A randomised controlled crossover trial to assess the effectiveness of, preference for and length of structured reply letters when communicating with referring practitioners

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Abstract

Title

A randomised controlled crossover trial to assess the effectiveness of, preference for and length of structured reply letters when communicating with referring practitioners

Statement

“I have made this letter longer than usual as I lack the time to make it short” (Blasie Pascal 1623-1662)

Objectives

To identify whether :

1. Structured reply letters from consultants were more effective at communicating with and/ or preferred by practitioners when compared to consultants’ standard reply letters.
2. There were differences in the length of the two formats.

Null Hypothesis

No significant difference exists between practitioner’s awareness of key patient information when receiving either the structured consultant reply letter or the standard consultant reply letter. No significant difference exists between the word counts of the two letter formats.

Design

Randomised controlled crossover trial.

Setting

Liverpool University Dental Hospital (LUDH).

Participants and methods

Participants were recruited from practitioners referring orthodontic patients to LUDH. Seventy five practitioners were stratified by consultant and randomised in blocks to receive either the structured or standard letter first, followed by the alternative format six weeks later. For both groups, the word count was recorded by the secretaries. 'Knowledge and satisfaction' questionnaires were dispatched with the letters, completed by practitioners and returned to the department.

Outcome measures

The primary outcome measure was the practitioners' awareness of the key information contained within the letter. The secondary outcome measure was the secretarial typing times for the letters.

Results

The response rate was 87%. There was a statistically significant improvement in practitioners' awareness of their patient's status (odds ratio 8.84 95% CI 1.08, 72.52) and the action required (odds ratio 4.13 95% CI 1.10, 15.45) after receiving the structured letter. Practitioners showed a strong preference ($p<0.001$) for the structured consultant reply letter which were statistically significantly shorter than the standard format with a mean difference of 108 $\pm$ 10 fewer words (mean difference: 108: 95% CI -118.14, -97.86).

Conclusions

This trial demonstrated that there was a statistical significant improvement in practitioners' perceptual and actual awareness of their patient's status and any action required, having received the structured letter. The structured reply letters had significantly fewer words than the standard letter. Practitioners strongly preferred the structured reply letter format.

Acknowledgements

I would like offer my sincerest gratitude to my supervisor Dr Jayne Harrison. Having had little previous experience in conducting research she has guided, inspired and motivated me to through my three years of studies at the University of Liverpool. Her enthusiasm and perpetual energy has motivated all her students, including me. Her dedication to numerous research projects does not go unnoticed and I am sure she worries that she sometimes spreads herself to thin, but regardless of this almost insurmountable workload she sets an example of a world class researcher. At times no doubt I have made her feel like she was knocking her head against a brick wall with frustration, despite this she remained accessible and forever willing to help me. The experience has broadened my perspectives and outlook on research and for this I am indebted to her.

I have been delighted to interact with Mr Stephen Rudge over the past three years and thank him for his clinical and academic support. He once captivated me with a “post it” note inscribed with three attributes he wanted me to grasp in order to fulfil my potential. I have found them to be very applicable to all aspects of life not just my research study. They read: 1. Systematic approach, 2. Precision and 3. Attention to detail.

I hope my nomination for him to bear the Olympic torch in 2012 is successful and is received as a small token of my gratitude.

Further thanks should be offered to David Waring for initiating the trial and those that assisted me during it. Mrs Sue Pender for her assistance in developing the knowledge and satisfaction questionnaires. Trish and Jenny, the departmental secretaries, who were tormented by my impromptu spot checks. Girvin Burnside for his statistical input and the three orthodontic consultants Dr Jayne Harrison, Mr Stephen Rudge and Professor Neil Pender. The latter has sculpted an excellent research environment for this study to be both a smooth and rewarding experience for me.

Sacrifice can be defined as:

"Willingly foregoing something of value in the belief that in the future something more valuable will be attained."

To my loving wife Rebecca, beautiful daughter Jessica and welsh sheepdog Leo who undoubtedly made the greatest sacrifices. You have provided unwavering love and support and I am deeply thankful for this.

To you I give you my full and unrivalled attention!

Consort guidelines

CONSORT, which stands for Consolidated Standards of Reporting Trials, encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs).

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation (CONSORT 2010)

The CONSORT Statement comprises a 25-item checklist outlined below:

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	page No
Title and abstract			
	1a	Identification as a randomised trial in the title	2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	16
	2b	Specific objectives or hypotheses	47-49
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	50
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	52
	4b	Settings and locations where the data were collected	51
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	62
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	62
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	51
	7b	When applicable, explanation of any interim analyses and stopping guidelines	51
Randomisation:			52

Sequence generation	8a	Method used to generate the random allocation sequence	55
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	55
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	52
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	52
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	62
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	63
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	63
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	68
	13b	For each group, losses and exclusions after randomisation, together with reasons	68
Recruitment	14a	Dates defining the periods of recruitment and follow-up	51
	14b	Why the trial ended or was stopped	52
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	71,72
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	70
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	76,78

	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	76-78
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	68-85
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	107
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	94
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	93
Other information			
Registration	23	Registration number and name of trial registry	50
Protocol	24	Where the full trial protocol can be accessed, if available	63
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	160

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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1. Introduction

'I have made this letter longer than usual because I lack the time to make it short' (Blaise Pascal, 1623-1662)

The British medical system is based on the principal of referral and this is likely to continue. It has been claimed that the communication between hospital Consultants and referring practitioners has become solely dependent on the letter of referral and reply, a type of two way exchange, for information, facts and opinions ensuring mutual isolation (Pringle, 1991). Almost every report published within the National Health Service (NHS) has made reference to or recommendations to improve this relationship between primary and secondary care. To date the evidence suggests this remains a formidable task (Tanner, 2006).

As the NHS moves in an increasingly market driven direction, competition between private sector and neighbouring hospitals may ultimately intensify. The development of a hospital dental service, which can meet the needs of both General Dental Practitioners (GDPs) and consumers, is therefore paramount. Communication is one aspect of this which could improve professional and patient relationships (Pulia, 2011). A referral based service between GDPs in primary care and consultants in hospital based specialities is well established. Good communication between these parties is pivotal in ensuring optimal patient management and continuing education of practitioners (Gagliardi, 2002).

Patient care hinges on an adequate and timely exchange of information between treating practitioners (Pringle, 1991). Ensuring that letters meet the needs of the letters' recipients potentially saves time for the clinicians and patients, reduces unnecessary repetition while helping to avoid patients being dissatisfied or confidence in dental professionals being lost (Pringle, 1991).

Managers and administrators have recognised the additional imperative for addressing referral communications. Standardised letters have a potential to collect the minimum data set thereby satisfying the requirements of the Department of Health (Wallis, 1993).

A substantial amount of time is spent by clinicians writing or dictating letters to referring practitioners (Tattershall, 2002). The extent to which these letters contain the relevant information that is required by the recipient is largely unknown. Pringle (1991) described the consultant reply letter as the "most neglected route of GP education"

It is evident that numerous problems exist within our current referral system. The ability to collect the minimum data set is a requirement set out by the Department of Health, and at present the referral letters have no means to collect such data. Instead this data is collected via a separate minimum data sheet. If a standardised letter can be designed in such a way to collect this information, not only will we satisfy the Department of Health but, it would have the potential to improve the efficiency of the orthodontic department.

The problem of inadequate communication potentially damages our professional working relationships and has a resultant impact on effect to the standard of patient care we ultimately provide. A standardised letter can potentially improve these communication channels and subsequently improve our professional working relationships and raise standards of patient care (Pulia, 2011).

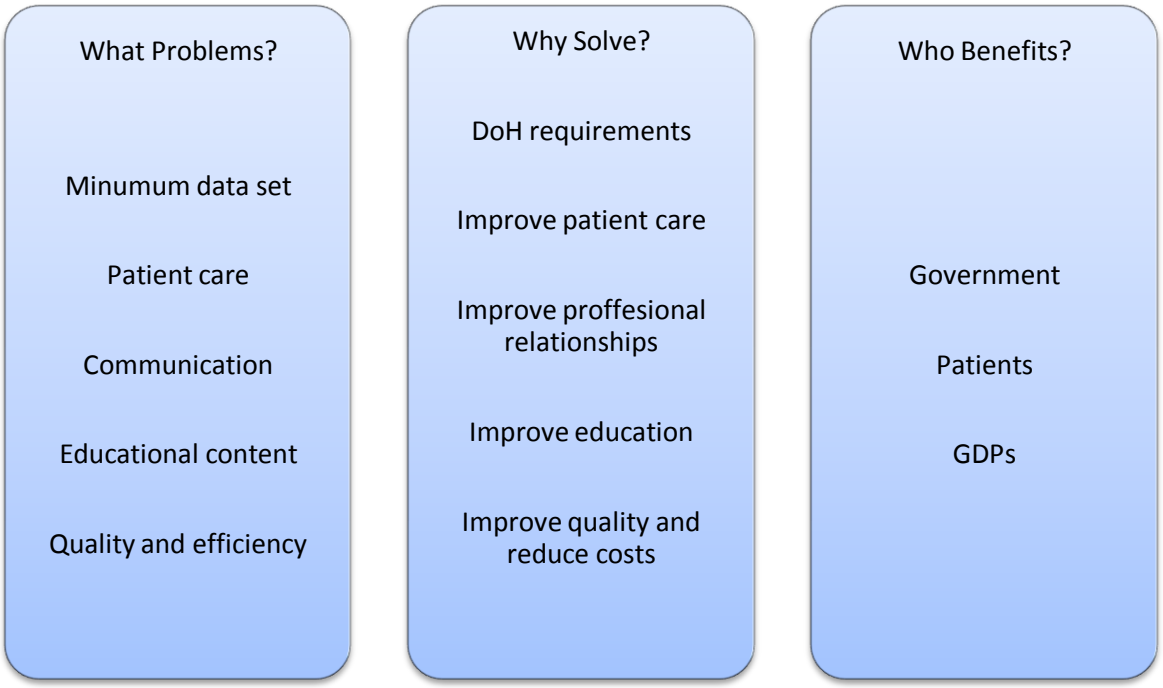
The lack and inconsistency of educational content within the current referral system potentially neglects one of the most important sources of knowledge and educational exchange between primary and secondary care (Pringle, 1991). A structured reply letter can potentially improve the uptake of knowledge to GDPs. The letters could also provide some form of clinical case specific continued professional development allowing the introduction of continued professional development into referral system (Gagliardi, 2002).

The current referral system is at times inefficient and expensive. The introduction of a structured letter template can potentially reduce both dictation and typing times for

departmental consultants and secretaries. In a time of financial difficulties and government spending reviews, the structured letter has potentially large cost savings to the health budget. If continued professional development can be provided through our referral system, then this could potentially ease the burden on the current more expensive methods of continued professional development delivery.

In summary, it is clear problems exist with the current referral system (Pringle, 1991, Tattershall, 2002). If it can be proven that a standardised structured letter format is accepted by our referral source and can deliver the same core information to GDPs then we can potentially deliver a more efficient and cost effective quality of service to our patients and referring clinicians. We can revolutionise the way we as a specialism deliver continued professional development to our GDPs making it more case specific and cost efficient and improving the knowledge and education of our practitioners. Figure 1.1 illustrates the problems associated with our current consultant reply letters, outlines the reasons the letters need to be modified and the benefits in doing so.

Figure 1.1 Referral problems, solutions and benefactors



To date few studies have investigated the information content of consultants' reply letters and recipients' preferences. Research in this field appears scarce. This study will aim to add to the evidence that the introduction of a standardised structured letter pro-forma is of potentially great benefit to the orthodontic profession.

The recent regional Mersey audit by Waring in 2007 investigated the deficiencies within our orthodontic referral letter system. The study proposed the use of a structured reply letter and proposed this be robustly tested by a randomised controlled trial. This audit therefore provided the impetus to instigate this study.

2. Literature review

Traditional perceptions of the two branches of the medical profession (primary and secondary care) were summarised rather bluntly by Horder in 1977. He described the primary care clinicians as being jealous of the status, facilities, and income of their specialist counterparts. Resentful of their colleagues' achievements, relationships were strained for many decades (Marshall, 1998). He described the specialists' view of their referring practitioners as nothing more than somebody to carry out the task of sorting the minor from what was major and to refer the latter to the hospital. While it may appear a little exaggerated much of the literature in the 1960s and 1970s confirmed the problems between the two parties (Stevens, 1966, Honigsbaum, 1979). More recent research, addressed in this literature review highlights that there might still be problems with mutual understanding and communication. Specialists complain about inadequate information and unnecessary referrals while primary care practitioners express dissatisfaction with the delays and the content of information received.

2.1 Educational content of letters

Pringle commented in 1991 that '"consultants' reply letters are not being utilised as learning tools for GP education". This prompted Gagliardi (2002) to undertake a systematic review of the use of referral reply letters for continuing medical education. She carried out the systematic literature review between 1990 and 2001 which formed the basis of her MSc project at the University of Toronto, Canada.

The search strategy identified 1250 articles of which 9 met the inclusion criteria. Three of the studies were based upon content analysis of replies to referral letters (Pringle, 1991, Westerman, 1990, Couper, 1996). Pringle (1991) found that 26 % of referral replies had educational content. Whilst Westerman (1990) reported that 54% of the panel of specialists and 44% of the panel of GPs, judging the referral reply letters thought that they offered

suitable educational content. The third content analysis study (Couper, 1996) used a pre/post design to examine the influence of a structured referral letter on the quality of referral replies. The study found that significantly more information about follow up care was included in reply letters after the use a pro-forma referral letter.

The remaining six articles were survey studies (McConnell, 1999, Meara, 1992, Van der Kam, 1998, Newton, 1992, Stalhammer, 1998 and Ghandi, 2000). The surveys demonstrated that GPs felt that information regarding diagnosis, treatment options, treatment plan and follow up care were of utmost importance.

Although the Gagliandi (2002) study had numerous exclusions, one of which being 'dental referrals', it raises some crucial issues. Her review highlights the importance of the relationship between primary and secondary care. The review identifies that little educational content is currently included in reply letters from specialists to GPs. The review identifies that GPs are receptive to the idea of greater educational content to be contained within the letters and speculates why educational content is perhaps negated. Generalists and specialists have opposing perspectives and opinions on the role of the consultation and use different strategies in caring for their patients which directly influences the referral letter. Specialists may purposely withhold information of an educational nature from the referral letter believing that appropriate care would be delivered best within the secondary care environment or because patients may be privy to the letter. The view that specialists refrain from providing feedback to avoid seeming patronising was also suggested. The review demonstrated that GPs would welcome more feedback and that they would prefer teaching that is directly related to their clinical practice rather than the traditional formal education such as lectures.

The review reinforces what Pringle (1991) believed, that referral letters were a neglected route of education to the referring practitioner. It adds weight to the idea that the use of an enhanced referral reply letter can offer an inexpensive way to transfer practice based

relevant information from specialists to referring GPs leading to improved continuity and overall quality of care.

The rate of referrals to and from general practitioners (GPs) to specialists varies, with reports ranging from 5% to 15% of patients seen (Gagliardi, 2002). GPs usually make referrals to seek specialist advice on diagnosis and treatment or ask the specialist to direct the patient care. Many methods of communication are available to clinicians including, telephone, paper (including mail and fax), “curbside conversations” and electronic mail. It has been found that structured written formats transmit more information than informal channels (Anderson, 2000).

Despite the crucial role of consultant referrals, the medical literature suggests that GPs receive little or no information regarding the care of their patients with studies of referral letters consistently reporting that practitioners are dissatisfied with their content and quality (Grol, 2003). The aforementioned study investigated both referral letters and subsequent reply letters to hospital specialists in the Netherlands. His findings demonstrated that the quality of both referral and reply letters could be improved. A particularly striking and new finding, from his study, was the apparent lack of real exchange of information. Reply letters often contained only standard clinical details with little or no consideration for diagnostic information. The requests of the referral letter were rarely given an explicit answer. The study found a weak correlation to the standard of both referral and reply letters, with better referral letters only partly resulting in better reply letters. It would appear from his study that the two letter types reflect two unrelated worlds. When the reply letter starts with an explicit reply to the referral letter’s specific request an explicit answer is generated four times more often. It appears most specialists do not consult the referral letter when formulating the reply letter. Including the reason for referral in the reply letter can potentially improve the communication between the two parties.

2.2 Structured reply letter studies

A number of studies have been undertaken to investigate the quality of referral letters from General Dental Practitioners (GDPs) (McAndrew, 1997, Hammond, 1996) and medical practitioners (Rawal, 1993) to hospital consultants. There are very few recent studies that investigate the content of consultant reply letters (Tomlinson, 2006, Saha, 2006) and fewer still investigating Orthodontic consultants' reply letters.

Lloyd (1993) attempted to improve the quality of correspondence by introducing and promoting the use of a problem list within the letter. A letter written in a structured format with both a problem list and management plan was introduced by Rawal (1993).

Rawal (1993) investigated the use of a structured letter containing a problem list and management proposals. One hundred General Practitioners (GPs) were randomly allocated to receive either a standard or structured reply letter. He discovered that 88% preferred the structured reply letter. He found the structured reply letters obliged the writer to state the problem and detail how it should be managed. It became evident that the majority of GPs refer to the copies of past correspondence for a summary specific to the patient. He determined that the structured letters were shorter to dictate and easier to transfer to computers. Although the letter requires greater discipline, the study highlights how the structured reply letters were preferred.

A study by Ray (1998) looked at patients attending open access chest pain clinics within the Royal London Hospital. After attendance by a patient, a response letter was produced and subsequently assessed by the GPs. Recipients preferred the structured computer generated reply letters to unstructured dictated letters.

Newton (1992) set up a study to canvass the views of all general practitioners and consultants in Newcastle regarding the content of referral letters and replies. They aimed to assess the feasibility of standardising certain aspects of referral letters and subsequently

use the information for audit purposes. He recognised that letters were typically the sole method of communication between general practitioners and hospital specialists and could function as a means of education between both parties. Since patient care hinged upon this communication medium, the authors felt that it was very important it should be undertaken as effectively as possible. In their study they distributed postal questionnaires to all practitioners and consultants in Newcastle. Two hundred and seventy four doctors replied, representing a 77% response rate. The results demonstrated that the use of standardised categories to state the reason for referral was not endorsed. 63% of general practitioners felt that the consultants reply letter should include the 'worth' of the referral, however, only 34% of consultants agreed with this. The authors highlighted that the educational element in the reply letters was some way off performing its function on a regular basis. Newton (1992) recognised the role standardised reply letters can have in professional led audit while utilising the administrative values gained from the data.

2.3 Letter studies from medical specialities

A small number of studies have investigated the specialist letters within the cancer care setting. Bado (1984) highlighted, in a study of 97 GPs, that recipients' preferred letters which contained specific technical information. Specifically, diagnosis, results of any investigations and any treatment plan. Social details were regarded as less important. The study demonstrated that 80% of GPs wanted information on patient prognosis, yet only 20% of letters provided this.

Tattersall (1995), an oncologist from Sydney Australia undertook an audit of his reply letters. He identified eight items defined as essential by the majority of the letters' recipients. These were:

1. Diagnosis
2. Clinical findings
3. Test results

4. Further tests
5. Treatment options
6. Recommendations
7. Prognosis
8. Likely benefits of treatment
9. Possible side effects of treatment

Half of the letters' recipients felt medical history, drug and social history were not considered essential yet many of the letters contained them.

McConnell (1999) investigated letters from oncologists to referring practitioners. A total of 7 oncologists, 11 GPs and 10 surgeons were interviewed and asked to express what information should be present in the reply letters after the initial oncologist assessment. They identified thirty two categories of preferred information and compiled a list of the problems associated with inter professional communication. From this data researchers developed a questionnaire that aimed to explore the views of a wider sample. A national Australian survey was conducted on oncologists, surgeons and GPs and identified five key categories of information from the original 32. These included:

1. History
2. Psychosocial concerns
3. Examination and investigation findings
4. Future management/ expected outcome
5. Treatment management plan

Letters were then gathered by a large group of oncologists, studied for their contents and compared to the previously outlined preferences. The results demonstrated that letters commonly contained information on examination findings yet rarely mentioned treatment

plan, expected outcome and psychosocial concerns. The study highlighted that a delay in receiving the letter was of the greatest concern. The study proposed the construction of a specific template letter for oncologists.

