



# **United Kingdom Cystic Fibrosis Database**

## **Version 2 User Guide**

# **CONTENTS**

## **Overview of Version 2 of the UKCF Database**

### **HOW TO USE VERSION 2**

- 1: Initial one-off tasks for upgrade to version 2**
- 2: Routine tasks for regular data transfer to Dundee**

### **LIST OF CHANGES IN VERSION 2**

- 3: Improving data input quality**
- 4: New reports**
- 5: Transferred patients**
- 6: Recording deaths or reverse diagnoses**
- 7: Correcting a wrongly registered patient**
- 8: Printing or deleting information**
- 9: Data Protection Act requirements**

## **Appendix: Confirmation of successful upgrade**

## **Overview of Version 2 of the UKCF Database**

The UKCF Database has been improved and version 2 is now being released to all participating clinics. This has been done for two reasons:

- **Over 60 clinics** are now participating in the project, and version 2 incorporates a number of suggestions and requests both at data entry level and in the form of more information reported back from the database.
- The new Data Protection Act has imposed upon us a greater requirement for both data accuracy and data security. In addition, patients may request copies of any information stored for them, and it is much simpler to do this in version 2.

### **This document is divided into two parts:**

The first part describes how to use the new version 2.

- It summarises the one-off tasks required to install version 2 on your machine.
- Once this has been done, it lists what should be done every time before zip data is transferred to Dundee.

The second part lists the key changes from the original database with brief descriptions of each one. These include

- changes to data entry
- new reports available
- a facility to “Amend Status” for a patient to record transfers, deaths and reverse diagnoses
- removing incorrect Snapshot or Annual review information from the database
- removing all of a selected patient’s details if the patient withholds consent
- encrypting data on the zip disk before posting to Dundee.

## **1: Initial one-off tasks for upgrade to version2**

In order to upgrade your database to version2, you will need to

1. Run the V2Implementer provided on your zip disk
2. Perform the checks listed below to ensure the accuracy and completeness of your data
3. Inform the National team in Dundee when your upgrade is completed.

### **□ Run the V2Implementer**

#### **❖ First do a Backup (not transfer) of your database on a zip, label & date it, & store securely away and close the database (Quit)**

- Click 'Start-Programs-Windows Explorer' and double click on 'Removable Disk [D:]' on the left.
- On the right hand side, double click 'V2Implementer' or 'V2Implementer.mde'
- Say 'OK' when the program tells you it is about to upgrade your copy of the Database to version2
- The program then asks 'Where is your current UKCF Database?' If you are running your database on a CF Trust computer, at this stage, simply click 'Open'. (If you are running the database on your own computer, please locate the database for the program using the Windows dialog box).
- The upgrade will now begin and should take one or two minutes. When it has finished, the program will let you know. Click 'OK'. Close Windows Explorer.
- Go into your database as you would normally and check that it is working satisfactorily. (A quick check for version2 is that if you select the Biography Browse/amend option on the Main Menu and select a patient to browse, it will be blue!).

### **□ Checks for data accuracy and completeness**

1. On the Main Menu, click the Reports button, and then scroll down and select Checks 9 – AR vs Biography genotypes. Click View. When it asks for Year of Review, enter an asterisk (press shift and 8 together). The report lists all Annual Reviews where the genotype recorded on the Biography is not the same as that recorded on the Annual Review.
  - Please determine whether the Annual Review or the Biography is correct
  - If the Biography is wrong, amend it using the Biography – Amend option
  - If the Annual Review is wrong, leave it be for now as version2 ignores genotypes entered on the Annual Reviews, but print a list of all such records and send to Dundee. At a mutually convenient time, the Annual Reviews genotypes can be cleared out.
2. On the Main Menu, click the Reports button, and select Checks 10, 11 and 12 in turn to show if there are any duplicate Clinic Visits, Annual Reviews or Biographies respectively. If there are any:
  - Find the paper form corresponding to the duplicate record
  - Select each duplicate record in turn (using the Browse/Amend screen) and press Delete.
  - Check the remaining record against the paper form to confirm that the details on the computer are correct, and Amend it if it is not

3. On the Main Menu, click 'One-off Fixes' and select 'Delete AMENDED records' and say OK.
  4. On the Main Menu, click 'One-off Fixes', select 'Fix Clinic Visit Antibiotic Nulls' and say OK.
  5. On the Main Menu, click the Reports button, and then scroll down and select 'General – Deceased Patients'. If this is not a complete list, please use the 'Amend Status' button on the Main Menu.
- **Please inform the National team when the upgrade is completed** by completing the 'Successful Upgrade' form attached in the appendix to this document.

