Field-Testing Report

International Public Health Consultants

Consultation: Pretesting instructions for preparing parenteral Artesunate
For the: Medicines for Malaria Venture (MMV)

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EXECUTIVE SUMMARY

WHO recommends parenteral artesunate in preference to quinine for the treatment of severe *P. Falciparum* malaria in adults and children. Intravenous injection is the preferred route of administration although intramuscular can also be given. The challenge however will be to ensure that healthcare providers (mainly nurses) fully understand how to prepare and administer the product. MMV has developed training materials to illustrate these steps and facilitate the correct use of the product. This documents reports on the first stages of testing these materials to enhance comprehension, relevance/appropriateness to the context and attractiveness.

The field testing described in this document was divided into 3 stages: preliminary/piloting stage; principal field testing stage and validation stage. Sixty five (65) health workers, across 7 institutions in Coast Province, Kenya were interviewed, using a qualitative framework. The one-to-one in-depth interviews took the form of a conversation in which the consultant probed deeply to uncover levels of understanding. The questions were regularly reshaped to focus on 'trouble spots' within the job aid. This approach prompted questions from the respondents and respondents often proposed solutions. Challenges raised in each interview informed the questioning in subsequent interviews. The interviews lasted on average 45 minutes and decreased over the course of the field testing. The time a respondent needed, to reach an appropriate level of understanding provided an important indication of comprehension – which represented the key outcome of the process. The approach used placed the enquiry as close to the users of the job aid as possible so as to capture the 'insiders' views" and allow the respondents/informants to feel at ease to share their experience and interpretation of the guide, without fear of judgement or failure.

Analysis of responses was ongoing and new versions of the job aid, that incorporated lessons learned from the previous day were tested daily. Key changes to the job aid over the course of the field testing included:

Density of information – Information in the poster was simplified and presented less densely;
Flow of information - The flow of information was modified significantly. Numbering was readdressed and a more systematic approach was adopted.
Authenticity of images – Changes were made the ensured that the images used were authentic and aligned with the ways things are done in practice, within a developing world public hospital/health centre context.
Best Practice - Changes were made that promoted best practice in nursing practice, with particular emphasis on drug preparation, sterile approach and safe administration.
Dosing tables and schedules - Dosing for various for infants through to grown adults raised many challenges, but ultimately, changes that allowed for ease of administration as well as patient safety were achieved.

The job aid that emerged from this intensive field testing process was found to be responsive to the needs of the health personnel who will be treating patients with severe malaria. The 3 stage process was able to ensure that the findings were representative of health worker perceptions of the job aid in Coast Province. The result of the field testing process is a job aid where the steps are clear and the information flows logically; best practice is consistently emphasised; the information presented is appropriate to the health worker cadres who will use the guide; all non-essential information has been removed and key safety requirements are included. The guide is attractive and engaging and can now assist and remind health workers when treating severe malaria in accordance with well-defined guidelines. The guide will effectively complement training.

Introduction

Severe malaria is a medical emergency. After rapid clinical assessment and confirmation of the diagnosis, full doses of parenteral antimalarial treatment should be started without delay.

WHO recommends parenteral artesunate in preference to quinine for the treatment of severe *P. Falciparum* malaria in adults and children.[1] Intravenous injection is the preferred route of administration although intramuscular can also be given.

Parenteral artesunate has been the treatment of choice for adults with severe malaria since 2006.

With the publication of the AQUAMAT trial[2] in 2010, a multi-centre study conducted in over 5,000 African children hospitalized with severe malaria, there is now sufficient evidence to recommend artesunate above treatment with either artemether or quinine. This very large randomized controlled trial, which enrolled 5,425 children < 15 years of age across Africa, showed a significant mortality reduction by 22.5% in the artesunate group when compared to the quinine group. The incidence of convulsions, coma, and hypoglycaemia developing after hospitalization was also significantly reduced.

Parenteral artesunate will be available in 3 different strengths: 30 mg/ 60 mg/ 120 mg. It has several advantages over quinine and artemether. In addition to the proven efficacy, it is easier to prepare and administer. The absorption is rapid and predictable, it kills all stages of the parasite's asexual cycle and it also has a good tolerability. (See Annex 1 – comparative table).

The challenge however will be to ensure that healthcare providers (mainly nurses) fully understand how to prepare and administer the product. MMV has developed training materials to illustrate these steps and facilitate the correct use of the product. This documents reports on the first stages of testing these materials for comprehension and attractiveness with health workers who represent the likely users of the product, who are currently or anticipate treating severe malaria in the future.

Purpose and Objectives

The overall goal of the exercise was to develop high quality job aids. These field tested job aids would ensure the correct use of the Artesunate product, even if minimal training or sensitisation takes place once the drug becomes incorporated into the national Malaria strategy for Kenya.

The key outcomes of the field testing exercise were enhanced:

i) Comprehension
ii) Relevance/Appropriateness
iii) Attractiveness

The specific objectives for each outcome were as follows:

i) **Enhance Comprehension** of instructions/pictograms to ensure:
   a) Systematic flow of information and ordering of steps that makes sense to a range of health worker cadres;

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[1] World Health Organization, Guidelines for the treatment of malaria, Second edition, Geneva, 2010; http://www.who.int/malaria/publications/atoz/mal_treatchild_revised.pdf

[2] Dondorp A *et al.* Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial; *The Lancet,* Vol. 376, Issue 9753, Pages 1647-1657, 13 November 2010

b) Accurate calculation of vial number and appropriate dose - based on patient's weight, product strength and route of administration;
c) Correct product preparation (reconstitution / dilution);
d) Careful and feasible withdrawal of the product;
e) Accurate administration of the product per route of administration and dose (mls);
f) Appropriate actions to discard any left-over product;
g) Correct application of dosing schedule based on patients' progress and response to the drug.

ii) **Ensure Relevance / Appropriateness** of instructions/pictograms to guarantee:

a) Cultural acceptability;
b) Alignment of illustrations to practice and expectations;
c) Correct level of complexity/simplicity of images, language, tables for various cadres of health workers;
d) Value of information – removal of anything redundant or inclusion of key points.

ii) **Emphasise Attractiveness** of instructions/pictograms to ensure:

a) Engaging illustrations;
b) Removal of redundant or irrelevant images;
c) Acceptable colours for the context;
d) Legibility of text and appropriate spacing.

Permission and Ethical Considerations

Formal approval for the study was awarded by the Ministry of Public Health and Sanitation, see Annex 1.

