





General Practitioner Direct Access to CT Pathway: A Novel Straight-to-Test Model for Patients With Non-Specific Concerning Symptoms

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ABSTRACT

Background: This study aimed to evaluate the direct-to-test computed tomography (CT) scan pathway for primary care for the investigation of patients with non-specific and serious symptoms (SNSS) that may be related to a diagnosis of underlying cancer. **Methods:** We evaluated all patients referred to the Sunderland Serious Non-Specific Symptoms pathway directly to the CT scan pathway between December 2017 and June 2019 to assess the rate of SNSP, cancer diagnoses, frequency of benign conditions, and effectiveness of the service. Patients over 18 with non-specific symptoms including unexplained weight loss, recent or progressive pain of unknown aetiology, severe constitutional symptoms or other symptoms that made the general practitioner (GP) to be suspicious of malignancy were offered rapid access contrast-enhanced CT scanning of the thorax, abdomen, and pelvis.

Results: A total of 411 patients were referred through the GP CT pathway. Of these 411 patients, 46 were diagnosed with cancer, whilst 76 were diagnosed with an incidental finding. Twelve different cancers were diagnosed in total, with an average time to diagnosis of 14 days. Of the cancer diagnoses, just over a quarter were diagnosed at Stage 1.

Conclusions: The SNSS pathway is a streamlined GP direct access CT service for patients with serious but non-specific symptoms and has similar aims to the Accelerate, Coordinate, and Evaluation (ACE) Wave 2 pathways, which were funded by Cancer Research UK. The SNSS pathway was successful in reducing the time from the presentation of symptoms in primary care to a definitive diagnosis for patients with non-specific symptoms and has the potential to increase the proportion of cancers diagnosed at an early stage. As a direct-to-test pathway, the cancer conversion rate of 11% was higher than many other similar SNSS paths reported in the literature.

Abbreviations: ACE, Accelerate, Coordinate, and Evaluation; CT, computed tomography; GP, general practitioner; MDC, multidisciplinary diagnostic centre; SNSS, non-specific and serious symptoms; STSFT, South Tyneside and Sunderland NHS Foundation Trust.

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1 of 7

1 | Introduction

Cancer survival rates in the United Kingdom fall behind those in other European countries. Late diagnosis is a key contributor to the low survival rates of cancer in England. It is estimated that at least 5000 deaths could be prevented each year in England with earlier diagnosis [1, 2].

Of all cancers diagnosed in England, 21% are diagnosed after presenting as an emergency, with over three-quarters diagnosed as late-stage cancer. Those who presented as an emergency had higher mortality rates, particularly within the first month of diagnosis. Emergency patients were more commonly older patients with an advanced stage of cancer [3].

Amendments to existing cancer pathways have been trialled to reduce the proportion of patients presenting with late-stage cancer. For example, a Danish three-legged multidisciplinary diagnostic centre (MDC) cancer model was implemented for patients with non-specific and serious symptoms (SNSS) and signs of cancer (NSSC-CPP). The Danish three-legged strategy for diagnosing cancer, which includes urgent referral pathways to secondary care for symptoms suspicious of a specific cancer, urgent referral to diagnostic centres for rapid evaluation of patients with non-specific, serious symptoms and easy access to 'No-Yes-Clinics' for cancer investigations for those patients with common symptoms in whom the diagnosis of cancer should not be missed [4].

Between March 2012 and March 2013, an analysis of 1878 patients of a multidisciplinary diagnosis centre for patients with serious non-specific symptoms in Denmark found 16.2% had a cancer diagnosis after 6 months of follow-up. The most common types were lung cancer (17.9%), colorectal cancer (12.6%), haematopoietic tissue cancer (10.1%) and pancreatic cancer (9.2%) [4].

An alternative model, the suspected CANcer (SCAN) pathway, was developed in Oxfordshire [5], based on both the Danish MDC and Accelerate, Coordinate, and Evaluation (ACE) Wave 2 pathways, which was funded by Cancer Research UK (CRUK) [6]. Patients presenting to their general practitioner (GP) with non-specific but concerning symptoms underwent initial diagnostic tests, for example, blood investigations. If these were inconclusive and cancer was suspected, patients

were referred to the MDC, which had access to a range of specialist expertise and clinical tests. The evaluation is still ongoing, but initial findings suggest that this pathway is increasing diagnoses of early-stage cancer.