In a recent study Thong (2010) undertook a quality assurance survey to improve communication between ENT specialists and general practitioners and was recently published in the literature. The study was based at an Otorhinolaryngology head and neck department in Singapore and sampled 1700 GPs. Two letter formats were dispatched to the GPs for their scrutiny. One consisted of free text and the other was in the form of a structured format with a summary at the beginning. Unfortunately the study had a 32% response rate which was disappointing and means that the results must be interpreted with caution. Despite this, the 535 GPs opinions expressed an overwhelming 96% preference for the structured reply letter which is in broad agreement with other studies. The authors thought that the structured reply letter format allowed readers to identify the information they desired easily and this improved the quality of correspondence between specialist and GPs

Scott (2004) set out to evaluate explicitly the quality of reply letters for new patients referred to clinics at a tertiary teaching hospital in Brisbane, Australia. Letters were audited retrospectively for 10 different specialties at the Princess Alexandra Hospital over a 3 month period. The audit assessed 297 new patient referrals against numerous quality attributes. The study achieved a response rate of 69% and identified specific short falls in reply letters while suggesting areas for improvement. Specifically, the authors believed that the letters should contain a list of medical problems, provide education to recipients while minimising technical jargon. The authors favour listed information, which was felt to reduce redundant information, while ensuring important information was not overlooked. The study concluded that the use of structured reply letter templates facilitated a more consistent inclusion of key information to the recipient.

2.4 Letter studies from dental specialties

Noble (1994) conducted an orthodontic audit to assess how Orthodontists communicated with their referring practitioners. Over 100 questionnaires were sent to GDPs and an 83% response rate was achieved. His results demonstrated that 59% of GDPs felt a brief, but formal, treatment plan was required in the letter. This was seen to assist the GDPs in answering questions from both patient and parent. It can be concluded from the study that effective cooperation between the GDP and Orthodontist is essential to ensure the delivery of high quality care. However, excessive amounts of information can be counterproductive and wasteful of resources.

Hammond (1996) conducted a study involving 268 GDPs and 13 consultants to determine the content of reply letters from orthodontists. This study concluded that GDPs valued highly the following items:

1. Date Seen
2. Name of clinician
3. Treatment plan
4. Short case description
5. Length of wait prior to commencing treatment.

The length of wait was also deemed an important factor by Tomlinson (2006), who thought it could prevent a possible 'loss to care'.

A peer review amongst restorative specialists, on the quality of their communication with referring dental practitioners, was undertaken by Rickets (2003). The study aimed to assess the quality and appropriateness of replies to practitioners from specialists and trainees in restorative dentistry. Seven practitioners took part in the study and assessed 5 referral and reply letters for 5 patients they had seen for consultation. These reply letters were peer reviewed against strict criteria including medical history, clinical findings, clarity, treatment

plan and tooth notation. Interestingly, the study demonstrated a generally favourable response to the letters which conformed to the agreed criteria. However, particular problems were identified with the tooth notations, as the reply letters used different forms of tooth notation including FDI, Palmer and UR / UL / LL / LR. It was concluded that a further study, by other specialities, would be advisable.

Saha (2006) evaluated the quality of written reports provided by consultants in restorative dentistry to GDPs in the West Midlands. The study highlighted that the use of bullet points was deemed important in summarising the content of the letter concisely. Therefore, the opportunity exists to improve communication by using a structured reply letter with a bullet point format.

2.5 Randomised controlled trials on reply letters

Two randomised trials into the structured reply letters were identified (Melville, 2002, Wynn, 2004). Melville (2002) undertook a randomised control crossover trial to assess the effects of structuring clinic correspondence. The study was undertaken at Keele University medical department and consisted of 32 participants, randomised to read either the unstructured or the structured letter first. The outcome measures were identified as the number of correct items recognized, the letter rating, letter preference and reading time. The results suggested that the structured letter was statistically significantly ($p<0.02$) better at allowing key points to be identified. The authors found there to be no reduction in reading time between the two formats but a statistically significant preference and higher rating in favour of the structured reply letter. This study does not test the structured reply letter in the "real world" as only one case scenario was examined and therefore its results may not be generalisable and should be interpreted with caution. One interesting aspect of the study was that the authors reviewed psychological literature and suggested that the process of language involves three brain "modules" interacting. An "orthographic module" interprets lines and curves as characters, a "semantic module" grammar, and a "phonological module" spoken words.

They conclude that their findings support the hypothesis that the structured letter enhances strategic reading, by possibly improving the semantic processing pathways.

The second randomised control trial (Wynn, 2004) took place in Stockport and involved 210 GPs who were randomly allocated to one of four prototype letters. The GPs were asked to rate the letters on readability, structure, content and overall feel. Unfortunately the study only achieved a response rate of 42% so is likely to suffer from response bias. However, the results demonstrated that GPs had a statistically significant preference for structured reply letters and was in keeping with previous studies. The study suggested that structured reply letters were deemed easier and quicker to read, easier to extract information from and generally preferred by the GPs.

2.6 Site specific studies

A more recent audit carried out in Mersey Deanery (Waring, 2007) investigated whether the content and format of the current orthodontic consultant reply letters were appropriate or whether they required improvement. The study sought to address whether or not:

1. Orthodontic reply letters were too long or too short.
2. The information given was too much or too little.
3. GDPs were clear as to what was happening to their patient and what actions were subsequently required.

The study also gathered information to assess:

1. What information was requested by GDPs.
2. What form the reply letter should take.
3. The preferred tooth notation.
4. The preferred communication medium.

The audit revealed that an alarming 29% of GDPs were unaware of the status of their patients and 25% were unsure as to what action was required to be undertaken by them.

The GDPs expressed a preference for summaries of the diagnosis and treatment plan in a list format rather than free text. The audit identified that GDPs prefer the Palmer style of tooth notation. Although this was deemed to be the most popular tooth notation system it was noted that this can cause difficulties when electronic communication is used. Aspects of the treatment plan were thought to be more important than information about the examination. The audit highlighted that GDPs considered that a significant proportion of the information contained within the reply letters was obsolete and that potentially relevant information may be poorly communicated. Clearly this is likely to affect the efficiency of the referral service and may influence the GDPs' choice of provider. An improvement in the quality of reply letters was identified as a necessity. The audit proposed that a structured reply letter following orthodontic consultation should be introduced within the Liverpool University Dental Hospital Orthodontic department. The authors considered this to be greatly beneficial in providing referring primary care dentists with information that they wanted and to reduce administration time and secretarial workload, thus providing substantial time and cost benefits. The structured format would also instil a greater level of consistency to the letters allowing for inclusion of key information.

The structured reply letters were deemed to be quicker to dictate allowing a quicker response time in communicating with the GDP. If this was correct then a reduction in secretarial time required and subsequent cost benefits could be expected.

It was from this audit that the current trial was developed. The proposed structured letter used in the current trial was designed to include three summary boxes. The first for diagnosis to include the patient's age, incisor classification, skeletal pattern and complicating factors. The second for the treatment plan to contain information regarding the type of appliance to be used and expected duration of treatment. The final box was entitled "Action Required" and was to include information on which teeth may require extraction or restoration and what is expected of the GDP to do.

The structured reply letter was designed to address the needs of the practitioners in the Mersey region. Practitioners have been critical of previous letters with respect to their length and the overwhelming amount of obsolete information with little or no relevance to the recipient. Figure 2.1 is an example of the text contained within one such letter.

Figure 2.1 An example of a criticised consultant reply letter

Dear Mr . . . . . .

Re: Patient . . . . . .

"Thank you for having referred this patient back to me for Orthodontic reassessment, now that the UL3 has erupted palatally positioned."

"I saw the patient, initially, in relation to your re-referral on 30th April 2010 when they confirmed that patient would wear fixed appliances (but still not headgear) but I did note that his oral hygiene was not yet of a sufficiently high standard to place fixed appliances. Nevertheless, with respect to the latter, in the hope that it would improve significantly within a reasonably short period of time, I have referred him for a lateral skull radiograph taken in the cephalostat so that I could check my clinical impression of the features such as skeletal pattern and incisor inclination that I had made when I saw the patient previously for a consultation in June 2009."

"I then saw the patient for a fuller consultation on the 8th July 2010, when my main findings in relation to the previous diagnosis and treatment plan (June 2009) were as follows:

"The patient is aware of an unerupted tooth, but otherwise happy regarding his malocclusion and doesn't really want to have anything that would involve surgery"

"The skeletal pattern is, clinically, at least, mild Class II, with a Frankfurt mandibular planes angle which appears to be close to average, or slightly increased, and a slightly increased lower anterior face height. The patient can open approximately three fingers width inter-

incisally (mine not his own), there is no obvious mandibular deviation and he reports no symptoms of temperomandibular dysfunction"

"Teeth present were upper 7654321/12C4567 and lower 7654321/1234567"

"The lower arch exhibits probably mild crowding, overall: although there is an approximately 20 degree mesio-buccal rotation of the LL3, there is also a little bit of spacing between the incisors; LL5 is slightly lingually positioned, LL4 is slightly buccally positioned; as a whole, the lower labial segment appears clinically proclined. There is a spacing tendancy in the upper arch, with space between the UR4, UR3, UL4, ULC, UL2, UL1; UR2 is midly mesio-palatally rotated and there is slight buccal positioning of UR3 and UL5; the upper labial segment is clinically proclined."

"The molar relationship is bilaterally Class I. The incisor relationship is Class II, division 1 with an overjet of about 6mm and an overbite which is increased and complete. The upper dental centreline is to the right of the lower and the discrepancy is almost but not quite half the width of a lower incisor. There is a crossbite tendency of the LL3 with the ULC, but when the patient closes in centric relationship, there is no obvious mandibular displacement detectable prior to his achieving maximum intercuspation."

"The oral hygiene and gingival condition are fair/poor in places. There is evidence of some early attrition having occurred to the LL1, LL2 and possibly UR2. ULC has lost about a third of its clinical crown height through attrition."

"Radiographs revealed the presence of all permanent teeth to include the third molars, the crowns of which were still calcifying when the previous OPG radiograph was taken in July 2007; a more recent OPG radiograph taken in May 2009, indicated that there was still a significant amount of root left of ULC, but UL3 had been moving occlusally, but also mesially, and is almost certainly palatally positioned behind the UL2. A number of the teeth have fine

tapered roots, but they are also quite long: in the event of active orthodontic tooth movement, these teeth can be at an increased risk from root resorption, although I would not see this as an absolute contraindication to having orthodontic treatment. No lateral ceph radiograph was taken as it appeared that the patient might not be able to have comprehensive orthodontic treatment without some dento-alveolar surgery, which he didn't want."

"The patient may need to see his General Dental Practitioner regarding his oral hygiene procedures. These would need to be of higher standard if orthodontic appliance treatment was to be considered. You will need to monitor the attrition of the teeth and in the event of not having orthodontic treatment to discuss the possible restorative dentistry implications in the ULC region, if this tooth did not last him a lifetime and the UL3 did not erupt, naturally, into a favourable position."

"If the patient was to have comprehensive treatment for his maloclussion, then this would involve the fitting of upper and lower fixed appliances and I feel that he would most likely need to be prepared to wear headgear, if temporary anchorage devices were not available. Dento-alaveolar surgery would be needed to surgically expose and probably bond a gold chain to the UL3 and the upper left deciduous canine ULC would also need to be removed. Details of this treatment would need to be confirmed, probably with the taking of a lateral ceph radiograph, but one would only take the latter if the patient was definitely prepared to have dento-alveolar, whilst the UL3 remained unerupted."

"Another possible alternative, if the patient wasn't automatically going to have fixed appliances would be to consider the extraction of the upper left deciduous canine ULC and still dento-alveolar surgery to expose and possibly bond a gold chain to the UL3, but then to apply traction to the latter tooth using a removable appliance, not recognising that complete alignment of this tooth might not be possible by these means, (additionally the LL3 might

impede full alignment) and then the patient might need to accept the possibility of having fixed appliance treatment."

"Either of the above orthodontic treatment might need to be followed by a period of retention. They would be borderline for being carried out by a suitable experience practitioner working outside the hospital service."

"If the patient was not having orthodontic appliance treatment to actively bring the UL3 down into alignment, then his options would be:

To just accept the situation and monitor the possible further eruption of UL3. I think that there is a high chance that UL3 will eventually erupt, naturally, of its own accord, although I cannot say exactly how soon. However, one could not guarantee that the tooth would then be in good alignment – if the patient was unhappy about the situation then he would have to accept the possibility of orthodontic appliance treatment (which would be suitable for an appropriately experience practitioner working outside the hospital service to carry out)."

"OR"

"One could consider the extraction of the upper left deciduous canine ULC in the hope that this would encourage a more normal path eruption of the UL3. There is a possibility that this might have a positive impact on the situation, but an improvement could not be guaranteed. If space was being lost, in the meantime, then a removable space maintainer might be fitted. The main disadvantage of carryout this treatment is that the patient is almost 16 years of age and this type of interceptive approach is usually recommended in a younger age group. The same consideration regarding possible appliance treatment if the UL3 did erupt l, but wasn't in a good position, would apply as for monitoring option described above. Any orthodontic treatment involved would be suitable for an appropriately experienced practitioner working outside the hospital."

"At the time of their consultation, I explained to the patient and his mother, in outline form, the possible options for managing the mal-positioned UL3. It seemed that the patient was quite certain the he did not want to have any dento-alveolar surgery, but they were

considering the possible extraction of the upper left deciduous canine ULC, but recognising that the patient is older than average for having this interceptive measure carried out, and also that it would leave him with a spaced whilst one awaited the possible natural eruption of the UL3 (but even if it did erupt one could not guarantee that its position would be then good). I did say that it might be possible to align the UL3 orthodontically, with fixed appliances, if it erupted, although headgear wear might only be avoided (assuming that temporary anchorage devices were not available), if the increased overjet was accepted, although one might need to recognise that the ability to fully align the UL3 might be influenced by the positions of the lower teeth (and that would require possibly a fixed appliance to align).

"Having summarised the initial appointment in June 2009 I can inform you that the UL3 has erupted and the patient is now concerned about the position of UL3 and his slightly increased incisal overjet. The skeletal pattern was confirmed as being mild to moderate Class II, with an increased maxillomandibular planes angle and lower anterior face height. The UL3 has now erupted, it is palatally positioned and slightly rotated. The crowding in the lower labial segment with respect to the LL3, may be slightly worse; the lower labial is of normal inclination in relation to the mandibular plane but proclined for the maxillomandibular planes angle. The oral hygiene and gingival condition are generally reasonable but only fair in some areas. I believe that you have identified that he requires a dental restoration"

"With respect to my treatment plan of June 2009 I think his oral hygiene still needs reinforcing and, if he is getting new dental caries, then the reason for this would need to be explored and, ideally, corrected. The attrition of the teeth would still need to be monitored"

"If the patient was to have comprehensive Orthodontic treatment for his malocclusion, then I feel it could either be corrected now with extractions or without i.e on a non extraction basis (no teeth to be removed). The latter would be, marginally, although not fully my preference because it would involve the use of headgear which the patient is not currently prepared to

do; additionally interdental stripping in the lower labial segment would be required to provide the space for alignment in this area. If we did not use interdental stripping the extraction of lower second premolars could be considered although, I am cautious in this approach as I feel we may be left with a residual overjet and/or space since there is only minimal crowding. My preference would be for interdental stripping as it involves no loss of sound teeth. If the patient was to have extractions, then I feel one could consider the upper and lower left first premolars (UL4/LL4) and then, only if there were problems in achieving a satisfactory occlusal result, might one then subsequently consider, possibly although not definitively, similar extractions on the right side"

"Active orthodontic treatment would need to be followed by a period of retention. Six months' full time wear of, for example, removable Hawley type retainers could be followed by a period, in theory, during which wear was progressively reduced to test the stability of the tooth positions. However, if the patient was not prepared to accept any return of the pre-treatment malalignment in the lower labial segment and/or there were concerns regarding a tendancy for UL3 to re-rotate and/or the overjet reduction was not appearing to remain naturally stable (I am not sure if the patient has sufficient competence for this however favourable growth can be surprising in such patients) then long term retention might need to be considered possibly via a bonded lingual retainer from canine to canine to maintain the alignment or long term nights only wear of removable retainers. I would personally opt for long term retention because of the patients' pre-treatment concerns. However I still have some doubts with the potential ability of the patient to provide satisfactory oral hygiene required for such a retainer and may review my thoughts on this matter over the duration of

Orthodontic treatment."

"The Orthodontic treatment plan described above should be suitable for an appropriately experienced practitioner working outside the hospital service to carry out"

"If this patient was having the above orthodontic treatment plan then they would need to aware of the risk of root resorption to the teeth with fine tapered roots and the likelihood of long term retention. (on balance on further reflection, probably, via long term nights only wear of removable not fixed retainers)"

"If the patient was <u>not</u> having comprehensive orthodontic treatment for his malocclusion, then one could <u>alternatively</u> just align the upper teeth with a fixed appliance recognising there might still be some spacing the upper labial segment and also that his overjet would not, probably, then be reduced; the resultant alignment might not be perfect and there would be a risk of some malalignment returning to the UL3 if long term retention was not employed (either by a bonded lingual retainer from canine to canine or long term nights only wear with a removable retainer). This orthodontic treatment should definitely be suitable for an appropriately experienced practitioner working outside the hospital service to carry out."

"Alternatively, if the patient was not having any orthodontic appliance treatment at all for his maloclussion, then it would need to be essentially accepted from an orthodontic perspective and any possible restorative dentistry options explored for improving the aesthetics particularly in the UL3 region"

"At the time of their consultation, it seemed as if the patient wanted to opt for comprehensive orthodontic treatment with the extraction of teeth. They understand that his caries would need to be completely under control and his oral hygiene of a high standard first. I am discharging this patient back fully to your care but should his oral hygiene improve sufficiently, then if you wanted to treat him yourself in the department

(for training purposes but working under my direction), then I would have no objection to you making a re-referral for this"

"I will gladly see this patient again at any time in the future should you require my further advice"

"Thank you for the loan of the orthodontic study models which I am now returning. If you, or anybody else involved in the patients care, wanted to view the lateral ceph radiograph taken then please could I trouble you to contact the X-Ray department, directly as they have the digital image"

It is clear from the above example that the letter contains a detailed explanation of the patients' orthodontic problem and is advantageous from a medico-legal view point. The letter is presumably addressing a dentist in primary care with a special interest in orthodontics and in part this may explain the great amount of information contained within it. However, the letter is approximately 2500 words and contains numerous repetitions. Excessive amounts of information may be considered to be counterproductive and wasteful of resources (Noble, 1994). While it describes the consultants' thought process and rationale for his treatment options in great depth it fails to display the relevant information on the diagnosis, treatment plan and action required by either a specialist practitioner or general dental practitioner in a simple and easy to read concise format. To dictate and type such a letter is not only time consuming for the consultant and secretary but also for the practitioner to read. In a busy clinical environment the practitioner may not be able to read such a lengthy letter and extract the salient information relevant to their patient. Such a letter may alienate the consultant and practitioner and may lead to a loss of future referrals. This letter gives a suitable example of why a structured letter may be a more favourable alternative.

The structured letter could provide the same information in a condensed summarised format and potentially free up time for consultants, secretaries and practitioners improving their

working relationships. Figure 2.2 illustrates that the information can be condensed into the following key points:

Figure 2.2 Condensed letter from figure 2.1

Diagnosis:	*Class II division 1 incisors*
	Class 2 skeletal base
	Initially Impacted UL3 and retained ULC
	Mild crowding in the lower arch
Treatment plan:	*Upper and lower fixed appliances*
	Surgical exposure and alignment of UL3
	Accept residual overjet
Action required:	*Improve oral hygiene*
	Restorations as required by GDP
	Treat outside the hospital or in the hospital under my guidance

2.7 Summary of literature review

It can be seen that the delivery of healthcare hinges on how effectively information is conveyed between parties. It can also be seen that many of the studies have limited generalisability because of the small sample size of referring doctors and specialists. However, the evidence, albeit weak, would suggest that clinicians in primary care are dissatisfied with the content of referral replies and therefore, the potential exists to improve communication and ultimately healthcare standards, by using a structured reply letter.

Studies of the quality of reply letters note that many fail to:

1. Address adequately the issues that prompted the referral (Noble, 1994)
2. Express the reasons behind specialists' conclusions and recommendations (Saha, 2006)
3. Contain sufficient educational content (Pringle, 1991)
4. Be dispatched promptly (McConnell, 1999)

There appear to be clear advantages in introducing a structured format for communicating with GDPs. These include the use of clear headings to allow the reader to identify the desired information easily and other obligatory fields to ensure key information is consistently included. It has been suggested that specialities explore the possibility of introducing a standard specialty specific letter for use when communicating with GPs and GDPs alike.

The literature has identified that GPs would prefer teaching that is directly related to their clinical practice instead of traditional formal education such as lectures. Should a standardised letter, containing a greatly improved educational content, be developed then it could provide some basis for Continuing Professional Development (CPD) hours within the specialty.