## **2: Routine tasks for data transfer to Dundee**

Every time you do a zip data transfer to Dundee, please ensure the following are done:

4. Update your database for any patients transferred, deceased or 'reverse diagnosed'
  5. Delete incorrect records for any patients whose details have been marked as 'Amended'
  6. Perform data validity and completeness checks
  7. Encrypt your database prior to sending it in the post
  8. Include annotated / corrected error log from previous verification
  9. Include copies of new paper forms for verification
- 
- ❑ **Update your database for any patients transferred, deceased or 'reverse diagnosed'**
    - On the Main Menu, select the Amend Status button and select status change as required.
    - For detailed instructions, please refer to section 5 or section 6 as appropriate.
  
  - ❑ **Delete incorrect records for patients marked as 'Amended'**
    - On the Main Menu, click 'One-off Fixes' and select 'Delete AMENDED records' and say OK. This will get rid of all incorrect records that have been amended.
    - For detailed instructions on how to use this option, please refer to section 7.
  
  - ❑ **Perform data validity and completeness checks**
    - On the Main Menu, click the Reports button, and select Checks 1 to 8 in turn. When it asks for Year, enter an asterisk (press shift and 8 together) for all years or specify the year. Please check the values for Centiles, Standard deviations or percent predicted lung functions as appropriate.
    - If you are happy with a value that is never-the-less displayed on the report as a value outside the 'normal' range, please let the National team know this when you send in your zip for verification.
    - For further details on the reports, please refer to section 4 .
  
  - ❑ **Encrypt your database**
    - When you request a transfer for posting to Dundee, the program will ask for a password. Please make a note of this (it is case sensitive). Phone the National team or forward the password separately by letter or email as the database cannot be opened without it.
    - For detailed instructions on how to use this option, please refer to section 8
  
  - ❑ **Include annotated / corrected error log from previous verification**
  
  - ❑ **Include copies of new paper forms for verification**

### **3: Improving the quality of data entered into the database**

The following changes have been made to Clinic Visits, Annual Review and Biography data entry

#### **□ Changes to Clinic Visits**

- Height and weight checks
  - At the time of data entry, the program warns if the centile values are outside the range 3- 97%
  - The program checks that height is always greater than weight
  - The program warns if height is less than that recorded at the previous visit, or over 10cm greater than that at the previous visit
  - For patients over 18 years of age, there is a new 'No Change' button which enters the same height into the database as that at the last visit
- FEV1 and FVC checks
  - The program checks that FVC is always greater than or equal to FEV1
  - The program checks the values entered if  $FVC - FEV1 < 0.09$ , or  $FVC - FEV1 > 3$
  - The program warns if percent predicted lung function is outside the range 5% to 135%
- The date of the last clinic visit (and all the data on the form) relates to the date information was last entered into the system. For clinics only doing one Snapshot per year, this will be 12 months.
- Short-term antibiotics should be the 3 most common if the patient has been on more than 3 drugs
- The program no longer allows you to enter a 'new' clinic visit if it has already been entered.
- Browse screens are now blue, Amend screens are green. (New Clinic Visit entry remains white)
- There is the option to select a visit and print it, or indeed delete it (via Browse/Amend screen)
- Enzymes have now to be selected from a drop-down list. Only if the enzyme you require is not on a drop down list should you type it in. The list includes Creon 40000.
- You no longer need to enter millions of dashes for 'Hospital admissions'. The program does it now

#### **□ Changes to Annual Reviews**

- Date of Annual Review on the Select Annual Review screen is now the actual date of the visit (rather than the date the visit was entered into the computer as before)
- Genotypes can no longer be entered on the Annual Review. If the genotype written on the form is different to what is displayed on the screen, please change it using the Biography/Amend option
- Complications in last period should include **all** complications the patient has had in the last period (whether or not he has had them in the period before that as well)

