PROTOCOL COVER SHEET

STUDY TITLE:	**An evaluation of an eReferral Management & Triage System for Minor Oral Surgery Referrals from Primary Care Dentist**
INVESTIGATOR:	Professor Iain A Pretty Professor of Dental Health, The University of Manchester School of Dentistry Dental Health Unit, 3A Skelton House Manchester Science Park Manchester M156SH United Kingdom
STUDY PHASE:	Effectiveness, implementation and impact
OBJECTIVES:	To assess the effectiveness, implementation and impact of eReferral management and triage for minor oral surgery
PARTICIPANTS:	i) Female and male adults referred from primary dental care practitioner for Minor Oral surgery ii) Dentists working in primary and secondary care iii) Commissioners and NHS secondary care managers
STRUCTURE:	Mixed methods: Interrupted time series design combined with qualitative analysis
NUMBER OF CENTRES:	1 (NHS Sefton)
PRIMARY OUTCOME:	Number and ultimate destination of referrals made by General Dental Practitioners for MOS
SAMPLE:	A census approach will be taken: All primary care dental practices and secondary care hospitals within NHS Sefton/ will be incorporated into the study. Purposive sampling will be used to select a smaller qualitative sub-sample.

ESTIMATED TOTAL SAMPLE SIZE:

ADVERSE REACTIONS:	N/A
STUDY ORIGINATORS:	Professor Iain A Pretty

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I. INTRODUCTION

BACKGROUND

Minor Oral Surgery (MOS) referrals represent the largest volume, and cost, of referrals from primary dental care to secondary care. MOS referrals, in the main, involve the extraction of teeth and these treatments may be supplemented by adjunct IV sedation offerings. Care is typically provided in oral surgery units within acute hospitals and is consultant led with trainees of various levels undertaking the procedures. The average cost of an MOS referral to acute trusts in the North West region is circa £650. In the North West the total charge for MOS referrals in 2009/10 was £53,864,857.

Referrals from Primary Care General Dental Practitioners (GDPs)

The introduction of the 2006 dental contract provided a Band II payment for tooth extraction that, on North West averages, provides a fee of £75 for one or more teeth to be extracted within a single course of treatment. Figures from acute trusts and eReporting data suggest an exponential increase in referrals of MOS to secondary care. There are a number of reasons postulated for this including perverse incentives in the dental contract (GDPs receive payments for referrals alone at the same Band II level) and that younger dentists may have limited competency as undergraduate experience in MOS treatments is limited (MEE Report, 2010). A number of acute trusts in the North West have struggled to deliver capacity against this increase in demand and work has been undertaken to manage this through a number of routes and approaches.

Current demand management strategies for MOS – NHS Manchester

NHS Manchester has continued the early work started in NHS Trafford with the introduction of the hybrid referral management pilot. All referrals to secondary care are captured (either by post, email or fax) and then scanned for paper-based triage. A website provides practitioners with a live status check on their referral's progress. This work has taken place under the Dental QIPP programme stream in the North West for demand management. By producing an agreed proforma, requiring adherence to a minimum dataset (including provision of appropriate radiographs) and ensuring administrative procedures to check compliance, there has been a 9% reduction in referrals into all dental specialties as well as the diversion of considerable numbers of referrals into primary care and advanced primary care settings. It is important to recognize that, given the drive to decrease costs whilst improving quality of care across the NHS, referral management systems are developing rapidly.