A well conducted randomised controlled trial is essential to add a high level of evidence to this subject in the specialty of orthodontics.

Figure 2.3: Summary of findings from literature review

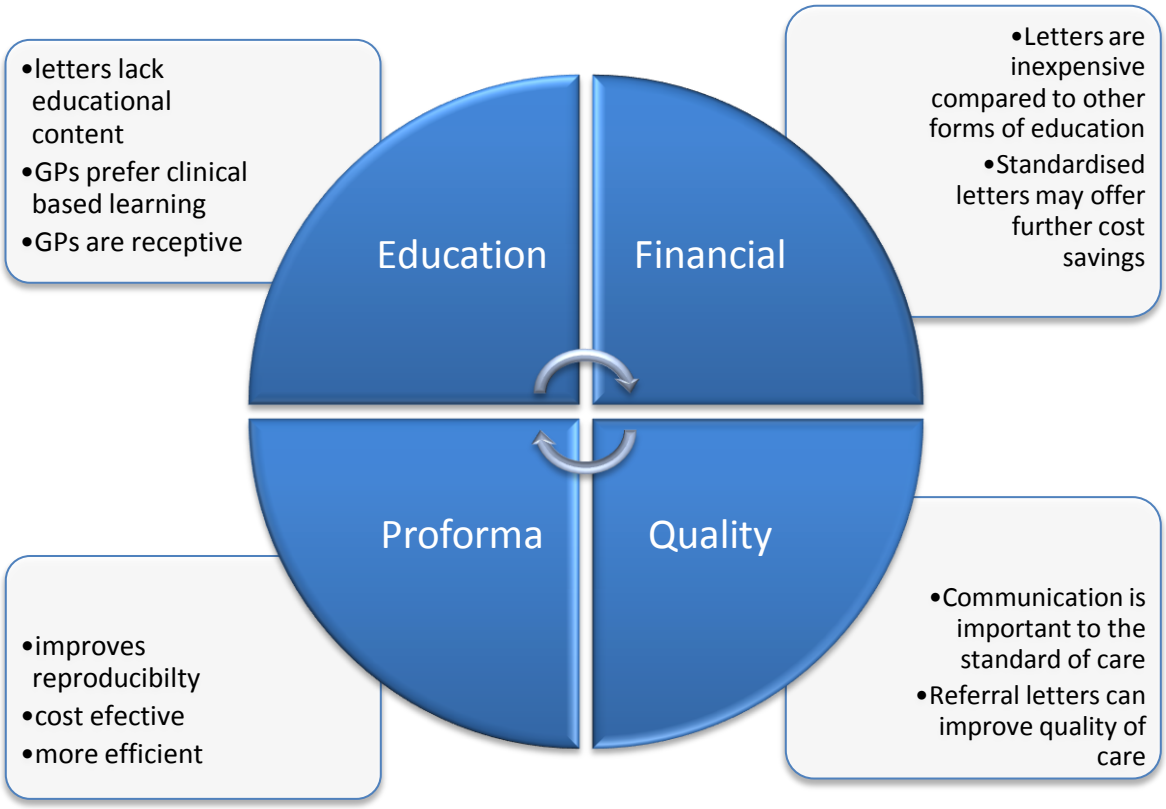


Table 2.1: Summary of previous studies

Study	Aims	Design	Results	Conclusions	Credibility
Bado 1984	Assess what information is given to GPs and how it fulfilled their needs.	Postal Survey 97 GPs ranked topics according to importance.	75% response rate. Technical information deemed more important than social. Letters missed information about what the patient had been told.	Letters should include information regarding what the patient has been told.	Low level of evidence
Westermann 1990	To improve care between specialists and GPs while assessing the reply letter with regard to content, value and teaching.	Content analysis (audit) on a random sample of referral letters by 4 GPs and 4 specialists on 144 letters.	75% felt the letter was good at explaining treatment plans. 54% of specialists and 44% of GPs felt the letter contained good educational content.	Communication requires improvement between primary and secondary care.	Low level of evidence. Subjective to only 8 examiner preferences.
Pringle 1991	Assess educational content in reply letters.	Content analysis of 288 referral letters (Audit).	Only 26% of letters had educational content.	Consultant reply letter is the most neglected route of GP education	Low level of evidence
Meara 1992	To assess the adequacy of medical discharge letters.	Postal survey to GPs of 2040 patient letters.	85% response rate. 77% contained follow up plans, 90% contained relevant medical information. Only 32% contained information on prognosis.	Consultant reply letters require improvements.	High response rate but low level of evidence.

Newton 1992	To gain information on condition, quality, appropriateness of referral letters for audit.	Postal survey to 157 GPs and 159 consultants.	77% response rate. 89% of GPs and 83% of consultants did not endorse structured reply letters.	Structured reply letters were not endorsed.	Low level of evidence.
Lloyd 1993	To determine if GPs have a preference to receiving a reply letter containing a structured problem list.	Postal survey on 100 GPs with 100 referral letters. 50 in a structured and 50 in a unstructured format.	93% response rate. 84% preference to the structured reply letter format.	Structured reply letters were favoured by the majority GPs.	Low level of evidence.
Rawal 1993	To assess the attitude of GDPs to a structured reply letter containing a problem list and management proposal. To assess GDPs preference.	100 consecutive GDPs referring to the department were randomised to one of two letter formats to assess	92% response rate. 88% preference towards the structured reply letter.	GDPs prefer structured reply letters.	Prospective trial but no information regarding randomisation
Couper 1996	To assess the quality of letters and inclusion of key information.	Content analysis (audit) of 111 responses to consecutive referral letter before and after introduction of a proforma letter.	No difference in quality of replies before or after introduction of the new letter proforma.	Proforma letter make no difference.	Low level of evidence.
McAndrew 1997	To discover what GDPs want with regard to content and timeliness.	Postal survey to 256 GDPs referred to single centre in 1 month.	60% response rate. 60% felt the letter was not received promptly enough.70% satisfied with overall letter content.	Majority of GDPs like current letter just request it to be more prompt.	Low level of evidence.Low response rate.GDPs surveyed more than once.

Stalhammer 1998	To assess importance of key information contained within letters.	Postal survey of 295 GPs asked to rank importance of letter aspects.	69% response rate. Highest rank given to diagnosis. Lowest rank given to treatment options.	Evidence of dissatisfaction with current referral process which GPs wish to improve.	Low level of evidence. Low response rate.
Van Der Kam 1998	Inclusion of key information within reply letters.	Postal survey of 246 GPs.	61% response rate. 25% felt follow up care was poorly described.	Reply letters require considerable improvement.	Low level of evidence. Low response rate.
Gandhi 2000	GP satisfaction with reply letters.	Postal and email survey of 84 GPs on 160 GP referrals.	57%response rate via post. 70% response via email. 63% dissatisfied.	Email is more effective at achieving higher response rates. GPs request improved letters.	Low level of evidence
Melville 2002	Do structured reply letter improves letters comprehension, rating, preference reading time and inclusion of key information compared to a traditional letter	Randomised control crossover trial. 32 participants.	78% preference toward structured reply letters. No difference in reading time observed.	Structured reply letters reduce the chance of omitting key information.	Small sample. No sample size calculation.

Ricketts 2003	To peer assess written communication between consultants and SpRs in restorative dentistry with GDPs.	Peer reviewed using a proforma. 7 participants reviewed 5 referral letters and ranked each letter.	Confirmed positively with agreed criteria. Problems identified with tooth notations.	Favourable letters when reviewed by Peers.	Questionable relevance to GDPs. Small sample.
Scott 2004	To explicitly evaluate the quality of reply letters for new patients attending clinic.	Content analysis (audit) of 10 specialities.	Received 294 referrals and retrieved 204 (69% response rate). 56% contained diagnosis.53% had rationale for treatment.9% had prognosis.	Consultant reply letters need improvement.	Low level of evidence.
Wynn 2004	Whether highly structured reply letters are preferred over unstructured prose.	Randomised control trial to assess structured reply letters against traditional letter formats. 210 GPs allocated to one of four letters.	42% response rate. High preference to structured reply letters.	Structured reply letter improve communication and reduce the likelihood of omissions.	Low response rate. Response bias.
McConnell 2006	To determine the function and preferred content of reply letters as perceived by GPs.	28 structured interviews.	Delays in receiving letters are of greatest concern. Reply letters contain too much information on background and history. GPs want proposed treatment and expected outcomes and these are frequently missed.	Consultants need to review and modify the letters they send.	Opinions of 28 GPs. Small sample.

Saha	**2006**	Assess the views of GDPs with regard to content, style, readability provided by restorative consultants 3 letter formats.	Postal survey of 100 GDPs sent a standard, summary and bullet point letter format.	96% satisfied with current format. On receiving the other 2 letters the exhibited an 87% preference for the bullet point format.	Bullet point formats provide the best format for structured reply letters.	Low level of evidence.
Waring	**2007**	To assess the opinion of Merseyside GDPs regarding length, format and appropriateness of orthodontic reply letters.	Postal survey audit to 330 pre- notified GDPs	76% response rate. 82% preferred summaries in a list format. 29% unaware what was happening to their patient. 25% unaware of what action was required of them.	Too much obsolete information is contained within the current letter format and is poorly communicated.	Low level of evidence.
Thong 2010		To determine the type of reply letters preferred by GDPs.	Postal survey to 1700 GPs receiving a structured and traditional letter format.	32% response rate. 96% preferred the structured reply letter. 64% felt that traditional letter formats took longer to read.	High preference for structured reply letters. Improvements are required between primary and secondary care.	Poor response rare. Response bias.

3. Aims of Study

The aim of this study was to identify whether a structured consultant reply letter was a more effective method of communication with practitioners when compared to a consultant's standard letter. The study also aimed to identify any differences in the dictation and typing time required for the two letter formats.

4. Objectives of Study

The objectives of the study were to compare the practitioners' awareness of their patient's status and the actions required following receipt a letter formats. The study also compared the word count of the letters written in the different formats as an indicator of the time taken by consultants to dictate the letters and secretaries to type then.

5. Null hypotheses

The study tested the null hypothesis that there was no significant difference between practitioners' awareness of key patient information when receiving either the structured consultant reply letter or the standard consultant reply letter.

The study also tested the null hypothesis that there was no statistically significant difference between the word count of the structured consultant reply letter and the standard reply letter.

6. Design

The study was a randomised, controlled, crossover trial with practitioners allocated to either:

Group 1: Control (practitioners received the standard reply letter first followed by structured reply letter 6 weeks later)

or

Group 2: Intervention (practitioners received the structured reply letter first followed by standard reply letter 6 weeks later).

6.1 Ethical approval

In undertaking any study, researchers inevitably face ethical dilemmas which arise out of competing obligations and conflicts of interest. All research proposals involving data collection on human individuals normally requires ethical approval to ensure the safety, rights, dignity and well being of the participant and researcher. This mechanism ensures that the research design demonstrates respect to participants and minimises the any potential harm to participants.

The protocol for this study, together with the supporting documentation, was submitted for review to the Liverpool Audit Research Ethics Committee. Favourable ethical approval was granted in February 2010 REC number 09/H1005/79 (Appendix 11.11).

The study was also registered with the Faculty of Medicine Research Support Office at the Liverpool University of Liverpool sponsorship and indemnity department. The Research and Development, of the Royal Liverpool Broadgreen University Hospital Trust reference number was 3830.

Participants who entered into this research study did so freely and willingly, knowing and understanding what they were volunteering to take part in. Participants were given as much information about the research as possible via a Practitioner Information leaflet (Appendix 11.5). They were also invited to contact the researchers if they wanted to discuss any issues surrounding the study further. The invitation to participate and the Practitioner Information leaflet was accompanied by consent form (Appendix 11.7) so that full, valid and informed consent was obtained from participants. All attempts were made to conduct the research openly and without deception.

The ethical issues pertaining to this study were as follows:

Either of the two letter formats had the potential to compromise patient care. Although this was possible it was considered unlikely. Practitioners potentially could have become confused by the two sequential letters and undertaken action upon their patient which could have been inappropriate for their healthcare needs. For example, upon receiving the second letter format the practitioner may have proceeded to duplicate the actions requested. In extreme circumstances, inappropriate extraction of teeth may have occurred.

6.2 Sample and Setting

Participants were recruited from general dental and specialist practitioners referring patients to the orthodontic department of Liverpool University Dental Hospital between February 2010 and September 2010.

6.3 Sample Size

Adequate numbers of referring practitioners were required to provide the study with sufficient power to detect a statistical difference between the awareness of the status of their patient after receiving each of the two letter formats.

Sample size was calculated based upon statistical advice from Dr Girvan Burnside (Liverpool University Dental Hospital statistician). A total sample size of 75 practitioners

were needed to provide 80% power to detect an increase in practitioner awareness of key data from 75% to 95% at a significance level of $p<0.05$. The sample size of 75 did not allow for drop outs. A realistic proportion of dropouts were thought to be 10% meaning 83 practitioners were needed to meet the sample size allowing for attrition. The recruitment was stopped upon achieving this figure.

6.4 Inclusion criteria

Potential participants were recruited from practitioners referring patients to the orthodontic department at Liverpool University Dental Hospital (LUDH). A letter inviting practitioners to participate in the trial was sent to all referring practitioners (Appendix 11.5) and informed consent obtained from those who wanted to participate in the trial. Strict inclusion and exclusion criteria were adhered to. The inclusion criteria were a single practitioner, from any one practice who referred a patient to the orthodontic department at Liverpool University Dental Hospital. Practitioners were excluded if they worked within multiple practices and had already been selected once. Medical practitioners were also excluded unless they held a dual medical dental qualification.

6.5 Consent

Potential participants were sent information about the trial (Appendix 11.6). Any questions or concerns were answered by the trial co-ordinators and the practitioners were invited to participate. Written informed consent was obtained from those practitioners willing to participate (Appendix 11.7)

6.6 Randomisation

The concept of random allocation when comparing different treatments has been an important aspect of the design of experiments ever since the pioneering work of Fisher (1935). These first randomised control trials were in agriculture where the experimental

units were plots of land to which the treatments, various crops and fertilizers, were assigned in random arrangement (Pocock, 1983). The purposes of such randomisation were:

1. To guard against any use of judgement or systematic arrangements leading to one treatment getting plots with poorer soil (to avoid bias).
2. To provide a basis for the standard methods of statistical analysis such as significance tests.

Randomisation was stratified by consultant and generated in blocks of 6 practitioners using an electronic random number generator by the chief investigator (Dr Jayne E Harrison). The Chief Investigator was not involved in the recruitment or allocation of the interventions. Cards bearing the allocation were placed in consecutively numbered opaque, sealed envelopes and passed to the Principal Investigator for allocation.

6.7 Stratification

Stratification in a clinical trial is related to allocation of the interventions within the population. It controls for known prognostic factors (in this case the consultants) and divides them into homogenous groups prior to allocation. In any randomised control trial it is desirable that the treatment groups should be similar in size and relevant characteristics (Pocock, 1983). Random allocation in this trial took place within each consultant subgroup. Stratification means that a randomization list was generated for each consultant. It was thought necessary to stratify by consultant because consultants' individual letter style was considered to be a potential confounding factor. The letter styles of each consultant could potentially influence the participants' responses. This was thought necessary to reduce allocation bias.

Within the referral base, some practitioners refer directly to a particular consultant whilst others write 'Dear Sir' referrals which are then distributed between the consultants by the clerical and secretarial staff.

Two issues made the research team decide to stratify the referrals by consultant. Firstly, the practitioners that refer specifically to the different consultants may have been systematically different in some way and secondly, the consultants' letters may have been systematically different. As both these issues may have influenced the responses of the practitioners, it was thought a reasonable precaution to stratify the allocation by consultant so that the outcome data from each consultant could be assessed individually and compared before the data were pooled if appropriate. If it were found that data from an individual consultant were different from the others, then the data would not have been pooled. By stratifying the randomisation by consultant, it ensured that the number of practitioners within each consultant's subgroup allocated to receive the standard or structured letter first, would be balanced. If the allocation had not been stratified by consultant, then there would have been a risk that an unequal number of practitioners, whose patients were seen by the individual consultants, would have been allocated to the standard or structured letter first.

The aim of stratification was therefore to minimize the imbalance of practitioners between the consultants. Normally the consultants would be allocated to a group randomly and while this maintains a good overall balance, it can lead to imbalances within sub-groups. Without stratification the statistical usefulness of the study would be reduced (Pocock, 1975). Peto (1976) argues that stratification is an unnecessary elaboration of randomisation. However Pocock 1983 has the attitude that stratification is like an insurance policy in that its primary aim is to guard against the unlikely event of the treatment groups ending up with some major differences in characteristics. In this study stratification adds credibility and allows the reader to be more convinced when valid conclusions are achieved (Pocock, 1983).

6.8 Randomisation and Block design

Randomisation is important to balance the groups for all known and unknown factors that may influence the outcome. Randomisation minimises allocation bias and allows for robust statistical analysis.

Pocock (1983) advises against deterministic methods of randomisation such as alternate allocation or allocating by the day of the week, date of birth or odds or evens because these forms of open allocation may be consciously or subconsciously influenced by the person allocating the sequence and can be considered as quasi-randomisation (Cochrane Handbook). Instead, he outlines the need for non-deterministic randomisation and describes various methods of randomisation.

Simple randomisation, where each group is independent can produce differently sized groups and in a study of only 75 practitioners, it would not be recommended. Equal group randomisation requires a fixed sample size and is liable to be influenced by the predicting the sequence.

Blocking is the preferred method of allocation and is used to ensure balance between the intervention groups. In this trial, participants were randomly allocated in of six blocks. Each block contained equal numbers of control (standard letter) and intervention (structured letter). The order was rearranged so that all possible permutations are created. The six block randomisation used is outlined below in table 6.8.1 and the block randomisation code in table 6.8.2:

Table 6.8.1: Randomisation allocation

Random numbers	Block allocation
7	AAABBB
8	BBBAAA
1	ABABAB
1	ABABAB
5	BABAAB
8	BBBAAA
2	ABBAAB
5	BABAAB
7	AAABBB
1	ABABAB
6	BABABA
8	BBBAAA
7	AAABBB
6	BABABA
4	BAABAB
7	AAABBB
3	ABABBA
2	ABBAAB
8	BBBAAA
4	BAABAB

Table 6.8.2 Block randomisation code

1	2	3	4	5	6	7	8
A	A	A	B	B	B	A	B
B	B	B	A	A	A	A	B
A	B	A	A	B	B	A	B
B	A	B	B	A	A	B	A
A	A	B	A	A	B	B	A
B	B	A	B	B	A	B	A

A block was chosen at random and participants were allocated according to the block. The PI did not know the size of the blocks during the time of allocation so that he could not predict the next allocation. Another block was then chosen at random until the required sample size was reached.

Several methods can also be used to make the groups more similar. Matching is not advisable since the allocation is not concealed (Pocock, 1983). Instead, the use of stratification by consultant was used to adjust for this confounding factor.

6.9 Parallel versus Crossover design

The study could have been designed in either a parallel or crossover structure. In a parallel group design, each participant would have received a single letter format. In a crossover design, each participant received both letter formats being studied.

Parallel study designs are preferable when there are strong concerns about carryover effects (Lavori, 1983) or it is inappropriate for participants to receive both interventions for example, a functional appliance to correct an overjet and then headgear even with a suitable washout period. In this trial it was thought that the carryover effect would be negligible and that a 6 week “wash out” period would be appropriate, so a crossover design was thought to have

advantages over the parallel group design. Variability between the practitioners was the largest problem posed by applying a parallel group design (Lavori, 1983). In a crossover design, this variation was eliminated because comparisons were made within the same participant (Senn, 1993). In a parallel designed study Meinert (1986) advised that a sample size of above 50 per group, would allow the randomisation process to balance out most variables.

The study was designed to be a randomised controlled crossover trial because there are several advantages from structuring the trial in this way as opposed to two parallel groups. The confounding covariates were reduced as each participant served as his or her own control. In a parallel group trial different treatment groups are often found to be unbalanced for some confounding factors. In a randomised controlled crossover trial such imbalances are impossible unless, of course, the participants changed systematically during the study (Sufken, 1996). However, this study was designed so that an equal number of participants received each of the letter formats first ensuring that if there were changes during the study, the randomisation process should balance that out.

The second advantage of the crossover design was that it was statistically more efficient because it requires fewer participants and a lower sample size than if the trial was a parallel group design. This offers a practical advantage over parallel designed trials when a single centre is being used and allows recruitment to be achieved more quickly (Pocock, 1983).