The consultant described the purpose of the field testing to each respondent and sought his/her consent, using the information sheet in Annex 2. The consent was explained and upon agreement, the interview was initiated. If consent was not obtained, most likely due to patient load, low staff numbers or an emergency; any other eligible member staff (nursing officer, pharmacists, clinical officers or medical officers) was approached. Respondents were reimbursed for their time with a 100 KES phone voucher.

Methodology and Sampling

The field testing described in this report consisted of three phases: the preliminary stage, the principal stage and the validation phase.

Preliminary Stage: The preliminary stage involved concept formulation and piloting of the first drafts of the job aid. The qualitative, in-depth interview guide was developed and piloted. MMV reviewed the outcome of the 3 pilot interviews, to confirm whether the approach was generating the quality of data desired. In addition key changes were made to the job aid post piloting.

The pilot interviews were conducted with a Senior Nurse familiar with Artesunate injection, a Paediatrician not familiar with the injection and a Malaria technocrat and pharmacist within the Ministry of Public Health and Sanitation.

Principal Stage: The principal stage was carried out over 4 days in 4 health institutions in Mombasa where severe malaria is treated. This stage involved intensive field testing of the job aid. The tools were revised in situ and the revised materials were re-tested daily, having incorporated the key changes from the previous day of testing.

Table 1: Description of sampled health facilities – Principal Stage

Name of Institution	Brief Description
Bamburi Cement Factory Staff Clinic	A private, company funded out patient facility free to staff and family of Bamburi Cement. Offering curative and preventative outpatient services. The clinic is a satellite clinic of Mombasa Hospital – a private hospital in Mombasa. The facility refers all patients with severe malaria to Mombasa Hospital.
Coast General Provincial Hospital	A 400 bed provincial government teaching hospital. In theory, Coast General receives all referrals from district hospitals.
Tudor District Hospital	Recently converted from a health centre to a district hospital, the hospital only houses maternity in-patients. All severe patients with malaria are given the first dose and transferred to Coast General.
Aga Khan Hospital	Part of the Aga Khan Health Services, it is a 96-bed acute care facility, providing general medical services, specialist clinics and high-tech diagnostic services. This facility stocks Artesunate in its' pharmacy and uses Artesunate as first line for severe malaria.

District boundaries have changed recently and this has altered the population figures. These figures are based on the 2007 census.

Validation Stage: The validation phase was conducted over 4 days in 3 health institutions in Malindi and Kilifi described in Table 2. The validation stage represented the final stage of field testing. Having overcome the larger hurdles, this stage allowed us to refine the details of the job aid and to validate the changes to date. This stage was carried out in 3 facilities.

Table 2: Description of sampled health facilities – Validation Stage

Name of Institution	Brief Description
Malindi District Hospital	A 183 bed District Hospital serving Malindi, a District with a population of approximately 500 000.*
Tawiq Hospital	A 50 bed Private Hospital, offering curative and preventive in and out patient services.
Kilifi District Hospital	A 172 bed District Hospital serving Kilifi District, a District with a population of approximately 200 000.*

Sampling: The facilities were purposefully sampled by the Ministry of Public Health representative. A total of 65 health workers were interviewed throughout the 3 stages. Appointments were made with those interviewed during the preliminary stage, whilst for the Principal and Validation Stages, introductory visits with hospital administrators were arranged 1-2 weeks in advance and permission granted for the consultant to rotate through the hospital and to select health workers at random during unannounced rounds of pediatric, outpatient, ICU, adult medicine, adult surgery and accident and emergency wards. A brief description of the field testing facilities is presented in Table 1 and 2 and the cadre of health workers interviewed listed in Table 3.

Table 3: Cadre of Health Workers interviewed

	Pharmacist or Pharmacy Tech	Clinical Officer	Nursing Officer	Medical Officer
Preliminary Stage				
No single institution	1	0	1	1
Principal Stage				
Bamburi Cement	1	0	1	1
Coast General	2	3	13	1
Tudor District Hospital	1	2	2	0
Aga Khan	2	0	3	4
Validation Stage				
Malindi District Hospital	1	3	4	4
Tawfiq Hospital	1	0	2	1
Kilifi District Hospital	0	3	5	2
Total	**8**	**11**	**30**	**13**

Qualitative Approach: The one-to-one in-depth interviews took the form of a conversation in which the consultant probed deeply to uncover levels of understanding. The line of questioning in each interview varied from person to person. The interview generally started with a request that the respondent take 2 minutes to read through the guide – to get oriented with the format and with the flow of information and numbering. The respondent was then asked to take the interviewer through the guide step-by-step as though they were teaching a colleague how to use the drug. When it was evident that certain sections were being effectively understood and levels of comprehension were high, the interviewer focused attention on 'trouble spots' and on how these could be improved. The questions were regularly reshaped to focus on these 'trouble spots' in the instruction guide. The trouble spots prompted questions and clarification and respondents often proposed solutions. Issues raised in each interview informed the questioning in subsequent interviews. Elements that were well understood were addressed early on and most attention was given to areas that remained unclear or where respondents stumbled repeatedly.

The interviews lasted on average 45 minutes during the preliminary and principal stage and 30 minutes during the validation stage. The amount of time required for interviews decreased as the job aid became more effective at communicating the dense amount of information. The time a respondent required, seeing the job aid for the first time, to reach an appropriate level of understanding provided an important indication of comprehension.

Analysis: The nature of this qualitative field research meant that 'analysis' was ongoing. The consultant sifted through field notes and digital recordings daily to decode the responses and to test evolving conclusions through testing new drafts/edits. The daily analysis was also to ensure that all key outcomes were being assessed. The key findings were compiled and discussed daily so that modifications could be made to the guide before the subsequent day of field testing. All changes during the principle stage of testing took place in-country with the exception of changes to illustrations. Changes to the job aid during the validation stage were done after debriefing with the team in Geneva.

Key Findings – Preliminary Stage

The preliminary piloting stage was focused on refining the interview approach and less on testing the job aid, against the required outcomes. However, key changes were initiated as a result of the feedback from the initial stage – in relation to the poster and the poster reminder. Both the original versions are illustrated below.