- Transplant status now allows a patient to have had any combination of boxes ticked on the form
  - Glucose Tolerance now has an extra box for 'patient known to be diabetic'. This marks the patient as diabetic on the database.
  - The program no longer allows you to enter a 'new' visit if it has already been entered.
  - Browse screens are now blue, Amend screens are green. (New review entry forms remain white)
  - There is the option to select a visit and print it, or indeed delete it (from the Browse/Amend screen)
- **Changes to Biographies**
- Where cause of diagnosis is by screening, the program requires this box to be checked if it is by genetic/neonatal screening. In this case, the age at diagnosis must be less than 3 months. If age at diagnosis is greater than 3 months, please enter the data under 'Other'.
  - Browse screens are now blue, Amend screens are green. (New Biography entry remains white)
  - To print a Registration/Biography form, use Biog button on Main Menu
  - To delete a Registration and Biography, use the Delete Selected Patient(s) button in One-off Fixes

#### **4: New reports**

The Reports button on the Main Menu now produces 3 categories of reports. Before running a report, please click the 'One-off fixes' button on the Main Menu and click the 'Delete AMENDED Records' button. To print a report when you are viewing it on your screen, use the File – Print option (but do ensure it will fit on a page first!).

10. Reports for a given patient, selected by number
11. Reports to check data quality prior to sending zip data to Dundee
12. Reports with general information pertaining to the clinic.

#### **□ Reports for a given patient, selected by number**

- **By Patient – Biography** – shows biography and registration summary details
- **By Patient - LF BMI ET Summary** – shows lung function, height, weight, BMI and Exercise Tolerance values for every visit entered in the system
- **By Patient LF BMI ET Averages**– shows lung function, height, weight, BMI and Exercise Tolerance values averaged for all visits entered in the system
  - For each of these, either enter the first 4 characters of the patient ID followed by an asterisk to select a specific patient.
  - If you simply type in an asterisk, you will get information on all your patients
  - The next question asks for the year, and again, either specify the year (in the format 2001 etc), or type an asterisk for all years

#### **□ Reports to check data quality prior to sending zip data to Dundee (run numbers 1 to 8)**

- **Checks 1 - Height SDS Outside Range** – this will display a patient's details if either the patient is not average height or there is an error in one or more of the following values entered: height, year of visit, year of birth (Biography form), sex (biography form)
- **Checks 2 - Weight SDS Outside Range**– this will display a patient's details if either the patient is not average weight or there is an error in one or more of the following values entered: weight, year of visit, year of birth (Biography form), sex (biography form)
- **Checks 3 - BMI SDS Outside Range**– this will display a patient's details if either the patient is not average BMI or there is an error in one or more of the following values entered: height, weight, year of visit, year of birth (Biography form), sex (biography form)
- **Checks 4 - FEV1 % Pred Outside Range** – patients outside the range 5% to 135% are listed by visit. Please check for an error in one or more of the following: FEV1, height, year of clinic visit, year of birth (biography form), sex (biography form).
- **Checks 5 - FVC % Pred Outside Range**– patients outside the range 5% to 135% are listed by visit. Please check for an error in one or more of the following: FVC, height, year of clinic visit, year of birth (biography form), sex (biography form).
- **Checks 6 - FEV1 Equals or Exceeds FVC** If the 'blow' is done correctly, FEV1 should always be less than FVC. Further, the FVC reading should be between about 0.1 and 3 greater than the FEV1 reading. If your paper form does not show this, there is probably not a great deal you can do about this. You may however like to consider setting either the FEV1 or the FVC to a "?" in the database so that the program knows to ignore it in the calculations for the audit graphs.
- **Checks 7 - CV's with no Reviews** – please specify the year
- **Checks 8 - Reviews with no CV's**– please specify the year
- **Checks 9 - AR vs Biography Genotypes** - one-off report. For details, please refer to Section 1

- **Checks 10 - Duplicate Clinic Visits Entered** - one-off report. For details, please refer to Section 1
  - **Checks 11 - Duplicate Annual Reviews Entered** - one-off report. For details, please refer to Section 1
  - **Checks 12 - Duplicate Biographies Entered** - one-off report. For details, please refer to Section 1
- **Reports with general information pertaining to the clinic**
- These provide information for the entire clinic. Where asked for the year, either enter a specific year, or enter an asterisk for all years. (Some of this information will also be available in the **By Patient - LF BMI ET Summary** and **By Patient – Biography** reports if used with the asterisk option).