The disadvantages of conducting the trial in a crossover design are as follows. The participants receive the letters in a randomised order dictated by the randomisation sequence contained within the envelope. The order in which participants receive the letters could potentially affect the responses to the letters. This could happen in two ways. Firstly, there is a “carry over” effect between receiving the two letters which has an effect on the participant’s responses to the second letter they receive and potentially affects the primary outcome measure. Senn, (1993) argues that the difficulties with this so called “carry over” effect have been grossly exaggerated. The effect can be reduced by having a longer “wash

out" period between receiving the two formats. It was thought that 6 weeks would be suitable in this trial but is not supported by any evidence.

Secondly, there may be a "learned" effect with regard to the second letter. Participants potentially could consciously or subconsciously memorise the information contained in the first letter and apply it to the second format. Although unlikely, a "wash out" period reduces this and overall, its effect is likely to be negligible.

Finally, the crossover design may have created a reduction in response rate when compared to the parallel design. Simply, by extending the study length could have lead to a greater number of participants declining to take part in the study and a greater level of withdrawals from the trail. (Edwards, 2009). Despite this potential disadvantage, the response rate in this trial was very good.

It was carefully considered that a crossover design would be appropriate in this situation to be both reliable and feasible.

6.10 Recruitment

Referral letters were received by each of the three participating consultants namely Dr Jayne Harrison, Mr Stephen Rudge and Professor Neil Pender. The Orthodontic consultants were asked to complete a log sheet detailing the patient's name, patient's date of birth and unique identifier, GDP name and address (Appendix 11.9). When each A4 sheet had been completed the log was passed to the Principal Investigator to input the information into an excel spreadsheet. Each GDP was assigned a unique identifier and was sent a 'starter pack' that contained a covering letter, information leaflet, consent form and self addressed envelope (no stamps or pre paid envelopes were provided). Practitioners willing to participate in the study returned the signed and dated consent forms to the department. Upon receipt of the consent form the Principal Investigator entered the practitioner into the trial and assigned a randomisation envelope numbered according to the consultant to whom they had referred their patient.

6.11 Reply letter dictation

Upon acceptance into the trial the initial referral letter was retrieved from the Partial Bookings Office at the Liverpool University Dental Hospital. The initial referral letter was identified by using the data previously collected on the Practitioner and Patient identifiers. The numbered envelope, containing the randomisation, was then secured to the referral letter with a single staple, and remained fixed until the consultation appointment.

When the patient arrived for their consultation appointment they were examined in the usual manner and clinical notes were made as normal. Upon completion of the consultation, the consultant opened the envelope to reveal the order of letter dictation. The consultant stapled this postcard to the Minimum Data Set sheet at the rear of the notes. The consultant then dictated the 2 letters in accordance with the order on the postcard (structured or standard first followed by the alternative format). The consultants were provided with a template to utilise as a guide to the format of the structured letter (Appendix 11.2). The consultants placed a sticker on the front of the patient's notes bearing the words 'LETTER TRIAL' to assist the secretaries. In the event that the patient did not attend the consultation appointment the envelope was removed and passed to the Principal Investigator to re-assign to a subsequent patient referred by that practitioner.

Although no formal structured training was provided for the consultants prior to the trial, each had received starter pack (Appendix 11.9) containing information about the study and were free to discuss any concerns or confusions with the research investigators prior to or during the trial.

6.12 Reply letter generation

After the initial orthodontic consultation the dictation tape was complete the tape was passed from the consultants to the departmental secretaries (TL and JL) for the generation of the two letter formats. A computer template designed in Microsoft Word[1] had been provided to aid the generation of the structured reply letter (Appendix 11.2). For each of the letters, an electronic word count was made and recorded onto the appropriate log sheet. The letters were signed by each individual consultant and passed to the principal investigator for dispatch.

Although no formal structured training was provided for the departmental secretaries prior to the trial, each had received a starter pack (Appendix 11.10) containing information about the study and were free to discuss any concerns or confusions with the research investigators prior to or during the trial.

6.13 Reply letter dispatch

The completed letters were dispatched in accordance with the randomisation sequence. Each format was sent together with a cover letter (Appendix 11.5), a Knowledge and Satisfaction questionnaire (Appendix 11.8) and an unstamped self addressed envelope. The knowledge and satisfaction questionnaires were partially completed by the Principal Investigator to include the practitioners' unique identifier, patient identifier and the letter format (A) Standard or (B) Structured. The second letter was placed in a holding tray with a note attached identifying the dispatch date 6 weeks after the first letter dispatch date. The excel spreadsheet was updated to log the progress of each participant within the trial.

[1] Microsoft® Word 2007 software

6.14 Blinding

Blinding of the practitioner, consultant and administration staff was impossible. The data analyst was blind to the practitioner and letter format.

6.15 Intervention

Participants in the intervention group received the structured reply letter first followed by the standard letter format 6 weeks later.

6.16 Control

Participants in the control group received the existing standard letter format first followed by the structured letter format 6 weeks later.

6.17 Both groups

The word count was recorded by the secretaries on a log sheet (Appendix 11.10). Knowledge and satisfaction questionnaires were dispatched with each of the letters, completed by the practitioners and returned to the department using self addressed envelopes. A cover letter, thanking the participants for their cooperation with the trial was also included (Appendix 11.5).

6.18 Outcome measures

The primary outcome measure was the practitioners' awareness of the key information contained within the letter. The secondary outcome measure was the word count which was used as an indicator of the administration time required for dictating and typing.

6.19 Data Archiving

Provisions were made for the safe and secure archiving of the research data. All data was entered onto specifically designed "data log sheets". The data was anonomysed by giving a unique reference number to the practitioners' details and referred patient's unique hospital number and randomisation allocation. This was kept in a secure locked filing cabinet in the Chief Investigators (Dr Jayne Harrison) office to comply with Trust policy. All other log sheets were held in a box file and stored in a locked filing cabinet within the orthodontic department. Patient and practitioner identifiable information was stored separately from the coded information and accessed via a different password. Trust registered departmental computers were used for data storage complied with Trust recommendations. No information was managed on personal lap top computers or unsecured hard drives. All data was password protected and accessible only by the named research team of Chief Investigator (Dr Jayne Harrison) and Principal Investigator (Mr James Davies). Hospital notes were maintained according to the normal system. Custodianship of data was held by the Principal Investigator who ensured that data complied with the Trust's data protection policy. The Principal Investigator is aware of the location of all archived research data and is open to any monitoring procedures that may be required e.g. audits. Although no formal restrictions apply for how long data can be held after the study is complete, provision has been made for their safe disposal 5 years after completion of the study.

6.20 Data Analysis

Data was transferred from the returned knowledge and satisfaction questionnaires and word count log sheets to computer software programmes namely, a Microsoft Excel[2] database and a Statistical Package for the Social Sciences (SPSS)[3] for data analysis . Data was double entered to allow completeness and accuracy of the data to be checked. A 10% random selection of sheets were collected and checked by the Principal Investigator for error and the data was screened for any outliers. The data was cleansed by checking for

[2] Microsoft® Excel 2007 software
[3] IBM® Statistical Package for the Social Sciences SPSS Statistics 17.0.1

obvious errors and impossible data. Data was checked for normal distribution using the Shapiro–Wilk test for normalisation.

The difference in the practitioner's perceived awareness of the status of their patient, after receiving each of the two letter formats was analysed using Chi Square test for categorical data. The actual awareness was determined from the departmental Minimum Data Set. The differences between the perceived and actual status of the patient between the two letter formats was calculated using Chi squared test for paired categorical data.

The difference in the word counts of the two letter formats and the mean difference and associated confidence intervals were reported. Weighted mean difference with p value was also calculated together with medians and inter-quartile ranges.

The practitioners' preference for each of the letter formats was compared using the Wilcoxon signed ranks test to grade the number of negative, positive and tied ranks and identify any increase or decrease in rank scores between the two letter formats. A summary of the statistical tests used are outlined below:

Chi Squared test:

The Chi squared statistical test can be used to determine if there is statistical significance between the expected frequencies and the observed frequencies in one or more categories (Altman, 1991).

The assumptions of the Chi Squared test are:

1. Quantitative data
2. One or more categories
3. Independent observations
4. A sample size larger than 10

Wilcoxon signed rank test:

The Wilcoxon signed rank test is a non parametric test for use with two related samples or repeated measurements on a single sample (Miller, 1969). It is used as an alternative to the student t test when the population is not normally distributed.

The assumptions of the Wilcoxon signed rank test are:

1. That the samples are independent
2. The data is derived from a continuous population
3. The data is ordinal

Shapiro-Wilk:

The Shapiro-Wilk statistical test tests if the data is normally distributed (Altman, 1991).

Median:

A median is described as the numerical value separating the higher half of a sample, a population, or a probability distribution, from the lower half. The median of a finite list of numbers can be found by arranging all the observations from lowest value to highest value and picking the middle one. If there is an even number of observations, then there is no single middle value; the median is then usually defined to be the mean of the two middle values.

Inter-quartile range:

The inter-quartile range (IQR) is a measure of statistical dispersion. It is calculated by equating the difference between the third and first quartiles

Weighted mean difference:

Weighted mean difference is used to combine measures on continuous scales (such as weight), where the mean, standard deviation and sample size in each group are known. The weight given to the difference in means from each study (how much influence each study has on the overall results) is determined by the precision of its estimate of effect and, in the statistical software in RevMan[4].

Confidence intervals:

Confidence intervals are a measure of the uncertainty around the main finding of a statistical analysis. Estimates of unknown quantities, such as the odds ratio comparing an experimental intervention with a control, are usually presented as a point estimate and a 95% confidence interval. This means that if someone were to keep repeating a study in other samples from the same population, 95% of the confidence intervals from those studies would contain the true value of the unknown quantity. Alternatives to 95%, such as 90% and 99% confidence intervals, are sometimes used. Wider intervals indicate lower precision; narrow intervals, greater precision (Altman, 1991).

Odds ratio:

The odds ratio is a measure of effect size, describing the strength of association or non-independence between two binary data values. It is the ratio of the odds of an event in one group to the odds of an event in another group. In studies of treatment effect, the odds in the treatment group are usually divided by the odds in the control group. An odds ratio of one indicates no difference between comparison groups. For undesirable outcomes an OR that is less than one indicates that the intervention was effective in reducing the risk of that outcome (Altman, 1991).

[4] Review Manager (RevMan) [Computer program]. Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

6.21 Data Protection

In the interests of security, wherever possible all research data was anonymised. The data was stripped of its identifiable information and given unique reference numbers. All questionnaires had an identification number to identify them to comply with the Trust's data protection policy. The completed questionnaires were stored in a locked filing cabinet in the Chief Investigator's office. The data storage complied with the Data Protection Act 1998.

A step by step summary of the methodology of this study can be found in Appendix 11.12.

7. Results

7.1 Introduction

For the purposes of clarity, the results have been organised as recommended by the consolidated standards of reporting trials (CONSORT) statement (Altman 2001). Results are outlined and displayed in suitable tables and graphs below.

7.2 Participants flow through the RCT

Table 7.1 shows the flow of participants through the trial. The table depicts information from the 6 stages of the trial (invitation, enrolment, exclusions, letter generation, drop out and completion). The table shows from the 142 practitioners who were invited to participate, 88 (62%) accepted and 54 (38%) declined or did not respond giving a total of 88 consented practitioners. This was in excess of the sample size requirement but allowed for drop outs. Two participants did not meet the inclusion criteria set out within the studies design and 2 participants withdrew their consent during the trial. Seven patients failed to attend their consultation appointment so a total of 77 letters were generated. Two participants failed to complete the study resulting in a total of 75 practitioners completing the trial.

Table 7.1: Participants progress through the trial

Invited to participate	142
Declined or no response	54
Consented	88
Excluded (did not meet inclusion criteria)	2
Withdrew consent	2
Patient failed to attend consultation	7
Letter generated	77
Dropout	2
Completed Participants	75

Figure 7.1 illustrates the flow diagram of the RCT. From the 142 practitioners who were invited to participate in the trial 88 (62%) accepted and 54 (38%) declined or did not respond giving a total of 88 consented practitioners. This was in excess of the sample size requirement but allowed for drop outs. One participant was excluded because they were a medical practitioner and did not hold a qualification in dentistry. One participant was excluded because they were outside the Mersey area (Cornwall). Of the 88 consented practitioners, 86 were then randomised to either the control group (AB) or the intervention group (BA).

Of the 86 practitioners consented, 9 (10%) did not have letters generated. This was because:

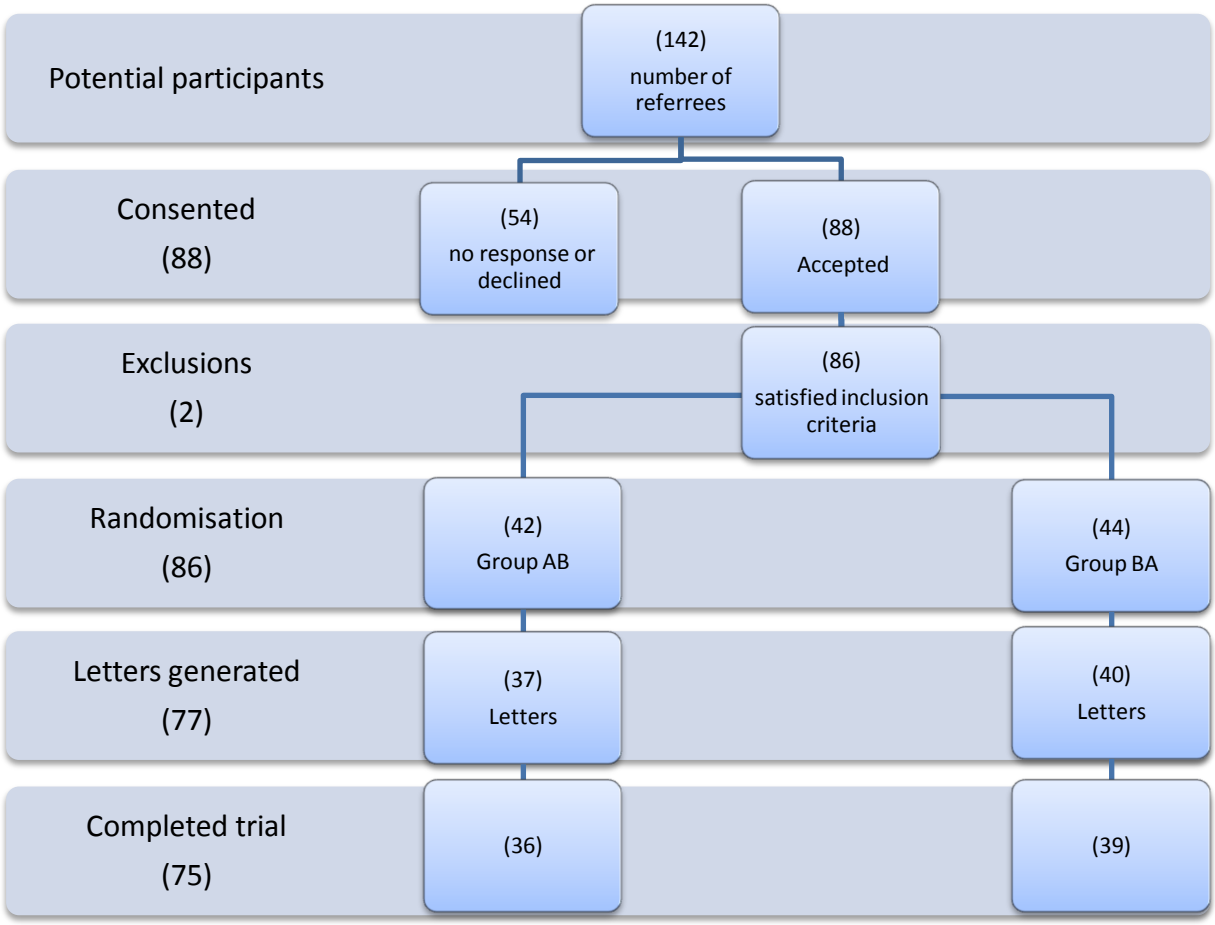
- The envelope was not tagged to the referral source
- Their patient failed to attended the consultation clinic
- The consultant failed to see the randomisation envelope
- The randomisation envelope became detached from the referral letter during transit.

Seventy seven letters were therefore generated in each format and 77 knowledge and satisfaction questionnaires were dispatched with each of the letter formats.

Eleven (13%) of consented practitioners failed to complete the trial. Nine (10%) failed to have letters generated and were categorised as missing data. Of those who had letters generated, only 2 (3%) failed to return the questionnaires. Those 2 participants who failed to respond to either of the questionnaires and after numerous telephone calls and repeat questionnaires one can only assume they had withdrawn their consent. The low dropout rate could be due to consenting practitioners before including them into the trial and that non-responders were contacted and encouraged to respond until questionnaires are returned.

The overall response rate was calculated as 87% of eligible consented practitioners.

Figure 7.1: Flow diagram of participants



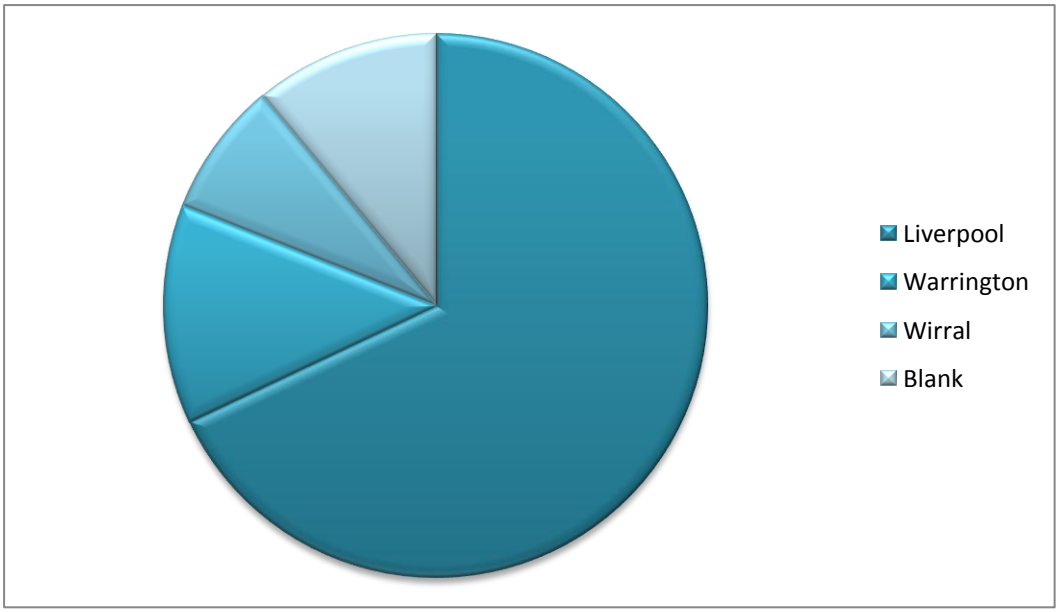
7.3 Participants' demographic details

The majority of the 75 participants were from Liverpool (68%) with the remainder from the Warrington and Wirral postcode areas. The location of participants is displayed in table 7.2, while figure 7.2 is a graphical representation of the participants' location in the form of a pie chart.

Table 7.2: Location of participants who completed the trial

Postcode	Number
L1-L39	51
WA1-WA11	10
CH42-CH63	6
Blank	8
TOTAL	75

Figure 7.2: Regional locations of participants.



The study participants were predominantly from the graduation years 2000-2009 (Figure 7.3) signalling a younger age group within the sample. A majority of 57% of the participants graduated on or after 1990.