Computed tomography (CT) scanning is a commonly used investigation in secondary care, both to evaluate patients with a potential diagnosis of malignancy, also to stage cancers at presentation and monitor the efficacy of treatments in patients with cancer.

The Sunderland Non-Specific Symptoms pathway was set up in 2017, funded in part by the Northern Cancer Alliance, to allow a pilot direct-to-test route from primary care to secondary care diagnostic services for the evaluation of patients with symptoms assessed as being serious but not organ-specific. The inclusion criteria for the Sunderland pathway are listed in Table 1. The patient group captured by the Sunderland pathway is similar to that of the other national ACE pilot sites, but the direct-to-test model makes it unique amongst the pilot pathways.

The current objectives of the SNSS pathway are closely aligned with the CRUK ACE initiative, which has overarching objectives to increase early cancer diagnosis, reduce emergency presentations of malignancies and improve the patient experience.

The objectives of the SNSS pathway are as follows: (1) To reduce the time to diagnosis for this patient group from the first presentation of symptoms in primary care to a definitive diagnosis. (2) To improve the overall patient experience by reducing the number of stages that patients follow before having a confirmed diagnosis and treatment plan. (3) To obtain information on the level of alternative (noncancer) diagnoses causing the patient's symptoms and the level of incidental findings demonstrated on CT imaging in this group. (4) To obtain primary care physicians' perspectives about their experiences of the pathway.

Thus, our evaluation question was the following: 'What are the measurable impacts of GP direct access to CT scanning of the thorax, abdomen and pelvis with expedited referral in patients with non-specific but concerning symptoms?' The pathway was evaluated based on the short- and long-term diagnostic yield. Patient experience and pathway satisfaction were also evaluated, as well as GP experience with the pathway.

TABLE 1 | Referral criteria and exclusion criteria for SNSS GP CT scan.

Inclusion referral criteria	Exclusion criteria
Unexplained weight loss of more than 5% within the preceding 3 months	Glomerular filtration rate (GFR) of less than 45
Recent or progressive pain of unknown aetiology of more than 4 weeks duration	Known allergy to contrast media
Severe constitutional symptoms, for example, fatigue, nausea, sweats of unknown aetiology of more than 4 weeks duration	Known risk of contrast-induced nephropathy
Other symptoms causing the GP to have a high suspicion of malignancy, (often described as GP's 'gut feeling')	Morbid obesity
The patient does not fit any other urgent or 2-week criteria based on GP's assessment of their clinical symptoms	Age under 18 years

2 of 7 Organ Medicine, 2025

2 | Materials and Methods

2.1 | Ethical Considerations

This study was classified as a service evaluation and falls outside the definition of research within the NHS as defined by the Health Research Authority. Approval for the evaluation was given by South Tyneside and Sunderland NHS Foundation Trust (STSFT), and Caldicott approval was given. Consistent with other SNSS service evaluations that form part of the national ACE projects, informed consent was not been obtained, as this project is a service evaluation.

2.2 | SNSS Pathway

Patients over 18 years of age who presented to primary care with non-specific symptoms that included unexplained weight loss, recent or progressive pain of unknown aetiology, severe constitutional symptoms or other symptoms that could indicate malignancy were offered rapid access contrast-enhanced CT scan of the thorax, abdomen, and pelvis. If the GP suspected that a patient was eligible to be referred to this route, he completed a set of routine investigations (Figure 1) at the point of referral for CT.

The referral and exclusion criteria for the straight-to-test pathway are provided in Table 1.

The radiology department then conducted an internal escalation of positive findings suggestive of malignancy to the relevant subspecialty for outpatient review and multidisciplinary team (MDT) discussion. Any urgent or unexpected findings were communicated to the GP in accordance with the Radiology Department Standard Operating Procedure for the notification of unexpected or urgent findings.

The GP reviewed the patients with negative findings, and a decision was made for expectant management or referral to the relevant subspecialty based on screening information and clinical assessment.