NEED

There is a need to protect and preserve secondary care dental services for those who need them; the current demand on such services threatens their sustainability. The research team was originally alerted to the potential risks to services by a failure of a local acute trust to manage oral surgery referrals within the 18-week directive. A range of approaches were taken to manage the issue at the time – but the dramatic increase in such referrals threatens services across England, not only in terms of the access to care for patients but for the training and educational functions undertaken in such settings. In their report of 2010 the Kings Fund state that simple measures to manage demand are unlikely to succeed – or may have unintended consequences that can only be managed by taking a whole systems approach to service redesign. Such an approach needs a robust research methodology to ensure that the evaluation delivers the required outputs for the NHS to inform such redesigns on a wider footprint and to understand the risks and benefits. The NHS, and the dental budget, are facing considerable challenges, not least the requirement to make savings in the region of £15-20 billion over the next 4 years. This requirement has led to the development of the QIPP agenda and as such there are considerable opportunities to work across sectors and secure organizational change. Working together with commissioners, primary care, secondary care and academia the current climate offers opportunity for change – but change that must be informed by evidence. Since the outline bid was described there have been further significant developments in defining and reorienting MOS services within the North

West. The need for a reduction in the number of centres, and "lone working" consultants has been recognized. Alongside this recognition by consultants has been an acknowledgment that this infrastructure change must be accompanied by change within primary care and the associated care pathways – the need for central referral capture and management has therefore never been greater. If service redesign is to succeed it must, as described in the Kings Fund report, occur at all levels within the pathway and be evidence based. The literature on dental referral management is sparse – with the focus of investigators on the development of referral forms (Sadler, 1993) or primary care MOS services (Dyer, 2009) without an assessment of the implementation of such systems and the associated need for behaviour change against a backdrop of contractual and financial incentives to refer. Several studies have examined the "appropriateness" of referrals but these studies have largely concentrated on the completeness of the record – rather than its true appropriateness for the care patients receive (McGoldrick et al 2001, Woolley 2009). Researchers have often failed to design referral forms on an evidence-based approach or have failed to capture patient need rather than professionally induced demand for the referral. The applicants recently undertook the development of a referral form for dental sedation that included a section to be completed by the patient themselves – and thus involving the service user in the decision to refer (Coulthard 2011, Pretty 2011). There is a need to expand this type of approach into an integrated referral management system. The impact of demand and referral management systems on adjunct dental specialties, training provision and case mix within acute trusts, has not been robustly assessed on a whole systems basis. Indeed, some early work undertaken by the principle investigator (in NHS Trafford) on referral management resulted in coding changes at the acute trusts rendering the same charge to the PCT but for half the activity level. These behaviours, at all levels within the NHS structures providing care, need detailed assessment if referral management is to make a sustainable and real difference to both the quality of patient care and the cost of that care. A thorough economic evaluation will enable the complex interplay between primary and secondary care budgets to be assessed, as well as measuring the opportunity costs and benefits of diversion services.

Purpose of this study
There is a need to balance the potential reduction of costs through managing the number of secondary care dental referrals for MOS against clinical quality, service experience and the broader NHS need to train the clinical workforce. This study will be conducted in order to answer a number of questions relating to the impact of the introduction of the eReferral management system. There are four main questions, around which the research will be structured:

- How does remote centralised referral management (RCRM) impact on GDP behaviour and referral, behaviour and practice?
- How does RCRM impact on secondary care providers?
- How does RCRM impact on patients?
- How does RCRM impact on the NHS?

II. AIMS
The aim of this study is to investigate how an eReferral management and triage system impacts on stakeholders and the referral system, using mixed research methods.

III. STUDY DESIGN

Mixed methods: Interrupted time series design combined with qualitative analysis.

IV. INVESTIGATORS

The Principal Investigator for this study will be:

> Professor Iain A Pretty
> Professor of Public Health Dentistry
> Dental Health Unit
> Williams House
> Lloyd Street North
> Manchester Science Park
> MANCHESTER
> M15 6SE

Other individuals involved in this study include:

a) Dr Tanya Walsh   (University of Manchester; Statistical support)
b) Dr Joanna Goldthorpe   (University of Manchester; Qualitative/ Study Manager)
c) Dr Colette Bridgeman   (NHS Manchester; Consultant in Dental Public Health)
d) Prof Martin Tickle   (University of Manchester; Dental Public Health)
e) Dr Lesley Gough   (NHS Sefton; Consultant in Dental Public Health)
f) Professor Stephen Birch   (University of Manchester; Health Economics)
g) Ms Samantha Illingworth   (NHS North West; Head of Primary Care)
h) h) Dr Caroline Sanders   (University of Manchester; Qualitative)
i) i) Ms. Gina Lawrence   (Trafford CCG; Executive director of Commissioning)
j) Ms Michaela Goodwin   (University of Manchester; Research Assistant)

V. APPROVAL OF THE PROTOCOL

The protocol will be reviewed and approved in writing by NHS ethics through IRAS and the University of Manchester following submission of an appropriately completed form. Ethical approval will be sought regarding the inclusion of patient's personal data and interviews.

