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An Investigation to the Compliance and Effectiveness of the Two-Week Wait Rule for Urgent Suspected Oral Cancer Referrals

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Abstract

Aim: To compare the compliance to and effectiveness of the two-week wait rule for detecting urgent suspected oral cancers over one year period in East Sussex Healthcare NHS Trust with contemporaneous published data from studies undertaken in regional and international Oral and Maxillofacial departments to highlight areas for change in local practice in terms of referral protocol and further education of practitioners.

Method: From September 2014 to August 2015, the records of 158 patients referred under the two-week wait rule were collected retrospectively. Data collected included date of the initial referral, first consultation, diagnosis/signing of consent form, treatment(s) undertaken and whether there was a dysplasia/malignancy.

Results: From the 158 patients, ten patients were found to the have oral cancer (6.3%). There was a compliance of 96.2% for patients to be seen within two weeks of the referral. The mean average waiting time was 7.6 days for the first appointment. The "decision to treat" date to operation average interval was 29 days (range 17-62 days). The mean interval of receipt of "referral to treatment" was 71 days (range 40-97 days). Six of the patients (60%) were treated with excisional biopsy and four patients with neck dissection and reconstruction. Patients between the ages 40 to 49 years old made up half of the sample. There was no difference in incidence in disease on a month-by- month basis.

Conclusions: These results and findings were consistent with other national and international studies demonstrating both compliance with the two week "referral to treatment" rule and the detection rate of oral cancer. Public awareness campaigns and further education for primary care practitioners, as well as an update referral online system, are recommended to improve the detection rate and efficiency of the two-week wait rule

Keywords: NHS Trust; Oral and Maxillofacial; Consultation; Diagnosis/signing; Dysplasia/malignancy; Excisional biopsy

Abbreviations: DH: Department of Health; NICE: National Institute for Health and Care Excellence; GP: General Practitioners; GDP: General Dental Practitioners; OMFS: Oral and Maxillofacial Surgery; EDGH: East Bourne District General Hospital; GMPs: General Medical Practitioners; SHOs: Senior House Officers; MDT: Multi-Disciplinary Teams.

Introduction and Review of the Literature

Introduction

In 1997, the Department of Health (DH) published a white paper called "The new NHS Modern, Dependable" in which it promised to improve waiting times for patients with cancer by guaranteeing that anyone suspected of having cancer would be seen by a specialist within two weeks of referral. This policy was implemented for breast cancer nationally in April 1999 and for all other cancers, including head and neck cancer, in December 2000 [1]. The National Institute for Health and Care Excellence (NICE) has issued a set of referral guidelines for any suspected cancer based upon the degree of severity [2]. This is an update from the Department of Health's [3] version of the guideline, "Referral guidelines for suspected cancer".

Referral timelines used in this updated guideline include:

- **Immediate**: an acute admission or referral occurring within a few hours
- **Urgent**: the patient is seen within the national target of urgent referral (currently at two weeks)
- **Non-urgent**: all other referrals.

The NICE guidelines have attempted to assist general practitioners (GPs) and general dental practitioners (GDPs) alike to make decisions when patients present with symptoms that may be caused by cancer.

A revised guideline from the Department of Health was issued in 2007 called the Cancer Reform Plan. The most significant change was the timeline of assessing a patient started from receipt of the referral from the GP/GDP. The guidelines for the two week wait include:

- Starts on receipt of the referral
- Clock stops on attendance at clinic or diagnostic test relevant to referral
- Patient cannot be rejected if not available in two weeks
- Clock does not stop if patient unfit or other medical need take precedence, unless cancer is ruled out.
- Only GP can downgrade referrals
- No referrals can be refused.

The aim of this study is to investigate the compliance and effectiveness of the two-week wait rule for urgent suspected oral cancer referrals in East Sussex Healthcare NHS Trust.

Hospital records of urgently referred patients, aged over 16 years old, to Oral and Maxillofacial Surgery (OMFS) were retrospectively studied over the period from 1st September 2014 to 31st August 2015. From the clinical notes, the date each referral was received was noted, as well as the past clinical sessions, indicating the waiting period for an initial consultation, diagnosis and treatment. All results within this period were monitored for any dysplasia and/or malignancy. All data was recorded anonymously and no interaction with patients was needed. Research and Development (R&D) approval was sought from East Sussex Healthcare NHS Trust.

From the collected data, it was hoped the Trust can identify any From September 2014 to August 2015, the records of 158 patients referred under the two-week wait rule were collected retrospectively. Data collected included date of the initial referral, first consultation, diagnosis/signing of consent form, treatment(s) undertaken and whether there was a dysplasia/malignancy.

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There was a compliance of 96.2% for patients to be seen within two weeks of the referral. The mean average waiting time was 7.6 days for the first appointment. The "decision to treat" date to operation average interval was 29 days (range 17-62 days). The mean interval of receipt of "referral to treatment" was 71 days (range 40-97 days). Six of the patients (60%) were treated with excisional biopsy and four patients with neck dissection and reconstruction. Patients between the ages 40 to 49 years old made up half of the sample. There was no difference in incidence in disease on a month-by- month basis.

Conclusions

These results and findings were consistent with other national and international studies demonstrating both compliance with the two week "referral to treatment" rule and the detection rate of oral cancer. Public awareness campaigns and further education for primary care practitioners, as well as an update referral online system, are recommended to improve the detection rate and efficiency of the two-week wait rule well as an update referral online system, are recommended to improve the detection rate and efficiency of the two-week wait rule.

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Review of the Literature

Search strategy: In order to facilitate a review of literature, a clinical question needs to be formulated. The PICO tool [4], focusing on patient problem/population, intervention, comparison and outcome, was used and the following questions were calculated to find clinically relevant evidence in the literature:

- How effective is the two-week wait rule at detecting oral cancer in the literature compared to referrals in East Sussex?
- How compliant are hospital units in assessing patients referred under the two-week wait rule by primary care in the literature compared to East Sussex?

The following databases were used; Google Scholar, PubMed/MEDLINE, National Center for Biotechnology Information, Web of Science, Ovid, Science Direct, using terms "two week wait", "oral cancer", "head and neck cancer", "oral squamous cell carcinoma", "cancer referrals", "urgent referral", "fast-track cancer referral" and "cancer guidelines". This introduction will include the incidence of oral cancer; the time points in oral cancer, national guidelines from the Department of Health (DH) and National Institute for Health Care and Excellence, reformed DH guidelines in 2007, causes of delays in compliance to the two week wait rule, the benefits to patient from earlier diagnosis/treatment and the effectiveness of referrals.

Incidence

The incidence of head and neck cancer affects approximately 8-15 per 100,000 of the UK population [5]. Prior to the enforcement of the 2WW, Scully et al. [6] reported that an average interval for general practitioners referring suspected oral cancer patients to a specialist unit was approximately a month and 'patients seeking advice from their practitioner' caused the greatest delay. Oral, lip and pharynx cancer was the 13th most common cancer in England in 2014 accounting for 2.3% of all new cases [7]. The sex incidence of oral cancer was split towards males with it being the 11th most common (3% of all males cases) and in females the 16th most common (1% of all new cases).

