pathways. Two sites were selected in GM to pilot the referral pathway; Oldham and Wythenshawe, this case study focuses on the Oldham experience.

E.1.1 Aims and objectives of the GM pilot project

The GM pilot aims to increase the number of patients diagnosed earlier with cancer at stage 1 and stage 2. The patient will attend a Multidisciplinary Diagnostic Clinic (MDC) that provides a structured pathway for patients in whom the GP has a clinical suspicion of cancer, but who do not necessarily meet the criteria for existing pathways in a bid to:

- Confirm diagnosis and refer to tumour specific MDT to have agreed treatment plan or discharge patient within28 days from receipt of GP referral
- Improve patient experience
- Improve outcomes and survival rates- achieve world class outcomes, through diagnosis at an earlier stage
- Improve the patient pathway from presentation to diagnosis and on to treatment
- Simplify referral process for GPs and the patient
- Reduce/avoid unnecessary hospital admissions
- Promote health awareness from both a public and professional point of view

E.1.2 The MDC model as identified in GM

MDC Team:

Lead Clinician/Gastroenterologist, Project Manager, Clinical Nurse Specialist, Booking and Scheduling Manager, CCG Cancer Lead/GP Lead, and Navigator.

Team engagement:

The Greater Manchester (GM) steering group meets quarterly and the Oldham ACE 2 operational group meets monthly

Communication:

There are internal and external (aimed at identified secondary care professionals and GPs) communication plans in place

Patients are given an MDC information leaflet at the GP consultation from which they are referred.

Referral criteria:

Decreased appetite

Nausea

Non-specific abdominal pain

Lymphadenopathy

Persistent Pain

Unexplained DVT

Non-specific iron deficiency anaemia

Fatigue

Weight loss

Hepatomegaly

Splenomegaly

Bloating

Continued patient or family concern

Non-specific abdominal pain

Lymphadenopathy

Persistent Pain

Unexplained DVT

Non-specific iron deficiency anaemia

GP concern

Exclusion criteria:

Some symptoms (listed below) indicate a specific cancer. These should be investigated or referred in accordance with the NICE NG12 guideline and not considered for the ACE pathway:

Post-menopausal bleeding

Abnormal vaginal bleeding

Rectal bleeding

Altered bower habits

Malena

Dysphagia

Hematemesis

Haematuria

Shortness of breath

Cough

Haemoptysis

Diagnostic pathway:

The MDC is based at the Royal Oldham Hospital with convenient access to diagnostic facilities. The MDC is designed for ambulatory patients with non-specific but concerning symptoms of suspected cancer, needing an urgent diagnosis. Clinical decisions are made by senior medical staff. The MDC provides advice and guidance to primary care on the assessment outcome. The MDC works to the following core principles:

- Access – open to primary care following mandatory GP assessment
- Managed referral process – defined referral process and criteria for patients presenting with non-specific but potentially serious symptoms
- Senior decision making – the MDC will be overseen by a consultant senior level clinician who takes clinical responsibility for the patient episode
- Administrative and pathway support – improve clinical effectiveness by the provision of the CNS and Navigator to support and assist clinicians as well as helping to manage data collection, communication and performance monitoring.
- Close links to key departments and individuals – Consultants and Clinical Nurse Specialists, MDT coordinators, A&E, Radiology, Endoscopy, Pathology, Acute Oncology Service.

GPs are required to complete a mandatory assessment. The assessment includes:

- Clinical examination,
- Urgent blood tests including FBC, U&E, LFT, Bone profile, TFT, LDH, PV/CRP, Ferritin, Glucose, HbA1c, Mononucleosis test, Coeliac screen, HIV test. Also PSA and beta-HCG (MEN), CA125 (women). The list of blood tests is under regular review and will be amended on agreement at the monthly operational meeting.
- Urgent chest x-ray
- Urinalysis

The GP reviews the results and decides whether or not the referral remains appropriate. The referral form requires a short narrative, explaining why cancer is suspected. To support the referral process further, the referral form lists a range of “specific” symptoms that will prompt the GP to consider an alternative referral pathway.

Patients will be seen within a maximum of 14 days of referral. It is a one-stop clinic model, where the patient will have a clinical assessment and a range of tests including a CT scan and or endoscopy, with the majority of patients receiving their results on the same day.

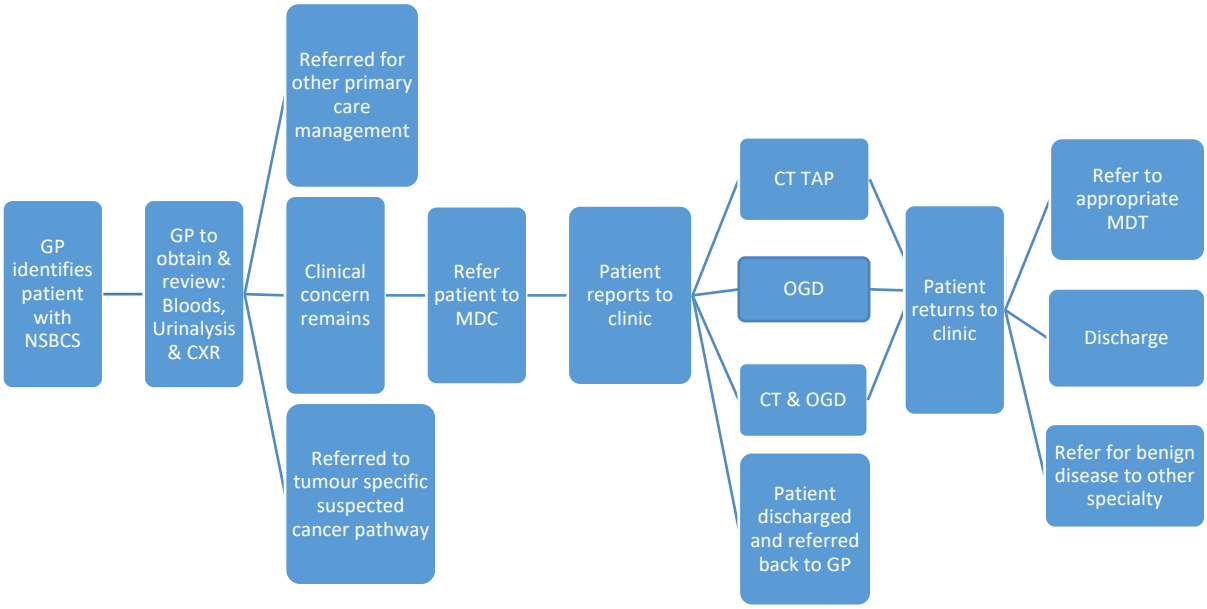


Figure1 Greater Manchester MDC pathway

Patient management plan:

The MDC will provide a diagnosis wherever possible and/or a definitive management plan, onward referrals will be made as appropriate:

- Referral to a tumour specific MDT
- Referral for additional investigations
- Review in a non-cancer clinic
- Referral to acute oncology/specialist palliative care
- Discharge to primary care with advice
- Offer of opportunistic lifestyle advice where cancer was excluded.

Patient experience:

Patient experience feedback will be collected using the ACE patient experience survey.

E.2 Evaluation methodology

The qualitative evaluation of the ACE programme draws on the principles of realist evaluation (Pawson and Tilley, 1997) to develop a contextualised account of the way in which change emerges. See section 2.1 for details of realist methodology.

The underlying programme theory for the GM and the Oldham site was:

A) If you develop a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes will improve
B) MDC clinics are an opportunity for health promotion and signposting to lifestyle support services

For the purposes of this case study, a total of 13 1:1 interviews with key informants were carried out.
Analysis of the interviews resulted in the development of a Context, Mechanisms and Outcomes (CMO) model (figure 2)

The CMO model considers the contexts, mechanisms and outcomes that were apparent in the implementation of the initiative. Each of the key mechanisms is considered in turn within the case study.

Normalisation Process Theory (NPT) provides the theoretical basis for understanding how the initiative is understood, implemented and embedded into normal practice. NPT considers four areas; coherence, cognitive participation, collective action, and reflexive monitoring. See section 2.2 for details. Each of these areas are considered in turn in table 1.

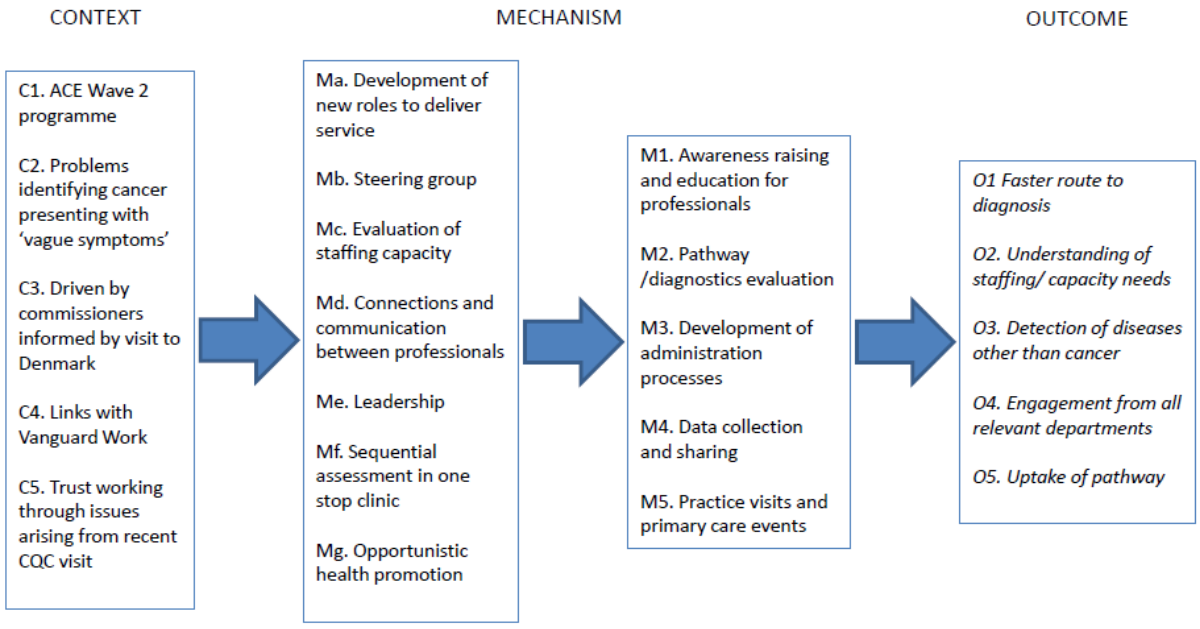


Figure 2 CMO model for Oldham

E.3 Contexts, Mechanisms and Outcomes

E.3.1 Ma Development of new roles to deliver the service

Context and Mechanisms

The MDC at the Royal Oldham Hospital sits within the Greater Manchester (GM) conurbation. The GM Cancer Board oversees cancer services across this area. GM identified that patients who experienced vague but concerning symptoms often presented late to secondary care and often did not have a smooth pathway leading to diagnosis. In 2015 the GP cancer lead and commissioning representatives from Oldham CCG went to Denmark to look at the work being done there to implement MDCs for vague symptoms. Following that visit the GM Cancer Board successfully submitted an expression of interest to the ACE Wave 2 initiative. The successful application led to the development of 2 pilot MDCs in Oldham and South Manchester.

The development of the MDC pathway was actively led by a project manager from the GM Cancer Commissioning Programme and at a local level by commissioning managers and the lead cancer nurse.

New posts were also developed to support the development and implementation of the MDC, including a navigator role, clinical nurse specialist and gastroenterologist roles were modified to provide clinical expertise to the MDC.