The Principal Investigator will ensure all relevant staff participating in the study has appropriate up to date enhanced checks carried out by the Criminal Records Bureau (CRB) prior to study commencement.

VI. DURATION OF STUDY

39 months

VII. SUBJECTS

Patients referred for Minor Oral Surgery by participating sites
Clinicians involved in referral and triage activities
NHS commissioners
NHS Acute trust managers

Inclusion / exclusion characteristics

Patients must:

1. Be referred for oral surgery
2. Be able to understand the patient information leaflet and be able to give informed consent
3. Adults aged > 18

IX. STUDY DESIGN
Interrupted time series design combined with qualitative analysis

Phase 1, preparative work and baseline data collection
Months 1-12
Baseline data collection: Referral data, SUS/ SLAM data/ practice questionnaires
Installation of new referral system and training

Phase 2, virtual implementation (implementation1)
Months 12-24
Sandbox (virtual) implementation of referral system (all referrals ultimately to secondary care, with monitoring of potential DWSpI & primary care cases)
Data collection: Referral data, SUS/ SLAM data
Interviews with professionals
AQP commissioning process
Financial Assessment

Phase 3, full implementation (implementation 2)
Months 24-36

Full implementation of eReferral system (system fully operational, with diversion to primary care settings)
Data collection: Referral data, SUS/ SLAM data
Interviews with service users (post implementation of referral management)
Interviews with professionals (post implementation of referral management)
Economic evaluation

It is important that there is high precision in comparison of the methods of triage and that erroneous referrals should ideally to be sent to secondary care rather than primary care, to ensure patient safety and service quality. The sensitivity and specificity of the triage has consequently been assessed in a recent study (Research Ethics Committee approval: London Fulham, reference 12/LO/1912).

This study will address the impact of the introduction of the new eReferral system and will comprise two main components, which will be described in more detail below:
   1. Interrupted time series study
   2. Qualitative interviews with service users and clinicians and subsequent thematic analysis

Interrupted time series study

This is a before and after methodological approach, which will involve collection of baseline data over 12 months, followed by staged implementation. Implementation will take place over two phases: a sandbox, or virtual implementation of the system (referral decisions made by GDPs will be captured, however all patients will ultimately be treated in secondary care) followed by full implementation of the system, (appropriately referred patients being treated in both primary and secondary care settings).

The pilot study suggests that changes in referral behaviour can be detected as early as three months following the introduction of a management system. The cost reductions seen by triage diversion are seen immediately. However, in order to understand the long-term implications of the referral system, including any reactive behaviour by GDPs or Secondary Care providers we are proposing to run the introduction of the system for 12 months and the full diversion service for a further 12 months. This should allow a full financial year's worth of cost data to be assessed as well as determining the degree of adaptation to the system. The time period will also enable a robust assessment of primary care treatment quality – i.e. there will be sufficient time to determine if cases treated in primary care return to secondary care for additional or remedial treatment as well as tracking seasonal variations in

referrals. For example we have noted decreases in referral volumes around December and January (relating to the holiday period) and increases in volumes round March (relating to end of financial year).

