Data-Related Issues

OUTLINE

1. Update from Each PAROS Country
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2. Updates to PAROS Taxonomy
3. Data Migration Template
4. PAROS Study Log (Sites)
5. IRB Register
6. Quality Assurance Plan

1. Update from Each PAROS Country – Using ePAROS

Singapore

- IRB approvals obtained for 7 institutions (island-wide coverage)
- Entering live data (i.e. gone 'live')
- ~300 entries entered

Thailand

- IRB approval obtained for Rajavithi Hospital (Bangkok)
- Entering live data (i.e. gone 'live')

Malaysia

- IRB approval status

- Gone 'live' in University Sains Malaysia (Kelantan), Hospital Kuala Lumpur (KL), Hospital Sungai Buloh (Selangor)

- ~122 cases entered

- Main issue with entering:

  o Difficulty getting hospital data from ED

  o Affects mostly cases that are conveyed to hospital

1. Update from Each PAROS Country – Using ePAROS

Australia

- IRB approval status

- Shipment of server and its maintenance

- ePAROS platform will be adopted

Dubai

- IRB approval obtained (currently being translated)

- Actively populating database

- In demo version, but will go 'live' soon

- Main issues/queries:

  o Request to change race to "UAE nationals, Arab, Asian, Others"

  o Quality of Life question involving EQ-5D would have to be done on discharged patients (via interview or phone call)

1. Update from Each PAROS Country – Using ePAROS

Turkey (Izmir)

- Going to apply for IRB approval

- Main issue:
    - Newly implemented Health Transformation Programme affected data collection team (caused many doctors to switch institutions)
    - Progress expected after April 2011

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

Updates

- Taipei, Korea, Japan using this method

- Requires recoding

- Start recoding with Taipei (currently in the works)

2. Updates to PAROS Taxonomy

#18. Arrest witnessed by	Check only *ONE* that applies from the list provided.
	Not witnessed is defined as the arrest event was neither seen nor heard by anyone.
	Arrest witnessed is defined as the arrest was *seen or heard* by another person.
	A bystander is defined as any person who responded and was *NOT* on duty with the EMS team or private ambulance crew at the time of the arrest.
	If the patient responded to bystander's CPR or defibrillation, and has ROSC prior to EMS team or private ambulance arrival, but later re-arrest in front of EMS team or private ambulance, the arrest would *NOT* be considered witnessed by EMS team or private ambulance.
	Bystanders include passer-by, lay person, member of the public, family member, police, private general practitioner, healthcare provider from nursing home/dialysis center, etc.
	Bystander – healthcare provider defined as bystander medical personnel who are *NOT* part of the EMS team. This option does not take into consideration whether the healthcare provider is a family member or relative of the patient.
	Bystander – family defined as the person who is known to be a family member or relative of the patient who is *NOT* a healthcare provider.
	Bystander – lay person defined as other bystander who is a non-relative / family member and a non-healthcare provider.
	Where there are overlaps between the sub-categories of Bystander, the option should be selected in the following order: (1) Bystander – healthcare provider; (2) Bystander – family; then (3) Bystander – lay person.
	Sites that did not distinguish the three sub-categories of bystanders should enter their data into "Bystander – lay person".
#19. Bystander CPR	Indicate "Yes" or "No".
	Indicate whether CPR (chest compressions with/without ventilations) was attempted by a bystander prior to arrival of EMS team.
	Bystander includes passerby, lay person, member of the public, family member, police, private general practitioner, healthcare provider from nursing home/dialysis center, etc.

2. Updates to PAROS Taxonomy

#23. *First arrest rhythm*	Defined as the *FIRST* cardiac arrest rhythm captured by EMS team/Private ambulance after placement of defibrillator pads or electrodes.
	Check only *ONE* that applies from the list provided.
	Abbreviations: VF – Ventricular fibrillation
	VT – Ventricular tachycardia
	PEA – Pulseless electrical activity
	If the first arrest rhythm was captured by an AED *without ECG display*, select either "Unknown shockable rhythm" or "Unknown unshockable rhythm" where applicable.
	Sites that did not distinguish the shockable rhythm of VF and VT, by default should enter their data into "VF".
	Indicate "Unknown" if unable to obtain any information.