Characteristics of mechanisms and outcomes

The navigator role was specifically developed to support the pathway. It is an administrative role responsible for receiving referrals, liaising with the CNS to arrange clinic appointments, ensuring investigations are ordered and reports are available in clinic. The navigator also acts as a contact for patients from the point of referral, she also the meets patients when they arrive for their appointment and takes them to the departments where they are scheduled to have tests such as CT or endoscopy, to ensure that everything gets done in the timescales allotted. The role also involves data collection and tracking the patient.

Anecdotal evidence from the interviews suggest patients appear to value the support provided by the navigator:

"I would say it provides a better patient experience. A lot of them say it's such a nice atmosphere when they come. They're really anxious, but because there are only two of us that they meet at first, and then I'm taking them along that journey. I think they feel like they can ask questions, and they know what's happening. That's what a lot of people say. Because we'll tell them exactly what's going to happen one the day and what time we are going to do it and it makes them feel a bit more secure" Navigator

The clinical nurse specialist (CNS) role is key to the success of this model and was developed with the CNS being the first point of contact for patients presenting to secondary care. The CNS carries out a detailed assessment and then the patient has a CT scan, which is "hot reported". The report is reviewed and if necessary they have a gastroscopy prior to be being seen in clinic later on the same day. The CNS supports the patient through the assessment process. Other CNS related developments include the CNS being able to review CT reports to decide whether the patient needs a gastroscopy:

"Initially the CT report would then be reviewed by the gastroenterologist. They would decide if an OGD was required. If it was required they would stay nil by mouth, go to the gastroscopy and then go to clinic afterwards. If they weren't having the gastroscopy they could have the venflon out, they could eat and drink, and then they would see the consultant in the afternoon. What we found was I was spending a lot of time once we got the CT report chasing around trying to get the gastroenterologist available, because he was doing other things, to review the CT scan . . . . . So we discussed it in the operational group meeting and we've now written a protocol so that I can assess the CT report and decide if the patient needs an OGD or not. That speeds things up considerably on the day, because a lot of time we're not getting the CTs back within an hour" CNS

Currently there are 4 MDC slots available per week provided over 2 days, with gastroenterologists providing the service. Although the patients sometimes require more generic diagnostic skills this has not created problems.

Interpretation

Staff interviewed all seemed appreciative of the new roles. It was evident from the interviews that there was a shared understanding of the purpose of the MDC pathway and it was viewed as bringing additional value to patients. It was however thought to be a

resource rich service which would need to change if it were to be sustainable in the long term.

In terms of normalisation process theory, we are unable to conclude that the new roles have become completely normalised as we did not interview the clinicians when we conducted the final set of interviews. The CNS and navigator roles however are well established and functioning well.

E.3.2 Mb Steering Group

Context and Mechanisms

In order to deliver the project within the ACE timeframe a GM wide steering group was formed, comprising of managers, commissioners, clinicians, people affected by cancer and support staff from the 2 Greater Manchester (GM) pilot sites; Oldham (Oldham Royal Hospital) and Manchester South (Wythenshawe Hospital). This steering group developed the business case for ACE and brought together the key stakeholders required to plan and implement the plot MDC pathway. An operational group also meets at Oldham on a monthly basis.

Characteristics of mechanisms and outcomes

The steering group continues to meet on a quarterly basis. Initially it met to develop the business case, define the MDC pathway and agree evaluation metrics. As the pathway was implemented the focus became more operational and became a forum for reviewing and monitoring progress.

The steering group was viewed as being effective by those interviewed:

"*The steering group works well and it's a useful forum for sharing ideas across sites and provides away to discuss specific problems and potential ways of addressing them"*

Navigator

Membership of the GM steering group is largely unchanged with key individuals remaining involved. The operational group membership is also unchanged except for the lead clinician at Oldham, who due to clinical commitments does not get to the meetings, however, he works closely with the CNS who has taken on day to day leadership responsibility of the pilot at a local level

More recently the operational group has been considering how to roll out the model to neighbouring hospitals within GM and at the feasibility of expanding capacity at existing sites.

Interpretation

One of the reasons the steering group has been effective in that it was formed to develop the business case. This ensured a shared vision for the pilot and an opportunity for key stakeholders to shape the pilot, ensuring shared ownership as the pilot progressed.

E.3.3 Mc Evaluation of staffing capacity

Context and Mechanisms

The navigator and CNS both work full time, in addition to delivering the MDC pathway, they also provide support to the acute oncology service. The gastroenterologists who provide the clinician input into the MDC currently provide 4 slots each per week, due to be increased to 6 slots over 2 days.

Characteristics of mechanisms and outcomes

At the time of the final interviews in spring 2018 139 patients had been seen in clinic, on occasions clinic capacity was being exceeded but they managed each patient individually:

"*We're exceeding capacity on some occasions for clinics. We're only doing an OGD on approximately a third of the patients, so two thirds of those aren't requiring gastroscopy. We have diagnosed 17 cancers 7 of which are now deceased. The clinic still runs on 2 days. We are looking at expanding the clinic to make it 6 slots instead of 4. There is also talk about expanding it out to Heywood, Middleton and Rochdale as well as just Oldham"* CNS

CT capacity and endoscopy capacity has not been a major issue and is not thought to be a problem should the service expand, there may however be a problem with "hot reporting" of CTs i.e. reporting them within the hour of being done.

Both the CNS and navigator report having spare capacity should the service expand.

Interpretation

The clinicians have taken on this role in addition to existing responsibilities. If the service is to be further expanded there is a need to ensure job plans are reviewed and clear job descriptions exist outlining the nature of the role.

E. 3.4 Md Connections and communications between professionals

Context and Mechanisms

There was agreement across a range of key stakeholders including commissioners, primary and secondary care that there were problems identifying cancer presenting with vague symptoms and that it would be appropriate to design a structured diagnostic pathway that would improve patient experience and outcomes.

Characteristics of mechanisms and outcomes

Both internal and external communication plans were developed. A significant amount of communication occurred within the steering and operational groups with members of the group cascading information to colleagues in their respective teams/departments. Interviewees reported good communication and that whilst the MDC consultants were too busy to attend the operational group they were always supportive and accessible:

"*When something needs discussing AA (the CNS) contacts Dr D to talk about it or we email him to tell him we need his input. It works quite well really"* Navigator

The pathway and referral criteria were also sent out to GPs and there is some anecdotal evidence that this combined with discussions with GPs have helped raise awareness of the pilot:

"The pilot is going well, GPs are aware of it, the majority are referring in and seem happy with it" GP lead

Some work is also happening with the GPs to try to understand more about the patients who have been referred via this route:

"We are in the process of writing to the GPs who have referred in to find out if they have any case studies, just very briefly to summarise where they feel maybe that the availability of the clinic has really helped in the sense that they didn't have to send a patient to A&E or they didn't have to admit the patient for inpatient investigations" GP lead

There have been GP education events and the pathway and referral criteria were also sent out to GPs and there is some anecdotal evidence that this, together with discussions with GPs has helped raise awareness of the pilot.

Interpretation

The provision of consistent messages in a range of formats across directorates/stakeholder organisations is key to the success of such pilots.

E. 3.5 Me Leadership

Context and Mechanisms

Project Leadership was provided by the GM cancer programme manager supported by the GM steering group. At a local level clinical leadership was provided by a consultant gastroenterologist, day to day leadership of the MDC pilot was provided by the CNS.

Characteristics of mechanisms and outcomes

The model of leadership employed in GM/Oldham pilot site appears to work well. Tasks are achieved and progress monitored via the operational group. Service developments and innovations are also encouraged and supported via the GM steering group:

"So the doctor (in Oldham) wasn't maybe quite as able to drive the project due to capacity as the one in South Manchester for example, but he recognised that the lead nurse had the skills and she compensated very competently for this really . . . . . she had the skillset to be able to run this independently. That's quite encouraging to see that this is something that could be CNS driven and organised" GP lead

Interpretation

It is clear that whoever is the leader, consistent and credible leadership is a necessary component of a successful project.

E. 3.6 Mf Sequential assessment

Context and Mechanisms

The MDs observed in Denmark were ones which were "one stop" in nature, i.e. patients were assessed, investigated and given a diagnosis all on the same day.

Characteristics of mechanisms and outcomes

The vast majority of patients are seen, investigated and given a diagnosis on the same day. Anecdotally, the majority of patients seem to like this approach:

"Patients seem to like the service, the majority get a diagnosis on the same day, those that don't have cancer who are the majority are reassured quickly and they like that"

Project manager

Those patients not receiving a diagnosis on the same day generally require further investigations and/or referral to other specialties.

Interpretation

One stop clinics reduce the number of hospital attendances and reduced the amount of anxiety experienced by patients who are waiting for a diagnosis.

One stop clinics require directorate to work together to ensure diagnostic and clinic slots are available at are times that are complimentary. They are also heavily dependent on the

E. 3.7 Mg Opportunistic health promotion

Context and Mechanisms

Given that the majority of patients are not expected to have a cancer diagnosis but will have been anxious about a potential diagnosis of cancer and as a result may be susceptible to opportunistic health promotion messages, it was decided to build some health promotion such as advising on smoking, alcohol and a healthy diet into the pathway.

Characteristics of mechanisms and outcomes

"We have the smoking cessation information pack if they're smokers. We have an alcohol information pack if they're heavy drinkers and they agree to it.

All the non-cancer patients get an information pack that has the NHS Screening timeline, a signs and symptoms Z card from Macmillan, which has a man and a women on each side and it shows you signs and symptoms. We also include the Cancer Research UK Cut Your Cancer Risk leaflet" CNS

This sort of health promotion is systematically offered to all patients who do not have a cancer diagnosis in the MDC. Whilst this seems intuitively to be a good idea we have no way of knowing how receptive patients are to this sort of advice at this stage of the pathway.

Interpretation

Attendance at the MDC is a time-consuming process and staff report that patients are often tired and relieved when they are told they do not have cancer raising the question as to whether this is the most appropriate time to offer short health promotion interventions.

E.4 Conclusions

13 1:1 interviews were conducted throughout the evaluation period, generating a significant amount of qualitative data. The CMO configuration presented reflects the key findings resulting from our analysis.

To summarise, the outcomes specified in the CMO table (figure2) were evidenced in the following ways:

O1. Faster route to diagnosis – there is a perception that prior to the development of the MDC pathway some of these patients were managed in primary care for an unnecessarily long time because GPs did not have an appropriate pathway to refer them. In addition, these patients were sent for unnecessary tests or were referred numerous times via a range of pathways, creating a delay in diagnosis.

Informal feedback from GPs indicates that they feel this is a faster route to diagnosis for both cancer and non-cancer patients. However, to date a small number of cancers have been detected via this pathway and those that have been detected have been at a later stage.

Q2. Understanding of staffing/capacity needs – Interviewees state they understand capacity better in relation to this pathway. Initially, slow uptake proved to be frustrating, particularly for the clinical staff. More recently, demand for the service has increased. There is a need to increase clinician capacity in the MDC (there are plans to extend the existing MDC clinics from 4 to 6 slots per clinic) and if the MDC is further rolled out there needs to be consideration of radiology capacity to continue hot reporting of CT scans. The navigator and CNS currently have spare capacity which could be utilised if the clinics were expanded

Q3. Detection of diseases other than cancer - Interviewees report that they have identified a significant amount of non-cancers requiring ongoing management.

Q4. Engagement from all relevant departments – Interviewees report good engagement from the all departments.

Q5. Uptake of pathway – At the time of the final set of interviews the majority of GP practices were using the pathway. There is anecdotal evidence they find it useful. Demand has increased which would indicate that they have simplified the referral process.