2.3 | Setting

The local population of Sunderland is primarily urban or semiurban and is relatively stable without great mobility. Social

Box: Tests Performed in Primary Care at Referral

Full Blood Count (FBC)

Urea and Electrolytes (U & E)

Liver Function Tests (LFTs)

C Reactive Protein (CRP) or Erythrocyte Sedimentation Rate (ESR)

Mid Stream Urine (MSU)

Myeloma Screening

Cancer Antigen 125 (CA125)

Prostate Specific Antigen (PSA)

FIGURE 1 | Tests performed in primary care at the point of referral.

deprivation affects a significant element of the population, which is higher than the national average. There is a significant burden of morbidity from a heavy industrial history, with cancer rates in the under-75 group significantly higher compared with the national average. The index of multiple deprivation in Sunderland is 38 compared to the national average of 20 [7].

STSFT is a large acute Trust located within the city of Sunderland. Provides cancer services to the local population of approximately 285,000 people and subregional services to a population of 850,000 in some subspecialties, including urology. Service delivery is supported by tertiary and regional services based in Newcastle upon Tyne providing oncology and radiotherapy. STSFT is the main secondary care provider for the local population commissioned by the Sunderland Clinical Commissioning Group (now Northeast and North Cumbria Integrated Care System [ICB]), comprising 38 general practices in 5 localities.

The cancer incidence rate in Sunderland (663.1 per 100,000) is higher than the English average (606.7 per 100,000). The cancer mortality rate in Sunderland (338.9 per 100,000) is also higher than the English average (285.4 per 100,000). The rate of people under 75 years of age dying of cancer (classified as premature cancer deaths) in Sunderland (175.5 per 100,000) is higher than the English average (141.5 per 100,000) (Public Health England, 2016). One-year cancer survival in Sunderland (69.4%) is similar to the English average (70.2%). In total, 20.9% of Sunderland patients are diagnosed with cancer through emergency routes. This is similar to the English average (20.1%). The higher number of patients diagnosed through emergency routes may indicate a late diagnosis and may be closely related to poor survival. Less than half (48.4%) of cancers with a known stage are diagnosed early in Sunderland [7].

2.4 | Recruitment

Participants were recruited from 38 GP practices in Sunderland referring to the direct access CT service within STSFT from a population base of 285,000 patients within Sunderland.

2.5 | Data Collection

Primary endpoints included the following: (1) Diagnostic yield in terms of the number and type of cancers detected; (2) Stage of the disease at presentation if a malignancy is demonstrated on CT; (3) Number and nature of noncancer diagnoses. (4) Patient and GP experience and surveys to gain feedback.

Data were collected on an Excel spreadsheet regarding the number of patients referred, demographic information, symptoms leading to referral, investigations performed, onward referrals made both for suspected malignancy and evaluation of incidental findings, dates of clinic appointments, and MDT

discussions and short-term (within 30 days) diagnoses including grading and staging of malignancy where applicable. The patient evaluation was conducted in two waves to explore their experiences of being referred through the pathway.

2.6 | Data Analysis

Quantitative data regarding the use of services, cancer type and stage were analysed using descriptive statistics.

Data from GP and participant experience surveys were summarised narratively.

3 | Results

A total of 411 patients were referred through the GP CT pathway. The average age of the patient referred was 69 (range 26–93), and the sample was made up of more women (56%) than males (44%) (more detailed demographic information is presented in Table 2).

Of these 411 patients, 404 attended the CT scan, with an average time to the investigation of 14 days. Seven patients chose not to attend their CT appointment.

In total, 46 patients (11%) were diagnosed with cancer, whereas 76 (19%) were diagnosed with an incidental finding. Twelve

TABLE 2 | Participant demographic information.

	n	%
Sex		
Male	180	44.0
Female	231	56.0
Age group		
< 30	1	2.4
30-39	12	2.9
40-49	23	5.6
50-59	63	15.3
60-69	81	19.7
70–79	119	29.5
80-89	102	2.4
90-99	10	2.4
Attendance rates		
DNA	7	1.7
Attended for CT	404	98.3
Cancer stage		
1	12	26.1
2	0	0.0
3	4	8.7
4	26	56.6
Missing data	4	8.7

different types of cancer were diagnosed in total (Figure 2), the most commonly identified being lung cancer (n = 13, 28.3%), followed by haematological cancers (n = 8, 17.4%) and colorectal and pancreatic cancers (n = 5, 10.9%).

