Using existing databases to identify and contact participants:

Lessons from the ASCEND Study

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Disclosures

- Research grants from:
  - British Heart Foundation
  - Merck
  - Bayer
  - Abbott

ASCEND: The Research Question

ASCEND: A Study of Cardiovascular Events iN Diabetes

- For people with diabetes who have not yet had a heart attack or stroke:
  - Is low-dose aspirin beneficial?
  - Are omega-3 fish oils beneficial?
  - Are these treatments safe?

The Study Design:
2x2 factorial design randomised trial of aspirin vs placebo and omega-3 FA vs placebo

	Aspirin tablets	Placebo tablets	
Omega-3 Fatty acids (FA) capsules	3750 Aspirin + Omega-3 FA	3750 Omega-3 FA	7500 Omega-3 FA
Placebo capsules	3750 Aspirin	3750 Neither	7500 Placebo
	7500 Aspirin	7500 Placebo	

The Problem

The Solution

- Streamlined
- Cost effective
- Simple eligibility criteria
- Mail-based trial design

No study clinics required


ROYAL MAIL
Mr Diabetic Patient
1 Aspirin Avenue
FISHTOWN
Oxfordshire
ASW 1ND
ROYAL MAIL

The Funding

- British Heart Foundation special project grant £2.7 million
- Bayer/Abbott: study drug and funding for packaging

The Next Problem

- Identification of potentially eligible study participants
  - Central databases
    - Hospital-based registers
    - Regional registers (eg retinopathy screening)
  - Other approaches
    - Invited direct from GP
    - Self-nominate/friends & family

UK Trial: The Advantage

- Section 251 of the NHS Act 2006 allows the common law duty of confidentiality to be set aside in specific circumstances where anonymised information is not sufficient and where patient consent is not practicable.

- Ethics and Confidentiality Committee of the National Information Governance Board (NIGB) review and approve applications to use Section 251 support

http://www.nigb.nhs.uk

Central recruitment: contact details provided from central registers

Name and address

Date of birth and sex

NHS number (if available)

GP name and address

Patient data processed securely in the CTSU on behalf of lead clinician

Central recruitment: registers obtained

- 64 registers ~630,000 patients
- GP permission stage ~350,000 patients available for invitation
- Vital status check ~300,000 patients available for invitation

Central recruitment: invitations sent to potentially eligible patients

- Patients mailed
  - Invitation letter (from lead clinician)
  - Information leaflet
  - Screening questionnaire
  - Consent form
- 24 hour telephone service to deal with any questions about the study

Need help completing this form? Please call Freefone 0800 585323

Please read this **Agreement t**
SIGN and DATE the form usin

Please cross (☒) **EVERY bo**

☐	I have read and understood the leaflet **"ASCEND: Invitation to join a large medical research project"** ASCEND: Patient Information Leaflet [V8.2_121106]
☐	I have had an opportunity to telephone the Freefone number 0800 585323 and ask any relevant questions. All my questions have been answered to my satisfaction **OR** I decided that I did not need to ask any questions
☐	I understand that my participation in the ASCEND study is voluntary and that I am free to withdraw from the study at any time without my medical care or rights being affected
☐	I understand that information about my progress in the ASCEND study will be recorded on a computer database, and that these data will be stored securely and confidentially on a computer at Oxford University
☐	I agree that information about any serious illnesses (such as heart attacks, strokes or cancers) may be supplied in confidence to the study coordinators by my own doctors and by NHS and other central registries for use in the ASCEND study
☐	I agree that my hospital and other health records may be looked at in confidence by authorised individuals from the ASCEND study and by regulatory authorities to check the study is being carried out correctly
☐	I understand that my GP will be informed about this provisional agreement to participate in the ASCEND study, and that in about 2 months time I will have another opportunity to decide whether or not I want to join the long-term part of the study

I am happy to take part in ASCEND: ASCEND Screening Questionnaire [V3.4_240407]

Signature: (Please use blue or black ink)

& **PRINTED** name: Today's date: Day / Month / 20 Year

Please check that you have answered every question, and signed and dated the form.
Return the completed form in the F

Freepost RLUJ-TKES-SURB, ASCE
Old Road Campus, Headington, Ox

If you have any questions about the st
FREEFONE: 0800 585323 (preferably

If this questionnaire indicates that yo
a box containing ASCEND tablets (as
will be mailed to you. A copy of this
mailed.