As a result of good feedback from both GPs and patients, commissioners are considering rolling out the pilot to neighbouring areas.

In terms of fidelity to their proposed model, Oldham have delivered the specified pathway in the way that they envisaged, however there is consensus that at a local level this has been primarily due to the tenacity, commitment and leadership skills of the CNS.

In terms of Oldham's underlying programme theory, they believed that by developing a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes would improve, we have both anecdotal evidence from the interviews and data from the ACE Patient Experience Survey that patient experience is good. However, at the time of writing this case-study it is difficult to evidence whether patient outcomes have improved, though the quantitative evaluation may give further insights into this.

Oldham also believed that they could utilise the clinics for health promotion short interventions and signposting, they do systematically advise people about lifestyle related issues but currently have no way of measuring the impact.

In addition to the outcomes highlighted in section E3 the Oldham site aimed to confirm a diagnosis and where appropriate refer to a tumour specific MDT to have an agreed treatment plan of discharge within 28 days of referral from GP, they report that they are meeting this target and they state they have data to support this.

They also aspired to diagnose cancer at an earlier stage, to date the majority of diagnoses have been of advanced cancer.

Another aim was to reduce unnecessary admissions and although they currently have no evidence to support this, they are in the process of writing to GPs to ask for case-studies that illustrate this.

Applying a Normalisation Process Theory (NPT) framework to our findings, we conclude that the pilot has tested systems and processes and many elements of the pathway have become normalised (see section 2.2 for detail on Normalisation Process Theory).

Table 1 Oldham Normalisation process

	Coherence **What is the work?**	**Cognitive participation.** **Who does the work?**	**Collective action** **How does the work get done?**	**Reflexive monitoring** **How is the work understood?**
Systematic explanation of mechanisms and components at work	GM Cancer Collaborative, Oldham Royal, local CCGs, and GP practices recognised it as building upon previous cancer pathway redesign work. Education events and regular feedback from the Lead GP and the Project Manager, have reinforced the mechanisms of the "one stop" process.	GPs refer patients with concerning symptoms. CNS does the assessment, and arranges initial diagnostics. Scans and scopes done within secondary care on the same day. Patients are seen in a GI clinic. GPs informed of results. Where findings require it patient moved to appropriate pathway.	Information was provided in relation to the pathway. The CNS was given training and ongoing support provided by the Consultants. Detailed protocols for the pathway were also developed.	The steering group meets quarterly and operational group meets monthly. The work and challenges at a local level are led on a day to day basis by the CNS supported by the Project Manager.
Knowledge about the sources and operation of investments at work	Practices appear to have understood the mechanism of referring patients to the MDC.	Value of the intervention was promoted by GM Steering Group, Oldham Royal MDC team and local CCGs. There was consensus that the intervention was worthwhile from a patient perspective.	GP practices engaged in referring patients to the MDC. CNS responsible for initial assessment and ordering investigations. Radiology for CT scans. Navigator for booking and following up tests and tracking the patients, also for booking patients into clinic and accompanying the patient to departments where tests are undertaken. The consultants see the patients in clinic and managing them accordingly, refer on as appropriate or discharge back to the GP.	There is a good understanding of factors affecting the pathway across the small number of key stakeholders and within the steering group. The CNS AND Project Manager proactively manage issues and continue to work with others to develop the service. Data is scrutinised by the steering and operational groups.
Core questions	**How is a practice conceptualised by participants?** Viewed positively by General Practice, The GM steering group, the Oldham operational group,	**How do participants come to engage with a practice?** Practices were initially approached by the Lead GP and Project Manager .The project was actively supported by the GM	**How do participants enact a practice?** Follow protocol. Enlist support from Project Manager when necessary.	**How do participants appraise a practice?** Appraisal and feedback are encouraged via the steering and operational groups and regular contact

	the CCG, GP Lead, patients and providers at Oldham Royal.	steering group, the Oldham operational group, the local CCGs. More sustained engagement due to education and training of practices and ongoing support provided by the Project Manager, Lead GP and CNS.		with the Project Manager. Data is reviewed via the operational and steering groups.
Core questions		**How does it hold together in action?** Most GP Practices referring to the MDC. The CNS conducting the initially assessment and arranging investigations. Radiology coping with demand for the CT scans and "hot reporting". MDC Navigator role provides administration and tracking function. Most appropriate GI Consultant sees patients in clinic and decides most appropriate ongoing management. GPs receive feedback from MDC. Stakeholders feel that the service	**How do they decide on engagement and the purposes that it serves?** Discussions around value to the patient, Consideration of additional workload and subsequent impact on capacity. Project driven by CNS and Project Manager supported by a GP Lead and Lead Clinician and an engaged steering and operational groups.	**What are its effects of appraisal?** Appraisal has resulted in small changes to the pathway and the development of nurse led protocols. Appraisal has also led to the operational group currently developing a business case to roll out the service.

Appendix F – Manchester University NHS Foundation Trust (Wythenshawe Hospital)

F.1 Introduction and Background

Greater Manchester has some of the worst cancer outcomes in England, with high cancer incidence and high cancer related mortality rates which are associated with low uptake of screening programmes and late stage diagnosis. Despite having some of the highest rates of premature deaths due to cancer, Greater Manchester has made significant improvements in recent years, bringing one year survival rates and patient experience in some areas in line or ahead of all other areas in England.

Across Greater Manchester (GM) there was consensus that although significant progress had been made, in order to further improve clinical outcomes, focused action was required to support primary care colleagues in identifying and referring patients at an earlier stage. The objective of the GM ACE Wave 2 project was to develop appropriate referral pathways for patients in whom the GP has a clinical suspicion of cancer, but who do not necessarily meet the criteria for existing pathways. Two sites were selected in GM to pilot the referral pathway; Oldham and Wythenshawe, this case study focuses on the Wythenshawe experience.

F.1.1 Aims and Objectives of the GM MDC pilot project

The GM project aims to increase the number of patients diagnosed earlier with cancer at stage 1 and stage 2. The patient will attend a Multidisciplinary Diagnostic Clinic (MDC) that provides a structured pathway for patients in whom the GP has a clinical suspicion of cancer, but who do not necessarily meet the criteria for existing pathways in a bid to:

- Confirm diagnosis and refer to tumour specific MDT to have agreed treatment plan or discharge patient within28 days from receipt of GP referral
- Improve patient experience
- Improve outcomes and survival rates- achieve world class outcomes, through diagnosis at an earlier stage
- Improve the patient pathway from presentation to diagnosis and on to treatment
- Simplify referral process for GPs and the patient
- Reduce/avoid unnecessary hospital admissions

- Promote health awareness from both a public and professional point of view

F.1.2 The MDC model as implemented in GM

MDC Team:

Project Manager, Lead Clinician, Lead GP, Clinical Nurse Specialist, Radiographer, Navigator, Service Manager

Team engagement:

THE GM ACE 2 steering group meets quarterly and the South Manchester operational group meets monthly

Communication:

There are internal and external (aimed at identified secondary care professionals and GPs) communication plans in place

Patients are given an MDC information leaflet at the GP consultation from which they are referred.

Referral criteria:

Decreased appetite

Nausea

Non-specific abdominal pain

Lymphadenopathy

Persistent Pain

Unexplained DVT

Non-specific iron deficiency anaemia

Fatigue

Weight loss

Hepatomegaly

Splenomegaly

Bloating

Continued patient or family concern

GP concern

Exclusion criteria:

Some symptoms (listed below) indicate a specific cancer. These should be investigated or referred in accordance with the NICE NG12 guideline and not considered for the ACE pathway:

Post-menopausal bleeding

Abnormal vaginal bleeding

Rectal bleeding

Altered bower habits

Malena

Dysphagia

Hematemesis

Haematuria

Shortness of breath

Cough

Haemoptysis

Diagnostic pathway:

The Wythenshawe MDC is designed for ambulatory patients with non-specific but concerning symptoms of suspected cancer, needing an urgent diagnosis. Clinical decisions are made by senior medical staff. The MDC provides advice and guidance to Primary care on the assessment outcome. The MDC works to the following core principles:

- Access – open to primary care following mandatory GP assessment
- Managed referral process – defined referral process and criteria for patients presenting with non-specific but potentially serious symptoms
- Senior decision making – the MDC will be overseen by a consultant senior level clinician who takes clinical responsibility for the patient episode

- Administrative and pathway support – improve clinical effectiveness by the provision of the CNS and Navigator to support and assist clinicians as well as helping to manage data collection, communication and performance monitoring.
- Close links to key departments and individuals – Consultants and Clinical Nurse Specialists, MDT coordinators, A&E, Radiology, Endoscopy, Pathology, Acute Oncology Service.

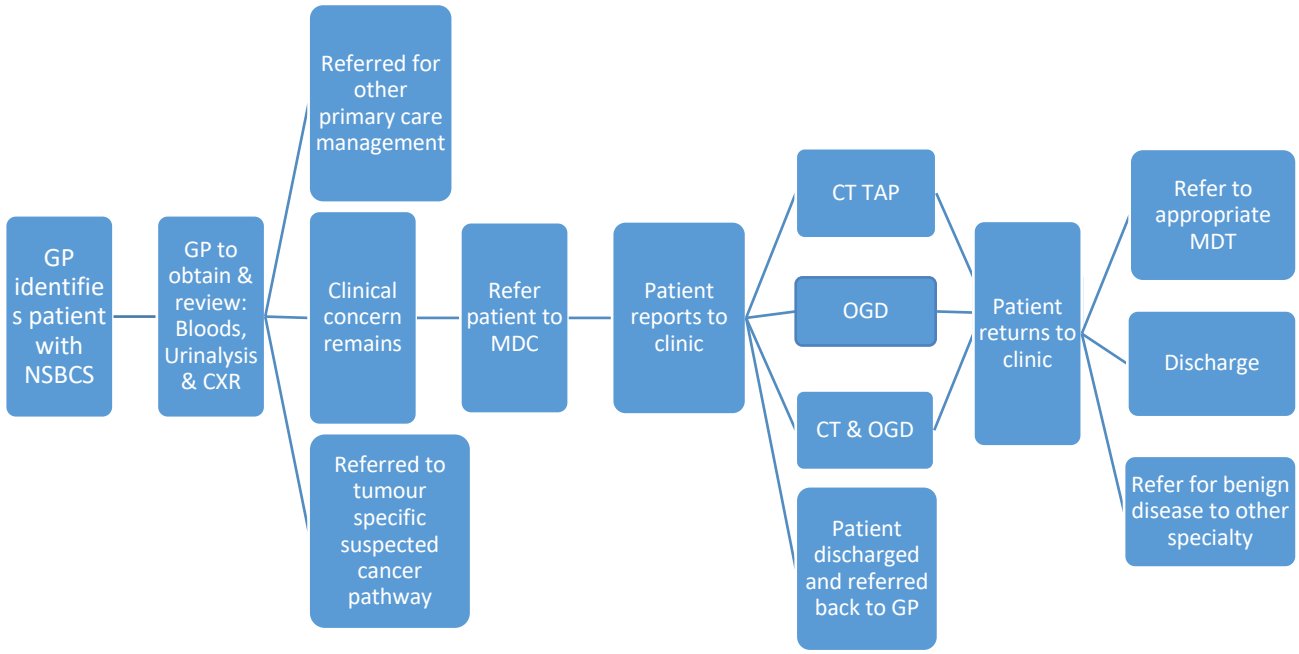
GPs are required to complete a mandatory assessment. The assessment will include:

- Clinical examination,
- Urgent blood tests including FBC, U&E, LFT, Bone profile, TFT, LDH, PV/CRP, Ferritin, Glucose, HbA1c, Mononucleosis test, Coeliac screen, HIV test. Also PSA and beta-HCG (MEN), CA125 (women). The list of blood tests is reviewed on a regular basis and will be amended on agreement at the monthly operational group meeting.
- Urgent chest x-ray
- Urinalysis

The GP reviews the results and decides whether or not the referral remains appropriate. The referral form requires a short narrative, explaining why cancer is suspected. To support the referral process further, the referral form lists a range of “specific” symptoms that will prompt the GP to consider an alternative referral pathway.

