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Re: Pulmonary Conduit Study

At a weekend retreat in the Data Center, we reviewed the progress and problems with the web-based data entry system for the Pulmonary Conduit study. The study itself looks like it will be very productive. We have identified 150 children under the age of 2 years leaving hospital with a pulmonary conduit. About one-third of these have Venpro conduits, one-third aortic homografts and one-third pulmonary homografts.

However, it is clear that there are some problems with the data entry system as follows:

- 1) Data entry is incomplete. About one-third of the patients that have been assigned numbers have no data entry.
- 2) We have no way of validating the data in the Data Center. If we do see an aberrant value in a file, the only way of confirming the entry is to contact the person in the CHSS institution.
- 3) Follow-up of these patients is very difficult because many are followed at a non-CHSS institution or their follow-up may be unknown within the CHSS institution as it may be done entirely by Cardiology.

The bottom line of all this is that the work is labor intensive for the Data Center staff and we are imposing an undue burden on your people within each institution.

We believe the study is important and can be successful. Further, Marshall Jacobs has been successful in obtaining two years of funding to support this study.

Consequently, we would like to revert to our previous tried-and-true process of having each individual institution send us copies of reports extracted from the child's health records. The reports required have been added to the revised PATIENT ENROLMENT FORM to reflect the different process of data collection (attached). In the near future we will contact centers regarding data collection of previously enrolled patients.

You will have to notify your IRB of the change in protocol. Some institutions will be required to amend their consent form to reflect this change. I would stress with them that it is an amendment and that the data collection process will revert to the same format as all of our other CHSS studies. Please refer to attached IRB-approved Sick Kids consent form. We have received institutional approval for these changes.

I am disappointed that we have to change the method of data collection but I do believe it will be necessary to successfully complete the conduit study. I am hopeful that the change will make it easier for your staff and the Data Center people and result in a better data-set with improved follow-up information. Follow-up contact with the parents need not change but **we encourage you to allow our Data Center staff to do the follow-up of your patients** as we tend to have more complete follow-up than most institutions that do it themselves. A copy of the Data Center follow-up form is attached.

Again, my apologies for burdening you with this change in format but our feeling is that it is important and will be of benefit in the long term. My thanks and regards.

Sincerely,

W.G. Williams, M.D.
Cardiac Surgeon
WGW/ol

Enclosures: 1) Patient Enrolment Form 2) Consent Form 3) Amendment Request & Approval
4) Questions & Answers 5) Questionnaire