Implementation 1: Virtual Referral management without diversion (year 2)
There is evidence to suggest that the process of collecting, assessing and administratively triaging referrals can result in a decrease of referrals into secondary care. The first twelve months of the intervention will therefore involve practitioners using the electronic referral system, the conditional entry process and the use of administrative and clinical triage. Although the system will capture the decision-making, no primary care diversion will be available and all patients will ultimately be seen in secondary care settings. Referrals that do not meet the threshold will be returned and the case notes system will be in operation enabling advice to be given and further information to be sourced. The system will therefore be operational, but patients will not be diverted to alternate providers. Data from this phase of the study will be used to assess primary care MOS need and applied to assist the procurement of appropriate services based on an AQP (any qualified provider) approach in preparation for the full implementation of the system. In addition, data from this phase will be used to assess the potential activity loss from the acute trust providers.

Implementation 2: Full Referral management with diversion (year 3)
The system will be fully operational and implemented with the use of primary care MOS services.

Outcomes
The primary outcome will be the number and ultimate destination of referrals: rejected, primary care, primary advances or secondary care. There are three main sources of data that will be collected:

a)   Referrals entering acute trusts from dentists via the referral receipt centre of the relevant hospitals

b)   NHS monitoring data received by the local Primary Care Trust and the Payment by Results system including tariff charges associated with this type of activity

c)   Reporting data from NHS business services authority on referrals made by practitioners

This data will be collected continuously, throughout the duration of the study.

In addition to the primary outcome additional metrics will be provided based on the assessment of patient demographics (age, and IMD score), practice profile and treatment type. These data will provide a rich picture of the likely predictive variables involved in service diversion and will assist in service planning in the future. For example commissioning bodies can use these data, matched to a health needs assessment, to plan the level of primary care provision required. They may also be used to assist in administrative triage to reduce the burden on clinical triagers.

Cost effectiveness
In order to estimate the incremental costs (i.e. the net costs incurred by implementing the management and triage programme) costs will be calculated from the perspective of the commissioning body based on banded treatment costs for primary care services (including the MOS primary care service) and actual fees for secondary care (based on tariff charges for new patient assessment, follow on appointments and treatment complexity). In addition the cost of the management/triage programme, and any redirected referrals will be calculated based on primary data collection on the labour, capital and consumables used by the programme. Total costs and mean cost per patient will be compared across each implementation of the system from baseline, through implementation one and two. Costs will include any costs associated with care arising from treatment failures arising during a one-month period post treatment (such failures tend to be acute and hence a 4 week period is sufficient to detect these). The difference in total costs between baseline and implementation 1 and 2 will be used to

calculate a mean cost per referral avoided based on the programme's objective of avoiding unnecessary referrals. Costs to patients and patient carers will also be calculated using data collected by questionnaire on costs incurred in travelling to and from, and waiting and being treated at treatment facilities. These costs will include both the opportunity of cost of time as well as out of pocket costs for public transport costs or private transport, parking etc. Incremental patient costs will be combined with incremental service costs to provide a proxy for societal costs.

Qualitative element

How does remote centralised referral management (RCRM) impact on GDP referral behaviour and practice?

Purposeful sampling will be used to select general dental practices that vary according to parameters included in the quantitative evaluation, including the practice profile according to IMD and patient demographics. We will aim for maximum variation in levels of affluence and population characteristics, such as age and ethnicity. Approximately 10-15 practices will be sampled at the start of Implementation 1 (virtual implementation with no primary care diversion). GDPs and other key members of the practice (where appropriate e.g. receptionists/ practice managers) will be interviewed to discuss previous referral processes and expected changes associated with the new referral system (approximately 2 members of staff from each practice). In addition, further sampling (up to 10 practices) will be conducted following Implementation 1 and based on findings of initial qualitative interviews and the quantitative analysis, to include practices with high, low and medium levels of overall referrals as well as targeting those with high numbers of rejections or referrals into primary care. Semi structured interviews will be conducted to explore reasons for referral rates. Topic guides will be used as prompts, but will also allow for exploration of participant generated issues and will be revised accordingly as new issues emerge. Each practitioner will be interviewed at least twice, in order to investigate the impact of the intervention experienced by practitioners over an extended time period. Those recruited at implementation 1 will be interviewed again during the implementation 2 phase, and those recruited at the start of implementation 2 phase will be interviewed once at the beginning of that phase and once several months later when they have had time to experience impacts of the system. Based on the assumption that 2 staff members from approximately 20 practices will be interviewed, around 80 interviews will be conducted in total.