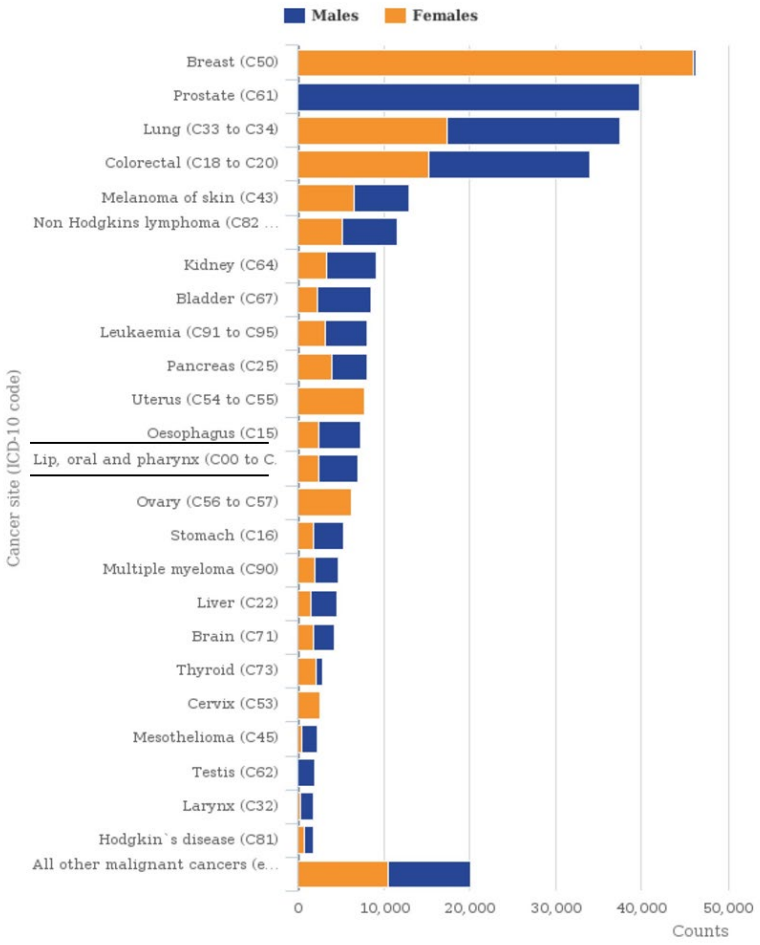

Figure 1: The number of cancer registrations by 24 major sites, with lip, oral and pharynx cancer highlighted, England, 2014 [7].

Time Points In Oral Cancer

The natural squealers of oral cancer starts from early intracellular changes to a developmental clinical detectable lesion ending ideally, if indicated, in treatment. Speight and Morgan [8] described the pathology of cancer. Demonstrating that each of these time points may take several years to manifest clinically and this slow manifestation counts for the majority of the cancer timeline. McLeod, et al. [9] showed the stages of cancer in Figure 1 from precancerous changes to definitive treatment. Basic understanding of carcinogenesis suggests that 'the longer a cancer is present then the larger it will become and the increase likelihood it will metastasise'.

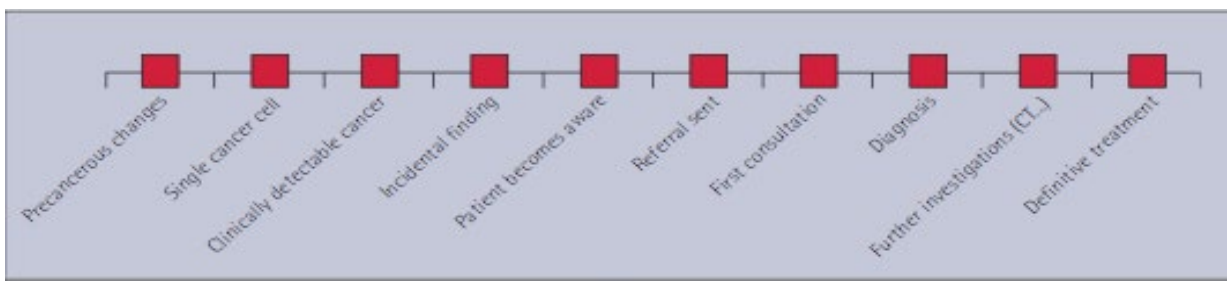

Figure 2: Time points in cancer.

Introduction of guidelines: (DH – The NHS Cancer Plan 2000) and National Institute for Health Care and Excellence 2005 [10]

The NHS Cancer Plan, published in September 2000, Rimmer, et al. [5] introduced targets for when suspected cancer patients are referred urgently. These include the 2WW rule stating that patients should be assessed within 14 days of the referral. In addition, the document states there should be an upper limit of 31 days from diagnosis to "decision to treat" and 62 days from "referral to first stage of treatment". Such targets aim to improve prognosis through earlier diagnosis and therefore earlier and effective treatment.

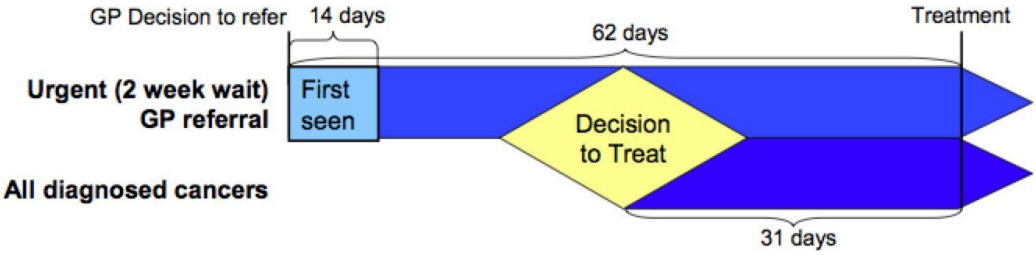

Figure 3: Timeline of the 2 week wait cancer rule in Cancer Plan 2000 [11].

Although referrals from general dental practitioners in the primary care setting are not mentioned in the NHS Cancer Plan [10], it is assumed that such referrals would not be exempt from the guidelines. Changes in the NICE guidelines include providing advice on regular dental check-ups in high-risk patients (smoking, high alcohol intake, chewing betel nut tobacco) and having a shorter interval of minimum three months between check-up appointments. The maximum interval of 24 months between checkup appointments as recommended by NICE is reserved for low-risk patients. In addition, people with symptoms of hoarseness should now be seen at three weeks or longer (from 6 weeks in the old Department of Health guidelines) for a chest X-ray, as well as referrals for parotid or submandibular masses and for chronic sore throats. The updated NICE 2005 guidelines also include specific recommendations for management of suspected thyroid cancer.

