FINAL REPORT ON ISABEL CLINICAL TRIAL

DATE: 01.10.2003

Principal investigator: Dr P Ramnarayan*
Clinical research assistant: Helen Fisher**
Research supervisor: Dr J Britto*

*Imperial College London & **ISABEL Medical Charity

Participating NHS Trusts:
Norfolk and Norwich University Hospital, Norwich, Norfolk
Northwick Park Hospital, North West London Hospitals NHS Trust, Harrow
Princess Alexandra Hospital, Harlow, Essex
Ipswich Hospital, Ipswich, Suffolk

SUMMARY OF RESULTS SO FAR:

Variable of interest	Result
Total number of attempted uses	~500*
Total number of actual uses – complete or incomplete	176
Total number of complete uses	125
Total number of uses eligible for study (available medical notes)	104
Total number of records examined by expert panel	**104**
Additional 'significant' diagnoses added after ISABEL reminders	**14**
Additional 'significant' tests added after ISABEL reminders	**6**
Additional 'significant' management steps added after ISABEL	**1**
Mean change in diagnostic quality score after ISABEL usage	5.6
Mean change in investigation quality score after ISABEL usage	1.5
Mean change in management quality score after ISABEL usage	0.4
Overall additional time taken for ISABEL consultation (median)	**1 min 38 sec**

- Reasons for large discrepancy between attempted uses and complete uses: users clicking ISABEL icon multiple times when webpage not loading quickly; users attempting to use main site and not interested in trial site; some testing by trial investigators to check trial icons; and incomplete episodes where users look at ISABEL results but fail to submit their revised opinions – computer timeout 4 hours.

Comments:

1. ISABEL has reminded the doctor about a 'significant' diagnosis (as judged by an expert panel) 14/104 times in this clinical study so far (**1 out of 7 times**; 13.5%). This is in comparison to figures from the previous simulated study, where ISABEL reminded the doctor about a 'significant' diagnosis **1 out of 8 times** (12.5%).

2. ISABEL has prompted the ordering of 6 'significant' tests in 104 patients (**1 out of 17 times**; 5.8%), in contrast to the simulated study, where ISABEL reminded the doctor about performing a 'significant' test in roughly 1 out of 10 cases.

3. These benefits were accrued in **1 ½ min** extra time spent with the system.

<u>Date of meeting</u>: 1st October 2003

<u>Present at meeting</u>: William Maton-Howarth, P Ramnarayan, Joseph Britto, Jason Maude, Dick Curry

Background:

ISABEL is a paediatric decision support system, consisting of a novel differential diagnostic tool. Diagnostic suggestions are integrated with text from standard textbooks, images, management algorithms and clinical 'experiences'. The system is provided free on the Internet by the ISABEL medical charity (www.isabel.org.uk) for all registered healthcare professionals. System performance has been evaluated previously: ISABEL presented 'clinically accurate' diagnostic reminders more than 90% of the time. A recent simulated assessment of the tool's impact indicated that doctors significantly positively modify their diagnostic and management plans in 1 out of every 8 episodes of usage, when prompted by ISABEL. The current multi-centre clinical study aims to assess the real-life impact of the usage of the ISABEL system by junior paediatricians at 4 NHS hospitals.

Report on trial:

1. Trial centre enrolment:

Junior doctors started using ISABEL at the trial centres in November-December 2002. Due to variability in the dates of completion of local R&D procedures, this start date was staggered. The first hospital to start using ISABEL was Northwick Park (27/11/2002); the last hospital to start was Norfolk and Norwich University Hospital (12/12/2002). All junior doctors at each centre attended group sessions introducing them to a specially configured ISABEL trial website in November 2002. This session was repeated on at least 2 occasions per centre to capture the attendance of all junior doctors. These sessions were undertaken by Dr P Ramnarayan, Dr J Britto and Helen Fisher. Due to change-over of doctors in Feb-Mar 2003, the group training sessions were repeated once at each centre during the induction program for new doctors.

2. ISABEL trial site usage:

Key computers within the paediatric department at each centre were set-up to auto-login to ISABEL using a centre-specific login and password, so that participating doctors did not have to log into ISABEL individually (see table 1). In order to maximise data collection, it was ensured that only the trial site (*not* the public site) could be accessed by the trial centre.