Figure 7.3: Year of qualification of participants

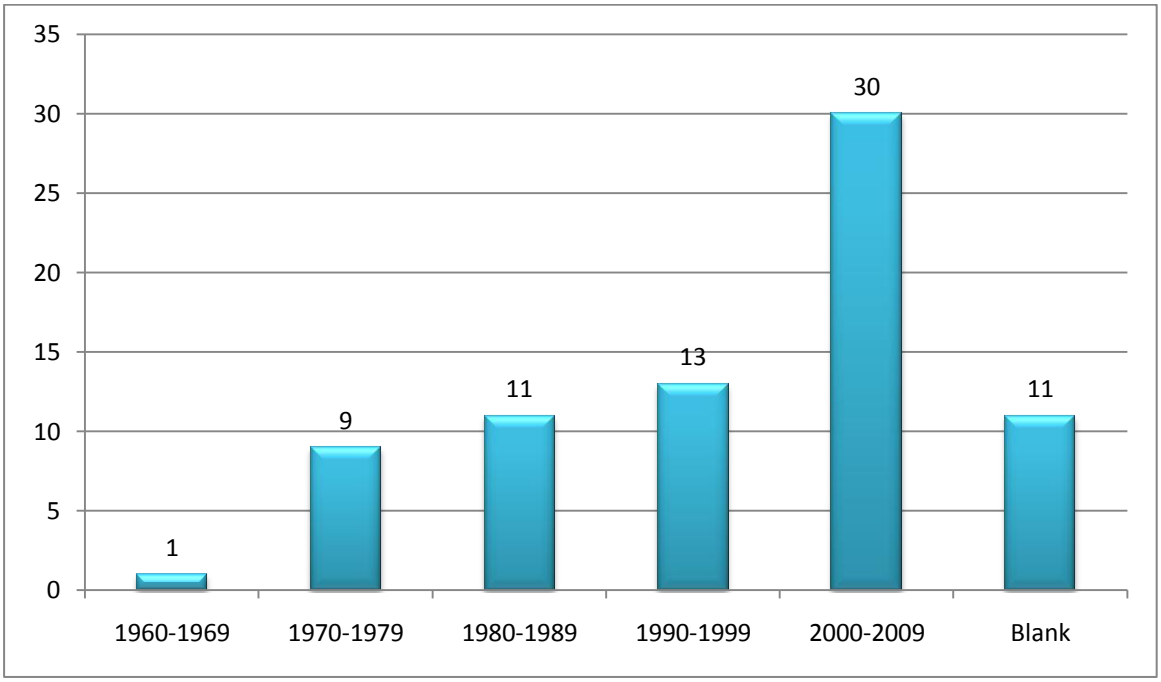


Table 7.3 shows that 42 respondents were male while 25 were female this represented a percentage of 56% and 33% respectively. The remaining 8 (11%) failed to complete the gender section of the knowledge and satisfaction questionnaire.

Table 7.3: Gender of participants

Gender	Number / Percentage
Male	42 (56%)
Female	25 (33%)
Blank	8 (11%)
TOTAL	75 (100%)

A greater number of male participants consented to take part in the trial. Cross referenced against those invited to participate (Table 7.4) shows a total of 76 males were asked to participate and 42 accepted representing 55%. Twenty five of the 51 females invited to consent accepted representing 49%. This is considered representative of the gender in our studies targeted population. The odds ratio was calculated from the gender of participants who were invited to participate and those who did not. The odds ratio was 1.28; 95% CI 0.63, 2.62 and therefore was not statistically significant.

Table 7.4: Gender of those invited to participate

Gender	Number / Percentage
Male	76 (54%)
Female	51 (36%)
Unknown	15 (10%)
TOTAL	142 (100%)

7.4 Randomisation

Randomisation generated an approximate 50:50 split between the two groups (Table 7.5). 49% were randomised into group AB (standard followed by structured letter) and 51% were randomised into group BA (structured followed by standard letter). The block randomisation utilised in this study was therefore deemed effective.

Table 7.5: Breakdown of the randomisation

AB (standard followed by structured letter)	42
BA (structured followed by standard letter)	44
TOTAL	86

7.5 Referral to letter generation

Although the majority (79%) of referrals were seen by the clinicians who received the letter, there was some cross over between the consultants (Table 7.6)

Table 7.6: Referrals received and letters generated by consultants

Consultant	Referrals received	Randomisation AB (Standard Structured)	Randomisation BA (Structured Standard)	No letter generated	Letters generated
A	39	20	19	2	32
B	21	10	11	4	19
C	26	12	14	3	26
TOTAL	**86**	**42**	**44**	**9**	**77**

Consultant A received 39 referrals from consented participants and saw 31 of those personally, an additional 1 from consultant C generating 32 letters. Two of consultant A's referrals did not lead to a letter being generated personally.

Consultant B received 21 referrals from consented participants and saw 15 of those personally, an additional 4 from consultant A generating 19 letters. Four of consultant B's referrals did not lead to a letter being generated personally.

Consultant C received 26 referrals from consented participants he saw 22 of those personally, an additional 2 from consultant B and 2 from consultant A generating a total of 26 letters. Three of consultant C's referrals did not lead to a letter being generated personally.

7.6 Primary outcome measure

The perceived awareness of the practitioners following receipt of each letter format was similar when compared to what was actually happening to their patient (Table 7.7). This suggested that practitioners were able to determine what was happening to their patients e.g. placed on waiting list, discharged or onward referral.

The results suggest that there was no statistically significant difference between standard and structured consultant reply letters in participants' perceptual awareness of what was happening and what was actually happening to their patient when receiving each of the letter formats.

Table 7.7: Practitioners' awareness of what was happening to their patient having received each of the letter formats

Perceived awareness /Actual awareness	Letter A (Standard)	Letter B (Structured)
No / Yes	1	0
No / No	1	0
Yes / Yes	67	74
Yes / No	6	1
TOTAL	75	75

Chi –Square 5.919 degrees of freedom 3 p = 0.11

When there are small numbers of counts in the table, the use of the chi-square test statistic may not be appropriate. Specifically, it has been recommended that this test not be used if any cell in the table has an expected count of less than five. Under this scenario, converting the data to binary data was recommended to allow a more robust method of testing the hypothesis. The odds ratio statistic was therefore calculated to compare practitioners whose

perception of what was happening to their patient was actually correct against those whose perception differed from the true status of the patient. The odds ratio for awareness of the status of referring practitioners' awareness was 8.84 (95% CI 1.08, 72.52) in favour of the structured letter. This demonstrates that the practitioners' awareness of key patient information was statistically greater having received the structured letter when compared to the standard consultant reply letter. However, these results were only just significant and should be interpreted with caution due to the wide confidence intervals.

The perceived awareness of the practitioners following receipt of each letter format was similar when compared to what action was actually required of them (Table 7.8). This suggested that practitioners were able to determine what action was required for their patients e.g. extraction of teeth, restorative intervention or improvement in oral hygiene.

The results suggest that there was no statistically significant difference between standard and structured consultant reply letters in participants' perceptual awareness of action required and what actions were actually required for their patient's when receiving each of the letter formats.

Table 7.8: Practitioners' awareness of action required in each of the letter formats

Perceived awareness / Actual awareness	Letter A (Standard)	Letter B (Structured)
No/ Yes	0	0
No / No	3	0
Yes / Yes	64	72
Yes / No	8	3
TOTAL	75	75

Chi-Square 5.743 **Degrees of freedom 2** **p =0.06**

A conversion to binary data was again recommended as a more robust method of testing the hypothesis. The odds ratio statistic was therefore calculated to compare practitioners whose perception of what actions were actually correct against those whose perception differed from the true action required of the practitioner. The odds ratio for awareness of the action required of referring practitioners' was 4.13 95% CI 1.10, 15.45.

This demonstrates that the practitioners' awareness of action required was statistically greater having received the structured letter when compared to the standard consultant reply letter. However, the result should be interpreted with caution.

7.7 Secondary outcome measures:

7.7.1 Word count by consultant

Table 7.9 demonstrates the word count contained within the standard letter format (A) for each of the 3 Consultants. The table shows that Consultant A dictated a total of 7466 words for the 32 number of standard letters produced. This equated to a mean of 233.3 and a median of 277 words per standard letter. Consultant B dictated a total of 3869 words for the 19 number of standard letters produced. This equated to a mean of 203.6 and a median of 207 words per standard letter. Consultant C dictated a total of 5642 words for the 26 number of standard letters produced. This equated to a mean of 217.0 and a median of 217.5 words per standard letter.

Table 7.9: Word count by consultant on Letter A (standard consultant reply letter)

	Consultant A =32	Consultant B = 19	Consultant C = 26
Total Words	7466	3869	5642
Mean	233.3	203.6	217.0
Standard Error	16.5	16.5	14.4
Standard Deviation	47.5	36.6	37.4
95% CI	201, 255 (233±32)	171, 235 (203±32)	189, 245 (217±28)
Median	227	207	217.5
Inter-Quartile range	188.5, 265.5	172, 242	195.5, 238

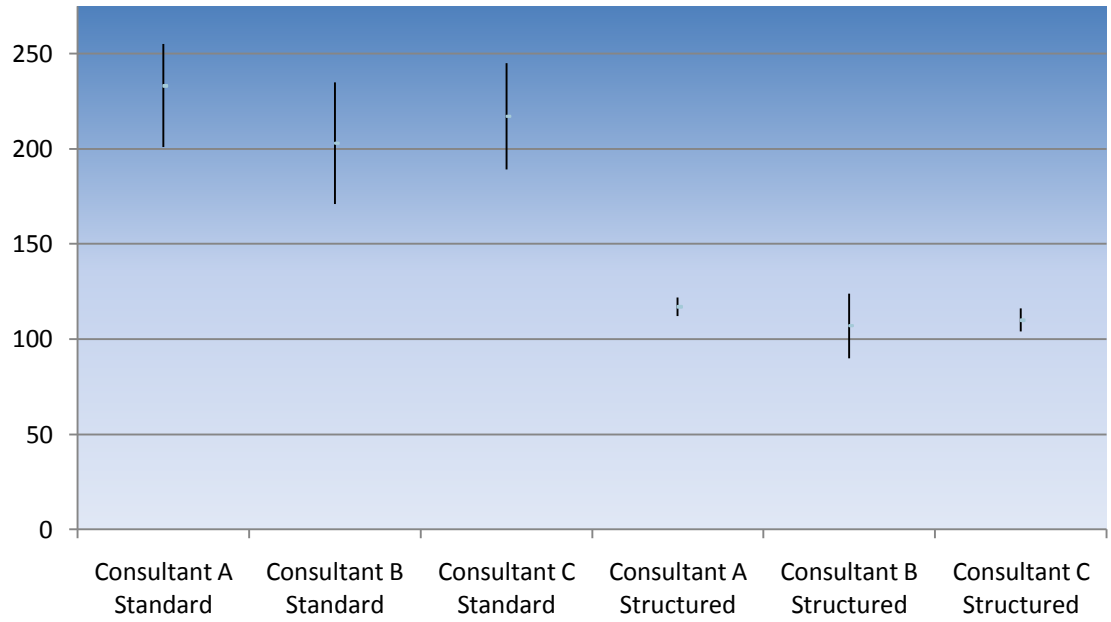
Table 7.10 demonstrates the word count contained within the structured letter format (B) for each of the 3 Consultants. The table shows that Consultant A dictated a total of 3748 words for the 32 structured letters produced. This equated to a mean of 117.1 and a median of 116 words per structured reply letter. This was 116 fewer words than the standard letter. Consultant B dictated a total of 2033 words for the 19 structured letters produced. This equated to a mean of 107.0 and a median of 113 words per structured reply letter. This was 96 fewer words than the standard letter. Consultant C dictated a total of 2849 words for the 26 of structured letters produced. This equated to a mean of 109.6 and a median of 111.5 words per structured reply letter. This is 107 fewer words than the standard letter.

Table 7.10: Word count by consultant on Letter B (structured consultant reply letter)

	Consultant A = 32	Consultant B = 19	Consultant C = 26
Total Words	3748	2033	2849
Mean	117.1	107.0	109.6
Standard Error	3.7	8.4	2.9
Standard Deviation	13.3	18.7	7.6
95% CI	112, 122 (117±5)	90,124 (107 ±17)	104, 116 (110± 6)
Median	116	113	111.5
Inter-Quartile range	129.75, 102.25	138, 88	104.75, 114

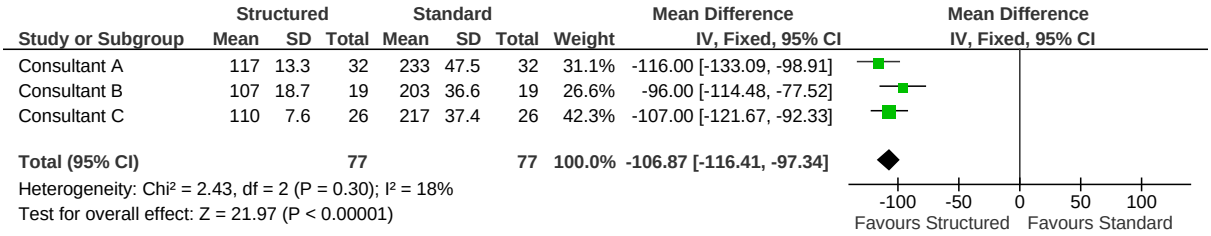
It is evident from the overlapping confidence intervals for each of the two letter formats that Consultants were similar in the number of words contained within each of their reply letters. It is clear that the structured reply letters contain fewer words than the standard consultant reply letter. (Figure 7.4)

Figure 7.4: Mean word count with 95% confidence intervals for each letter format by Consultant



The mean difference in word count of structured and standard letter formats stratified by consultant was calculated. No significant difference in heterogeneity was evident and so the fixed effects model for Mean Difference was utilised. This also allows the data to be pooled for secondary outcomes. The overall effect was observed with $p < 0.00001$.

Figure 7.5: Mean difference in word count of structured and standard letter formats stratified by consultant



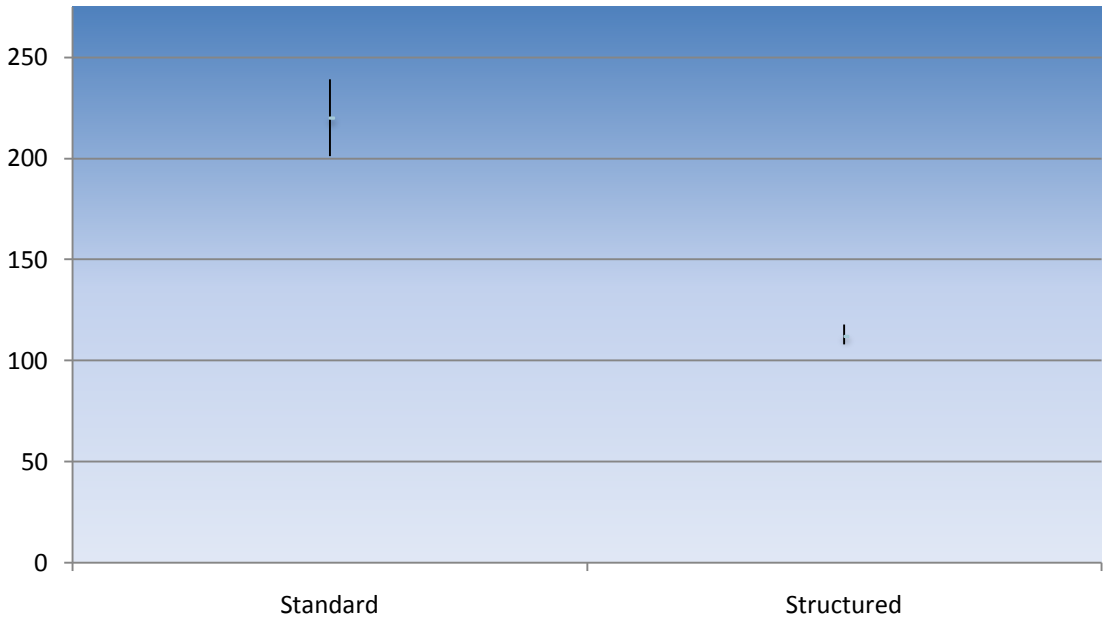
When the consultants were pooled a total of 16977 words were dictated for letter A (standard reply letter). This equated to a mean word count of 220.5 and a median of 216 words for the standard consultant reply letter. A total of 8630 words were dictated for letter B (structured reply letter). This equated to a mean word count of 112.1 and median 113 for the structured consultant reply letter. The difference was observed to be 108 fewer words contained within the structured consultant reply letter. (Table 7.11)

Table 7.11: Pooled word counts for A (standard letters) and B (structured letters)

	Letter A (standard)	Letter B (structured)
Total Words	16977	8630
Mean	220.5	112.1
Standard Error	9.7	3.1
Standard Deviation	43.2	14
95% CI	201, 239 (220 ± 19)	108, 118 (112 ± 6)
Median	216	113
Inter Quartile Range	259, 173	127, 99

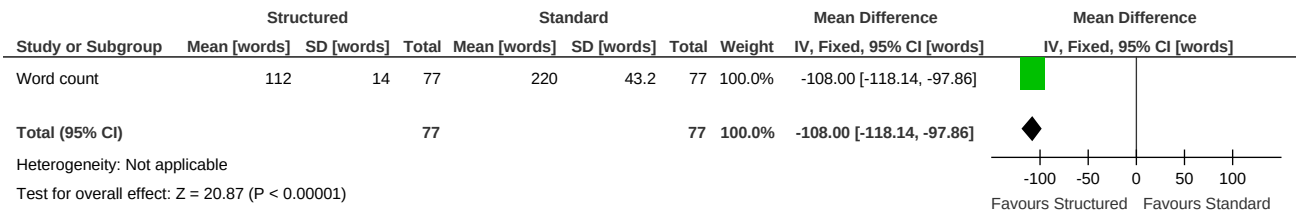
The graph in figure 7.6 illustrates a mean word count of 108 fewer words, within the structured reply letter when compared to the standard consultant reply letter.

Figure 7.6: Word count and 95% confidence intervals for the two letter formats



The mean difference between the word count in the two letter formats was statistically significantly different at -108 ± 10 (98, 118) at the significance level of p<0.00001 (Figure 7.7). This can be interpreted to illustrate that the structured reply letter contains 108 fewer words when compared to the standard consultant reply letter.

Figure 7.7: Mean difference in the word count between standard and structured letter formats



7.8 Letter Preferences

Practitioners ranked the letter formats according to whether they wished to receive that style of letter in future correspondence with the department. The results are detailed in Table 7.12

Table 7.12: Participants' preference for each letter format

Preference	Letter A (Standard)	Letter B (Structured)
Strongly Disagree /Disagree	11	1
No preference	40	5
Agree /Strongly agree	24	69
TOTAL	75	75

Chi square 54.69	**degrees of freedom 2**	**p<0.00001**
Fishes exact test	**two tailed p value**	**p<0.00001**
Odds ratio	**31.17 95% CI 3.82, 254.35**	

The result suggested that the practitioners strongly prefer the structured letter format.

The majority (52%) of those receiving the standard letter had no preference to receiving letters in the future in this format. 15% disagreed or strongly disagreed and 33% agreed or strongly agreed that they wanted future communication is the standard format.

A greater majority (92%) of those receiving the structured letter agreed or strongly agreed they wished to receive future letters in this structured format. 7% had no preference while 1% disagreed or strongly disagreed.

When comparing how participants ranked the standard letter to the structured letter, the increase or decrease in rank between each of the scores was analysed using the Wilcoxon signed rank test.

The Wilcoxon signed ranks test was used to grade the number of negative, positive and tied ranks (Table 7.13). The Z score was -6.381 based upon the negative ranks at a significance level of $p<0.0001$. This demonstrates a statistically significant difference in preference for the structured letter.

Table 7.13: Wilcoxon signed rank test to assess practitioners' letter preferences

Rank	N
Negative	4
Positive	59
Ties	12
TOTAL	75

Z -6.381 p<0.0001

Since a 23% of the studies sample population were specialists, the letter preferences of the 2 groups were independently analysed using, the Wilcoxon signed rank test.

The Wilcoxon signed ranks test was used to grade the number of negative, positive and tied ranks (Table 7.14). Specialist practitioners had a Z score of -2.11 at a significance level of $p < 0.0349$. GDPs had a Z score of -5.97 at a significance level of $p < 0.0001$. This demonstrates a statistically significant difference in preference for the structured letter. The GDPs and specialists independently showed a statistically significant preference for the structured reply letter format.

Table 7.14: Wilcoxon signed rank test to assess specialist practitioners' and GDPs letter preferences

Rank	Specialists N	GDPs N
Negative	4	0
Positive	10	49
Ties	3	9
TOTAL	17	58
	Z -2.11 p < 0.0349	**Z-5.97 p < 0.0001**

Consultants were assessed independently for their individual reply letters using the Wilcoxon signed ranks test to grade the number of negative, positive and tied ranks (Table 7.15). Each of the consultants' practitioners had a statistically significant preference for the structured reply letter formats ($p < 0.0003$, $p < 0001$, $p < 0.004$).

Table 7.15 Wilcoxon signed rank test to assess practitioners' letter preferences for each consultant

Rank	Consultant A	Consultant B	Consultant C
Negative	1	0	4
Positive	24	17	4
Ties	5	2	17
TOTAL	30	19	25
	Z -4.01 p<0.001	**Z -3.62 p<0.0003**	**Z -2.88 p<0.004**

Many of the participants were keen to express themselves in the free text box entitled “comments” (Table 7.16). Four participants made comments on the standard letter format with 1 deemed to be positive and 3 negative. Sixteen participants made comments on the structured letter, with 11 positive, 2 negative and 3 indifferent.

