Data-Related Issues

OUTLINE

1. **Update from Each PAROS Country**
   a. Status (demo/live version, no. of cases entered)
   b. Issues Faced
2. **Revised Data Migration Template**
3. **Status of Implementation of PAROS Study Log**
4. **IRB Register – Approval Status**
5. **Updates in the ePAROS System**
6. **Data Quality Assurance Plan**

1. Update from Each PAROS Country – Using ePAROS

Singapore

- 415 entries entered (as of 24 Jun 2011)

Thailand

- Rajavithi Hospital: 2 cases entered (as of 24 Jun 2011)

Malaysia

- IRB approval status
  - Hospitals: approval notification received, pending letter
  - Universities: pending approval/letter
- 166 cases entered (as of 24 Jun 2011)
- Main issues with entering:
  - Difficulty getting hospital data from ED
  - Affects mostly cases that are conveyed to hospital

1. Update from Each PAROS Country – Using ePAROS

Australia

- Progress on ePAROS platform going live

- Status of cases entered into ePAROS

- Updates on Canberra:

  - Set-up: one ambulance service and two major receiving hospitals in Canberra

  - Next steps

Dubai

- Status of translated IRB approval letter

- 32 'live' cases and 33 'demo' cases entered (as of 29 Jun 2011)

Turkey (Izmir)

- Updates

1. Update from Each PAROS Country – Using Export Data Online

Updates

- Taipei, Korea, Japan using this method

- Requires recoding

- Data recoding with Taipei is in its finishing stages

- Data migration template has been finalised

2. Revised Data Migration Template

Osaka

		PAROS				JAPAN-OSAKA				RECONCILED CODES
Section	Number	Data Element	Code	Levels	Format	Data Element	Code	Levels	Format	
Mode of Transportation	#1A	Patient brought in by	1	EMS	Integer					All cases = 1
			2	Non-EMS						
	#1B	If "Non-EMS", please specify	1	Private ambulance	Integer	NA				NA
			2	Own/private transport						
			3	Public transport						
Incident Information	#2	Date of Incident	NA	dd/mm/yyyy	Date (dd/mm/yyyy)	v_15	_	Date	Date (yyyy/mm/dd)	Change format from (yyyy/mm/dd) to (dd/mm/yyyy)
	#3	Location of incident (optional)	NA	6-digit zip/postal code	Integer	NA				NA
			999999	Unknown						
	#4	Location type	1	Home residence	Integer	v-37	1		Integer	1 = #4-1
			2	Healthcare facility			2			2 = #4-5
			3	Public /commercial building			3			3 = #4-3
			4	Nursing home			4			4 = ??? (can be classified as either PAROS variable 3, 7 or 8)
			5	Street/highway			5			5 = #4-9
			6	Industrial place			6			6 = #4-2
			7	Transport center			7			7 = #4-4
			8	Place of recreation			8			8 = #4-3
			9	In EMS/provate ambulance			9			9 = #4-50
			50	Other						
	#5A	Date of birth	NA	dd/mm/yyyy	Date (dd/mm/yyyy)	NA				NA
	#5B	Age	NA	Days / Months / Years	Integer	v_20	_	Years	Integer	
	#6	Gender	1	Male	Integer	v_19	1	Male	Integer	1 = #6-1
			2	Female			2	Female		2 = #6-2
	#7	Race (optional)	1	Chinese	Integer	NA				NA
			2	Malay						
			3	Indian						
			4	Eurasian						
			50	Other						

2. Revised Data Migration Template

Taipei

		PAROS					TAIWAN-TAIPEI				Reconciled Codes	
Section	Number	Data Element	Code	Levels	Format	Number	Data Element	Code	Levels	Format		
Mode of Transportation	#1A	Patient brought in by	1	EMS	Integer						All cases = 1	
			2	Non-EMS								
	#1B	If 'Non-EMS', please specify	1	Private ambulance	Integer		NA				NA	
			2	Own/private transport								
			3	Public transport								
Incident Information	#2	Date of Incident	NA	dd/mm/yyyy	Date (dd/mm/yyyy)		Date of incident			Date (??/??/yyyy)		
	#3	Location of incident (optional)	NA	6-digit zip/postal code	Integer		NA				NA	
			999999	Unknown								
	#4	Location type	1	Home residence	Integer		Location type		Home residence	Text	Home residence = 1	
			2	Healthcare facility					Education		Education = 3	
			3	Public /commercial building					Public / commercial building		Public / commercial building = 3	
			4	Nursing home					Nursing home		Nursing home = 4	
			5	Street/highway					Street / highway		Street / highway = 5	
			6	Industrial place					Industrial place		Industrial place = 6	
			7	Transport center					Place of recreation		Place of recreation = 8	
			8	Place of recreation					Other		Other = 50	
			9	In EMS/private ambulance								
			50	Other								
	#5A	Date of birth	NA	dd/mm/yyyy	Date (dd/mm/yyyy)		NA				NA	
	#5B	Age	NA	Days Months Years	Integer		Age (years)		NA	Integer		
	#6	Gender	1	Male	Integer		Gender		M	Text	M = 1	
			2	Female					F		F = 2	
	#7	Race (optional)	1	Chinese	Integer		NA				NA	
			2	Malay								
			3	Indian								
			4	Eurasian								
			50	Other								
	#8A		1	Yes: 'No medical history'	Integer		Medical history		N		N = #8A-1	
			2	No: 'No medical history'					Unknown		Unknown = #8B-1	
	#8B		1	Yes: 'Unknown medical history'	Integer		Heart disease		Y		Y = #8C-1	
			2	No: 'Unknown medical history'					N		N = #8C-2	
	#8C		1	Yes: Has Heart disease	Integer		Diabetes		Y		Y = #8D-1	