Patients will be seen within a maximum of 14 days of referral. It is a one-stop clinic model, where the patient will have a clinical assessment and a range of tests including a CT scan and or endoscopy, with the majority of patients receiving their results on the same day.

Figure 1 GM MDC pathway



Patient management plan:

The MDC will provide a diagnosis wherever possible and/or a definitive management plan, onward referrals will be made as appropriate:

- Referral to a tumour specific MDT
- Referral for additional investigations
- Review in a non-cancer clinic
- Referral to acute oncology/specialist palliative care
- Discharge to primary care with advice
- Offer of opportunistic lifestyle advice where cancer was excluded.

Patient experience:

Patient experience feedback will be collected using the ACE patient experience survey and an internally developed survey will also be conducted.

F.2 Evaluation Methodology

The qualitative evaluation of the ACE programme draws on the principles of realist evaluation (Pawson and Tilley, 1997) to develop a contextualised account of the way in which change emerges. See section 2.1 for details of realist methodology.

The underlying programme theory for the GM ACE Wave 2 pilot at the Wythenshawe site was:

C) If you develop a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes will improve
D) MDC clinics are an opportunity for health promotion and signposting to lifestyle support services

For the purposes of this case study, a total of 19 1:1 interviews with key informants were carried out.

Analysis of the interviews resulted in the development of a Context, Mechanisms and Outcomes (CMO) model (figure 2)

The CMO model considers the contexts, mechanisms and outcomes that were apparent in the implementation of the initiative. Each of the key mechanisms is considered in turn within the case study.

Normalisation Process Theory (NPT) provides the theoretical basis for understanding how the initiative is understood, implemented and embedded into normal practice. NPT considers four areas; coherence, cognitive participation, collective action, and reflexive monitoring. See section 2.2 for details. Each of these areas are considered in turn in table1.

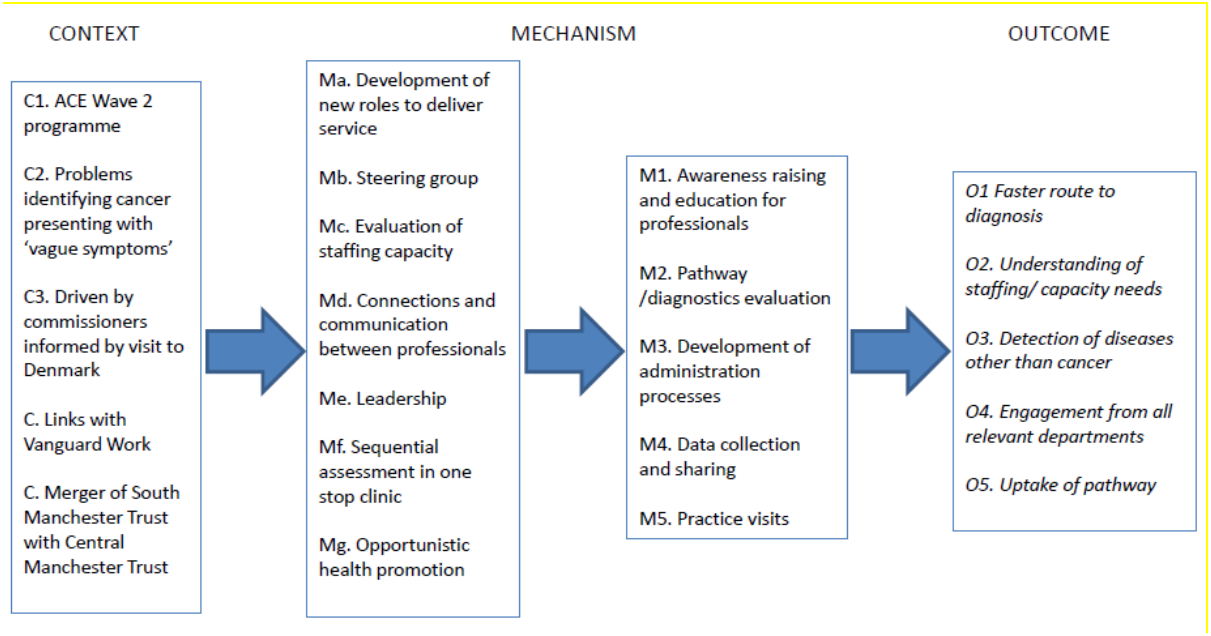


Figure 2 CMO model for Wythenshawe

F.3 Contexts, Mechanisms and Outcomes

F.3.1 Ma Development of new roles to deliver the service

Context and Mechanism

The MDC at the Wythenshawe Hospital sits within the Greater Manchester (GM) conurbation. The GM Cancer Board oversees cancer services across this area. GM identified that patients who experienced vague but concerning symptoms often presented late to secondary care and often did not have a smooth pathway leading to diagnosis. In 2015 the representatives from Oldham CCG went to Denmark to look at the work being done there to implement MDCs for vague symptoms. In addition, cancer colleagues from Wythenshawe Hospital expressed an interest in running a vague symptoms clinic. As a result the GM Cancer Board successfully submitted an expression of interest to the ACE Wave 2 initiative. The successful application led to the development of 2 pilot MDCs in Oldham and Wythenshawe Hospital.

The development of the MDC was actively led by a project manager from the GM Cancer Commissioning Programme and at a local level by a GP cancer lead, lead gastroenterologist, cancer manager, a CNS and a navigator.

New posts were also developed to support the development and implementation of the pathway, including a navigator role, clinical nurse specialist and gastroenterologists were modified to provide clinical expertise to the MDC.

Characteristics of mechanisms and outcomes

The navigator role was specifically developed to support the pathway. It is an administrative role responsible for receiving referrals, liaising with the CNS to arrange clinic appointments, ensuring investigations are ordered and reports are available in clinic. The Navigator also acts as a contact for patients from the point of referral, she also the meets patients when they arrive for their appointment and takes them to the departments where they are scheduled to have tests such as CT or endoscopy, to ensure that everything gets done in the timescales allotted. The role also involves data collection and tracking the patient.

Evidence from the interviews suggest that the project team appear to value the role of the navigator:

"I think we were already establishing that the navigators role was key" Project manager

The clinical nurse specialist (CNS) role is key to the success of this model and was developed with the CNS being the first point of contact for patients presenting to secondary care. The CNS carries out a detailed assessment and then the patient has a CT scan, which is hot reported. The report is reviewed and if necessary they have a gastroscopy prior to be being seen in clinic later on the same day. The CNS supports the patient through the assessment process. Other CNS related developments include the CNS being able to review CT reports to decide whether the patient needs a gastroscopy when a consultant is unavailable:

"Protocols have been developed to allow the CNS in the absence of a consultant to assess the CT and decide whether the patient needs an OGD prior to being seen in clinic" CNS

Currently gastroenterologists see patients in the MDC. Although the patients sometimes require more generic diagnostic skills, this has not created problems.

Interpretation

Staff interviewed all seemed appreciative of the new roles. It was evident from the interviews that there was a shared understanding of the purpose of the MDC pathway and it was viewed as bringing additional value to patients. It was however thought to be a resource rich service which would need to change if it were to be sustainable in the long term.

In terms of normalisation process theory, we are unable to conclude that the new roles have become completely normalised as this work is not recognised in the clinicians' job

plans. The CNS and navigator roles however are well established and functioning well though they currently have significant spare capacity.

F.3.2 Mb Steering Group

Context and Mechanism

In order to deliver the project within the ACE timeframe a GM wide steering group was formed, comprising of managers, commissioners, people affected by cancer, clinicians and support staff from 2 Greater Manchester (GM) pilot sites; Oldham and Wythenshawe. This steering group developed the business case for ACE and brought together the key stakeholders required to plan and oversee the pilot MDC pathway. An operational group also meets on a monthly basis at Wythenshawe to address local operational issues.

Characteristics of mechanisms and outcomes

The steering group continues to meet on a quarterly basis. Initially it met to develop the business case and brought together key stakeholders. As the pathway was implemented the focus became more operational and became a forum for reviewing and monitoring progress.

The steering group was viewed as being effective by those interviewed:

"*The steering group works well and everyone that sits on that group is so accommodating, so approachable, and I would not have a problem going to anybody with any concerns"*

CNS

"Yes, the steering group has worked well and been a useful forum for shaping the project and dealing with issues, also for keeping people updated" Manager

Membership of the GM steering group and Wythenshawe operational groups are largely unchanged and key individuals remain involved.

Interpretation

One of the reasons the steering and operational groups have been effective is that they have a shared vision for the pilot and provided an opportunity for key stakeholders to shape the pilot, ensuring shared ownership as the pilot progressed.

F.3.3 Mc Evaluation of staffing capacity

Context and Mechanisms

The Navigator works 30 hours per week and CNS works 32 hours per week, both have sufficient capacity to expand their current workload.

The gastroenterologists who provide the clinician input into the MDC currently provide 4 slots each per week.

Characteristics of mechanisms and outcomes

At the time of the final interviews in spring 2018 Wythenshawe had experienced pressures on clinic capacity:

"We've got more patients than we can see, because we only have 1 clinic per week, where we see 4 patients, and we invariably will get more than 4 referrals . . . . . We're still working to the cancer targets, so they've got to be seen within 14 days. Those patients that can't be seen in the ACE clinic, they have to go to a normal 2 week wait clinic. . . . . They usually go to a gastro clinic. Yes, it's hard to work. They are trying really hard to get another clinician on board to facilitate another clinic. There's been maternity leave within the gastro team, and we've tried clinicians outside of gastro, but for one reason or another it's just not worked" Navigator

The team are hopeful that in September when the gastroenterologist on maternity leave returns to work they may be able to increase the number of ACE slots offered each week.

CT capacity and endoscopy capacity has not been a major issue and is not thought to be a problem should the service expand, there may however be a problem with hot reporting of CTs i.e. reporting them within the hour of being done.

Interpretation

The clinicians have taken on this role in addition to existing responsibilities. If the service is to be further expanded there is a need to ensure job plans are reviewed and clear job descriptions exist outlining the nature of the role.

F.3.4 Md Connections and communications between professionals

Context and Mechanisms

There was agreement across a range of key stakeholders including commissioners, primary and secondary care that there were problems identifying cancer presenting with vague symptoms and that it would be appropriate to design a structure diagnostic pathway that would improve patient experience and outcomes.

Characteristics of mechanisms and outcomes

Both internal and external communication plans were developed. A significant amount of communication occurred within the steering and operational groups with members of the groups cascading information to colleagues in their respective teams/departments. Interviewees reported good communication.

There have been GP education events and the pathway and referral criteria were also sent out to GPs and there is some anecdotal evidence that this, together with discussions with GPs has helped raise awareness of the pilot:

"GPs are increasingly aware of the service and those who have used it seem to like it"

GP lead

Some work is also happening with the GPs to try to understand more about the patients who have been referred via this route:

"We have AA the GP Lead and she's written to the GPs who have referred in to ask for case studies to illustrate the value of the service" Lead clinician

Interpretation

The provision of consistent messages in a range of formats across directorates/stakeholder organisations is vital if all stakeholders are to be kept informed and engaged.