Figure 1: Poster Reminder - First Version – tested during piloting

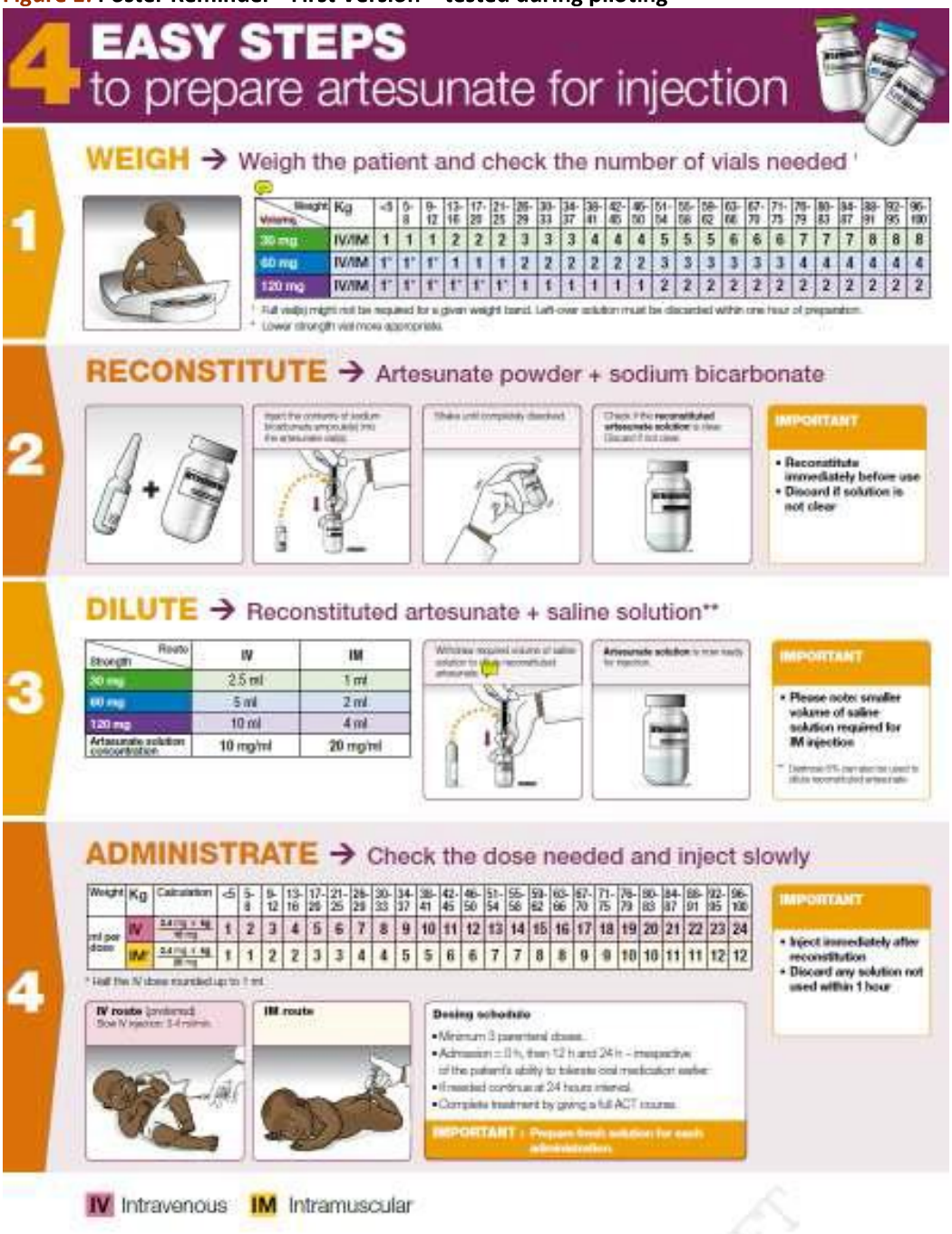
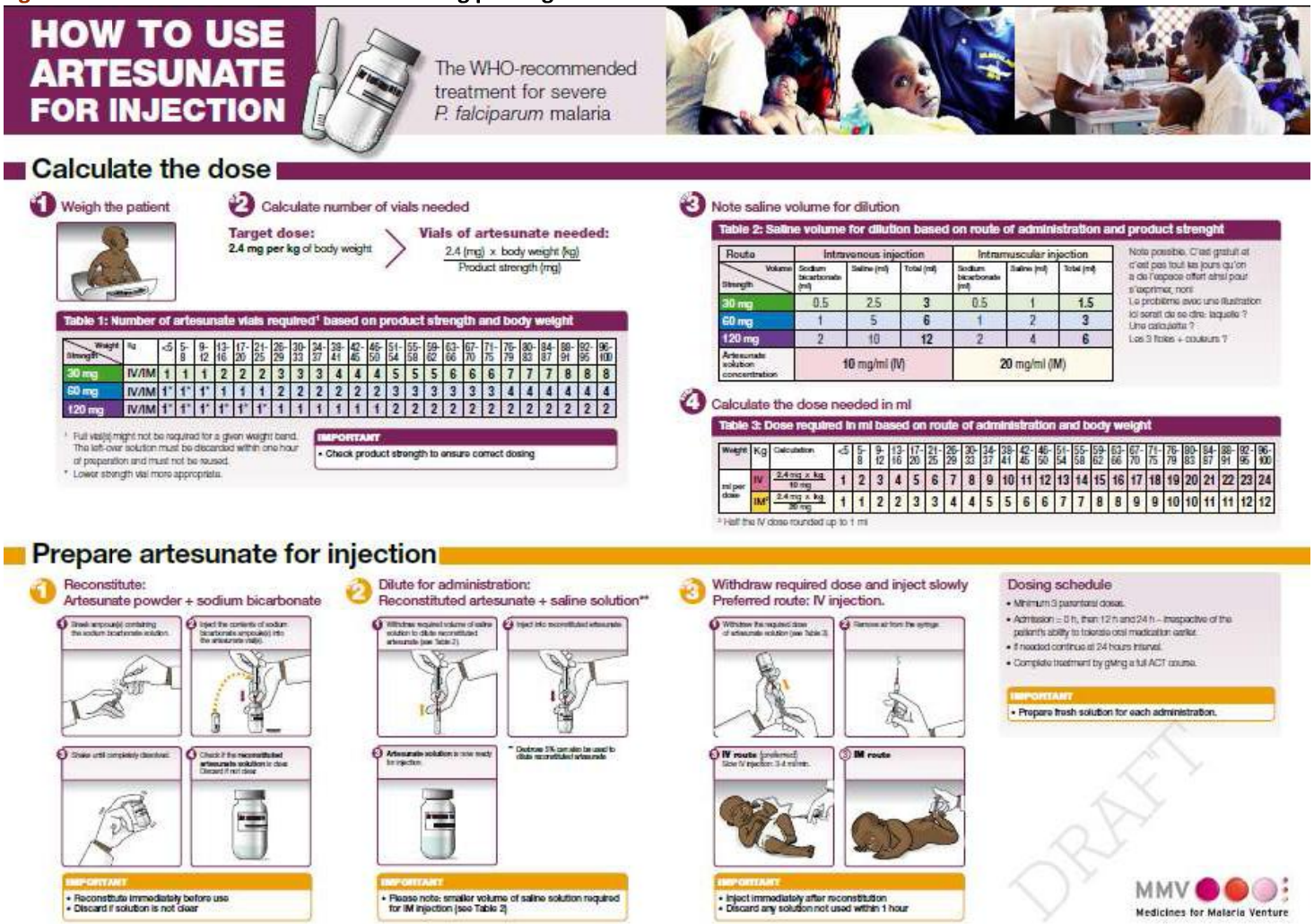


