Facilitating harms data capture by non-clinicians utilizing a novel data collection tool

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Background

Limited evidence on the safety of ACTs in real life settings

- Repeated use
- Vulnerable populations

Post-marketing surveillance

- Detect rare, possibly serious events that may be associated with a drug
- Inform on potential risk factors

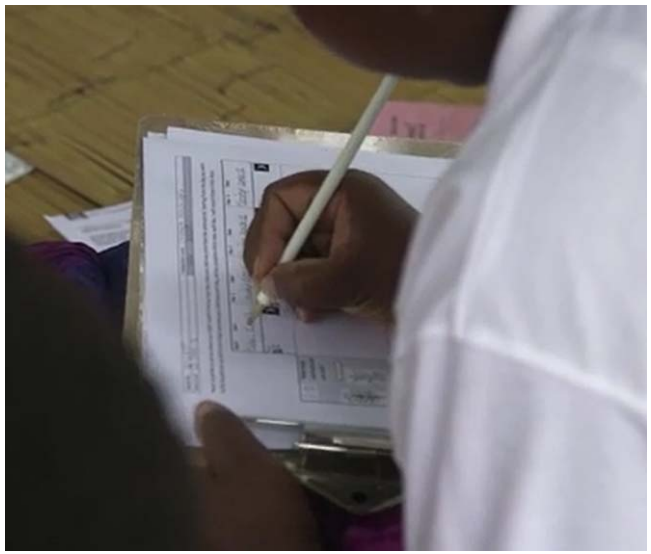
Issues

- Weak system
- Aimed at conventional healthcare system

Designing Adverse Event Forms for Real-World Reporting

Aim

To develop user-friendly AE reporting forms to capture information on events associated with ACTs



Development

Review of existing forms

↓

Form development workshops*

↓

Pretesting*

*with target end-users (Community Medicine Distributors, Community Health Workers, Fieldworkers)

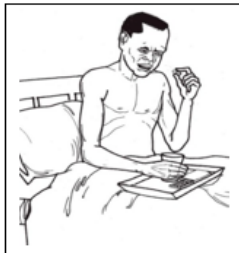
For use by data collectors with limited knowledge of adverse events

Patient ID: _____

ACTIVE ADVERSE EVENT REPORT FORM (PROSPECTIVE) – PART A (PRE-TREATMENT)

Version 3.0 (Adult)

Show the picture story to the respondent. Use the story to explain why you are filling in the form with them. Invite questions



The man takes medicine for malaria

The man is being sick. This may or may not be due to the drug

The reporter fills this form with the man

Discuss with the patient:
Why we are filling in this form:

- We are trying to find out people's experiences with using [Study Drug]
- I would like you to tell me what happened before and after you took [Study Drug]
- I would like us to fill this form in together

1. 1 Reporter ID		1.2 Reporter Contact		1.3 Reporter Job Title		1.4 Report Number	/A	1.5 Date Part A Completed: (DD/MM/YYYY)	

2.1 Patient ID		2.2 Age(yrs)		2.3 Weight (kg) *If known*		2.4 Height (cm)*If known*		2.5 Sex M/F		2.6 Pregnant? Y/N	
										2.6.1 If Y	

3. Presenting problem

3.1 Symptoms before being prescribed [Study Drug]:

3.2 Diagnosis_____ 3.3 Confirmed by: Rapid Diagnostic Test? Yes ☐ No ☐ 3.4 Malaria Blood Slide

4. Medication History

4.1 Did the patient try any treatment for these symptoms before attending the health facility? Yes ☐ No ☐;
4.1.1 If yes, what did the patient take?

4.2 Did the patient use any trad remedies for this illness? Yes If Yes, give details if known

4.3 Does the patient take any medicines regularly (e.g. for diabetes, family planning, ARVs, TB medicine, epilepsy, etc) Yes ☐ No ☐;
4.3.1 If yes, what does the patient take (names of drugs and doses if known)?