The most commonly identified stage of cancer at diagnosis was Stage 1 (n = 12, 26.1%), although around half of the cancer stage data were missing from the final data set.

For patients diagnosed with incidental findings listed in Table 3, the most common systems of abnormality were pulmonary (n = 24) and gastrointestinal abnormalities (n = 20).

There were 76 (19%) incidental findings generated as diagnoses from the 404 patients who attended the CT scan.

3.1 | Findings From the GP Survey

Fifteen general practice staff completed surveys: 12 GPs, 1 advanced nurse practitioner and 2 practice managers. Of these participants, 9 (60%) stated that they were aware the Trust was offering CT scanning for patients from primary care with vague symptoms, and 10 (75%) said they had used this pathway. Of the 10 participants who said they had used the service, 7 (70%) were satisfied with their experience using the pathway. Of the remaining three participants, one had only just sent the referral, and the other two were unsatisfied with their experience. Eight out of 10 who had used the service said that they had received a CT report and that it was clear and well written.

Participants also identified several ways the service could be improved, including having shorter waiting times, letting the GP practice know if the patient does not attend the first appointment, improving the requesting process and providing information on the pathway and what actions are needed when incidental findings are identified.

3.2 | Findings From the Patient Survey

Ninety-one patients completed feedback forms in total, 63 on Wave 1 and 28 on Wave 2 for a response rate of 22%. The patients in Wave 1 reported that they had positive experiences when they were given time to ask questions or talk about their concerns and when they received their results promptly, without having to chase them. For the 28 participants who completed the Wave 2 evaluation, the average number of times they had seen a healthcare professional about their symptoms before referral to the hospital was 3 (range 1-10). Of the 25 who were referred by their GP, 22 (88%) agreed that a member of staff had explained what would happen and that their GP had explained their test results in a way they could understand, either 'definitely' or 'to some extent'. Overall, 16 out of 24 (67%) said they 'definitely' felt involved in the decisions made about their care by the hospital and GP practice, whereas 7 out of 24 (29%) said they did 'to some extent'. Only one participant reported not being involved in their care.

4 of 7 Organ Medicine, 2025

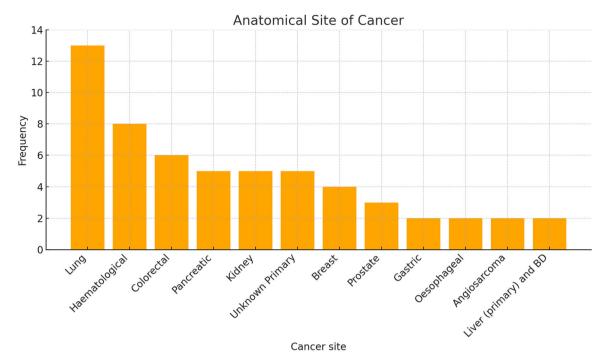


FIGURE 2 | Anatomical site of cancer.

4 | Discussion

We have outlined the initial findings from the SNSS pathway, a streamlined GP direct access to the test model using contrast-enhanced CT. The pathway aims to reduce the time presentation to a definitive diagnosis for patients with serious but non-specific symptoms and to increase the proportion of cancers diagnosed at an early stage in this patient group. Of the 411 patients referred to this pathway, 404 patients underwent CT scanning with 7 patients choosing not to attend their appointment. In total, 11% (46) were diagnosed with cancer.

The most common cancer in this cohort was lung (28%), followed by haematological cancers (17%) and colorectal and pancreatic cancer (both 11%). Approximately a quarter of the patients were diagnosed with Stage 1 cancer, and over half (56%) who had a cancer diagnosis were diagnosed with Stage 4 cancer. Data were missing about the cancer staging in four patients. Nearly one-fifth of patients received a noncancer diagnosis after being referred through the streamlined CT pathway.

