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Qualitative interview study exploring the early identification and referral of patients with suspected head and neck cancer by community pharmacists in England

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ABSTRACT

Objective To explore pharmacists' perceptions of, and attitudes towards, the early identification and referral of patients with signs and symptoms indicating potential diagnosis of head and neck cancer (HNC) in community pharmacy settings.

Design Qualitative methodology, using constant comparative analysis to undertake an iterative series of semistructured interviews. Framework analysis facilitated the identification of salient themes.

Setting Community pharmacies in Northern England.

Participants 17 community pharmacists.

Results Four salient and inter-related categories emerged: (1) Opportunity and access, indicating frequent consultations with patients presenting with potential HNC symptoms and the accessible nature of community pharmacists; (2) Knowledge gap, indicating knowledge of key referral criteria, but limited experience and expertise in undertaking more holistic patient assessments to inform clinical decision making; (3) Referral pathways and workloads; indicating good working relationships with general medical practices, but limited collaboration with dental services, and a desire to engage with formal referral pathways, but current practices based entirely on signposting resulting in a potential lack of safety-netting, no auditable trail, feedback mechanism or integration into the multidisciplinary team; (4) Utilisation of clinical decision support tools; indicating that no participants were aware the Head and Neck Cancer Risk Calculator (HaNC-RC V2) for HNC but were positive towards the use of such tools to improve decision making. HaNC-RC V2 was seen as a potential tool to facilitate a more holistic approach to assessing patient's symptoms, acting as a prompt to further explore a patient's presentation, requiring further investigation in this context.

Conclusions Community pharmacies offer access to patients and high-risk populations that could support HNC awareness initiatives, earlier identification and referral. However, further work to develop a sustainable and cost-effective approach to integrating pharmacists into cancer referral pathways is needed, alongside appropriate training for pharmacists to successfully deliver optimum patient care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The early detection of cancer is a worldwide health priority. There is limited research into the role of pharmacists in this context; this is the first qualitative study that has explored the role of community pharmacists in the early identification and referral of head and neck cancer.
⇒ Semistructured interviews provided rich qualitative data exploring community pharmacists' experiences in practice.
⇒ An iterative process of concurrent data collection and constant comparative analysis facilitated the simultaneous exploration, refinement and enrichment of key themes.
⇒ All participants were recruited from English community pharmacies, limiting the transferability of findings to different healthcare systems.

INTRODUCTION

The early recognition of cancer symptoms is a priority for the WHO; timely diagnosis and access to treatment improves the probability of survival as well as less morbid and expensive treatment.[1] Therefore, strategies to promote the recognition of warning signs and symptoms and to expedite the diagnosis of symptomatic cancer are required.

The role of community pharmacies in the early detection of cancer is gaining increasing attention.[2–4] In June 2022, National Health Service (NHS) England announced that pilot schemes will be developed in community pharmacies, allowing pharmacists to refer patients with potential signs of cancer directly into secondary care to meet the ambition of the NHS Long Term Plan to increase the proportion of cancers identified at an earlier stage.[5 6]

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Pharmacies are easily accessible; 90% of the population in England lives within a 20 min walk of their local pharmacy, with even greater accessibility (99.8%) in the areas of highest deprivation.[7] Recent statistics show that there are over 1.2 million informal consultations in community pharmacies in England each week; nearly a quarter of a million of these consultations result from patients being unable to access another part of the NHS.[8] This highlights the strain across the healthcare system, but also the potential for pharmacies to engage with patients.

Head and neck cancer (HNC) is the eighth most common cancer in the UK.[9 10] Incidence rates of HNC are rising; risk factors for HNC include tobacco and alcohol use, and increasingly exposure to high-risk human papillomavirus (HPV).[11] Patients are often only diagnosed when the disease reaches an advanced stage.[10] Therefore, HNC represents an example of where there is a need to explore mechanisms for earlier identification and referral of patients with signs and symptoms suggestive of HNC.