For head and neck cancers, signs and symptoms warranting urgent referral by NICE criteria are:

- Ulceration of oral mucosa persisting for more than three weeks
- Oral swellings persisting for more than three weeks
- All red/red and white patches of the oral mucosa
- Dysphagia persisting for more than three weeks
- Hoarseness persisting for more than six weeks
- Unilateral nasal obstruction, particularly when associated with purulent discharge
- Unexplained tooth mobility not associated with periodontal disease
- Unresolving neck masses for more than three weeks
- Cranial neuropathies
- Orbital masses

The level of suspicion for oral cancer is further increased if the patient is a heavy smoker or chronic alcohol drinker, aged over 45 years and male. Other forms of tobacco use (e.g. chewing betel, gutkha or pan) should also arouse suspicion of oral cancer. There has been some opposition to the introduction of the two-week wait rule. Sikora [12] states the lack of evidence-based strategy behind the waiting list targets, guideline symptoms and a more 'significant effort to improve the quality of cancer care is essential if we are really going to make an impact and save lives'. The face that the introduction of the 2WW rule may not be actually improving patient care is supported by East, et al. [13] who reported a mean wait of 7.3 days (range 7-10 days) for the 'two week rule' and 8.5 days (range 1-26 days) for direct referrals. This difference was not statistically significant. Interestingly, East et al. [13] showed that with the introduction of the 2WW rule there was an average of 26 days (range from 14-46 days) from the first appointment to operation for 'urgent' direct referrals to the consultant and 35 days for the one 'two week rule' referral. Treatment by radiotherapy was significantly longer for both groups – 61 days for 'urgent' and 42 days for 'two week rule'. In summary, the compliance between referral and first appointment was within the guidelines yet interval times to treatment were longer than the suggested targets. Interestingly, there was a shorter wait for urgent direct referrals than "2WW" referrals to operation suggesting no real benefit of the 'two week rule' being introduced.

Reform of guidelines – DH The Cancer Reform Strategy 2007

As a result of these changes and amendments, Richards [14] reported that over 99% of urgently referred patients are now seen within two weeks. This may be down to the slight

change in the timeline of referrals. All patients must be first seen within 14 days of receipt of GP/GDP urgent suspected cancer referral and treated within 62 of receipt, rather than decision to refer.

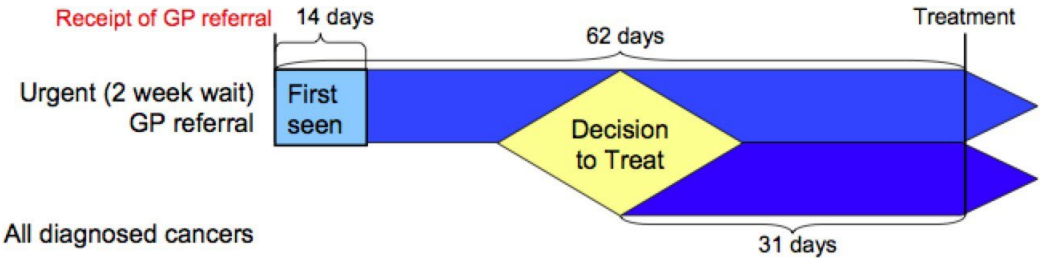

Figure 4: Timeline of referrals in Cancer Reform Strategy 2007 [11].

Causes of delays in compliance to two week wait rule (2WW)

The standard 2WW referral proforma fails to discriminate effectively between malignant and non-malignant disease and for every case confirmed with oral epithelial dysplasia and/or malignancy, 25 to 30 patients had to assessed and evaluated [15]. Clinical workforce time should be considered as potentially overloaded as a consequence of introducing guidelines for suspected oral malignant disease. Dental check-ups and examinations offer some opportunity to educate the public about oral cancer in high risk groups yet only found 30% do so routinely. Worryingly, Warnakulasuriya and Johnson [16] found that only 50% of dentists enquired about high-risk habits such as smoking and heavy alcohol consumption. Also, only 84% of dental practitioners claimed to have performed routine oral mucosa screening at regular appointments. This in turn could lead to negligence and a delayed a potential referral.

A number of previous literature have reported on oral cancer delays in the United Kingdom [6,17-19] with the majority of causes due to delays in patients seeking attention, delay in medical and dental practitioners referring patient for diagnosis and treatment. Kaing, et al. [20] found the greatest delay was at the diagnostic stage in Australia with similar findings in Brazil [21-25].

Does the two week rule have any benefit? – emphasis on earlier diagnosis/treatment

With the relatively low incidence of oral cancer (2%) contributing to all malignant tumors in the UK, there is 'little to no doubt' that early diagnosis and treatment improves both morbidity and mortality. This theory was first found in breast cancer treatment by Richards, et al. [26] as well as in urology. Allen et al.[27] concluded that fully complying with the two-week wait rule is unlikely to improve survival in urological cancers with a 'bottleneck' created further along the diagnostic pathway after the first assessment, resulting in delays to initial treatment. Gastroenterlogical fast-track referrals under the two week waiting standard are being met but at the expense of a substantial increase in waiting timed for routine referrals [28]. Similarly, Shah, Williams and Irvine [29] found 'no evidence that a delay of more than two weeks between referral from primary care to specialist care had any impact on outcome' for oral cancers.

In addition, Hollows, McAndrew and Perini [18] found that there was no statistical correlation between T-stage, alcohol or cigarette use and the patient delay in presentation. Patient factors and education into oral cancer need to continue to avoid most of these delays. After referral to a medical or dental practitioner, 69% of the sample was referred within a week and yet there were no significant differences between the T-stages presenting to either group of practitioners or in the delay of the referral for each stage. McKie et al. [30] findings showed that fewer early cancers were identified with the 2WW compared to other referral routes. These results may be explained by the fact that 'the nature of the disease prevents early detection as symptoms are minimal as guidelines are not sensitive enough; further patient education is needed to encourage patients to seek medical advice early or some general practices are yet to refer patients via this route.'

To support this view, East, Stocker and Avery [13] demonstrated during a respective review of case notes in a six month period that only 3 out of 22 newly diagnosed oral cancers were referred under the 'two week rule'. Singh and Warnakulasuriya [31] discussed that 'to their knowledge no pilot study was conducted before the implementation of NHS cancer care referral guidelines for head and neck cancers'. They also suggest a review of the guidelines through consultation with 'experts in the field, with a view to refine the symptomatology in the current guidelines'.

Effectiveness of Referrals

Only in recent years has new research relating to the 'two week rule' and head and neck cancer been published. Previously, other papers focused mainly on breast and colorectal cancer. Debnath, et al. [32] found that the actual incidence of colorectal cancer in '2WW' referrals was "disappointingly low' at 9%. Walsh, et al. [33] reported a 14% detection rate for colorectal cancer yet the majority of the cancer patients were referred with an 'urgent' direct letter from a general practitioner. Similar to Walsh, et al. [33] East, Stocker and Avery [13] had experienced the same trend but with an even lower oral cancer detection rate of 6%. This was over six months with a total of 48 patients referred in under the 2WW

Rimmer, et al. [5] found that only 9% of the referrals sent under the 2WW were diagnosed as malignant disease compared to 7.4% from Hodgson, et al. [15] Further investigation could be carried out to study the causes of the two week-wait effectiveness and if any possible amends could be made to improve clinical time in specialist oral medicine centres. Williams, et al. [34] who found a detection rate of 11% in oral cancers, also questioned the high number of inappropriate or non-urgent referrals received increasing 'patient's anxiety, clinical workload and waiting times' for patient that would have had a lower probability of cancer. Such improvements may reduce the time and emotional stress patients may suffer unnecessarily but yet it is appreciated that offering reassurance and excluding malignancy is challenging without a specialist opinion [5] McLeod, et al [9] make a well-argued point that although early oral carcinoma may be 'quite subtle in appearance and mimic a number of other conditions' a high level of suspicion should be taken by general dental practitioners during examinations'. Therefore it is advisable that 'a low threshold for referral to a specialist Centre be held'.