Figure 2: **Poster - First Version – tested during piloting**



The 3 key informants interviewed as part of the preliminary stage had the following reactions to the tools illustrated above:

Density of information: The general consensus during the preliminary stage was that the poster reminder (Figure 1) was 'friendlier' and contained a more manageable volume of information whilst the poster (Figure 2) was perceived as "too busy" with high density of information and with tables that were too "academic" for health workers.

Flow of information: In addition to the density of information, there were concerns with the flow of information, particularly relating to the Poster. There was an impression that the numbering could be clearer and more systematic and that there should be only one set of numbers to follow.

> "I did not understand the flow of steps from the start, now that I've studied it, I've understood. But I think I could have understood more quickly if the instructions had run vertically, rather than across. I lost my place and jumped from vials to preparing the injections instead of moving across the poster. I wonder why they are not doing the steps going down rather than across…" (Pilot Respondent)

> "Perhaps if the weight and mls per dose ran up/down rather than across, it would be easier to find one's place… As nurses we are just more familiar with tables running the other way – up/down…" (Pilot Respondent)

IV and IM to be clearly distinguished: In the poster and poster reminder, IM and IV were combined in the same dosing table, in a manner that the respondents found confusing. The nursing key informant was concerned that if the IM and IV information are presented too close together, a serious error could occur in dosing. It was even proposed that the two posters be separated, since the IM route would be more appropriate to peripheral health facilities and was not necessary in a district hospital, for example. This was also proposed as a way to simplify the posters.

Number of vials: The table containing the number of vials elicited much confusion: a confusion that persisted through much of the principle stage. In addition, it was pointed out that asterisks are not well understood and even if understood are not used when in a hurry.

Presence of a calculation: The respondents had different opinions regarding the presence or absence of a formula for dose calculation. The nursing officer felt that if the nurse is not required to make the calculation herself, then there is no need for the formula to be in the table. She felt that this information could be available as a reference, perhaps in the booklet.

> "Nurses don't want to make the calculation if they don't have to – she does not have much time, it is better if she finds the answer in mls/dose in the table she can move ahead. The rationale behind the calculation is an important reference, but not when they have a very sick child waiting to be treated... isn't it?" (Pilot Respondent)

On the other hand, the paediatrician felt that the calculation were very helpful.

> "So as someone coming at this for the first time, I'd like to see the calculation… I think it is always good to know the appropriate calculation - the doses they provide in these tables are a rough wide range. If you want to be very accurate you need the formula, so you could give less than 2mls." (Pilot Respondent)

Dosing

One of the facilities where the preliminary stage was conducted was a research site during the AQUAMAT trial. The nursing officer interviewed was very familiar with administration of the drug. When she reviewed the first versions of the job aid, she raised concerns about the "lack of precision" in the dosing table, particularly for paediatrics and the malnourished children she treats on her unit. The first version of the table is illustrated below.

Calculate the dose needed in ml

Table 3: Dose required in ml based on route of administration and body weight

Weight	Kg	Calculation	<5	5-8	9-12	13-16	17-20	21-25	26-29	30-33	34-37	38-41	42-45	46-50	51-54	55-58	59-62	63-66	67-70	71-75	76-79	80-83	84-87	88-91	92-95	96-100
ml per dose	IV	$\frac{2.4\text{ mg} \times \text{kg}}{10\text{ mg}}$	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	IM[2]	$\frac{2.4\text{ mg} \times \text{kg}}{20\text{ mg}}$	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	10	10	11	11	12	12

[2] Half the IV dose rounded up to 1 ml

The dosing table that they developed for the AQUAMAT trial was suggested as an alternative approach to dosing, at least for paediatrics. A section of this is illustrated below. Again, the up-down direction of the table was preferable. The dilution factor was different in the dosing schedule below.

2: ARTESUNATE DOSING SCHEDULE

INJECTION ARTESUNATE DOSE @ 2.4mg/Kg (Conc. 6mg/ml)

The Artesunate (60mg anhydrous Artesunic acid) should be diluted in 1 ml 5% bicarbonate, which comes in the same package as the Artesunate vial. Draw 1 ml of the bicarbonate into a 10 ml sterile syringe. Peel of the top of the Artesunate vial and clean the rubber with a 70% alcohol swab. Puncture the rubber top and add the bicarbonate to the Artesunate powder. Shake gently till all the Artesunate is dissolved. Do not shake too vigorously, since that will cause foaming of the solution. The reconstituted 1ml solution contains 60mg of Artesunate. This is then diluted with 9mls of 5% dextrose so that, in the end solution contains Artesunate 6mg/1ml. As an example: For a child of 10kg each dose should be 24mg which is equivalent to 4ml (*See dosing table below*).

Weight	Dose	
(Kg)	(mg)	(ml)
1.5 - 2.4	5	0.8
2.5 - 3.4	7	1.2
3.5 - 4.4	10	1.7
4.5 - 5.4	12	2
5.5 - 6.4	14	2.3
6.5 - 7.4	17	2.8

Weight	Dose	
(Kg)	(mg)	(ml)
26.5 - 27.4	65	10.8
27.5 - 28.4	67	11.2
28.5 - 29.4	70	11.7
29.5 - 30.4	72	12
30.5 - 31.4	74	12.3
31.5 - 32.4	77	12.8

Images: Various concerns were raised with regards to the pictures.

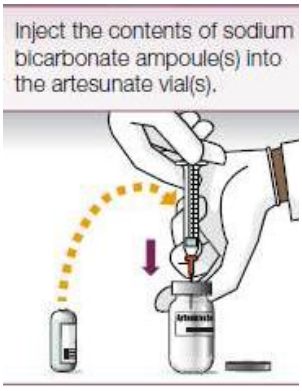
Precision in positioning of IM injection: Respondents raised concerns about the appropriateness of the IM injection site illustrated in the image below.