Signs and symptoms of HNC are dependent on the anatomical site affected and can include a range of common symptoms, which patients may present with in primary care, including oral ulceration, white or red patches in the oral cavity, sore throat, hoarseness or ear pain.Many possible signs of HNC are commonly encountered in primary care (such as oral ulceration), and patients may present to pharmacies for self-treatment and advice.Therefore, there is an opportunity for pharmacists, when presented with signs and symptoms potentially indicative of HNC to identify those requiring referral for more appropriate investigations. In the UK, National Institute for Health and Care Excellence Guidelines (NICE) provide recommendations (table 1) on when patients should be referred urgently to a suspected cancer referral (2-week wait) pathway.[12]

Clinical Decision Support Tools (CDST) aim to alert clinicians to early signs and symptoms of undiagnosed cancer and are effective in improving decision making in primary care.[13] The Head and Neck Cancer Risk Calculator (HaNC-RC V2) has been developed to support decision making in HNC;[14] this tool could be used by community pharmacists to support decision making around referrals; however, to the best of the authors' knowledge, this has not yet been explored. The HaNC-RC v2 tool is available via the following weblink http://www.orlhealth.com/risk-calculator-2.html

As such, this study explored the current practices, potential future roles and barriers towards and facilitators of, pharmacists in the promotion of HNC awareness, integration into referral pathways and the potential use of an HNC CDST.

METHOD

Design

This qualitative study adopted an inductive approach collecting data through an iterative series of semistructured interviews with community pharmacists in England.

Table 1 Suspected cancer: NICE recognition and referral recommendations for head and neck cancer[12]

Laryngeal cancer	Suspected cancer pathway referral In people aged 45 and over with: ► Persistent unexplained hoarseness or ► An unexplained lump in the neck.
Oral cancer	Suspected cancer pathway referral: ► Unexplained ulceration in the oral cavity lasting for more than 3 weeks. ► A persistent and unexplained lump in the neck. Urgent referral (< 2 weeks) for assessment for possible cancer by a dentist ► A lump on the lip or in the oral cavity. ► A red or red and white patch in the oral cavity consistent with erythroplakia or erythroleukoplakia Suspected cancer pathway referral by a dentist when assessed by a dentist as having either: ► A lump on the lip or in the oral cavity consistent with oral cancer. ► A red or red and white patch in the oral cavity consistent with erythroplakia or erythroleukoplakia.

NICE, National Institute for Health and Care Excellence.

Individual semistructured interviews lasting up to 45 min were undertaken face to face or using either video conferencing (MS Teams) or telephone, depending on participants' preference while adhering to COVID-19 restrictions.

An initial topic guide (online supplemental document 1) was developed by the lead investigators (AS and SB) based around the following domains: awareness of HNC symptoms and current practices; referral and patient signposting; use of risk prediction tools; perceptions of potential future roles in HNC identification/referral. The semistructured nature provided flexibility to explore other topics during the interview and in subsequent data collection. Interviews were audiorecorded and transcribed verbatim to facilitate analysis.

Participants

An invitation letter (online supplemental document 2) and participant information sheet (online supplemental document 3) were shared via dissemination through Local Pharmaceutical Committee mailing lists, national pharmacy body newsletters (Pharmacy Research UK and British Oncology Pharmacy Association), social media and the professional networks of the study team. An initial convenience sample of participants who responded to the invitation was implemented with snowball sampling (participants were asked to suggest colleagues who may be interested in participating) facilitating further recruitment and additional convenience sampling. Written consent was obtained prior to each interview.

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Analysis

The iterative nature of continuous data collection and constant comparative analysis facilitated the enrichment and further exploration of concepts in subsequent interviews.[15] Framework analysis was used to identify key categories.[16 17]Framework analysis involved a five-stage process: (1) familiarisation with the data— immersion in the data was achieved via iterative cycles of reading and rereading of transcripts and listening to audiorecordings; (2) development of a thematic framework—the initial themes formed the basis of a thematic framework; (3) indexing data—data were indexed against the thematic framework; (4) charting—charts were produced of the data within the thematic framework and (5) mapping of the data—themes were reviewed until definitive concepts could be produced from the data.[16]

Themes were reviewed by the lead investigator (AS) and discussed with the wider research and patient and public involvement and engagement (PPIE) team until definitive concepts were agreed.

Patient involvement

PPIE was integrated throughout the project. Initially, the proposal was discussed during a Sunderland Royal Hospital HNC PPIE group meeting; and a patient representative from the University of Sunderland PPIE group attended project management group meetings. Furthermore, the project has been supported by the Trustees of the Northern HNC Charity.

