Feedback from the yellow fever mass vaccination campaign using fractional dose

Kinshasa, Democratic Republic of Congo
17-26 August, 2016
Context

• Yellow fever outbreak in Angola (first case reported in Dec 2015) unique due to urban nature
• DRC reported cases in connection with Angola in March 2016, outbreak officially declared on 23 April 2016
  • Local transmission in DRC was confirmed in May 2016 in zones bordering Angola (13 confirmed cases to date are autochthonous)

<table>
<thead>
<tr>
<th>Cumulative data up to 12 October</th>
<th>ANGOLA</th>
<th>DRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cases reported to central</td>
<td>4,220</td>
<td>2,916</td>
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<tr>
<td>Total samples tested</td>
<td>3,666</td>
<td>2,800</td>
</tr>
<tr>
<td>Total confirmed cases</td>
<td>884</td>
<td>77*</td>
</tr>
<tr>
<td>Total reported deaths</td>
<td>373</td>
<td>120</td>
</tr>
<tr>
<td>Total deaths among confirmed cases</td>
<td>121</td>
<td>16</td>
</tr>
</tbody>
</table>

*including 7 cases of sylvatic YF not associated with the outbreak
Distribution of confirmed yellow fever cases in DRC as of 12 October 2016
Mass vaccination campaign response, DRC

Target pop: 2 m
Doses sent: 2.2 m
Coverage (admin): 98-114%

Target pop: 975,681
Doses sent: 1.1 m
Coverage (admin): 70-114%

Target pop: 10,515,589
Doses available: 5.8 m

Reactive vaccination campaign May 2016: 9Z in Kongo Central + 2 ZS in Kinshasa
Reactive vaccination campaign 20-29 July 3 ZS in Kwango and 1 ZS in Kisengo
Preventive vaccination campaign 17 August – 5 September in 15 ZS along Angola border + 32 ZS in Kinshasa
Confirmed cases, vaccination not planned
Preventive campaign using fractional dose
Kinshasa, 17 – 26 August

- **Target area:** 32 health zones in Kinshasa
- **Target population:** 7,586,400
- **Vaccine doses available for Kinshasa:** 2,500,000
- **In order to ensure rapid vaccination of entire target population in Kinshasa, a fractional dose strategy was considered:**
  - **Fractional dose:** $\frac{1}{5}^{th}$ (0.1 ml) of full dose administered subcutaneously (SC) using BCG syringe and needle
  - Everyone over the age of 2 years would receive a fractional dose ("minimal dose")
- **Children 9-23 months and pregnant women received a full dose**
Regulatory considerations

• Considering the global supply situation and the recommendations by WHO, National authorities in DRC provided approval to use fractional dose for the first time in the country

• Political decision to go ahead with the campaign

• In-country approval process
  – Meeting in Geneva with DG, IVB and PED teams to clarify issues
  – Waiver was granted to import vaccines
  – Import authorizations and registration in country were handled in the emergency context
  – **Vaccine:** 10 full-dose vials (5 ml per vial), Bio-Manguinhos (Brazil)
Logistical challenges

• 3 different types of syringes were required (0.5 ml for full dose, 0.1 ml for fractional dose, 5 ml for reconstitution) – over 13 million syringes shipped!

• Availability of 0.1 ml syringes was limited in the country – 2 million borrowed from polio stockpile

• Vaccine from Brazil was without VVM: challenge to have sufficient quantities of vaccine carriers to maintain cold chain. Provision of additional 3800 vaccine carriers and 200 coolers.

• Waste management for such a large scale campaign
Communications and Training

• 1 day training was conducted for all vaccination staff
• Fractional dose communicated as “minimal dose”
• Press conference held prior to campaign with key press offices in Kinshasa
• Social mobilization through proactive engagement of local television, print and radio media, posters, banners, announcements and door-to-door visits
Information posters and bulletins

**Fièvre jaune**

Protégez-vous contre la fièvre jaune:
- Faites-vous vacciner
- Portez des vêtements couvrant le corps
- Dormez sous une moustiquaire
- Placez des écrans anti-insectes aux fenêtres
- Utilisez des produits répulsifs

**Consultez un médecin si vous présentez les symptômes suivants**
- Fièvre
- Jaunisse
- Douleurs musculaires
- Mal de tête
- Sanglants

**Le vaccin contre la fièvre jaune**

Est la meilleure protection contre la maladie.

Unicef, Organisation mondiale de la Santé, République Démocratique du Congo.
Implementation

• **Fixed posts:** 2,404 immunization posts were operational for 10 days of vaccination

• **Teams:** 14,424 vaccinators supported the campaign
  – Each team included a minimum of 5 vaccinators, 2 recorders, 1 social mobilizer/community engagement expert, 1 volunteer to maintain order, and 1 for waste management

• **Monitoring:** 32 WHO supervisors and 96 independent campaign monitors were deployed across all 32 zones
Recording

• Tally sheets recorded full and fractional dose administration

• Vaccine recipients were given a specially designed card indicating which dose (full or fractional) was received.