F.3.5 Me Leadership

Context and Mechanisms

Project Leadership was provided by the GM Cancer Programme Manager and supported by the GM steering group. At a local level leadership was provided by a consultant gastroenterologist supported by a trust cancer manager and GP cancer lead.

Characteristics of mechanisms and outcomes

The model of leadership employed in GM/Wythenshawe Hospital appears to work well. Tasks are achieved and progress monitored via the steering and operational groups. Service developments and innovations are also encouraged and supported via the GM steering group and local operational group.

Interpretation

It is clear that consistent and credible leadership is a necessary component of a successful project.

F.3.6 Mf Sequential assessment in one stop clinic

Context and Mechanisms

The MDCs observed in Denmark were "one stop" in nature, i.e. patients were assessed, investigated and given a diagnosis all on the same day.

Characteristics of mechanisms and outcomes

The vast majority of patients are seen, investigated and given a diagnosis on the same day. Anecdotally, the majority of patients seem to like this approach:

"Patients seem to like the service, the majority get a diagnosis on the same day, those that don't have cancer who are the majority are reassured quickly and they like that"

Project manager

Those patients not receiving a diagnosis on the same day generally require further investigations and/or referral to other specialisms.

Interpretation

One stop clinics reduce the number of hospital attendances and reduced the amount of anxiety experienced by patients who are waiting for a diagnosis.

One stop clinics require directorates to work together to ensure diagnostic and clinic slots are available at are times that are complimentary. They are also heavily dependent on the availability of radiologists to "hot report" scans and clinicians to provide the patient with a diagnosis.

F.3.7 Mg Opportunistic health promotion

Context and Mechanisms

Given that the majority of patients are not expected to have a cancer diagnosis but will have been anxious about a potential diagnosis of cancer and as a result may be susceptible to opportunistic health promotion messages, it was decided to build some health promotion such as advising on potential lifestyle changes into the pathway.

Characteristics of mechanisms and outcomes

The proposed health promotion elements of the pathway do not appear to have been as successful as the team hoped:

"So it's (health promotion) definitely part of our model and it's definitely something that does need to be expanded, however I do find with a lot of the patients – not that I let it put me off, but a lot of the patients do not want to engage in reducing smoking, reducing alcohol or doing exercise. They flatly refuse . . . . . They just don't want to engage." CNS

Interpretation

Attendance at the MDC is a time consuming process and staff report that patients are often tired and relieved when they are told they do not have cancer and are anxious to leave the hospital, raising the question as to whether this is the most appropriate time to offer short health promotion interventions.

F.4 Conclusions

19 1:1 interviews were conducted throughout the evaluation period, generating a significant amount of qualitative data. The CMO configuration presented reflects the key findings resulting from our analysis.

To summarise, the outcomes specified in the CMO table (figure 2) were evidenced in the following ways:

O1. Faster route to diagnosis – there is a perception that prior to the development of the MDC pathway some of these patients were managed in primary care for an unnecessarily long time because GPs did not have an appropriate pathway to refer them on. In addition, these patients were sent for unnecessary tests or were referred numerous times via a range of pathways, creating a delay in diagnosis.

Informal feedback from GPs indicates that they feel this is a faster route to diagnosis for both cancer and non-cancer patients. To date only a small number of cancers have been detected via this pathway and those that have been detected have been at a later stage.

Q2. Understanding of staffing/capacity needs – Interviewees state they understand capacity better in relation to this pathway. Initially, slow uptake proved to be frustrating, particularly for the clinical staff. More recently, demand for the service has increased. There is a need to increase clinician capacity into the MDC (there are plans to extend the existing MDC clinics hopefully when a gastroenterology consultant colleague returns from maternity leave) and if the MDC is further rolled out there needs to be consideration of radiology capacity to continue "hot reporting" of CT scans. The navigator and CNS currently have spare capacity which could be utilised if the clinics were expanded

Q3. Detection of diseases other than cancer - Interviewees report that they have identified a significant amount of non-cancers requiring ongoing management.

Q4. Engagement from all relevant departments – Interviewees report good engagement from the all departments at the time of the final interviews.

Q5. Uptake of pathway – At the time of the final set of interviews the majority of GP practices were using the pathway, there is anecdotal evidence they find it useful. Demand has increased and as a result of good feedback from both GPs and patients they are considering rolling out the pilot to neighbouring areas.

In terms of fidelity to their proposed model, South Manchester have delivered the specified pathway in the way that they envisaged, however there is consensus that at a local level this is an expensive resource and will need to be delivered differently in the future if it is to be sustained.

In terms of Wythenshawe underlying programme theory, they believed that by developing a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes would improve, we have both anecdotal evidence from the interviews and data from the ACE Patient Experience Survey that patient experience is good. However, at the time of writing this case-study it is difficult to evidence whether patient outcomes have improved, though the quantitative evaluation may give further insights into this.

Wythenshawe also believed that they could utilise the MDC clinics for health promotion short interventions and signposting, however this has been met by a largely negative response from patients and we currently have no way of measuring the impact of these short health promotion interventions.

In addition to the outcomes highlighted in section F3 the GM Wythenshawe site aimed to confirm a diagnosis and where appropriate refer to a tumour specific MDT to have an agreed treatment plan of discharge within 28 days of referral from GP. They report that they are meeting this target and they state they have data to support this.

They also aspired to diagnose cancer at an earlier stage; to date the majority of diagnoses have been of advanced cancer.

Finally, they aimed to reduce unnecessary admissions and although they currently have no evidence to support this, they are in the process of writing to GPs to ask for case-studies that illustrate this.

Applying a Normalisation Process Theory (NPT) framework to our findings, we conclude that the pilot has tested systems and processes and many elements of the pathway have become normalised (see 2.2 for detail on Normalisation Process Theory).

Table1 South Manchester Normalisation Process

	Coherence **What is the work?**	**Cognitive participation.** **Who does the work?**	**Collective action** **How does the work get done?**	**Reflexive monitoring** **How is the work understood?**
Systematic explanation of mechanisms and components t work	GM Cancer Collaborative, Wythenshawe Hospital, local CCGs, and GP practices recognised it as building upon previous cancer pathway redesign work. Education events and regular feedback from the Lead GP and the Project Manager, have reinforced the mechanisms of the "one stop" process.	GPs refer patients with concerning symptoms. CNS does the assessment,and arranges initial diagnostics. Scans and scopes done within secondary care on the same day. Patients are seen in a GI clinic. GPs informed of results. Where findings require it patient moved to appropriate pathway.	Information was provided in relation to the pathway. The CNS was given training and ongoing support provided by the Consultants. Detailed protocols for the pathway were also developed.	The steering group meets quarterly and operational group meets monthly. The work and challenges at a local level are led on a day to day basis by the Lead Clinician supported by the CNS and Manager.

Knowledge about the sources and operation of investments at work	Practices appear to have understood the mechanism of referring patients to the MDC.	Value of the intervention was promoted by GM Steering Group, Wythenshawe MDC team and local CCGs. There was consensus that the intervention was worthwhile from a patient perspective.	GP practices engaged in referring patients to the MDC. CNS responsible for initial assessment and ordering investigations. Radiology for CT scans. Navigator for booking and following up tests and tracking the patients, also for booking patients into clinic and accompanying the patient to departments where tests are undertaken. The consultants see the patients in clinic and managing them accordingly, refer on as appropriate or discharge back to the GP.	There is a good understanding of factors affecting the pathway across key stakeholders and within the steering group. The Lead Clinician, CNS and Manager proactively manage issues and continue to work with others to develop the service. Data is scrutinised by the steering and operational groups.
Core questions	**How is a practice conceptualised by participants?** Viewed positively by General Practice, The GM steering group, the Wythenshawe operational group, the CCG, GP Lead, patients and providers at Wythenshawe Hospital.	**How do participants come to engage with a practice?** Practices were initially approached by the Lead GP and Project Manager The project was actively supported by the GM steering group, the Wythenshawe operational group, the local CCGs. More sustained engagement due to education and training of practices and ongoing support provided by the Project Manager, Lead GP and CNS.	**How do participants enact a practice?** Follow protocol. Enlist support from Project Manager when necessary.	**How do participants appraise a practice?** Appraisal and feedback are encouraged via the steering and operational groups and regular contact with the Project Manager. Data is reviewed via the operational and steering groups.
Core questions		**How does it hold together in action?** Most GP Practices referring to the MDC. The CNS conducting the initial assessment and	**How do they decide on engagement and the purposes that it serves?** Discussions around value to the patient, Consideration of additional workload and	**What are its effects of appraisal?** Appraisal has resulted in small changes to the pathway and the development of nurse led protocols.

		arranging investigations. Radiology coping with demand for the CT scans and “hot reporting”. MDC Navigator role provides administration and tracking function. Consultant sees patients in clinic and decides most appropriate ongoing management. GPs receive feedback from MDC. Stakeholders feel that the service is worthwhile.	subsequent impact on capacity. Project driven by Lead Clinician and Manager supported by a GP Lea, CNS and an engaged steering and operational group,	

Appendix G – Oxford University Hospital Trust (Oxfordshire SCAN Pathway)

G.1 Introduction and Background

Oxfordshire has a predominantly white population (90.85%), the remainder of the population comprises of Asian (4.84%), Black (1.75%) and mixed ethic (2.02%). BME communities form 22.4% of Oxford City's population, with lower proportions in more rural districts: 7.8% in Cherwell, 3.2 % in West Oxfordshire.

Oxfordshire CCG has a population of 647,085, served by 77 GP practices. Rural districts (67%) rank in the 10% lest deprived, and urban (33%) in the 20% most deprived in England.

Oxfordshire's cancer incidence (425.2 cases per 100,000) is significantly higher than the UK average (402.8 cases per 100,000). Cancer mortality (191.7 per 100,000) is lower than the national average.

The Oxfordshire ACE Suspected Cancer (SCAN) MDC pathway pilot links Oxfordshire CCG and Oxford University Hospital Trust (OUHT) with the Oxford Allied Health Science Imaging Network and the Nuffield Department of Primary Care Health Science. The pilot aims to develop a model for expansion through the 7 NHS network trusts which make up the local Cancer Alliance.

Oxford University Hospital Trust (OUHT) is made up of four hospitals providing a range of specialist services (John Radcliffe, Churchill Hospital, Nuffield Orthopaedic Centre and the Horton General Hospital.

The initial MDC pilot site was located at the Churchill and John Radcliffe Hospitals.

G.1.1 Aims and Objectives

To pilot a primary care led MDC pathway for patients with "low risk but not no risk" symptoms of cancer, falling outside of 2 week wait pathways referral criteria.

The MDC project objectives were to:

- Improve the patient experience by reducing the time from first referral to diagnosis.
- Reduce cancer stage at diagnosis by lowering the referral threshold for suspected cancer.

- Identify the optimal configuration of GP and Specialist input to diagnose cancer in this group.
- Measure the impact of referrals made to existing 2 week wait pathways.
- Reduce the number of emergency presentations.

G.1.2 ACE model

SCAN MDC Team:

Operational Service Manager for Radiology, Statistician, Macmillan GP, Divisional Director for Clinical Support Services/Radiologist, CCG Clinical Lead /GP, CCG Project Manager, Clinical Research Operational Manager – Radiology, SCAN Navigator/Radiographer, SCAN MDC Clinician.

Team engagement:

The MDC steering group meets monthly; in addition there are separate meetings within the different departments represented at the steering group.

Communication:

There are internal and external communications plans in place.