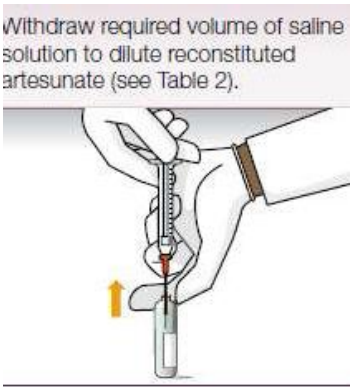
> "This picture is giving an impression of where to administer the IM injection. But it is not being shown correctly. I think it may be important to show exactly where to administer the IM in an infant and in an older child and to be more precise in the imaging." (Pilot Respondent)

Administration through an IV line: Initial impressions during the preliminary phase, highlighted concerns with the 'authenticity' of the image relating to administering IV bolus within an African government hospital setup.

> "This image is showing an extension line, but these are hardly ever used, for it has cost issues, they usually have the IV line direct. If these instructions are for the third world, I suspect extensions are rare and costly in most places." (Pilot Respondent)

***Distinguishing Ampoules used in various steps*:** The importance of distinguishing the sodium bicarbonate ampoule from the saline or dextrose ampoule was highlighted at this early stage.



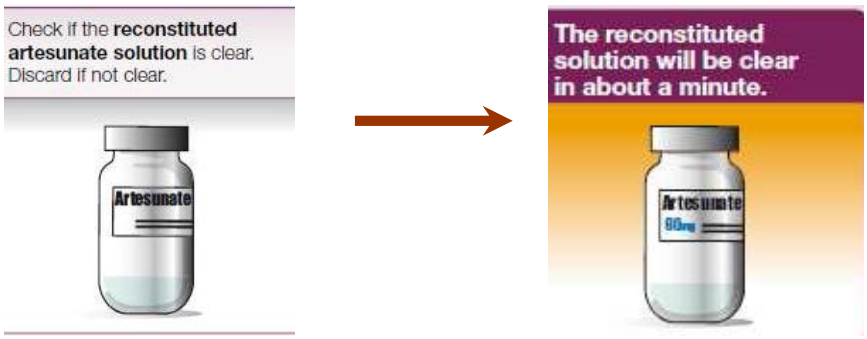


Sterile technique: There was a general feeling that the job aids need to encourage sterile technique and best practice through the images. The informants drew attention to the fact that no assumptions should be made that nurses will use the proper technique to prepare and administer the drug. Job aids were seen as an important mechanism to promote best practice. Some of the images in the first version of the poster and reminder did not actively promote sterile technique – for example the mixing of the vial with a finger on top of the sterile seal, would be seen to break the sterile barrier.

Photo Header: The photo header at the top of the first version of the poster raised some interesting reactions that were incorporated into subsequent drafts.

> "They are nice for colour, but they do not remind me of severe malaria – they are more primary care pictures, normal malaria, not malaria treated in-patient." (Pilot Respondent)
>
> "Perhaps to add colour, the tabs with the pictures, showing the steps could have more colour? So they stand out – as they are important." (Pilot Respondent)

Coloring: The tabs with instructions were described as being a bit 'dull' and requiring some more color to draw the attention of health workers to the various steps.



Key Findings – Principal Stage

The principal stage represented the main body of the field testing exercise. The results were generated over 4 days and the key findings will be grouped under the headings used within the posters. Importantly, MMV decided to abandon the poster reminder after the piloting phase and dedicate attention to the poster.

Figure 3: Poster Version 2 - tested Day 1 Principal Stage

Figure 4: Poster Version 3 - tested Day 1 Principal Stage

Weighing: This was well understood as a key and initial step. Weighing scales were checked in all facilities to see if they were functioning and whether weight could be read to the decimal of ten, required for the more précised dosing tables incorporated into the new versions. Both digital and floor standing mechanical models with either a balance beam and sliding weights or a display were located for adults and pediatric scales included hanging spring scales and balance beam scales. All scales showed weight in kilos and in decimals of a kilo.

The picture of a baby being weighed was considered unnecessary and was removed.

Check Dose: this step raised the following concerns:

- **What is the dose – mg/kg and how would we calculate this in the absence of the table?**
  Doctors and Pharmacists insisted on knowing the dose from the start. They communicated that they needed to learn this information for prescriptions and could not rely on the job aid being available when they needed it.

- **What are the mls to administer and how do you calculate the 'mls' in the absence of the table?**
  The table was perceived as a valuable resource since certain doctors in the public health facilities indicated that the prescription would most likely only specify the dose '2.4 mg/kg' and the calculation of mg and ml for a particular patient would be completed by the nurse. On the other hand, in private facilities, doctors said they were required to indicate on the prescription the exact dose and 'mls' needed for a particular patient, and therefore they would need to know how to calculate the 'mls'.

- **Are there two or three strengths?**
  In the initial versions the first reference made to various *strengths* was at the dilution step. This was perceived to be too late to introduce the various strengths since it related to the number of vials needing reconstitution. It was proposed that 'strengths' of vials be introduced at a very early stage.

- **Concentration required for each route**
  In the initial versions, the required final concentration of the drug was highlighted at the reconstitution stage. Medics and pharmacists and some nursing officers wanted to better understand the rationale for a two stage preparation of the drug – reconstitution and dilution and the influence this had on concentration. Observing the concentration drop (once it was explained) clarified what happens to the drug during the two step reconstitution-dilution and why it is essential.

- **Calculating dose for >51.4 kilos**
  The statement 'for patients over 51.4kg calculate dose required based on the table above' found at the bottom of the dosing table, made sense to a minority of respondents. Requests for further clarification or an example were put forward. In addition, some respondents assumed 51.4 kilos was the cut off weight and that the dosage for a 51.4 kilo patient applied to all ages over 51.4 kgs. The relevance of 51.4 kilos was raised. Respondents across all facilities suggested a more appropriate cut off of 70 kilos, followed by an example of an equation for mg or 'mls', for patients in excess.

Dosing Schedule: The 3 parenteral doses regardless of a patients' capacity to take oral medication was well understood by the majority of respondents. The follow-up action requiring a 'complete dose with a 3 day course of ACT' was frequently misunderstood by a striking majority, who were not familiar with 'ACT' as a drug category. Suggestions to include the word – oral Artemesinin Combination Therapy (ACT) like AL were requested. In addition, those not familiar with the dosing of oral ACT noted the need to include dose and frequency for an oral ACT drug, either on the poster or in the booklet.

The requirement to follow up with ongoing parenteral treatment every 24 hours if the patient is unable to take oral medication was understood by the majority, however the 'cut off' or 'maximum dose' was requested by 90% of the respondents, in this stage of testing. Clarification on when to reevaluate and/or retest the patient was called for, since health workers are familiar with this kind of protocol with Quinine.