Table 1

Name of hospital	Number of doctors enrolled*	Number of computers for trial
Princess Alexandra, Harlow	21	2
Ipswich Hospital	12	4
Norfolk and Norwich Hospital	16	4
Northwick Park Hospital	31	4

* *Doctors included those on neonatal unit posting*

The overall usage of the trial site at each centre (complete uses) is summarised below, month-wise:

Table 2

Name of hospital	Dec '02	Jan '03	Feb '03	Mar'03	Apr'03	Total
Princess Alexandra, Harlow	5	6	4	1	9	25
Ipswich Hospital	1	3	4	6	6	20
Norfolk and Norwich Hospital	9	7	15	11	8	50
Northwick Park Hospital	6	7	3	3	11	30
Total usage	21	23	26	21	34	**125**

3. *Collection of relevant data from medical records:*

One clinical research assistant collected medical records from trial centres from patients on whom ISABEL was used. This was done weekly to maximise data collection. Only medical information, as recorded by the examining doctors in the notes, prior to the date and time of ISABEL usage, was copied. This was anonymised and used for quality assessment. There was some loss of data at this step: not all ISABEL uses were usable due to multiple reasons:
- Some uses were not associated with an identifiable real patient
- Some uses were incomplete and could not provide useful data.

Table 3 summarises up to date data on numbers of medical records available for assessment.

Table 3

Name of hospital	Dec '02	Jan '03	Feb '03	Mar '03	Apr'03	Total
Princess Alexandra, Harlow	5	6	4	1	8	24
Ipswich Hospital	1	1	4	5	5	16
Norfolk and Norwich Hospital	4	6	14	10	6	40
Northwick Park Hospital	5	7	2	3	7	24
Total usage	15	20	24	19	26	**104**

4. *ISABEL trial data assessment by consultant panel:*

A consultant panel consisting of 4 paediatricians unrelated to the ISABEL development team was constructed in December 2002. A meeting to discuss the scoring procedure (and to make uniform rules for scoring to improve consensus) was held in early January 2003. Only copies of medical notes with usable information were provided to the panel members according to an incomplete block design (see attached document) starting in January 2003. This scheme ensured that all 4 panel members assessed 20% of all notes and a further 20% was assessed by at least 2 members. These would be used to provide an indication of agreement between panel members.

5. *Results of changes in subjects' plan quality:*

Using the panel assessments, table 5 shows changes in subjects' plans for the patients:

Table 4: Number of "appropriate" suggestions reminded by ISABEL

Diagnoses	Investigations	Management
14	**6**	**1**

Table 5: Mean (95% CI) change in scores for subjects' plans, pre- and post-ISABEL

Mean difference in score (diagnoses): 5.6 (95% CI 3.62-7.58), p<0.001
Mean difference in score (investigations): 1.5 (95% CI 0.21-2.79), p<0.01

6. Impact of ISABEL diagnostic reminders on final diagnosis at discharge

Final diagnoses were available for patients from 3 of the 4 participating hospitals. These were obtained from clinical coding departments in 2 hospitals, and examination of medical records concerned by the consultant involved in one hospital. The quality of clinical coding diagnoses was poor, compared to the final diagnoses provided by the consultant.

Diagnostic suggestions selected by the subjects for inclusion in the post-ISABEL list that turned out to the final diagnosis are shown below:

Princess Alexandra Hospital: **1** (Clinical coding)
Ipswich Hospital: **2** (Clinical coding)
Northwick Park Hospital: **2** (Consultant)

7. Additional time expended for ISABEL consultation:

Median additional time taken by junior paediatricians to use ISABEL during the trial was 1 min 38 sec (IQR 50 sec - 3 min 21 sec).

8. Qualitative feedback from subjects (questionnaire) – major themes

- Major hurdle to usage: No access to computers while working. One computer shared by multiple users, for multiple purposes.
- Not enough time during routine work to stop and use trial site (necessity to record additional data, as opposed to main site)
- Unavailability of all the facets of ISABEL as in main site
- Not possible to search ISABEL for an image/guideline without having to go through the entire differential diagnostic pathway

9. Users' subjective scores

As part of the study, at the end of each completed episode of ISABEL usage, the doctor was asked to rate how ISABEL was useful as a:
   a) Tool for the clinical management of that specific patient
   b) As an educational tool, providing reference material
This was rated on a scale from 0 to 5 (0 – not at all, 5 – very much). The results are summarised below:

Mean score for utility in patient management: 1.57
12 episodes were scored >/=4 (indicating a higher level of usefulness). Paradoxically, only 3 of these episodes matched the ones where 'significant' diagnoses were reminded to the doctors, indicating that the doctors had different reasons for indicating how useful the tool was in the patient's management.

Mean score for utility as educational tool: 2.36