transfusionoutcomes
research collaborative

NEONATAL ALLOIMMUNE THROMBOCYTOPENIA (NAIT) REGISTRY WEB DATA ENTRY

Department of Epidemiology and Preventive Medicine
Monash University

Data Entry User Guide

NAIT REGISTRY DATA ENTRY WEB APPLICATION

Data Entry User Guide

Version 0.2
April 2010

© TTP Registry
Department of Epidemiology and Preventive Medicine
School of Public Health and Preventive Medicine
Faculty of Medicine, Nursing & Health Sciences
Monash University

This user guide was compiled by
Louise Phillips and Jessica Oddy

Contact details
Web Access Data Manager: Waranon Buranasiri
depm-traumaweb@med.monash.edu.au
Ph: 03 9903 0169

Information Systems Manager: Andrew Hannaford
depm-traumaweb@med.monash.edu.au
Ph: 03 9903 0001

Project Manager: Louise Phillips
Louise.Phillips@med.monash.edu.au
Ph: 03 9903 0051
Mob: 0417 722 449

Postal address:
DEPM
Monash University
The Alfred Centre
Melbourne VIC 3004

Delivery address:
6th Floor
The Alfred Centre
99 Commercial Road
Melbourne VIC 3004

Table of Contents

System Requirements 1
Web Browser 2
Preferred Browsers 2
Language of the browser 2
Auto-complete Password 3
Web Access and Security 4
New Login 5
Changing Login Details 5
Changing your Password 5
Changing your Email Address 6
Changing your Security Question 7
Password Recovery 8
Account Locked 11
Restricted Access 11
Logout and Timeout 11
Navigation 12
Patient List 12
Menu Bar 13
Data Entry Guidelines 15
General Principles 15
Required Field Validation 15
Range and Regular Expression Validation 15
Page Validation 16
Page Warnings 17
Date and Time Fields 17
Adding a New Case 18
Case Registration 18
Case Registration Page Data Entry Summary 19
Institution/ Hospital/ Site 20
Patient Family Name (Maternal) 20
Patient Given Name (Maternal) 21
Date of Birth (Maternal) 21
Parental Demographics Page 23
Parental Demographics Page Data Entry Summary 24
Registry Number 25
Maternal Details: Family Name and Given Name 25
Maternal Details: Date of Birth 25
Maternal Details: Age 25
Maternal Details: Genetic Ethnic Heritage (Grandparents) 25
Maternal Details: Weight 25
Maternal Details: Height 25
Maternal Details: Gravidity 26
Maternal Details: Parity 26

Paternal Details: Family Name and Given Name 26
Paternal Details: Genetic Ethnic Heritage (Grandparents) 26
Clinical Background Page 27
Clinical Background Page Data Entry Summary 28
Case Description 30
Possible Alternative Cause of Clinical Presentation 30
Stage at Which Case was Identified 31
Reason for Case Identification 31
Other Fetal Abnormality 32
Any Previous NAIT Affected Offspring 32
Previous NAIT Affected Offspring: Details of Severity 32
Comments on Any Previous Poor Pregnancy Outcomes 33
Maternal Platelet Count at Diagnosis 33
Date of Maternal Platelet Count (DD/MM/YYYY) 33
Maternal ABO Group 33
Parental Testing Page 34
Parental Testing Page Data Entry Summary 35
Antenatal Clinical Details Page 41
Antenatal Clinical Details Page Data Entry Summary 42
Estimated date of delivery 45
Site of antenatal management 45
Gestation at which case is identified 45
Cranial imaging performed? 45
Cranial imaging findings 45
Complications during pregnancy 45
Outcome of Pregnancy 46
Cause of Death 47
Is Post-mortem to be performed? 47
Comments on Findings at Post-Mortem 47
Antenatal Testing and Therapy Page 48
Antenatal Testing and Therapy Page Data Entry Summary 50
Date of procedure 54
Procedure 54
Fetal platelet count at fetal blood sampling 54
Fetal platelet count post transfusion 54
Platelet type 54
Complications of Procedure 55
Other Therapy 55
Postnatal Demographics Page 58
Postnatal Demographics Page Data Entry Summary 59
Child Family Name and Given Name 60
Child Sex 60
Child Birth Weight 60
Date of Delivery 60
Gestation at Delivery 60
Mode of Delivery 60

Timing of Delivery 61
Site of Antenatal Management 62
Transferred Patient 62
Postnatal Clinical and Testing Details Page 63
Postnatal Clinical and Testing Details Page Data Entry Summary 64
Clinical Manifestations 66
Child's First Platelet Count 66
Child's First Haemoglobin Count 66
Child's First Total WCC 66
Child ABO Blood Group 67
Child Rhesus (D) Group 67
Date of First Blood Counts 67
Child's Lowest Platelet Count 67
Date of Child's Lowest Platelet Count 67
Cranial Imaging Performed? 67
Cranial Imaging Findings 68
Postnatal Therapy Page 69
Postnatal Therapy Page Data Entry Summary 70
Required Postnatal Therapy 72
Platelet Transfusion 72
Therapy Details: Intravenous Immunoglobulin 73
Postnatal Outcomes Page 74
Postnatal Outcomes Page Data Entry Summary 75
Outcome of Episode 77
Nature of Persistent Impairment 77
Cause of Death 77
Other Autopsy Findings 78
Comments 78
Editing Data 79
Record editing 80
Editing or Deleting on the Antenatal Testing and Therapy or Postnatal Therapy pages 81
Printing a Case 82

section

1

System Requirements

The NAIT Registry database requires only the recommended web browser, Microsoft Internet Explorer 7.0 (IE) to operate.

This software can be obtained from the Microsoft website at:

http://www.microsoft.com/windows/ie/ie6/evaluation/sysreqs/default.mspx

It is not necessary to install any software other than this web browser.

Below are the minimum requirements your computer needs to run Internet Explorer 7. Please note that is it possible that some components may require additional system resources not outlined below.

Minimum Requirements	
Computer/Processor	Computer with a Pentium IV processor or higher
Operating System	Windows XP Service Pack 2 (SP2), Windows XP Service Pack 3 (SP3), Windows XP Professional x64 Edition, or Windows Server 2003 Service Pack 1 (SP1)
Memory	For Internet Explorer 7: - Windows XP Service Pack 2 (SP2) - 64 MB - Windows XP Service Pack 3 (SP3) - 64 MB - Windows XP Professional x64 Edition - 128 MB
Display	Super VGA (800 x 600) or higher-resolution monitor with 256 colours Screen resolution at 1024 x 768 or higher is recommended setting for best view
Peripherals	Modem or Internet connection; Microsoft Mouse, Microsoft IntelliMouse®, or compatible pointing device

Note: Internet Explorer 7 setup installs the majority of its files on the drive where the Windows operating system is installed, regardless of the installation location you choose. To free up space on your hard disk in order to meet disk-space installation requirements, do so on the drive where the Windows operating system is installed.

Web Browser

Like any web site a web browser is required to access the NAIT Registry database system.

Preferred Browsers

Microsoft Internet Explorer 7 (IE) (or newer version) is the web browser for which the NAIT database system has been developed. Alternatively, Mozilla Firefox 3.0 or newer version is also supported. However, some of the reporting features are not fully supported by Mozilla Firefox. A free copy of Mozilla Firefox can be downloaded from:

http://www.mozilla.org/

Users may experience some difficulty if using browsers other than those recommended.

Language of the browser

All dates in the application are in Australian format DD/MM/YYYY. Therefore it is *very important* that your browser is configured in Australian date format. Most browsers are set to default to American settings so this will need to be adjusted.

Date format is determined through the browser's language set up. To set the language in **Internet Explorer 7 (IE)**, click on **Internet Options** on the **Tools** menu. On the general tab, click **Languages**. Click **Add** and select **English (Australia) [en-au]** form the list. Make sure it is at the top of the list by clicking the **Move Up** button. The same screen can be found in **Firefox** through **Tools** menu, **Options**, **Advanced** tab and **Edit Language**.

If a TTP database page cannot be displayed because of a date error, or the current patient label displays the date differently from what is shown on the patient list, check the language settings for your browser.

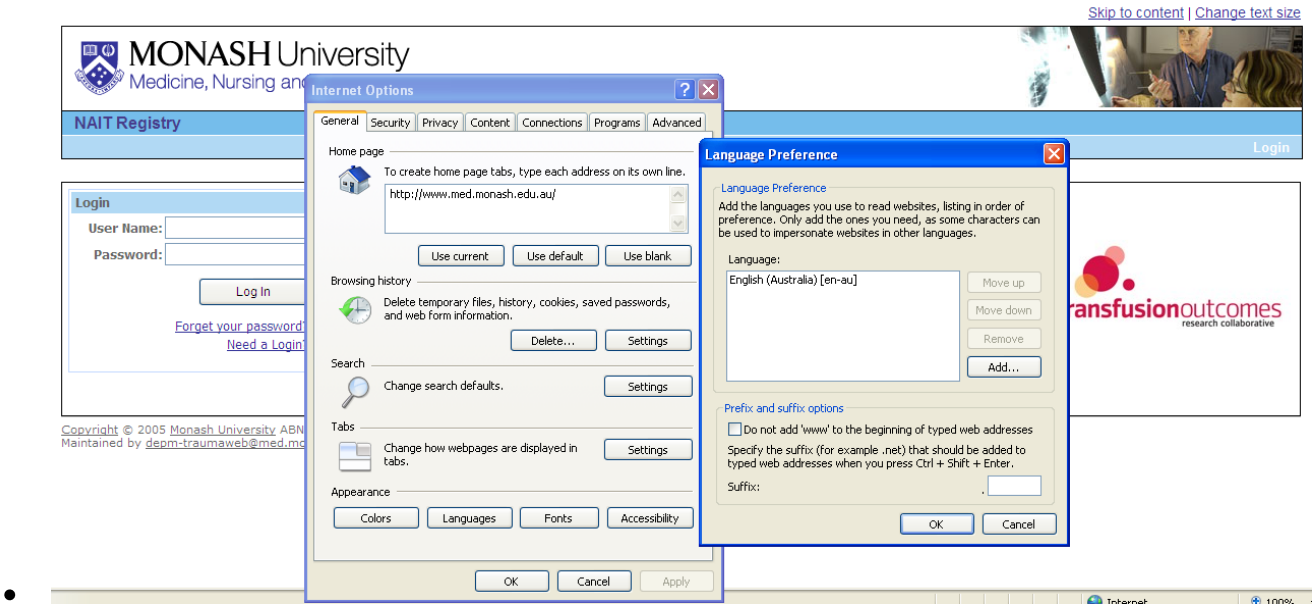


Figure 1: Language preference window after setup

Auto-complete Password

Most web browsers provide an option for remembering the password used to log into a web site on that computer. Due to the sensitive nature of the NAIT Registry data, the auto-complete password option **must be turned off** to ensure privacy.

To do this in **Internet Explorer**, click on **Internet Options** on the **Tools** menu as shown in Figure 2. On the **Content** tab in the personal information section, click on **AutoComplete**. When the AutoComplete settings box appears uncheck **Prompt me to save passwords** and **User names and passwords on forms** boxes and click **Clear passwords**. Please note that this will clear any web-based addresses that have automatically saved passwords so be sure to record your passwords before completing this process.

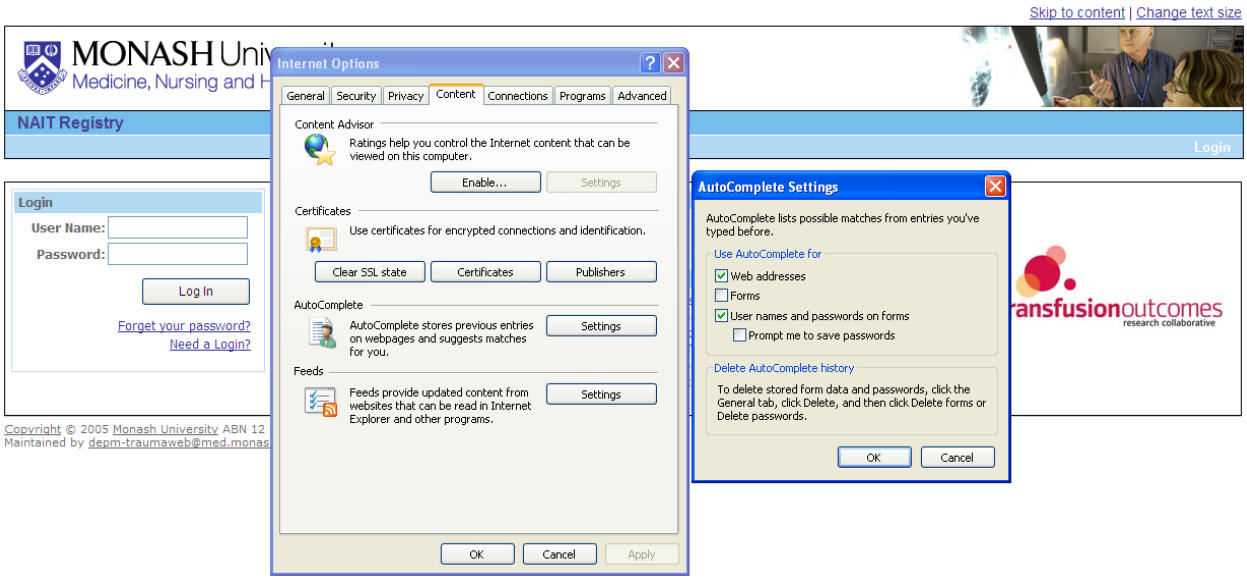


Figure 2: How to stop auto-complete password in Internet Explorer

section 2

Web Access and Security

As with all web pages on the internet, the NAIT Registry web application can be accessed by specifying the URL address in the web browser. The URL Address for this application is:-

transfusionoutcomes research collaborative https://trauma.med.monash.edu.au/NAIT/Application/home.aspx

On accessing the web site, you will need to click on **Web Data Entry** to be directed to the NAIT Registry login page below.

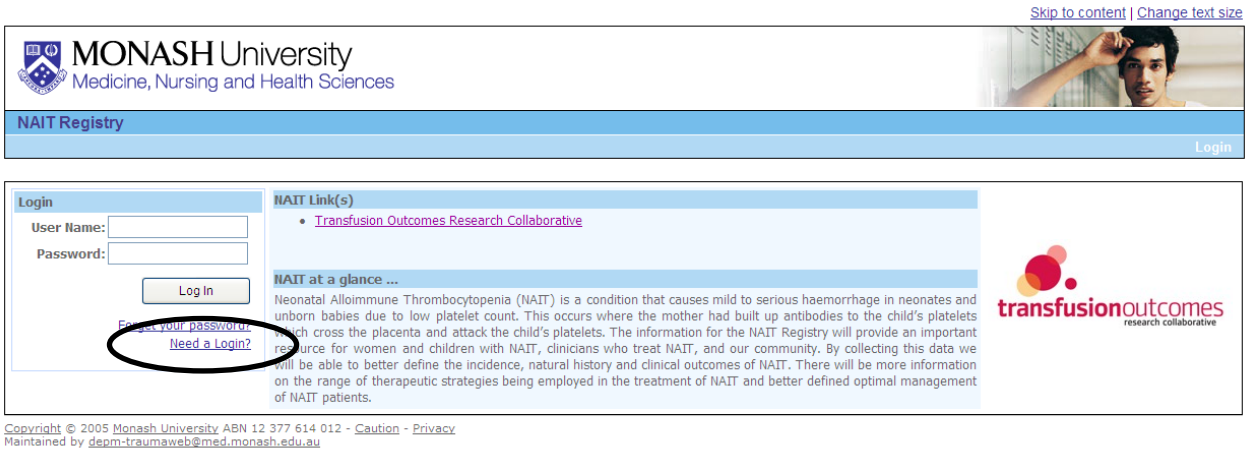


Figure 3: Login page viewed in IE 6.0

In order to access data in the application, a User Name and Password are required. If you already have a login, you can bypass the next section and go directly to **Changing Login Details** on page 5, otherwise a new login needs to be provided to you by NAIT Registry IT Staff.

New Login

To request a new login, click on **Need a Login?** as shown in Figure 3 above. This will open up your email and automatically address an email to the NAIT Registry IT staff. In the body of the email please provide your full name, the hospital or site you represent and the email address to which you wish to have your login information sent (if different from the account sending). A user name will be created from the first character of your given name and at least 6 characters from your surname. Your user name and temporary password will be emailed to you within 24 hours. On receipt of the new login and password it is imperative that the password is reset to something more secure and personal that is easily recalled. You will also need to provide a security question for further verification.

Changing Login Details

After logging in with your user name and password, you will be presented with 3 sub menus on the right of the menu panel.

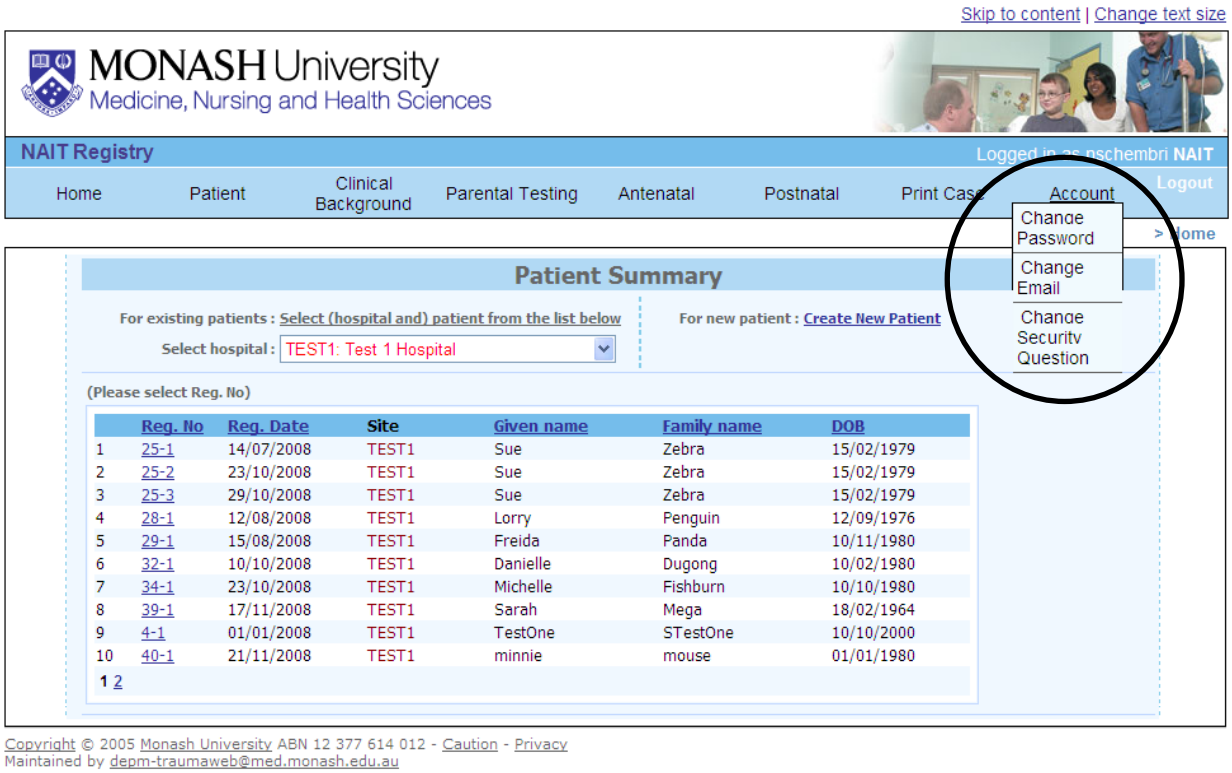


Figure 4: Home Page after logging in, displaying links to Change Password, Email Address and Security Question

Changing your Password

To change the password, click on the **Change Password** Link as indicated in Figure 4 above. You will be presented with the screen on the following page:

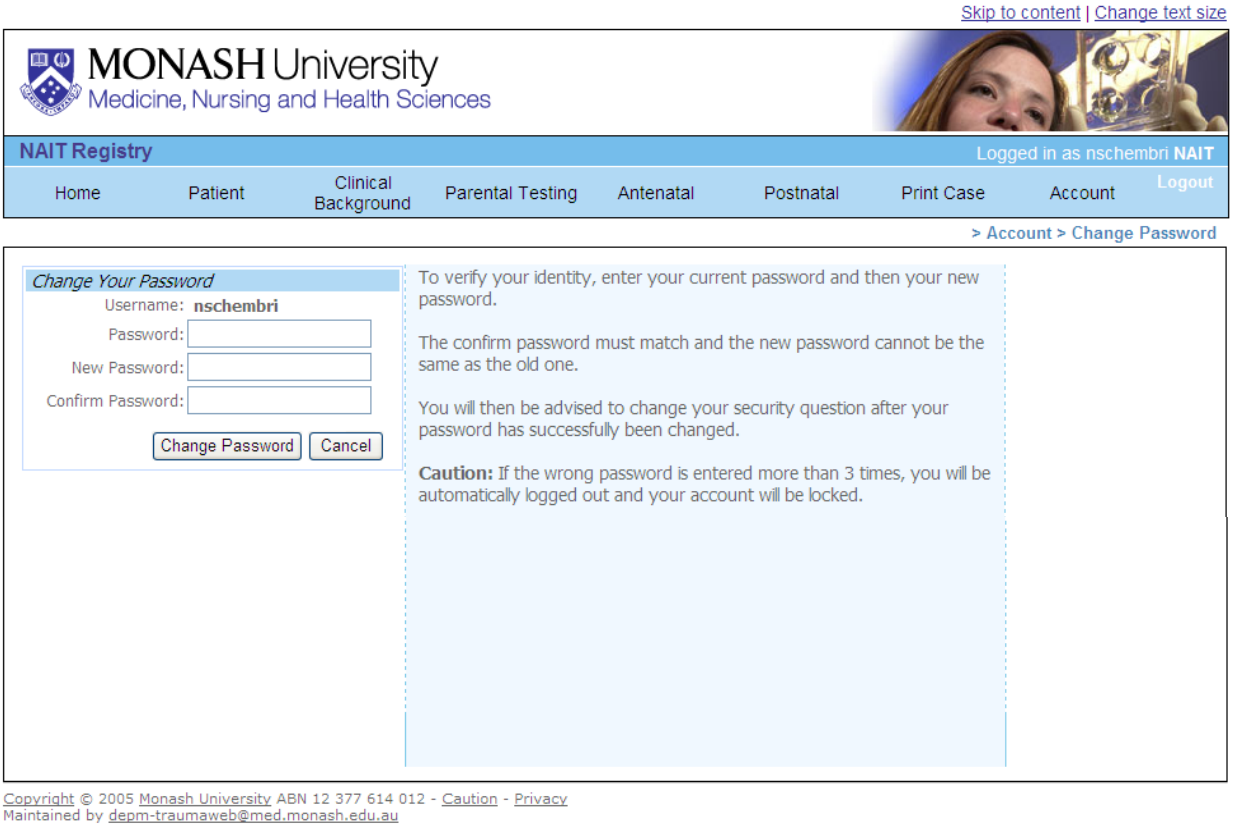


Figure 5: Changing your password

After entering your old password, create a new password of at least 7 characters, with at least one non-alpha-numeric character (eg! @ # $ % ^ & * ( ) ?). It should be something more personal and able to be readily recalled, without being obvious. Visit the Monash University ITS web site for assistance in choosing a good password. http://www.its.monash.edu.au/staff/security/passwords/goodpassword.html.

