ACCESS SMC

Achieving catalytic expansion of seasonal malaria chemoprevention in the Sahel

Safety monitoring & SMC

KAMPALA PARTNERS MEETING 18-20TH JANUARY 2016

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UNITAID

outlines

- Planning approach
- Developing action plan
- Next steps
- Details on Serious Adverse Events reported so far

Planning PV approach

Geneva workshop (Oct 2014) with bringing together:

1. Malaria programme managers & PV responsible persons from the SMC countries
2. Safety Medicine Department of WHO HQ
3. Global Malaria Control Programme
4. WHO experts from other departments (Vaccine & Neglected disease with MDA)
5. WHO/TDR and LSHTM

- Weaknesses in the safety monitoring system (SMS) with needs in terms of training of the PV and Malaria control programmes for implementing safety monitoring
- To arrange a training workshop for PV coordinators and Malaria Control Managers
- Regional networking and sharing information for improving the SMS
- Regional Panel to review events
- Needs for innovative approaches

Developing PV action plan

Build on existing system and strengthening it

Rabat workshop (May 2015) with bringing together:

1. Malaria programme & PV responsible persons from the SMC countries
2. WHO collaborative PV centre team of Morocco
3. WHO safety department representative
4. LSHTM, UCAD, Senegal PV focal person, MC and WHO/TDR

- Discussed training tools for safety monitoring
- Discussed optimal safety monitoring system and reporting requirements (VIGIFLOW)
- Developed an action plan for each country to be ready for 2015
  - Detection, management, response, reporting and follow-up
  - Assessment of causality by the National Safety Committee
  - Reporting to UPPSALA (VIGIFLOW, VIGIBASE)

Developing PV action plan

Constraints:

1. Weaknesses of PV system in all countries for various reasons
    - Chad with no PV system in Place
    - Gambia with partial system in place
    - Guinea with no VIGIFLOW access
2. Countries with National Safety Committee on paper only
3. Few countries reporting in VIGIBASE

Progress:

- Chad joined WHO PV system
- Gambia full member of WHO
- All countries have VIGIFLOW access

1. National authorities are well informed in all countries
2. All countries are reporting events

Next step

Rabat workshop (Feb 2016) with bringing together:

1. Malaria programme & PV responsible persons from the SMC countries
2. WHO collaborative PV centre team of Morocco
3. WHO collaborative PV centre of Ghana
4. WHO safety department representative
5. LSHTM, UCAD, Senegal PV focal person, MC, WHO/AFRO PV and WHO/TDR

Objective:

- Lessons learned and corrective actions
- Regional Safety committee 1st meeting (review of events reported and imputability) which will report to the Drug Safety Advisory Committee in Geneva (April 2016)
- Exploring innovative ways for monitoring Safety in the context of MDA

Details on SAEs reported so far

Guide for health facilities

UNITAID ACCESS SMC malaria consortium CRS

Safety monitoring for SMC: Guide to the rare severe side-effects of SMC drugs, for health facilities

Condition	Description	Actions
Stevens-Johnson syndrome (severe skin rash) 	Painful red or purplish rash that spreads and blisters. Then the top layer of the affected skin dies and sheds. May begin with flu-like symptoms.	Notify. Medical emergency that requires hospitalization. Avoid all sulfa-containing drugs in future.
Hepatotoxicity (jaundice) 	Signs of liver injury include yellow eyes, dark coloured urine, with loss of appetite, nausea, vomiting or abdominal pain, or weakness.	Notify. Confirm with lab tests of liver function if possible. Refer to hospital.
Extra-pyramidal syndrome (neurological disorder) 	Involuntary muscle movements in the face and neck. May include lip smacking, tongue movements, blinking, and head or finger spasms. The patient may have difficulty moving the arms and legs, and slur their words.	Notify. Avoid AQ in future. Refer to hospital.
Repeated vomiting 	Repeated vomiting can start hours after drug intake, and in severe cases can persist for several days with vomiting several times per day.	Eligible for SMC in the next round, but advise the family to bring the child to clinic if symptoms recur.

- Severe adverse reactions to SMC drugs are very rare.
- Cases of conditions marked "Notify" should be reported immediately to Dr._____ at this number: Tel. _____
- For all suspected side effects, mild or severe, a Pharmacovigilance Form should be completed.
- When completing the Pharmacovigilance Form, record when the symptoms started, and ask about ALL medications including traditional medicines the child has received in the last 2 weeks.