Table 7.16: Practitioners' feedback for each letter format

Rating	Letter A (Standard Letter)	Letter B (Structured letter)
Positive	"majority of letters from LUDH are informative"	**"**much better"
		"easy to find relevant information"
		"easier to read"
		"better than before"
		"really imformative and easy to read layout. Very good"
		"much easier to read, nice design and preferred format"
		"makes the service look more professional"
		"really like, concise, easy to read"
		"much quicker to read. Really like"
		"Excellent format"
		"concise and relevant"
Negative	"typographic errors could be a problem - one corrected but a little unclear. Parents should be copied in as should dentist. No NHS number."	"I am not this pts gdp. Action required section should be for the action of the gdp not my self confusing"

Rating	Letter A (Standard Letter)	Letter B (Structured letter)
	"format is similar to what I am used to. Explanation given is brief and to the point in this case which is good. I do object to being sent back pages and pages of waffle to wade through before getting to the point which is something I do experience elsewhere in the region"	"Quite clear but lacking in some details which dentist might want to know. Is it single arch fixed or both arches, will there be long term retention. Also use of abbreviations may not be clear to all especially if patient was copied into the letter e.g spr, ludh."
	The use of stamped addressed envelopes would be appreciated particularly when I have volunteered to take part in the research."	
Indifferent		"I am sick of receiving a book from St Helens"
		"different"
		"no mention of any carious teeth in diagnosis but then states that patient needs restorative rx"

8. Discussion

This study may be the first well designed randomised controlled crossover trial, carried out to assess the effectiveness, preference and length of structured reply letters. The study was carried out with the "real world" setting of a hospital department with individual patient variables that the structured letter had to deal with. This study addresses the future investigations set out in the Mersey regional audit by Waring 2007 which suggested the undertaking of a randomised control trial into structured reply letters.

8.1 Summary of the main findings

1. No statistically significant difference was observed between standard and structured consultant reply letters in participants' perceptual awareness of what was happening and what was actually happening to practitioners' patients', when receiving each of the letter formats.
2. No statistically significant difference was observed between standard and structured consultant reply letters in participants' perceptual awareness of action required and what actions were actually required for practitioners' patient's, when receiving each of the letter formats.
3. The Null hypothesis that there was no significant difference between practitioners' awareness of key patient information when receiving either the structured consultant reply letter or the standard consultant reply letter cannot be rejected.
4. A more robust statistical test demonstrated that the practitioners' awareness of key patient information was statistically greater when receiving the structured letter when compared to the standard consultant reply letter. Although, this rejects the null hypothesis that, that there was no significant difference between practitioners' awareness of key patient information when receiving either the structured consultant

reply letter or the standard consultant reply letter, the result should be interpreted with caution.

5. The mean difference between the word count in the two letter formats was statistically significantly different at -108 $\pm$ 10 (-98, -118) at the significance level $p<0.00001$.
6. The null hypothesis that there was no statistically significant difference between the word count of the structured consultant reply letter and the standard reply letter can be rejected.
7. A statistically significant difference in preference for the structured letter was observed at a significance level of $p<0.0001$.
8. The overall response rate was 87% of eligible consented participants.
9. All the practitioners were recruited into the trial from the Mersey region.
10. The majority of participants within the study graduated after 1990.
11. 23% of participants were specialist practitioners however; both specialists and GDPs had a statistically significant preference for the structured reply letter format.
12. Gender of participants was considered similar to that of the UK dental profession population.

8.2 Interpretation of results

8.2.1 Recruitment

The overall response rate of 87% was considered to be higher than the majority of previous investigations into referral letters (Thong, 2010, Tomlinson, 2006, Newton, 1992). The high rate of response is due to the diligence, persuasion and perseverance of the Principal Investigator. Non-respondents were contacted by the principle investigator and repeat questionnaires were dispatched. This attention to detail and organisation stimulated a high level of response in the study and should be considered in future studies. Despite being high, unfortunately the response rate may have been improved further by the inclusion of stamped addressed envelopes. This was not sanctioned by the finance division of the University Research Department. One practitioner was particularly disgruntled with the lack of stamped addressed envelopes so much so they expressed their opinion in the free text section of the knowledge and satisfaction questionnaire. The practitioner commented that "The use of stamped addressed envelopes would be appreciated particularly when I have volunteered to take part in the research." A goodwill gesture of providing stamped addressed envelopes shows a level of appreciation and failing to do so may have affect practitioners' enthusiasm toward future collaborative research in our department. The recent Cochrane review by Edwards in 2009 highlighted that the use of stamped addressed envelopes increased the response rates considerably ($p<0.00001$). Other methods were also identified to increase the response rates of postal questionnaires. These included monetary incentives, the use of recorded delivery, teaser envelopes, prior notifications of the study, follow up contact, shorter questionnaires, personalised questionnaires and the use of handwritten envelopes. Although this study did not employ financial incentives, stamped addressed envelopes, teaser envelopes or personalised questionnaires it did employ prior notification to participants, a short questionnaire, handwritten envelopes and follow up contact was provided.

8.2.2 Participant's demographics and referral source

All the practitioners were recruited from the Mersey region. Sixty eight percent were from Liverpool and the remainder from the Wirral and the areas surrounding Warrington. Eleven percent left the postcode section of the knowledge and satisfaction questionnaire blank. The records of these participants were identified to be within the Mersey region. Since it was a regional study the results are applicable to the Merseyside area in North West England. A previous audit (Warring, 2007) had identified practitioners' concerns with consultant reply letters as many of the practitioners already received extremely long reply letters from consultants. This potentially may have influenced the results in favour of the structured reply letters as concerns had already been expressed within this region of UK. Primary care practitioners seem keen for a change or improvement in the format of consultants' letters. The extent to which the results are generalisable to other parts of the UK is uncertain since practitioners outside of the Mersey region were excluded and may respond differently to the letter formats (Evans, 2003).

Twenty three percent of participants were identified as being specialist practitioners encompassing the specialties of Orthodontics, Restorative, Oral Surgery and Paediatric dentistry. Having undergone additional post graduate training and being largely based in the hospital service creates a potential different opinion about consultant reply letters compared to General Dental Practitioners since their educational needs may be considerably different (Gagliardi, 2002). This potential bias is likely to be minimal since the specialist practitioners were independently analysed and found to be similar to their counterparts in their preference to letter formats.

The majority of participants within the study were less than 45 years of age. This suggests the study was conducted on a younger sample that may have substantially different opinions and educational needs than older practitioners (Gagliardi, 2002). This effect could be due to the Mersey region having a younger population of dentists than average or the younger

referrers were more enthusiastic toward research. Alternatively, perhaps older GDPs see fewer NHS and a greater number of private patients. Either way this could have potentially put an overestimation and bias toward the preference for the structured reply letter format observed in this study.

There is evidence of a greater male involvement within the study (56%). However this is representative of the referring population (General Dental Council annual report, 2010). The total number of male individuals on the dentist register at the end of 2010 was 58%, compared to 42% female (General Dental Council annual report and accounts, 2010). No statistically significant difference was observed between the gender of respondents and non respondents. Our study is therefore similar to the gender of dentists in the UK.

8.2.3 Letter attributes

A generalised spread of letters generated by the three consultants was observed with one seeing 32 patients from referring practitioners, one 26 and the other 18. One consultant did dictate more words than the other two however; the confidence intervals overlapped suggesting that they had a similar number of words contained within each of their reply letters. This homogeneity between the consultants' letters allowed the data to be pooled and analysed collectively. The mean number of words contained within the structured reply letter was 112 $\pm$ 6 compared to the standard consultant reply letter which contained 220 $\pm$ 19 and was considered statistically significantly different at a significance value of $p < 0.0001$. The structured consultant reply letter can therefore be considered to reduce the number of words within the text by approximately 50%. As practitioners' were more aware of key points of information having received the structured letter, it can be suggested that the word count was reduced by omitting redundant text whilst retaining key information. Assuming a minimum typing time of 50 words per minute for a NHS secretary (NHS jobs 2011), it equates to a saving of 2 minutes per letter or approximately 1 hour per day based upon an average typing of 25 reply letters per working day. The additional time saving could be used

to reduce secretarial workloads or allow for an increase of 8 consultant reply letters to be typed per day. Based upon an NHS secretarial salary of between £15,860 and £21,798 with the average being £18,829 (NHS Careers website, 2011), this equates to a minimum financial cost saving of approximately £5000 per year in our orthodontic department. If the structured consultant reply letter was implemented throughout the University Dental Hospital then the savings would be far greater. Fully implementing and integrating a structured reply letter across the National Health Service could, in theory, provide substantial cost savings.

With further advancements in digital dictation, voice specific recognition and "mail merge" integrated computer software packages, the burden on secretarial support could be reduced substantially offering potentially massive cost savings.

8.2.4 Methodology and Randomisation

The study was a randomised controlled crossover trial and could be considered the highest level of evidence available on structured reply letters. The study could have been designed in either a parallel or crossover structure as discussed in section 6.9. Using a crossover deign allowed the participants to receive both letter formats for the same referred patient. One could argue that waiting 6 weeks between dispatching the different letter formats is insufficient and potentially create a memory bias (Bruce, 2009). However, in reality I think it has little bearing on practitioner's responses and in a busy healthcare environment where practitioners routinely see 30 patients per day the likelihood of recalling the responses recorded about the first letter are minimal.

Randomisation was stratified by consultant and generated in blocks of 6 practitioners using an electronic random number generator by the chief investigator (Dr Jayne E Harrison). The Chief Investigator was not involved in the recruitment or allocation of the interventions. Cards bearing the allocation were placed in consecutively numbered opaque, sealed

envelopes and passed to the principal investigator for allocation. This has been shown to be an effective method of randomisation (Bruce, 2009) and this was confirmed with an approximate 50:50 split between the control and intervention groups. The relative merits of randomisation, stratification and block randomisation are discussed in sections 6.6, 6.7 and 6.8 respectively.

8.2.5 Referral to letter generation

One consultant received more referrals than the other two and therefore produced more letters in the trial. There was no significant difference in the word counts of either of the letter formats for the three consultants, so it is unlikely that this had any significant effect on the overall word counts. However, it may have influenced the results with regard to practitioner preference. If practitioners particularly disliked that consultant's standard letter then the preference toward the structured consultant reply letter may have been overestimated. If the number of letters, allowed to be generated by each consultant, had been limited to 25 this potential source of bias could have been reduced.

8.2.6 Key information contained within letters

The findings from this study suggest that the structured reply letter may be significantly better at communicating key information to the practitioner when compared to the standard consultant reply letter. However, this result should be interpreted with caution due to the reliability of the statistical test employed and that the result was only just into significance. When comparing the 2 letter formats it may be more appropriate to suggest that the formats were similar in communicating key information to the practitioner with regard to what was happening to their patient and what actions were required of them. This suggests that the structured consultant reply letter is as effective at relying key patient information to the practitioner as the standard consultant letter format. The introduction of the structured

letter template should therefore not impact negatively on the quality of information exchanged between both parties. While having no impact on the quality of information exchanged between the consultant and referrer it potentially enhances the consistency of standardisation of consultant reply letters by ensuring a structured format and the inclusion of key patient information (Waring, 2007).

8.2.7 Practitioner preferences

The study identified a strong preference toward the structured reply letter by participating practitioners. The practitioners perceived them to be easier to read, easier to find relevant key information quickly and felt they provided a more professional image of hospital services. Overall, an overwhelming 92% felt that they would like to receive future correspondence in the structured letter format. The remaining 7% had no preference and only 1% disagreed entirely. Despite this, I feel the structured consultant reply letter should not be used blindly as a "one size fits all" approach. It merely complements our existing letter style. It should certainly not make the use a standard consultant reply letter obsolete. Instead, the standard consultant reply letter should be used when the patient's clinical case is better communicated in that format however, a significant proportion of cases may be suited to the structured reply letter. In this study of 75 letters, no problems were encountered in using the structured letter template however, consultants, practitioners and secretaries are all fully aware that letters exist that will not and do not integrate easily to a structured letter format. With this in mind, the standard letter should not be decommissioned.

8.2.8 Comparisons with previous research

Previous studies have suggested deficiencies in numerous areas of standard consultant letter formats. These include:

1. The inadequate assessment of the issue surrounding the referral (Hodge, 1992).

2. Too much technical information and obsolete text (Westerman, 1990).
3. Omission of clinically relevant information (Cummins, 1980).
4. Lack educational content (Gagliardi, 2002).
5. Too long (Waring, 2007).
6. Difficult to identify key information quickly and concisely (Waring, 2007).
7. Too slow to be dispatched (McConnell, 1999).

This study highlighted that 92% of practitioners who received the structured consultant reply letter would prefer to receive future letters in this format which is in broad agreement with Wynn (2004), Melville (2002) and Saha (2006). The later demonstrated an 81% preference for structured reply letters. Tattershall (2002) also demonstrated a preference towards the structured reply letter and stated that this type of letter format significantly enhanced the quality of correspondence between healthcare professionals. A study by Waring (2007) on general dental practitioners' opinions regarding reply letters from consultant orthodontists, also found that 82% preferred summaries in a list format as opposed to free text. The sample population in the current trial is drawn from the same population sampled in the regional audit, so it is pleasing that the trial has found that the letter format suggested by the audit, as the preferable option, has been acceptable to the practitioners.

The study is also in broad agreement with that of Newton (1992) which found that the structured reply letter was able to accomplish the basic objective of transferring clinical and administrative information between healthcare providers.

A low response rate can give rise to sampling bias if the non response is unequal among the participants regarding exposure or outcome. The response rate is therefore a valuable indicator to quality and validity. However a lower response rate does not necessarily mean a lower accuracy but increases the likelihood of it. Because this trial attempted to make its results generalisable to a larger population a high response rate was crucial. A mailing response rate of 50% is said to be a minimum target if the non-respondents views are not to

overturn the respondents although 60% is deemed to be good and above 75% is preferable (Cook, 2009).

The response rate of 87% in this trial is comparable with other studies conducted into consultants' letters. Thong (2010) recorded the lowest response rate of 32%, although the author did obtain 535 replies from a large sample of 1700 practitioners. Tomlinson (2006) achieved a response rate of 60% while Newton (1992) reported a response rate of 77%. The 87% achieved in this study can be considered high and is only bettered by a similar postal study (Rawal, 1993) where a response of 92% was achieved. The previous audit conducted on the same sample population as this trial by Waring (2007) achieved a response rate of 76%. The conclusions drawn from the current trial can therefore be considered to be representative of the sample population which increases the validity of the results and may allow them to be applied to a larger population.

One study (Scott, 2004) reported the word count contained within their structured reply letter. The median word count was calculated to be 270 words and varied between different specialities (range of medians 160 to 345). The word count exceeded 370 words in 25% of letters and exceeded 500 words in 5%. The current trial found the mean number of words contained within a structured consultant reply letter to be 112 $\pm$ 6 with a median of 113 (IQR 105, 119) and therefore was considered to be lower than the aforementioned studies.

Another study (Melville, 2002) used reading time as their outcome measure. The authors found no statistically significant difference when comparing the reading time of the two letter formats between GPs. One could surmise that reading time was proportional to word count and therefore typing times.

However, no previous studies have compared the number of words contained in the structured reply letter to the standard consultant reply letter. A 50% reduction in the word count between the two formats has added more justification to the implementation of such

templates within the NHS. This finding can be used as a bench mark in future research concerned with structured consultant reply letters.

8.3 Implications for clinical practice

The results of this study provide potential opportunities for clinicians in both primary and secondary care, hospital managers, healthcare commissioners and government politicians alike.

The results of this study allow the orthodontic department at Liverpool University Dental Hospital to address the previously raised issue of practitioners' dissatisfaction with the current standard consultant reply letter (Waring, 2007) by introducing the structured consultant reply letter. The findings showed that practitioners in the Mersey region had a strong preference for the structured letter format and its introduction in the orthodontic department at Liverpool University Dental Hospital may satisfy the needs of the referring practitioners. This will allow the clinicians to improve their written communication and may ultimately enhance their professional relationships with their colleagues (Waring, 2007).

The evidence suggests that reducing the number of words contained within the consultant reply letters could potentially have considerable financial implications. Secretaries will have fewer words to type per letter which may potentially free up time within their working day which could be utilised to increase productivity or reduce the hours of secretarially time required and potentially allow for budget savings.

The transcription of letters is a significant cost issue for all healthcare trusts. It is an essential service and one that is responsible for a significant part of the departmental budget.

The departmental medical secretaries are usually working at full capacity and it is rarely possible to achieve targeted turnaround times for clinical correspondence: indeed most Trusts have to employ expensive temporary staff in order to meet those targets. The

structured reply letter could assist in making the targets more achievable with existing resources.

With the NHS beginning to make immediate efficiency savings, in order to meet the increasing demands on NHS services, a revision to the 2010/11 NHS Operating Framework, sets out changes to key priorities for the NHS including plans to reverse the rise in management costs seen in the last year (Department of Health: Revision to the Operating Framework for the NHS in England 2010/11). By introducing a structured reply letter template may potentially reduce the secretarial burden and may assist in achieving these goals.

The secretaries in most hospital based healthcare services are dedicated to typing up all the consultant letters that a medical expert has dictated into their recording device. In the orthodontic department at Liverpool University Dental Hospital typed written letters are passed from the secretary back to the consultant, who in certain circumstances has to spend just as much time again, correcting them. The cost of duplication of effort by both parties is considerable. Medical and Dental NHS secretaries, being a specialized career, are costly. The hourly costs for consultants are even higher.

A potential efficiency saving could be achieved if the clinicians dictation was translated directly into text by a machine with voice recognition technology. By integration of this machine with computer software devices, containing a structured consultant reply letter template could then eliminate time-consuming elements of this process. This would not only allow the NHS to make considerable budgetary savings, but it could help reduce the time taken to update patient records and dispatch letters to practitioners following a consultation.

This study only identifies a potential departmental saving and does not provide the figures for the NHS to quantify this. Data from Nuance Healthcare in the United States of America, (Naunce Solutions ® White paper, 2009) show that twenty healthcare organizations, from

across the United States, have already saved over one million dollars in transcription costs as a result of implementing computer aided medical transcription services.

Leeds Teaching Hospital Trust has recently implemented Nuance's speech technology "Speech Magic" and is improving productivity on a large scale. Introduced in the Radiology department, the new speech recognition system has allowed the department to save money by reducing the use of external agency secretaries and freeing up time to allow their full time secretaries to devote more hours to consultant support and ultimately patient care (Nuance Solutions ® 2010).

Southport and Ormskirk Hospital NHS Trust recently announced that: "One of the problems in the past has been that a fair proportion of the secretaries' time has been taken up with dealing with patients' enquiries, which is seen as a priority, and this has sometimes resulted in a backlog of typing" (Southport and Ormskirk NHS statement, 2010). The structured consultant reply letter template used in this trial could be integrated with the trusts recently introduced semi-automated computer systems and digital dictation system to address such problems and produce a more efficient service for patients and referring practitioners.

Potential exists for the structured consultant reply letter to be integrated with clinical software programmes and minimum data set. This could take the form of patient specific characteristics being input into the software at the chair side during the consultation appointment that satisfied both structured reply letter and the minimum data set requirements. The ability of the software to then construct an automated consultant reply letter within the specified template design may provide further efficiencies savings by removing the dictation and data transfer processes altogether.

Introduction of a structure to the reply letters may potentially improve the consistency of the inclusion of key information contained within consultants' reply letters. Standardisation of the consultants' reply letters in this manner allows consultants to include educational material within their letters consistently. If these letters could be validated by an educational

body and scored appropriately, the consultant could potentially deliver Continued Professional Development specific to the patients' clinical problem who the practitioner referred. Not only would this make each consultants' reply letter a potential learning opportunity, it would satisfy practitioners' desire for Continued Professional Development to be directly related to their clinical work (Gagliardi, 2002).

Training and Continuing Professional Development for healthcare professionals are considered to be important strategic instruments in improving health (Clarkson, 2003). There is a recognised shortage of information using evidence in the "real" dental practice and a recognised readily available source of education would provide a significant improvement (Clarkson, 2003). This educational component in the letter would need to include:

1. Concise educational aims and objectives.
2. Clearly anticipated outcomes.
3. Quality control.

In delivering a system of Continuing Professional Development based around a referral system has the potential to satisfy the general dentists view that education should be more clinically relevant (Gagliardi, 2002).

8.4 Untoward events during the trial

After the exclusion criterion was applied, the study randomised a total of 86 participants to the control and intervention groups. However, only 77 letters of each format were actually generated and dispatched to the practitioners. This loss of 9 letters represented 10% of the total data and they were classified as missing data. One could argue this should have been included within the trial if we were to apply the "intention to treat" analysis, but with no primary or secondary outcome data to derive from these letters, I cannot envisage how this could have had an effect on the overall outcome of the trial and it was therefore justifiable to

classify the data as missing. However, this missing data was taken into account when calculating the response rate which therefore reduced the rate. Eighty seven percent of eligible consented practitioners completed the trial compared with a response rate of 97% eligible consented practitioners who had reply letters generated.