Semi-structured interviews will be conducted that are designed to include exploration of the following topics as well as identifying other emergent themes for further exploration.
- The reasons for referrals
- The drivers for referrals under the current contractual systems
- The management of rejected referrals – what do they do and what happens to the patients?
- What is the impact of the eReferral system on existing work practices?
- What are the problems, benefits and outcomes for the practice using the system?
- What can be changed or improved?
- What do they feel about patients being directed to primary care?
- How do they manage the case notes system and is the clinical advice helpful?
- What happens to rejected patients during the implementation phase 2?

In addition, interviews will be 'active' in asking practitioners to talk through and demonstrate the processes entailed in making referrals prior to and following the introduction of the new system. They will also be asked to provide examples based on real cases to illustrate problems and benefits of old and the new referral systems.

How does RCRM management impact on secondary care providers?

The diversion of patients to primary care is a potential threat to secondary care providers. This threat can potentially destabilize essential services, alter case mix dramatically, affect training opportunities or

services at risk. It is essential that secondary care services are preserved where necessary and that they adapt to the changes in service requirements. This is not only necessary for QIPP savings to be realized but also for services to reflect needs rather than being demand or professionally driven.

The metric data from both the eReferral system outcomes as well the actual secondary care charges will inform this piece of work. We will select individuals with experience of the three acute settings available to NHS Sefton referrers – the Dental Hospital, the Foundation Trust (Aintree) and the smaller district general (Ormskirk). Multiple qualitative methods, including observation and semi-structured interviews will be used. A member of the research team will visit the three acute settings and spend at least one clinic session observing the general running of the clinic, the work that key practitioners do, and the patients treated. This individual will 'shadow' key practitioners and record observations using field notes in order to capture key aspects of the organisation and running of the clinic at implementation 1, prior to service diversion. These observational visits will then be repeated at implementation 2.   Additionally, qualitative semi-structured interviews will be conducted with key practitioners, and where possible will coincide will observational visits to the acute settings at the two time-points (implantation 1 and implementation 2). The following key practitioners will be interviewed:

- NHS managers with responsibility for minor oral surgery services
- NHS Consultants working in minor oral surgery units
- Training programme leads / directors
- Specialist trainees in minor oral surgery units.
- PCT finance directors with responsibility for secondary care budgets[1]

Again, an iterative approach will be taken to modifying topic guides and following up key issues raised by participants. The content of topic guides and the number of interviews carried out will be somewhat dependent on earlier study findings. However we propose that approximately 12 interviews will be carried out in total. Topic guides will initially address issues of organisational change management generally and will be modified as the study progresses. These data will again be collected during both levels of the intervention to determine any incremental effect resulting from the introduction of referral management alone and subsequent diversion to primary care (for example, reductions in wait time for secondary care). Data from the initial period will facilitate these discussions as there will be a predictive model describing likely activity loss in the second period.

How does RCRM impact on patients?
From the pilot work the research team believe that patients respond well to diversion to primary care. Primary care providers can usually offer a wide range of flexible appointment times, often in extended hours, and the estate is usually accessible on transport routes and within reach of easy parking. Out of some 600 diverted patients only 7 have refused treatment at the selected provider and in each case this has related to travel distance rather than any objection to the care setting. Providers report that patients want to be seen quickly and this tends to over ride any other consideration in terms of provider choice.

However, patient choice is only one area of interest. Secondary care providers have raised concern about the quality of service offered in primary care and many feel that patients will ultimately return to secondary care, often with complications from the initial treatment. Quality of care is a major concern within QIPP programmes and as such the research team recognize the importance of this element of the research bid as it enables the cost savings to be placed into context.