If the questionnaire suggests that the
shall write and tell you.

Thank you very much

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The Pennine Acute Hospitals NHS

NHS Trust

Old Road Campus
Headington, Oxford
OX3 7LF

Mr Thomas White
24 Raspberry Road
Gardentown
Gardenshire
GA3 5TR

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Office Fax: 01865 743961
Freefone: 0800 585323
E-mail: ascend@ctsu.ox.ac.uk
Website: www.ctsu.ox.ac.uk/ascend

Dear Mr White,

26 January 2010

ASCEND: A Study of Cardiovascular Events iN Diabetes

We are writing to invite you to participate in the ASCEND research study of the prevention of heart attacks and strokes in people with diabetes. At **the Diabetes Centre at The Royal Oldham Hospital, we are working with Oxford University's Clinical Trial Service Unit to help identify suitable people for this nationwide study.** So, we are writing (having first informed your GP, Dr Rose Gardener) to all those people on our local diabetes register who are aged over 40 and may be suitable, in order to find out whether they might be interested in taking part. The purpose of the study is to assess whether aspirin and/or naturally-occurring oils are useful for preventing heart attacks and strokes in people with diabetes who have not had circulatory problems.

Please read the enclosed Information Leaflet entitled "ASCEND: Invitation to join a large medical research project". It is then up to you whether or not you would like to take part. If you would like to, then please complete the attached questionnaire. Based on your answers, the study coordinators will write and tell you whether or not you would be suitable.

If you have any questions regarding the study you may telephone the study co-ordinators (Professor Jane Armitage or Dr Louise Bowman) on Freefone 0800 585323. Alternatively, you may wish to discuss matters with your GP or diabetes nurse before deciding whether to join. If you do not want to take part this will have no effect on your usual medical care. If you want to join the study then please complete the questionnaire and sign the Agreement to Participate. We hope you will decide to take part in ASCEND. If you do not want to participate then please indicate this on the questionnaire on the back of this letter so that you do not get approached again. In either case, please return the questionnaire in the Freepost envelope provided.

Dr Deepak Bhatnagar
Consultant/Senior Lecturer in Diabetes & Metabolism
Royal Oldham Hospital

Dr Biswa Mishra
Consultant Diabetologist and Endocrinologist
Royal Oldham Hospital

Enc: Information Leaflet
Freepost envelope

DRS [V1.13_061109] Pt ID: A777-7771

ASCEND Screening Questionnaire [V3.4_240407]

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British Heart Foundation

ASCEND: Screening Questionnaire

INSTRUCTIONS FOR COMPLETION:

Please complete the questionnaire in BLOCK CAPITALS using blue or black ink.

Please place a cross in the appropriate box, e.g. Yes [X] No [ ]

(If you make a mistake, fill the entire box and mark the correct box, e.g. Yes [■] No [X])

OR write clearly in the appropriate boxes, e.g. Day 26 / Month 01 / Year 2007

1. Contact Details

Please write your name and contact details clearly in the boxes provided.

Title: Mr [ ] Mrs [ ] Ms [ ] Miss [ ] Other [ ]

First name(s):

Surname:

Address:

Postcode:

Home telephone number (inc. code):

Daytime telephone number (inc. code):

2. Personal Details

Date of birth: Day / Month / Year 19

Sex: Male [ ] Female [ ]

3. Joining ASCEND

Please read the enclosed leaflet **(ASCEND: Invitation to join a large medical research project)**, and indicate whether you are interested in taking part in ASCEND: Yes [ ] No [ ]

If you answered **YES**, then please complete **ALL** the remaining sections of this questionnaire, sign and date the form, and return it in the FREEPOST envelope provided.

