

## Looking after yourself when you have diabetes – A research project

### Guidance for Practices

#### Background

People with learning disabilities have higher than average levels of diabetes. Many of the self-management materials for type 2 diabetes have not been tested to see if people with learning disabilities can use them. We want to identify this group of patients and interview them about their diabetes management.

OK-Diabetes is a research project funded by the NIHR HTA Programme. We have ethical approval (12/YH/0304) and R&D approval from the CCGs.

#### Inclusion Criteria

- adults 18+ years,
- type 2 diabetes, not using insulin
- with mild to moderate learning disability\*

#### Exclusion Criteria

- Learning disability acquired from disease in adult life, e.g. learning difficulty due to adult-onset dementia or stroke
- Secondary diabetes (such as steroids, pancreatitis, endocrine disorders etc) and rare causes of diabetes (such as MODY: maturity onset diabetes of the young).

### Identification Process

#### First (and the most important):

Perform the searches detailed in the attached document “Read Code search for practices”. There are SystmOne and EMIS versions attached.



### Second:

- i. Bring this project information to the person who does the diabetic clinics – can they think of anyone not found by search 1?
- ii. Record the No. of patients identified in the log
- iii. Exclude those who do not have type 2 diabetes
- iv. Exclude anyone on Insulin or with other exclusion criteria (see above)
- v. Refer those left into the study

### Third:

- i. Bring this project information to a practice team meeting/MDT – can they think of anyone not found by search 1?
- ii. Record the No. of patients identified in the log
- iii. Exclude those who do not have type 2 diabetes
- iv. Exclude anyone on Insulin or with other exclusion criteria (see above)
- v. Refer those left into the study

### Fourth:

- i. Ask reception staff if they know anyone who always comes with a supporter or has a taxi called for them who they suspect do these things because they have learning disabilities.
- ii. Record these numbers in the log
- iii. Exclude those who do not have type 2 diabetes
- iv. Exclude anyone on Insulin or with other exclusion criteria (see above)
- v. Refer those left into the study

**In addition:** Keep us in mind! Please place some referral forms in with the information kept in the diabetes clinic rooms to jog the memory of the staff who regularly see patients about their diabetes. Please also explain this study at team meetings and practice nurse meetings.

[If you have any problems running these searches please contact Amy Russell

██████████ ██████████ Mob: ██████████. She can come out to your practice and help you search.

### Referrals Forms

Please complete one referral for per patient.

- Try to speak to the person or their supporter either in person or on the phone.
- If you cannot contact them after 3 attempts send the letter provided in your pack.
- Complete the referral form in all circumstances including:
  - Unable to contact to sent letter
  - Contacted and patient refused further information about the study
- If you see the patient in person complete the form including the agreement to contact. Then **tear off the back page** and give it to the patient.
- When you have filled out the referral form please use the freepost envelope provided to post it back to Amy.



- Amy will post an information booklet to the participant (if you have given them one she will still do this – that way we ensure they have a copy at home).
- One week later she will contact them to answer questions and to ask if they are OK to meet her.
- When they meet she will assess mental capacity, take formal consent and conduct the interview (if appropriate).
- After the interview you will receive a Medical Records Form. Please complete this and post it in a freepost envelope back to Amy.

### Site Files

When you refer someone into our study by contacting them and then returning the referral form to us you become a research site.

At this point we will send you a site file that contains all of the documents about the research.

You do not need to do anything, just keep this file for your records. If you want to receive training on what site files are and what should be in them please do contact Amy and she will organize this.

### What Next?

When we have contacted a person and interviewed them we will gain their consent to access their medical records, through their healthcare team, to allow us to record some measurements.

Once we have their consent we will send a letter with instructions, a form and a pre-paid envelope to the nominated person at your practice.

This form requests readings from their medical records including HbA1c, BMI and BP. If any number is not available this is okay, there is a space to record this. The form is then posted in the pre-paid envelope back to University of Leeds.

### FAQs

Q. What do I do if I don't know if the person is mild/moderate/or severe learning disabilities?

A. This is not a problem. The research team can make this decision. Refer the person in as normal, feel free to record your concerns on the referral form.

Q. Some people with undiagnosed LD will be unhappy being approach by this study, what do I do?

A. We understand that learning disability is not a label some people will want attributed to them. None of our materials mention learning disabilities. We do not conceal it but it will be up to the research team to broach this topic with the person. If they do not see themselves in that way they do not have to take part.

Q. How do I know if the person I am referring has mental capacity to consent?

A. The research team are trained in making mental capacity decisions. Refer the person into the



### Summary of Procedure:

1. Search for eligible patients
2. Log results
3. Speak to patients
4. Complete referral forms
5. Post referral forms back to Amy

**If you have any further questions or want any clarification please contact Amy M. Russell.**

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