2. Updates to PAROS Taxonomy

#29. *Prehospital advanced airway*	Indicate "Yes" or "No".
	Indicate whether advanced airway was used during the course of resuscitation. If advanced airway was used, indicate which type of airway was inserted. Check only *ONE* that applies from the list provided.
	Abbreviations: ET – endotracheal intubation LMA – laryngeal mask airway
	Please note that Oropharygeal (also known as oral airway, OPA or Guedel airway) and Nasopharyngeal airways are *NOT* advanced airways but are only airway adjuncts.
	Cricothyrotomy and tracheotomy are classified as advanced airways. These data should enter into "Other".
	Any advanced airways used by private general practitioner or healthcare provider prior to EMS team arrival should be included as prehospital resuscitation.
#30. *Prehospital drug administration*	Indicate "Yes" or "No".
	If drug was administered during the course of resuscitation, indicate which of the listed drugs were administrated during the course of resuscitation. Check *all that applies* from the list provided.
	Drugs administration prior to EMS team arrival should be included too, example drugs administered by private general practitioner or healthcare provider from nursing home.

2. Updates to PAROS Taxonomy

#44. *Advanced airway used at ED*	Indicate "Yes" or "No".
	If advanced airway was used, indicate which type of airway was applied during ED resuscitation. Check only *ONE* that applies from the list provided.
	Abbreviations: ET – endotracheal intubation
	LMA – laryngeal mask airway
	Please note that Oropharygeal (also known as oral airway, OPA or Guedel airway) and Nasopharyngeal airways are *NOT* advanced airways but are only airway adjuncts.
	Cricothyrotomy and tracheotomy are classified as advanced airways. These data should enter into "Other".

3. Data Migration Template

Country Data Person to

- Match PAROS Data Element with own variable

- Check for missing data

- Clearly differentiate missing data from pending data

- Try to minimise empty cells

- Address data queries raised by Coordinating Centre

- Verify data against source (to ensure accuracy & completeness of data)

3. Data Migration Template

PAROS Variable #

	A	B	C	D	E	F	G	H	I	J
1			#2	#9 - (hh:mm:ss)	#11 - (hh:mm:ss)				#13 - (hh:mm:ss)	
2	System number	Case number	Date of incident	Time call received at dispatched center	Date of dispatched	Time ambulance dispatched	Date of departed	Time ambulance departed	Date of ambulance arrived at scene	Time ambulance arrived at scene
3	990602001	1006020049515	2/6/2010	0:49:51	2/6/2010	0:50:25	2/6/2010	0:51:00	2/6/2010	0:54:00
4	990602002	1006020508272	2/6/2010	5:08:27	2/6/2010	5:08:49	2/6/2010	5:09:16	2/6/2010	5:12:38
5	990602003	1006012042422	1/6/2010	20:42:42	1/6/2010	20:43:41	1/6/2010	20:44:26	1/6/2010	20:55:46
6	990602004	1006012040482	1/6/2010	20:40:48	1/6/2010	20:41:28	1/6/2010	20:41:52	1/6/2010	20:45:22

3. Data Migration Template

Matching Done in Singapore (Using Taipei as Example)

- Data fields addressed:
    - Name of PAROS Data Element
    - Numbering of PAROS Data Element
    - Name of [Country]'s Data Element
    - [Country]'s Data Coding
    - Queries