IV route as preferred route: The footnote and reference star, emphasizing the IV route as the preferred route of administration was not captured by respondents and this needed to be emphasized more effectively. Footnotes and asterisks are not a well understood concept and are inconsistent with the purpose of a job aid within a busy work environment.

Order of Events and Positioning: The positioning of the 'check dose' step seemed to vary by type of health care provider. Medical officers/Doctors and Pharmacists often expressed a preference to have the dose information at the beginning of the guide. However, nurses preferred to see this information closer to stages of administering the drug, otherwise they needed to refer back to the 'check dose' table when being asked how many 'mls' to withdraw and the rate of administration. This step of referring back carried some risk of error. Since nurses may revert back to the wrong table, for example to the dilution step (directly above) and administer the 'mls' specified per route of administration. Instructions to 'recheck dose in table, withdraw and administer' were suggested by some respondents. Alternatively, to bring the 'check dose' step closer to the final administration step to avoid error.

Number of vials: Prior to reconstitution, the health worker needs to know how many vials to reconstitute and prepare for dilution.

Various approaches were tested to ensure that health workers chose the correct number of vials, while minimizing wastage, and recognizing that the contents of a vial would not necessarily be used in their entirety. The versions tested can be seen below.

Weight / Strength	kg	<5	5-12	13-25	26-37	38-50	51-62	63-75	76-87	88-100
30 mg	IV/IM	1	1	2	3	4	5	6	7	8
60 mg	IV/IM	1*	1*	1	2	2	3	3	4	4

IM use dosing

Weight kg	Dose		No. of vials	
	mg	ml	30mg	60mg
1.5 - 2.4	5	0.3	1	1
2.5 - 3.4	7	0.4	1	1
3.5 - 4.4	10	0.5	1	1
4.5 - 5.4	12	0.6	1	1
5.5 - 6.4	14	0.7	1	1

In an attempt to consolidate the information, one version placed the mls and the number of vials side by side. However, some respondents chose to add the vials rather than choosing the most appropriate strength for the number of mg in the prescribed dose. At this point the word – OR – was added. See below.

Intraveinous route (IV)
Concentration: 10mg/ml
Dose: 2.4 mg/ kg

Weight kg	Dose		No. of vials		
	mg	ml	30mg	or	60mg
1.5 - 2.4	5	0.5	1	or	1
2.5 - 3.4	7	0.7	1	or	1
3.5 - 4.4	10	1.0	1	or	1
4.5 - 5.4	12	1.2	1	or	1
5.5 - 6.4	14	1.4	1	or	1
6.5 - 7.4	17	1.7	1	or	1

The table for number of vials changed as the dosing table became more precise and ultimately the table reverted back to an older format but with more clarity around the weight bands and strengths.

CHECK VIALS NEEDED

* lower strength vial reduces wastage

Strength \ Weight	less than 12 kg	13-25 kg	26-37 kg	38-50 kg	51-62 kg	63-75 kg	76-87 kg	88-100 kg
30 mg	1	2	3	4	5	6	7	8
60 mg	1*	1	2	2	3	3	4	4
120 mg	1*	1	1	1	2	2	2	2

Best Practice: The reconstitution step continued to raise concerns (initially highlighted in the pilot) about best practice as it relates to aseptic technique. Nurses were concerned that the images were not promoting best practice, with particular reference to the shaking of the bottle and the contamination of the top of the vial was raised by nurses. "That is *not* how we mix a bottle that must remain sterile for injection purposes" said one pediatric nurse. Over time, this was addressed and tested.

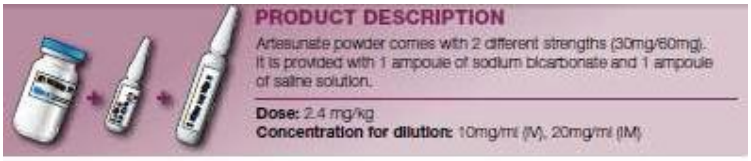
In addition, the angle of the hands that illustrate the reconstitution was raised as 'awkward and uncomfortable' by a medical surgical nurse. This applied to the injection of the diluting solution into the vial, as well. The positioning of the IM injection in the administration step raised serious concerns and respondents confirmed that the RUQ (right upper quadrant) of the buttocks would be the appropriate illustration as it can apply to pediatric and adult populations, although pediatrics nurse prefer to use the thigh. Related to the site of injection was the concern about the maximum number of mls per injection site and the need to rotate sites for the 3 doses and or for a single adult IM dose. The IV site would need to show a branula/IV cannula directly into the hand, without an extension line. Extensions lines are not used for administering drugs. Labeling date and time on a reconstituted drug was considered best practice and was raised as an important step, often forgotten.

Dilution: This step raised the most 'trouble spots' of all the steps. Nurses were not familiar with a two step 'reconstitution – dilution' process and some were easily confused by the requirements. The mls of saline, per route and per strength proved very challenging. Initially, this was the first time health workers became aware that the Artesunate comes in various strengths – information that is essential to the reconstitution and dilution stages. It was evident that the new information at this late stage in the guide overwhelmed some. Looking at the required volume was proposed as a step in its' own right and injecting the required volume as a subsequent step.

In addition, questions as to whether other 'dilutants' such as 'water for injection' could be used instead of saline was raised because hospitals only procure 500ml bottles of saline. This lead to discussions about introducing a 'product information or description' section at the beginning of the poster. Also, questions were raised about the reconstitute and the diluting agent and whether these would be provided with the vial of artesunate – to address problems in procuring or ensuring availability of

reconstitute and dilutant. Setting the scene with product information, dose, concentration and strength, before beginning the steps, was raised repeatedly.

This was introduced towards the end of the principal stage of testing.



Administering

Syringe size: Following discussion about administering doses that are inconsistent with the decimals on available syringes, the field testing team reviewed the syringes used across the sites to see how appropriate the dose calculations were.

The two smallest syringes available are the 2ml syringe and the 5 ml syringe. These both have small decimals of 0.10 of a ml. The next size available is the 10 ml which has 0.5 ml divisions and the 20 ml syringe which has 1 ml divisions as does the 40 ml syringe.

