

ABSTRACT

TITLE

Rethinking the 'one-stop' neck lump clinic during COVID-19 and beyond: A novel pathway and pilot study

OBJECTIVES

Current guidelines advocate 'one-stop' neck lump assessment for cancer referrals. We pilot a novel pre-clinic ultrasound pathway, present the outcomes and discuss strengths and limitations especially in view of the current COVID-19 pandemic.

DESIGN

Retrospective study of a novel pathway for patients referred as a 'two-week-wait' with a neck lump.

SETTING

Tertiary care hospital.

PARTICIPANTS

117 patients referred with a 'suspicious' neck lump between March 2018 and June 2019.

MAIN OUTCOMES AND MEASURES

Time to cancer diagnosis, discharge or change in pathway.

RESULTS

99 patients underwent pre-clinic ultrasound assessment 8.02 days from referral with 30 also undergoing biopsy. Patients were followed-up 14.1 days (range 2 - 26 days) from initial referral. A positive impact was seen in 92.9% of patients, where at first clinic appointment 45 patients were discharged, ten listed for surgery, 12 diagnosed with a malignancy, six referred to other specialities and 19 removed from the cancer pathway. Repeat ultrasound was inadvertently requested for one patient and two patients were reviewed prior to biopsy results leading to an additional appointment being required.

CONCLUSION

Pre-clinic ultrasound is an alternative to the current 'one-stop' neck lump pathway. We demonstrate a reduction in clinic visits, faster diagnosis and low proportion of unnecessary scans. Our pathway requires minimal service restructuring with potential cost savings. During the COVID-19 pandemic, it has enabled us to minimise face-to-face consultations and aerosol generating procedures (AGPs).

Further refinement is required to streamline and make the process more robust. A larger study with direct comparison to the 'one-stop' clinic is required to assess further strengths and limitations.

Keywords: Neck lump, One-stop clinic, Head and neck malignancy, COVID-19, Lymphoma

KEY POINTS

- The COVID-19 pandemic has altered the approach to head and neck cancer management for the foreseeable future
- The current 'one-stop' neck lump approach has a number of limitations with limited evidence of effectiveness
- New pathways are needed that adhere to pandemic restrictions whilst delivering faster cancer diagnoses
- Pre-clinic ultrasound scanning in expert hands is a safe and effective screening tool in patients presenting with suspicious neck lumps
- Ultrasound scanning before clinical assessment is safe, reduces the need for face to face consultations and limits the number of AGPs performed.

Rethinking the 'one-stop' neck lump clinic during COVID-19 and beyond: A novel pathway and pilot study

INTRODUCTION

Current government targets require that a patient should wait a maximum of 14-days between referral by a primary care practitioner to being seen by a hospital specialist (1). With growing pressures and an aim to reduce the two-week-wait pathway further, it is becoming increasingly more difficult to deliver timely cancer services. Figures from NHS England showed that between July and September 2018, the two-week cancer target had been missed for the first time. Furthermore, a target to start treating 87% of cancer patients within 62 days of referral has been missed for 19 successive quarters (2). Evidence suggests that the bottleneck occurs between GP referral and the decision to treat and is primarily due to a lack of diagnostic capacity (2). With new standards introduced in April 2020 to ensure that patients with suspected cancer receive a diagnosis within 28 days of referral, these pressures are only likely to increase (3). A programme of austerity, an ageing population and the cost of emerging technologies are increasing financial pressures on the NHS, which cancer care is not immune to. Head and neck cancer specifically is expensive to manage with a recent study in the USA suggesting it is the most expensive cancer to treat (4). Adding to this, head and neck cancers are predicted to continue rising in England by over 50% in the next 5 years (5).