RESULTS

A total of 17 community pharmacists from the North of England participated in this study; 10 participants were female and 7 were male, 5 worked as locum pharmacists, and experience ranged from recently registered pharmacists to those with over 30 years' experience in community pharmacy. In-depth semistructured interviews were carried out between July 2021 and August 2022 until data saturation was achieved.

Opportunity and access

Participants described the accessible nature of pharmacists and their integration into the communities that they serve. This has become more apparent during the COVID-19 pandemic where pharmacists described being the first port of call for many patients with health needs.

> The real benefit that patients see inis that we are always available, anyone can walk off the street, anytime, anywhere, and speak to a pharmacist. I think the public really seen the benefit of how we support people and help our communities. (P5)

Consultations frequently occur with patients who either cannot, or will not, engage with other healthcare services, choosing to self-mange conditions with the advice of pharmacists. Participants described unmanageable workloads as a result of high levels of patient demand, in particular citing the 'open access' and 'free advice' that pharmacists provide to many members of the public. This workload was balanced alongside providing additional services such as immunisation clinics, requiring significant resources to sustain.

> Community pharmacy is hard place to be. I am drowning inprescriptions and increasingly consulting patientsabout everything and anything. They come to see me as they can't get to see anyone else. It's crazy really, we are just an open door for free advice. I am not sure any other healthcare professional works this way. (P14)

This was particularly highlighted as an issue with patients not accessing NHS dental services, with a lack of service availability, dental phobias and issues relating to the cost of dental care frequently reported by patients.

> Patients tell us they're not registered in a dentist. Sometimes this is because they say they can't find one in the area, but I think much of the time it is due to the cost of dental care. It's a big disincentive given the financial difficulties facing many people. (P6)

Existing pharmacy-based services and pharmacists' roles in the provision of smoking cessation and alcohol-focused interventions also provide opportunities to interact with those patients who may be at highest risk of HNC. Education and promotional activities were seen by pharmacists as being important elements of their role but they reported little prior engagement with HNC awareness campaigns.

> We do a lot around smoking cessation, we have been running clinics for years and do really well supporting patients. Same with promotional campaigns like alcohol awareness, mental health, sexual health etc. where we promote awareness of symptoms to patients. I don't recall doing anything specific with head and neck cancers. (P1)

All participants reported frequent consultation with patients presenting with signs and symptoms, which may be associated with HNC. This would include patients seeking advice around the management of common minor ailments, such as mouth ulcers, sore throats, hoarseness and ear pain.

> The usual ones would be mouth ulcers, sore throats, and oral thrush. I see commonly, tonsillitis, hoarse voice, swollen glands. A lot of ENT type presentations really. (P1)

KNOWLEDGE GAP

All participants were aware of the key NICE referral criteria as specified in table 1. Patients presenting with these symptoms would typically be referred by the pharmacist to visit their general practitioner (GP) for further

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assessment, with no sale of over-the-counter (OTC) medicine usually made in this case.

> I look for red flags which would stop me from selling a product or giving a patient reassurance that something is self-limiting. In this context it would be some sort of lesion in the mouth, or certainly an ulcer, that had been there for weeks. Trouble swallowing and a hoarse voice, again if they had been present for a few weeks, or hadn't responded to initial over-the-counter treatment. I would be advising the patient to see the GP. (P11)

Most participants reported that they would not usually undertake a more holistic assessment of a patient with such symptoms. For example, pharmacists would not typically probe patients presenting with a non-healing ulcer to explore the presence of other symptoms, such as weight loss, or to identify key information such as alcohol status which is known to increase risk of HNC.

> Some of the questions on the tool (HaNC-RC v2) are interesting. I am not sure I would have ever put them together. If someone had an ulcer, I might ask if they smoke, but Iwouldn't think to ask about how much they drink, or if they have lost weight, or whether any of those other symptoms are present. I would have made my decision to refer to the GP regardless. (P15)

Many of the participants reported a need for further training in clinical decision making if required to undertake more advanced clinical roles, such as a more detailed assessment of a patient with suspected HNC. There was also limited knowledge and very little training for pharmacists in relation to undertaking any form of oral examination; participants described feeling confident in diagnosing oral thrush or oral ulceration, but this was the extent of their current skill set.