2. Revised Data Migration Template

Essential Documents

- o At least 3 months of sample data (in English)

- o Data taxonomy of country's variables (in English):

    - List of variables

    - Definitions of variables

    - Format, capacity and how data for each variable is collected

2. Revised Data Migration Template

How to Start

- Match PAROS Data Element with own variable
- Check for missing data
- Clearly differentiate missing data from pending data
- Try to minimise empty cells
- Adherence to Data Quality Assurance plan

3. Status of Implementation of PAROS Study Log

	A	B	C	D	E
1	S/N	DATE OF ARRIVAL INTO ED	NAME OF PATIENT	IDENTIFICATION / SOCIAL SECURITY NUMBER	CASE NO. (AS PER ePAROS)
2					
3					
4					
5					

- To ensure traceability at each site, the link between the case number (issued by ePAROS) and the actual patient's details should be retained

- This should be maintained by each site

- For confidentiality and privacy of patients to be observed, there is no need for sharing beyond each site

- Status of implementation

4. IRB Register
– Approval Status from Each Participating Country

COUNTRY	STATUS
Australia	Pending IRB approval letter
Japan	Pending IRB waiver letter
Korea	Pending IRB application status
Malaysia	Pending approval letters
Singapore	Approval letters obtained from DSRB and CIRB
Taiwan	?
Thailand	Approval letter obtained from Rajavithi Hospital
Turkey	Pending approval from IRB and response from Izmir health directorate
United Arab Emirates	Pending translated approval letter

5. Updates in ePAROS System

- **Ability to add races**
  - Different types of races can now be added in the system specified to each country by Study Data Administrator
- **Automated Country, City/EMS district and Site numbers**
  - Country, City/EMS district and site numbers in the Patient Enrollment Form are now automated for each user account i.e. user does not need enter the above information
- **PAROS website link**
  - Link on the ePAROS home page is updated

6. Data Quality Assurance Plan

- **Purpose**
  - To uphold data integrity

- **Three levels of data personnel**
  - (International) study level: Study Data Administrator
  - Regional or country level: Regional/Country Data Administrator
  - Site level: Site Data Administrator

6. Data Quality Assurance Plan

(International) Study Data Administrator

ROLES & RESPONSIBILITIES	QUALITY CONTROL ACTIVITIES
a. Request for a copy of approvals and related information b. Issue ePAROS access to data personnel at the site, regional, and country level c. Conduct training on the ePAROS system d. Liaise with server provider on any systemic change to ePAROS e. Clarify queries with other data administrators f. Carry out for-cause investigations g. Work with the Regional/Country Data Administrators for data recoding and migration (if applicable)	a. Maintain Quality Control log for issues identified and/or rectified by Study Data Personnel b. Perform logical and consistency checks (e.g. using range and field type checks)

6. Data Quality Assurance Plan

Regional/Country Data Administrator

ROLES & RESPONSIBILITIES	QUALITY CONTROL ACTIVITIES
a. Provide prompt responses (within two working weeks) to Study Data Administrator upon request for information or clarification b. Clarify queries with other data administrators (site, study) c. Maintain a copy of valid approval from the ethics review board (or equivalent) for the country or region d. Report regional or country-wide accrual rate when requested by Study Data Administrator e. Report any deviation from protocol involving data entered into ePAROS f. Work with the other data administrators to resolve corrections or issues in a timely manner g. Be trained in using ePAROS (if applicable) h. Assist in the training of users using the ePAROS (if applicable) i. Ensure that data to be migrated is accurate, complete and correctly mapped (if applicable) j. Work with the Study Data Administrator for data recoding and migration (if applicable)	a. Maintain Quality Control log for issues identified and/or rectified by Regional/Country Data Administrator b. Ensure correctly matched cases based on identifiers (if applicable) c. Ensure correctly translated fields in the data collection form as validated by back translation (if applicable) d. Ensure that validated data collection form is uniformly applied throughout the participating region and country e. Ensure that data from a region or country is accurate, complete and provided/entered in accordance to recommended timelines (see Section 4) f. Perform logical and consistency checks (e.g. using range and field type checks)