You will need to enter the password again to confirm and prevent unauthorised use. Not only should the password be changed for a new login, but all existing logins should regularly change their password and security question.

Changing your Email Address

Your email address is used to communicate any login details with you as well as any outages that may occur. It is therefore important that your current email details are registered. To do this, click on the **Change Email Address** Link as indicated in Figure 4 previously. You will be presented with the screen on the following page.

To verify your identity, enter your password and then overwrite your current email address. The new email address cannot be the same as the old one.

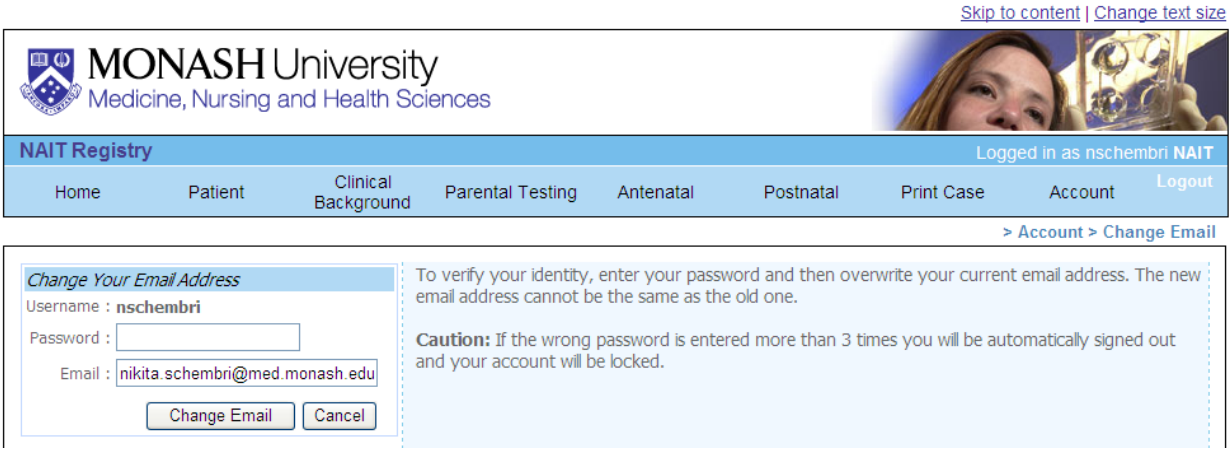


Figure 6: Changing email address

Changing your Security Question

Your security question is used to verify your login details in the event that you cannot recall your password. It is therefore important that you change this when you change your password and that it is not shared with anyone else. To do this, click on **Change Security Question** as shown in Figure 4. You will be presented with the screen in Figure 7 below to enter a question and answer:

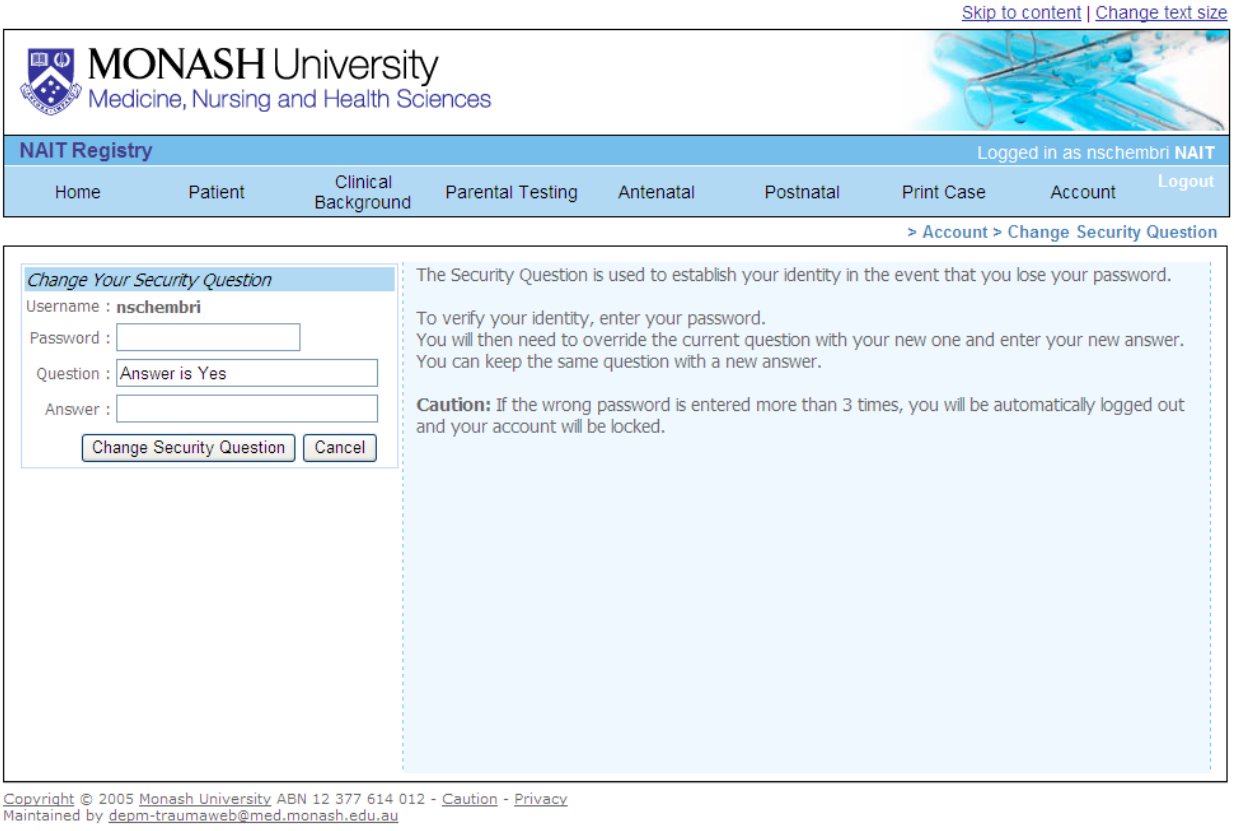


Figure 7: Changing your security question

Password Recovery

If your password is misplaced, a new password can be requested by clicking **Forget your password?** on the login page as shown in Figure 8 below:

Figure 8: 'Forget you password?' link on the login page

You must firstly supply your User Name:

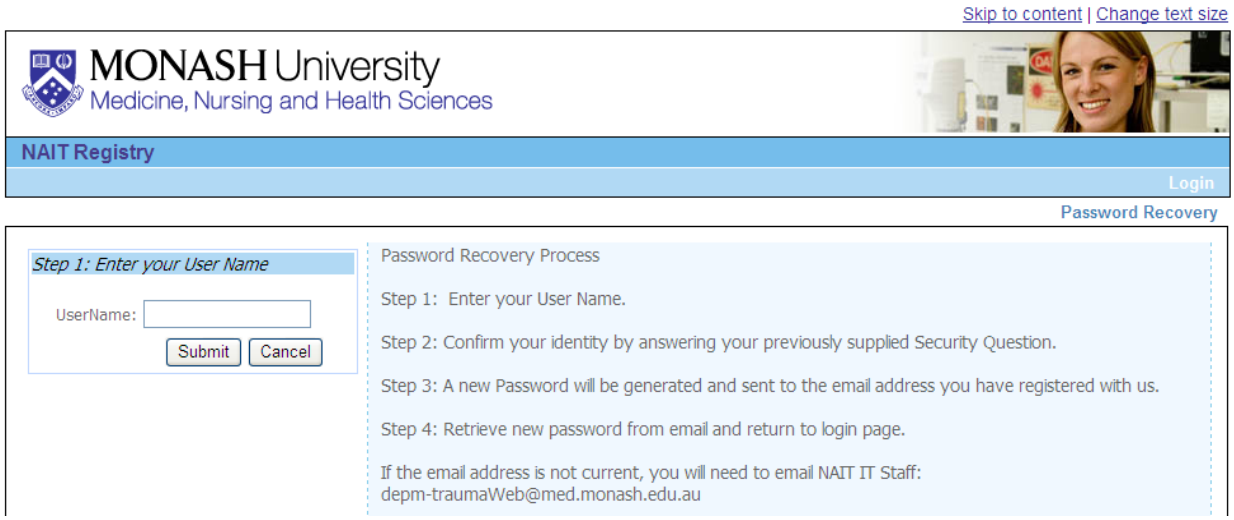


Figure 9: Password Recovery page - submitting user name

The security question is then asked in order to identify the user.

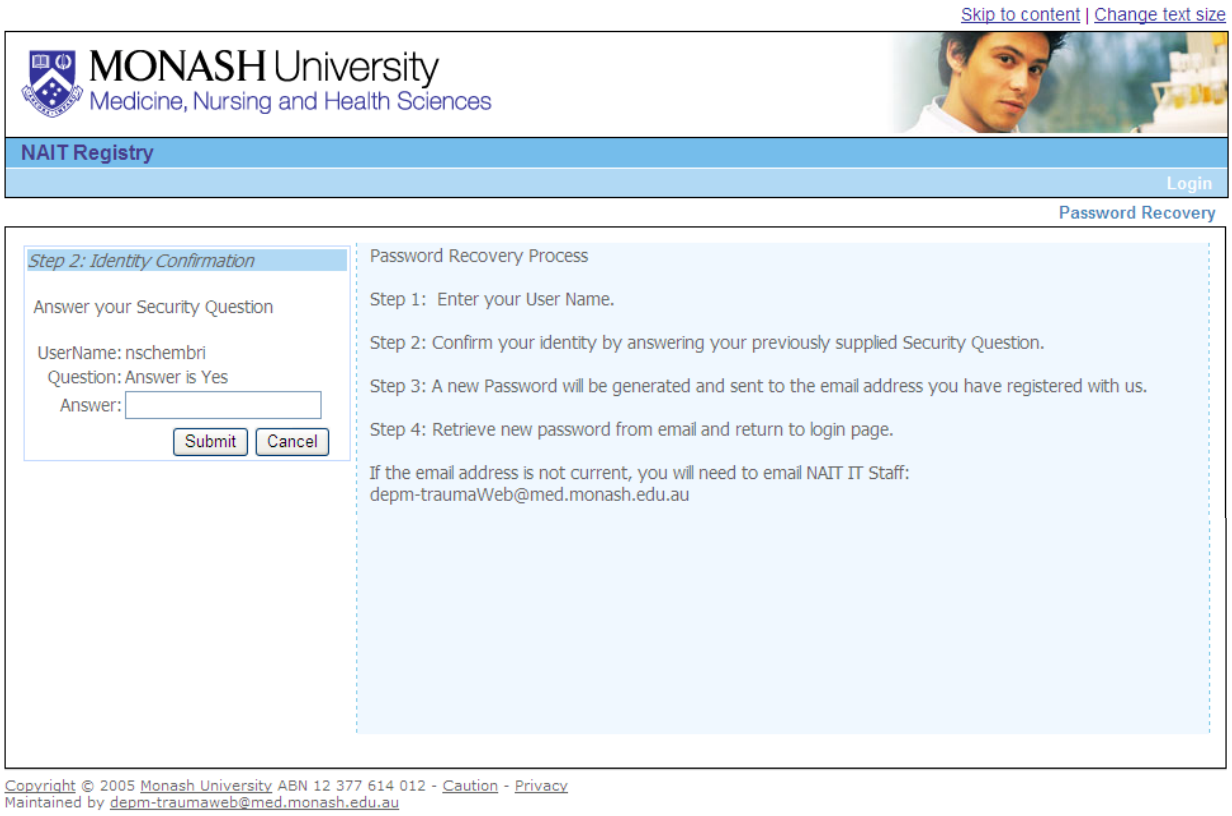
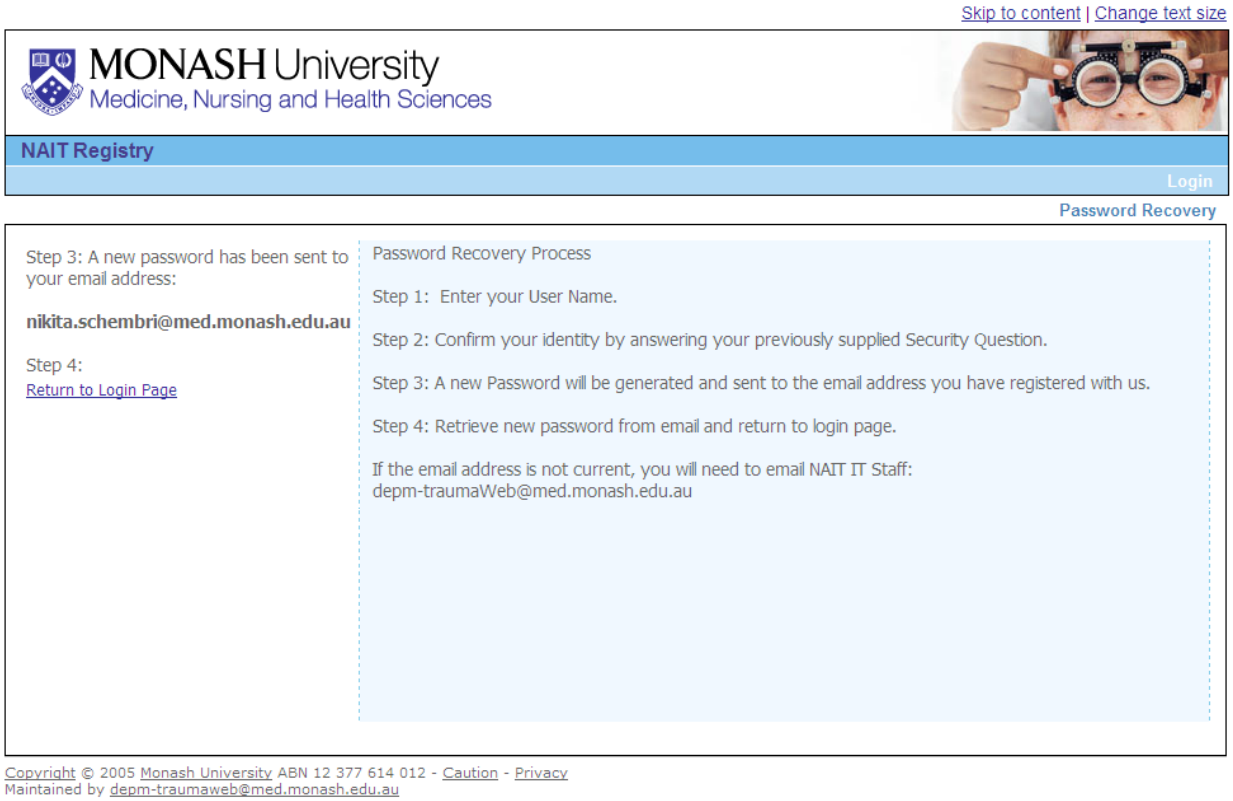


Figure 10: Password Recovery Page - Security Question and Answer

If the answer is correct a new password is generated and sent to your registered email address with a confirmation message (as in Figure 11 below). It is very important to keep the answer to security question private.



Subject: NAIT New Password Delivery
From: depm-traumaweb@med.monash.edu.au
Date: 1:44 PM
To: nikita.schembri@med.monash.edu.au
Cc: depm-traumaWeb@med.monash.edu.au

```
Dear Data Collector,

We have received your request regarding your lost password. Now your password has been reset and sent to you on this email.
Please keep the content of this email disclosed and CHANGE THE NEW PASSWORD IMMEDIATELY after your first logged-in.
For more details of how to change password please refer to the Data Entry User Guide.

        User Name:     nschembri
        New Password:  @dn)qd(7k!K5M)


This email was automatically generated by the NAIT Web Application.
Any enquiry please contact NAIT Staff. Contact details can be found on the web site.

https://trauma.med.monash.edu.au/nait

Best regards,
NAIT IT Staff.
```

Figure 11: Password recovery page - confirming password being recovered and email address to which the new password is sent. Also, an example email generated after the process.

Account Locked

The maximum number of attempts at supplying your password is three. If this number is exceeded, your account will be locked and you will be unable to access the database. You will be directed to the login page with the error message below.

The same restrictions apply to the number of login attempts and answering the security question. You will need to contact NAIT Registry IT staff to unlock your account.

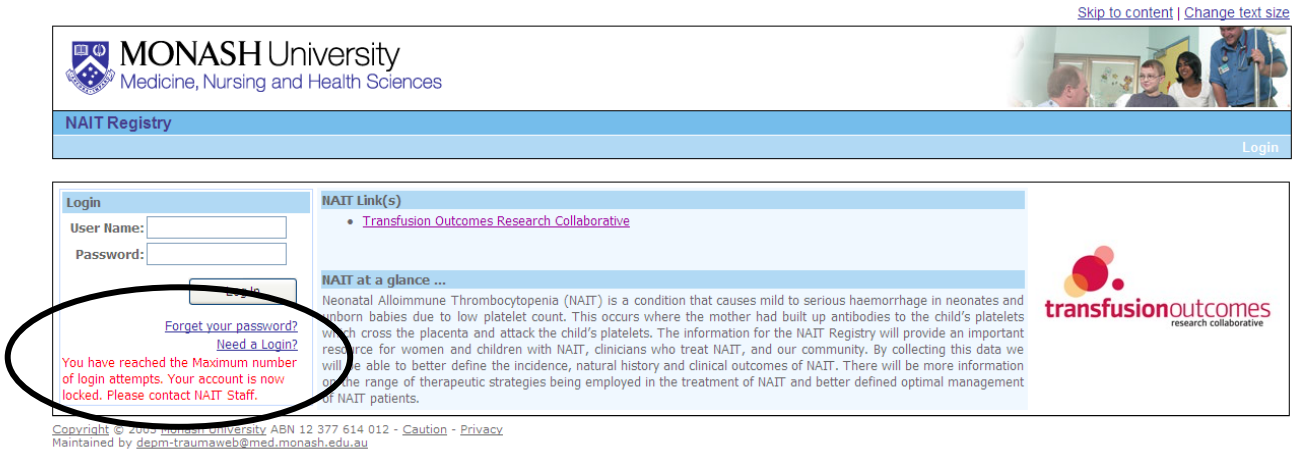


Figure 12: Login page with the error message of maximum login trial exceeded.

Restricted Access

On establishing a new login, you will be granted access by NAIT Registry IT staff to data from the hospital specified in the Login request. This request is verified by NAIT Registry staff. You will not be able to access data from other project sites.

Logout and Timeout

You are advised to logout every time you finish working with the database by using the logout icon on the top right hand side of the main menu bar. This is to ensure unauthorised access does not occur. If you do leave your computer for any period of time it is strongly recommended that it is locked by pressing Control-ALT-Delete simultaneously and clicking on **Lock Workstation**. This should be standard organisation-wide practice. Users will need to re-enter the network and/or computer password to access the computer.

The TTP Registry is programmed to timeout after 30 minutes of inactivity. You will need to re-enter your login details at this point.

section 3

Navigation

Patient List

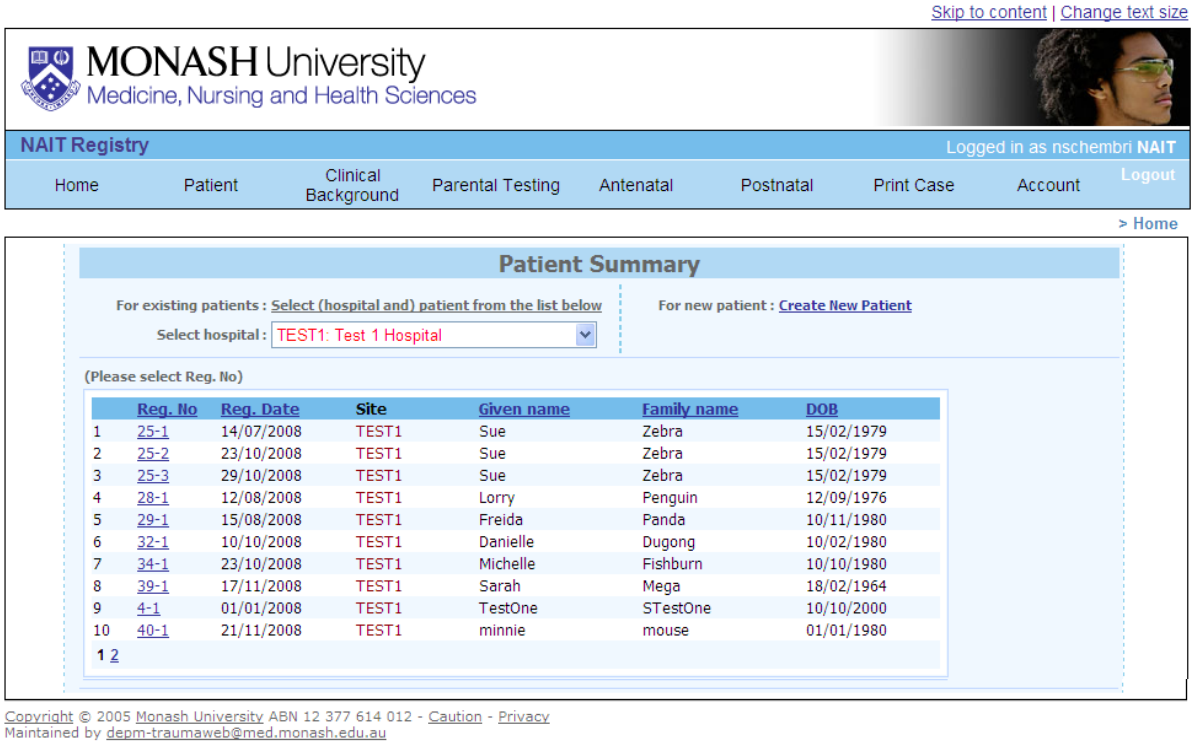


Figure 13: Home Page after logging in, displaying Patient List

Upon logging in a summary list of patients already on NAIT Registry (based on the restricted access discussed in the previous section) will appear. This list consists of their unique patient number, a hyphen, and the admission number – together these form the Registry number for a patient.

A patient record is selected by clicking on the Registry number.

Once the new case is created or an existing case selected, all subsequent data entry pages display information from the patient summary at the top of the page below the menu bar (shown in Figure 14).

Menu Bar

The menu bar is the primary means by which details of an existing or new patient are viewed or entered. After an existing patient is selected from the **Patient List**, you can access details relating to various aspects of that patient's information by clicking on any of the menu bar options from **Patient** through to **Complications and Outcome** (Figure 14).

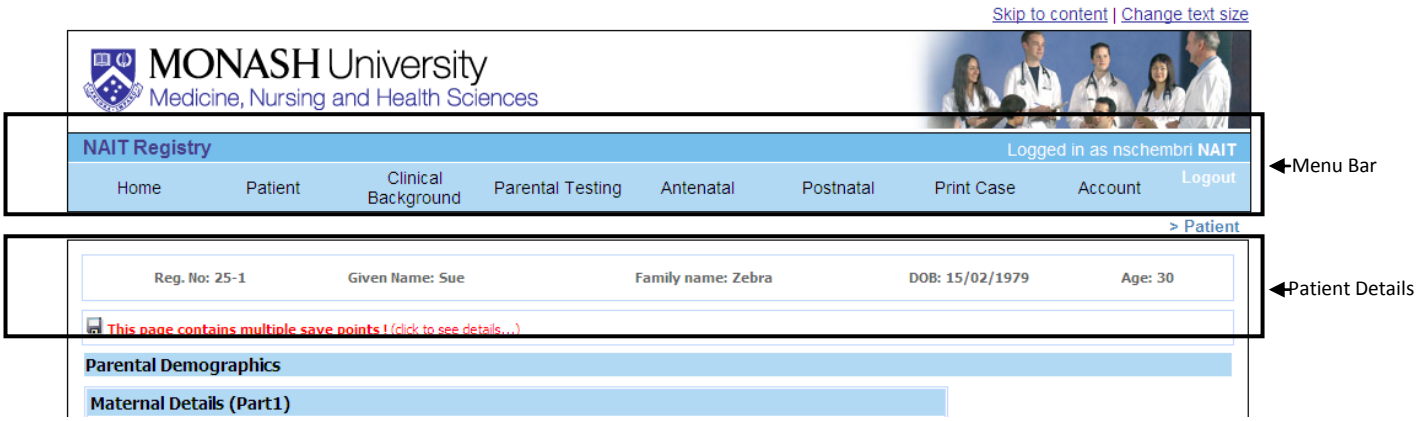


Figure 14: Patient Details screen highlighting Patient Information

The name of the page on view is displayed under the menu bar to the far right (Figure 15).