> I don't think we have the training to undertake more invasive assessments at least. I could identify thrush or an ulcer, but have never learned how to undertake any form of oral examination, or integrate things from such an assessment into a more complete clinical decision. (P16)

Participants described the nature of OTC consultations in a pharmacy setting as a barrier for more thorough clinical assessment of patients; if a patient had a likely red flag, this would usually result in a quick decision to refer.

> If any patient has any of those red flags, like an ulcer which hadn't gone away, I think that would be an automatic referral. Sometimes you must stop patients telling you everything because you just know straightaway you can't treat this patient yourself. (P14)

Referral pathways and workloads

Pharmacists described strong relationships with GP practices, although the nature of the location of some pharmacies (town/city centres) sometimes meant that services were provided to patients from a wider range of practices, diluting the collaboration. Where pharmacies served patients from fewer practices the relationships were typically closer and facilitated by personal acquaintance with practice colleagues.

> We have a good relationship with ourpractices. There are only 2 practices where, I am guessing 95% of our patients are registered. We know each other quite well. (P7)

Several participants worked as locums, meaning that they regularly worked in new pharmacies, with different teams, serving different populations across the North of England. The frequent use of locums across the community pharmacy sector and draw of pharmacists into other roles within the NHS was seen as a challenge in this context. Participants described being unfamiliar with local procedures, and not having the relationships with GP practices that a regular pharmacist may have. Some also reported a lack of communication between the locum and the regular pharmacy team making it difficult to pass on information for example, following up a patient that had been referred.

> As a locum I can be in a different pharmacy every day. The sector is now reliant on locums, as many good pharmacists have moved to work inPrimary Care Networks. Locum-ing can be difficult, you do your best on the day, but you don't know the area, patients, or the GP practice. It makes informal referrals risky as there is no way of following up. (P12)

The relationships with dental service providers were described as poor, with limited communication and collaboration between pharmacy and dental teams. Pharmacists; therefore, described this as a significant barrier to referral and collaboration with dental providers.

> You would ideally refer to a dentist as they are the experts in oral health. But there are no protocols for that, we don't really ever talk to each other…where I work is quite deprived and people just won't go to the dentist. (P3)

Referrals between pharmacies and GP practices are typically informal, with most pharmacists simply signposting patients to see their GP when patients were unsuitable for pharmacy only care. Where serious concerns were present, pharmacists explained that they may contact practices directly to ask for review appointments to be made, although for some participants there were challenges when speaking to reception staff instead of the doctor.

> We don't have any formal referral process. It would all just be signposting. If I wasworried about a patient I would perhaps ring the GP on their behalf, but a lot of the reception staff will say, "Well, the patient needs to ring us, the patient needs to get in touch." (P6)

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The process of signposting (informal referral—typically verbal instruction to a patient advising need to visit another health professional) and lack of a formal process was seen by pharmacists as potentially being problematic as there was no safety net (mechanism to ensure that patients were reviewed and did actually attend) to ensure patients were reviewed, with a lack of any auditable referral trail.

> In our pharmaciesit is all informal signposting, unfortunately it is just a case of advising the patients to go. If they don't go, unfortunately we can't really do anything about it and I don't know if they actually followed through and attended. Unless there was a proper referral process in place patients could easily be missed. There are no records. (P7)

The lack of formal pathways meant that pharmacists received little feedback on the outcome of any referrals made. Information would typically only come directly from a patient if they returned to the pharmacy in the future. This lack of feedback on referral outcomes was seen as a significant barrier to the pharmacists' own clinical development as they were unclear if referrals were appropriate or if they were resulting in unnecessary consultation time and/or patient distress.

> We are out the loop. The only feedback we get is if the patient comes backwith a prescription or if they say something to us. It's frustrating at times as you never know if you did the right thing to refer…I might be making really good quality referrals, or equally I could be wasting the GP's time. (P1)

> My big concernwould be that pharmacists are going to refer huge number of patients and that the services in secondary care won'tcope. (P13)

Participants described a need to ensure any future HNC referral pathway involving pharmacists should result in feedback, such as being copied into clinic letters to support their development, encourage integration of pharmacists into the clinical team and to support pharmacists following up patients who might not attend future assessment appointments. For example, if the pharmacist is aware that a patient did not attend a 2-week wait appointment but attends the pharmacy again, this is an opportunity to intervene and discuss with the patient to encourage attendance.