The results of the GP and patient satisfaction surveys indicate that although they experienced the direct access service largely positively, there were some areas in which the pathway could improve. For example, both GPs and patients identified a need for shorter waiting times to receive test results, whilst patients valued the opportunity to talk to a healthcare professional about their concerns and be able to ask any questions about the test process. The GPs identified other areas for improvement, such as receiving more information about the pathway and what referrals to make if a patient has a noncancer diagnosis.

The results of this study, with 11% of patients receiving a cancer diagnosis, are higher than in other studies evaluating a streamlined diagnostic pathway. Dolly et al. [8] evaluated 1341

patients referred via GPs to a Rapid Diagnostic Clinic for the evaluation of serious non-specific symptoms between 2016 and 2019. Cancer was diagnosed in 7% of the patients presenting to the clinic with lung, haematological and colorectal cancers being the most common primary sites, and 31% having early (Stage 1 or 2) stage tumours. Serious noncancer conditions were present in 36% of patients through their pathway. The patients in this pathway had a mean age of 62.

Chapman et al. [9] evaluated the results of five MDCs which formed part of a series of MDC pilot sites, in London, Airedale, Greater Manchester, Leeds and Oxford. The patients in this evaluation also presented with similar serious but non-specific symptoms but as the referral criteria for each MDC differed, so this was not a homogenous group. This series of 2961 patients referred from primary care had an average age of 66.7 demonstrated an 8% cancer detection rate with upper gastrointestinal and lung cancers being the most common. Most of the cancers (54.4%) detected were at a late stage of disease, Stage 4. There were no data about other conditions detected by the MDC pathway.

In general, the UK-published series of the MDC model pathways, which includes our pathway, has a lower cancer detection rate than the earlier Danish series on which the MDC model was based. Ingeman et al. [4] in a series of 1278 patients with serious non-specific symptoms with a mean age of 65.9 years reported a 16.2% cancer diagnosis rate within 6 months, of which the most common primary sites were lung (17.9%), colorectal cancer (12.6%), haematopoietic tissue cancer (10.1%) and pancreatic cancer (9.2%). A strong association was found between GP-estimated cancer risk at referral and the probability of cancer, often described as the 'GP's gut instinct'.

Few studies have addressed the question of the costeffectiveness of MDC pathways, with most published series

TABLE 3 | Incidental findings on CT scans.

Organ system	Nature of finding	
Pulmonary	Pulmonary nodules	14
	Atelectasis	5
	Mediastinal adenopathy	1
	Lobar collapse	1
	Bronchiectasis	3
Cardiac	Pericardial effusion	1
Vascular	Abdominal aortic aneurysm	1
	Thoracoabdominal aortic aneurysm	1
	Dilated aortic root	1
Renal	Renal calculus	4
	Ureteric calculus	1
	Complex renal cyst	1
	Pyelonephritis	1
Head and neck	Thyroid goitre	2
	Thyroid cyst	1
	Thymic lesion	1
Gastrointestinal	Rectal polyp	1
	Small bowel obstruction	1
	Achalasia	1
	Retroperitoneal lymphatic lesion	1
	Polyp ascending colon	1
	Oesophageal wall thickening	1
	Gastric wall thickening	1
	Caecal polyp	1
	Retroperitoneal lymphadenopathy	1
	Inflammatory pelvic mass	1
	Adrenal adenoma	4
	Gallbladder thickening (benign)	2
	IPMN (probable)	1
	Diverticulosis	1
	Diverticulitis/perforation	1
	Pancolitis	1
Hepatobiliary	Common bile duct stone	1
	Liver cirrhosis	2
	Portal vein thrombosis	1
	Bulky but normal pancreatic head	1
	Chronic pancreatitis	4
Gynaecological	Ovarian cyst	4
-)g	Fibroid	1
	Endometrial polyp	1
Non imaging	Threadworms	1

(Continues)

TABLE 3 | (Continued)

Organ system	Nature of finding	
	MGUS	1
	Total	76

focusing on the diagnostic yield of a specific pathway or group of pathways. Assessing cost-effectiveness remains problematic due to the lack of a readily identifiable control group. Sewell et al. [10] address this question in a novel way by using a modelling exercise to assess cost-effectiveness. In total, 189 patients attended a Rapid Diagnostic Centre (RDC) in Port Neath Talbot Hospital in Wales. Of these patients, 46% were male, and the mean age was 70 years (standard deviation [SD] = 12.9 years; minimum = 26; maximum = 95). Most patients presented with unexplained weight loss, pain, fatigue and shortness of breath.