Patients are given an MDC leaflet at the GP consultation from which they are referred.

There are plans to evaluate patient experience as part of the national evaluation and also at a local level.

Referral Criteria:

Patients need to be registered with an Oxfordshire CCG General Practice and presenting with “vague” or non-specific symptoms which could represent cancer or serious disease but which do not link to a designated pathway for urgent investigation or referral.

The scope also covers:

- Patients where there is no other urgent referral pathway suitable for this clinical scenario.
- Over 40 years of age.
- Unexplained weight loss.
- Severe unexplained fatigue.
- Persistent nausea or appetite loss.

- New atypical pain (e.g. diffuse abdominal pain or bone pain).

Exclusion criteria:

- Those patients already on a designated 2 week wait pathway.
- Those patients who are suitable for a 2 week wait pathway.
- Referral via secondary care Emergency Department attendance.
- Patients <40 years of age.

The service will take any Oxfordshire CCG patients.

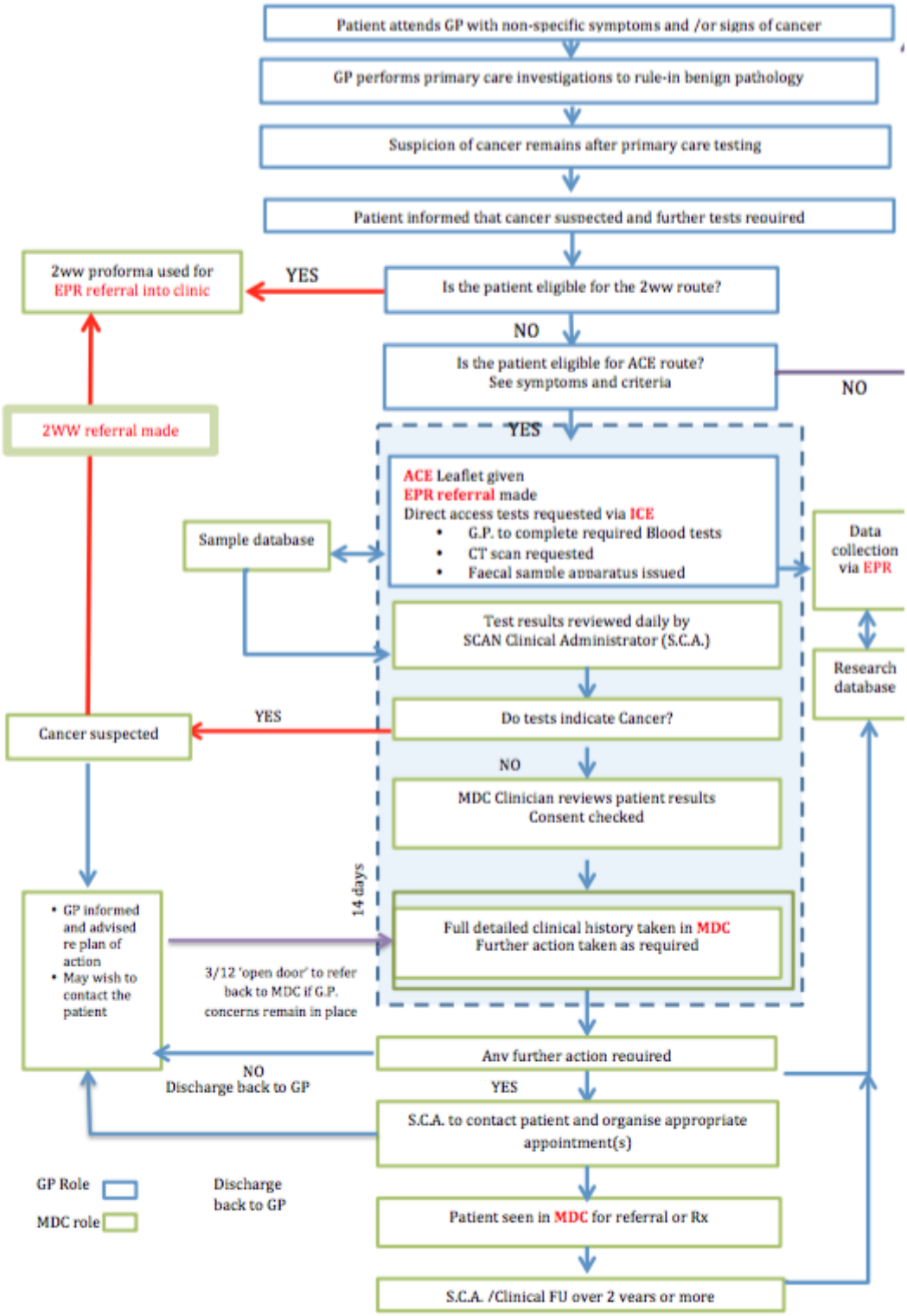


Figure1 Oxfordshire SCAN pathway

Diagnostic pathway:

The patient presents to the GP with "low risk but not no risk" symptoms and signs, falling outside existing 2 week wait pathways and included in the 2015 NICE guidance which remain unresolved by the tests available to the GP.

After discussion with the patient the GP will give the patient the "Suspected CANcer (SCAN) MDC pathway pilot information leaflet. The GP then orders direct access triage tests with rapid turnaround times (of less than 5 days), these will include:

- A panel of blood tests, including; FBC, LFTs, INR, CRP, ESR, U&Es, eGFR, Calcium, Phosphate, TSH, Glucose, HBA1c and HIV.
- Urine dipstick for haematuria
- Faecal immunochemical testing (FIT) (part of an additional study nested within the SCAN pathway)
- Low dose CT imaging

The patient will bring the FIT test with them to the CT scan appointment.

GPs retain clinical responsibility for the patient until their MDC appointment. The clinical information obtained will direct the patient's subsequent flow through the pathway. The Navigator will co-ordinate results and ensure that the patient is available to be seen.

Pathway options include:

A) Referral to Cancer site specific group via agreed patient pathway within 2 weeks of GP referral. GP to be informed.
B) Referral for additional direct access investigation such as OGD within 1 week after discussion with MDC clinician.
C) Referral to MDC to be seen by clinician.

At the point of referral to the MDC the accepting hospital clinician becomes responsible for the patient. When the diagnosis is reached the patient will be treated then discharged back to the care of the GP with a full summary and any appropriate care plan. If no diagnosis is reached by moving through the pathway the patient will be followed up for 2 years by the GP using a structured follow-up plan and allowing re-entry to the pathway if necessary.

There are slots for CT scans 7 days per week at the Churchill Hospital site and 2 MDC clinics per week (4 patients in each) at the John Radcliffe Hospital.

Patient experience:

Patient experience feedback will be collected for all patients coming through the MDC using the ACE Patient Experience Survey and the Suspected Cancer pathway (SCAN) Patient Questionnaire.

Associated research:

In addition to piloting the ACE SCAN pathway, Oxfordshire intend to keep blood and faecal samples for bio banking. Patients will consent for this separately.

At the point at which GPs refer to the SCAN pathway they will also be asked to estimate the percentage (%) risk of cancer for the patient given the clinical situation leading to referral.

G.2 Evaluation Methodology

The qualitative evaluation of the ACE programme draws on the principles of realist evaluation (Pawson and Tilley, 1997) to develop a contextualised account of the way in which change emerges. See section 2.1 for details of realist methodology.

The underlying programme theory for the site was:

E) If you develop a pathway for quick diagnosis for patients with vague symptoms, patient experience and outcomes will improve
F) You can improve patient experience by providing a navigator role and provision of MDC clinic appointments outside normal OPD hours

For the purposes of this case study, a total of 26 1:1 interviews with key informants were carried out.

Analysis of the interviews resulted in the development of a Context, Mechanisms and Outcomes (CMO) model (figure 2)

The CMO model considers the contexts, mechanisms and outcomes that were apparent in the implementation of the initiative. Each of the key mechanisms is considered in turn within the case study.

Normalisation Process Theory (NPT) provides the theoretical basis for understanding how the initiative is understood, implemented and embedded into normal practice. NPT

considers four areas; coherence, cognitive participation, collective action, and reflexive monitoring (see section 2.2 for details). Each of these areas are considered in turn in table 1.

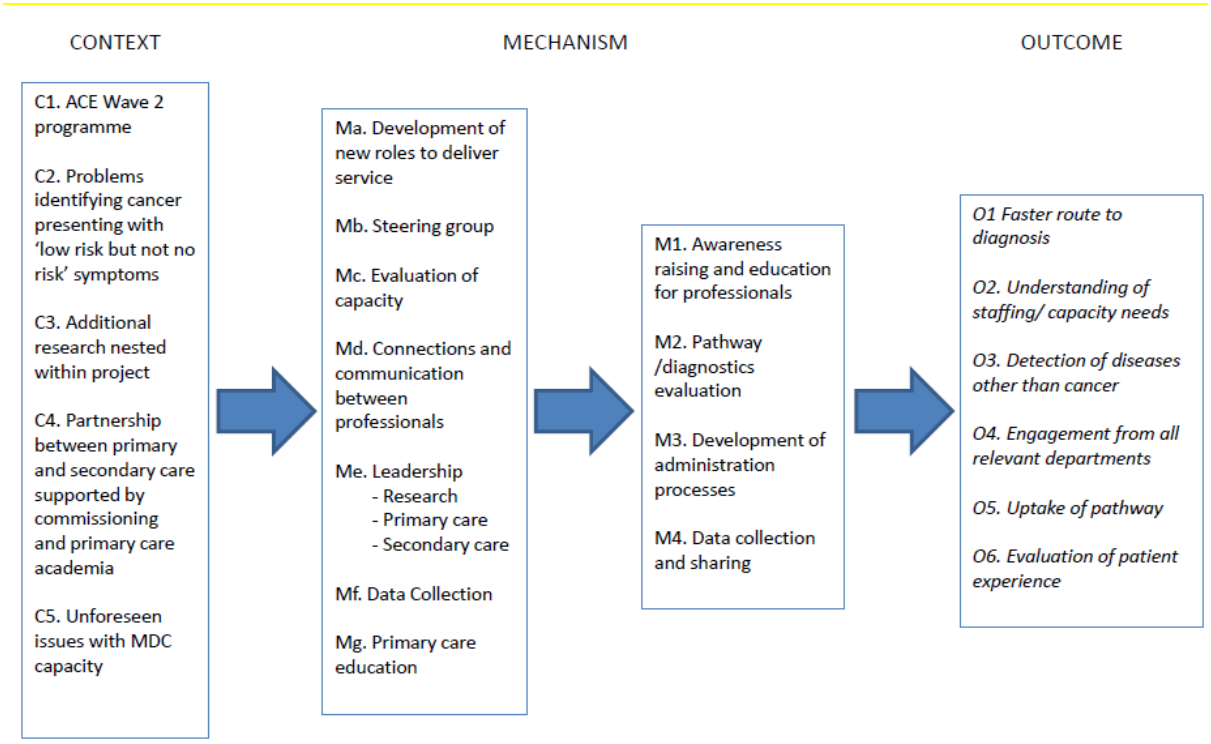


Figure 2 CMO for Oxfordshire SCAN pathway

G.3 Contexts, Mechanisms and Outcomes

G.3.1 Ma Development of new roles to deliver service

Context and Mechanism

Oxfordshire identified that there were problems identifying cancer presenting with "low risk but not no risk" symptoms, as a result they developed the ACE suspected Cancer (SCAN) MDC pathway pilot. This built upon previous pathway redesign work in the area. The organisational culture in Oxfordshire CCG and OUHT was one which was receptive to and supportive of change, it was also one which was supportive of research and as a result, in collaboration with the Nuffield Department of Primary Care Health Science they built a number of separate research elements into the pathway. These included: collecting blood samples for bio banking; collecting faecal samples and asking GPs to estimate the percentage (%) risk of cancer for the patient given the clinical situation leading to referral.