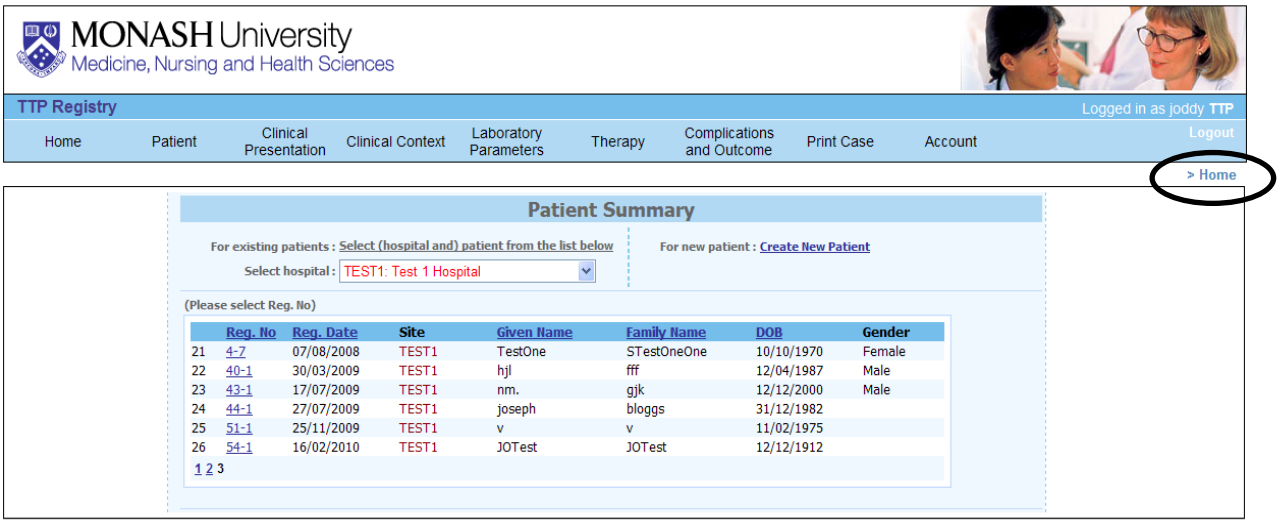


Figure 15: Home page identifying the current page.

Hint For both recommended browsers, users can press **F11** on their keyboard to switch to Full Screen display which reduces the need for scrolling.

Login information is also displayed on the menu bar at the far right. As shown below, your user name is displayed, following the text **Logged in as;** in this example 'nschembri'.

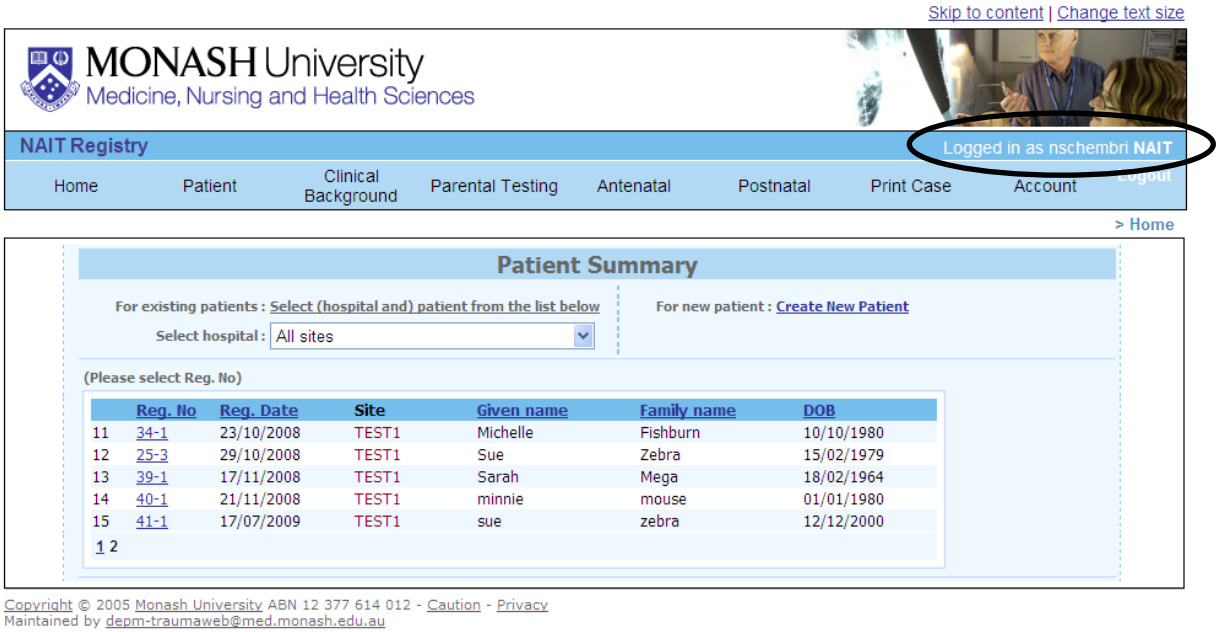


Figure 16: Home Page screen with Login information

section

4

Data Entry Guidelines

General Principles

In order to maintain data integrity some data items are deactivated. This prevents data from being entered when it is unnecessary. When new data is being populated, some data items are activated only after a particular value has been entered.

Required Field Validation

All data items on each page must be completed, unless they are deactivated by the application. A red asterisk adjacent to a data item indicates that this field has been left un-entered (Figure 18). An explanation is given at the bottom of the screen when you attempt to save the data.

Range and Regular Expression Validation

To prevent invalid input into text boxes, Range and Regular Expression validators provide a way to examine the validity of data in each textbox. A Range validator allows a certain range of numbers for numeric or date input. Regular Expression validators only allow particular non-alphanumeric text input. Should you still not be able to decipher the offending character, refer to each form's summary table in this guide for detailed validation rules.

A red asterisk will pop up after leaving the text box when invalid characters are identified. An error message will only be displayed after you attempt to save.

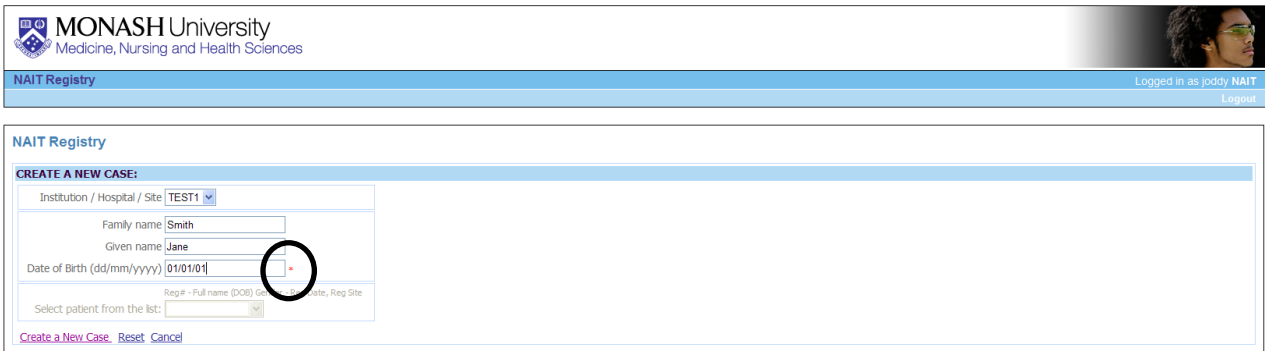


Figure 17: Create a new patient screen with red asterisk indicating missing data.

Page Validation

Page Validation is another means of controlling the consistency of data. It prevents invalid data from being entered in the database. A red-colored error message will appear on the screen notifying the reason of the validation failure. Page validation fires after the save button has been clicked. All validation must be satisfied before the data is saved by the database.

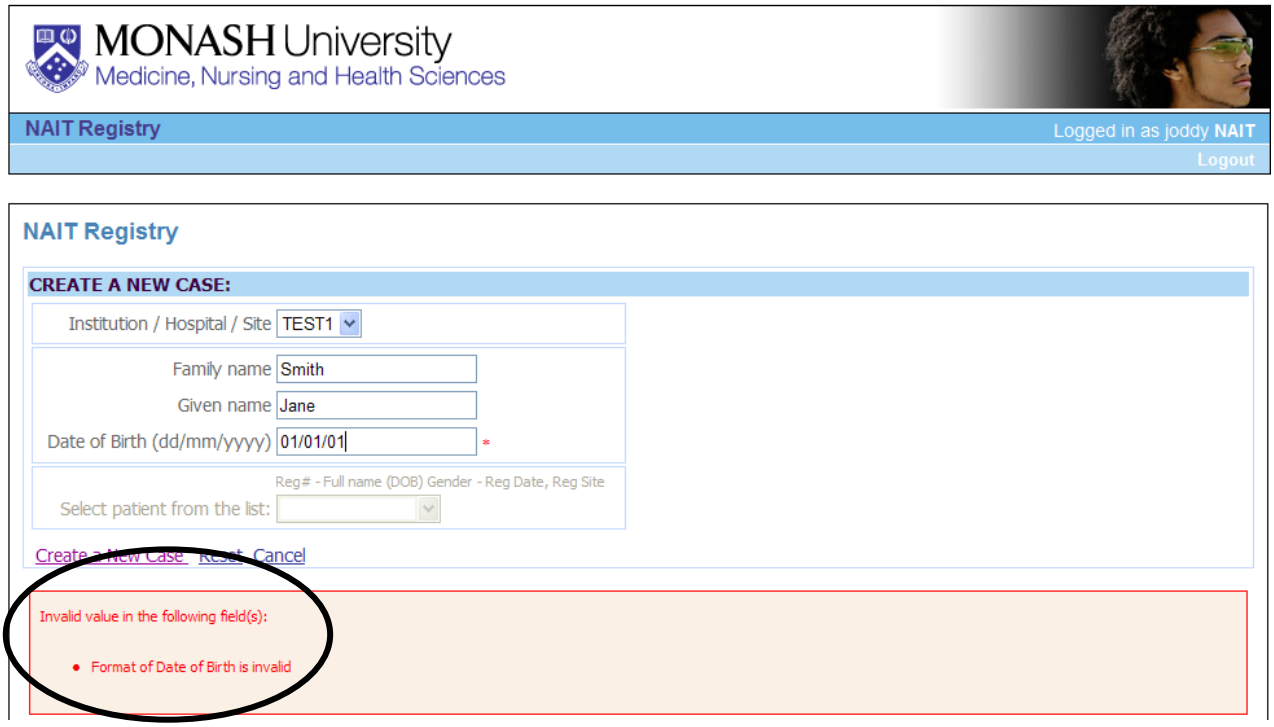


Figure 18: When save is selected, error messages are shown in red if any data items fail validation tests or are incomplete.

Page Warnings

A warning message is different from an error message and does not stop data from saving. This is often used for a reminder of an unknown date and time. It is shown in blue and remains in view when saved. This allows data to be saved even when they contain some unknown values. All date and time textboxes will generate **an unknown date time warning message** when they contain a value of unknown date: 09/09/9999 or unknown Time: 00:00.

Date and Time Fields

There are a number of factors to consider with date and time fields:

1. Dates are in the format: DD/MM/YYYY. You are not required to enter the forward slash character (/) in between days, month and years. If the date is unknown, enter 09/09/9999.

2. Times are in 24 hour format: hh:mm. You are not required to enter the colon (:) in between hours and minutes. If the time is unknown, enter 00:00. If the time is known and is 00:00 hours, please enter 00:01.

3. Some fields accept both date and time in the same field in the format: DD/MM/YYYY hh:mm. If a date and time are unknown, enter 09/09/9999 00:00. A 'space' is required between the date and time formats.

4. All dates and times are sequential. For example, the date of first identifiable symptom must be earlier than the date of diagnosis. An error will be raised if dates and times are not in the correct sequence.

section

5

Adding a New Case

To add a new case, click on **New Case** on the menu bar. Once the data entry process has started, patients are ideally entered as a complete dataset. It is therefore advisable to have all data readily available before starting. This process involves entering patient details, clinical presentation and context information, laboratory parameters, therapy, complications and outcome.

Hint

Clicking on the NAIT Registry banner (previously indicated in Figure 19) will take you out of new case mode, and reinstate the main menu and patient list.

Case Registration - New

When entering a new case on the **Patient Page**, the **Main Menu** and **Patient List** are hidden from view.

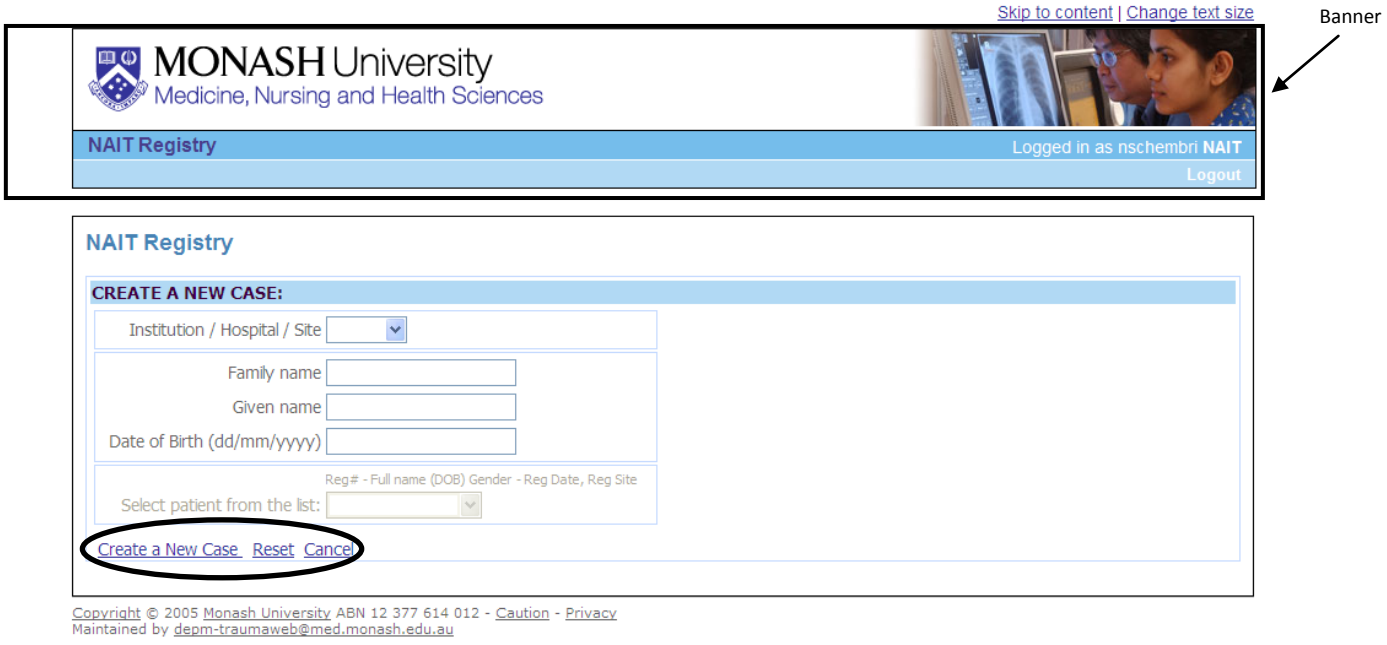


Figure 19: Hospital and patient Information page for a new case with no main menu or patient list.

A summary of the patient page data items and the validation that takes place is provided on the next page, with specialised behaviour explained in the last column.

Hint

Clicking on **Create A New Case** will take you to the **Patient Demographics** Information page. Clicking on **Cancel** returns you to the home page (indicated in Figure 19).

Case Registration Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Institution / Hospital / Site	Always	Drop down list	Select from list	-	N/A
Family Name	Always	Free Text	Alphanumeric	Not applicable	N/A
Given Name	Always	Free Text	Alphanumeric	Not applicable	N/A
Date of Birth	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	Not applicable (not allowed to be unknown on search screen)	N/A

Institution/ Hospital/ Site

Most Data Collectors will be able only to enter data for one hospital. Where data collectors are responsible for data collection at more than one hospital, multiple hospitals are displayed in a drop down list.

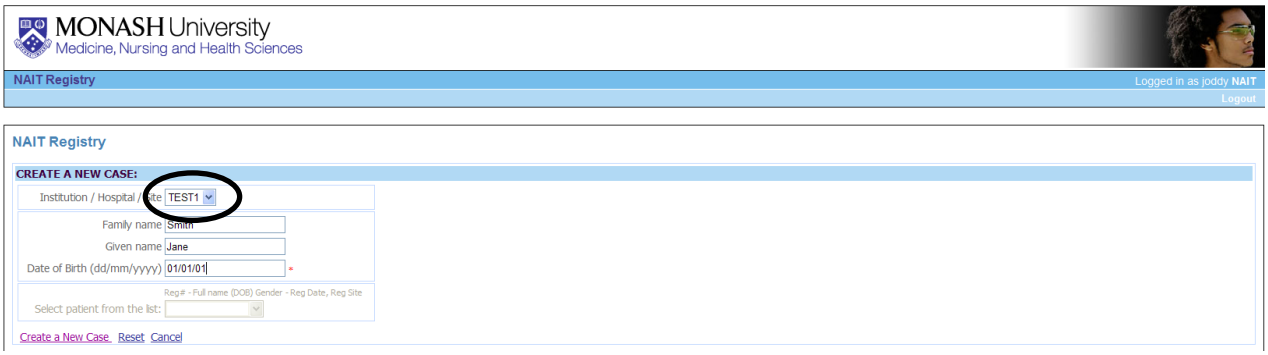


Figure 20: Case registration page with hospital field indicated.

Patient Family Name (Maternal)

The patient's family name and given name are alphanumeric free text fields. The information that is entered as alphanumeric free text on the case registration page automatically populates throughout the subsequent case-related pages.

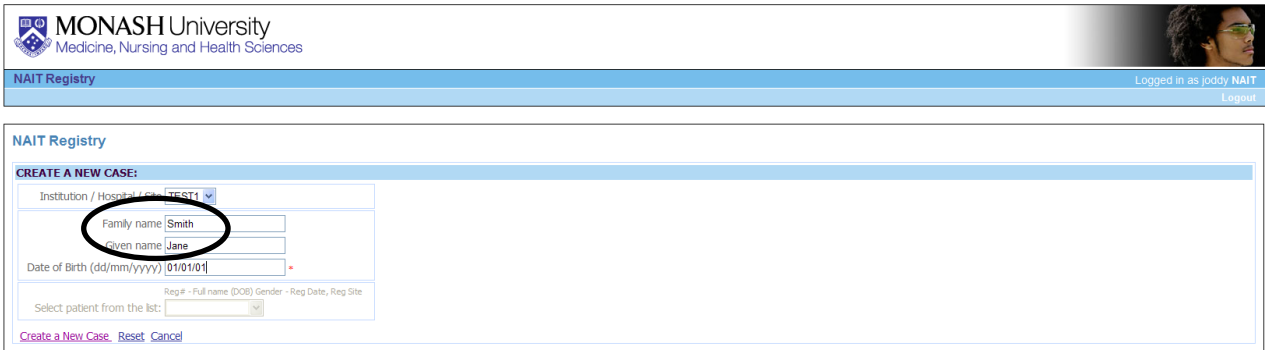


Figure 21: Case registration page with name and date of birth fields indicated.

Family name should be recorded in the format preferred by the person.

Punctuation

If special characters form part of the family name they should be included, e.g. hyphenated names should be entered with a hyphen. Examples:

Hyphen: e.g. Wilson-Phillips.
Do not leave a space before or after a hyphen, i.e. between the last letter of 'Wilson' and the hyphen, nor a space between the hyphen and the first letter of 'Phillips'.

Apostrophe: e.g. O'Brien, D'Agostino.
Do not leave a space before or after the apostrophe, i.e. between the 'O' and the apostrophe, or a space between the apostrophe and 'Brien'.

Full stop: e.g. St. John, St. George.
Do not leave a space before a full stop, i.e. between 'St' and the full stop. Do leave a space between the full stop and John.

Space: e.g. van der Humm, Le Brun, Mc Donald.
Record the family name leaving one space between each word.

Some people do not have a family name and a given name; they have only one name by which they are known. If the person has only one name, record it in the **Family Name** field and leave the **Given Name** field blank.

Patient Given Name (Maternal)

Given name(s) should be recorded in the format preferred by the person. If the person's given name is not known, but the first letter (initial) of the given name is known, record the first letter in the preferred **Given name** field. Do not record a full stop following the initial. Some people do not have a family name and a given name; they have only one name by which they are known. If the person has only one name, record it in the **Family name** field and leave the **Given name** field blank.

Punctuation:

If special characters form part of the given name they should be included, e.g. hyphenated names should be entered with a hyphen.

Refer to examples under "Patient Family Name Maternal", page 20.

Date of Birth (Maternal)

If date of birth is not known or cannot be obtained, an estimated age in years should be used for adults. When date of birth is an estimated value, use 0101, and, the estimated year.

When confident that all case registration details have been entered correctly select **Create a New Case**.

When **Create a new case** is selected the following warning will display:

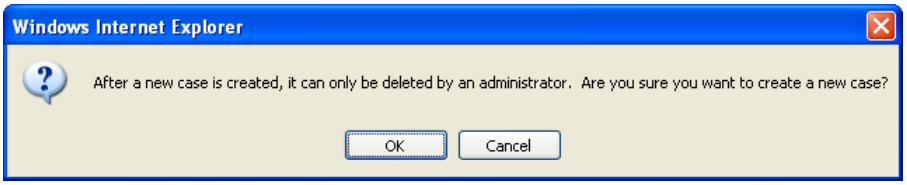


Figure 22: Case registration page warning.

It is very important to check with the mother on possible previous registration with their maiden name, or with any surname changes. If you are unable to locate a patient whom you believe has previously been registered, please contact Registry staff.

Once you have created a new case, information from the patient summary is displayed at the top of each page, below the menu bar on subsequent pages to identify the active record (see Figure 23).