Aim and Objectives

The aim and objectives of this dissertation are:

- To investigate in a retrospective study the compliance and effectiveness of the two-week wait rule for detecting urgent suspected oral cancers over the period from 1st September 2014 to 31st August 2015 in East Sussex Healthcare NHS Trust.
- To compare the compliance and effectiveness of the two-week wait rule in East Sussex Healthcare NHS Trust with contemporaneous published data from studies undertaken in oral and maxillofacial departments on a regional and international scale.
- To highlight areas for change in local practice in terms of referral protocol and further education of practitioners.

Statement of the Problem

In spite of existing guidelines such as the National Institute for Health Care and Excellence's 2005 version and Department of Health's The Cancer Reform Strategy 2007, there is still a major problem in the lack of public awareness relating to oral cancer and its associated risk factors such as smoking, chewing betel nut and alcohol intake [16]. This is may be due to the infrequency of oral cancer presentation in primary care settings and its low national incidence.

This lack of awareness could potentially cause a delay in the referral only adding to patient's anxiety and clinical diagnostic interruptions. For example, in the case of upper aero-digestive tract cancer delays of up to one month correlate to a poorer prognosis [22] yet whether this correlates to oral cancer in East Sussex and its areas is yet to be seen. The effectiveness of referrals for cancer as a whole is very low. As mentioned previously, colorectal cancer incidence in 2WW referrals are at only at 9% [32] and at 14% [33] respectively. In relation to oral cancer detection, the figure is even lower on average at 8.8% [35] with a recent systematic review finding the lowest range at 2.2% [36] to the highest detection at 14.6% [37] The research on the two-week wait rule with head and neck cancer is relatively unexplored and an accurate representation of the local population in East Sussex is somewhat unknown.

The Oral and Maxillofacial Department at East Sussex includes East Bourne District General Hospital (EDGH) and the Conquest Hospital in Hastings. Only East Bourne DGH receives 2WW referrals from primary care services including general medical practitioners (GMPs) and general dental practitioners (GDPs) although referrals from general dental practitioners in the primary care setting are not mentioned in the NHS Cancer Plan [10], it is assumed that such referrals would not be exempt from the guidelines. Changes in the NICE guidelines include providing advice on regular dental check-ups in high-risk patients (smoking, high alcohol intake, chewing betel nut tobacco) and having a shorter interval of minimum three months between check-up appointments. The maximum interval of 24 months between checkup appointments as recommended by NICE is reserved for low-risk patients. In addition, people with symptoms of hoarseness should now be seen at three weeks or longer (from 6 weeks in the old Department of Health guidelines) for a chest X-ray, as well as referrals for parotid or submandibular masses and for chronic sore throats. The updated NICE [2] guidelines also include specific recommendations for management of suspected thyroid cancer.

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McKie, et al. [30] findings showed that fewer early cancers were identified with the 2WW compared to other referral routes. These results may be explained by the fact that 'the nature of the disease prevents early detection as symptoms are minimal as guidelines are not sensitive enough; further patient education is needed to encourage patients to seek medical advice early or some general practices are yet to refer patients via this route.' To support this view, East, Stocker and Avery [13] demonstrated during a respective review of case notes in a six month period that only 3 out of 22 newly diagnosed oral cancers were referred under the 'two week rule'. Singh and Warnakulasuriya [31] discussed that 'to their knowledge no pilot study was conducted before the implementation of NHS cancer care referral guidelines for head and neck cancers'. They also suggest a review of the guidelines through consultation with 'experts in the field, with a view to refine the symptomatology in the current guidelines'.

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Statement of the Problem

In spite of existing guidelines such as the National Institute for Health Care and Excellence's 2005 version and Department of Health's The Cancer Reform Strategy 2007, there is still a major problem in the lack of public awareness relating to oral cancer and its associated risk factors such as smoking, chewing betel nut and alcohol intake [16]. This is may be due to the infrequency of oral cancer presentation in primary care settings and its low national incidence.

This lack of awareness could potentially cause a delay in the referral only adding to patient's anxiety and clinical diagnostic interruptions. For example, in the case of upper aero-digestive tract cancer delays of up to one month correlate to a poorer prognosis [22] yet whether this correlates to oral cancer in East Sussex and its areas is yet to be seen. The effectiveness of referrals for cancer as a whole is very low. As mentioned previously, colorectal cancer incidence in 2WW referrals are at only at 9% [32] and at 14% [33] respectively. In relation to oral cancer detection, the figure is even lower on average at 8.8% [35] with a recent systematic review finding the lowest range at 2.2% [36] to the highest detection at 14.6% [37]. The research on the two-week wait rule with head and neck cancer is relatively unexplored and an accurate representation of the local population in East Sussex is somewhat unknown [38].

The Oral and Maxillofacial Department at East Sussex

includes East Bourne District General Hospital (EDGH) and the Conquest Hospital in Hastings. Only East Bourne DGH receives 2WW referrals from primary care services including general medical practitioners (GMPs) and general dental practitioners (GDPs) on a daily basis. These referrals are assessed before clinics by OMFS, Staff Grades and Senior House Officers (SHOs) assist in the assessment of referral cases under the supervision of a single consultant on a daily basis. These referrals are assessed before clinics by OMFS consultants. Weekly clinics run on a certain day specially for two week fast- track referrals. Registrars, Staff Grades and Senior House Officers (SHOs) assist in the assessment of referral cases under the supervision of a single consultant.

The Trust has a close partnership with the Royal Sussex County Hospital in Brighton where any referrals, which do detect oral and/or head and neck cancer, are transferred to for treatment and management by multi-disciplinary Teams (MDT). After recovery, post-operative care and management from the surgeons, speech and language therapists, dieticians, specialist Head and Neck cancer nurse and associated teams, the patients are discharged back to their local hospital for continued follow-up management with the maxillofacial team. Within East Sussex, East Bourne and Hastings cover a wide catchments area, which includes the High Weald countryside and its surrounding towns. This area has a population of approximately 800,200 in 2014. The largest city/town in East Sussex is Brighton. Understanding the numbers and reasoning behind referrals to these departments is essential to ensure the two-week wait rule pathway is used correctly and properly. Referrals sent in should be appropriate and seen within the time limit to aid efficiency. A fine balance must be struck between using the rule as a 'safety net', increasing patient anxiety with unnecessary fear and essentially detecting cancer.

Once trends in referrals are studied in East Sussex, potential change in local practice, referral pathways and further education for healthcare professional could be suggested to help improve the effectiveness of the two-week wait rule. In addition, any necessary changes to support the Oral and Maxillofacial department at East Sussex NHS Trust in achieving compliance could be suggested. This audit will help predict need for treatment, utilize staff and clinical time more efficiently and ensure better use of secondary healthcare. Any potential change to the guidelines and cancer referral system would be on a national level and changes would have to be recommended based on a collective evidence basis.