6. Data Quality Assurance Plan

Site Data Administrator

ROLES & RESPONSIBILITIES	QUALITY CONTROL ACTIVITIES
a. Provide prompt responses (within one working week) to other data administrators upon request for information or clarification b. Clarify data queries with other data administrators c. Maintain a copy of valid approval from the ethics review board (or equivalent) for the site d. Report accrual rate at site when requested by Region/Country and Study Data Administrator e. Report any deviation from protocol involving data entered into ePAROS f. Work with the other data administrators to resolve corrections or issues in accordance to recommended timelines (see Section 4) g. Attend training of the ePAROS system as and when required (if applicable) h. Work with the Regional/Country Data Administrator for data recoding and migration (if applicable)	a. Maintain Quality Control log for issues identified and/or rectified by Site Data Administrator b. Ensure correctly matched cases based on identifiers (if applicable) c. Ensure correctly translated fields (if applicable) d. Ensure that data from site is accurate, complete and provided/entered in accordance to recommended timelines (see Section 4) e. Perform logical and consistency checks (e.g. using range and field type checks) f. Ensure that data transcribed from source documents to (paper) data collection form is accurate and complete (if applicable)

6. Data Quality Assurance Plan

Data Flow and QC Checks

Direct Entry Online (ePAROS)

Paper Source	— Data Entry →	ePAROS	— Data Checks →	Cleaned PAROS Data
	QC ❶		QC ❷	

QC ❶: Site performs QC on ePAROS data against source data
QC ❷: Logic Data checks on ePAROS data by Regional/Country and/or Study Data Administrator

Export Field Entry

Existing Registry	— Export Data →	PAROS Data Migration Template	— Data Checks →	Cleaned PAROS Data
			QC ❶	

QC ❶: Logic Data checks exported data by Regional/Country and/or Study Data Administrator

6. Data Quality Assurance Plan

Data Checks

TYPE OF DATA CHECKS	DESCRIPTION	FREQUENCY
Direct Entry Online		
Computer checks in ePAROS	Entered data will be subjected to systemic validation rules	When entering data into ePAROS
Logic data checks	Checks will be on all data fields entered for a particular case (see Annex B)	Logic data checks performed at the site or region level should be done within 2 calendar months from incident date of case. On the study level, a frequency table will be worked out with the Study Data Administrator
Export Field Entry		
Logic data checks	Checks will be on all data fields migrated onto the data migration template (jointly worked out with the Study Data Administrator). Reference can be taken from the logic data checks using the Direct Entry Online method (see Annex B)	Frequency of check by Study Data Administrator on the fields selected for checking depends on the frequency of batch transfer worked out with the individual country or region

Where necessary, the Study Data Administrator can conduct audit checks on the site/region.

6. Data Quality Assurance Plan

Responsibilities of Site PI

- Ensures data completeness and accuracy from site
- Be apprised of the data-related issues raised by working with other data personnel

6. Data Quality Assurance Plan

Recommended Timelines

TYPE OF DATA ENTRY	RECOMMENDED TIMELINES
Direct Entry Online (ePAROS)	Data entry: Case should be entered into ePAROS 2 calendar months from the incident date of case Data checks: Checks should be performed no more than 2 calendar weeks from the completion Resolution of data query to site: 3 work-weeks from time the query was raised Resolution of data query to region/country: 1 calendar month from time the query was raised
Export Field Entry	A frequency timeline for data migration will be worked out jointly with the Study Data Administrator

6. Data Quality Assurance Plan

Access to Data

▸ Privacy of subjects must be maintained

▸ Sharing of ePAROS usernames and passwords is not allowed

TYPE OF DATA ADMINISTRATOR	ACCESS RIGHTS	SYSTEMIC RIGHTS
Study Data Administrator	Access to every case entered into ePAROS study-wide	View and amend all sections
Region/Country Data Administrator	Access to every case entered into ePAROS for the said region or country	View all sections
Site Data Administrator	Access to every case entered into ePAROS for the said site	• Administrators entering EMS and Hospital data: view and amend all sections • Administrators entering EMS data only: view and amend EMS data only • Administrators entering Hospital data only: view all sections, but amend hospital data only

6. Data Quality Assurance Plan

Quality Control Log

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	PAROS		Improving Outcomes from Pre-hospital and Emergency Care across the Asia-Pacific											
2								EMS & HOSPITAL DATA QUERIES						
3		PAROS QUERY / COMMENTS							REGION / SITE REPLY					REMARKS
4	Case number							Case number						
5	Section							Section						
6	Variable							Variable						
7	Query/Comments							Reply to query / comments						
8														
9														
10														
11														
12														
13														
14														
15	Case number							Case number						
16	Section							Section						
17	Variable							Variable						
18	Query/Comments							Reply to query / comments						
19														
20														
21														
22														
23														
24														
25														

All Quality Control logs should be maintained at each site, region and country. The Study Data Administrator can request for a copy of the Quality Control logs from sites or regions/countries on an ad-hoc or regular basis

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