## **5: Transferred Patients**

This section lists how to

13. Transfer your patients to another clinic

14. Register patients transferred to you from another clinic

### **□ Transfer your patients to another clinic**

- On the Main Menu, click the Amend Status option, and select the clinic and patient to transfer. Click Transfer and enter the new clinic and date of transfer (ddmmyy). Then click Done
- The program tells you it will now prepare the patient transfer files. Say ok
- When the program asks if you want to print listings of patient data, **say Yes** as the new clinic will find this transfer information helpful.
- For Year of visit, enter asterisk and the program will summarise growth and lung function values for the last five years.
- The program now prints
  - Patient's registration and biography forms
  - summary of the growth and lung function
  - latest Annual Review and Clinic Visit
- Please send this information to the new clinic for their information.
- Please also send a copy of the Patient's Consent form to the new clinic (but keep the original for your own records as the patient will still be on your database for historical reasons)
  
- If you have transferred a patient in error, you may reverse the status of the patient as follows:
  - On the Main Menu, click the Amend Status option, and select the patient
  - Click Re-instate the selected patient (bottom of the screen) and click Done.

### **□ Register patients transferred to you from another clinic**

- If the patient has been transferred from any of the 60 or so clinics that are participating in the database, please ensure that the Registration and Biography forms have been sent to you by the previous clinic.
- Obtain the patient's signed, informed consent to go on your database and file it in your consent folder
- Register the patient in your own clinic using the Patient Registration Form option on the Main Menu
- Please ensure that the Patient ID generated is the same as it was in the patient's previous clinic (especially the last 5 characters!)
- Enter the patient's Biography details

- The database will is now ready to accept clinic visits and annual reviews for the patient

## **6: Recording death or reverse diagnosis**

This section lists how to

15. Record deaths

16. Record reverse diagnoses

### **□ Recording deaths**

- On the Main Menu, click the Amend Status option, and select the patient. Click Death
- Enter the date and cause of death. You may enter further information in 'Notes'.
- Click Done
  
- If you have recorded a death in error, you may reverse this as follows:
  - On the Main Menu, click the Amend Status option, and select the patient
  - Click Re-instate the selected patient (bottom of the screen) and click Done.

### **□ Recording reverse diagnoses**

- On the Main Menu, click the Amend Status option, and select the patient. Click Reverse Diagnosis
- Enter the date at which the diagnosis was reversed
- Click Done
  
- If you have recorded a reverse diagnosis in error, you may reverse this as follows:
  - On the Main Menu, click the Amend Status option, and select the patient
  - Click Re-instate the selected patient (bottom of the screen) and click Done.

## **7: Correcting a wrongly registered patient**

If a patient has been registered with incorrect details on the Registration Form, they will have been allocated a wrong number on the database. To correct this

17. Complete a new paper Registration Form for the patient with the correct details
18. Complete a new paper Biography Form for the patient with the correct details
19. Generate the new, correct number for the patient and enter the new biography into the computer
20. Amend all clinic visits and annual reviews from the old to the new number
21. Delete all records with the old number

- ❑ **Complete a new paper Registration Form for the patient with the correct details**
- ❑ **Complete a new paper Biography Form for the patient with the correct details**
- ❑ **Generate the new, correct number for the patient and enter the new biography into the computer**
  - From the Main Menu, select Patient Registration New and register the patient in the normal way
  - Print a new sheet of labels and destroy the old ones
  - Select Patient Biography New and enter the Biography for the patient against the new number
- ❑ **Amend all Clinic Visits and Annual reviews from the old to the new number**
  - Using the Clinic Visit Amend option, select each visit in turn for the patient under the old number
  - Change the number over to the new number and go through to the end of the screens and click Finish
  - Repeat for each Annual review
- ❑ **Delete all records with the old number**
  - From the option 'One-off Fixes' click the Delete AMENDED Records button
  - From the option 'One-off Fixes' click the Select and Delete Patient(s) button

## **8: Printing or deleting information from the database**

In version2 it is possible for clinic staff to delete incorrect information by themselves, or print a specified clinic visit or annual review.