• The cards also included a disclaimer that they were not considered YF certificates valid for international travel
RÉPUBLIQUE DÉMOCRATIQUE DU CONGO
MINISTÈRE DE LA SANTÉ PUBLIQUE

PROGRAMME ELARGI DE VACCINATION
CAMPAGNE DE VACCINATION CONTRE LA FIEVRE JAUNE

Province : __________________________ Zone de santé : __________________________
Dose administrée: Dose entière ______ Dose minimale ______
Date de vaccination: ______/_____/20_____
Nom / Prénom: ________________________________________________________________
Age: __________________________________________ Sexe : ________________________
VAA N° Lot: __________________________ Diluant N° lot: ________________________

Conservez cette carte avec votre carnet de vaccination/de santé.

Note: Ce document n’est pas un certificat de vaccination contre la fièvre jaune et n’est pas valide pour voyager.
# Campaign coverage

<table>
<thead>
<tr>
<th>Administrative coverage</th>
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<tbody>
<tr>
<td>Target population</td>
<td>7,586,400</td>
</tr>
<tr>
<td>No. reported vaccinated (total)</td>
<td>7,898,365</td>
</tr>
<tr>
<td>No. reported vaccinated (fractional dose)</td>
<td>7,466,998</td>
</tr>
<tr>
<td>No. reported vaccinated (full dose)</td>
<td>431,367</td>
</tr>
<tr>
<td>Coverage (administrative)</td>
<td>104%</td>
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<thead>
<tr>
<th>Rapid convenience assessment</th>
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<tbody>
<tr>
<td>Households sampled</td>
<td>10,300</td>
</tr>
<tr>
<td>No. respondents</td>
<td>58,021</td>
</tr>
<tr>
<td>No. respondents reported vaccinated</td>
<td>56,974</td>
</tr>
<tr>
<td>Coverage (RCA)</td>
<td>98%</td>
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</tbody>
</table>
Rapid convenience assessment
Vaccine acceptance

Reasons for non-vaccination (n=1,046)
- Lack of motivation: 30%
- Refusal: 21%
- Traveling: 10%
- Illness: 8%
- Parents were absent: 12%
- Non-resident: 6%
- Other: 13%

Reasons for vaccine refusal (n=219)
- No response: 36.1%
- Team was not courteous: 1.4%
- It is not for me to decide: 5.0%
- Don’t know: 8.7%
- Other: 13.7%
- Vaccine dangerous: 35.2%

*data from Rapid Convenience Assessment = 58,021 respondents
Waste management

• More than 20,232 safety boxes were collected and safely incinerated following the campaign

(over 11,000 tonnes of waste generated).
Immune evaluation of fractional dose
INRB/US CDC study

• **Primary Objective:** Assess the immunologic response to a fractional dose of YF vaccine **28 days** after vaccination by age group

• **Secondary objectives:**
  – Determine if *pre-existing flavivirus antibodies* influence the immunologic response
  – Assess whether the fractional dose vaccination results in sustained immunologic response at **12 months** post vaccination.

• **4 age strata:** 2-5 years, 6-12 years, 13-49 years, 50+ years

• Results expected late 2016 / early 2017
Main challenges noted

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<th>Programmatic Consideration</th>
<th>Experience in Kinshasa</th>
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<tr>
<td>Maintenance of adequate cold chain at immunization sessions, given low thermostability of reconstituted YF vaccine</td>
<td>Cold chain maintenance at the immunization sessions was a major concern – 69% of sites observed did not have temperature monitoring devices; 16% were not correctly keeping reconstituted vials in the foam cushion; 11% did not have sufficiently cold ice packs</td>
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</tbody>
</table>
| AEFI reporting and investigation | • AEFI monitoring did not generate sufficient data to enable comparison between fractional and full doses  
• Information on AEFI reporting was only available for vaccination sites (no reports from healthcare facilities)  
• Most of the AEFI notifications from the vaccination sites were lacking individual case based reporting forms  
• Patient care was delayed in reference hospitals and investigation was not carried out at district/province level for all suspected serious cases due to the absence of resources allocated to that activity. |
## Operational Experiences Gained

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<td>Administration of 0.1mL or 0.5mL, variable by population</td>
<td>Vaccinators understood the programme and were able to administer correct doses to the variable groups.</td>
</tr>
<tr>
<td>Wastage</td>
<td>Average numbers of fractional doses able to be drawn from each vial were not accurately counted, however, an average wastage rate of only 3.2% (0.3% - 8.8%) was calculated overall.</td>
</tr>
<tr>
<td>Availability of 0.1mL syringes</td>
<td>Procured sufficient volumes through manufacturer and loan from Polio program.</td>
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<tr>
<td>Septum integrity with multiple piercings</td>
<td>Despite multiple punctures to the vial septum, no leakage or bits of septum degradation/debris were observed in any of sessions.</td>
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<tr>
<td>Community understanding and acceptance</td>
<td>Fractional dosing was generally well understood by the population, but questions were raised. No significant resistance to fractional dose observed; No issues with false rumours or concerns specifically related to fractional dosing</td>
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