If you answered **NO**, then return the questionnaire in the FREEPOST envelope provided (but do not complete the remaining sections).

4. GP Details

Please give your GP's surname and initials, as well as the address of the GP practice.

GP surname: GP initials:

Address:

Postcode:

Need help completing this form? Please call Freefone 0800 585323

5. Medical History

5.1 Has a doctor ever told you that you had any of the following?

*Please cross **ONE** box only for each question*

a)	Diabetes, Type 1 or Type 2 (i.e. "sugar" diabetes)	Yes [ ]	No [ ]
b)	Heart attack	Yes [ ]	No [ ]
c)	Angina (chest pain from the heart)	Yes [ ]	No [ ]
d)	Stroke or ministroke (sometimes called TIA)	Yes [ ]	No [ ]
e)	Coronary artery bypass operation (CABG or "cabbage")	Yes [ ]	No [ ]
f)	Coronary angioplasty ("balloon", "stent" insertion or PTCA)	Yes [ ]	No [ ]
g)	Other arterial surgery or angioplasty (e.g. leg bypass) (Do not include angiogram)	Yes [ ]	No [ ]
	If **Yes**, please specify:		
h)	Liver disease (active or chronic, or cirrhosis)	Yes [ ]	No [ ]
	If **Yes**, please specify:		
i)	Cancer **within the last 5 years** (e.g. skin, breast, lung, bowel etc)	Yes [ ]	No [ ]
	If **Yes**, please give the type of cancer:		
j)	Other serious illness	Yes [ ]	No [ ]
	If **Yes**, please specify:		

S-240407

5.2 In the last 6 months have you been in hospital with, or has a doctor said you have:

a)	Active peptic (stomach or duodenal) ulcer?	Yes [ ]	No [ ]
b)	Bleeding from the stomach or bowel?	Yes [ ]	No [ ]

6. Current Medication

As a participant in ASCEND, you would be asked not to use NON-STUDY aspirin, medications containing aspirin or blood thinning drugs on a regular basis (i.e. more than one day per week) unless this becomes necessary.

6.1 Do you currently take any of the following regularly?

*Please cross **ONE** box only for each question*

a)	Aspirin (e.g. Anadin, Caprin, Disprin, Imazin, PostMI)	Yes [ ]	No [ ]
b)	Warfarin (Marevan), Acenocoumarol (Nicoumalone, Sinthrome) or Phenindione	Yes [ ]	No [ ]