The reasons behind the missing data were explored and it was found that either:

1. The patient never attended the consultation clinic within the trial accrual period;
2. The consultant failed to recognise the randomisation envelope stapled to the initial referral letter;
3. The consultant ignored the randomisation envelope stapled to the initial referral letter;
4. The randomisation envelope was inadvertently removed or lost from the initial referral letter, or
5. The patient was seen by a junior member of staff and not by the consultant.

Of the 77 letters generated, only 2 participants failed to return the 2 sets of 'knowledge and satisfaction' questionnaires. These practitioners were telephoned on numerous occasions and evidently had not left the workplace. Repeat 'knowledge and satisfaction' questionnaires were dispatched but on each occasion were not returned. One of these may have been making a stand over the principles of the department not providing stamped addressed envelopes but never the less, one can only assume that they had withdrawn their consent. The secondary outcome (word count) data was recorded and analysed as normal.

Despite all their efforts one consultant seemed unable to grasp the concept of the trials crossover design. Despite dictating the first reply letter as instructed on the card in the envelope, on several occasions this consultant only dictated a single letter and had to dictate the second letter at a later date at the investigators' request. Ideally the letters were meant to be dictated in succession and in this handful of cases (4/19) this was not possible. Although informal discussions were held with each of the 3 consultants and information packs were

issued about the trials dynamics, a more structured training for consultants about the trials methodology may have assisted in avoiding these errors. Future trials should explore the avenue of incorporating formal training pathways for dictation and use of the structured reply letter template.

Several days after starting the trial, it quickly became evident that one secretary was struggling with recording the secondary outcome data and appeared to have frequent omissions in the log sheet. On questioning her it was evident that she was manually counting each word and perhaps unsurprisingly was finding the task of word counting particularly labourious and time consuming. This issue was quickly identified and the secretary was given suitable training in the use of electronic word counting to allow her to continue this task with a little less difficulty. Fortunately, the letter formats were saved in a specific document and allowed the data to be checked and verified.

8.5 Hypothesis

Primary

The null hypothesis, that there is no significant difference between practitioners' awareness of key patient information when receiving either the structured consultant reply letter or the standard consultant reply letter was accepted.

The structured reply letter was shown to be as effective as the current standard reply letter when communicating with healthcare professionals.

Secondary

The null hypothesis that there was no statistically significant difference between the word count of the structured consultant reply letter and the standard reply letter was rejected.

Letters produced in the structured format were half as long as the standard format. As secretaries work on a word per minute scale this 50% reduction in words (on average 108

fewer) equated to a time value of 2 minutes per letter and considered statistically significant $p<0.0001$.

8.6 Limitations of the trial

This randomised controlled crossover trial, into the effectiveness of structured reply letters, has provided a high level of evidence on which to base our findings (Evans, 2003).

Randomised controlled trials are considered by most to be the most reliable and robust form of scientific evidence to influence healthcare policy and practice because they have the potential to reduce bias. Results of randomised controlled trials may be combined in systematic reviews which are increasingly being used in the conduct of evidence-based medicine.

Despite the known advantages of randomised controlled trials, one should not consider them to be impervious to predicament and it is important to note that this trial had several shortcomings which are outlined below.

The extent to which the results can be generalisable to outside the sample population is uncertain since those practitioners outside of the Mersey region were excluded. What is true in one region of the United Kingdom is not necessarily true for every region. In a different Dental Hospital, with different consultants and referring practitioners, with different needs, the results may have been different.

Single centre randomised controlled trials provide results that are low risk of error bias. However this is ranked behind multicentre randomised control trials and systematic reviews because it is based upon a single population. Skill mix, staffing, resources and expertise unique to this region will impact on the findings (Evans, 2003).

Many of the participants recruited into the trial were likely to have been involved in the previous regional audit conducted by Waring (2007). This means that participants recruited

into this study may have already been sensitized to the idea of structured reply letters and therefore could potentially make them unrepresentative of the population as a whole. However, the audit was conducted in 2005 so some 23% of practitioners would not have qualified at this point.

The demographics of participants were not necessarily representative of the wider dental population as 23% had undergone further specialty training. This compares to 10.5% of specialists in the UK dental workforce and equates to a two fold increase (General Dental Council Annual Report and Accounts, 2010). However, the results suggested that their responses were similar to the General Dental Practitioners.

Despite randomisation and stratification of the practitioners by consultant, into control and intervention groups there were a greater number of referrals to one consultant. The uneven distribution between consultants may have potentially biased the results since this consultants' letters may have been better or worse than their counterparts. However, the findings suggested they were similar on both letter formats with regard to letter preference. In future trials one could consider ceasing recruitment at a predetermined number depending on the sample size.

The trial was unable to adjust to the possibility that the results may have been biased at the level of the individual letter, because the quality of the letter may have been dictated to by the complexity of the case. For example, a practitioner may perceive a letter to be favourable because the problem, solution and action required was relatively simple and easy to understand, while a more complex set of issues may be perceived less favourably due to the difficulty of relaying the information and the practitioners' grasp and understanding of the case. However, this potential effect would have been diluted by practitioners receiving both letter formats based upon the same individual case.

The study was conducted within the dental specialty of orthodontics therefore the results may only be applicable to letters generated by an orthodontic consultant to referring

practitioners. It would however be interesting to see how the results are perceived amongst practitioners in other dental and medical disciplines.

Although this randomised controlled trial could be considered the “gold standard” in evidence what it cannot control for is the Hawthorne effect (Landsberger, 1958). This is a form of reactivity, whereby subjects improve or modify an aspect of their behaviour being measured, in response to the fact that they are being studied, not in response to a manipulation. Simply by testing the effectiveness of the structured consultant reply letter will in part improve its performance.

Despite the aforementioned weaknesses I believe this study still adds a considerable level of high evidence to the research base.

8.7 Suggested Improvements

One method of obtaining a true representative population sample would be to undertake a multi-centre randomised controlled crossover trial, including a broad range of dental and medical specialties, to assess the effectiveness of the structured consultant reply letter in a “real world” setting (Evans, 2003). Organising such a study would need a greater level of financial support and time commitment so was considered beyond the level of a specialist registrar’s research thesis.

Recruitment of participants could have been made more equal by putting a limit on the number of participants assigned to each consultant. In this trial this would have meant no more than 25 practitioners could have been assigned to each of the three consultant orthodontists. Introducing such a limit to this trial may have affected the length of the data accrual period beyond what was achievable within the research component of the DDSc since our department has an unbalanced pattern of referrals to orthodontic consultants.

However, a perceived disadvantage of placing such a limit may have reduced the “real world” effect.

The trial could have been improved further by providing a greater level of structure and time to train the consultants in dictating, the structured letter format and the secretaries in using the structured letter templates. Such training programmes have been shown to be more effective at producing structured letters of greater quality and could have enhanced the overall standard and consistency of letter writing between individual consultants (Hook, 2006).

The letter could be further developed with appropriate computer software to allow for automatic text box re-sizing and improved page layout design on a case by case basis. Having had discussions with the secretaries on their perception of the letter, they felt this to be advantageous and would have saved more time.

8.8 Future research

As previously suggested the results of this study provide potential opportunities for clinicians in both primary and secondary care, hospital managers, healthcare commissioners and government politicians alike to develop the structured reply letter further.

Future research, based on the findings from this randomised controlled crossover trial, can be targeted in the follow areas:

1. **Voice recognition and computer software**

   The development of voice recognition dictation, integrated with computerised software, containing the structured reply letter template is something which is possibly an exciting avenue to explore. The structured reply letter could be trialed in combination with this and assessed to see if its results maintain the quality of the consultant reply letters while and if further efficiency savings can be made.

2. **Specific training programmes in letter writing**

   It would be interesting to see if the structured consultant reply letters could be improved further by the mandatory training of consultants in letter writing and secretaries in the use of the structured letter template. With consultants undergoing tuition in both dictation and structuring of the letter the quality could assessed to identify if this is worthwhile.

3. **Specific structured reply letters in different dental and medical specialties**

   As previously discussed, one of the trials' limitations was that it was only carried out in one dental specialty. It would be interesting to see if the success of the structured reply letter in orthodontics could be replicated in other dental and medical disciplines. I suspect modifications may need to be made to allow it to be speciality specific. I would suggest that a pilot study in another discipline could be undertaken within the Liverpool University Dental Hospital to assess the success of the structured reply letters across disciplines.

4. **Detailed evaluation of financial cost benefits in the NHS**

   This trial only provides a potential departmental saving and does not provide the absolute figures for the NHS to quantify this. In order to assess the true potential cost benefits through efficiency savings across the NHS, the trial would need to be piloted in a small hospital to assess is viability when confronted with multi disciplines each having specific requirements of the letter template. Having assessed the performance of the structured reply letter in a regional hospital, the next logical step would be a national pilot study or multicentre randomised controlled trial.

5. **The effect of structured reply letters on overall patient care**

   To date studies have only postulated as to the actual impact structured reply letters have on the overall standard of patient care and no research has evaluated it directly. One can hypothesise that the reduction in time needed to construct the structured consultant reply letters could have a knock on effect on how quickly a practitioner

could receive and therefore carry out any necessary tasks. However, the effect on patients' care is difficult to measure.

6. **Measurement ease in finding relevant information contained within the letters**

   This trial was able to identify whether practitioners' could obtain key information from the consultants' reply letters. Having identified that practitioners' are equally capable of obtaining this key information for either letter format an area of further investigation and potentially a more valuable outcome could be the ease in doing so.

7. **The potential role of the educational content contained within the structured reply letter and its value in Continued Professional Development.**

   The extent to which both standard and structured letters have an educational content could be explored further. The potential to provide clinically specific education to primary care practitioners is one which could be of benefit to both writer and recipient. Evaluation of the educational value of each letter could lead to a Continued Professional Development score being assigned to that letter and therefore provide clinically relevant learning outcomes.

8. **Links with the minimum data set, clinical records and automated letters**

   Finally, it would be interesting to identify how the structured consultant reply letter could be integrated with clinical dictation software programmes. This could take the form of patient specific characteristics being inputted into the software at the chair side by an assistant during the consultation appointment which could also be incorporated into the minimum data set requirements. The ability of the software then to construct a consultant reply letter, within the template design could then be tested.

9. Conclusion

This trial was set up on the recommendations of a regional audit by Waring (2007) which identified numerous shortcomings with the existing referral pathway. The trial proposed that a structured reply letter should be introduced for the letters to referring practitioners following orthodontic consultation within the orthodontic department Liverpool University Dental Hospital. The authors considered this to be potentially beneficial in providing referring primary care dentists with information that they wanted and was likely to reduce administration time and secretarial workload, thus providing a substantial time and therefore cost benefit. The structured format also could instil a greater level of consistency to the letters allowing key information to be included more readily.

The aims of this trial were therefore to identify whether a structured consultant reply letter was a more effective method of communication with practitioners when compared to a consultant's standard letter. The trial also aimed to identify if any difference existed in the dictation and typing time required for the two letter formats.

The objectives of the study were to compare the practitioners' awareness of patient status and the subsequent actions required following receipt of the two letter formats. The trial also attempted to compare the secretarial and consultants' time required to dictate and type both the structured and standard letters.

The study tested the null hypothesis that there was no significant difference between practitioners' awareness of key patient information when receiving either the structured consultant reply letter or the standard consultant reply letter.

The study also tested the null hypothesis that there was no statistically significant difference between the typing times of the structured consultant reply letter and the standard reply letter.

The response rate of the study was 87% and was comparable with similar studies. The conclusions drawn from this study could therefore be considered to be representative of the sample population and may be applied to a larger population. The trial conclusions are as follows:

1. There was a statistical significant improvement in participants' perceptual awareness of their patient's status having received the structured reply letter format.
2. There was a statistical significant improvement in participants' perceptual awareness of any action required having received the structured reply letter format
3. There was a statistically significant difference in preference of the structured reply letter.
4. The structured reply letters were statistically significantly shorter than the standard reply letter. The structured letter is 50% shorter.

This research was undertaken within an era of economic uncertainty and financial constraints affecting the public sector to which the NHS is undoubtedly not immune. The NHS is undergoing its biggest change arguable since its creation; however, times of change are also accompanied with periods of limitless opportunities.

I believe the structured consultant template letters may assist in meeting our future NHS financial targets without the loss of front line clinical staff. The study therefore proposes the promotion of the structured reply template across the various dental specialities in the Liverpool University Dental Hospital.

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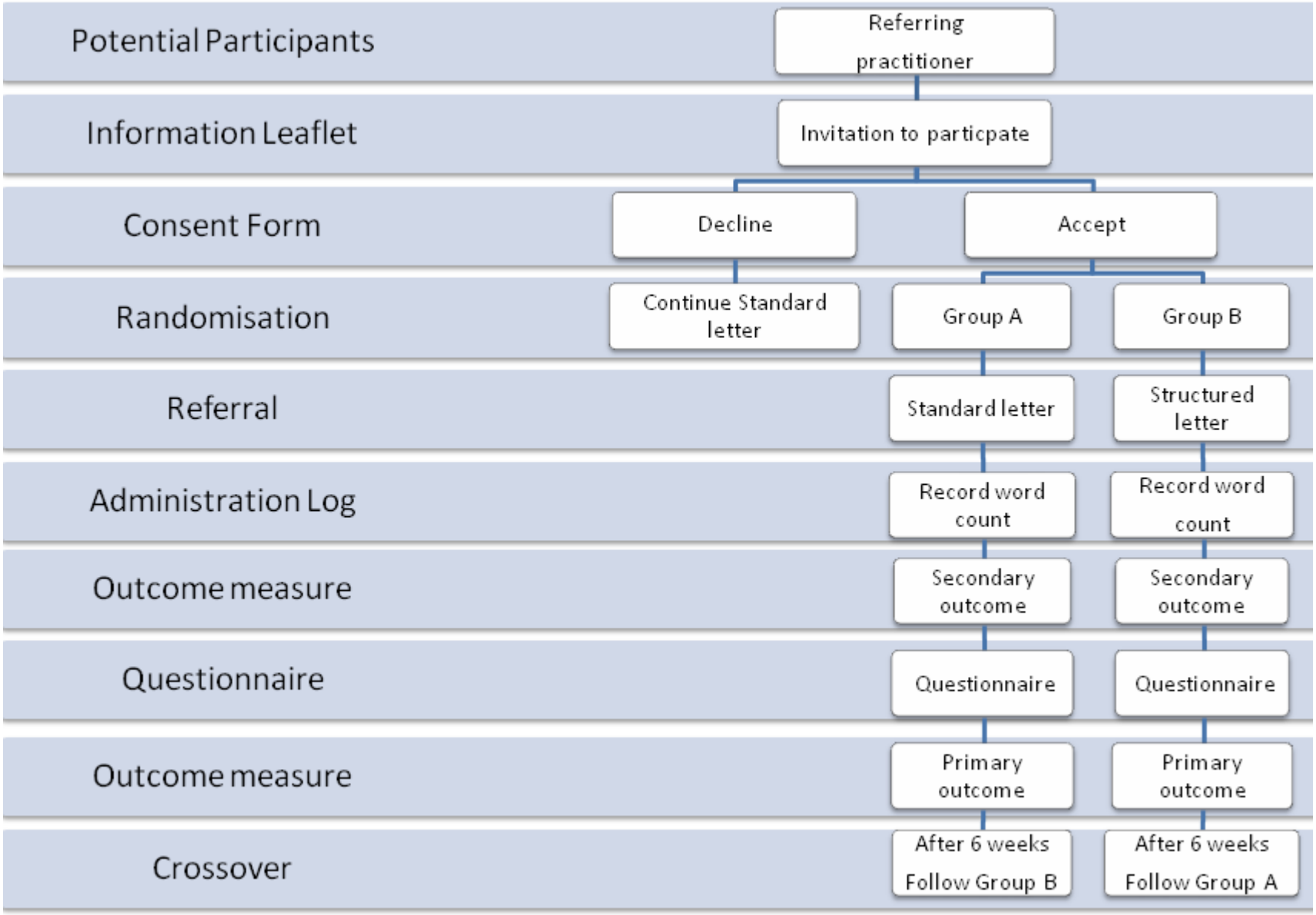
11. Appendices

11.1 Appendix 1

RCT Flow chart


Potential Participants
Referring practitioner
Information Leaflet
Invitation to particpate
Consent Form
Decline
Accept
Randomisation
Continue Standard letter
Group A
Group B
Referral
Standard letter
Structured letter
Administration Log
Record word count
Record word count
Outcome measure
Secondary outcome
Secondary outcome
Questionnaire
Questionnaire
Questionnaire
Outcome measure
Primary outcome
Primary outcome
Crossover
After 6 weeks Follow Group B
After 6 weeks Follow Group A

11.2 Appendix 2

Structured Letter Template

[GDP]

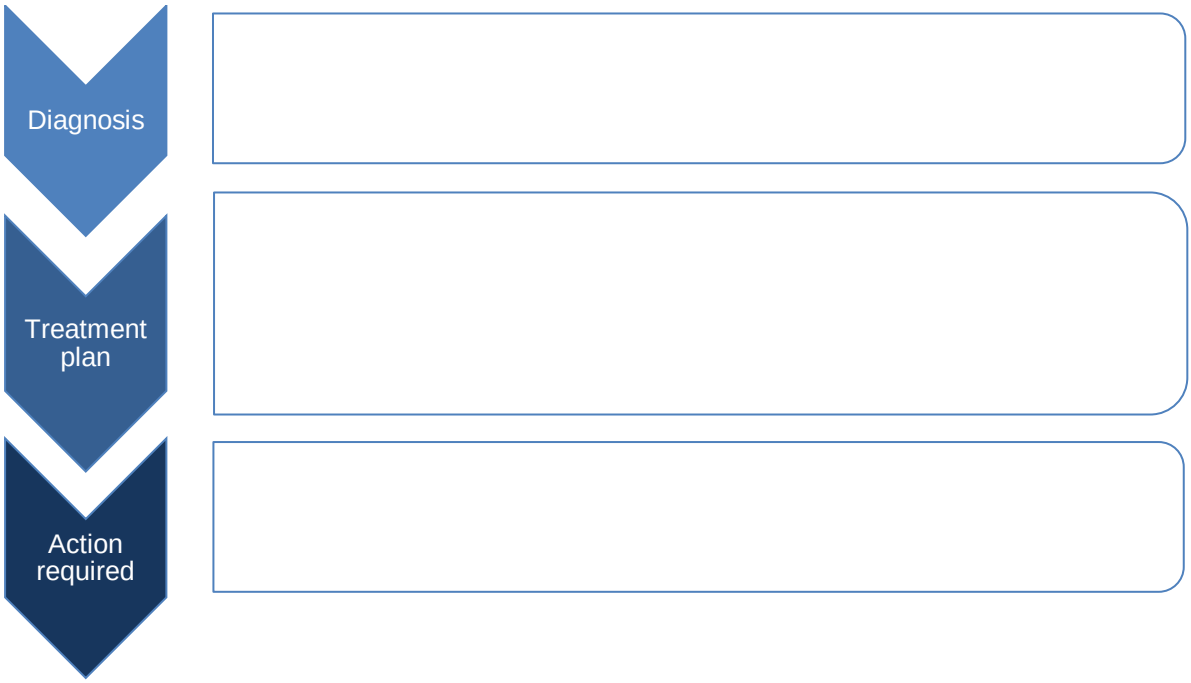
[Dental Surgery address]

[Today's Date]

Dear [GDP]

Re: Patient name, Patient address Patient DOB. RQ123456789

Thank you for referring the aforementioned patient. Please find the summary of the consultation below.



We will endeavour to keep you informed of his progress and any decisions that are made. Please do not hesitate to contact us should you require any further information.

Yours Sincerely

Consultant Orthodontist

11.3 Appendix 3

Structured Letter Example

The Royal Liverpool and Broadgreen University Hospitals
NHS Trust

Liverpool University Dental Hospital
Pembroke Place
Liverpool
L3 5PS

Tel: 0151 706 2000
Fax: 0151 706 5807

☎ 0151 706 2000 ext 5021
Fax 0151 706 5031

Our ref:

ORTHODONTIC DEPARTMENT
CONSULTANT -

Dr
Dental Surgery

Liverpool

Dear

Miss **dob**

Clinic 18th January 2011 NHS No

Thank you for referring the aforementioned patient. Please find the summary of the consultation below.

Diagnosis

- Age 13.
- Skeletal 2.
- Mild Class III incisor relationship.
- Mild crowding.

Treatment plan

- Upper and lower fixed appliance therapy with possible premolar extractions in all four quadrants.
- This treatment is not growth related and can be carried out at any time.