Methodology and Methods

Sample

The sample consisted of patients that were referred under the two-week rule to East Sussex NHS Trust between 1st September 2014 to 31st August 2015. These referrals are mostly received from General Medical Practitioners (GMPs) and General Dental Practitioners (GDPs). Occasionally clinical staff from other hospital departments can refer internally should suspicion arise from the patient's signs and symptoms. These types of referrals are fairly rare but an OMFS Senior House Officer (SHO) would be vetting any internal referral over the phone and via brief clinical examination on wards and, if appropriate then, an assessment arranged within the two weeks by the OMFS team. External referrals were completed on a Head and Neck Clinic – Sussex Cancer Network (two week wait) pro forma with patient details, date of referral, tick box of possible Head and Neck cancers and which hospital the referral should be send to (Appendix 1). This form was faxed over to the relevant number and printed out in the patient's hospital notes ready for the first initial assessment by OMFS.

Alternatively, some GMPs or GDP's wrote letters to the OMFS department under the two week wait rule stating necessary patient details, date of referral and the suspected head and neck cancer. These were either faxed over or sent first class in the post. These letters had to explicitly state that the referral was under the two-week wait rule otherwise the referral letter was not counted as urgent. From these referrals, further appointments were made for biopsies to be taken of the suspected lesion. The date of the referral, first consultation, diagnosis/signing of consent form and treatment(s) undertaken were noted on the data collection sheet in Appendix 2. Skin cancers on the head and neck region are also sent to OMFS under the two week wait. These patients are assessed and appropriate management is decided with surgical removal for cancers or conservative methods for non-cancers. Surgical removal included excisional biopsies with clear margins and topical creams/ advice for conservative methods. These were excluded from the sample.

The total number of referrals sent to East Bourne District General in those twelve months was 158.
The 'treated within 31 days of "decision to treat" date was taken at the signing of the consent form and not necessarily the appointment date following the biopsy.

Inclusion and Exclusion Criteria

Criteria for selection of the sample patients were:

- Patients referral under the two week wait rule to OMFS
- Patients who attended Eastbourne District General Hospital
- Patients who attended between 1st September 2014 to 31st August 2015
- Patients over the age of 16

- Patients who have oral/Head and Neck cancer
- Patients who were treated and/or referred to other hospitals for treatment

There is one specific exclusion criteria of skin cancers sent to the maxillofacial department. These were not included in the sample.

Ethical and R&D Approval

Local ethical approval was initially sought including permission from the OMFS department itself. Formal NHS ethics approval was not required as there was no direct contact with patients in the study; only data from patient's records were used. University of Kent's Centre for Professional Practice granted Research and Ethics approval, pending R&D confirmation from the Trust. There was consultation with the East Sussex NHS Trust R&D Manager who confirmed the study was an audit and approved the research to be carried out. Evidence of ethical approval for this study is provided in Appendix 3 as a headed letter.

Data Collection

Patient Records: Individual patient records were analyzed by looking at the paper form of the referral and date recorded. The dates for further correspondences/appointments for a diagnosis and start of treatment were noted as well as the outcome of the referral i.e. the biopsy was malignant or not. These entries into patient's notes, in the form of hand written or dictated letters, ranged from an OMFS SHO with supervision from a higher colleague or a registrar or consultant themselves. Operation sheets and histopathology reports from biopsies gave dates of when the treatment procedure took place and when the biopsy was reported on therefore giving the dates for diagnosis. The date of the signing of the consent form was recorded for the "decision to treat". Records not in use for over a year were stored in Medical Records and access to the majority of the notes was simply requested.

Electronic databases

To back up the physical patient's notes, the clinical letters and histology reports were also located on "Esearcher", an electronic patient database. Should any hardcopy report or clinical letter be missing from the patient's file, a quick search under the correspondence tabs located the relevant letter. The date was noted and double checked against any paper clinical letters, reports or clinical note entries.

Sample size

The sample group included all referrals and not a random selection. The study outlines to audit all cancer referrals in the one year period. Selecting random numbers does not give an accurate and fair representation of the true compliance and effectiveness of cancer referrals.

Missing patient notes

There were a few instances where patient notes could not be obtained. This would be the case when the patient notes were located at a different hospital. In these cases, the electronic database allowed access to correspondence and histology reports. The missing patient case files were requested at a later date and the dates cross-referenced to ensure minimal observer bias.

The original referral letter from the general dental or medical practitioner was not scanned or uploaded electronically, and therefore all paper notes had to be found to collect the date.

Statistical Analysis

The results for both compliance and detection rate were processed by Microsoft Excel 2011 and Graph Pad Prism version 6.0h into charts and figures. Analysis involved descriptive prose statistics, Pearson's chi squared, student t-test and Mann-Whitney test where appropriate, considering $p<0.05$.

Results and Analysis

There were a total of 158 referrals with suspected oral cancer sent to East Bourne District General Hospital during 1st September 2014 to 31st August 2015. All the patients referred under the two-week wait rule between this twelve month period were studied.

Compliance

Of seen within two weeks of receipt of referral:
The distribution of the number of patients that were seen within the two-week from receipt of referral is shown in Figure 5.

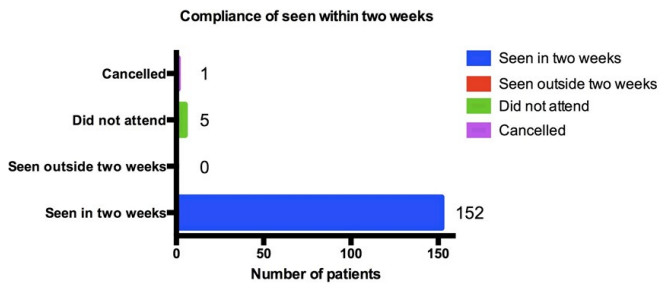

Figure 5: Graph showing the distribution of patients seen within two weeks of receipt of referral. Figures displayed are actual patient numbers.

The total percentage of patients compliant was 96.2%

(n=152) with did not attend (DNA) and cancelled patients accounted as non-complaint (3.8%, n=6). The mean average waiting time for the first consultation was 7.6 days (range 6-11 days). All patients were given an appointment within 14 days.

In comparison to other literature, Table 1 shows the mean average waiting time within the 14 days.

Author/Audits	Period (months)	Mean average (days)
Shah, et al. (2005) [29]	31	6
East,et al. (2005) [13]	6	7.3
McKie, et al. (2008) [30]	12	7
	12	9
	12	9.5
Present audit	12	7.6

Table 1: Comparison of mean average waiting times between referral and initial appointment with other published studies.

The table above illustrates that the average time for an initial appointment is Days, just over a week.

There was a statistical relationship between the previous published studies and the present studies for mean average waiting times ($p<0.05$)

Of treated within 31 days of "decision to treat": As said previously, this data was taken as the date the consent form was signed and therefore treatment required due to evidence of dysplasia and/or malignancy. There were ten positive results of malignancy from a previously arranged biopsy. The mean wait from "decision to treat" date to operation was 29 days (range 17-62 days) within the two-week wait rule.

Of treated within 62 days of receipt of referral: From the ten patients that were treated, there was a mean interval of 71 days (range 40-97 days) from receipt of referral to treatment. Six of the patients (60%) treated were treated with excisional biopsy alone with the other four treated by further surgery (neck dissection and reconstruction).

Effectiveness

Number of malignant cancers

Of the 158 two-week referrals, ten patients were found to have positive malignant oral cancers (6.3%, positive predictive value).