Neck lumps are a common finding in head and neck cancer and is a first presentation in approximately 13% of patients (6). The specialist 'one-stop' neck lump clinic was recommended in the UK by the National Institute for Clinical Excellence (NICE) in 2004 as part of the attempt to improve outcomes in head and

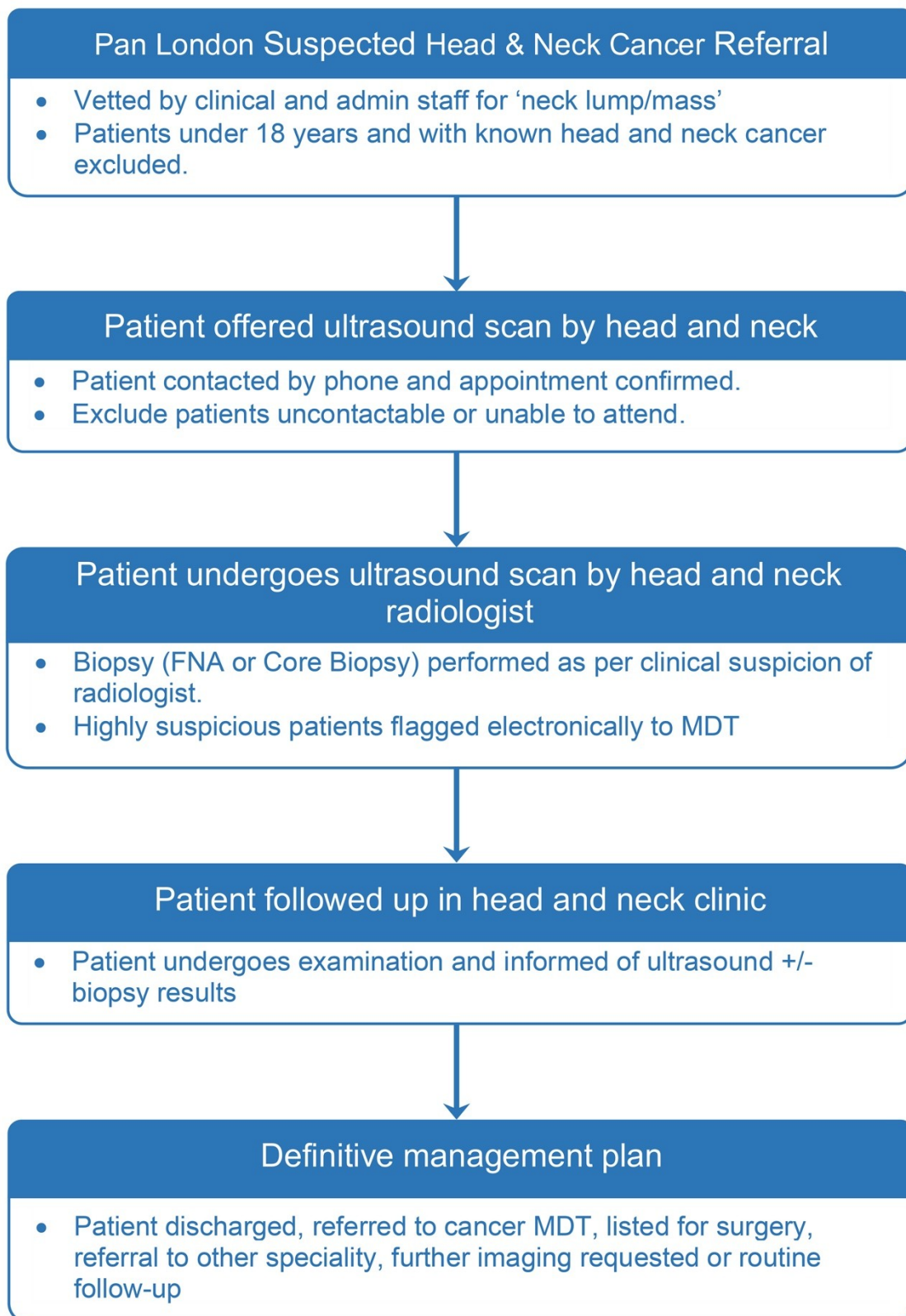
neck cancer (7). These clinics aim to provide clinical, radiological and cytological assessment for a patient with a suspicious neck lump in a single setting and attendance. Outcomes from such clinics have been encouraging with the majority of patients either discharged or a cancer diagnosis made at the first appointment (8,9). However, in its current format, a *true* one-stop neck lump clinic can be difficult to staff and maintain in a timely manner with patients often taking longer than 14 days to be seen or requiring repeat attendance for imaging or pathology results (10). This has led many institutions to opt for a different approach in managing neck lump referrals (11,12). The originally described one-stop clinic advocated for flexible nasoendoscopy, a potentially aerosol generating procedure (AGP), in all patients prior to ultrasound. The COVID19 pandemic has placed additional pressures on services coupled with a need to decrease face-to-face interactions and fewer AGPs where possible. We describe a pilot conducted at our institution that streamlines the use of our current resources and facilities, improves the patient service and delivers an efficient and timely cancer service.