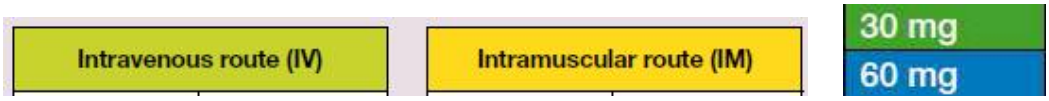
IV bolus timing: *A* slow IV bolus was recognized as standard practice by some nurses while others were alarmed because they misread 3-4 mls/per minute as 3-4 minutes. Clearly, this important instruction needed to be spaced out and made clearer. Various versions were tested.

A question if an intraosseous line would be appropriate for the IV bolus was raised by one medical doctor who said infants with severe malaria often come with severe dehydration with collapsed veins.

IM procedures: In follow up to the IM site being aligned with practice, questions were raised about whether the IM injection should be administered slowly or as normal, since the guide stipulated slow administration. This was clarified with medical advisors at MMV and clarified for respondents.

Color and font and size of poster

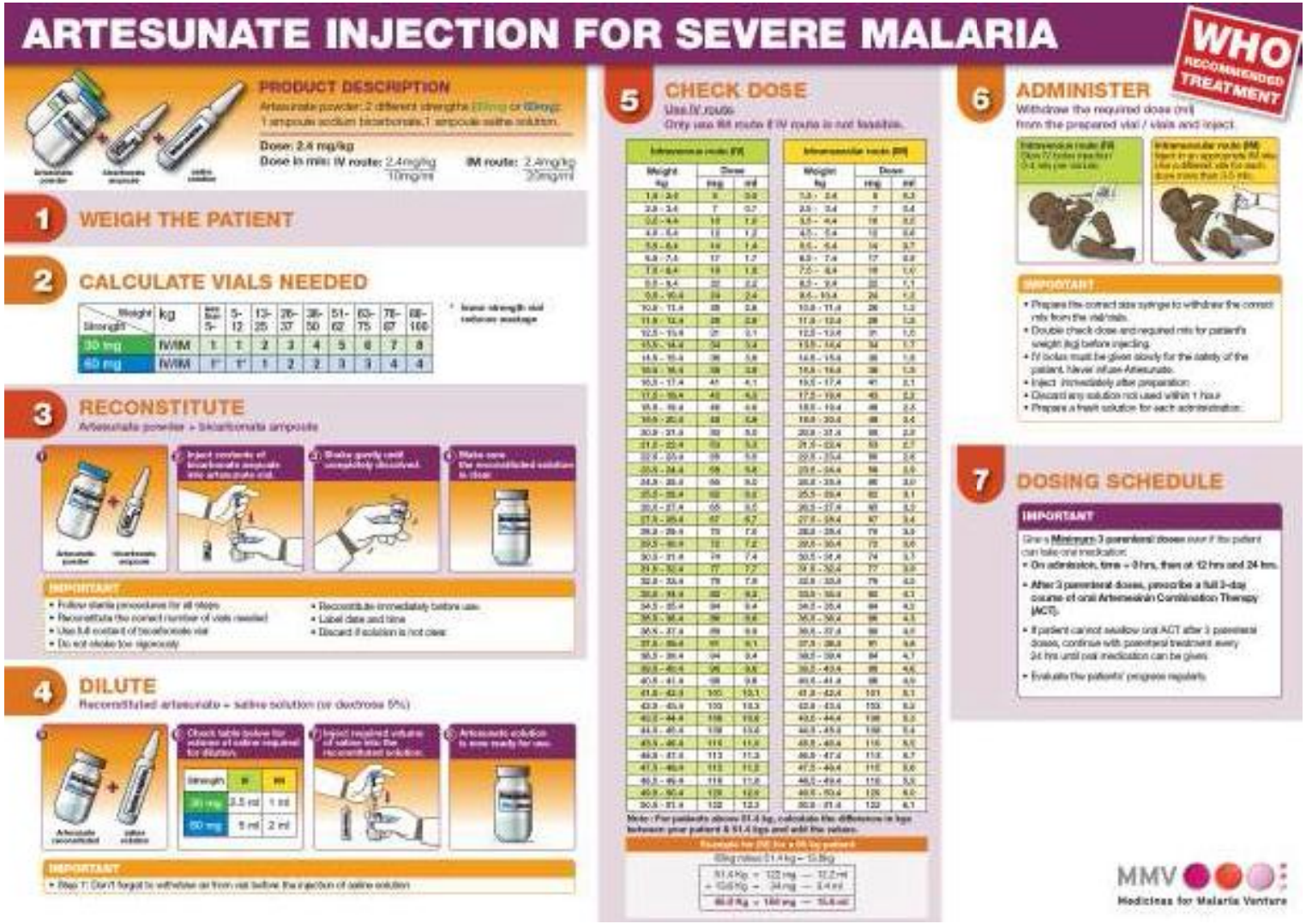
The color coding of IM and IV and of the vial strength, throughout the job aid, were perceived as very helpful.



The usefulness of the selected colors and font sizes were more difficult to assess on the smaller prints used when testing edits. However no one raised major concerns with font or color at this stage, since the tabs had been brightened post piloting. A few asked if the guide would still be legible if photocopied – as this was likely to happen in government facilities if they were supplied with fewer copies than required. A black and white version for cheap reproduction was proposed. There were mixed opinions on size, which depended on the location where the guide would be mounted. Pharmacists and medical officers preferred smaller sized guides while nurses tended to appreciate the bigger posters for their treatment rooms and smaller ones for their injection trolleys. A mix of two or three poster sizes would be appropriate.

Figure 5: **Version tested Day 3**

Figure 6: **Version tested - Validation Phase**



Key Findings – Validation Stage

This was the final stage of testing and involved refining the details of the job aid, to confirm that the changes made prior to this stage, had indeed enhanced comprehension, relevance and attractiveness.

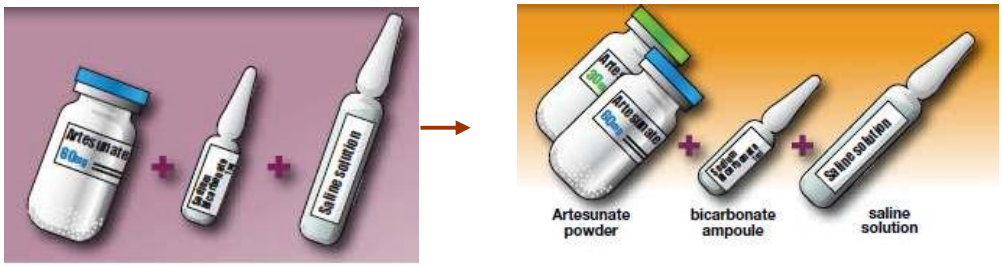
Product Description

The inclusion of a section continued to be an effective starting point for the job aid, as revealed during the principal field testing stage. A few small issues persisted during the validation stage.