Leaders from commissioning, secondary care and primary care academia were all supportive of the pilot, a Project Manager was also appointed by the CCG and a number of new roles were developed to support and deliver the pilot, including; Navigator roles and the MDC clinician roles.

Characteristics of mechanisms and outcomes

A navigator role was developed which was viewed as being key to the success of the proposed model. At the time of the final interviews there were 2 navigators in post; one with a nursing background (0.5 wte) and one with a radiology background (1.0 wte).

The navigator is the first point of contact within secondary care. The navigator with the Radiology background checks that the patient is eligible for the ACE SCAN pathway. Both navigators are able to check consent for the nested research, take bloods and book the patient in for their CT scan. The navigator with the radiology background scans the majority of patients, though other Radiographers within the department are also able to carry out the scans. If the scan indicates that cancer is suspected, the patient is referred to the appropriate pathway and the GP is informed if no cancer is indicated on the scan the patient is booked into the MDC for a full clinical assessment and further management if required. Where possible the Navigator accompanies the patient to the MDC appointment. Following the MDC the navigator feeds back to the GP.

The Navigator input has worked well in terms of providing continuity for the patient and anecdotally, patients appear to value the role:

"XX has been great and the patients and the patients seem to value having some-one who can support them from the point at which they get referred in" CCG project manager

Navigator capacity has been an issue as the pilot has progressed. As the number of referrals have increased the full time navigator has found it difficult to take more than a few days annual leave at a time as there is only backfill from her nurse colleague at the latter end of the week. This approach to maintaining service cover is not sustainable in the long term.

The navigator is also responsible for retrieving data for the data analyst, which is a source of pressure at a time when Navigator capacity is becoming limited. At the time of the final set of interviews the management team had developed a job description for a data collection clerk and were hoping to go out to advert in the near future.

The MDC clinicians delivering the MDC at the time of the final interviews were not the same individuals who had this role at the outset of the pilot due to the initial clinicians leaving the organisation. The current 2 clinicians currently provide 3 slots each per week and are specialists in elderly care. The role does differ from how they routinely practice:

"Because I'm a geriatrician we tend to see an older cohort with similar problems of weight loss, non-specific changes in bloods that nobody quite knows what's going on. But obviously it's a bit backwards because we see them in clinic and then organise tests whereas with 9the SCAN pathway) the test is done first, then we see the patient. So they are sort of similar but they are definitely a younger cohort. And, as I see it's a bit tricky sometimes when the scans are identifying abnormalities if you've not met the patient to know how much you should pursue or whether it's appropriate to be organising m*ore tests"* MDC clinician

The initial clinicians had an ambulatory care background, which was viewed as being an ideal skill set for the MDC:

"AA has all the right skills and expertise to deliver the MDC as he is a very experienced clinician with an ambulatory care background" CCG project manager

Unfortunately, due to unforeseen circumstances, the original clinicians were no longer able to provide a service to the MDC, as a result the MDC was suspended for a number of months until replacements could be identified. The new clinicians have seen the backlog of patients that resulted from the clinic suspension, however recently the numbers of referrals and consequently the numbers of patients requiring MDC consultation has increased and there is insufficient capacity to meet demand resulting in another backlog. In an effort to address this waiting list one of the original MDC clinicians (who moved to another area) has agreed to come back to do some additional clinics, providing 8 slots on a Saturday. This will address the problem in the short term but is not a sustainable option in the longer term.

The project manager has been an important role in the planning of the SCAN pathway as the clinical leaders driving the project had limited time to address operational issues and/or monitor detail:

"We wouldn't have got this far without ZZ as we are all busy with other roles and responsibilities it's vital to have someone to do the following up, chasing things and ensuring they get done" GP lead

As the pilot has progressed the project manager has been dealing with other initiatives and has more recently been working with colleagues to develop a business case for funding to ensure the continuation of the pathway post pilot period.

Interpretation

Thenavigator role has worked very well but it is evident that in Oxford the radiography expertise has been more important that nursing expertise due to the fact that that most patients referred on to the pathway are scanned prior to any other intervention. For the future sustainability is an issue and there is a need to identify tasks which could be delegated to others. Stakeholders also acknowledge the need for more robust backfill arrangements to cover the radiographer navigator role.

G3.2 Mb Steering Group

Context and Mechanism

In order to deliver the SCAN pathway pilot a steering group including managers, commissioners, clinicians, primary care and academics was established in the planning stages of the pilot. The inclusion in the steering group of key individuals who would be required to plan and implement the pathway also ensured that they were “bought into” and supportive of the pilot.

Characteristics of mechanisms and outcomes

The steering group continues to meet regularly and leads from primary care/CCG, academia and radiology take responsibility for leadership of their own areas and liaise with colleagues to ensure actions are delivered upon and people are updated regarding progress of the pilot.

Initially the steering group was focused on planning the pilot, as the pilot has progressed, the focus changed to operational issues and monitoring progress. The only area not currently represented on the steering group are the MDC clinicians, due to the fact that do not have capacity to attend the meeting. In order to ensure that they are communicated with and have an opportunity to feedback to the steering group, the Navigator liaises with them following each meeting. Whilst this approach is acknowledge as not being ideal, interviewees indicate that it is effective. The GP lead is also considering meeting with the MDC clinicians on a quarterly basis.

Membership of the steering group is largely unchanged with all key individuals remaining involved and actively engaged.

The primary care lead and radiology lead are also involved with the local Cancer Alliance who have plans to roll out the SCAN pathway model across the Thames Valley area.

Interpretation

One of the reasons the steering group was effective was that it was formed during the early planning stages of the pilot, which ensured that members had a clear understanding of the purpose of the ACE SCAN pathway and enabled them to contribute to the design of the pathway, ensuring they felt ownership. The non-involvement of the MDC clinicians could be a risk in the long term, though there plans to continue liaising with them following steering group meetings and to provide a mechanism for their issues to be discussed and acted upon.

G.3.3 Mc Evaluation of capacity

Context and Mechanism

As discussed in section Ma, the navigator capacity has been under pressure, mainly due to the fact that the radiographer navigator has a number of responsibilities, including; triaging referrals, consenting patients for research which is nested within the pilot, scanning patients, attending MDCs with patients, reporting findings to GPs, helping the data analyst to retrieve secondary care data and performing a range of associated administrative duties. The need to fulfil all of these responsibilities is causing significant pressure and is not sustainable. Unfortunately, the navigator from a nursing background is unable to triage referrals or carry out the scans and as she works part time has limited capacity to provide support with the administrative tasks.

CT capacity has not been a problem due to the fact that the department as a whole and the radiographer Navigator are extremely flexible and able to offer scan after normal working hours and on weekends if necessary.

Interviewees did not report pressures in other diagnostic services.

MDC capacity is an ongoing issue. Problems were experienced when the MDC had to be put on hold due to the initial clinicians being unable to provide the service. During that time patients were either diverted elsewhere or those who were deemed as non -urgent

following their CT were put on a waiting list. Two different clinicians now provide 4 slots each per week. This was sufficient to deal with demand at first but as numbers of referrals have increased there is now insufficient capacity. This additional workload is not included in their job plans, neither do they have the capacity to attend meetings or follow up patient related actions.

Characteristics of mechanisms and outcomes

The navigator role is complex and varied and there is a recognition that some of the activities undertaken by the post holder could be done by someone else, as a result a job description has been developed for an administrative post to help with the inputting and extraction of data:

"Yes there is a lot to do and it's really busy now the numbers (of referrals) have increased but the job description for the data person has been done and I believe it will go out to advert soon, it needs to as I just haven't got the time to be doing it" Radiographer navigator

In an effort to solve the growing backlog of referrals of patients needing to be seen within a MDC, one of the initial clinicians (who left to take up another post) has agreed in the short term to provide additional support:

"So DD who was the previous doctor that was doing it, has come back to do some at weekends and he's doing like a whole day on Saturdays to help clear them (the patients)"

MDC clinician

Interpretation

New roles such as the navigator role often develop organically and as a result careful monitoring and review are required to ensure that the tasks undertaken are appropriate and that the post holder has sufficient capacity to deliver their key functions.

Capacity issues can also occur when clinicians are asked to take on responsibilities in addition to their routine responsibilities. A review of job plans and having clear job descriptions that include administrative time prior to commencing involvement in the pilot may have alleviated some of the frustrations relating to following up tests, making onward referrals and referrals and attending steering group meetings.

G.3.4 Md Connections and communication between professionals

Context and Mechanism

There was agreement across a range of stakeholders including primary and secondary care that there were problems identifying cancer presenting with vague symptoms and that it would be appropriate to design a primary care led pathway for patients with "low but not no risk" symptoms of cancer, falling outside 2 week wait pathways. In order to communicate this both internal and external communication plans were developed.

Characteristics of mechanisms and outcomes

A significant amount of formal communication was planned, with pilot updates being communicated both within primary and secondary care in a variety of formats. Interviewees reported that communication was good, with consistent messages being conveyed in a wide variety of formats:

" We've tried to ensure that everyone is updated on progress with the pilot and we've used different mechanisms to do this, including; newsletters, pieces in existing newsletters and email updates, of course you can always do more in terms of communication but what we've done to date seems to have been effective" Project manager

The SCAN pathway and referral criteria were also sent to GPs and there is some anecdotal evidence that this combined with discussions with practices helped raise awareness of the pilot.

Interpretation

The importance of the need for providing consistent messages in a range of formats across directorates/stakeholder organisations is vital if all stakeholders are to be kept informed and engaged.

G.3.5 Me Leadership

Context and Mechanisms

There were clinical leaders from primary care, secondary care and academia supported by technical staff and managers from the CCG and secondary care who were responsible for designing and implementing the MDC pathway. Project management was provided by CCG project managers.

Characteristics of mechanisms and outcomes

The leads for primary care, secondary care and academia all had their own structures and processes in place with their respective teams, as a result they took leadership responsibility for their own areas of expertise and for feedback from the steering group to their own teams, ensuring any actions were addressed.

This devolved style of leadership has enabled the team to effectively implement the SCAN MDC pathway and test out the systems and processes they have developed.

Interpretation

Consistent credible leadership is vital for a project to succeed. Where a model of joint leadership is employed it is essential for the leaders to have a clear, shared vision and implementation plan to work to.

G.3.6 Mf Data

Context and Mechanisms

A significant amount of data collection was required to support this project, some of it outside of the ACE requirements to support the nested study, in order to collect this, data sharing agreements needed to be developed.

Characteristics of mechanisms and outcomes

Developing and progressing the data sharing agreement took a significant amount of time and a lot of liaison between key stakeholders. At the time of the final interviews it looked like it was going to get signed off imminently, but the process had proved frustrating for all involved:

"I hadn't anticipated how long it would take to sort this out or how frustrating the whole thing would be" Macmillan GP Facilitator/Clinical researcher

"The whole data sharing agreement has definitely been the biggest challenge, it's taken an inordinate amount of time to resolve, you think something has been agreed and then find out it hasn't, it's been one step forwards and 2 steps back. However we have a meeting next week when hopefully it will get signed off" Project manager

In addition the data analyst is currently having to get data from more than one database and currently does not have access to secondary care data. As a result, the navigator has been accessing the secondary care data on behalf of the data analyst which has caused additional pressure on her role. There are however plans in place to alleviate this by recruiting some administrative support to help with inputting and extracting data.