Number of adverse events reported

Countries	AEs	SAEs
Burkina Faso	2054 (94% vomiting)	1 (oedema)
Chad	0	1 (oedema)
Gambia	668	1 (Extra pyramidal syndrome)
Guinea	33	0
Mali	7 (vomiting and abdominal pain)	1 (oedema)
Niger	1418 (96% vomiting)	3 (1 death)
Nigeria	2 (rash and vomiting)	0

Reported SAE by country

Burkina Faso : 1 SAE

Zorgho District, health centre of Paspanga

Age : 22 months, boy

weight : 12 kg

drugs received : SPAQ (lot N° : LP150417, expiration date 22 april 2018)

Date of 1rst dose of CPS : 01st august 2015

Date of onset of symptoms : 01st august 2015

Time before onset of symptoms : 1h 30 mn

Duration of symptoms : less than 24 h

Clinical symptoms : vomiting, generalized itching and face oedema

Mothers has an History of allergy of sulfa drugs

Evolution : recovered

District : Mandelia; Village: Mailao

Age : 20 months; Sex : male

Weight : 12 kg, Height : 86 cm

Medicine received : Sulfadoxine-Pyrimethamin + Amodiaquine

Date of 1rst dose of CPS : 27/08/2015 at 08h30

Number of SMC cycle : second cycle

Excluded from the 1rst cycle due to vomitting

Date of onset of symptoms : 27/08/2015 on evening

Symptoms:

- Drowsiness, weakness.
- Oedema : face, hands and legs

Date of consultation : 28/08/2015

1rst treatment : Dexamethasone

Return home the same day with oedema starting reabsorbed

On 1rst october : child suffer from diarrhoea, fever, polyuria and polydipsia

Evolution : at the date of january 15th, the child was found well at home.

Niger : 3 SAE

N°	District/ Village	Age-Sex	Medication	Date of SMC dose	Date of onset	Symptoms	Treatment	Evolution
1	Zinder	3 yrs-Female	SP+AQ	08/08/2015	09/08/2015	Vomiting Fever Coma	Ceftriasone, Artesunate, Glucose	Recovered
2	Aguié/ Gazori	3yrs-female	SP+AQ	19/10/2015	19/10/2015	Severe repetitive vomiting	Metoclopramide	Recovered
3	Zinder/ Franco	18 mths-Female	SP+AQ	10/08/2015	10/08/2015	Fever, Severe repetitive vomiting, Convulsion	ciprofloxacin, analgin, ceftriasone, Quinin	Died

Gambia : 1 SAE

District : Bansang; Village: Mabally Kuta

Age : 28 months; Sex : male

Weight : 10 kg,

Medicine received : Sulfadoxine-Pyrimethamin + Amodiaquine

Date of 1rst dose of CPS : 28 october 2015

Date of onset of symptoms : 28 october 2015

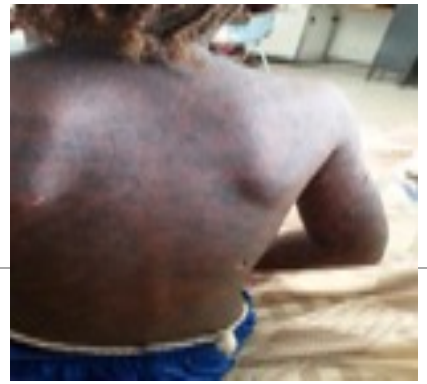
Time before onset of symptoms : 30 minutes

Symptoms : involuntary muscle movement of the face and neck, blinking of eyes and finger spasms, difficulty in moving arms and legs

Duration of adverse reaction : 3 hours

Evolution : recovered

Senegal



2014

2 SAEs reported (total about 2 million treatments)

- 1 Stevens Johnson syndrome in 9-yr-old girl 1 week after first SMC cycle
- 1 Lyell syndrome occurred in 10 years girls, 10 days after 1st SMC

Both recovered well, after 2 weeks admission

Instructions to avoid SMC drugs in future

2015

3 SAEs reported

- Generalized seizure, convulsions and coma which ended like a tetanus crisis in 5 yrs-old girl
- Anaphylactic shock in 7yrs-old by
- Generalized rash and oedema in 9 months-old boy
- All recovered during admission

All coming from same region

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