Again, mixed methods are employed. As the first implementation does not employ a diversion the system is somewhat hidden from patients – as they will attend their usual secondary care setting. However, the use of threshold rejections in the first implementation will be assessed by postal questionnaires to all patients for whom their referral was rejected and a proportion of others sent to secondary care to establish a baseline level of satisfaction and cost. In implementation level two an initial postal questionnaire again will be sent to all patients processed through the referral management system. These questionnaires (previously used by BIRCH, Christell H et al) will be used to collect the primary data on costs incurred by patients and patient carers including out of pocket costs associated with public transport fares, private transport and parking and time spent travelling to and from, and

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[1] It is recognized that these individuals may reside in the NHS NCB

waiting and being treated at, the facilities. Patients will be asked, within the questionnaire for consent to view their dental treatment records. From those consenting, a clinical case review will be undertaken to establish; for each case:

- Treatment provided vs. treatment requested on referral form
- Accuracy of referral information and any errors detected (for example on the medical history)
- Any adjunct sedation used whether requested or not
- Number of sessions of treatment required to complete the course of treatment
- Any complications of the treatment requiring further clinical intervention
- Number of review appointments

The research team (PRETTY) has recently developed a data collection tool for such case note review as this has been deployed in an assessment of referral and triage management of child general anaesthetic cases.

Qualitative in-depth semi-structured interviews will be conducted with a sample of patients selected from each triage group (specialist primary care & secondary care) to ensure maximum variation according to parameters such as age, gender, socio-economic status and according to outcome of the triage system, in terms of the treatment pathway followed. We estimate we will interview between 20-30 patients for this part of the study. Patients will be interviewed very early in the process as close to point of referral as possible and will be followed up further down their care pathway in order to explore their experience and views about the treatment decision made. An iterative approach to data collection will be adopted as in previous phases to allow for intermittent analysis and further sampling where necessary. For example, further patients will be sampled later implementation 2 to ensure we include some cases where the decision may have been problematic and to explore a range across the triage groups. The main focus of these interviews will be an in-depth analysis of service user experience, as well as understanding and perceptions of quality and safety regarding service provision. Personal histories of dental service experience will be elicited, and patients will be asked to reflect on good and bad experiences, changes in the system, and markers of good quality service and care.

How does RCRM impact on the NHS? Whole Service Assessment & making change happen
This final stage of the project takes a holistic view of the project and will ensure that unintended consequences are not missed. Referral management is complex process that interfaces with primary and secondary care providers, each of which has different drivers, incentives and ambitions. A need to recognize this and ensure that stakeholders are properly heard is essential to the process of change management within dentistry.

A. Selection practices

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All General Dental practices and acute trust providers within NHS Sefton will be involved in data capture, with settings sampled purposively for qualitative research, as outlined above.

B. Screening and Selection of Subjects

Patients

During implementation 1 & 2 *all* patients referred from GDPs in Sefton will be triaged and processed via the referral management system. Prospective study participants will be identified via the referral management centre and assessed for eligibility by Professor Iain Pretty.

All participants must have been appropriately referred for MOS and consented to the study (please see participant flow diagram, appendix 2). Participants will be asked to provide consent for the following:

i)   For the research team to see their referral notes (example below)
ii)   To complete a questionnaire
iii)   To take part in a semi structured, qualitative interview
iv)   For the research team to view records held by their GDP (for follow up purposes)

Participants will be given a choice of face to face or telephone interviews. For the face-to-face interview participants will be given a choice of venue, either at the University of Manchester, a community venue such as café or in their homes. Interviews will be carried out towards the end of stage 2 and during phase 3 (implementation stages).

Patient information sheets will be sent to participants direct from the referral capture centre following receipt of their referral in order to allow participants sufficient time to decide if they would like to participate in the study. Following their clinical consultation at either specialist primary care or secondary care clinics, eligible patients would be advised by their treating clinician they were eligible for the study and, if they wished to consent, a research nurse was available to take this and answer any further questions they might have. The consent process with the CRN Research Nurse will take place in a non clinical setting within the hospital. Patients would be under no obligation to see the CRN staff and may leave the appointment without further contact. The treating clinician will remind the patient that they are under no obligation to participate and nor will their on-going care be affected by their decision. .