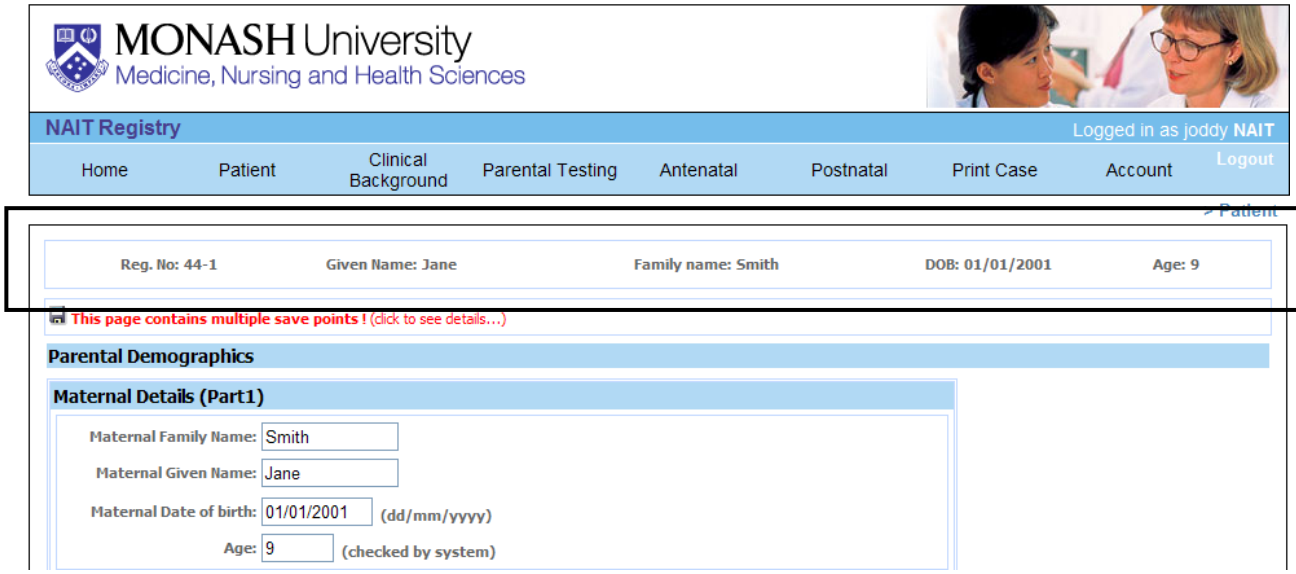


Figure 23: Patient details screen highlighting patient Information.

Parental Demographics Page

When entering a new case on the **Parental Demographics** Page, the **Main Menu** and **Patient List** are still hidden from view. The Patient Information is now visible because the patient exists on the database.

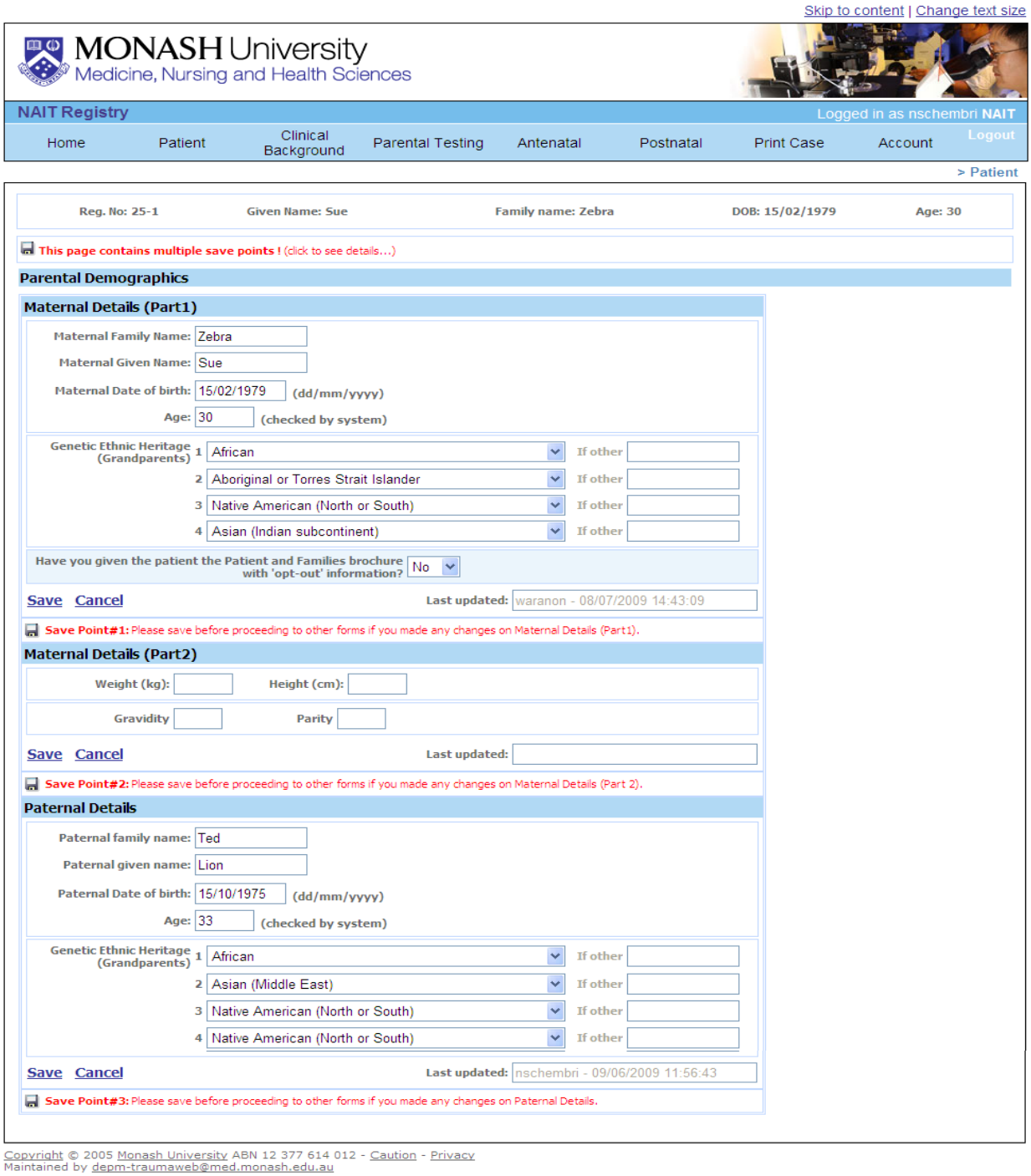


Figure 24 Parental Demographics Page with an example case.

A summary of the **Parental Demographics** data items and validation is displayed on the following page.

It is important to note that this page contains multiple save points. Data for each section must be saved independently in order for the information to be retained on the system. Any data not saved will be lost and required to be re-entered.

Parental Demographics Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Registry Number	Automatic	Automatic	—	—	Assigned on creation of patient or addition of new pregnancy to existing patient (see below)
Maternal Details: Family Name	Display only on this screen	Automatic	—	—	Populated with data from Screen 1
Maternal Details: Given Name	Display only on this screen	Automatic	—	—	Populated with data from Screen 1
Maternal Details: Date of Birth	Display only on this screen	Automatic	—	—	Populated with data from Screen 1
Maternal Details: Age	Always	Text Box	Numeric: Decimal (2)	-1	N/A
Maternal Details: Genetic Ethnic Heritage 1-4	Always	Four Drop Down Menu	Select from List	Unknown	N/A
Maternal Details: Weight (kg)	Always	Text Box	Numeric (Range 10-300)	-1	N/A
Maternal Details: Height (cm)	Always	Text Box	Numeric (Range 50-250)	-1	N/A
Maternal Details: Gravidity	Always	Text Box	Numeric (1-20)	-1	N/A
Maternal Details: Parity	Always	Text Box	Numeric (0-20)	-1	N/A
Paternal Details: Family Name	Always	Free Text	Alphanumeric	Unknown	N/A
Paternal Details: Given Name	Always	Free Text	Alphanumeric	Unknown	N/A
Paternal Details: Date of Birth	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	09/09/9999	N/A
Paternal Details: Genetic Ethnic Heritage 1- 4	Always	Four Drop Down Menu	Select from List	Unknown	N/A

Registry Number

The registry number is automatically generated on creation of a patient or addition of a new pregnancy to an existing patient. The registry number takes the form *xxxx-y* where *xxxx* is a unique patient number, assigned on registration, and *y* is the episode number, so for the patient's first pregnancy *y* is 1, second pregnancy *y* is 2 and so on.

Maternal Details: Family Name and Given Name

These fields will be automatically populated from the information provided in Screen 1.

Maternal Details: Date of Birth

This will be automatically populated from the information provided in Screen 1.

Maternal Details: Age

Maternal age in years at the time of diagnosis of NAIT.

Maternal Details: Genetic Ethnic Heritage (Grandparents)

People from different parts of the world have slight differences in the types and proportions of genetic traits. We are interested in finding out if NAIT is related to different genetic populations and consequently need to know about the ethnic origin of the patient. Because Australia is a diverse multicultural community, many people are born from parents of different ethnic background. A patient's parents themselves may be of mixed ethnic derivation. For this reason, we ask for ethnic heritage of each of the patient's four grandparents.

Patient origin is answered from a choice of four drop down menus, one for each grandparent. Each drop down menu contains the following choices:

- African
- Native American (north or south)
- Asian (Indian subcontinent)
- Asian (Middle East)
- Asian (other)
- European
- Polynesian/Melanesian (including New Zealand Maori)
- Aboriginal or Torres Strait Islander
- Other

Selection of **Other** allows free text entry of details.

It is important that this question is answered in terms of genetic ethnic origin rather than cultural identification. For example, a person may identify as French because they grew up in France even though their ancestry is African. In this instance **African** should be chosen rather than **European**.

You will notice that there is no option to choose "Australian", Australian citizens need to choose either **Aboriginal or Torres Strait Islander** or another relevant category, e.g. **European**.

Maternal Details: Weight

Maternal weight should be measured in kilograms (kg) and reported to the nearest 0.1kg.

Maternal Details: Height

Mother's height measured in centimetres (cm).

Maternal Details: Gravidity

This is the number of times the mother has been pregnant. For her first pregnancy the maternal gravidity =1, for her second pregnancy maternal gravidity =2 and so on. Miscarriage or abortion should still be included in the gravidity count.

Maternal Details: Parity

The total number of previous pregnancies experienced by the woman that have resulted in a live birth or a stillbirth. For example, if she has had three pregnancies that resulted in one live birth and two miscarriages before 20 weeks, her parity would be 1.

Paternal Details: Family Name and Given Name

This information should be collected about the father of the child where available.

Family Name should be recorded in the format preferred by the person. Punctuation: If special characters form part of the family name they should be included, e.g. hyphenated names should be entered with a hyphen. Please see Maternal Details for examples.

Some people do not have a family name and a given name; they have only one name by which they are known. If the person has only one name, record it in the 'Family Name' field and leave the 'Given Name' field blank.

Given name(s) should be recorded in the format preferred by the person. Punctuation: If special characters form part of the given name they should be included, e.g. hyphenated names should be entered with a hyphen. Please see Maternal Details for examples.

If the person's given name is not known, but the first letter (initial) of the given name is known, record the first letter in the preferred 'Given name' field. Do not record a full stop following the initial. Some people do not have a family name and a given name; they have only one name by which they are known. If the person has only one name, record it in the **Family Name** field and leave the **Given Name** blank.

Paternal Details: Date of Birth

If date of birth is not known or cannot be obtained, an estimated age in years should be used for adults. When date of birth is an estimated value use 0101 and the estimated year.

Paternal Details: Genetic Ethnic Heritage (Grandparents)

See explanation of Maternal Genetic Ethnic Heritage above.

Patient origin is answered from a choice of four drop down menus, one for each grandparent. Each drop down menu contains the following choices:

- African
- Native American (north or south)
- Asian (Indian subcontinent)
- Asian (Middle East)
- Asian (other)
- European
- Polynesian/Melanesian (including New Zealand Maori)
- Aboriginal or Torres Strait Islander
- Other

Selection of **Other** allows free text entry of details.

Clinical Background Page

When entering a new case on the **Clinical Background** Page, the **Main Menu** and **Patient List** are still hidden from view. The Patient Information is now visible because the patient exists on the database.

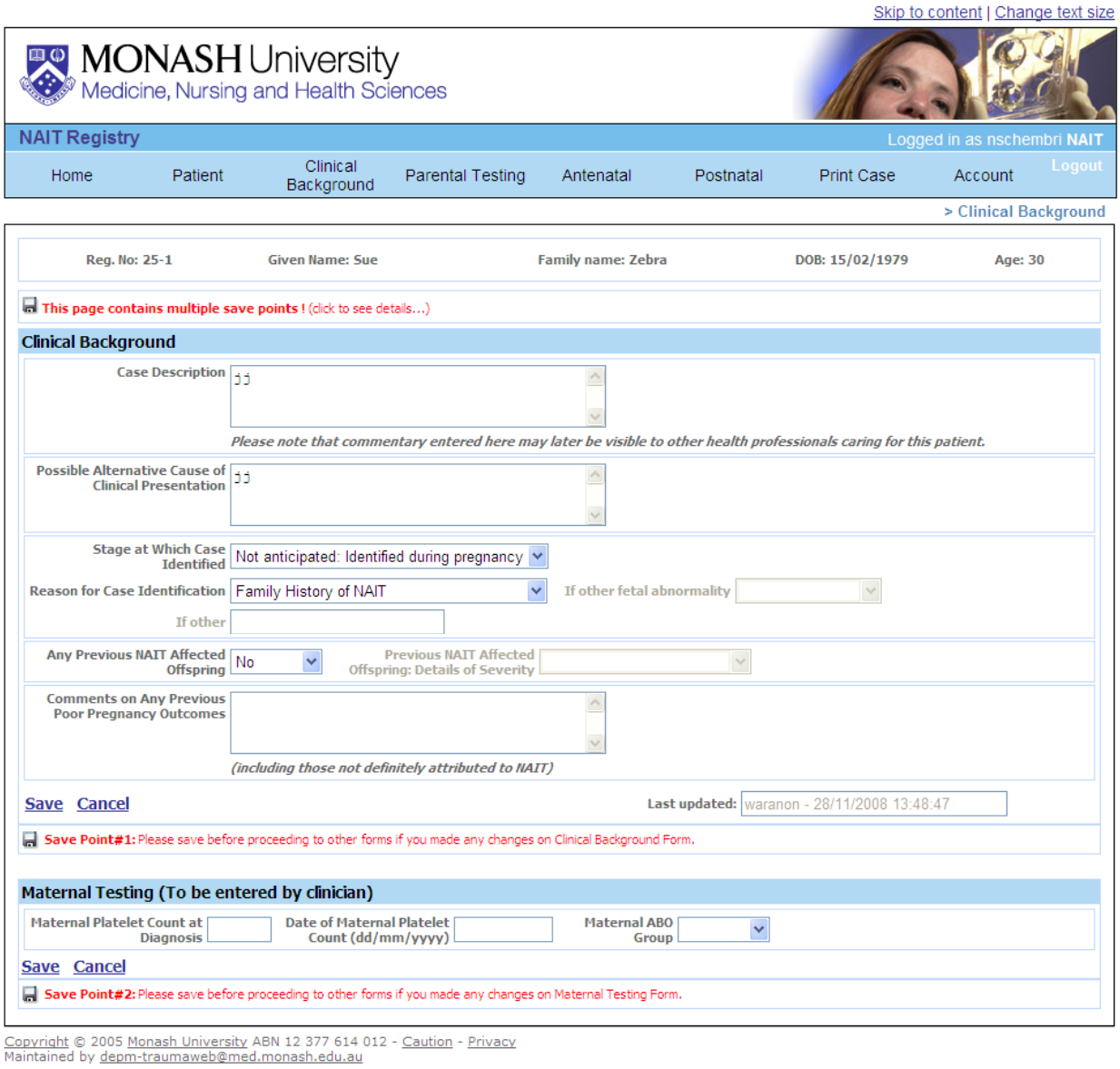


Figure 25 Clinical Background Screen with an example case.

The purpose of this page is to elucidate the context in which this case of NAIT was identified and to report on relevant clinical history.

Please note this page contains two save points. Each section must be saved separately for data to be retained on the system.

A summary of the Clinical Background data items and the validation that takes place is displayed on the next page.

Clinical Background Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Case Description	Always	Free Text	Alphanumeric	Not applicable	N/A
Possible Alternative Cause of Clinical Presentation	Optional	Free Text	Alphanumeric	Not applicable	N/A
Stage at Which Case Identified	Always	Drop Down Menu	•Anticipated prior to pregnancy •Not anticipated: Identified during pregnancy •Not anticipated: Identified following delivery	Not applicable	If "Not anticipated: Identified following delivery" is selected
Reason for Case Identification	Always	Drop Down Menu	•Family History of NAIT •Personal History of NAIT Affected Offspring •Thrombocytopenia in Fetus or Newborn •Bleeding in Fetus or Newborn •Other fetal abnormality •Other	Not applicable	If "Other Fetal Abnormality" is selected, a further field becomes available. Selection of "Other" allows free text entry of details
Other Fetal Abnormality Detail	If "Reason for Case Identification" = "Other fetal abnormality"	Drop Down Menu	•Hydrocephaly •Prosencephaly •Ventriculomegaly •Other	Not applicable	Selection of "Other" allows free text entry of details

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Any Previous NAIT Affected Offspring	Always	Drop Down Menu	•Yes •No •Unknown	Unknown	If "Yes" is selected "Details of severity" field becomes available
Previous NAIT Affected Offspring: Details of Severity	If "Any Previous NAIT Affected Offspring" ="Yes"	Drop Down Menu	•Mildly affected •Severely affected (live birth) •Intrauterine fetal death	Not applicable	N/A
Comments On Any Previous Poor Pregnancy Outcomes	Optional	Free Text	Alphanumeric	Not applicable	N/A
Maternal Platelet Count at Diagnosis	Always (Clinician)	Text Box	Numeric (0-2000)	-1	N/A
Date of Maternal Platelet Count	Always (Clinician)	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	09/09/9999	N/A
Maternal ABO Group	Always (Clinician)	Drop Down Menu	•A •B •O •AB •Unknown	Unknown	N/A

Case Description

A description of the case is required. This should be comprehensive but it should be noted that the commentary entered here may later be visible to other health professionals caring for this patient. This field should include a description of the initial reason for looking into the case, any procedures or tests undertaken, and the course of treatment. Please also include specific information on why the treatment course taken was considered appropriate and when in the course of pregnancy this treatment was given. We are interested to gain some sort of understanding as to why certain treatments are given to treat NAIT, when during pregnancy, and the factors that may influence these treatment decisions.

For example, it is not sufficient to give the case description as "Pregnancy x 2", instead here are some useful examples of a case description…

"First pregnancy was complicated by NAIT – sibling was born with severe thrombocytopenia diagnosed after delivery when they were found to have petechiae but no intracranial haemorrhage or other bleeding complication. This is the second pregnancy (G2P2). Mother was treated with IVIg 2g/kg/week from 14 weeks as this was considered a high risk pregnancy. FBS was performed at 22/40 and again prior to delivery. No IUT required, IVIg was continued throughout the pregnancy. Baby born by caesarean section at 36 weeks."

"First pregnancy (G1P1) with no known complications prior to delivery. Emergency caesarean section performed for fetal distress. Baby was small for gestation (2.4kg). Baby was noted to have petechiae and facial bruising. First FBE was done at 24 hours – baby was found to be thrombocytopenic (platelet count 13). No evidence of an intrauterine infection or congenital disorder. Other FBE indices (Hb, WCC) were normal. No evidence of intracranial haemorrhage on ultrasound. Mother had a normal platelet count and no history of autoimmune disease. Baby was treated with 2 platelet transfusions and a single dose of IVIg (because of the degree of thrombocytopenia) and did not have any haemorrhagic complications."

Possible Alternative Cause of Clinical Presentation

This field is optional. If there is a possible cause for the clinical presentation other than NAIT identified, then this should be entered here. For some patients it will be **Not applicable** as there will be no alternative cause of clinical presentation other than NAIT.

For example, if the clinical presentation was neonatal thrombocytopenia diagnosed after delivery and another cause of thrombocytopenia was identified, such as sepsis, then this should be entered in this field. If there was no other cause for the thrombocytopenia identified, then an entry in this field is not required.

Stage at Which Case was Identified

This is to document when during the course of the pregnancy or post-natal period NAIT was first suspected or diagnosed. The following options are available from the drop down menu:

ANTICIPATED PRIOR TO PREGNANCY

It was identified prior to pregnancy that the baby was at risk of NAIT. This may be because of personal history (prior offspring affected by NAIT) or family history.

NOT ANTICIPATED: IDENTIFIED DURING PREGNANCY

There was no relevant past history to indicate the pregnancy was at risk of NAIT. NAIT was suspected or diagnosed during the pregnancy (for example if the fetus developed a complication due to thrombocytopenia such as an intracranial haemorrhage).

NOT ANTICIPATED: IDENTIFIED FOLLOWING DELIVERY

There was no relevant past history to indicate the pregnancy was at risk of NAIT. NAIT was suspected or diagnosed following delivery (for example, bruising or petechiae observed on baby after delivery).

If NAIT was **Not Anticipated: Identified following delivery** then later antenatal screens (refer page 41) are not available for data entry.

Reason for Case Identification

This is to report why or how the case was identified; only one option can be selected. The following options are available from the drop down menu:

FAMILY HISTORY OF NAIT

This option should be chosen if anyone in the patient's (or their partner's) immediate family (children, parents, siblings or grandparents) has ever been diagnosed with NAIT or produced NAIT affected offspring.

PERSONAL HISTORY OF NAIT AFFECTED OFFSPRING

This mother has given birth or miscarried offspring affected by NAIT.

THROMBOCYTOPENIA IN FETUS OR NEWBORN

This option should be selected if NAIT was identified after thrombocytopenia was detected in the fetus or newborn. Thrombocytopenia refers to a low platelet count and is diagnosed by laboratory tests. The most common symptoms of thrombocytopenia include bruising, petechiae (small red spots on the skin) and signs of bleeding in sites. This option should only be chosen if thrombocytopenia is confirmed by laboratory tests but other adverse consequences (such as bleeding) are not present.

BLEEDING IN FETUS OR NEWBORN

This option should be selected if NAIT was identified as a result of bleeding either in the fetus or neonate. For example, if NAIT was diagnosed following the finding of thrombocytopenia and intracranial haemorrhage in a newborn.

OTHER FETAL ABNORMALITY

Selection of this option will allow a further field to be accessed for details of the abnormalities.

OTHER

Selection of this option will allow a further field to be accessed for other details.

Other Fetal Abnormality

The following options are available from the drop down menu:

HYDROCEPHALY

Also known as hydrocephalus, this is an abnormal buildup of cerebrospinal fluid (CSF) in the ventricles of the brain.

PROSENCEPHALY

A very rare condition involving abnormal development of the forebrain.

VENTRICULOMEGALY

This is a brain condition that occurs when the lateral ventricles become dilated. The most common definition uses a width of the atrium of the lateral ventricle of greater than 10 mm.

OTHER

If none of the options above adequately describes the reasons for the case identification then this option should be selected. Selection of this option will allow a free field for data entry to explain the case identification.

Any Previous NAIT Affected Offspring

NAIT affected offspring include all pregnancies, whether resulting in live births or not, in which NAIT has been suspected or confirmed. Selection of **Yes** will allow details to be entered in the following fields. From the drop down menu the following options are available:

- Yes
- No
- Unknown

Previous NAIT Affected Offspring: Details of Severity

This field becomes available if **Yes** is selected in the **Any Previous NAIT affected offspring** field. If multiple offspring have been affected please choose the most severe relevant option and include details of all affected offspring in the following field **Comments on Any Previous Poor Pregnancy Outcomes**.

This field will bring up the following options from a drop down menu:

MILDLY AFFECTED

Includes neonates that have isolated mild or moderate thrombocytopenia with no haemorrhagic complications and no long-term morbidity.