3. Data Migration Template

	A	B	C	D	E	F	G	H	I
	PAROS Data Element	**Mode of Transport**	**Date of Incident**	**Location Type**	**Age (Years)**	**Gender**			
	Numbering in PAROS CRF	#1	#2	#4	#5	#6	#8	#8 - (3:Heart disease)	#8 - (4:Diabetes)
	Taiwan-Taipei Data Element	NIL	Date of Incident	Location Type	Age	Gender	Medical history	Heart disease	Diabetes
4			2/6/2010	Street/Highway	24	M	Unknown	N	N
5			2/6/2010	Nursing home	78	F	Y	Y	N
6			1/6/2010	Home residence	90	M	Y	N	N
7			1/6/2010	Industrial place	80	M	Y	N	Y
8			1/6/2010	Place of recreation	55	F	N	N	N
9			1/6/2010	Other	59	M	Y	Y	N
10			1/6/2010	Unknown	77	M	Y	Y	Y
11			2/6/2010	Public/commercial building	70	M	Y	N	N
12			2/6/2010	Education	103	F	Y	Y	Y
13			2/6/2010	Home residence	78	F	Unknown	N	N
14	**Taiwan-Taipei Data Coding**	All cases are transported by EMS		Education = #4 - (3: Public/commercial building) Home residence = #4 - (1: Home residence) Industrial place = #4 - (6: Industrial place) Nursing home = #4 - (4: Nursing home) Other = #4 - (50: Other) Place of recreation = #4 - (8: Place of recreation) Public/commercial building = #4 - (3: Public/commercial building) Street/Highway = #4 - (5: Street/highway) **Unknown = ***			N = #8 - (1: No) Unknown = #8 - (99: Unknown) If is **Y**, then <u>at least one</u> of the medical history has to be **Y**.	**Y** = Patient has heart disease.	**Y** = Patient has diabetes
15	**Queries to Taipei**			**Pending reply from Yi-Ting:** **Unknown & Blank = Missing data?**					

4. 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

5. IRB Register

Details

- Country

- Region (if applicable)

- Title of Project

- Name of IRB and Organisation

- Name of PI

- Initial submission: Date of Approval / Expiry

- Renewal: Date of Approval / Expiry

A copy of IRB approval should be forwarded to the Network Secretariat when obtained.

5. IRB Register

	A	B	C	D	E	F	G	H	I	J	K
1							**INITIAL SUBMISSION**		**RENEWAL**		
2	S/N	COUNTRY	REGION (IF APPLICABLE)	TITLE OF PROJECT	NAME OF IRB & ORG	NAME OF PI	DATE OF APPOVAL	DATE OF EXPIRY	DATE OF APPROVAL	DATE OF EXPIRY	REMARKS
3	1	Singapore	SingHealth Institutions: - CGH - KKH - SGH	Determining the Cost-Effectiveness of Strategies ti Improve Survival from Out-of-Hospital Cardiac Arrest in Singapore	SingHealth Centralised IRB (CIRB)	Assoc Prof Marcus Ong	Waiver obtained	Waiver obtained			
4	2	Singapore	National Healthcare Group (NHG) Insitutions - NUHS - KTPH - TTSH - AH-JHS (included in Amendment)	Determining the Cost-Effectiveness of Strategies ti Improve Survival from Out-of-Hospital Cardiac Arrest in Singapore	NHG Domain Specific Review Board	Dr Benjamin Leong	4-Nov-10	3-Nov-11			Versions Used (Initial) - Application form: 1.0 - PAROS Protocol: 1.0 - Participation Info Sheet & Consent Form: 3.0 - PAROS Assent Form: 1.0 - PAROS EQ-5D: 1.0 - PAROS CRF: 1.0 Versions Used (Amendment) - Application form: 3.0 - Participant Assent Form: 2.0
5	3	Thailand	Rajavithi Hospital, Bangkok	Establishment of the Pan-Asian Resuscitation Outcomes (PAROS)	IRB: The Ethics Committee Org: Rajavithi Hospital	Dr Nalinas Khunkhlai	22-Jul-10	22-Jul-12			

6. Quality Assurance Plan

Purpose

- Define and standardise the processes and procedures

- Facilitate the study to be conducted in compliance (with protocol, applicable SOPs, GCP, IRB and Regulatory Authority requirements)

6. Quality Assurance Plan

Roles & Responsibilities of Site PI / Data Coordinator

- Prompt response

- Clarify data queries

- Maintain a copy of valid approvals (provide a copy to Network Secretariat / Data Person)

- Access to entered data (site, region, country level)

- Receive training on ePAROS (if applicable)

- Ensure data is cleaned up before entering into system or submitted for recoding (i.e. ensure accuracy and completeness) (if applicable)

6. Quality Assurance Plan

QA Procedures For Discussion

(A) Using ePAROS (site-level)	(B) Using Export Data (i.e. requires data migration)
• Data collection	• Data migration template
• Matching EMS & hospital outcomes	• Data upload procedures
• Data entry	• Data queries
• Data queries	• Data verification
• Data verification	

6. Quality Assurance Plan

(C) Miscellaneous

- Site visit

- Monitoring

- Audit procedures

- Maintenance of site logs

- Maintaining valid approvals (e.g. IRB approvals)