5.1 Appendix 2: Template Protocol for non-CTIMPs

ONSET

Optimising Consultation Summaries to Promote Good Health; Views of Adolescents Attending Diabetes Clinic

Version 7, 25November2018

MAIN SPONSOR: Imperial College London

STUDY COORDINATION CENTRE: University College London Hospital

IRAS Project ID: 240163
REC reference:

Protocol authorised by:

Name & Role	Date	Signature

Study Management Group

Chief Investigator: Dr David Inwald, Consultant in Paediatric Intensive Care, Honorary Clinical Senior Lecturer, Imperial College London

Co-investigators:

Dr Billy White, Consultant in Adolescent Diabetes and Obesity, University London College Hospital, Hon Senior Lecturer, UCL Institute of Child Health, Specialist in adolescent diabetes and obesity

Ann-Eneli Allas, MSc student, Imperial College London, Paediatrics and Child Health

Clinical Queries

Clinical queries should be directed to Dr David Inwald who will direct the query to the appropriate person

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Joint Research Compliance Office
Imperial College London and Imperial College Healthcare NHS Trust
Room 215, Level 2, Medical School Building
Norfolk Place
London, W2 1PG
Tel: **0207 594 9459/ 0207 594 1862**
http://www3.imperial.ac.uk/clinicalresearchgovernanceoffice

This protocol describes the "Optimising Consultation Summaries to Promote Good Health; Views of Adolescents Attending Diabetes Clinic" study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Table of Contents

GLOSSARY OF ABBREVIATIONS

UCLH	University College London Hospital

STUDY SUMMARY

TITLE	Optimising Consultation Summaries to Promote Good Health; Views of Adolescents Attending Diabetes Clinic
DESIGN	Qualitative study involving interviews with young adults face to face and over the phone
AIMS	What are young people's beliefs about the role of consultation summaries and how they can be improved to promote good health
OBJECTIVES	To understand whether consultation letters are being read by the young people To explore their opinions about consultation letter contents and their impact To explore young people's ideas for optimising these letters
POPULATION	12-18 young people aged 12-18 who have been visiting UCLH adolescent diabetes outpatient clinic chosen using purposive sampling
ELIGIBILITY	Adolescents aged 12-18 years attending a diabetes outpatient clinic
DURATION	**16 Months. April 2018 – August 2019**

1. INTRODUCTION

1.1 BACKGROUND

Patient participation in decision making process about their care promotes patient satisfaction and confidence (Harris and Boaden, 2006). As part of this, allowing patients to see letters written about them enables trust, encourages patients to be involved in decision making process and allow patient understanding (Baxter et al., 2008). Given all above, the 2000 NHS plan made it a requirement that all medical correspondence between health professionals is shared with patients (Department of Health, 2004).

It is estimated that 40-80% of information discussed during a consultation is forgotten immediately (Kessels, 2003). Given this, written summaries have shown to be an effective method of improving patient recall of information by 20.8% (Chan et al., 2002).

The literature on the benefits/disadvantages of consultation summaries is largely focused on adult patients with little research done to explore the views of adolescent population. Where the patient is a child, the literature is only focussed on parents of children and not the children themselves. Limited research has shown that parents/care givers report clinic letters being useful in assisting with better understanding and management of their child's condition (Lawton et al., 2015; Waterston and Lazaro, 1994).

It is not known if young people value consultation summaries in the same way. Only one study focused on adolescent views reports young people wishing to receive summaries about themselves and finding them useful (Bartle et al., 2004).

Adolescence is an important time of an individual's life. This is the time when many independent health behaviours are established. During adolescence, young people start showing more interest in their own health and often wish to participate in decision making processes regarding their care. The role of health workers at this stage is to appreciate young people as individuals (Viner and Macfarlane, 2005). Clinic summaries addressed directly to young people might play an important role in assisting with establishment of health behaviours and promoting good health in young people.

1.2 RATIONALE FOR CURRENT STUDY

The aim of this research is to understand the views of adolescent patients on consultation summaries and identify factors can improve these summaries and subsequently their health and well-being.