METHODS

A dedicated one-stop neck lump clinic that perfectly conforms to the NICE 2004 guidelines is not available in our institution. Instead, all patients referred with suspicion of head and neck cancer are seen irrespective of the signs or symptoms for the referral. Head and neck clinics are led by a consultant head and neck surgeon with access to a same day walk-in consultant led ultrasound service with provision to perform fine needle aspiration (FNA) and core biopsy. This functions alongside a 'one-stop triple imaging' cancer staging service (ultrasound, CT and MRI) that we have previously described (13).

The new 'neck lump pathway' involved identifying all patients referred with a suspicious neck lump from the referral form and clinical history. Referrals are vetted by a combination of dedicated head and neck admin staff, cancer nurse specialists and specialty head and neck registrars. Where there was insufficient information as to the presence of a neck lump, clarity was sought from the referrer after which if there remained uncertainty, patients were excluded from the pilot and instead seen in clinic as normal. Eligible patients were then allocated to one of eight consultant radiologist led ultrasound slots per week where patients would have their diagnostic ultrasound and FNA and or core biopsy if required. Following this, patients were seen in a head and neck clinic where they were clinically examined, informed of their imaging findings and if taken, their pathology results. A management plan was then agreed with the patient which includes reassurance and discharge from clinic, routine follow up, referral to the cancer multidisciplinary team (MDT) meeting, referral to another specialty, listing for surgery or the need for further investigations. A record of patients on the pathway was kept prospectively whilst outcomes and results were collected retrospectively and analysed. Figure 1 summarises the pathway.

Figure 1: Proposed ultrasound pre-clinic ultrasound pathway



RESULTS

117 patients were identified as being referred with a suspicious neck lump between March 2018 and June 2019. All were offered an ultrasound scan by way of phone call and all confirmed their willingness to attend. 18 patients failed to attend their appointment and were therefore offered a repeat appointment but were excluded from the study. The remaining 99 patients underwent ultrasound assessment by a head and neck consultant radiologist 8.02 days (range, 1 – 21 days) from referral. 30 (30.3%) of these patients had a biopsy at the same time; 16 of these were core needle biopsies and the remainder FNA cytology. Patients were followed-up in clinic 14.1 days (range, 2 – 26 days) after *initial* referral.

A positive impact was achieved in 92.9% of patients. At the first surgical appointment, 45 patients were discharged (45.5%), 10 were listed for surgery (10.1%), a cancer diagnosis made in a further 12 patients (12.1%), 6 patients (6.1%) referred onwards to another speciality and 19 patients (19.2%) taken off the cancer pathway and followed up routinely.

7.1% of patients did not benefit from the new pathway. Four patients (4.0%) were retrospectively found to have inaccurate referrals that, following history and examination, did not warrant an ultrasound investigation. Repeat ultrasound was inadvertently requested for one patient (1.0%) and two patients (2.0%) were reviewed prior to biopsy results being available and were required to return for the results. The final diagnoses are summarised in table 1.

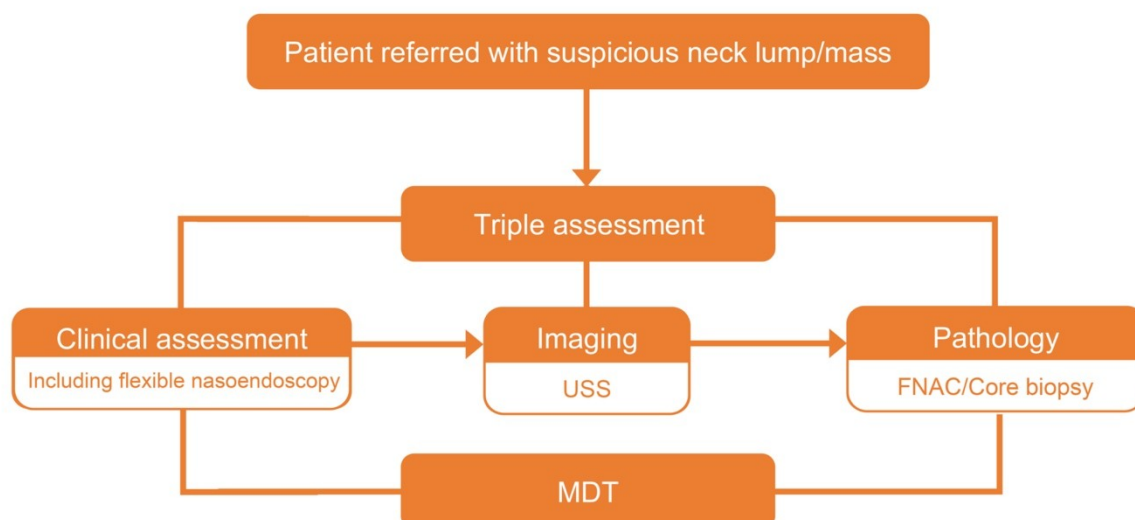
Table 1: Final diagnosis from 2 week wait neck lump referrals