The RDC outcomes were categorised into four groups: cancer diagnosis with referral to a specialist (n = 23, 12%), noncancer diagnosis (n = 30, 16%), no serious pathology found with discharge to GP (n = 68, 36%) and no diagnosis; continue investigations (n = 68, 36%). From these data and using a complex modelling exercise, they note total staff costs per half-day clinic were calculated as £2640 with CT scan and other test costs amounting to £118.21 per patient. At its start-up phase, the RDC they analysed was seeing 2.78 patients per clinic. Their modelling study while complex and based on multiple assumptions (which the authors acknowledge). Their study makes the point that maximum capacity of five patients per clinic, RDC outperforms standard clinical practice with a 56.0% probability of being cost-effective. This study is of importance as it is the first to highlight the relatively high staff cost issue in the RDC model compared with the relatively low investigation cost. Logically, this would make a direct-to-test (DTT) model more financially viable.

Certainly, the DTT model we have reported produces a very similar cancer detection rate with a similar spectrum of primary tumours compared to the clinic-based MDC models. A high proportion of patients presenting with late-stage cancers is a feature of all the reported pathways.

The strengths of this evaluation were the incorporation of both patient and primary care feedback into the evaluation, a feature which is not present in the other published MDC pathways. This pathway also features a DTT model where the initial investigations are performed in primary care, and the CT scan of the thorax, abdomen and pelvis is performed at the request of the GP if the referral criteria are met, without any clinical triage at secondary care. In this model, the patient remains under the care of the GP who has assessed their symptoms and is only referred to secondary care services dependent on symptomatology and test findings. This reduces the number of patients absorbed into secondary care systems and streamlines the investigation process for patients. In the context of the COVID pandemic and the necessity of reducing face-to-face contact during this period, the pathway proved resilient and remained fit for purpose.

6 of 7 Organ Medicine, 2025

The limitations of the evaluation were the relatively low response rate from the general practice workforce survey. The lack of an identifiable control group has been highlighted as a weakness in all the published evaluations of the SNSS pathways. There are no convincing data on the outcome for this largely uncaptured patient group before the advent of the pathways, so it cannot be demonstrated conclusively that their outcomes in terms of rapidity or cancer diagnosis of disease stage are improved as a result of the pathways. General practice feedback was positive and also enabled further improvements to the pathway on an iterative basis. Patient experience questionnaires produced overwhelmingly positive feedback with patients feeling more involved in their care. There is a small amount of missing data concerning cancer staging with 8.7.% of patients having no recorded stage of their cancer, which could be verified.

The data and results of this evaluation are specific to this pathway model in the context of the local population of Sunderland. The results and outcomes are not generalisable outside this context.

5 | Conclusions

Late diagnosis of cancer, which often manifests as an emergency presentation, remains a significant healthcare challenge in the United Kingdom, which lags other European countries in many aspects of cancer outcomes. Cancers do not always present, usually as outlined in the 2-week waiting pattern for guidance. This research provides a pathway which could help reduce the late diagnosis of cancer.

Author Contributions

Julie Cox and Yitka Graham designed the evaluation pathway. Julie Cox oversaw database development. Julie Cox and Yitka Graham wrote the protocol. All authors reviewed and provided comments on the article, were involved in the execution of the evaluation and analysis of results and have read and approved this article.

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Ethics Statement

This study is not classed as research as it is an evaluation of an adopted service and therefore falls outside the definition of research within the NHS, which is defined by the Health Research Authority (HRA). As such, this evaluation is not subject to the Department of Health's Research Governance Framework for Health and Social Care (2017). Consistent with other vague symptoms service evaluations that form part of national ACE projects, informed consent has not been obtained, as this project is not research. As this evaluation is not research, but an evaluation of a service, informed consent was deemed unnecessary. This project has obtained clinical governance and departmental approval within STSFT, as well as Caldicott approval from the Caldicott Guardian to contact patients with an anonymised patient experience survey.

Consent

As the study was not deemed research, informed consent was not required.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data will be provided on reasonable request.

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