> There needs to be proper integration of pharmacists into these pathways. This would include being copied into letters etc., so we can see outcomes. Knowing if my referrals were appropriate would be key. If I don't get this information I can't learn and improve.(P15)

> I know my patients well. If pharmacists were part of the process and involvedin communication, we could support patients who were distressed during the process, but also, help encourage patients to attend for appointments if we knew that they missed them. (P11)

The participants were mostly in favour of integrating pharmacists into direct suspected cancer referral pathways, particularly given issues which some of their patients report in accessing other healthcare services. However, it was clear that there need to be clear referral criteria, and also appropriate safety netting to (1) support patients distressed about the need for a suspected cancer pathway referral and (2) support those patients which do not meet the criteria but in the pharmacists' clinical judgements warrant further review. Some of the participants reported needing additional training in the consultation skills required to support patients in such circumstances, which were described as poor in current education and training programmes.

> I think it isimperative that we be given the tools and the training to be able to take that kind of responsibility (direct referrals) on. I genuinely think it would save lives (P2)

> I do not think I have had much training in how to support patients, and you can see how this is challenging if you are referring to a cancer pathway. (P3)

UTILISATION OF CDST

Some of the pharmacists reported being familiar with the use of CDSTs in practice. The main example given was the FeverPAIN or Centor criteria used to assess the need for antibiotics in patients presenting with a sore throat. Pharmacists were positive on the use of these tools to support clinical decision making around recommending OTC medicines or referring patients onwards.

> I use tools in practice,things like the FeverPainand Centor criteria are useful. Theygive confidence in your decision aboutreferring or if likely self-limiting and I can suggestsimple medication to relieve symptoms. (P11)

When shown the HaNC-RC V.2 tool during the interviews, the pharmacists described it as seemingly straightforward to use and potentially useful in practice. It was seen as a potential means of helping to justify their referral decisions, and to support triage by other services to assess urgency of need for specialist review. None of the participants had used the tool in practice when assessing HNC risk in patients.

> It approaches things methodically with structure so you don't go 'offpiste' and miss something significant. Secondly, if you're on the edge of making a referral, if you've got a clinical score on a system that met the threshold it is going to encourage you to go that way. It's confidence and validation of your clinical judgement that could help. (P16)

The main benefit of the HaNC-RC v2 was seen to be the way it facilitates a more holistic approach to assessing patient's symptoms, acting as a prompt to further explore

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a patient's presentation during consultations. For example, participants described typically looking out for key 'red flag' symptoms, but not exploring how multiple symptoms could be linked together to increase HNC risk and interact with demographic information such as age, gender, smoking and alcohol consumption.

> You look for key symptoms which differentiate between a minor illness, or a serious symptom which requires referral. I would n't often probe further questions like those in the tool. I might ask about smoking if it was a mouth ulcer, but would n't ask about alcohol use or some of those other symptoms. I am not sure I would have associated them together. (P11)

Discussion

This qualitative interview-based study exploring the role of community pharmacists in England adds to a small body of evidence on the role of pharmacists in the early identification and referral of patients with suspected cancer.[2–4] This is a novel and innovative approach to addressing the worldwide problem of late cancer diagnosis; and the insights of participants will be valuable in understanding how to further develop pharmacists' roles in this field and to support a system-wide approach to integrating pharmacists into cancer referral pathways. This is timely considering the recent announcement by NHS England to develop pilots in practice in an attempt to increase the number of cancers caught at an earlier stage.[5]

This study has demonstrated that community pharmacies offer opportunities to reach some patients that other healthcare services struggle to engage with. This includes patients self-managing symptoms that are potentially markers of HNC, and those that are at high risk, such as smokers and those drinking alcohol in excess.

Relationships between pharmacies and GP practices are usually strong, however, current referral processes are mainly based on signposting patients with a lack of any formal auditable trail. Pharmacists have a good awareness of key NICE referral criteria for HNC, but have limited expertise in undertaking more thorough clinical assessments of patients; utilisation of CDSTs, such as the HaNC-RC v2 could facilitate a more detailed assessment of patients by pharmacists to support referral decisions and their use needs to be further explored in future research.