6.2 Are you known to be allergic to aspirin or omega-3 fatty acid (fish oil) supplements? Yes [ ] No [ ]

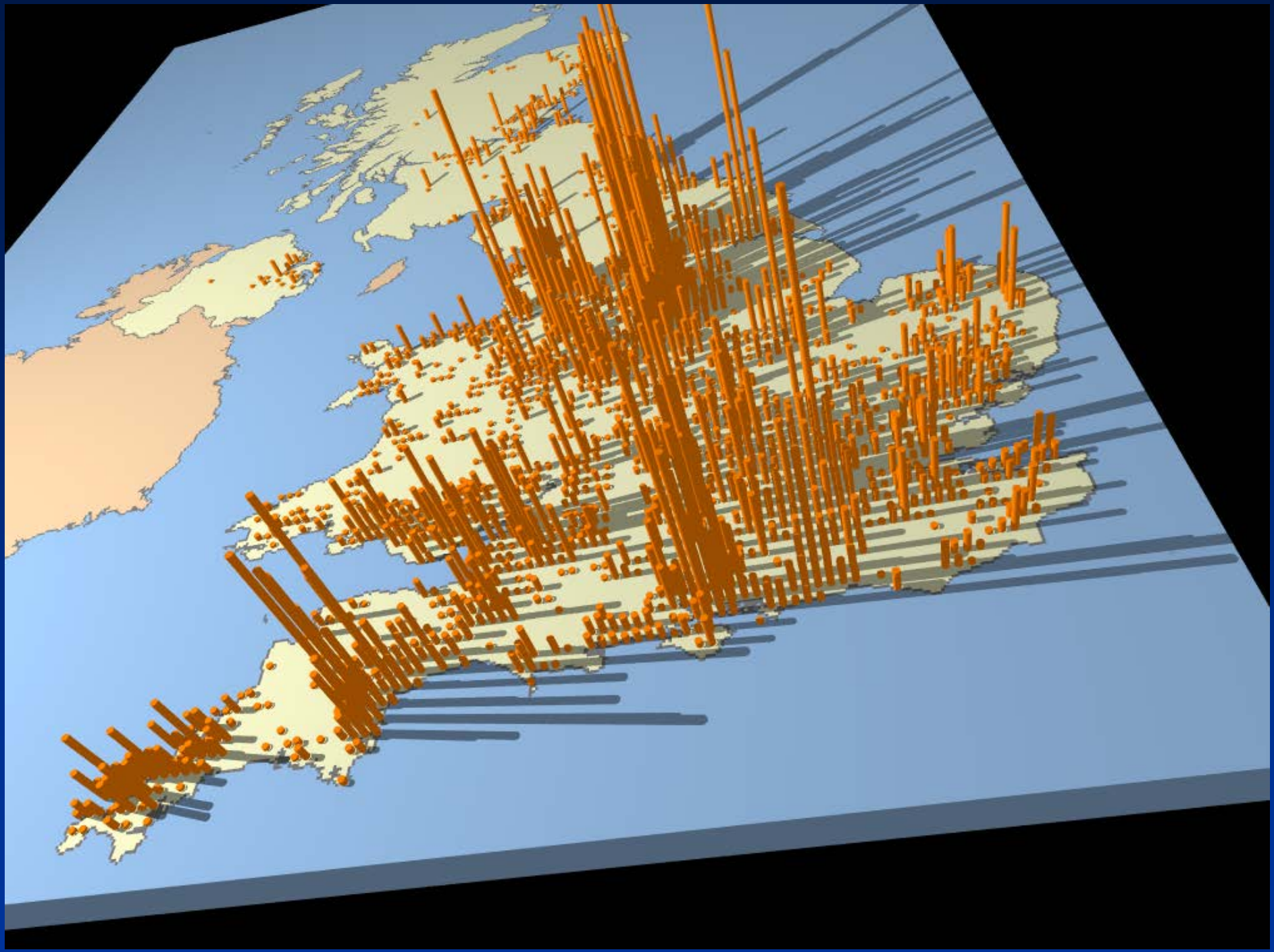
6.3 Are you willing to avoid medications containing aspirin (apart from ASCEND study treatment) during the course of the study? Yes [ ] No [ ]

(N.B. you could use paracetamol instead for pain relief)

ASCEND: recruitment completed July 2011

	Centrally-held Register	GP practices	Others *	Total
Invitations sent	300,188	120,875	2223	423,286
Patients enter Run-in	16,104	9,741	635	26,480
Patients randomised	9013 (3.0%)	6037 (5.0%)	430 (19%)	15,480 (3.7%)

* HPS follow up/Self/friends/Hospital referral



The Potential Obstacles

- Patients: 28 requests to anonymise data
- Hospital trusts
- Primary Care Trusts
- GPs
  - Welsh Retinopathy Screening Database

Summary of experience in ASCEND

- Successful recruitment of 9000 trial participants using centrally-held databases
- Few serious concerns were raised (and discussion often leads to patient joining study)
- Other methods of recruitment are slower, less cost-effective, and more difficult to control
- Follow-up is on-going, results anticipated 2017

British Heart Foundation

ASCEND

A Study of Cardiovascular Events iN Diabetes