NICE National Institute for Health and Care Excellence

January 2020 Surveillance of suspected cancer: recognition and referral (NICE guideline NG12)

Surveillance report

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Surveillance decision

We will not update the NICE guideline on suspected cancer: recognition and referral.

Reasons for the decision

New evidence and information identified during the surveillance review was considered not to have an impact on current guideline recommendations.

Changing context and service delivery

Stakeholders highlighted that NHS England published its Long Term Plan for Cancer in 2019. The NHS Long Term Plan includes, among other relevant areas, the introduction of new, faster diagnostic standards. The Rapid Diagnostic Centre (RDC) Vision and 2019/20 Implementation Specification outlines the introduction of new pathways in lung cancer, prostate cancer, colorectal cancer and oesophago-gastric cancer. The National Cancer Programme will evaluate the RDC programme with an initial evaluation expected by mid-2020. The implementation is in very early stages (it is estimated that the rapid diagnostic centres will be fully implemented by 2028), therefore it was considered that this change in the service delivery does not have an impact in the guideline now but it might have an impact in the future. We will monitor the progress of the initial evaluation and any further assessments of the RDC implementation and consider the results for impact on the guideline when available.

Stakeholders also commented that the National Cancer Programme is reviewing the Cancer Waiting Times Guidance v10, particularly the direct access to a suspected cancer pathway for those patients with abnormal test results. A further review is also underway as part of the Clinical Review of Standards. National best practice timed pathways in colorectal cancer, lung cancer, prostate cancer and oesophago-gastric cancer have also been published.

Furthermore, it was noted that the impact of the recent interim review of national screening programmes in England may need to be taken into account. Although there is a link between cancer screening at a population level, screening and surveillance of high-risk populations, and how general population (and high-risk patients) presenting with symptoms in primary care are referred onwards, it is not currently clear how this interim

review impacts on NICE guideline NG12, which excludes screening. Nonetheless, we will monitor the progress of this review of national screening programmes as any changes to screening strategies could have a downstream impact on the context within which NICE guideline NG12 recommendations are implemented.

We will not update the guideline at this time because changes in service delivery are still being implemented into the system. We will monitor and track these areas and the results of the evaluations, so we can assess any impact on NICE guideline NG12 in future surveillance reviews (or before, if the results are published).

Symptoms of suspected cancer

Some topic experts noted new symptoms that could be included for particular cancers such as cervical or breast cancer. Information gathered during this surveillance review highlighted similar areas to those noted by topic experts, including new symptoms in some types of cancers such as throat pain in oral cancer, or new cancers such as hypopharyngeal or pharyngeal cancer that are not currently covered in the guideline.

Stakeholder feedback from consultation also noted that new symptoms or symptom combinations need to be added into recommendations for certain cancers such as pancreatic cancer, ovarian cancer, sarcomas, and head and neck cancers.

Overall, we did not identify new evidence to support the inclusion of new symptoms or cancers; or the evidence identified was considered limited in terms of the quantity and quality to warrant an update of the recommendations.

Family history and genetic test results were also mentioned as relevant factors to inform referral decisions in suspected cancer. It is known that there are genetic diseases such as Lynch syndrome, which increase the risk of developing certain type of cancers (such as colorectal cancer). However, we did not identify any evidence on risk factors different from those already included in the guideline (age and smoking) that have an impact on the predictive power of symptoms included in the guideline.

Additionally, genetic testing is currently a rapidly evolving area but no new evidence was identified through this surveillance review to inform an update to the guideline. Genetic testing will be noted for consideration again at the next surveillance review of the guideline, by which time there may be developments in the evidence base and service delivery in this area.

Colorectal cancer – symptom profile of low-risk patients

Topic experts and stakeholders highlighted the need to reinstate the colorectal cancer symptom profile in low-risk patients to improve implementation of recommendation 1.3.4. The symptom profile was removed following the introduction of NICE diagnostics guidance on quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care (DG30). We will amend the recommendation to reintroduce the symptom profile of low-risk patients.

Prostate cancer age-specific reference range for prostate-specific antigen levels

Stakeholders noted that recommendation 1.6.3 is challenging to implement because the age-specific reference range for prostate-specific antigen level included in the recommendation is not explicitly described. It was argued that this lack of clarity is causing variability in clinical practice and people are being treated differently depending on the age-specific reference range adopted by healthcare professionals. The Public Health England prostate cancer risk management programme recommends an updated referral value for men aged 50 to 69 of 3 ng/ml. However, this guidance covers an asymptomatic population so it is not currently known if the referral value is applicable to men who would be covered by NICE guideline NG12 (men with symptoms attending primary care). Given that the age-specific reference range is not explicitly described in the recommendation and that its use could be now inaccurate; we propose to address this issue through our refresh process.

Oral cancer

In recommendation 1.8.3, a referral from the GP to a dentist is considered in people with a lump on the lip or in the oral cavity consistent with oral cancer, or a red or red and white patch in the oral cavity consistent with erythroplakia or erythroleukoplakia. Stakeholders stated that there is no formal referral route from primary care to the dentist. They considered that this recommendation causes unnecessary delays and potentially limits the accessibility to services among people with fewer resources. When the recommendation was developed, the committee noted that the symptoms included in the recommendation did not have a positive predictive value (PPV) greater than 3% to recommend a suspected cancer referral for oral cancer. They considered that a PPV greater than 3% could be reached if these symptoms were assessed by a professional with expertise in this area. They also felt that the reduction of unnecessary referrals to secondary care services

resulting from a lesion being seen by a more expert clinician balanced the risk associated with a short delay. In this surveillance review, no new evidence was identified to have an impact on current guideline recommendations. We considered the lack of formal referral from primary care to dentist as a service delivery issue. We will ensure that the information on implementation issues that we have identified in this surveillance review are disseminated via appropriate channels within NICE.