Comparison between other oral cancer detected in 2WW

To see if this study's detection rate was statistically significant, comparison between recent audits and studies in the last decade can be assessed. The table below shows the recent papers/studies that have

First author, year	No in study	Conversion detection rate	Percentage (%)
Williams, 2002 [34]	100	11	11.0
Lyon, 2004 [39]	171	25	14.6
Shah, 2005 [29]	150	9	6.0
East, 2005 [13]	48	3	6.3
Singh, 2006 [31]	76	6	7.9
Duvvi, 2006 [40]	187	19	10.2
Hobson, 2008 [41]	177	22	12.4
McKie, 2008 [30]	1079	118	10.9
Ahmad, 2011 [42]	114	6	5.3
Haikel (first audit) 2011 [43]	163	17	10.4
Haikel (second audit), 2011 [43]	542	53	9.8
Miller (first audit), 2012 [44]	63	7	11.1
Miller (second audit), 2012 [44]	49	3	6.1

Madhvani, 2012 [45]	252	20	7.9
Joshi, 2012 [36]	362	8	2.2
Davey, 2012 [46]	446	27	6.1
Kayhanian, 2013 [47]	50	6	12.0
Present audit	158	10	6.3

Table 2: Collected conversion detection rate of other audits/studies since 2002 (adapted from Langton et al. 2016 [35].

The total pooled conversion rate of all 17 past studies (positive predictive value) was 8.8%. There were a total of 4028 two-week referrals made collectively with 360 cancers diagnosed and the percentages of the detection rate ranging from 2.2% to 14.6%. There is a statistical relationship of detection rates between this audit and previous studies where $p<0.05$.

Ages of malignant cancers

The distribution of malignant cancers related to patient age can be seen in Figure 6. The range was wide with the total sample starting from 17 years old to 80 with a mean age of 47. Patients between the ages 40 to 49 years old made up half of the sample. There was a secondary minor peak in the age group 50 to 59 years old (n=2), with the rest spread fairly equally between the other age groups. No 60 to 69 year olds were found to have any malignant cancers in the study.

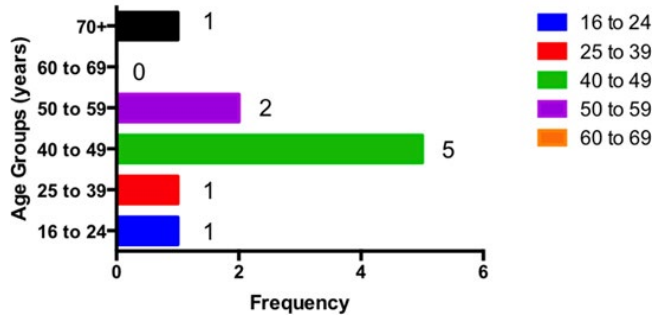

Figure 6: Distribution of oral cancer according to age groups in years. Figures displayed are actual patient numbers.

There is a loose trend between age and the distribution of malignant oral cancer but there was no significant statistical relationship (p=0.0659).

Time of the year

As seen in Figure 7, the spread of incidence of the malignant cancers was sporadic and shows very minor peaks around the winter months in February and November (n=2 for both months) at 20%, albeit no incidence in December and January. There were no cancers in March and July.

The actual numbers were fairly constant during the year and there was found to be no significant statistical relationship (p=0.6985).

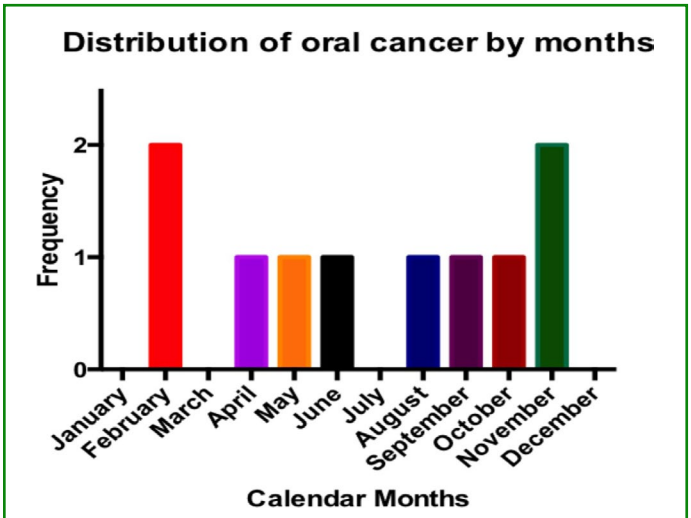

Figure 7: Distribution of oral cancer according to calendar month.

Discussion

Critique of Methodology

This study was a retrospective audit and there were naturally tendencies for flaws and incomplete or missing clinical data records resulting in gaps in some information. Both written paper records were cross-matched with electronic databases that included biopsy reports and dates for any following treatment. This was necessary if the written paper notes were not found or certain paperwork was missing/not printed out and placed in the notes. The original proforma for the referral was not electronically available and therefore all paper clinical notes had to be located to note the referral date.

There were differences in using the two-week rule proforma or writing a letter by primary practitioners. If the letter didn't explicitly state that it was referred under the two-week wait rule then it was not actioned with an appointment within two weeks. Within the study there was one malignancy in

the year period that had such a letter and was not technically under the rule therefore not counted as part of the study.

In addition there were difficulties in knowing when and what date to take for "decision to treat". As stated from Martin [11] the "decision to treat" is the date the patient agrees a treatment plan and not necessary the day the consent form is signed. Not all written notes explicitly stated that patient was happy for treatment to go ahead and therefore this date was very subjective. The consent form date was used as an arbitrary figure as it was a good indication of the patient agreeing to a treatment plan but may not be as wholly representative of patient's decision.

Compliance

Of seen within two weeks of receipt of referral: This study found 96.2% compliance to patients seen within two weeks. Similar findings have been reported with Shah, et al. [29] and Hobson, et al. [41] both quoting 98% and 95.5% compliance respectively. Additionally, a more recent study by Rimmer, et al. [5] reported that 80.7% of patients were seen within two weeks of referral and that the majority of patients had failed to attend the first appointment offered to them and therefore skewing any results. Had these outliners being excluded, the figure would be at around 98%.

The total figures of patients that had missed their first initial appointment, whether cancelled or did not attend, could be explained by the lack of knowledge, such as the unknown potential seriousness of the issue and the affect cancer could have, or the lesion resolving spontaneously.

With the mean average waiting time in this study being 7.6 days this was fairly consistent with findings of numerous other studies [29,30,43] This can be explained by an NHS requirement, following the 1998 White Paper by the Department of Health. A Cancer Services Collaborative was established to test new approaches to streamlining the processes between referral and first hospital visit and therefore achievement of the two-week target was incorporated into the performance rating regime for NHS trusts.

Ways to improve compliance

Failure to obtain 100% was due to patients failing to attend therefore giving a DNA percentage or cancellation percentage (patients rescheduling their first appointment). Other authors have previously suggested some changes to the proforma. Haikel, et al. [43] argued, "Removal of certain symptoms that do not seem to correlate with a malignant diagnosis might be appropriate. Specifically, these were cranial neuropathy, orbital mass and unexplained tooth mobility''. Alternative referral pathways for these symptoms could be advised as well as suggesting including a section for primary care practitioners, medical or dental, to confirm that they have discussed the route of referral with the patient. This would inform the patient of the importance of presenting to the first initial appointment on time and without delay.