SEVERELY AFFECTED (LIVE BIRTH)

Includes neonates with severe thrombocytopenia and / or major haemorrhagic complication due to NAIT (e.g. intracranial haemorrhage).

INTRAUTERINE FETAL DEATH

Fetal death in utero. This includes miscarriages and still births.

Comments on Any Previous Poor Pregnancy Outcomes

This field is optional and will only apply to some cases. If the patient has had a previous poor pregnancy outcome then a comprehensive description of the case is required. Please refer to **Case Description** section on the previous page for examples of appropriate level of detail for case descriptions. If multiple offspring have been affected, please include details of all pregnancies and outcomes.

Maternal Platelet Count at Diagnosis

Maternal Platelet Count must be entered by the diagnosing clinician in the units $x10^{9.}$

Date of Maternal Platelet Count (DD/MM/YYYY)

This is the date the maternal platelet count was obtained. This date should not be earlier than the Date of Diagnosis.

Maternal ABO Group

Maternal ABO blood group is to be filled out by the treating clinician. The following options are available from the drop down menu:

- A
- B
- O
- AB
- Unknown

Parental Testing Page

When entering a new case on the **Parental testing Page**, the **Main Menu** and **Patient List** are still hidden from view. The Patient Label is able to be viewed as the patient exists on the database.

For every State except Western Australia (WA), details for this page will be entered onto the NAIT database directly by the Australian Red Cross Blood Service (ARCBS). When a new case is registered, the ARCBS laboratory will automatically be requested to enter the test results directly onto the Database. In Western Australia, testing for NAIT is undertaken by the Royal Perth Hospital laboratory. When a new case from WA is registered, the Royal Perth Hospital laboratory will be automatically requested to enter test results directly onto the Database.

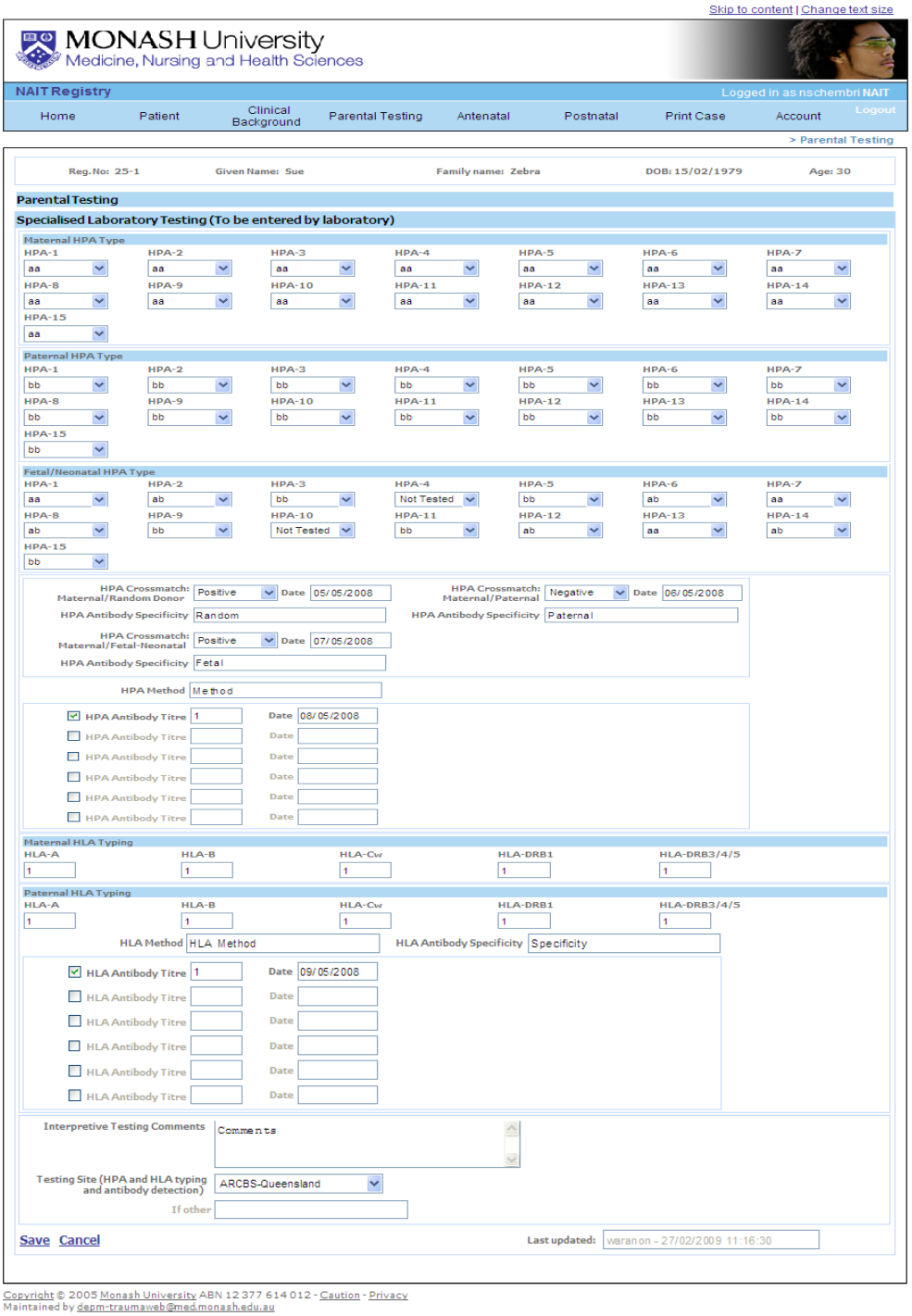


Figure 26 Parental Testing Page in New Case Mode.

A summary of the **Parental Testing** data items and the validation that takes place is displayed on the next page, with more specialised behaviours referenced in the last column.

Parental Testing Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Maternal HPA Type	Always	Multiple Drop Down Menus (Row): HPA 1-15(arrange in row)	(for each type) •AA •AB •BB • Not Tested	Not applicable	Default "Not Tested"
Paternal HPA Type	Always	Multiple Drop Down Menus (Row): HPA 1-15 (arrange in row)	(for each type) •AA •AB •BB •Not Tested	Not applicable	Default "Not Tested"
Fetal/Neonatal HPA Type	Always	Multiple Drop Down Menus (Row) HPA 1-15(arrange in row)	(for each type) •AA •AB •BB •Not Tested	Not applicable	Default "Not Tested"
HPA Crossmatch: Maternal/Random Donor	Always	Drop Down Menu	•Positive •Negative •Not tested	Not applicable	Default "Not Tested"
Date if "HPA Crossmatch: Maternal/Random Donor" = "Positive" or "Negative"	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	09/09/9999	N/A
HPA Antibody Specificity	Optional	Text Box	Alphanumeric	Not applicable	N/A
HPA Crossmatch: Maternal/Paternal	Always	Drop Down Menu	•Positive •Negative •Not tested	Not applicable	Default "Not Tested"

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Date if "HPA Crossmatch: Maternal/Paternal" = "Positive" or "Negative"	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	09/09/9999	N/A
HPA Antibody Specificity	Optional	Text Box	Alphanumeric	Not applicable	N/A
HPA Crossmatch: Maternal/ Fetal-Neonatal	Always	Drop Down Menu	•Positive •Negative •Not tested	Not applicable	Default "Not Tested"
Date if "HPA Crossmatch: Maternal/ Fetal-Neonatal" = "Positive" or "Negative"	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	09/09/9999	N/A
HPA Antibody Specificity	Optional	Text Box	Alphanumeric	Not applicable	N/A
HPA Method	Optional	Text Box	Alphanumeric	Not applicable	N/A
HPA Antibody Titre	Optional	Multiple check and text boxes	Numeric (1-2048)	-1	If "check box" selected text must be entered and date field becomes available
HPA Antibody Titre Date Required if "HPA Antibody Titre" check boxes are selected	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	09/09/9999	N/A

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Maternal HLA Typing	Always	Five text boxes: HLA-A HLA-B HLA-Cw HLA-DRB1 HLA-DRB3/4/5 (Arrange in row)	Numeric (1-9999)	-1	N/A
Paternal HLA Type	Always	Five text boxes: HLA-A HLA-B HLA-Cw HLA-DRB1 HLA-DRB3/4/5 (Arrange in row)	Numeric (1-9999)	-1	N/A
HLA Method	Always	Text Box	Alphanumeric	Not applicable	N/A
HLA Antibody Specificity	Optional	Text Box	Alphanumeric	Not applicable	N/A
HLA Antibody Titre	Optional	Multiple check and text boxes	Numeric (1-2048)	-1	If check box selected text must be entered and date field becomes available
HPA Antibody Titre Date Required if “HPA Antibody Titre” check boxes are selected	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	09/09/9999	N/A

Interpretive Testing Comments	Optional	Free Text	Alphanumerical	Not Applicable	N/A
Testing Site (HPA and HLA typing and antibody detection)	Always	Drop Down Menu	•ARCBS-New South Wales •ARCBS-Queensland •VTIS-Victoria •Royal Perth Hospital •Other •Not Applicable	Not Applicable	Selection of "Other" allows free text entry of details

The following data items will automatically be filled out by ARCBS for all States except WA.

MATERNAL HPA TYPE

Human Platelet Antigens (HPA) are expressed on platelets. They are inherited as paired alleles – i.e. one from each parent. They are classified numerically (1 to 15) according to the date of discovery and in alphabetical pairs according to the allele frequency ('a' for high frequency, 'b' for low frequency). The maternal HPA type is the mothers' allele type for HPA antigens 1 – 15 (for example, for HPA 1 the allele type options include aa, ab or bb). HPA typing is only performed at reference laboratories (including the Australian Red Cross Blood Service).

PATERNAL HPA TYPE

As per maternal HPA type.

FETAL/NEONATAL HPA TYPE

As per maternal HPA type.

HPA CROSSMATCH: MATERNAL/RANDOM DONOR

This is the result of testing performed at a reference laboratory. This test involves the use of maternal serum with random donor platelets to determine compatibility.

HPA CROSSMATCH: MATERNAL/PATERNAL

This is the result of testing performed at a reference laboratory. This test involves the use of maternal serum with paternal platelets to determine compatibility.

HPA CROSSMATCH: MATERNAL/FETAL-NEONATAL

This is the result of testing performed at a reference laboratory. This test involves the use of maternal serum with fetal/neonatal platelets to determine compatibility.

HPA ANTIBODY SPECIFICITY

If a HPA antibody was detected, the specificity of this antibody should be entered in this field. For example, if the antibody is specific for HPA 1a.

HPA METHOD

This refers to the method of testing used to determine the maternal and paternal HPA type.

HPA ANTIBODY TITRE

This is the result of the HPA antibody titre (a measure of the concentration of antibody present).

MATERNAL HLA TYPING

This is the result of testing for maternal Human Leukocyte Antigen (HLA) typing. HLA antigens include class I and class II antigens. Results of typing for HLA antigens -A, -B, -C and –DRB are to be entered in this field. HLA typing is only performed at reference laboratories.

PATERNAL HLA TYPING

This is the result of paternal Human Leukocyte Antigen (HLA) typing. Results of typing for HLA antigens -A, -B, -C and –DRB are to be entered in this field.

HLA METHOD

This refers to the method used to determine the maternal and paternal HLA typing.

HLA ANTIBODY SPECIFICITY

If a HLA antibody was detected, the specificity of this antibody should be entered in this field.

HLA ANTIBODY TITRE

This is the result of the HLA antibody titre (a measure of the concentration of antibody present).

INTERPRETIVE TESTING COMMENTS

This refers to comments on the testing results provided by the reference laboratory.

TESTING SITE (HPA AND HLA TYING AND ANTIBODY DETECTION)

This is the reference laboratory which performed the HPA and HLA typing and antibody detection testing.

Antenatal Clinical Details Page

When entering a new case on the **Antenatal Clinical Details** Page, the **Main Menu** and **Patient List** are still hidden from view. The Patient Information is now visible because the patient now exists in the database

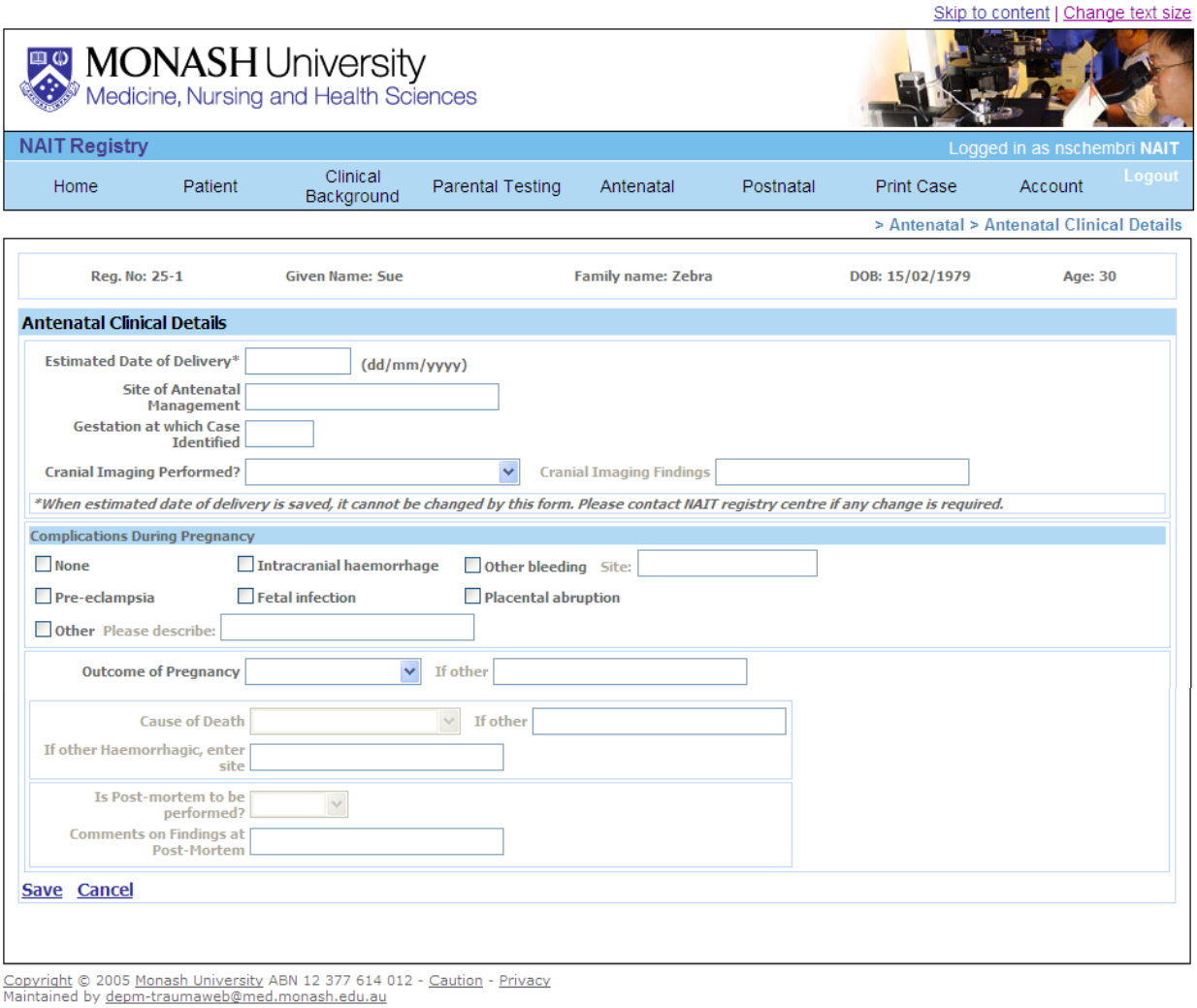


Figure 27 Antenatal Clinical details Page with an example case.

This page is not available if it has been indicated that the case was identified post-natally.

A summary of the **Antenatal Clinical Details** data items and the validation that takes place is displayed on the next page.

Antenatal Clinical Details Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Estimated Date of Delivery	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/2001)	09/09/9999	When "estimated date of delivery" is saved it cannot be changed by the user. Please contact NAIT Registry staff to make changes.
Site of Antenatal Management	Always	Free text	Alphanumeric	Not applicable	N/A
Gestation at which Case Identified	Always	Text Box	Numeric (0-50)	-1	N/A
Cranial Imaging Performed?	Always	Drop down menu	•Ultrasound •Magnetic Resonance Imaging •MRI along with CI and Ultrasound •Not Performed •Unknown	Unknown	If "Ultrasound" or "Magnetic Resonance Imaging" or "MRI with CI and Ultrasound" are selected, the field "Cranial Imaging Findings" field becomes available
Cranial Imaging Findings	Required if "Cranial Imaging Preformed" = "Ultrasound" or "Magnetic Resonance Imaging" or "MRI with CI and Ultrasound"	Free Text	Alphanumeric	Not applicable	N/A

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Complications During Pregnancy	Always	Check box (one or many)	•None •Intracranial haemorrhage •Other bleeding •Pre-eclampsia •Fetal infection •Placental abruption •Other	Not applicable	Selection of "None" renders other options unavailable. If "Other Bleeding" is selected, the 'Other Bleeding Site" field becomes available. If "Other" is selected the "Other: Please describe" field becomes available.
Other Bleeding Site	Required if "complications During Pregnancy" = "Other bleeding"	Free text	Alphanumeric	Not applicable	N/A
Outcome of Pregnancy	Always	Drop down menu	•Pregnancy Ongoing •Fetal Death in Utero •Live Birth •Other •Unknown	Unknown	If "Fetal Death in Utero" is selected, "Cause of Death" and related fields become available, Postnatal Clinical Details and Postnatal Therapy Screens become unavailable. If "Pregnancy Ongoing" is selected, Postnatal Clinical Details and Postnatal Therapy Screens are not available. If "Other" is selected "Other details" field becomes available.

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Cause of Death	Required if "Outcome of Pregnancy" = "Fetal Death in Utero"	Drop down menu	•Intracranial Haemorrhage •Other Haemorrhagic •Other •Unknown	Not applicable	If "Other Haemorrhagic" is selected "Other Haemorrhage site" field becomes available. If "Other" is selected "Other details" field becomes available.
Other haemorrhage site	Required if "Cause of Death" = "Other"	Free text	Alphanumeric	Unknown	N/A
Is Post-mortem to be performed?	If "Outcome of Pregnancy" = "Fetal Death in Utero"	Drop down menu	•Yes •No •Unknown	Unknown	If "Yes" is selected in the "Post-Mortem to be preformed?" field "Comments on Findings at Post-Mortem" becomes available
Comments on Findings at Post-Mortem	Optional If "Is Post Mortem to Be Performed?" = Yes	Free text	Alphanumeric	Not applicable	N/A

Estimated date of delivery

This is the estimated date the mother will give birth if she is still pregnant with the child. This field cannot be altered by the user once it is saved. If changes are required please contact NAIT Registry staff.

Site of antenatal management

Some NAIT pregnancies will be managed at sites other than those where definitive management of the birth or neonate takes place, particularly in situations where the patient resides in a different location. This is a free text box for entry of location of antenatal management.

Gestation at which case is identified

The number of gestation weeks for this pregnancy, at which time the diagnosis of NAIT is made. This date should correspond to the date of diagnosis.

Cranial imaging performed?

Cranial Imaging of the fetus in utero may be used to assess whether intracranial haemorrhage has occurred. A drop down menu will include the following options:

ULTRASOUND

> Ultrasound is a medical imaging technique that uses cyclic sound pressure with a frequency greater than the upper limit of human hearing.

MAGNETIC RESONANCE IMAGING

> Magnetic Resonance Imaging (MRI), or nuclear magnetic resonance imaging (NMRI), is primarily a medical imaging technique most commonly used in radiology to visualize the internal structure and function of the body.

NOT PERFORMED

> Select this option if no Cranial Imaging was performed.

UNKNOWN

> Select this option if **Cranial Imaging was performed** is unknown.

Cranial imaging findings

This field will become available if either **Ultrasound** or **Magnetic Resonance Imaging** are selected above. A summary of the findings of these investigations should be included.

Complications during pregnancy

Complications arising up to the period immediately preceding delivery should be included. The complications may have significantly affected either care of the patient or fetus during the current pregnancy and/or pregnancy outcome.

One or more boxes must be checked in this field.

The following options are available:

NONE

If this option is selected, all other choices are rendered unavailable.

INTRACRANIAL HAEMORRHAGE

An intracranial haemorrhage is a haemorrhage, or bleeding, within the skull. Select this option if a diagnosis of intracranial haemorrhage in the fetus has been made including fetal death in utero from this cause.

OTHER BLEEDING

This option should be chosen if bleeding other than intracranial haemmorhage has been identified in the fetus including fetal death in utero from this cause. Selection of this option makes available the **Other Bleeding Site** field.

PRE-ECLAMPSIA

Pre-eclampsia (sometimes also referred to as Toxemia) is a complex disorder characterized by hypertension (elevated blood pressure) and proteinuria (urine in the protein) developing after 20 weeks gestation. Pre-eclampsia is present in about 5-10% of all pregnant women and approximately 10-15% of these develop thrombocytopenia. Pre-eclampsia is also implicated in the destruction of fetal platelets and may result in fetal thrombocytopenia.

FETAL INFECTION

This includes infections acquired in utero or during the birth process. These include the TORCH infections (toxoplasmosis, rubella, cytomegalovirus and herpes simplex virus) and other infections including both viral and bacterial (e.g. group B streptococcus). Fetal infection may result in both decreased production and increased destruction of fetal platelets causing thrombocytopenia.

PLACENTAL ABRUPTION

Placental abruption is a complication of pregnancy, wherein the placental lining separates either partially or completely from the uterus of the mother. It is the most common cause of late pregnancy bleeding. Placental abruption may be associated with maternal coagulopathy including thrombocytopenia and disseminated intravascular coagulopathy (DIC).

OTHER

Selection of this option makes available the **Pregnancy Complications Other Details** field.

Outcome of Pregnancy

This field records the outcome of the current pregnancy. A drop down menu will include the following options:

PREGNANCY ONGOING

When data entry for a case commences, the pregnancy may still be ongoing and this option should be selected. This field should be revised later to indicate final outcome. If the **Pregnancy Ongoing** field is selected then **Postnatal Clinical Details** and **Postnatal Therapy** Screens will not be made available.

FETAL DEATH IN UTERO

Fetal death in utero is defined as the death of a fetus at any time after the 20th week of pregnancy and /or weight of 500g or more. If **Fetal Death in Utero** box is selected then **Cause of Death** fields will become available. The Postnatal Clinical Details and Postnatal Therapy Screens will not be available.

LIVE BIRTH

A live birth occurs when a fetus, whatever its gestational age, exits the maternal body and subsequently shows any sign of life, such as voluntary movement, heartbeat, or pulsation of the umbilical cord, for however brief a time and regardless of whether the umbilical cord or placenta are intact.

OTHER

Selection of **Other** will produce a free text box for data entry.

UNKNOWN

Select this option if outcome of pregnancy is unknown.

Cause of Death

If **Fetal Death in Utero** is checked then **Cause of Death** and **Is post-mortem to be performed?** fields become available. A drop down menu will produce the following options:

INTRACRANIAL HAEMORRHAGE

Intracranial haemorrhage is haemorrhage or bleeding within the skull.

OTHER HAEMORRHAGIC

Selection of this option makes available the **Other Haemorrhage site** field for data entry.

OTHER

Selection of this option will produce a free text box for data entry.

UNKNOWN

Select this option if cause of fetal death in utero is unknown.