*4.4 Does the patient use any t remedies regularly? Yes ☐ N give details if known*_____

5. Medicines Prescribed at this Visit (from records)

Drug name	Dose (e.g. 2 tabs, 1 cap, 1g, 500mg, 5ml, 1 tsp)	Frequency (e.g. once daily, twice daily)	Start Date (DD/MM/YYYY)	Number of days prescribed
5.1			___/___/_____	
5.2			___/___/_____	
5.3			___/___/_____	
5.4			___/___/_____	

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Pictorial design to aid communication in lower-literacy level settings

Diary format to record drug administration and event details in chronological relation to each other

to the hospital can you tell me the drugs and herbs your child took each day, and any symptoms old or new, each day. I will record these in this diary:

	Day 0 Date	Day 1 Date	Day 2 Date	Day 3 Date
	MONDAY 16/07/12	TUES 17/07/12	WEDS 18/07/12	THURS 19/07/12
	☀ ☽	☀ ☽	☀ ☽	☀ ☽
What drugs and herbs did you use?	In this row, show ALL drugs taken by the patient and each dose each day.			
	LA AM PN ¼	LA AM PN ¼	LA AM PN ¼	AM PN ¼
Describe your symptoms each day?	In this row, describe ALL symptoms, and unusual events experienced by the patient each day			
	FEVER COUGH VOMMITTING			

Evaluation

Do these forms enable non-clinicians to collect safety data which can inform on potential harms related to ACTs?

	Malawi	Uganda
Study	ACTia – Safety of repeated drug use in children	i: Use of RDTs to improve malaria treatment in the community in Uganda ii: Introducing RDTs in drug shops to improve the targeting of malaria treatment
ACT(s)	AL & DHA-PQ	AL
Participant age group	Children	Adults & children
Intervention	AL vs DHA-PQ	RDT vs presumptive treatment
Data collectors	Experienced fieldworkers	Experienced fieldworkers
Additional details	Safety data collected alongside adherence data on day 3 or 4	Safety data collected alongside economic, adherence and outcome data on day 4

Results

Dihydroartemisinin-Piperaquine (Children)

Event as reported	Preferred Term (MedDRA)	No. of patients (n=115)
Mouth sores	Stomatitis	3
Diarrhoea	Diarrhoea	2
Vomiting	Vomiting	2
Cough	Cough	2
Convulsion	Convulsion	2
Head sores/sores on neck	Skin ulcer	2
Yellowish eyes	?Jaundice	1
Swollen face	Swelling face	1
Weakness	Asthenia	1

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Event as reported – Artemether/lumefantrine	Preferred Term (MedDRA)	No. of children (n=576)	No. of adults (n=83)
Cough	Cough	11	0
(General body) weakness/Weak/Unable to stand	Asthenia	8	2
Vomiting	Vomiting	7	1
(High) fever/(Very) high temperature	Pyrexia	5	2
Flu	Influenza	4	0
Diarrhoea	Diarrhoea	3	0
Mouth sores	Stomatitis	3	0
Dizziness	Dizziness	2	5
Sweating	Hyperhidrosis	2	0
Swollen face	Swelling face	2	0
Skin rash	Rash	1	0
Abdominal pain	Abdominal pain	1	1
Joint pains	Arthralgia	1	0
Swelling of the lips	Lip swelling	1	0
Strong headache	Headache	1	2
Tired	Fatigue	1	0
Convulsions	Convulsions	2	0
Loss of appetite	Decreased appetite	1	0
Confused/Lost sense of understanding	Confusional state	1	1
Jumpy	Nervousness	1	0
Restlessness	Restlessness	1	0
Pain	Pain	1	0
Nausea	Nausea	0	1
Body itching	Pruritus	0	1

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Diarrhoea	Diarrhoea	3	0
Mouth sores	Stomatitis	3	0
Dizziness	Dizziness	2	5
Sweating	Hyperhidrosis	2	0
Swollen face	Swelling face*	2	0
Skin rash	Rash	1	0
Abdominal pain	Abdominal pain	1	1
Joint pains	Arthralgia	1	0
Swelling of the lips	Lip swelling*	1	0
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Interesting findings

- Different AE detection rates between fieldworkers
- Differences between AEs detected by fieldworkers and AEs detected on review
- Intensity of training

Conclusions

- Non-clinicians are capable of capturing a patient's experience following a malaria episode which can be used to detect adverse events
- Contribution of data to a centralized safety database
- Training and continuous feedback are paramount
- Not malaria-specific

Learn more about our resources

www.actconsortium.org/safetydatacollectiontools

www.actconsortium.org/drugsafetydatabase

Or contact Cheryl.Pace@LSTMed.ac.uk

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