Any delays after the onset of symptoms would appear to be the most significant factor in the late presentation of patients with head and neck cancer [43]. This was also reported in studies by Tromp, et al. [48,49] Brouha, et al. [50] and Carvalho, et al. [51]. Patient delay factors were found to be the most significant with only 39% of patients attended within 4 weeks of the onset of symptoms and 29% after 3 months [18] similar to 38% of patients delaying seeking professional advice for more than 3 months after first being aware of the lesion [1,52].

Of treated within 31 days of "decision to treat"

Once the patient is treated, then the pathway under the two-week wait rule ends. During this study the interval was 29 days with a range of 17 to 62 days. Hollows, et al. [18] found 95% of patients were treated within 6 weeks (42 days) of the first consultation. Other studies from East, et al. [13] reported the mean wait from first appointment to operation was 26 days (range 14–46 days) for 'urgent' referrals and 35 days for one 'two week rule' referral. Even so, the time between treatment and initial appointment would still breach the 31-day guideline. The reasons for a delay in these periods are multiple and complex. Practical explanations such a hospital capacity, waiting time of diagnostics, arranging post-operative care to patient factors such as thinking time and co-morbidities all contribute to a "decision to treat". Treatment may include admission for surgery, date the first medication is administered in an agreed course, the first dose of teletherapy, palliative care or active monitoring.

Of treated within 62 days of receipt of referral

Overall, there was an interval of 71 days in this study compared to a mean wait of 40 days (range 14 - 98 days) in Middleborough [13] Very few previous studies have commented on the interval of 62 days from the first initial appointment to treatment. Again, reasons behind a slightly longer period could be in the transfer of patient from East Bourne DGH to neighboring NHS Trusts such a Brighton's Royal Sussex County Hospital (RSCH). This is where the majority of Head and Neck cancer surgery is undertaken as well as any chemotherapy and/or radiotherapy for the East Sussex region. In addition, the Royal Sussex County Hospital does have an issue with insufficient inpatient capacity and the flow of surgeries from theatres suffers. The resulting affect is that certain surgeries will inevitably be delayed, postponed or cancelled.

Effectiveness

Number of malignant cancers

The detection rate of the two-week wait rule for Head and Neck cancers in Eastbourne, and its surrounding East Sussex region, was 6.3% for the academic year 2014/15. The detection rate in this study was similar to detection rates from other published papers as seen in Table 2, with analysis suggesting a decrease during the years that the two-week referral has been in effect from 10.6% for early years (pre-2008) and 6.6% (post-2008) where $p<0.001$ [35,53,54]. Some papers have suggested that there is an increase in the number of two- week referrals and has an important implication by overwhelming the system [55]. This was supported by a 42 percent increase in the number of referrals between 1999 and 2005 [53] and a 60 percent increased between 2001 to 2004 [56].

The size of the study with the total number of patients may affect the detection rate which larger groups resulting in a higher detection percentage [5] this would mean 93.7% of the referrals were diagnosed to be benign disease. There is still an importance to recognize these conditions and giving reassurance to a patient after a specialist examination excluding serious pathology should not be underestimated. Several other specialities including gastrointestinal [23,54,57] breast [53] colorectal [54], central nervous system [58] and gynecology [59,60] all have reported similar detection rates as to this study.

Ways to improve effectiveness

In an ideal world, all Head and Neck cancer patients would be referred via the two-week referral, with low risk patients seen routinely. Therefore certain changes would need to be suggested to improve its effectiveness. The overriding view from GDPs is the need for shorter waiting times for their patients to see an oral medicine hospital consultant [61] a typical view was that a method of achieving this would be 'to have more oral specialists and more clinics.' In addition, having a diagram of the oral cavity on the referral form, which could be marked to indicate the position of the lesion, was felt to be worthy of note. Access to telephone advice and the possibility of using electronic communication could also be considered. Some GDPs also mentioned a referral proforma, guidelines or checklist to help refer suspected patients. This is already in use from the NICE 2005 guidelines.

On the contrary, several authors have focused on the existing NICE guidelines themselves to improve detection rates. These guidelines were not initially developed in an evidence-based manner but as a consensus view [17,56] think that simple guideline symptoms alone are insufficient indicators of potential cancer. The number of referrals made without any risk factors identified on the proforma was very high (58.9%) but it is difficult to know whether there were truly no risk factors or whether they were simply not considered prior to referral [5] Certain referrals for example those of patients with 'acoustic neuroma') are clearly inappropriate and Haikel, et al. [43] argued that removal of certain symptoms that do not seem to correlate with a malignant diagnosis might be appropriate such as 'cranial neuropathy', 'orbital mass' and 'unexplained tooth mobility'.

However, cancer of the head and neck does not present often in either general medical or dental practice, and several authors [28,56] have commented on the need for clear guidelines together with an educational programme, but exactly what type of education is required to improve the accuracy of two-week referrals is not clear. Rimmer, et al. [5,62] suggested that a combination of education and changes to the proforma would increase its effectiveness. Primary care clinicians could receive specific training in the use of the proforma so that fewer patients are referred unnecessarily with it. Study days and guidelines for practitioners were seen as ways in which practitioners' knowledge of oral mucosal disease could be increased [61].

Age of malignant cancers

The mean age of Head and Neck cancers in our study was 47 years old with the most frequent age group between 40 to 49 years. Similar studies have also found the mean age of oral malignancy to be at 50 years old [15] and 61.2 years for males and 65.6 years old for females [18] respectively. Yet about 6% of oral cancers occur in young people under the age of 45 years [63,64]. A high proportion of cases are reported before the age of 40 in high incidence countries around the world. The first cases reported were in Scotland [65] and Denmark [66] with an increasing incidence in oral and oropharyngeal cancer and mortality rate. More recently, there have been Rising trends in oral cancer mortality for age groups 20 to 44 years in the US as well as Europe [67].

East Bourne has an ageing population and it is location on the South Coast is seen as an ideal place to retire and settle. Therefore the results are skewed towards the age populations above 40 years old with the average population age of 43 years according to the latest 2011 census [7]. Therefore there are a large number of referrals from ages above 40 compared to younger generations in East Bourne and its surrounding area. The exception would be Brighton where the age range would represent a typical city with a reversal demographic to East Bourne. This would include young families, a large student population and a workforce of young professionals making up the clear swell of adults

aged 20 to 44 years old [68].

Time of the year

In the present study there was no statistical difference between the frequencies of oral malignancy across calendar months with the joint highest peak, albeit very minor, in February and November. Unfortunately, there is no recent literature within the UK that has investigated the seasonal distribution of oral malignancy. The sample size is small and possible explanations for a peak in winter months are that patients are likely to visit their primary general practitioner, whether medical or dental, before a public holiday period such a Christmas and Easter. This could increase the numbers of patients and therefore a potential increase in referrals. Nationally, the median consultation rate is 5.3 meaning on average a general medical practitioner, nurse or other healthcare professional will see a patient just over five times per year [69].

Why wait for a period of two weeks?

There is certainly evidence that patients appreciate and value the fast-track referral system for suspected cancers [70]. This is also supported by Cornford, et al. [71] who also mention 'the psychological impact of a prompt, negative cancer diagnosis is valued by patients' and therefore would be a 'key motivator' in making an initial referral [72].