Is Post-mortem to be performed?

This field will only be available if the **Fetal death in Utero** is selected in **Outcome of Pregnancy** box. A drop down menu will provide the following options:

- Yes
- No
- Unknown

Comments on Findings at Post-Mortem

This field will become available if **Yes** is selected in the **Post-Mortem to be Performed** field. It allows free text entry of post-mortem details. When initial data entry is completed, findings from the post mortem may not yet be available, if so, leave this field blank. A red flag **### Post-mortem findings needs to be completed ###** is shown. Once post-mortem findings are available, they should be entered. NAIT registry staff will receive an automatic notification if this field remains blank for three months and will follow up with users to remind them to complete this field.

Antenatal Testing and Therapy Page

When entering a new case on the **Antenatal Testing and Therapy** Page, the **Main Menu** and **Patient List** are still hidden from view. The Patient Information is now visible because the patient exists on the database.

This page enables entry of multiple events of antenatal test or treatments.

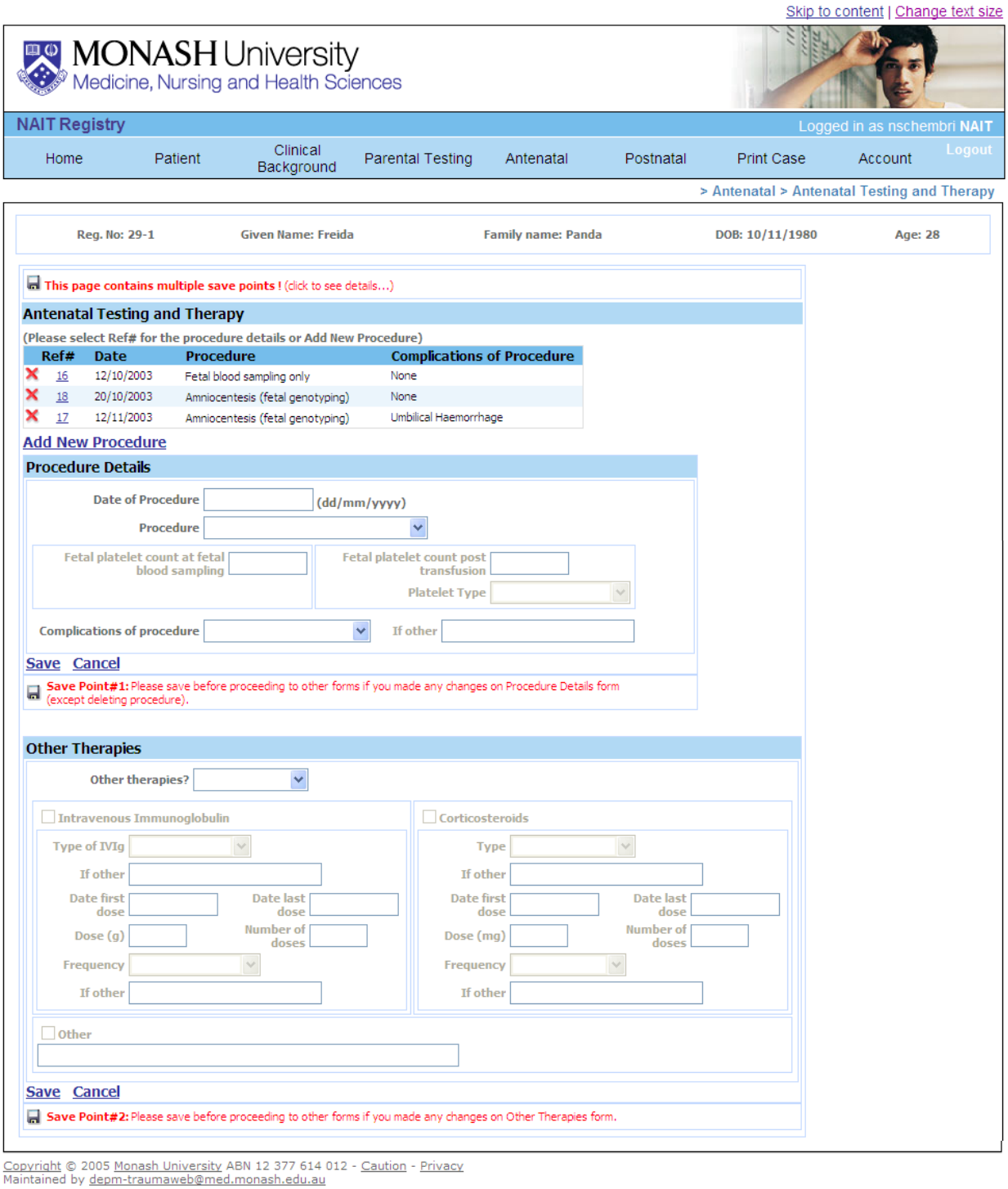


Figure 28: Antenatal testing and therapy page with an example case.

When accessed for the first time, no therapy will have been entered under the heading **Antenatal Testing and Therapy.** The following will appear; "there is no therapy, record for the patient selected". Details of testing or treatment procedures should be entered and saved. A summary of the details will then appear as shown in the figure above. Each new procedure is assigned a reference number which is shown on the left of the date the procedure was performed. Procedures may be deleted by clicking the red cross to the left of the procedure reference number, or edited by clicking on the reference number. The button **Add New Procedures** should be selected to add a subsequent procedure. Other therapies can also be included on this page.

Please note this page contains two save points. Each section must be saved separately for data to be retained on the system. A summary of the Antenatal Testing and Therapy data items and the validation that takes place is displayed on the next page.

Antenatal Testing and Therapy Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Date of Procedure	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/2001)	09/09/9999	N/A
Procedure	Always	Drop Down Menu	•Fetal blood sampling only •Platelet transfusion •Amniocentesis (fetal genotyping) •Not applicable	Not applicable	If "Fetal blood sampling only" is selected "fetal blood sampling" field becomes available. If "Platelet transfusion" is selected "fetal platelet count post transfusion" and "Platelet type" fields become available
Fetal platelet count at fetal blood sampling	If "Procedure" = "Fetal blood sampling only"	Text Box	Numeric (0-1000)	-1	N/A
Fetal platelet count post transfusion	If "Procedure" = "Platelet transfusion"	Text Box	Numeric (0-1000)	-1	N/A
Platelet Type	If "Procedure" = "Platelet transfusion"	Drop Down Menu	•HPA Matched •Non-HPA Matched •Maternal •Unknown	Unknown	N/A
Complications of procedure	Always	Drop Down Menu	•None •Umbilical Haemorrhage •Bradycardia •Cardiac Arrest •Fetal Death •Other •Not applicable	Not applicable	If "Other" is selected the "Other details" field becomes available

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Other therapies	Always	Drop down Menu	•Yes •No •Not Applicable	Not Applicable	If selected related fields become available
Intravenous Immunoglobulin	Optional if "Other Therapies?" = "Yes"	Check box	N/A	N/A	Selection of "Other" at either point gives free text box to specify
Type of IVIg	If "Intravenous Immunoglobulin" is selected	Drop Down Menu	•Intragam®P •Octagam® •Sandoglobulin® •Other	Chose "Other"	If "Other is selected "Other Details" field becomes available
Date first dose	If "Intravenous Immunoglobulin" is selected	DD/MM/YYYY	Date (Range since 01/01/2001)	09/09/9999	N/A
Date last dose	If "Intravenous Immunoglobulin" is selected	DD/MM/YYYY	Date (Range since 01/01/2001)	09/09/9999	N/A
Dose (g)	If "Intravenous Immunoglobulin" is selected	Text Box	Numeric (0-2000)	-1	N/A

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Number of doses	If “Intravenous Immunoglobulin” is selected	Text Box	Numeric (0-100)	-1	N/A
Frequency	If “Intravenous Immunoglobulin” is selected	Drop Down Menu	•Twice Weekly •Weekly •Alternate Weekly •Monthly •Other	Not applicable	If “Other is selected “Other Details” field becomes available
Corticosteroids	Optional if “Other Therapies?” = “Yes”	Check Box	N/A	Not applicable	If selected related fields become available
Type	If “Corticosteroids” is selected	Drop Down Menu	•Prednisolone •Hydrocortisone •Dexamethasone •Other	Not applicable	If “Other” selected “Other details” field becomes available
Date first dose	If “Corticosteroids” is selected	DD/MM/YYYY	Date (Range since 01/01/2001)	09/09/9999	N/A

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Date last dose	If “Corticosteroids” is selected	DD/MM/YYYY	Date (Range since 01/01/2001)	09/09/9999	N/A
Dose (mg)	If “Corticosteroids” is selected	Text Box	Numeric (0-2000)	-1	N/A
Number of doses	If “Corticosteroids” is selected	Text Box	Numeric (0-100)	-1	N/A
Frequency	If “Corticosteroids” is selected	Drop Down Menu	•Daily •Alternate Daily •Twice Weekly •Weekly •Other •Not applicable	Not Applicable	If “Other” selected “Other details” field becomes available

Date of procedure

This is the date of the specific antenatal procedure. Each procedure (i.e. antenatal test or therapy) should be entered separately.

Procedure

This refers to the antenatal procedure performed. Each antenatal procedure performed should be entered separately. From a drop down menu the following options are provided:

FETAL BLOOD SAMPLING ONLY

> Fetal blood sampling, also known as percutaneous umbilical blood sampling (PUBS), is a procedure to remove a small amount of blood from the fetus during pregnancy. If **Fetal blood sampling only** is selected then **Fetal platelet count** under **Fetal blood sampling** field becomes available.

PLATELET TRANSFUSION

> Platelet Transfusion here refers to the transfusion of platelets to the fetus while in Utero. If **Platelet transfusion** is selected then **Platelet Type**, and **Fetal Platelet Count Post-Transfusion** fields become available.

AMNIOCENTESIS (FETAL GENOTYPING)

> Amniocentesis is a medical procedure, in which a small amount of amniotic fluid, which contains fetal tissues, is extracted from the amnion or amniotic sac surrounding a developing fetus. The fetal DNA is then examined for genetic abnormalities.

Fetal platelet count at fetal blood sampling

This field is required if **Fetal blood sampling only** is selected as the procedure. The fetal platelet count on the date that fetal blood sampling was undertaken should be reported. If a subsequent fetal blood sample is taken, it should be entered as a separate procedure.

Fetal platelet count post transfusion

This field is required if **Platelet Transfusion** is selected as the procedure. The fetal platelet count most closely following the platelet transfusion should be reported here. If subsequent platelet transfusions are given, they should be entered as separate procedures.

Platelet type

This field is required if **Platelet Transfusion** is selected as the procedure. From a drop down menu the following options are provided for platelet type:

HPA MATCHED

> HPA matched or compatible platelets (usually collected by the Australian Red Cross Blood Service) are platelet concentrates collected from a donor who does not express the implicated platelet antigen. For example, for a case of NAIT due to maternal anti HPA 1a antibodies, matched platelets would be those from a donor who is HPA 1a negative. As the diagnosis of NAIT (and determination of the antibody specificity) may take some time, platelet concentrates that are negative for the platelet antigens most commonly implicated in NAIT cases (HPA 1a and HPA 5b) may be used. These should also be entered as HPA matched (even if the maternal platelet antigen type is not yet known).

NON-HPA MATCHED

This refers to platelet concentrates that have not been selected based on the HPA type of the donor. These include platelets collected by apheresis from a single donor and platelets pooled from multiple random donors (pooled platelet units).

MATERNAL

This refers to platelet concentrates that are collected from the mother (rather than from volunteer blood donors at ARCBS). These may be collected at the treating institution and require irradiation prior to transfusion.

UNKNOWN

This option can be selected if the type of platelet product (i.e. HPA matched, HPA unmatched or maternal) is not known.

Complications of Procedure

This refers to complications directly as a result of the antenatal procedure (antenatal test or therapy). From a drop down menu the following options are available:

NONE

Select this option if no complications are a direct result of antenatal procedures.

UMBILICAL HAEMORRHAGE

Bleeding from the umbilical cord due to the fetal blood sampling procedure or fetal platelet transfusion.

BRADYCARDIA

Fetal Bradycardia (slowed heartbeat, <100bmp) may occur in response to fetal blood sampling or transfusion.

CARDIAC ARREST

A cardiac arrest, also known as cardiopulmonary arrest or circulatory arrest, is the abrupt cessation of normal circulation of the blood due to failure of the heart to contract effectively during systole. In the context of fetal blood sampling or transfusion, cardiac arrest is an extreme form of fetal Bradycardia in which the fetal heart stops completely.

FETAL DEATH

This refers to fetal death as a result of the antenatal procedure.

OTHER

Other known complications of intrauterine procedures include intrauterine infection, premature rupture of membranes, emergency caesarean and others. Selection of this option will result in **Other Details** field becoming available.

Other Therapy

In some instances, as well as platelet transfusion, another therapy may also be prescribed. One or more of the following options can be selected and relevant details entered:

INTRAVENOUS IMMUNOGLOBULIN

Intravenous immunoglobulin (IVIg) is a blood product administered intravenously. It contains the pooled IGg immunoglobulin's (antibodies) extracted from the plasma of over one thousand blood donors. The use of IVIg by the mother during pregnancy is thought to reduce the severity of fetal thrombocytopenia in some cases.

Once this option is selected, the following data fields become available:

TYPE OF IVIg

The majority of IVIg used in Australia is the domestically produced Intragam®P. To guarantee an adequate, safe and secure supply the National Blood Authority has established contracts for the supply of two imported IVIg products; Octagam® and Sandoglobulin®. The following options are available:

- Intragam®P
- Octagam®
- Sandoglobulin®
- Other

If the patient received a combination of products, please choose **Other** and specify products and quantities.

DATE OF FIRST DOSE

Date of first antenatal IVIg dose is entered in the format DD/MM/YYYY.

DATE OF LAST DOSE

Date of last antenatal IVIg dose is entered numerically in the format DD/MM/YYYY.

DOSE

Dose volume should be entered in grams for each dose.

NUMBER OF DOSES

Please record the total number of doses the patient received in the antenatal period. Postnatal therapy is recorded elsewhere.

FREQUENCY

Please select the frequency of doses from:

- Twice weekly
- Weekly
- Alternate weekly
- Monthly
- Other

Selection of **Other** makes available **Other details** free text field.

CORTICOSTEROIDS

Corticosteroids are a type of hormone and are either produced by the adrenal cortex or synthesized. Steroids may be used either on their own or in combination with intravenous immunoglobulin therapy. Once this option is selected the following data fields become available:

TYPE

Commonly used corticosteroids are provided as the following options:

- Prednisolone
- Hydrocortisone
- Dexamethasone
- Other

Selection of **Other** makes available the **Other details** free text field.

DATE OF FIRST DOSE

Date of first antenatal corticosteroid dose is entered in the format DD/MM/YYYY.

DATE OF LAST DOSE

Date of last antenatal corticosteroid dose is entered in the format DD/MM/YYYY.

DOSE

Dose volume for each dose should be entered in mg.

NUMBER OF DOSES

Please record the total number of doses the patient received.

FREQUENCY

Will produce a drop down menu of the following options:

- Daily
- Alternate daily
- Twice weekly
- Weekly
- Other

Selection of **Other** makes available the **Other details** free text field.

Postnatal Demographics Page

Once the child has been born the **Postnatal Demographics** page should be completed.

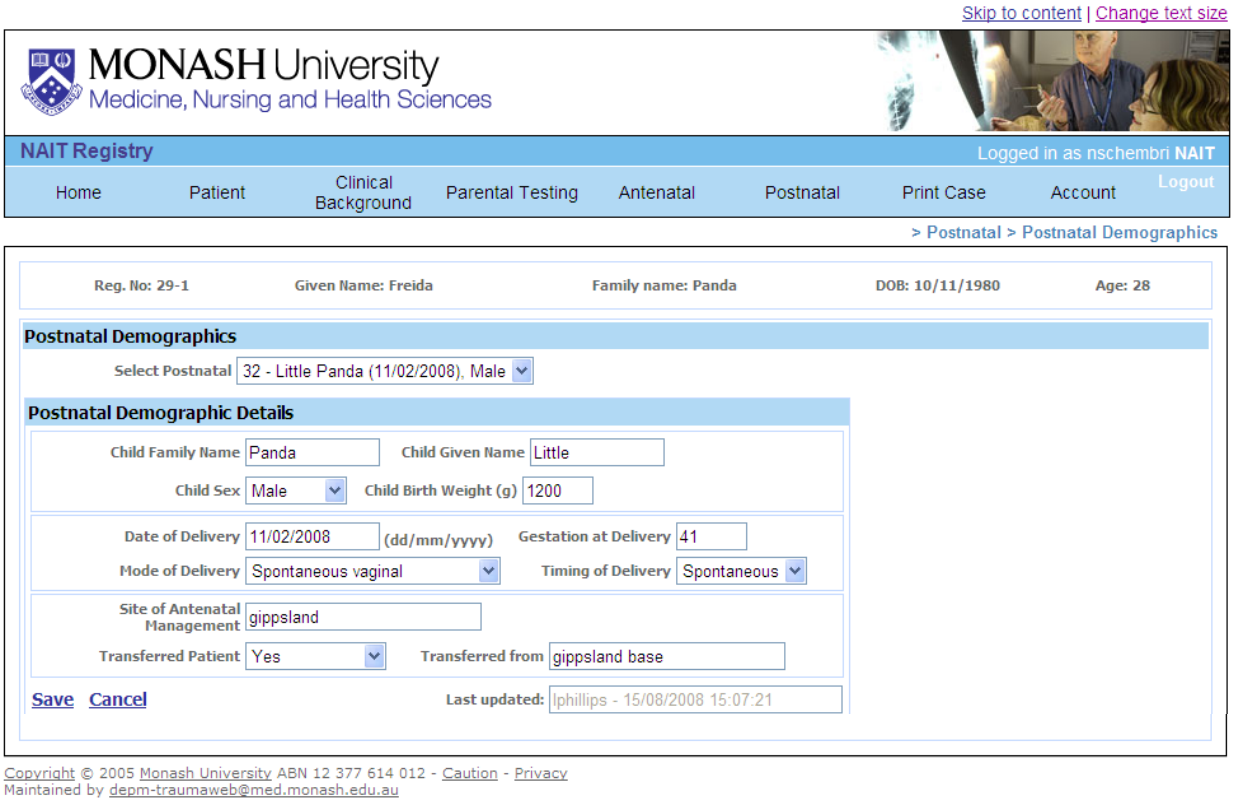


Figure 29: Postnatal Demographics Page with an example case.

When accessed for the first time for a patient, this page will be completely blank and the only option available under the heading **Postnatal Demographics** at the drop down list **Select Postnatal** will be **Add new**. Once details have be entered and saved, summary details of the baby will appear in this list. For multiple pregnancies, **Add new** can be selected again and details of a second or subsequent child recorded. Please note this only applies to multiple infants from the same pregnancy. Separate pregnancies from the same mother should be recorded as separate NAIT cases.

A summary of the **Postnatal Demographics** page data items and the method of data entry are displayed on the next page.

Postnatal Demographics Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Child Surname	Always	Free Text	Alphanumeric	Not applicable	N/A
Child Name	Always	Free Text	Alphanumeric	Not applicable	N/A
Child Sex	Always	Drop down menu	•Male •Female •Unknown	Not applicable	N/A
Child Birth Weight (g)	Always	Free Text	•Numeric (500-5000)	-1	N/A
Date of Delivery	Always	Text Box, DD/MM/YYYY	Date (Range since 01/01/1901)	Unknown values are not permitted for this field	N/A
Gestation at Delivery	Always	Free Text	Numeric (20-50)	-1	N/A
Mode of Delivery	Always	Drop down menu	•Spontaneous vaginal •Ventouse •Forceps •Caesarean (pre-labour) •Caesarean (after onset labour) •Unknown	Unknown	N/A
Timing of Delivery	Always	Drop down menu	•Spontaneous •Induced •Emergent •Unknown	Unknown	N/A
Site of Antenatal Management	Always	Free text	Alphanumeric	Not applicable	N/A
Transferred Patient	Always	Drop down menu	• Yes • No • Not applicable	Not applicable	If “Yes” selected, “Transferred From” field becomes available
Transferred From	Required if “Transferred Patient” = “Yes”	Free text	Alphanumeric	Not applicable	N/A

Child Family Name and Given Name

If the newborn does not yet have a name, use the mother's family name as the baby's family name. The given name should be registered using the mother's given name in conjunction with the prefix "Baby of". For example, if the baby's mother's given name is Fiona, the baby's name should be recorded as "Baby of Fiona". If a name is subsequently given, this field should be changed. An unnamed baby from a multiple birth should use their mother's given name plus a reference to the multiple births. For example "Twin 1 of Fiona" and "Twin 2 of Fiona" The following terms should be used for recording multiple births: Twin, Trip, Quad, Quin, Sext, and Sept.

Child Sex

From a drop down menu the following options are available:

- Male
- Female
- Unknown

Unknown should be used for babies for whom sex has not been determined for whatever reason.

Child Birth Weight

The first weight, in grams of the live-born or stillborn baby obtained after birth, or the weight of the neonate or infant on the date admitted if this is different from the date of birth and the former is not known.

Date of Delivery

Date on which the live-born or stillborn baby was born.

Gestation at Delivery

The estimated gestational age of the baby at the end of pregnancy in completed weeks, as determined by clinical assessment. The gestation at delivery may be determined using the date of the last menstrual period or based on an early fetal ultrasound. If accurate information on the date of the last menstrual period is not available and there was no early fetal ultrasound performed for this pregnancy, gestational age may be estimated by the clinician. For the purposes of calculation of gestational age from the date of the first day of the last normal menstrual period and the date of delivery, it should be kept in mind that the first day is day zero and not day one.

Mode of Delivery

From a drop down menu the following options are available:

SPONTANEOUS VAGINAL

Vaginal delivery with no assistance of instruments or surgical intervention.

VENTOUSE

Vacuum extraction device, or ventouse, may be used to assist the delivery of a baby when labour has not progressed adequately.

FORCEPS

Forceps are instruments designed to aid in the delivery of the fetus by applying traction to the fetal head. Many different types of forceps have been described and developed. Generally, forceps consist of 2 mirror image metal instruments that are manoeuvred to cradle the fetal head and are articulated, after which traction is applied to effect delivery. Where forceps are used to assist the extraction of the baby at caesarean section code as caesarean section.

CAESAREAN (PRE-LABOUR)

A caesarean delivery (also called a surgical birth) is a surgical procedure used to deliver an infant. It requires regional (or rarely general) anesthetic to prevent pain, and then a vertical or horizontal incision in the lower abdomen to expose the uterus (womb). Another incision is made in the uterus to allow removal of the baby and placenta.

Caesarean Section pre-labour may also be referred to as a planned or elective caesarean. There are a number of medical and obstetric indications for scheduling a caesarean delivery in advance, including the following examples: previous caesarean delivery, mechanical obstruction, unusually large infant, infection, multiple gestations, cervical cancer, infant has an increased risk of bleeding and placenta previa. In the setting of NAIT a caesarean delivery may be planned to avoid traumatic bleeding in a thrombocytopenic fetus.

CAESAREAN (AFTER ONSET LABOUR)

Some women who intend to deliver vaginally will eventually require caesarean delivery. Caesarean Section after the onset of labour may also be referred to as unplanned or emergency caesarean. Reasons for this include the following examples: labor is not progressing as planned, the baby's heart rate is not normal, breech birth, placental abruption, other medical emergency.