2. STUDY OBJECTIVES

1. To understand whether consultation letters are being read by the young people
2. To explore their opinions about consultation letter contents and their impact
3. To explore young people's ideas for optimising these letters

3. STUDY DESIGN

We are using patients attending a specialist diabetes clinic as our cohort and conducting a qualitative study involving individual interviews in clinic or over the phone.
Duration of the study is 16 months, April 2018 – August 2019.

Study population is 12-18 young people aged 12-18 who have been visiting UCLH adolescent diabetes outpatient clinic chosen using purposive sampling.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

We will recruit patients from a single diabetes clinic serving patients from a very wide geographic area with wide socio-economic backgrounds. We will recruit and interview **between August 2018 – April 2019.**

4.2 INCLUSION CRITERIA

Adolescents aged 12-18 years attending a diabetes outpatient clinic

4.3 EXCLUSION CRITERIA

Young people who cannot speak English (effective communication with colleagues during the study is the major aspect for valid data collection)

Young people who refuse to participate in individual interviews

4.4 WITHDRAWAL CRITERIA

Participant's wish to voluntarily withdraw from the study

5. ADVERSE EVENTS

5.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.3 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded.

5.3.2 Serious AEs
An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, relapse and death due to <condition>, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the <name of REC> where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
jrco@imperial.ac.uk
CI email d.inwald@imperial.ac.uk
Attention Dr David Inwald
Please send SAE forms to: REC
Tel: xxx (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

We will identify potential participants by accessing UCLH adolescent diabetes clinic clinic schedule. All patients attending an adolescent diabetes outpatient clinic on a particular day will be invited to participate in the study. Every potential participant will receive an invitation pack with the age appropriate information sheet enclosed by post 1 month before the appointment. Individuals will be invited to express interest via email or by phone, details of both will be provided on the participant information sheet.

The research team will telephone each potential participant 2 weeks before scheduled appointment with their doctor to remind them of their pending appointment, ensure that they have received the invitation pack and answer any questions about the study.

The patient's standard clinician will be able to answer any patient concerns about the study during their standard clinic appointment. We will run interviews on the day of the participant's scheduled appointment at the clinic (approximately 30-60 minutes after standard clinic appointment).

If a potential participant is unable to participate in the interview on the day of the appointment but would like to express his/her views and opinions on the matter, we will offer this participant an interview over the phone at a convenient time. Informed consent to participate in the interview over the phone will be taken in clinic by our researcher.

Prior to the beginning of the phone interview, we will inform the participant that the interview will be audio-recorded and they will be put on loud speaker. We will also let the participant know who is present in the room whilst he/she is being interviewed. We will ask the participant to remain in a quiet room with no relatives/friends present while being interviewed.

Participants will only be interviewed once. We will interview 12-18 participants in total or until theme saturation occurs (Peterson-Sweeney, 2005). Interviews will be held on the day of a participant's clinic appointment within the same hospital to optimise study participation rate and reduce associated travel expenses and time burden.

Interviews will be conducted by a researcher experienced in qualitative studies. The discussion will be held in a quiet room with refreshments provided. Phone interviews will also be conducted in a quiet room with one researcher in the room communicating with a participant. The discussion will take no longer than 30 minutes. Parents will be asked to remain in the waiting area during the study as per NCB Guidelines (NCB Guidelines for Research with Children and Young Adults, 2011).

The researcher will voice a series of prepared statements/questions to promote interview (appendix 1). Written assent/consent will be obtained from study participants and their parents (if present) at the beginning of the discussion or in clinic if phone interview is preferred. The discussion will be audio-recorded.

Audio-recordings from each discussion will be transcribed by Ms Ann-Eneli Allas. The transcripts will be immediately anonymised. Data analysis will involve a general thematic coding method and will be analysed by two independent researchers (Flick 2009).

7. DATA ANALYSIS

We will use constant comparative method for the coding process (Krueger and Casey, 2015). The coding process will consist of reading the transcript and analysing responses to statements given by the study participants one by one. We will examine responses to each statement and code each response according to what it describes. If there are several responses to the same statement given, these will be analysed for similarity. If similar, the same code will be given to each, if different, different codes will be given. This coding approach will be maintained for all responses.