There is very little literature on similar cancer fast-track referral systems in Europe or worldwide, besides the UK. One similar scheme is the Catalonian Cancer Plan [73] in Spain. Prades, et al. [74] looked at the Cancer Fast- track Programme for breast, colorectal and lung cancer. A period of 30 days was set between suspicion of cancer and start of treatment yet there is no universally predefined standard of time. Certain countries measure waiting times for cancer, albeit all have with different definitions of a 'waiting time' such as Canada (wait time for radiation or chemotherapy from referral), Greece (anecdotal evidence showing a three month wait for treatment) and Portugal (varying surgery waits from 72 hours to 60 days depending on urgency) [75].

The question is the two week system and its waiting times actually affect survival rates? Hanna, et al. [76] have stated that 'the two-week referral in isolation is unlikely to have any influence simply because it is only a small part of the overall management of cancer'. According to East, et al. [13] The two week rule appears to be of little actual benefit to patient with oral cancer and that there is 'no evidence that a delay of more than two weeks between referral from primary care to specialist care had any impact on outcome' for oral cancers [29].

Again, no evidence exists to suggest that seeing a patient with head and neck cancer within two weeks of referral makes any difference to their outcome [41], however intuitively it would seem that minimizing such delays is generally a good thing. Research via questionnaires found that patients find long waits and uncertainty about their diagnosis distressing [77]. In addition patients referred under this rule did not receive their initial consultation or treatment any sooner than compared to those referred urgently direct to a consultant, letter or otherwise. Hollows, et al. [18] also supported this claim that direct referrals were seen more quickly. There have been recent updates [78] in the UK guidelines issued by NICE but the effect they will have on effectiveness of referrals is yet to be seen or investigated.

Further research

This study focused on the compliance of a district general hospital's maxillofacial department with oral cancer under the two week referral, as well as the effectiveness of the two week referral to detect oral cancers. Many other pieces of literature have used similar methodology in similar collecting periods but in addition sought out the overall detection rate (sensitivity) i.e. the number of cancers diagnosed from different referral sources such as two week rule as well as direct letters and interdepartmental referrals. Hobson et al. [41] state that 44 per cent of patients with cancer came from outside the urgent referral pathway.

Furthermore, some studies extended their data collecting periods to multiple consecutive years rather than a single year similar to Haikel, et al. [43] and Miller, et al. [44] who repeated their audits in two separate years. Extending the length of data collecting should be considered. Future audits and studies in this Trust should include neighboring towns/Trusts e.g. Brighton, for a comparison between each local demographics, ethnicity, socio economic class (use as government benefits as a factor) and risk factors such as smoking and/or alcohol. A recent study in cotland found a 'widening gap in oral cancer incidence between affluent and deprived socio-economic groups by sex', especially in young males [79]. In the UK, there are similar findings with oral cancer risk highly correlating with socio-economic factors [80].

By establishing high-risk patient groups in the surrounding East Sussex region, preventative methods and increased public health processes can be developed. If a study like this is repeated, the genders of patients with malignant disease should be investigated for differences between two sexes. Previous studies have proven that more female patients seem to be developing oral cancers [81] with the incidence rate doubling for women from 1986 to 2006 [39]. Collection of data regarding the presence of oral malignancy and gender should therefore be considered. The origin of referrals could

be compared with general dental practitioners and general medical practitioners; previous studies have found slightly more patient referred by dental practitioners but their medical counterparts were far more likely to see advanced tumours and request an urgent second opinion or diagnosis of malignant disease [6].

It would be interesting to carry out a repeat of this project after a public health campaign; alerting the public to signs of suspicion for example an ulcer not healing for two weeks, hard or indurated rolled edges, associated bleeding or unexplained long term hard swelling. It is postulated that there may be an increased difference in detection rate under the two week system, but a potential increase in unnecessary referrals or referrals via different means other than the fast-track two week rule.

Strengths and weaknesses

This study provides an insight into how oral cancer is detected via the two week rule in East Sussex. It also provides evidence of how compliant the maxillofacial department is to seeing patients for their initial consultant within two weeks. From my perception this research was well conducted with two databases of information to collect data from, both electronically and hard copy paper form. One disadvantage was that the original referral form was not electronic and therefore the physical patient's notes had to be located to know the date of the referral. A year's data collecting was too short a period and therefore made results and analysis harder to draw conclusions from. With variations in detection rate of head and neck cancer as well as the small sample group, the results must be interpreted with caution. In addition, if study was repeated further demographics such as gender, socio-economic class and smoking and alcohol risk factors should be investigated alongside age and time of the year [82-84].

Conclusions and Recommendations

Conclusions

Within the population included for this study, the following conclusion can be made:

- East Sussex NHS Trust was compliant with the two week wait rule with an average wait of 7.3 days.
- There were similar waiting times for the initial appointment under the two week wait rule from previous recent studies.
- All patients were given an initial appointment within two weeks.
- East Sussex NHS Trust was also compliant with the "decision to treat"
- East Sussex NHS Trust was not compliant with treatment within 62 days of referral receipt.
- There was a low detection rate of oral cancer under the two week wait rule at 6.3%.
- There was a statistical relationship of the cancer detection rate between this study and previous recent studies.
- There was no statistical difference of cancers and ages but there was trends of malignant cancers were mainly found in ages above 40.
- There was no statistical difference seen in detection rate between calendar months.

Local recommendations

This study shows trends and relationships relating to oral cancer and its two week cancer referral system, as well as potential ways to improve compliance and detection rates. A public cancer awareness campaign into the signs of oral cancer should be started. Symptoms such as a neck lump persisting for three weeks or more, oral ulceration persisting for three weeks, hoarseness and red or white patches that may be bleeding. These campaigns would educate the public in what to look out for but hopefully increase the chances of detecting cancers. Within the campaign it would be recommended to only seek medical advice should the presence of these signs last for three weeks or more as not to unnecessarily scare the public.

An updated referral pathway from a paper system to an online system such as the Dental Electronic Referral System currently being rilled out in Kent/Surrey/Sussex may would potentially increase compliance and the detection rate of cancers. This is already a feature in neighboring Trusts in the South Coast such as Western Sussex Hospital Trust, which operate an online referral system where dental referrals can be linked to the patient's GP practice as well as additional radiographs and clinical photographs relating to the suspected lesion or ulcer. A feature can be added on a shared database between local dental/medical practices and hospitals of accepting the referral alongside clinical photographs of the suspected lesion or ulcer. These would prevent unnecessary benign lesions such as fibro epithelial polyps and mucoceles or oral ranulas being referred in under the cancer pathway. In addition, an initial appointment date could be displayed on the online database for both primary care practitioner and patient to note as to notify the patient and ensure the patient attends within two weeks.

Although not demonstrated in this piece of research, a potential recommendation can be put forward for further education into the signs and symptoms of oral cancers for dental practitioners and medical general practitioners with day courses. These could be encouraged alongside any essential continued professional development such as the General Dental Council's core subjects of Decontamination/ Disinfection, Radiography/ Radiation Protection and

Medical Emergencies. Refresher courses can also be made available for dental hygienists, therapists and clinical dental technicians as they regularly work in and around the oral cavity.

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