Participants reported significant workload challenges as a result of high volumes of medication supply, delivery of services such as immunisations and the open nature of pharmacies to members of the public. Managing the current volume of patients visiting pharmacies who report being unable to access other NHS services, without a contract that directly reimburses for the delivery of this professional advice, is unsustainable. This is supported by recent data in England where a national audit found that over 1.2 million consultations take place weekly in English community pharmacies, with a quarter of a million of these consultations because patients are unable to access their preferred part of the healthcare system.[8] Fundamental policy decisions around the roles of community pharmacy are required to prioritise the direction and remit of services provided so that it can be resourced and work loaded both effectively and sustainably.

This study required pharmacists to volunteer for participation and with all studies requiring time for an interview, there is a risk of self-selection bias. All participants were based in England and, therefore, the transferability of findings to other health and social care service models may be limited. This study only interviewed pharmacists and did not explore integration of community pharmacies within HNC pathways with other members of the existing multidisciplinary team. However, the qualitative methodology provided rich data based on experiences in clinical practice and the iterative process of data collection and analysis facilitated enrichment of data through subsequent interviews.

A previous qualitative study with patients diagnosed with lung, colorectal or gastro-oesophageal cancer found that half of the patients had initially tried to manage red flag symptoms by purchasing OTC medication prior to diagnosis.[18] This work supports the findings of our study, highlighting potential opportunities to use community pharmacies in earlier identification of suspicious symptoms. This study, however, found that frequent purchases of the same medication were not explored fully, highlighting the potential for patients with ongoing symptoms to be missed.[18] Several small-scale pilots have also found that pharmacist integration into lung cancer referral pathways is both feasible and acceptable, resulting in high-quality referrals.[19 20] However, outcome data are currently very limited and barriers to successful implementation were identified to include a lack of patient awareness of such services and pharmacists' roles, and concerns about perceived impacts on workloads.

Current NICE guidelines recommend a referral for dental review in patients presenting with a lump on the lip or in the oral cavity, or a red or red and white patch in the oral cavity consistent with erythroplakia or erythroleukoplakia.[12] However, our study found limited communication and referral pathways between dental, medical and pharmacy services, alongside participants reporting significant challenges in getting patients to access and engage with dentists. This is further supported by existing literature that highlights the lack of integration of dental teams within other NHS services.[21 22]Further research to explore how best to integrate medical, dental and pharmacy services is therefore required.

Major risk factors for HNC include alcohol and tobacco use, and HPV has been linked to increasing rates in the USA and Europe.[11] Pharmacists are already engaged with smoking cessation and alcohol services in community pharmacies. This may present opportunities to promote HNC risk and symptoms among those patients at highest risk. There is evidence of both increased incidence rates and mortality in areas of high deprivation[10 11]; 99.8% of

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patients from the most deprived areas of England live within a 20 min walk of a pharmacy,[7] therefore, work to explore the best way to engage these communities, particularly groups with limited engagement with other healthcare services should be prioritised. This should be explored further, alongside how best to target promotional activities among communities with highest incidence rates.

The next steps required include further exploration and process-mapping of referral pathways to ensure an integrated approach to developing pharmacists' roles in this field. This needs to include consideration of how referral outcomes and patient information is exchanged and feedback to referring pharmacists, and how this role is balanced against other competing demands. This works needs to draw on implementation science to facilitate sustainable and cost-effective care pathways in collaboration with patient groups, stakeholders, service commissioners and policy makers. Further exploration of the training needs for pharmacy teams to deliver such services is required and outcome data are needed to assess the effectiveness of such programmes and support the integration of pharmacists into HNC and other cancer pathways.

CONCLUSION

Community pharmacists offer a little explored route for the earlier identification and referral of patients with suspected HNC. Pharmacists have opportunities to engage with patients at high risk of HNC and with those that have limited engagement with other healthcare services; this includes activities to increase awareness of HNC among patients and the public, and through the assessment of patients with potentially suspicious symptoms.

Further work to develop a sustainable and cost-effective approach to integrating pharmacists into suspected cancer referral pathways is needed, alongside appropriate training for pharmacists to provide them with this new skill set.

There is, therefore, an urgent need to develop service models and ways of working, which use the access and opportunity pharmacy teams provide to prioritise prevention, early intervention and behaviour change interventions, particularly in areas of high need.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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