Action required

- Refer onwards to a Specialist Practitioner.

We will endeavour to keep you informed of any further outcome but please do not hesitate to contact us should you require any further information.

Consultant Orthodontist

DENTAL HOSPITAL REFERRAL GUIDELINES AND PROFORMAS ARE NOW AVAILABLE ON OUR WEBSITE:
www.rlbuht.nhs.uk/dental

11.4 Appendix 4

Standard Letter Example

The Royal Liverpool and
Broadgreen University Hospitals
NHS Trust

☎ 0151-706-5030
Fax 0151 706 5031

Liverpool University Dental Hospital
Pembroke Place
Liverpool
L3 5PS

Tel: 0151 706 2000
Fax: 0151 706 5807

DEPARTMENT OF ORTHODONTICS
Consultant:

25th January 2011

Dental Surgery

Liverpool

Dear Dr

Miss dob

Clinic 18th January 2011 NHS No

Thank you for referring for an orthodontic assessment.

is now 13 years of age and has a mild Class III incisor relationship upon a mild skeletal 2 base with mild crowding present in the upper arch but more moderate crowding in the lower.

Treatment for would be to consider using upper and lower fixed appliances and with premolar extractions in order to create sufficient space as the most likely option. However, we would not be able to accept her for care within the Hospital Service as she has an IOTN of 3d with treatment being relatively straightforward in management.

I would be grateful if you could refer her onwards to a Specialist Practitioner for care. She has now been discharged from the department.

Thank you for your help.

Kind regards

Yours sincerely

Consultant Orthodontist

DENTAL HOSPITAL REFERRAL GUIDELINES AND PROFORMAS ARE NOW AVAILABLE ON OUR WEBSITE:

11.5 Appendix 5

Cover letters

Orthodontic Department

Liverpool University Dental Hospital

Pembroke Place

Liverpool

L3 5PS

February 2010

Dear Colleague,

Re: Invitation to take part in an exciting randomised control trial

I am currently a Specialist Registrar in Orthodontics at Liverpool University Dental Hospital. As part of my DDSc Degree I am undertaking a randomised control trial comparing a new structured consultant reply letter with the type of letter you receive presently.

Since this research may directly affect the communication you receive from the Orthodontic department in the future, I would be grateful if you could take the opportunity to read the enclosed information sheet about the trial and if you wish to take part, please sign the consent form and return it back to me in the addressed envelope provided.

I would be very grateful for your assistance.

Yours Faithfully

James Davies

SpR Orthodontics

Orthodontic Department

Liverpool University Dental Hospital

Pembroke Place

Liverpool

L3 5PS

Dear Colleague,

Re: Please complete the questionnaire.

Thank you for taking part in this Randomised Control Trial.

Please read the enclosed letter and complete the attached questionnaire. I would be very grateful if you could return the completed questionnaire back to me in the addressed envelope provided.

Thank you for your assistance.

Yours Faithfully

James Davies

SpR Orthodontics

11.6 Appendix 6

Practitioner Information Leaflet

PRACTITIONER INFORMATION LEAFLET

Structured Reply Letter Study

You are being invited to take part in a research study that is looking at whether General Dental Practitioners (GDPs) and specialist orthodontic practitioners are aware of the outcomes and necessary action required following the referral of one of your patients to either, Liverpool University Dental Hospital or Halton General Hospital.

Before you decide whether to take part in the study or not, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take your time in deciding whether or not you wish to take part in the study.

What is the purpose of this study?

A referral based service between GDPs and specialist practitioners in primary care and hospital based specialties has been well established. Good communication between these parties is pivotal in ensuring continuing education of dental practitioners while ensuring optimal patient management. The study will be comparing structured reply letters with the existing letters. The structured reply letters are potentially a way of improving these communication channels.

The aim of this study is to identify whether a structured consultant reply letter is a more effective method of communication with GDPs and specialist practitioners when compared to a consultant's standard letter. The study will also aim to identify any difference in the administration time required for the two letter formats.

If the new letter format is found to be more effective, then it may become adopted practice within the Mersey region

Why have you been chosen?

Your practice is based within the Mersey deanery and you refer patients to the orthodontic departments at Liverpool University Dental Hospital or Halton General Hospital

Do you have to take part in this study?

It is up to you to decide whether or not to take part in this study. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If you decide to withdraw at any time or do not wish to take part, this will not affect your established professional relationship.

What will happen to you if you take part?

If you take part in this study, you will be allocated into one of two study groups. Neither you, nor the consultants to whom you refer; will be able to choose into which group you go. This allocation will be randomised.

- **Group 1** – After referring a patient you will receive a standard consultant reply letter from the consultant. After 6 weeks you will receive a structured reply letter. In addition to both letters you will be asked to complete a short questionnaire based on each letter format.

- **Group 2** – After referring a patient you will receive a structured consultant reply letter from the consultant. After 6 weeks you will receive a standard reply letter. In addition to both letters you will be asked to complete a short questionnaire based on each letter format.

We want to find out how effective the letters are at communicating information to our referring practitioners and how satisfied you are with each format. This will be done via a short questionnaire. We will then try and find out which format is more effective and identify how satisfied you are with each letter.

What are the risks and disadvantages of taking part?

There do not appear to be any risks or disadvantages if you take part in this study. The main difference between taking part or not, is that you will need to spend a few minutes completing the questionnaires.

What are the possible benefits of taking part?

Your thoughts and comments can assist in improving the communication channels between both parties.

Will your taking part in the study be kept confidential?

The health professionals involved in this study will need access to your name, and practice address. However, all information which is collected during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised by it.

What will happen to the results of the study?

The results of this study will form part of a research thesis. It is also hope they will be published in an international dental journal. The results may also be presented at professional dental meetings. As mentioned above, your confidentiality is important and you will not be identified by name in any publication or presentation.

Has the study been approved?

Yes. A Local Research and Ethics Committee have approved this study.

Contact for further information

If you have any further questions or want to discuss the study, please contact Mr James Davies on 0151 706 5068 (an answering machine service is available) or write to him at:

Orthodontic Department

Liverpool University Dental Hospital

Pembroke Place

Liverpool

L3 5PS

Thank you very much for taking time to read this leaflet and we hope you will consider taking part in this study.

You will be given a copy of this information leaflet and a signed consent form to keep.

11.7 Appendix 7

Consent Form

PRACTITIONER CONSENT FORM

Structured Reply Letter Study

CONSENT FORM

Centre: 09/h1005/79 Study number: 3830 Practitioner unique number: ……..

Researcher: Mr James Davies

A Randomised Controlled Trial to assess how effective a structured reply letter is at communicating with referring practitioners.

Please answer each question by initialling the box	**Initials**
● I have read and understood the information sheet provided dated February 2010 (version 1.6)	
● I have received enough information about this study	
● I have been given the opportunity to ask questions and discuss this study	
● All of my questions have been answered satisfactorily	
● I understand that my participation is voluntary and that I can withdraw from this study…	
● At any time	
● Without giving a reason	
● Without affecting my professional relationships	

I agree to take part in this study.

_____	_____	_____
Name of practitioner	Signature	Date
_____	_____	_____
Name of researcher	Signature	Date

	YES	**NO**
Copy given to participant		

11.8 Appendix 8

Knowledge & Satisfaction Questionnaire

Draft

GDP QUESTIONNAIRE

IN ANSWER TO EACH QUESTION, PLEASE MARK THE RELEVANT BOX WITH A CROSS IN BLACK PEN X

GDP No. ☐☐☐ **Practice No.** ☐☐

☐ **Male**
☐ **Female**

Year of qualification ☐☐☐☐

Practice postcode ☐☐☐☐ ☐☐☐

Q1. Are you aware of what is happening to your patient?

☐ Yes
☐ No

a) If yes, what do you think is happening to your patient?

b) If no, then go to Q2.

☐ Review
☐ Joint Planning
☐ Treatment Waiting List
☐ Discharged
☐ Patient undecided
☐ Other

Q2. Are you aware of what you need to do for your patient?

☐ Yes
☐ No

a) If yes, what do you think you need to do for your patient?
Please mark all boxes that apply.

b) If no, then go to Q3.

☐ Nothing
☐ Refer elsewhere
☐ Improve patient's oral health
☐ Await further contact
☐ Restorative treatment
☐ Extraction/s as required
☐ Other

Q3. I would like to receive future letters from the hospital in this format.

☐ Strongly agree ☐ Agree ☐ No Preference ☐ Disagree ☐ Strongly disagree

Please make any additional comments below.

Thank you very much for taking the time to complete this questionnaire.

11.9 Appendix 9

Consultant Starter Pack

Consultant Starter Packs

Dear Consultant,

Thank you for taking part in this randomised control trial to assess effectiveness of structured reply letters from consultants to referring practitioners. The following information pack contains important details which I would be very grateful if you could familiarise yourself with. If you have any questions please ask either me or Dr Harrison.

Referral

1. Arrival of new referral letter into your pigeon hole
2. Upon the collection of this letter please complete the attached log sheet to include:
    a. Unique patient number (pre recorded)
    b. Patient's name
    c. Patient's DOB
    d. GDP's name
    e. Practice address
    f. Referred to (pre recorded)
    g. seen by (completed at consultation most likely yourself)

Consultant appointment

3. Letter arrives at the orthodontic clinic for consultation appointment
4. If envelope is attached to letter this confirms this GDP and patient are part of the trial
5. Examine patient in normal manner
6. After examination please open the envelope to reveal a postcard

Dictation of letters

7. The post card will reveal the order in which you should dictate your letters
8. To assist the secretaries please start you dictation by saying "GDP Trail"
9. Please dictate a letter as you would do normally (standard) and in the structured format in the order requested by the postcard
10. Please dictate a structured reply letter using the attached format as your framework. Please dictate in the following order:
    a. Summary
    b. Treatment plan
    c. Action required
11. Pass tape to Jenny or Trish for typing as normal

Administrative tasks

12. Please staple the post card to the Minimum Data Set sheet in the back of the notes
13. Please place “GDP Trail” sticker on front of the patient’s notes (see attached stickers)

Signing the letters

14. Letters in both formats will be placed in your pigeon hole for signatures
15. Please sign both letter formats and place them together with the patient’s notes, in James Davies’ pigeon hole

Please find enclosed:

1. Log sheet
2. Structured letter format example
3. Trail stickers

Consultant code	GDP Name	GDP address	Patient Name	Patient Dob	Seen by

11.10 Appendix 10

Secretaries Starter Pack

Secretary Starter Packs

Dear Secretary,

Thank you for assisting in this randomised control trial to assess effectiveness of structured reply letters from Consultant Orthodontists to referring practitioners. The following information pack contains important details which I would be very grateful if you could familiarise yourself with. If you have any questions please ask either me or Dr Harrison.

In the next few weeks and months you will receive some dictated consultant letters in a different format. The letters will affect the following Orthodontic consultants:

- Dr Harrison
- Prof Pender
- Mr Rudge

The notes of the patients included in the trail will be marked with a sticker marked “GDP Trail” on the front of the notes and the dictation tape should start with the words “GDP Trail”. Only Orthodontic consultation clinics will be affected.

If the patient is included in the trail you will be asked to type 2 letters. One will be in the usual consultant’s format. The second will be a structured reply letter in the format of the attached letter (an electronic template will also be provided).

Before printing these letters I would be grateful if you could complete an electronic word count and record it on the attached log sheet. The log should include:

1. GDP’s name
2. Patient’s name
3. Patient’s Dob
4. Letter Format 1, this is the first letter typed (A = existing format, B= structured format)
5. Word Count, for the 1st letter to be found electronically after typing complete
6. Letter Format 2, this is the second letter typed (A = existing format, B = structured format)
7. Word Count, for the 2nd letter to be found electronically after typing complete

Thank you for taking time to read this and for your assistance in the trail.

Kind Regards

James Davies

Please find enclosed:

4. Log sheet
5. Structured letter format example

Secretaries Log sheet

Unique ref	Typist	Format	Word count
Gp121	Trish	A	300
Gp121	Jenny	B	150
Gp122	Trish	A	260
Gp122	Jenny	B	120

11.11 Appendix 11

Ethical Approval

North West 2 Research Ethics Committee - Liverpool Central

3rd Floor

Barlow House

4 Minshull Street

Manchester

M1 3DZ

Telephone: 0161 625 7818

Facsimile: 0161 237 9427

23 February 2010

Dr Jayne Harrison

Consultant Orthodontist

Liverpool University Dental Hospital

Liverpool Dental Hospital

Pembroke place

Liverpool

L3 5PS

Dear Dr Harrison

Study Title:	**Randomised control trial to assess the effectiveness of structured reply letters when communicating with referring Practitioners.**
REC reference number:	**09/H1005/79**
Protocol number:	**1.6**

Thank you for your letter of 19 February 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*	
REC application	2.2	03 November 2009	
Protocol	1.6	29 October 2009	
Investigator CV	J.Harrison	12 July 2008	
Investigator CV	J.Davies	30 October 2009	
Participant Information Sheet: Appendix C - Practitioner Information Leaflet	1.6	29 October 2009	
GP/Consultant Information Sheets	1.6 - Appendix B	29 October 2009	
Letter from Sponsor	Appendix G	29 October 2009	
Summary/Synopsis	1.6 - Appendix A	29 October 2009	
Questionnaire: GDP Appendix E - Non-validated Questionnaire	1.6	29 October 2009	
Appenidx F - Administrative Log	1.6	29 October 2009	
Data Protection and Research Read Guidance Notes	1	12 October 2009	
Response to Request for Further Information		08 February 2010	
Participant Consent Form	1.6	19 February 2010	
Referees or other scientific critique report		18 February 2010	
Response to Request for Further Information		19 February 2010	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H1005/79	**Please quote this number on all correspondence**

Yours sincerely

Professor Sobhan Vinjamuri

Chair

Email: carol.ebenezer@northwest.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Miss Sarah Fletcher*

11.12 Appendix 12

Methodology

Comprehensive Trial Flow

1. Arrival of letter
2. Placed in consultant's pigeon hole SJR, JH and NP
3. Consultant collects letter
4. Consultant completes an appropriate log sheet to include:
    a. Patient's name
    b. Patient's dob
    c. Unique patient number
    d. GDP's name
    e. Practice address
    f. Referred to/seen by
5. JD collects consultant log sheet and enters onto GDP data sheet to include:
    a. GDP's name
    b. GDP's unique number (GP001, GP002, GP003)
    c. Patient's name
    d. Patient's unique number (H01, H02, H03….., R01,R02, R03….., P01, P02, P03……)
    e. Unique code GP001/RR06
    f. Sent starter pack
    g. Accept or decline consent (complete after acceptance)
    h. Randomised envelope number (complete after acceptance)
    i. Date of first letter
    j. Date of second letter (six weeks after first)
    k. First questionnaire returned yes/no
    l. Second questionnaire returned yes/no
6. JD sends starter pack (cover letter, information leaflet, consent form (mark GDP and Pt number)
7. Consent returns JD updates 5g. GDP data sheet.
8. Locate referral letter from general office and staple randomisation envelope to letter. (see JEH for envelopes)
9. JD updates GDP data sheet with 5h. (envelope number)
10. Letter arrives at orthodontic clinic for consultation appointment
11. If envelope is attached to letter this confirms this GDP and patient are part of the trial
12. Consultant examines patient
13. Consultant opens randomisation envelope to reveal a postcard with the order of dictation
14. Consultant staples post card to minimum data set and places GDP trail sticker on front of notes
15. Consultant dictates two letters according to the order on the post card (structured or standard) consultants are provided with a template to aid format with the structured letter
16. Jenny and Trish receive dictation tape
17. Letters are typed up and placed in Consultant's pigeon hole
18. A word count is made electronically and entered onto log sheet
19. Consultant signs letters and places both formats and notes into JD pigeon hole

20. JD sends one letter with questionnaire marked A or B, patient number (HH08, 2nd H denoting seen by) and GDP number (GP001) according to post card sequence
21. Upon letter dispatch GDP log sheet is updated 5i. and 5j.
22. JD releases second letter and questionnaire marked 1 or 2 after 6 week lapse
23. Upon return of questionnaires entered for analysis

11.13 Appendix 13

Financing

- Paper £5 (500 A4 sheets)
- Envelopes £10 (500)
- Stamps £150 (500 @ 30p) (application rejected by university research department)
- Statisticians Consultancy fees Undisclosed

11.14 Appendix 14

Funding

The following funding was secured:

- Clinicians — JEH, NP salaried consultants LUDH; SJR salaried consultant HGH
- Chief Investigator — JEH salaried consultant LUDH
- Principle investigator — JCD Salaried Registrar from LUDH/HGH Trusts until 30/09/2011
- Data analysis — GB Consultant fees from departmental research budget
  JCD, JH salaried
- Supervisor — JEH salaried consultant LUDH
- Postage — Departmental Research fund (application rejected)
- Stationary — Departmental Research fund

11.15 Appendix 15

Sponsorship

UNIVERSITY OF LIVERPOOL

Miss S L Fletcher
Research Governance Officer
Legal Services

2nd Floor, Block C
Waterhouse Buildings
3 Brownlow Street
Liverpool L69 3GL

Telephone: +44 (0) 151 794 8790
Facsimile: +44 (0) 151 794 8728
Email: ethics@liverpool.ac.uk

Legal Services Reference: SP000444
Faculty of Medicine Reference: UoL000531

Friday, 23 October 2009

Dr Jayne Harrison
School of Dental Sciences

Dear Professor Harrison

I am pleased to confirm that the University is prepared to act as Sponsor under the Department of Health's Research Governance Framework for Health and Social Care (2005) for your study entitled "Randomised control trial to assess the effectiveness of structured reply letters when communicating with referring practitioners". This approval for sponsorship is subject to the following.

1. The University expects you, as Chief Investigator, to conduct the study in full compliance with the requirements of the Framework so that it is able to meet its obligations as Sponsor.

2. University professional indemnity and clinical trials insurances will apply to the study as appropriate. This is on the assumption that no part of the study will take place outside of the UK.

3. If you wish to conduct any part of the study in a site outside the UK, or you wish to sub-contract any part of the study to a third party you must contact Contract Services in the first instance to ensure that appropriate contractual arrangements are in place.

4. If you have not already done so, the NRES (National Research Ethics Service) application form for NHS ethical approval of this study should be sent to Contract Services for the Declaration of Sponsor to be signed and completed by the University. You may confirm to NRES that the insurances described in paragraph 2 above will extend to cover for non-negligent harm.

5. As the Chief Investigator, the University expects you to comply, where appropriate, with the University's policy on the use and / or storage of human tissues, details of which may be found at www.liverpool.ac.uk/humantissues.

I trust that this statement will enable you to proceed with your research but if you have any queries please contact me on 0151 794 8290 (email slfllet@liverpool.ac.uk). For general queries relating to University sponsorship please contact the Faculty of Medicine Research Support Office at medresteam@liverpool.ac.uk.

Yours sincerely

Miss Sarah Fletcher
Research Governance Officer

Cc Head of School, Dental Sciences
Mrs Lindsay Carter, Research Coordinator, Faculty of Medicine Support Office

11.16 Appendix 16

Project Milestones

Protocol	September 2009
Ethical approval	February 2010
Subject recruitment	March 2010 – November 2010
Data collection	February 2010 – March 2011
Data analysis	March 2011
Write up	March - August 2011
Submission	September 2011

11.17 Appendix 17

Presentations

UTG PRESENTATION

Harrogate September 25th 2011

RCT to assess structured reply letters: effectiveness, preference and length.

DAVIES. J. C.*[1], BURNSIDE. G.[2], HARRISON. J. E.[1]

Objectives: To identify whether:
1. Structured letters from consultants were more effective at communicating with and/or preferred by practitioners compared to consultants' standard letter.
2. There were differences in the length of the two formats.

Design: Randomised controlled crossover trial.

Setting: Liverpool University Dental Hospital (LUDH).

Participants and Methods*:* Participants were recruited from practitioners referring orthodontic patients to LUDH. 75 practitioners were randomised to receive either the structured or standard letter first, followed by the alternative format six weeks later. For both groups, the word count was recorded by the secretaries. 'Knowledge and Satisfaction' questionnaires were dispatched with the letters, completed by practitioners and returned to the department.

Results: The response rate was 87%.There was no statistically significant difference in practitioners' awareness of their patient's status (p=0.47) or action required (p=0.21). Practitioners showed a strong preference (p>0.001) for the structured format letters which were statistically significantly shorter (mean difference-108.0; 95% CI-118.14,-97.86) than the standard format.

Conclusions: There was no significant difference between practitioners' perceptual and actual awareness of their patient's status or the action required using either of the letter formats. The structured letters had significantly fewer words than the standard letters. Practitioners strongly preferred the structured letter.

WORD COUNT: 198