UNKNOWN

Select this option if **Mode of Delivery** is unknown.

Timing of Delivery

This field records the manner in which labour started. Labour commences at the onset of regular uterine contractions that act to produce progressive cervical dilation, and is distinct from spurious labour or pre-labour rupture of membranes. From a drop down menu the following options are available:

SPONTANEOUS

Labor beginning and progressing without mechanical or pharmacologic stimulation.

INDUCED

That which has been brought on by mechanical or other extraneous means, usually by the intravenous infusion of oxytocin or prostaglandins. If prostaglandins were given to induce labour and there is no resulting labour until after 24 hours, then code the onset of labour as spontaneous.

EMERGENT

Early delivery performed because of maternal or fetal compromise or an immediate threat to the life of the mother or fetus. This option should only be chosen in association with caesarean section deliveries.

UNKNOWN

Select this option if **Timing of Delivery** is unknown.

Site of Antenatal Management

The hospital or healthcare service where the mother received antenatal care may be different from the hospital at which perinatal or postnatal care was delivered. The site of care should be specified even if it is the same as the peri or postnatal care.

A free text box is available to include these details.

Transferred Patient

From a drop down menu the following options are available: **Yes** or **No**. If **Yes** is selected then a free text box is made available to specify where the patient was transferred from.

If the patient has been transferred, details may be entered twice, or more detail may be available from the other hospital. These fields allow us to cross-check or to follow-up where appropriate to ensure sufficient detail of total care is included in the Registry.

Postnatal Clinical and Testing Details Page

Once the child has been born the **Postnatal clinical and testing details** page must be filled out.

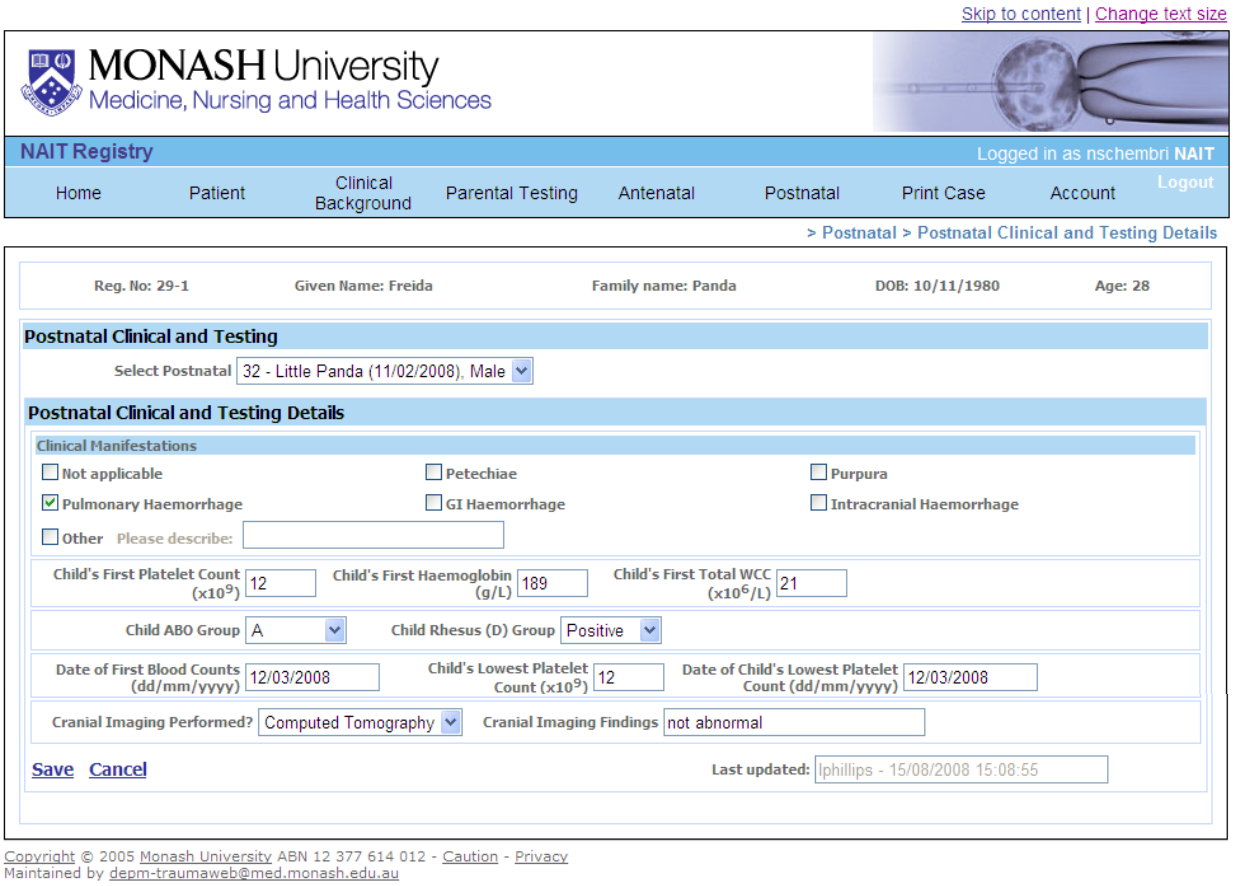


Figure 30: Postnatal Clinical and Testing details page with an example case.

When opened for the first time, this page will show details under the heading **Postnatal Clinical and Testing**, of the last infant entered on the previous page. If more than one infant has been added from this pregnancy, separate postnatal clinical and testing details can be added from each child by selecting them, in turn, from the drop down menu.

A summary of the **Postnatal Clinical and Testing Details** page data items, and the method of data entry, are displayed on the next page.

Postnatal Clinical and Testing Details Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Clinical Manifestations	Always	Check Box(One or many)	•Not applicable •Petechiae •Purpura •Pulmonary Haemorrhage •GI Haemorrhage •Intracranial Haemorrhage •Other	Not applicable	Selection of "Not applicable" renders all other options unavailable Selection of "Other" makes available "Other details" field
Child's First Platelet Count ($x10^9$)	Always	Text Box	Numeric (0-3000)	-1	N/A
Child First Haemoglobin (g/L)	Always	Text Box	Numeric (0-300)	-1	N/A
Child's First Total WCC ($x10^6$/L)	Always	Text Box	Numeric (0-100)	-1	N/A
Child ABO Group	Always	Drop Down Menu	•A •B •O •AB •Unknown	Unknown	N/A
Child Rhesus (D) Group	Always	Drop Down Menu	•Positive •Negative •Unknown	Unknown	N/A
Date of First Blood Counts	Always	Text Box, DD/MM/YYYY	Date (Must be as least as recent as date of delivery)	09/09/9999	N/A
Child's Lowest Platelet Count ($x10^9$)	Always	Text Box	Numeric (0-3000)	-1	N/A

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Date of Child's Lowest Platelet Count	Always	Text Box, DD/MM/YYYY	Date (Must be as least as recent as date of delivery)	09/09/9999	N/A
Cranial Imaging Performed?	Always	Drop down menu	•Computed Tomography •Ultrasound •Not Performed •Unknown	Unknown	If "computed Tomography" or "Ultrasound" are selected, "cranial Imaging Findings" becomes available
Cranial Imaging Findings	Required if "Cranial Imaging Performed?" = "Computed Tomography" or "Ultrasound"	Free Text	Alphanumeric	Not applicable	N/A

Clinical Manifestations

Frequently the thrombocytopenia in NAIT babies is mild and there may be none or few clinical symptoms. In cases with moderate to severe thrombocytopenia the infant may exhibit signs of bleeding such as petechiae or purpura. In up to 20% of NAIT affected infants there may be evidence of serious bleeding such as intracranial haemorrhage or pulmonary haemorrhage.

From a drop down menu the following options are available:

NOT APPLICABLE

This option should be selected if there are no clinical symptoms present.

PETECHIAE

A petechia is a small (1-2mm) red or purple spot on the body, caused by a minor haemorrhage (broken capillary blood vessels). Petechiae may be caused by physical trauma and are also seen in patients with thrombocytopenia.

PURPURA

Purpura is the appearance of red or purple discolorations on the skin that do not blanch on applying pressure. They are caused by bleeding underneath the skin. Purpura measure between 0.3 -1 cm. They are an indication that greater bleeding has occurred and may be the result of spontaneous bleeding or mild birth trauma in an infant with thrombocytopenia.

PULMONARY HAEMORRHAGE

Pulmonary haemorrhage refers to bleeding from the lung.

GI HAEMORRHAGE

Gastrointestinal bleeding or gastrointestinal haemorrhage includes any haemorrhage (loss of blood) in the gastrointestinal tract, from the pharynx to the rectum.

INTRACRANIAL HAEMORRHAGE

An intracranial haemorrhage is a haemorrhage, or bleeding, within the skull. Neonates with NAIT are thought to be at greater risk of intracranial haemorrhage within the first 72 hours after birth.

OTHER

Section of **Other** makes available the **Other Details** free text field.

Child's First Platelet Count

The first platelet count ($x10^9$) of the live-born infant obtained after the birth or the platelet count on admission, if the former is not known.

Child's First Haemoglobin Count

The first haemoglobin level (g/L) of the live-born infant obtained after the birth or the haemoglobin level on administration, if the former is not known.

Child's First Total WCC

The first total white cell count (WCC), ($x10^6$) of the live-born infant obtained after the birth or the total white cell count on admission, if the former is not known.

Child ABO Blood Group

The ABO blood group of the child. The ABO blood group system is the most important blood group system in blood transfusion. Blood types are inherited and represent contribution from both parents. Record here the child's ABO group phenotype from the following options:

- A
- B
- AB
- O
- Unknown

Child Rhesus (D) Group

The rhesus system is the second most significant blood group system in human blood transfusion. The rhesus (D) antigen is the most immunogenic of the five main rhesus antigens. Record here the child's Rhesus (D) group from the following options:

- Positive
- Negative
- Unknown

Date of First Blood Counts

The date refers to the platelet, haemoglobin and white cell counts above. If these tests were not all conducted on the same day please record the date of the platelet count. This date must be at least as recent as the child's delivery date.

Child's Lowest Platelet Count

The lowest recorded platelet count of the infant recorded during the hospital admission. In practice, this is likely to occur within the first 72 -96 hours following birth and platelet count usually returns to normal ranges within two weeks.

Date of Child's Lowest Platelet Count

This date refers to the platelet count above and must be at least as recent as the date of the child's delivery date.

Cranial Imaging Performed?

Cranial Imaging is used to assess if intracranial haemorrhage has occurred. From a drop down menu the following options are available:

COMPUTED TOMOGRAPHY

Computed tomography (CT) is a medical imaging method..

ULTRASOUND

Ultrasound is a medical imaging method.

NOT PERFORMED

Select this option if Cranial Imaging is not performed.

UNKNOWN

Select this option if it is not known whether cranial imaging has been performed.

Cranial Imaging Findings

If **Computed Tomography** or **Ultrasound** are selected in the previous field then this free text field becomes available. Please provide a summary of the cranial image results.

Postnatal Therapy Page

Once the child has been born the **Postnatal Therapy** page must be filled out.

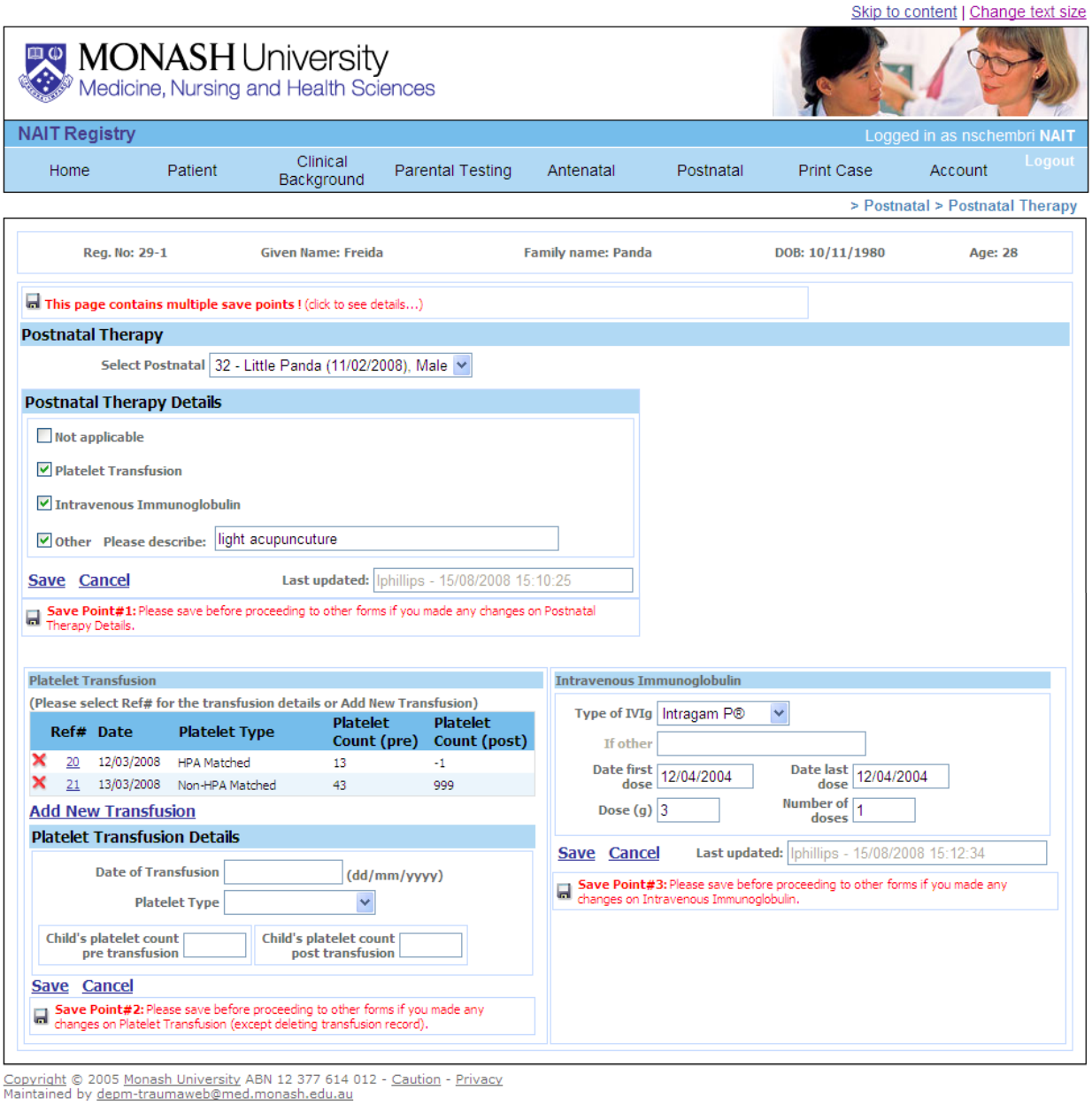


Figure 31: Postnatal Therapy page with an example case

When opened for the first time, this page will show details under the heading **Postnatal Therapy**, of the last infant entered on the previous page. If more than one infant has been added from this pregnancy, separate **Postnatal Therapy** details can be added from each child by selecting them in turn from the drop down menu.

Please note this page contains multiple save points. Each section must be saved separately for data to be retained on the system.

A summary of the **Postnatal Therapy** Page data items and the method of data entry are displayed on the next page.

Postnatal Therapy Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Postnatal Therapy Details	Always	Check Boxes(One or many)	•Not applicable •Platelet Transfusion •Intravenous Immunoglobulin •Other	Not Applicable	Selection of "Not applicable" renders remaining options unavailable. Selection of "Platelet Transfusion" or "Intravenous Immunoglobulin" makes available relevant fields for further details. Selection of "Other" makes available "Other Details" free text field.
Date of Transfusion	Required if "Platelet Transfusion" is selected in "Postnatal Therapy Details"	Text Box DD/MM/YYYY	Date must be equal to or later than date of birth	09/09/9999	Displayed in column, with ability to add additional column for additional transfusions.
Platelet Type	Required if "Platelet Transfusion" is selected in "Postnatal Therapy Details"	Drop Down Menu	•HPA Matched •Non-HPA Matched •Maternal •Unknown	Unknown	
Child's platelet count pre transfusion	Required if "Platelet Transfusion" is selected in "Postnatal Therapy Details"	Text Box	Numeric(0-1000)	-1	

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Child's platelet count post transfusion	Required if "Platelet Transfusion" is selected in "Postnatal Therapy Details"	Text Box	Numeric(0-1000)	-1	
Type of IVIg	Required if "Intravenous Immunoglobulin" is selected in "Postnatal Therapy Details"	Drop Down Menu	•Intragam®P •Octagam® •Sandoglobulin® •Ot •her	N/A	Selection of "Other" makes available "Other Details" free text field.
Date first dose	Required if "Intravenous Immunoglobulin" is selected in "Postnatal Therapy Details"	DD/MM/YYYY	Date range must be equal to or later than date of birth	09/09/9999	
Date last dose	Required if "Intravenous Immunoglobulin" is selected in "Postnatal Therapy Details"	DD/MM/YYYY	Date range must be equal to or later than date of birth	09/09/9999	
Dose (g)	Required if "Intravenous Immunoglobulin" is selected in "Postnatal Therapy Details"	Text Box	Numeric (0-2000)	-1	
Number of doses	Required if "Intravenous Immunoglobulin" is selected in "Postnatal Therapy Details"	Text Box	Numeric (0-100)	-1	

Postnatal Therapy Details

One or more of the following therapy options must be selected:

NOT APPLICABLE

If no therapy was given select this option. Selection of this option will render other options unavailable.

PLATELET TRANSFUSION

If this option is selected further fields relating to the transfusion become available.

INTRAVENOUS IMMUNOGLOBULIN

If this option is selected further fields relating to this therapy become available.

OTHER

Selection of **Other** enables a free text field to record therapy details.

Platelet Transfusion

The following fields will only be made available once **Platelet Transfusion** check box is selected. When accessed for the first time for each infant, no transfusions will have been entered. Under the heading **Platelet Transfusion** the following will appear: **There is no transfusion record for the patient selected**. Details of platelet transfusion must be entered and saved. A summary of the transfusion will then appear.

The button **Add New Transfusion** should be selected to add a subsequent transfusion. Each new transfusion is assigned a reference number which is shown on the left of the date in the summary line. Transfusions may be deleted by selecting the Red Cross to the left of the reference number. Details of the transfusion may be edited by clicking on the reference number. This brings the details of this transfusion back into the **Platelet transfusion details** fields where changes can be made and saved.

Date of Transfusion

Date of transfusion refers to the date on which the Platelets entered the vein of the infant. Only post-natal transfusion should be included here.

Platelet Type

This field is required if Platelet Transfusion is selected as the procedure. From a drop down menu the following options are provided for platelet type.

HPA Matched

HPA matched or compatible platelets (usually collected by the Australian Red Cross Blood Service) are platelet concentrates collected from a donor who does not express the implicated platelet antigen. For example, for a case of NAIT due to maternal anti HPA1a antibodies, matched platelets would be those from a donor who is HPA 1a negative. As the diagnosis of NAIT (and determination of the antibody

specificity) may take some time, platelet concentrates that are negative for the platelet antigens most commonly implicated in NAIT cases (HPA 1a and HPA 5b) may be used. These should also be entered as HPA matched (even if the maternal platelet antigen type is not yet known).

Child's Platelet Count Pre-Transfusion

The infant's platelet count (x109) most closely preceding the platelet transfusion should be reported here. This should be a postnatal sample if available.

Child's Platelet Count Post-Transfusion

The infant's platelet count (x109) most closely following the platelet transfusion should be reported here.

Non-HPA Matched

This refers to platelet concentrates that have not been selected based on the HPA type of the donor. These will include platelets collected by apheresis from a single donor and platelets pooled from multiple random donors (pooled platelet units).

Maternal

This refers to platelet concentrates that are collected from the mother (rather than from volunteer blood donors at ARCBS). These may be collected at the treating institution and require irradiation prior to transfusion.

Unknown

This option can be entered if the type of platelet product (i.e. HPA matched, HPA unmatched or maternal) is not known.

Therapy Details: Intravenous Immunoglobulin

The following fields will only be made available if the **Intravenous Immunoglobulin** check box is selected.

TYPE OF IVIg

The majority of IVIg used in Australia is the domestically produced Intragam®P. To guarantee an adequate, safe and secure supply, the National Blood Authority has established contracts for the supply of two imported IVIg products; Octagam® and Sandoglobulin® P. The following data selection options are available:

- Intragam®P
- Octagam®
- Sandoglobulin®
- Other

If the patient received a combination of products, please choose **Other** and specify products and quantities.

Date of First Dose

Date of first postnatal IVIg dose is entered numerically in the format DD/MM/YYYY.

Date of Last Dose

Date of last postnatal IVIg dose is entered numerically in the format DD/MM/YYYY.

Dose (G)

Dose volume for each dose should be entered in grams.

Number of Doses

Please record the total number of doses the infant received in the postnatal period. Antenatal treatment of mother or infant should be recorded elsewhere.

Postnatal Outcomes Page

Once postnatal therapy has been initiated the **Postnatal Outcomes** page must be filled out.

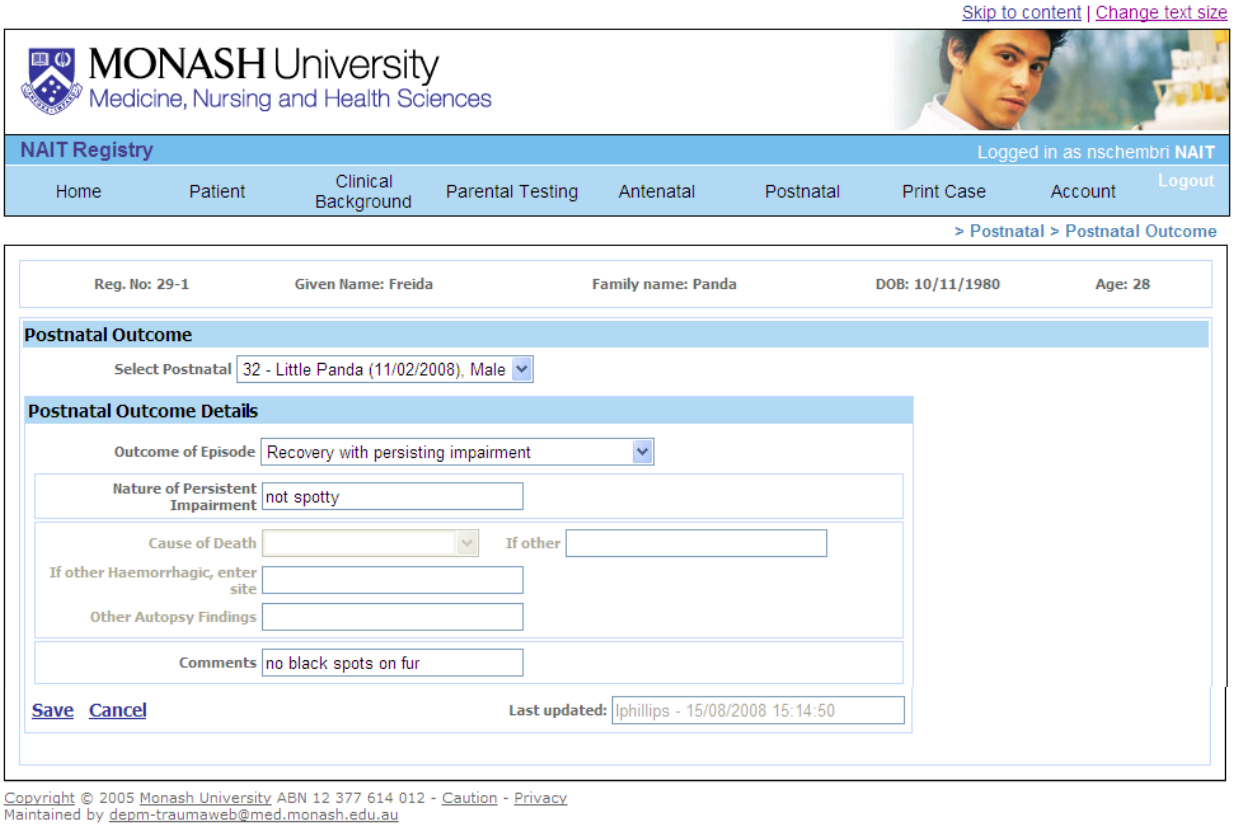


Figure32: Postnatal Outcomes page with an example case.