22. Deleting AMENDED records
23. Deleting an incorrect clinic visit or annual review
24. Removing a patient from the database
25. Printing a specified clinic visit or annual review
26. Printing a patient's registration and biography forms

### **□ Deleting AMENDED records**

- On the Main Menu, click 'One-off Fixes' and select 'Delete AMENDED records' and say OK. This will get rid of the original, incorrect records that have been amended.
- This should be done after any amendments have been done on the database. Otherwise, records will be double-counted by the reports and also by the Database Analyser

### **□ Deleting an incorrect clinic visit or annual review**

- From the Main Menu, select the Browse/amend option for the clinic visit or annual review
- On the next screen, select the patient and the visit to delete and click delete

### **□ Removing a patient from the database**

- First delete each clinic visit and annual review for the patient by selecting it in turn as described above
- On the Main Menu, select One-off Fixes and click Select and Delete Patients.
- Select the patient whose details you wish to remove, and click delete
- The program deletes these details and informs you
- ❖ Send a copy of the refusal form with the patient ID to Dundee to remove from the UK database
  
- If you select a patient to delete without first removing all their clinic visits and annual reviews, the program is unable to this and gives you a deletion error.
  
- If you try and delete a patient who is incompletely registered (ie has a registration but no biography), the program does not display that patient in the drop down list for you to select from. It will be necessary to complete a biography for this patient, and then delete all details.
  
- To delete an incorrectly registered patient (with no biography), enter a biography so the patient appears in the drop down list, then delete him as above

- **Printing a specified clinic visit or annual review**
  - From the Main Menu, select the Browse/amend option for the clinic visit or annual review
  - On the next screen, select the patient and the visit to print and click print
  
- **Printing a patient's registration and biography forms**
  - From the Main Menu, select the Biog button
  - Select the patient for whom you want to print the registration and biography form, or select All Patients to print Registration and Biography details for all your patients

## **9: Data Protection Act requirements**

The new Data Protection Act has required the following four areas to be addressed:

27. Encrypting information sent in the post
28. Providing printouts for patients if requested
29. Obtaining and keeping informed, explicit patient consent
30. Removing a patient from the database

### **□ Encrypting information sent in the post**

#### **▪ Transfer data**

- Zip data sent in the post to Dundee is most commonly a transfer. In version2, when you click the Transfer button on the Main Menu, the program will now ask for a password to encrypt the data. Supply it with a password and please make a note of it (it is case sensitive). When the copying to zip disk is complete and the flashing green light on your zip drive stops, please send the zip to Dundee in the normal way, along with the paper copies of the forms.
- Please also ring or write under separate cover and let us know your password in order that we may unencrypt your database in order to verify it.

#### **▪ Backup data**

- In the case of a backup which you normally do for your own security, you will not need to encrypt the data, and you may tell the Backup program that you do not wish to encrypt the database.
- However, in the rare instance that you need to send the full backup of your database to Dundee, please encrypt it as described above and let the National team know the password
- Please allow about two minutes for the Backup to complete - the flashing green light on your zip drive will stop

#### **▪ Database sent to you from Dundee**

- When a database is sent to you from Dundee, it will have been encrypted. The relevant password will be supplied to you at the time, along with instructions on how to access it.

### **□ Providing printouts for patients if requested**

- If patients wish to see what data is held for them, select each clinic visit and annual review and print it as described in section 7
- Print their registration and biography details, also described in section 7

### **□ Obtaining and keeping informed, explicit patient consent**

- Please explain the purpose of the data collection and obtain informed, explicit consent from your patients
- Please keep these consent forms in a folder for your own records
- If you transfer a patient, please send a copy of the consent form to the new clinic, but keep the original for your own records as the details for patients always remain on your database even after the patient is transferred.

- **Removing a patient from the database**
  - If a patient wishes to be removed from the database, please follow the instructions in section 7 for how to do this.

# UKCF Database

## Confirmation of successful upgrade to version 2

Clinic Code: \_\_\_\_\_

Upgrade done by: \_\_\_\_\_

Upgrade date: \_\_\_\_\_

Key upgrade tasks completed: (please tick all that apply)

- Implementer successful – browse screen is blue! \_\_\_\_\_
- Report ‘Check 9’ done and genotype errors fixed \_\_\_\_\_
- Duplicates, if any, deleted (Checks 10, 11 and 12) \_\_\_\_\_
- Deceased patients entered on database \_\_\_\_\_

Thank you for your help. Please post this completed form to:

Mrs Margaret Fraser  
UKCF Database  
Tayside Institute of Child Health  
University of Dundee  
Ninewells Hospital and Medical School  
DUNDEE DD1 9SY