For the minority of Sefton patients who chose to attend a secondary care clinic other than Ormskirk District General, patient information sheets and consent forms will be sent to participants direct from the referral capture centre following receipt of their referral, with stamped addressed envelopes enclosed to facilitate the return of consent forms. Following receipt of consent forms, participants will be sent questionnaires designed to collect baseline data, in time to coincide with their oral surgery consultation appointment. These questionnaires are to be completed after the consultation has taken place, so that patients will have an accurate idea of costs incurred. This system is required as some clinics have low number of eligible patients and hence cannot be staffed viably by CRN personnel. The ability for potential participants to ask questions of the research team is facilitated by the provision of telephone and email contact information.

Participants will be offered a gift voucher to the value of £10 to be redeemed with Amazon or a similar retailer on receipt of their questionnaire. This is to thank them for to completing the questionnaire and take part in the study.

Professionals

NHS commissioners, Acute Trust Staff and General Dental Practitioners will be approached by a member of the research team, either by telephone or face to face during the course of the study. Consent will be sought from these professionals prior to taking part in any interviews or focus groups.

C. Monitoring of the study

This study will be monitored by Staff from the University of Manchester Dental Health Unit, at periodic intervals by the principle investigator and consultants to ensure that the study is being conducted according to Good Clinical Practice Guidelines. NHS guidelines regarding 18 week waiting times will be adhered to.

G. Randomization
No randomisation necessary, a census approach will be adopted, which encompasses all practices and acute trust providers within NHS Sefton.

H. Outputs

Referrals	*Method*
Quality of treatment/ patient satisfaction	Questionnaire/ interviews
Time from referral to appointment	Data monitoring/ questionnaire
Patients' understanding of treatment pathway	Interviews
Number and ultimate destination of referrals	Data monitoring
Number and reasons for DNA appointments	Data monitoring/ questionnaire/ interviews

Rejected referrals	
What happened?	Data monitoring/ interviews

Costs	
Understanding of treatment pathway	Interviews
Quality of data	Data monitoring
Time of referral to appointment	Data monitoring

XI. DATA ANALYSES

Qualitative data analysis
Qualitative data analysis.
 The interviews will be digitally recorded and transcribed. All transcripts will be made anonymous and checked for accuracy. Analysis will draw upon some common techniques of grounded theory approaches (after Glaser and Strauss, 1967) including the technique of constant comparison whereby analysis will be carried out concurrently with data collection so that emerging issues can be explored iteratively. We will also follow stages of coding consistent with a grounded theory approach comprising initial coding of text segments, followed by re-coding and memo writing in order to generate conceptual themes. Themes will be constantly compared within and across cases, paying particular attention to negative cases and possible reasons for differences. The data will be organised with the aid of qualitative data software package ATLAS.ti. Emerging themes will be discussed regularly at research team meetings to enable refinement of conceptual categories and to discuss common threads or differences across the different respondent groups. The team will ensure an audit trail of all stages of the analysis to maximise credibility, dependability, confirmability and transferability (Pope & Mays, 2000; Lincoln & Guba, 1985).
Ethnographic techniques including observation and interviews have been found to be especially valuable in researching organisational change (McDonald, 2007), as well as changes in the provision of care (such as the use of telemedicine; May et al, 2001) and the adoption of new diagnostic technologies (e.g. Mol & Elsman, 1996) to investigate the impact of such changes and how they work in practice. In this study, the observational fieldwork will help to illuminate the impact of the e-referral system on the current work and practice of secondary care practitioners, and field notes will be analysed alongside interview transcripts to illustrate relevant issues raised in the interviews. Similarly, observation records may be used to help elicit interview data within the context of follow-up interviews. We will draw on

established theories of organisational change including *Normalisation Process Theory* which has been developed to study implementation and adoption (as well as barriers) of new work practices and technological interventions within whole health system contexts (May & Finch, 2009; Murray et al, 2010).