Final Diagnosis	Number of patients
Primary head and neck malignancy	2
Thyroid cancer	5
Lymphoma	4
Secondary metastasis	1
No abnormality	14
Reactive lymph nodes	25
Benign thyroid disease	9
Anatomical variation	5
Lipoma	8
Pleomorphic adenoma	5
Other salivary gland disease	9
Sebaceous cyst	2
Dental Abscess	2
Tuberculosis	3
Other	5

DISCUSSION

There is a national drive for patients with suspected cancer to be seen more quickly and a commitment by NHS England that 75% of cancer cases be diagnosed earlier in stages 1 and 2 (2). NICE Improving Outcomes guidelines in 2004 have previously made specific recommendations for a 'one-stop' model (Figure 2).

Figure 2: Pathway of the 'one-stop' neck lump clinic



In 2019, Rapid Diagnostic Centres (RDC) were proposed as a means to achieve the Faster Diagnosis Standard (FDS) due to be introduced in England in 2020 for patients to receive a diagnosis within 28 days of referral. Whilst no format has been defined for RDCs in the context of head and neck cancer, one key specification includes rapid access and ideally same-day assessment and tests for patients (14).

Our proposed pathway presents an alternative to the 'one-stop' clinic. We demonstrate a reduction in clinic visits, rapid diagnosis and a low proportion of unnecessary scans. Compared to the 'one-stop' clinic, our proposed pathway requires less service re-structuring and maximises use of existing resources with potential cost saving.

76 clinic appointments were saved across our cohort of 83 patients with patients being referred onwards directly to the relevant sub-speciality including haematology, infectious diseases, maxillofacial surgery or a dentist. 94% of patients were seen within the two-week referral rule, above the required standard set by the Department of Health of 93%(15). Whilst this was lower than the 97% which was achieved under our previous model, four of the five breaches that occurred were within the first two months of pilot implementation and were due to logistical or administrative reasons. Excluding these first two months, 98% of patients met the two-week referral rule. Furthermore, over 90% of patients were given a diagnosis at most 26 days, and on average 14 days from referral. Due to a flagging system within our electronic patient record (EPR) system, patients with suspected malignancy on ultrasound had subsequent management fast tracked leading to an even quicker average time from referral to diagnosis of 9.7 days. Of the 12 patients diagnosed with a malignancy, five underwent further imaging via our 'triple imaging' model previously described

(13) and discussion at a cancer MDT prior to their follow up appointment in clinic.

These findings are comparable or better than reported outcomes for one-stop neck lump clinics where waiting times alone are typically around two to three weeks.(9,12)

As with all pilots, we encountered a number of logistical and pathway hurdles to overcome throughout. Two patients were seen in clinic prior to their biopsy results being available due to delays in pathology processing. Both patients had benign disease, one with autoimmune thyroiditis and the other with a tuberculous node.

These patients were reviewed in clinic and reassured of the benign appearance of their neck lumps however were brought back again to be informed of the final biopsy diagnosis.