Interpretation

The data sharing issues have been complex and taken up a significant amount of time, with hindsight it may have been better if these had been addressed in the planning stages of the pilot prior to seeing patients.

G.3.7 Mg Primary Care education

Context and Mechanisms

In order to make GPs aware of the SCAN pathway the CCG project manager ensured that all practices had access to the pathway and referral criteria. This was delivered alongside training regarding common cancers and existing 2 week wait referral pathways.

Characteristics of mechanisms and outcomes

The CCG project manager, GP lead and clinical researcher were all active in promoting the SCAN pathway pilot at a range of primary care education meetings. Individual practices were also visited to reinforce information about the project and promote referral. The navigators routinely feedback to primary care once the patient has been seen in the MDC, they also liaise with the GP at the point of referral if there any queries or if the referral is inappropriate.

The education to GPs appears to have been effective as interviewees report that the majority of practices are referring to the SCAN pathway:

"Yes, the education seems to have worked, the majority of practices are now referring in and the numbers of referrals have increased accordingly" Navigator

Interpretation

Utilisation of existing primary care meetings appears to have been an effective way to access a number of practices to reinforce the messages about the SCAN pathway.

Regular contact from the navigators appears to have been viewed positively and has been a useful mechanism for developing credibility and for reinforcing messages around referral criteria and the purpose of the pathway.

4.0 Conclusions

26 1:1 interviews were conducted throughout the evaluation period, generating a significant amount of qualitative data. The CMO configuration presented reflects the key findings resulting from our analysis.

To summarise, the outcomes specified in the CMO table (figure 2) were evidenced in the following ways:

O1. Faster route to diagnosis – there is a perception that prior to the development of the SCAN pathway some patients were managed in primary care for an unnecessary amount of time because GPs did not have an appropriate pathway to refer them on or alternatively they were bounced around the system, creating unnecessary delays in diagnosis. Informal feedback from GPs indicates that this has been a faster route to diagnosis for cancer patients and in some instances for non-cancer patients, although this has not always been the case due to the fact MDC waiting lists have developed due to lack of MDC clinician capacity.

O2. Understanding of staffing/capacity needs – Interviewees state they understand capacity better in relation to the SCAN pathway. Recently demand for the service has increased, there have also been problems with MDC clinician capacity and short term measures have been employed to manage the backlog of patients. However there remains a need to review the navigator role and capacity and develop a plan to ensure sustainability of the MDC clinician role.

O3. Detection of diseases other than cancer- Interviewees report that they have identified a significant amount of non-cancers requiring ongoing management.

O4. Engagement from all relevant departments – Interviewees report good engagement from the majority of departments.

O5. Uptake of the pathway – At the time of the final set of interviews, the majority of GP practices were using the pathway, there is anecdotal evidence that they find it useful.

Demand has increased and as a result of positive feedback from both GPs and patients, they aim to roll the model out across the Thames Valley Cancer Alliance area.

O6. Evaluation of patient experience – Patient experience has been evaluated and both formal and informal feedback suggests that the pathway is valued, in particular the support provided pre diagnosis by the Navigator.

In terms of Oxfordshire's underlying programme theory, they believed that by developing a pathway enabling a quick diagnosis for patients with vague symptoms, patient experience and outcomes will improve. We have both anecdotal evidence from the interviews and data from the ACE patient experience survey which indicates that patient experience is good.

Oxfordshire also believed that the role of the navigator would also enhance the patient experience, anecdotal evidence seems to support this theory. Oxfordshire also originally provided MDC clinic appointments outside normal OPD hours as they felt this would also enhance the patient experience. Due to the change in clinicians staffing the MDC, however, the majority of patients are being seen within normal OPD clinic hours and we have no way of evidencing whether this is the case.

Applying a Normalisation Process Theory (NPT) framework to our findings, we conclude that the pilot has tested systems and processes and many elements of the pathway have become normalised (see section 2.2 for detail on Normalisation Process Theory), these have been analysed using a NPT framework and the results are shown in table 1.

Table 1 Oxfordshire Normalisation Process

	Coherence **What is the work?**	**Cognitive participation.** **Who does the work?**	**Collective action** **How does the work get done?**	**Reflexive monitoring** **How is the work understood?**
Systematic explanation of mechanisms and components at work	Oxfordshire CCG, Oxford University Hospital Trust recognised it as building upon previous cancer pathway redesign work. Education events and regular feedback from the Lead GP and the, Project Manager have reinforced the mechanisms of the process	GPs refer patients with concerning vague symptoms. Navigator checks the referral and arranges initial scan Patients are seen in MDC and informed of results. Where findings require it patient is moved to appropriate pathway	Training was provided in relation to the pathway to the GPs. The Navigator was given training and an in-depth induction and ongoing support for provided by the Consultants. Detailed protocols for the pathway were also developed	Working closely with the steering group helped appraisal of systems and processes by all stakeholders involved

Knowledge about the sources and operation of investments at work	The majority of practices understood the mechanism of referring patients and how it linked with the pathway. The education events with the GPs seemed to address these issues.	Value of the intervention was promoted by proponents of the service from h primary and secondary care. There was consensus that the intervention was worthwhile from a patient perspective.	GP practices engaged in referring patients to the MDC and doing initial bloods. Navigator responsible for checking referral and ordering missing bloods also for recruiting patients into nested research. Navigator/ Radiology for CT scans. Navigator for booking patients into MDC. The consultants see the patients in clinic and manage them accordingly, refer on as appropriate or discharge back to the GP where possible with a diagnosis.	There is good understanding of factors affecting the pathway across key stakeholders with the Steering group proactively managing issues and continuing to shape and develop the service as it rolls out and as they get an opportunity to scrutinise data. However there is a slight disconnect between the MDC Clinicians and wider work as they were not involved in the pilot from the outset and due to capacity issues are unable to attend the steering group.
Core questions	**How is a practice conceptualised by participants?** Viewed positively by General Practice, Oxfordshire CCG and Secondary care	**How do participants come to engage with a practice?** Practices were initially approached by the Lead GP and Project Manager The project was actively supported by the CCG, the University and Oxford University Hospital Trust. More sustained engagement due to education and training of practices and ongoing support	**How do participants enact a practice?** Follow protocol. Enlist support from Project Manager or other leads within the team when necessary.	**How do participants appraise a practice?** Appraisal and feedback encouraged via regular informal discussions between Primary Care, Academic and Radiology Leads and formally via the steering group.
Core questions	**How does it hold together in action?** Most GP Practices referring to the SCAN pathway. The Navigator reviewing the referral and arranging missing investigations. Radiology coping with demand for the CT scans though this is due to the flexibility of the department and in particular the Radiographer Navigator. Her current level is not sustainable in the long term. Navigator also provides administration and tracking function, again this is due to be addressed but is not sustainable in the long term. MDC Clinicians have more demand than capacity, this is currently being dealt with by an additional clinician doing an extra clinic on weekends, and again this is not sustainable moving forward. Stakeholders feel that the service	**How do they decide on engagement and the purposes that it serves?** Discussions around value to the patient, Consideration of additional workload and subsequent impact on capacity. These discussions are via the steering group	**How are their activities structured and constrained?** Practices are responsible for referring the patients to the SCAN pathway. The Navigator is responsible for checking referral and ordering missing bloods also for recruiting patients into nested research. Navigator/ Radiology for CT scans. Navigator for booking patients into MDC. The consultants see the patients in clinic and manage them accordingly, refer on as appropriate or discharge back to the GP where possible with a diagnosis. Navigator capacity is an issue as is MDC capacity and whilst they are managing at the moment the mechanisms in place are short term solutions only	**What are its effects of appraisal?** **Appraisal has resulted in small changes to the pathway**

Appendix H –GP Interviews

All sites were asked to provide names of GPs who had and had not used the pathways. 4 GPs from three sites consented to be interviewed. All 4 had used their local MDC pathway. One was from Airedale, one from Leeds and 2 from Oxford. All had used the pathway at least once, some up to 8 times.

Information about the pathways came to GPs through a variety of methods, often through personal contact. Some information comes through newsletters, but due to the number of pathways information can be missed.

> *"We were sent the information, but I get pathways for about 100 different things. I don't remember them all. Unfortunately, the SCAN pathway, which is the simplest, and the one that works best, went under the radar."* Oxford GP 1

GPs who had used the pathway and found it positive often reported that they discussed the pathway and recommended it to colleagues. Personal connections were an important way of raising awareness of the pathway.

> *"I had such a positive experience of it that I pinged an email round to the practice saying "This is wonderful. We should use this. It's really good"* Oxford GP 1

The feeling was that the pathways filled a gap in the system and provided a way to refer patients with concerning symptoms who did not fit into any current 2 week wait pathways. Prior to the introduction of the ACE pathway, GPs described having problems getting people into the right pathway as patients presented with symptoms that may not fit the criteria for any pathway exactly.

> *"You can fudge the system and force them into one system or the other knowing that even if I send them into the lung cancer system and it turns out to be something else, they'll sort it… the real bonus of this system is that we can be very honest in our referrals now in a way that we couldn't do before"* Oxford GP 2

While there are many similarities between the different ACE pathways, one difference between the SCAN pathway in Oxford and the ACE MDC pathways in Leeds and Airedale is the blood tests ordered by GPs. In Leeds and Airedale there is a battery of tests that GPs are required to do prior to referral. In Oxford, tests are ordered at the same time as a referral is

made so that all the tests are done by the time the patient is seen in the pathway. For GPs in Oxford, this process makes the system easy to use. For the other pathways, GPs reported sometime starting out considering referring to the ACE pathway, but once the tests has been done, the results suggest another pathway or treatment.

> *What we haven't got reported is people who start on the ACE pathway, because at the end of the day, the screening tests that you ask for potentially pick up a fair bit of pathology. Which stops those patients then being sent to you"* Leeds GP

Once referred into the pathway, GPs were happy with the feedback and outcomes from the MDC pathways.

> *"We tend to get a letter back from the oncologist, which tends to be really detailed with all the scan results and the follow up and what's planned from them. It's really thorough and quite helpful, it's done in a really timely fashion as well."* Airedale GP

While feedback was generally timely, there were delays initially in Leeds. However, this was resolved as the pathway became established.

> *"I did send [GP lead} back some stuff, the feedback….We didn't get the letters for about another six weeks, but I'm assuming things improved after that, because this is one of the early ones in the pilot"* Leeds GP

Having named people within the pathway who GPs could talk to if needed was a positive factor for GPs. The communication between the GPs and other clinician was felt to be effective.

> *"The specialist nurse that runs the clinic, I've spoken to her quite a few times. I have to ring her about things. She's been really helpful"* . Airedale GP

> *"It doesn't surprise me that it works very well. You've got clinicians working together to try and help a patient because communication backward and forward is very good"*
>
> Oxford GP 2

The GPs reported a range of outcomes, both cancer and non-cancer. Non-cancer diagnoses include benign renal disease, diverticulitis and adverse reactions to antibiotics. 2 of the 4 GPs reported that cancers had been detected through the pathway. Cancer findings were often late stage.

"I've had a couple of diagnoses from it, which were abdominal cancers …… Most of them have been relatively late, advanced cancer" Airedale GP

The feedback from GPs who used the services was generally positive. All were concerned about the future of the service and hoped it would continue after current funding finishes as it fills a gap for people who do not fit in any current 2 week wait pathways, but need to be seen as they have concerning symptoms.

"I think if it went away and there was no replacement, we'd be back to the old system of either having to make stuff up in order to get people gatewayed in to clinics that they're not particularly appropriate for. Or admitting people to hospital"