In order to avoid analysis errors, transcripts will be coded by two researchers (Ann-Eneli Allas and Dr Billy White) independently and differences agreed. Once the coding process is complete, we will categorize codes and analyse them for frequency, extensiveness, intensity, specificity, internal consistency and participant perception of importance (Krueger and Casey, 2015).

We will share the study outcomes with all participants and their families. We will submit the findings in a peer-reviewed medical journal.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1 ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the North West Haydock Research Ethics Committee (REC) and Health Regulator Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in

accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases, the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

We will follow NRES guidance on informed consent:

- Young people 16-18: informed consent will be obtained directly from the study participant.
- Young people aged 12-15
    - If parent/carer present, then consent will be obtained from the parent/carer. Assent will be obtained from the study participant.
    - If no parent/carer present, then individual will be assessed for Gillick competence, and if competent, consent will be obtained from the young person.

We will notify participants' General Practitioners of patient recruitment.

8.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

8.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5 SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6 FUNDING

Funding is not available for this study

8.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through UCLH.

10. PUBLICATION POLICY

The study registration and publication will be supported by The Imperial Open Access Fund and will be available in fully open access journals only.

11. REFERENCES

Bartle, D. (2004). Copies of clinic letters to the family. Archives of Disease in Childhood, 89(11), pp.1032-1033.

Baxter, S., Farrell, K., Brown, C., Clarke, J. and Davies, H. (2008). Where have all the copy letters gone? A review of current practice in professional–patient correspondence. Patient Education and Counseling, 71(2), pp.259-264.

Chan, Y., Irish, J., Wood, S., Rotstein, L., Brown, D., Gullane, P. and Lockwood, G. (2002). Patient Education and Informed Consent in Head and Neck Surgery. Archives of Otolaryngology–Head & Neck Surgery, 128(11), p.1269.

Copying Letters to Patients Good Practice Guidelines (2004) Department of Health

Flick, U. (2009). INTRODUCTION TO QUALITATIVE RESEARCH. 7th ed. [S.l.]: Sage Publications.

Harris, C. and Boaden, R. (2006). Copying letters to patients: the view of patients and health professionals. *Journal of Health Services Research & Policy*, 11(3), pp.133-140.

Kessels, R. (2003). Patients' memory for medical information. JRSM, 96(5), pp.219-222.

Krueger, R. and Casey, M. (2015). Focus groups. Los Angeles [u.a.]: Sage Publ., pp.137-161.

Lawton, J., Waugh, N., Noyes, K., Barnard, K., Harden, J., Bath, L., Stephen, J. and Rankin, D. (2015). Improving communication and recall of information in paediatric diabetes consultations: a qualitative study of parents' experiences and views. BMC Pediatrics, 15(1).

Medical Research Council (2017). Consent and Participant Information Sheet Preparation Guidance.

NCB (2011). Guidelines for Research with Children and Young Adults. London.

Peterson-Sweeney, K. (2005). The use of focus groups in pediatric and adolescent research. Journal of Pediatric Health Care, 19(2), pp.104-110.

The NHS Plan, paragraph 10.3 (2000) Department of Health

Viner, R. and Macfarlane, A. (2005). ABC of adolescence: Health promotion. BMJ, 330, pp.527-9.

Waterston, T. and San Lazaro, C. (1994). Sending parents outpatient letters about their children: parents' and general practitioners' views. Quality and Safety in Health Care, 3(3), pp.142-146.

EXAMPLE APPENDICES

Appendix 1 – Focus group discussion schedule

Tell us a bit about the letters you get

1. **Is the letter directed to you, your parent/carer, GP or another doctor?**
2. **Who reads the letter, you or your parent/carer?**
3. **Do you show consultation letters to?**

Letter content

4. **Is the language easy to understand (eg medical terms) What could be better?**
5. **Does the letter sound friendly or professional to you? How could it be better?**
6. **Is it too long/short? How could it be better?**
7. **Does it talk about the right things? How could it be better?**

Do these letters help you to improve your health?

8. **Are they helpful in any way? (motivate, remind, congratulate, give ideas)**
9. **Are they unhelpful in any way? (remind of negatives, demoralise, feel sad/worried/angry)**
10. **What else about your letters could help? Other ideas?**

Potential areas of improvement

1. **Is there anything that can be improved?**
2. **Is getting them by post ok? (email/text/postcards better?)**