Four patients did not warrant ultrasound assessment in this study based on their presenting complaint in clinic. All had a sensation of a lump in the throat rather than a neck lump. Separately, one patient was inadvertently sent for a repeat ultrasound scan having already had one prior to their appointment. This was noticed by the radiologist prior to performing the scan again, the clinician notified and scan cancelled. A further patient had a repeat ultrasound scan having already had one performed at our institution, requested by their GP, though this was not noted on the referral. Our institution has since implemented an electronic patient record (EPR) system that has streamlined the reporting process and communication between members of the multidisciplinary team. We have also introduced tighter vetting processes to reduce the number of unnecessary scans, however we acknowledge that there will always remain a small proportion of patients that may undergo scanning when not definitely indicated using our model. We feel that this is an

acceptable compromise considering that ultrasonography is a low cost, fast investigation with no known adverse effects.

Our pathway has a cancer pick up rate of 12.1% which is comparable with results from one stop neck lump clinics and other head and neck cancer pathways. 14% and 25% of patients were found to have no abnormality or reactive lymphadenopathy respectively which is in keeping with other studies (16).

We feel that our proposed pathway confers a number of advantages over the one-stop neck lump clinic. The NICE recommendations report that waiting times for patients to be seen in one-stop clinics are typically between two to three weeks with appointments typically taking an hour(17). One-stop clinics are also associated with high setup and running costs were estimated at £20,000 per annum in 2004. More importantly, clinics place a strain on already stretched resources and personnel who are taken away from routine activities whilst the clinic is running. In particular, both the Royal College of Radiologists and Royal College of Pathologists have recently warned of a shortage of the respective staff to meet diagnostic demands for cancer care(18,19). Whilst we have not made any formal cost calculations, the ability to integrate our proposed pathway into existing clinics, avoiding the need for additional dedicated staff or equipment maximises use of existing resources with inevitable cost saving implications.

Our results have shown that we are able to achieve diagnosis from the point of referral in as quick a time, if not quicker, than a one-stop neck lump clinic. Although our pathway necessitates an additional hospital visit, around 30% of patients in one-stop clinics require re-attendance for various imaging investigations (11).

Additionally, there is a need to identify p16 status in malignant cases of

oropharyngeal cancer for the purposes of TNM staging and also for future for phenotyping of tumours which a one-stop clinic does not allow sufficient processing time for. For this reason, and because of increased sensitivity and specificity rates compared with FNA, it is routine practice in our institution to perform image guided core biopsies for lymph nodes (and/or the primary tumour if not for biopsy under anaesthetic) if imaging appearances are highly suspicious of malignancy.

The current outbreak of 2019 novel coronavirus disease (COVID-19) has also highlighted further advantages of decreasing patient hospital visits and reducing face-to-face contact. The pathway is especially effective in avoiding unnecessary flexible nasoendoscopy; an APG and a requirement of the original 'one-stop' clinic *prior* to imaging and biopsy. 'One-stop' clinics typically require an hour per patient with patients rotating between seeing a surgeon, radiologist, waiting for results and then returning to a surgeon for the results with or without other members of the MDT. With current social distancing measures as well as the shortage of personal protective equipment (PPE), we do not feel that such a model is viable. We have continued with our pathway during the COVID19 pandemic with it being adapted to include telephone follow ups in appropriate cases. We see that current restrictions will likely remain for the near future, during which time we must continue to deliver timely cancer treatment. However, even after this pandemic is long behind us, the proposed advantages are transferrable to other communicable diseases and any future outbreaks or resurgences.

CONCLUSION

Head and neck cancer care has changed dramatically over the past decade and rates of disease are continuing to increase. There is a persistent push to provide ever faster diagnosis for patients within a system that is continuously under financial, resource and workforce constraints. We have shown that pre-clinic ultrasound scanning is a viable alternative to the current 'one-stop' neck lump pathway. Our results demonstrate a reduction in clinic visits, quicker diagnoses and a low proportion of unnecessary scans. In the new post COVID-19 norm, our pathway minimises face-to-face interaction and avoids the need for unnecessary potential AGPs with a resulting saving in PPE. Existing services can be adapted easily to our proposed pathway with minimal re-structuring to allow efficient use of existing resources with the potential for cost savings.

As with all new pilots, further refinement is needed to streamline and make the process more robust and a larger study with direct comparison to the 'one-stop' clinic to assess further strengths and limitations is required.

FIGURE LEGENDS

Figure 1: Proposed ultrasound pre-clinic ultrasound pathway

Figure 2: Original 'one-stop' neck lump clinic pathway

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author with the permission of University College London Hospitals NHS Trust.

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