Primary care testing

Topic experts and stakeholders highlighted primary care testing as an area of interest. They were particularly interested in:

- endometrial cancer and direct access from primary care to scans so the endometrial thickness could be assessed
- sarcomas and direct access to MRI from primary care if X-ray findings are uncertain and clinical concern persists
- lung cancer and direct access to CT scans from primary care
- use of serum-free light-chain analysis instead of Bence-Jones protein urine testing when assessing myeloma, and
- use of inflammatory markers in primary care.

We identified new evidence on primary care testing around the role of inflammatory markers for cancer diagnosis in primary care, or the use of urinary biomarkers in patients with haematuria, and low-dose CT scans in lung cancer. However, the evidence was considered limited in terms of the study design, the number of patients included and conclusions to have an impact on current guideline recommendations.

The diagnostic process

We identified new evidence on several aspects of the diagnostic process including assessing the impact of the urgent referral pathway in primary care; evaluating the impact of undertaking additional primary care investigations in patients who do not fulfil the criteria for urgent referral, and the use of electronic health records and decision support tools. New evidence identified supports the use of the 2-week referral pathway for suspected cancer. The use of electronic health records and decision support tools is an emerging area of interest, but more research is needed to assess the effectiveness of

those interventions in referral for suspected cancer.

For further details and a summary of all evidence identified in surveillance, see appendix A.

Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in the NICE guideline on suspected cancer: recognition and referral remain up to date.

The surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews.
- Examining related NICE guidance and quality standards and National Institute for Health Research (NIHR) signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.
- Literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the proposal with stakeholders.
- Considering comments received during consultation and making any necessary changes to the proposal.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence considered in surveillance

Search and selection strategy

We searched for new evidence related to the whole guideline.

We found 62 studies in a search for primary care-based studies published between

January 2014 and August 2019. Twelve relevant studies from a total of 14 identified by topic experts were also considered relevant but they were already included in our searches. Three relevant studies were identified in comments received during consultation on the 2019 surveillance review and were included. From all sources, we considered 65 studies to be relevant to the guideline.

See appendix A for details of all evidence considered, and references.

Selecting relevant studies

We included only primary care-based studies, as people with symptoms in primary care were the population of relevance to this guideline. We included relevant references that described important information about cancer symptoms in their abstracts such as positive predictive values, sensitivities, specificities, likelihood ratios, or odds ratios. We also included primary care-based studies on investigations for cancer in primary care following the same inclusion criteria used for cancer symptoms.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 5 were assessed as having the potential to change recommendations. Therefore, we plan to regularly check whether these studies have published results and evaluate the impact of the results on current recommendations as quickly as possible. These studies are:

- Raman spectroscopy and colorectal cancer
  - This is a randomised controlled trial assessing the diagnostic accuracy of the Raman spectroscopy test, which is a blood test that can be used in primary care in symptomatic patients to achieve an earlier diagnosis of bowel cancer.
- FIT – Can a dipstick test rule out bowel cancer?
  - This is a non-randomised diagnostic study assessing the accuracy of the faecal immunochemical test to triage symptomatic patients for a suspected cancer referral for bowel cancer in primary care.
- Biomarkers for ovarian cancer risk assessment
  - This is a case series pilot study assessing the accuracy of ovarian cancer

biomarkers in risk assessment of symptomatic patients in primary care.

- CANcer DIagnosis Decision rules
  - This is an observational cohort study aiming to identify alarm symptoms and signs for early prediction of lung and colon cancer.
- Electronic risk assessment for cancer for patients in general practice
  - This is pragmatic cluster randomised controlled trial investigating the effectiveness of electronic risk assessment tools for lung, colorectal oesophago-gastric, bladder, kidney, and ovarian cancer in primary care.

Intelligence gathered during surveillance

Views of topic experts

We considered the views of topic experts who were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to the guideline.

We sent questionnaires to 14 topic experts and received 8 responses. The topic experts who provided feedback were: GPs, a public health consultant, a clinical reader, a consultant radiologist, and a consultant oncologist. We also received feedback from Macmillan Cancer Support and their GP Advisors (1 questionnaire received).

Overall, 4 topic experts thought that the guideline should be updated and 4 thought that an update was not necessary. The issues that topic experts thought could be addressed in an update are discussed in detail in appendix A and in the reasons for the decision section.

Implementation of the guideline

A total of 6 experts provided information on the implementation of the guideline. Overall, it was considered that the guideline is well implemented. Also, resources such as the cancer maps, which summarise NICE guideline NG12 recommendations, were highlighted as very valuable for the implementation of the guideline in primary care.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal was to not update the guideline, we consulted with stakeholders.

Overall, 29 stakeholders commented.

Eleven stakeholders agreed with the decision not to update the guideline. These included 1 charity, 1 pharmaceutical company, 8 professional bodies, and 1 provider of services.

Eighteen stakeholders disagreed with the decision not to update the guideline. These included 6 charities, 1 commercial organisation, 4 professional bodies, 6 providers of services, and 1 university.

Key points raised during stakeholder consultation included:

- Oral cancer and the lack of a formal referral process from primary care to the dentist.
- Colorectal cancer and low-risk symptoms profile for faecal immunochemical testing.
- Prostate cancer and age-specific reference range for prostate-specific antigen levels.
- Rapid diagnostic centres and new cancer pathways.

These issues are discussed in detail in the reasons for the decision section. Also see appendix B for full details of stakeholders' comments and our responses.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

Stakeholders highlighted 1 issue related to the access to dental services for people presenting with symptoms of oral cancer that require further assessment by a dentist to determinate if suspected cancer referral for oral cancer is needed. This issue is discussed in the oral cancer section.

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we decided that no update is necessary.

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