When opened for the first time, this page will show details under the heading **Postnatal Outcomes**, of the last infant entered on the previous page. If more than one infant has been added from this pregnancy, separate postnatal outcome details can be added from each child by selecting them in turn from the drop down menu.

A summary of the **Postnatal Outcomes** Page data items and the method of data entry are displayed on the next page.

Postnatal Outcomes Page Data Entry Summary

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Outcome of episode	Always	Drop down menu	•Complete Recovery with no long term impairment •Recovery with persisting impairment •Death •Other •Not applicable	Not applicable	Selection of "Recovery with persisting impairment" makes "Nature of Persistent Impairment" available. Selection of "Death" makes "Cause of Death" and related fields available. Selection of "Other" makes "Other Details" field available.
Nature of Persistent Impairment	Required if "Outcome of Episode" = "Recovery with persisting impairment"	Free Text	Alphanumeric	Not applicable	N/A
Cause of Death	Required if "Outcome of Episode" = "Death"	Drop down menu	•Intracranial Haemorrhage •Pulmonary Haemorrhage •Other Haemorrhagic •Other •Not applicable	Not applicable	Selection of "Other Haemorrhage" makes "Other Haemorrhagic site" field available. Selection of "Other" makes "Other Details" field available.
Other Haemorrhagic site	Required if "Cause of Death" = "Other Haemorrhagic"	Free Text	Alphanumeric	Not applicable	N/A
Other Autopsy Findings	Required if "Outcome of Episode" = "Death"	Free Text	Alphanumeric	Not applicable	N/A

Data item	Data Entry Required	Type of Data Entry	Permitted Characters and Values	Unknown Values	Special Behaviour
Comments	Optional	Free Text	Alphanumeric	Not applicable	N/A

Outcome of Episode

The outcome of the episode should be determined once all treatment for NAIT has been completed. Infants with other medical issues or long-term impairment may continue to require medical treatment but the NAIT episode may be considered resolved when NAIT-related treatments (e.g. Platelet transfusion or IVIg therapy) are concluded.

From the drop down menu the following options are available:

COMPLETE RECOVERY WITH NO LONG TERM IMPAIRMENT

Choose this option if the infant has no persisting sequelae from the NAIT episode.

RECOVERY WITH PERSISTING IMPAIRMENT

This should be selected if the child has recovered from NAIT but has a persisting impairment as a consequence of this episode. For example, if there is a persisting neurological deficit from an intracranial haemorrhage, this should be entered here.

Selection of **Recovery with persisting impairment** makes **Nature of Persistent Impairment** field available.

DEATH

This should be selected if the child dies as a result of the NAIT episode. If the child dies from non-NAIT related causes please make this clear in the **Cause of death** or **Other findings** fields.

Selection of **Death** makes **Cause of Death** and **Other Autopsy findings** fields available.

OTHER

This should be selected if the child has a persisting impairment from causes other than NAIT. Please indicate in this field the nature of the impairment if present and the cause of the impairment.

NOT APPLICABLE

Nature of Persistent Impairment

This data entry box is only available if **Recovery with persistent impairment** is selected in **Outcomes of Episode**.

A full explanation of the impairment as a direct result of NAIT should be supplied.

Cause of Death

This field will only be available if **Death** is selected in **Outcome of Episode**.

From the drop down menu the following options are available:

INTRACRANIAL HAEMORRHAGE

An intracranial haemorrhage is a haemorrhage, or bleeding, within the skull. Neonates with NAIT are believed to be at greater risk of intracranial haemorrhage within the first 72 hours after birth.

PULMONARY HAEMORRHAGE

Pulmonary haemorrhage refers to bleeding from the lung.

GI HAEMORRHAGE

Gastrointestinal bleeding or gastrointestinal haemorrhage includes any hemorrhage (loss of blood) in the gastrointestinal tract, from the pharynx to the rectum.

OTHER HAEMORRHAGIC

Selection of **Other Haemorrhagic** provides a free text box to enter site of haemorrhage.

OTHER

Selection of **Other** makes available the **Other Details** field. Death due to a cause other than NAIT should be entered here. Please provide details of the cause of death.

Other Autopsy Findings

This field is only available if **Death** is indicated in **Outcome of Episode**. A summary of autopsy findings should be entered here.

Comments

Any additional comments may be entered here.

section

6

Editing Data

Once a patient and related data items have been entered, existing data for any screen of any patient from your hospital can be modified by typing or selecting new information and clicking on the save command button located at the bottom of each screen. Data validation procedures are the same as when adding a new case and, if there is no error, data changes will be saved and the **Last Updated** field updated with your user name and the date and time.

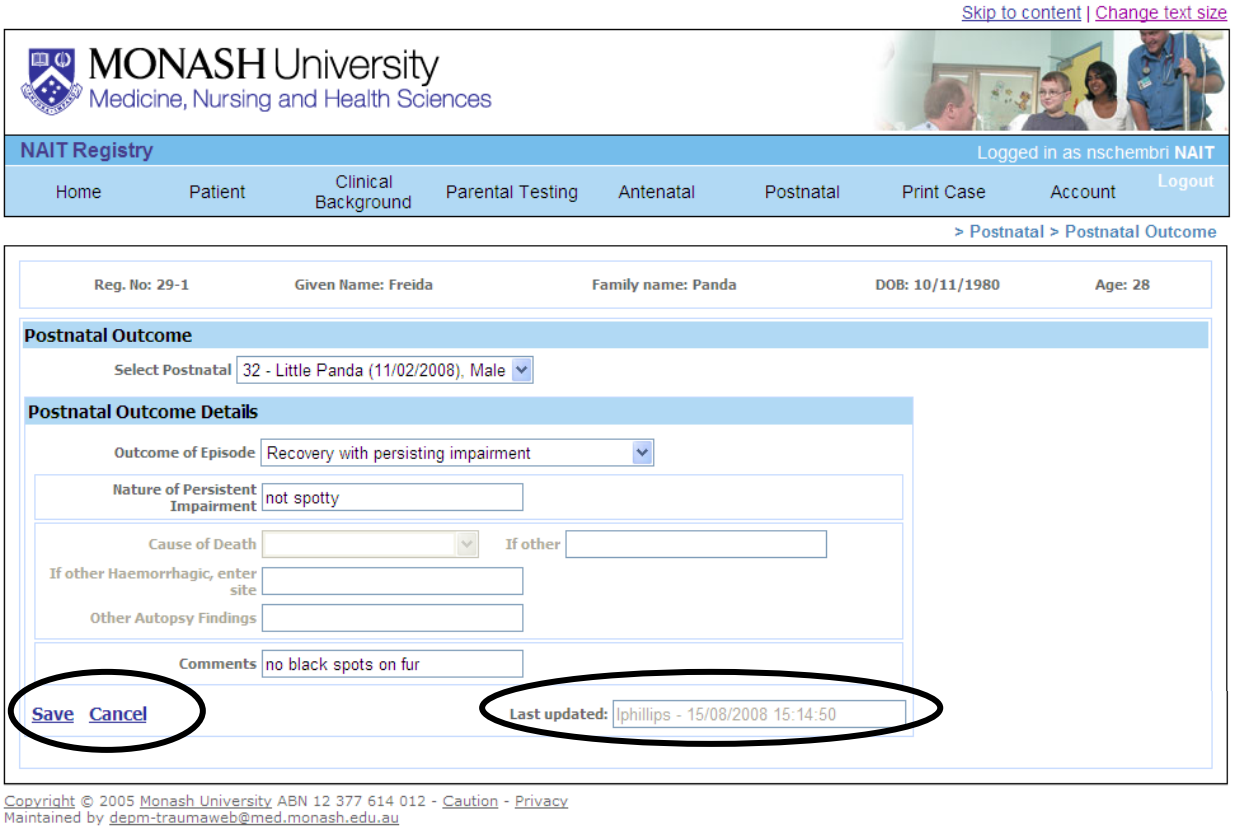


Figure33: Shows Postnatal Outcomes Page as an example of Last Updated Information and position of save and cancel buttons.

Record editing

1. Locate the record you wish to edit by using navigation controls on the 'Home' Screen.
2. Overwrite new data onto the appropriate existing data.
3. Select and press Save button located at the bottom of each record.

Use Cancel button to discard the change.

Editing or Deleting on the **Antenatal Testing and Therapy** or **Postnatal Therapy** pages

1. To edit any of the laboratory results already entered, locate the relevant results set in the list and click on the relevant line in the column **Ref #**. This will populate the **Details** fields below with the relevant results.

2. Make any changes as required and click **Save** at the bottom of the page to retain the corrections.

3. To delete any previously entered laboratory results, select the item and press **Delete** Image Button to the left of the appropriate reference number.

4. Answer confirmation prompt to allow record to be deleted.

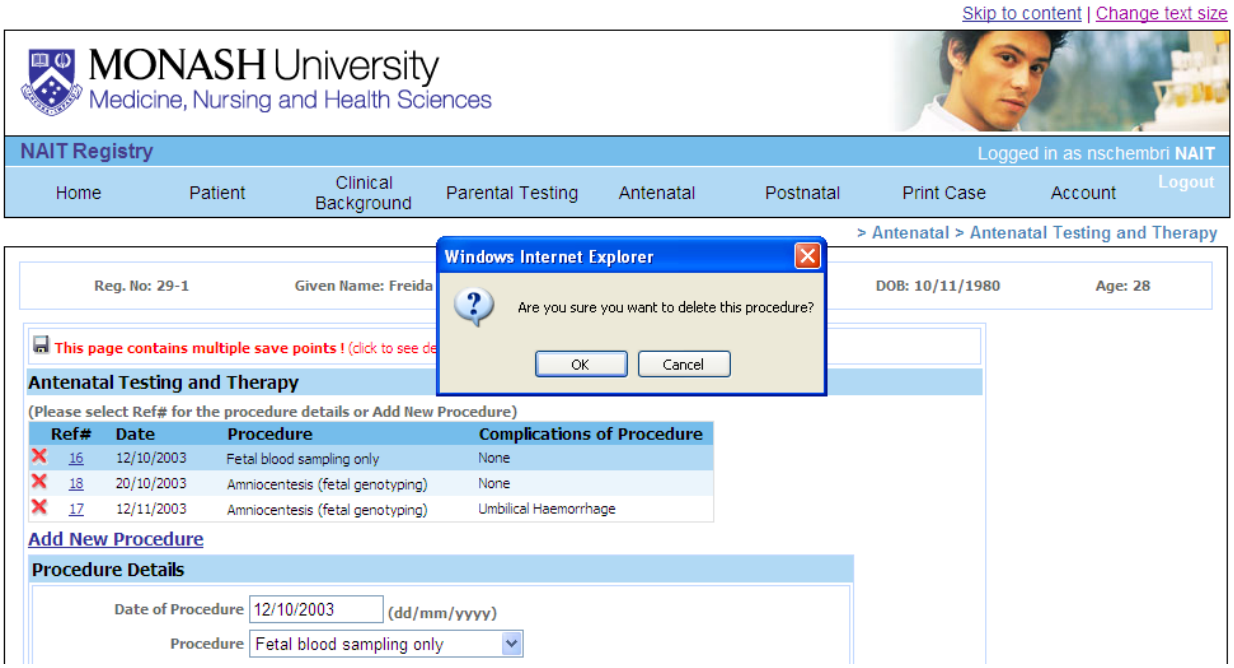


Figure34: Antenatal testing and Therapy Page showing confirmation prompt when deleting procedure

Hint Place mouse over the images to see the description of each button.

section

7

Printing a Case

Cases may be printed using the **Print Case** command located on the right hand side of the main menu.

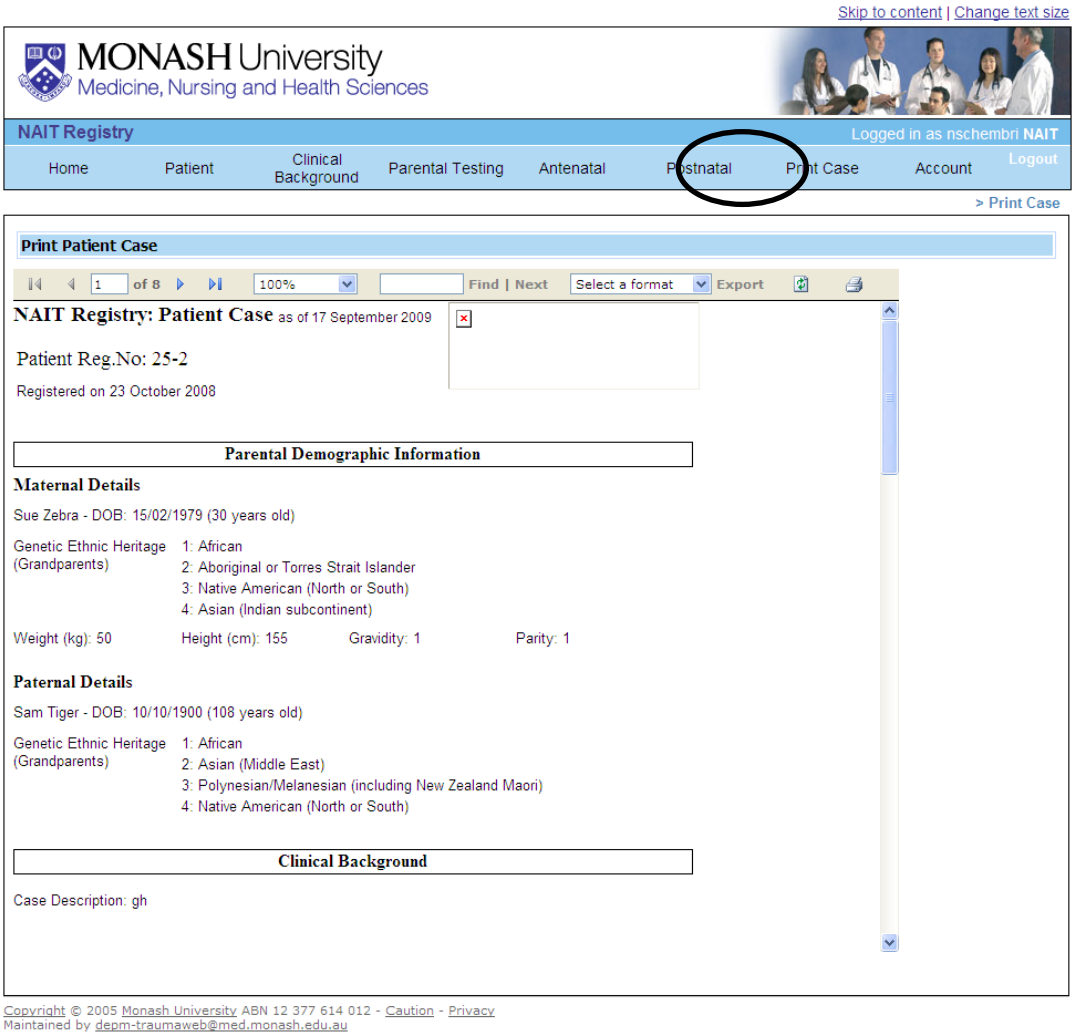


Figure: 35: Main Menu showing Print Case Command

The entire case information is supplied in a format that is able to be printed. A printout of a fictitious case is provided on the following pages.

NAIT Registry: Patient Case as of 30 June 2010

Patient Reg.No: 45-1

Registered on 16 June 2010

Parental Demographic Information

Maternal Details

Poppy Mak - DOB: 16/06/1976 (34 years old)

Genetic Ethnic Heritage (Grandparents)	1: European 2: European 3: European 4: European

Weight (kg): 80 Height (cm): 170 Gravidity: 2 Parity: 2

Paternal Details

Harry Mak - DOB: 15/05/1974 (36 years old)

Genetic Ethnic Heritage (Grandparents)	1: European 2: European 3: European 4: European

Clinical Background

Case Description: Previous pregnancy confirmed NAIT. This pregnancy referred during first trimester for management.

Possible Alternative Cause of Clinical Presentation:

Stage at Which Case Identified: Anticipated prior to Pregnancy

Reason for Case Identification: Personal History of NAIT Affected Offspring

Any Previous NAIT Affected Offspring: Yes

Previous NAIT Affected Offspring: Details of Severity: Severely affected (live birth)

Comments on Any Previous Poor Pregnancy Outcomes: Previous NAIT affected offspring diagnosed post natal with severe thrombocytopaenia and mild bleeding. No long term impairment. Serologically confirmed NAIT due to HPA-1a antibody

Maternal Testing (entered by clinician)

Maternal Platelet Count at Diagnosis: 185

Date of Maternal Platelet Count: 16/12/2009 Maternal ABO Group: O

Parental Testing

Specialised Laboratory Testing (entered by laboratory)

Maternal HPA Type

HPA-1: bb	HPA-2: ab	HPA-3: ab	HPA-4: ab
HPA-5: ab	HPA-6: ab	HPA-7: ab	HPA-8: ab
HPA-9: ab	HPA-10: ab	HPA-11: ab	HPA-12: ab
HPA-13: ab	HPA-14: ab	HPA-15: ab	

Paternal HPA Type

HPA-1: aa	HPA-2: ab	HPA-3: ab	HPA-4: ab
HPA-5: ab	HPA-6: ab	HPA-7: ab	HPA-8: ab
HPA-9: ab	HPA-10: ab	HPA-11: ab	HPA-12: ab
HPA-13: ab	HPA-14: ab	HPA-15: ab	

Fetal/Neonatal HPA Type

HPA-1: ab	HPA-2: ab	HPA-3: aa	HPA-4: bb
HPA-5: ab	HPA-6: aa	HPA-7: bb	HPA-8: aa
HPA-9: bb	HPA-10: ab	HPA-11: aa	HPA-12: ab
HPA-13: bb	HPA-14: aa	HPA-15: ab	

HPA Crossmatch: Maternal/Random Donor: Positive	Date: 16/01/2010
HPA Antibody Specificity: HPA-1a	
HPA Crossmatch: Maternal/Paternal: Positive	Date: 16/01/2010
HPA Antibody Specificity: HPA-1a	
HPA Crossmatch: Maternal/Fetal-Neonatal: Not Tested	Date:
HPA Antibody Specificity:	

HPA Method: HPA Method

HPA Antibody Titre:	Date:
HPA Antibody Titre:	Date:
HPA Antibody Titre:	Date:
HPA Antibody Titre:	Date:
HPA Antibody Titre:	Date:
HPA Antibody Titre:	Date:

Maternal HLA Typing

HLA-A: 1 HLA-B: 37 HLA-Cw: 7

HLA-DRB1: 101 HLA-DRB3/4/5: 28

Paternal HLA Typing

HLA-A: 6 HLA-B: 27 HLA-Cw: 6

HLA-DRB1: -1 HLA-DRB3/4/5: -1

HLA Method: HLA Method

HLA Antibody Specificity:

HLA Antibody Titre:	Date:
HLA Antibody Titre:	Date:
HLA Antibody Titre:	Date:
HLA Antibody Titre:	Date:
HLA Antibody Titre:	Date:
HLA Antibody Titre:	Date:

Interpretive Testing Comments: Maternal fetal incompatibility in HPA-1

Testing Site: VTIS-Victoria

Antenatal Clinical Details

Estimated Date of Delivery: 01/06/2010

Site of Antenatal Management: TEST1

Gestation at which Case Identified: 10

Cranial Imaging Performed?: Ultrasound - Cranial Imaging Findings: No evidence of haemorrhage

Complications During Pregnancy

Intracranial haemorrhage: No Other bleeding: No

Pre-eclampsia: No Fetal infection: No Placental abruption: No

Other: No

Outcome of Pregnancy: Live Birth

Antenatal Testing and Therapy

Ref# 39 Date of Procedure: 01/03/2010

Procedure: Fetal blood sampling only

Fetal platelet count at fetal blood sampling: 120	Fetal platelet count post transfusion: Platelet Type:

Complications of procedure: None

Ref# 40 Date of Procedure: 23/05/2010

Procedure: Fetal blood sampling only

Fetal platelet count at fetal blood sampling: 40	Fetal platelet count post transfusion: Platelet Type:

Complications of procedure: None

Ref# 41 Date of Procedure: 23/05/2001

Procedure: Platelet transfusion

Fetal platelet count at fetal blood sampling:	Fetal platelet count post transfusion: 150 Platelet Type: HPA Matched

Complications of procedure: None

Other Therapies

Other therapies?: Yes

Intravenous Immunoglobulin: Yes

Type of IVIg: Intragam P®

Date first dose: 01/01/2010 Date last dose: 29/05/2010

Dose(g): 2 Number of doses: 20

Frequency: Weekly

Corticosteroids: No

Type:

Date first dose: Date last dose:

Dose(mg): Number of doses:

Frequency:

Other: No

Postnatal Demographics

Ref# 45 Child Family Name: Mak Child Given Name: Ruby

Child Sex: Female Child Birth Weight (g): 3000

Date of Delivery: 01/06/2010 Gestation at Delivery: 37

Mode of Delivery: Caesarean (pre-labour) Timing of Delivery: Induced

Site of Antenatal Management: TEST1

Transferred Patient: No

Postnatal Clinical and Testing

Postnatal# 45 - Ruby Mak (01/06/2010), Female

Clinical Manifestations

Petechiae: No Purpura: No

Pulmonary Haemorrhage: No GI Haemorrhage: No Intracranial Haemorrhage: No

Other: No

Child's First Platelet Count: 40 ($x10^9$)

Child's First Haemoglobin: 210 (g/L)

Child's First Total WCC: 20 ($x10^6$ /L)

Child ABO Group: O

Child Rhesus(D) Group: Positive

Date of First Blood Counts (dd/mm/yyyy): 01/06/2010

Child's Lowest Platelet Count: 40 ($x10^9$)

Date of Child's Lowest Platelet Count (dd/mm/yyyy): 01/06/2010

Cranial Imaging Performed?: Ultrasound
- Cranial Imaging Findings: Normal

Postnatal Therapy

Postnatal# 45 - Ruby Mak (01/06/2010), Female

Platelet Transfusion: Yes Intravenous Immunoglobulin: Yes

Other: No

Platelet Transfusion

Ref# 33 Date of Transfusion: 01/06/2010 Platelet Type: HPA Matched

Child's platelet count pre transfusion: 40

Child's platelet count post transfusion: 150

Intravenous Immunoglobulin

Type of IVIg: Intragam P®

Date first dose: 01/06/2010 Date last dose: 06/06/2010

Dose (g): 2 Number of doses: 2

Postnatal Outcome

Postnatal# 45 - Ruby Mak (01/06/2010), Female

Outcome of Episode: Complete Recovery with no long term impairment

Comments: