

Diabetes Study

Summary guide for reporters.

When does the study start and how long will it last?

The study will start on 1st October 2021 and continue for 12 calendar months, until 30th September 2022. You should start identifying your cases from 1st October and you will receive your first monthly report request email (for your figures for October) on 1st November.

What figures do I need to report every month?

- The number of '**cases**' in the midwifery unit in the previous month.
- The number of women who **were admitted for labour care in the midwifery unit** in the previous month
- The number of women who **gave birth in the midwifery unit** in the previous month

What is a 'case' for this study?

Any woman with a diagnosis of diabetes during pregnancy (gestational or pre-existing) and admitted for labour care to a midwifery unit.

Does a 'case' have to give birth in the midwifery unit? What if they transfer to delivery suite during labour?

Cases **do not** have to give birth in the midwifery unit, as long as they are admitted for labour care in the midwifery unit with a diagnosis of diabetes (gestational or pre-existing).

What happens once I identify a case?

Each month you identify all the cases for your unit. Make a note of the identifying details for each woman in the Case Log of your white UKMidSS folder. You are asked to report the number of cases you have identified monthly. The confirmation email from UKMidSS will provide you with a unique Case ID, beginning **DP_** for each case you report. You should record each Case ID in the Case Log against the identifying details for each woman. We then ask you to send us detailed data about the **case** and **one control**, or comparison woman, **for each case**.

How do I select the 'control'?

It is very important that everyone selects the control in the correct way. For each case, the control is the woman who **was admitted to the midwifery unit immediately before the case** and did not fit the case criteria. Record identifying details for each control at the same time as your case in the Case Log in your white UKMidSS folder, matched to the correct Case ID.

How do I send you data on our cases and controls?

When you report a case, data collection forms for each case and control are created automatically in OpenClinica, our data entry system. When you send us a monthly report you will receive a link to access OpenClinica in your confirmation email.

To do the data entry you will need a username and password for OpenClinica. **If you do not have these, please contact us.**

Note: Case IDs and data collection forms are created automatically in OpenClinica when you report a case. You **do not ever** need to click on the Add New Subject link in OpenClinica.

Once you have access to the woman's electronic or paper notes you can enter the data in the forms in OpenClinica. There are sample forms on our website – these are for information only and should **not** be used to send us data. There is a detailed guide to entering data using OpenClinica in your white UKMidSS folder and on our website <https://www.npeu.ox.ac.uk/ukmidss/reporters>.

For the case and control forms, Section 1 contains questions intended to check (a) whether the woman fits the case definition and (b) whether the control has been correctly selected. **When entering data in any form, please always complete Section 1 first.**

What happens if I report a case in error or discover when I'm entering data that the woman does not meet the case definition?

Please contact us. We will remove the Case ID from our systems and from OpenClinica. Please do **not** attempt to change the status of, or 'stop', a case in OpenClinica yourself.

I've used OpenClinica to enter data on cases and controls for previous UKMidSS studies. Is anything in OpenClinica different for this study?

For this study, we are going to use a new version of OpenClinica. You will receive new log-in details. The data entry process is very similar to the previous version of OpenClinica and there is a webinar available on our [website](#) explaining the data entry step-by-step.

**If you have any problems or questions at all at any point,
please get in touch**

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