Quantitative data analysis
The quantitative analysis has been designed to evaluate the impact of a change in service, with the primary analysis using a piecewise regression / interrupted time series analysis (ITS) design. This is an appropriate methodology to evaluate the effects of a change in service delivery. Whilst it is acknowledged that the lack of a concurrent control group can be considered a weakness (Brown & Lilford, 2008), the nature of the investigation and implementation precludes such a design. The proposed study design and analysis will aim to minimize threats to internal validity (Ramsay et al, 2003): A single PCT boundary (NHS Sefton) with a diverse practice and patient profile has been identified for study; lengthy evaluation pre-intervention and during two stage implementation over three years will address any concerns regarding secular trends (Brown & Lilford, 2009). Additionally, trends observed in Sefton over the implementation period with be compared with national trends in oral surgery referrals through the examination of Hospital Episode Statistics (HES) data. This design will enable 24 months of referral management assessment during the study, and thus captures and enables the measurement of seasonal variations in referral patterns. Further, a large intervention effect has been observed in an earlier pilot study, with a re-direction of MOS referrals from secondary care to primary care based services of over 68% (data from Central Manchester Foundation Trust). The primary outcome measures will be the monthly reported number and ultimate destination of referrals from baseline through to six months, implementation stage 1 referral management alone (12 to 24 months) and Implementation stage 2, referral management with diversion (24 to 36 months). Analysing monthly data has a number of advantages: it enables the cyclical nature of referrals observed in the pilot study to be accounted for; will illustrate whether referral management alone (the process of collecting, assessing and administratively triaging referrals in the absence of diversion) results in a decrease in referrals into secondary care; short-term changes will not be missed; any observed effect is maintained or return returns to original levels. The principal analysis will be to determine whether the implementation of the Referral Management System with diversion has an effect that is significantly different from any underlying secular trend.

Statistical analysis will be undertaken using time series regression models. Pre-intervention and post-intervention (virtual and actual implementation) trends will be evaluated. In addition, the pre and post intervention effects at Sefton will be compared with national trends in order to further investigate the effects of possible secular trends. Analysis and reporting will be undertaken according to recommended quality criteria (Ramsay et al, 2003). The best fit pre intervention and post intervention lines will be estimated using linear regression and autocorrelation will be adjusted for by using the maximum likelihood methods where appropriate (Draper & Smith 1981). First order autocorrelations will be tested for statistically using the Durbin – Watson statistic and higher – order autocorrelations will be investigated using the autocorrelation and partial autocorrelation function.

Two effect sizes will be estimated. First, a change in level of outcome at the first point of after the introduction of the intervention will be estimated for each of the referral outcomes (Primary Care, Secondary care, DWSPI, rejected). This will be carried out by extrapolating the pre intervention regression line to the first post intervention point. The difference between this extrapolated point and the post intervention regression estimate for the same point will represent the estimated change in level of referrals. Secondly, a change in the slopes of regression lines will be investigated by calculating the post intervention minus pre intervention slope. The difference observed for each change will be further investigated for statistical significance.

Data will also be presented descriptively and graphically on the number and nature of referrals according to the referral destinations of rejected, primary care, primary advanced or secondary care.

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Any trends observed for referrals to secondary care for Sefton will be compared with national trends using Hospital Episode Statistics (HES), which will be obtained via NHS Sefton and analysed for statistical significance at each recorded time point.

Appendix 2
Referral Management
Participant flo

Main Referral Centre

Not MOS

MOS

Reject Patient

GDP referral from Primary Care:
All patients

Information complete

Incomplete/ illegible
information

Meets inclusion criteria

Does not meet inclusion
criteria (< 18 years, unable
to consent)

Consultation appointment
sent

Consultation appointment
as usual

Questionnaire & Consent
form sent

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Not consented
No further contact

Consent given
for interview