

ASIG Newsletter – September 2008

We are very pleased to report that as of 17th September we have 487 consented Scleroderma patients in the ASIG database. We recognise the enormous amount of work that goes into entering complete and accurate data and thank you for all your efforts. A more tangible reward will be publication success for our group, hopefully in the near future. Following is a list of studies we plan to do, plus some tips on how to maintain data quality. Always remember ... if in doubt read the manual (or contact Jill).

Current studies

Publication is a current priority for ASIG so that we can apply for further funding to ensure the ongoing viability of the database. The studies that are a priority at the moment are:

PAH – each centre has been approached to ascertain patient numbers for this study. Those participating will soon receive a report on your data and any missing areas.

RNA polymerase – at this stage this study only includes Royal Adelaide and St Vincent's as it is not routinely collected. If you would like to participate please contact Susanna to discuss.

Patient demographics – to be done early next year. A reminder will go out later in the year to let you know what fields we need completed.

Method paper – fortunately nothing required from centres for this!

Blood for research

An email was sent around regarding the blood. Essentially ... ASIG can pay up to \$20 per patient annually for local lab processing if they follow our protocol and can freeze the blood for transportation to Adelaide in batches. Most sites will need an ethics amendment to move the blood off site. Jill will arrange accounts with labs, account with a courier company and ethics amendments. If your lab will not process for this cost, contact Jill or Susanna to discuss options.

Managing patients who have died or chosen to withdraw

Once a patient has consented to the research their data can be entered in the database. The consent form advises them, *"If you do consent to any aspect of this research you can change your mind later. This means that you can ask that your health information that has not been processed be removed from the research, or that your stored blood sample be destroyed"*.

The health information or data is exported from the database almost daily by the administrator, Jill, and saved in a statistics package and at that point would be considered processed. Therefore, **once data is entered in the database it is considered processed** and should never be removed unless there has been a data entry error. Any data not entered in the database has not been processed so if the patient withdraws and requests that it be destroyed it should be destroyed, or left only on the medical record. This is a very important rule to follow. However, **ENSURE THAT YOU KEEP THE ORIGINAL SIGNED CONSENT** with other research records, as you may need to produce it if you are audited by ethics. All processed data must have a linked signed consent form. Make a note on the consent of the date of withdrawal.

Similarly with deceased patients, their data should remain in the database and the signed consent form retrievable.

If someone is adamant that they also want their data to be removed from the database, it is reasonable to ask them to put the request in writing and then we could oblige.

Keeping a record of those who do not consent to participate in database

Some patients may choose not to participate or the physician may decide that obtaining consent or involvement is too difficult due to language difficulties, advanced age or mental health issues. Could each site please keep an ongoing record of the patients who do not participate in the database – gender, reason for non-participation, and approximate age. The reason that we do this is so that we can report on how representative we believe our cohort is of the scleroderma population.

Recording patient responses to scales

The scales in the database entered by sites are the Guyatt under the second current symptom tab, and the Scleroderma HAQ and Rodnan score under the second examination tab. These are validated scales that have been shown to have items that are all statistically related – therefore we can add them up. If one is missing – try to get it filled in. If it is missing because the patient is too breathless to do housework then this is an “All the time”. If it is missing because the patient cannot do housework due to other conditions or is lucky enough not to have to do housework (!!), then leave it. Do not worry that you will not see a total score in the database.

If there are at least 75% (or maybe even 60% - depends on who you ask!) of responses given, it is standard practice to substitute the average response in the missing field so that an overall score can be calculated. This will not occur in the ASIG database but it can be set up to occur in the stats software package which is where it will be analysed. Therefore in the end the patient will actually obtain a score on the scale if only one item is missing and their data can still be used in analyses.

Recording alcohol consumption

If a patient gives a range for weekly consumption take the middle value (go up 1 to make a whole number. i.e. 7-10 becomes 9). Please do not leave blank and write in comments section – this will end up missing data. If a ‘social’ or ‘occasional’ drinker you should be able to average that out over one week – put in 1 if they have less than one a week but do drink.

Problem with excessive comments

As the database is growing in terms of numbers of patients and number of reviews, we need to limit the comments as they are causing a problem in the export. Please limit comments to the bare minimum that is required to clarify the data collection. Clinical notes would be best placed on the patient file. If notes are made to remind yourself or the administrator to take some action please ensure they are deleted once the action has been completed. We are working with the software developer on how to best manage the comments.

SF 36 and general HAQ

Everyone should be using the scannable versions of these documents now. We will still use the old versions so at some point please copy and post to Jill for processing. Let Jill know if you need an express post bag.

Changes to database that will occur in upgrade

- **Parents’ country of birth** – please specify (mo) or (fa). If only one country is listed it will be assumed it applies to both parents.
- **First language** will be changed to: **Are you confident reading English** - yes or no? So please type in text box: “confident with English” or “NOT confident with English”.
- **Race** – there will be an option for “other” in the upgrade and text box. For now please type in next comments section.
- **Family history of SSc**. List up to 4 first degree relatives (Parent/sibling/grand parent/cousin) including their gender and whether on maternal or paternal side of family.
- **Any first degree relative had**: heart disease, stroke or diabetes – this will be in upgrade so could record data in comments for now.
- **Current occupation** will change in the next upgrade to **current employment status**. Please type in ONE of the following:
part time, full time, student, unemployed, home duties, disability preventing work, retired.

- **Occupation at onset** – will change to “select 3 main industries spent time in prior to diagnosis” and the options are:
 - Petrochemical
 - Agriculture
 - Mining
 - Automotive
 - Manufacturing
 - Plumbing
 - Electrical
 - Computing/electronic
 - Construction
 - Textile
 - Driving
 - Laboratory
 - Beauty
 - Nursing
 - Health care
 - Cleaning
 - Teaching/education
 - Retail
- **Previous occupation** will be deleted so leave blank.