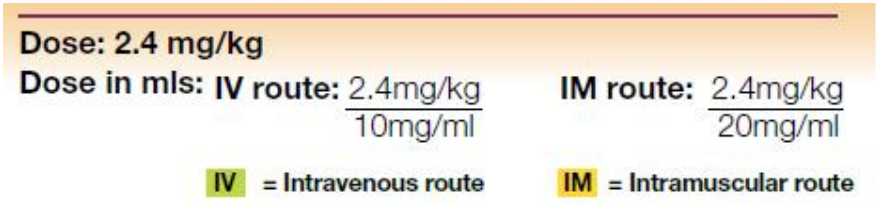
Some of those interviewed struggled to read the 'sideways' words on the vials and ampoules; they did not make the blue/green association with the vial strength (product recognition) and the 'mls' per dose formula confused some.

In addition to labels on the vials and ampoules, it was suggested that labelling the 3 components underneath the pictures, in addition to the words on the vials/ampoules, would be helpful.

Health workers needed to become familiar with the colour coding of the vials so that product strength would be well recognised at one glance. Including the 2 strengths and the colour coding in this section responded to the need expressed by respondents. Including the 120mg coloured vial may be valuable too.



Medics continued to insist on the need to see the formula and to know how to derive the mls per dose. This information clearly needed to be communicated at an early stage in the poster, to ensure that the poster worked to build capacity and over time was not indispensable to prescribers. Prescribers needed to know the dose and ideally, as was the case in the Aquamat trial, know how to calculate the mls per dose.



The formula above, which was introduced to respond to the request for a formula they could easily memorize, was incorporated into the Product Description section of the job aid. The formula was presented this way and retested. The interviews showed that this did not clarify things completely for the health workers who paid attention to the formula (which was not the majority). Some respondents, including medical officers appeared ill at ease with formulas that included a denominator in mg/ml. Once the consultant explained this formula, it was clearer and better understood. Respondents suggested that it would be better understood if the words *'how to calculate the dose in mls'* were added.

Finally, when re-listening to recordings of the interviews, the consultant noted that over 15 of the respondents during the validation phase, read 2.5 mg out loud when describing the steps as part of the interview process. This was despite the dose being 2.4 mg. Increasing the size of the 2.4 mg/ml so it stands out may be helpful for those with possible numerical dyslexia. Similar to the issue raised with certain text being misread, the ml and mg were regularly misread. It would be useful to increase font size of mg and ml in table so they difference is more noticeable.

Calculate/Check the vials needed

This section had very few concerns during this final stage of testing. The < sign was not well understood by all, replacing < with 'less than' was helpful. Simplification of the table and introduction of the 120 mg strength can be seen below.

CALCULATE VIALS NEEDED

Strength \ Weight	kg	<5	5-12	13-25	26-37	38-50	51-62	63-75	76-87	88-100
30 mg	IV/IM	1	1	2	3	4	5	6	7	8
60 mg	IV/IM	1*	1*	1	2	2	3	3	4	4

CHECK VIALS NEEDED

* lower strength vial reduces wastage

Strength \ Weight	less than 12 kg	13-25 kg	26-37 kg	38-50 kg	51-62 kg	63-75 kg	76-87 kg	88-100 kg
30 mg	1	2	3	4	5	6	7	8
60 mg	1*	1	2	2	3	3	4	4
120 mg	1*	1	1	1	2	2	2	2

Reconstitute

Managing more than one vial: One concern that arose at this late stage of testing was the logistics of lining up the required number of vials and reconstituting them all in a systematic way. Questions such as: "can I use the same syringe for all vials?" were raised and "do I reconstitute and dilute each vial one at a time or is it best to reconstitute all and then dilute all?"

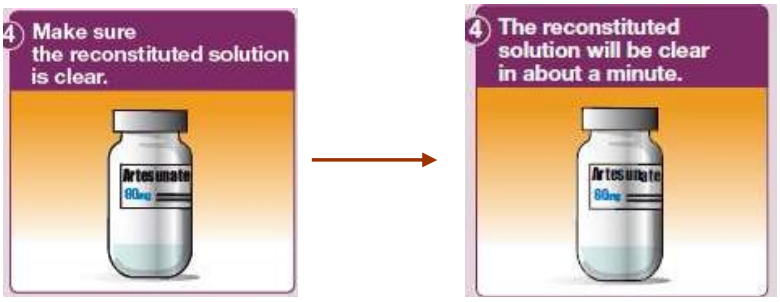
Knowing the order of events when reconstituting and diluting is something that should be emphasised during training and in the booklet. A reminder: **Reconstitute the correct number of vials needed,** has now been included in the poster.

Maintaining best practice & observing practice: During the validation stage, the consultant observed one nurse preparing one vial, from start to finish.

- She did not wear gloves to prepare the drug (she said she would only wear gloves when administering);
- She shook the vial by touching the seal at the top of the vial (breaking sterile technique);
- She added the bicarbonate and shook it, but the solution was not clear, instead it was cloudy. So she continued to shake quite vigorously, waiting for it to get clear, it did not go clear, until she added the saline.

Further observations may have been helpful, however, this observation illustrated that nurses may indeed need to be reminded of simple things like sterile technique, even if these steps are in line with basic nursing procedures.

Noting that the solution may be cloudy initially and will be clear after 1 minute would be useful to prevent health workers shaking too vigorously or 'discarding if solution is not clear' without weighting the appropriate amount of time.



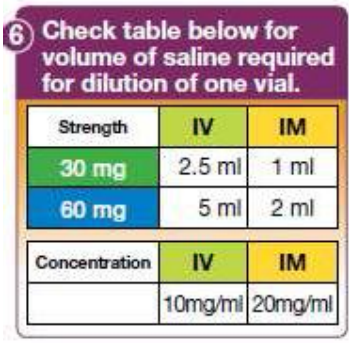
Purpose of reconstitution: Another issue raised during previous stages of testing and raised once again during this final stage was the 'purpose' of the bicarbonate. Clinicians felt that this should be noted on the job aid, to ensure that the step is well distinguished from 'dilution'. The purpose of the bicarbonate, either as a buffer or stabilizer appeared to be important in rationalising the *2 step Dilute-Reconstitute* process. This may need to be elaborated upon in the booklet.

Dilute

Observing dilution & the need to remove air from vial: During the observation described above, during dilution, the nursing officer proceeded to draw up the saline and inject the required volume, but because she had not removed the air from the vial, she could not inject the 5 mls, due to the small size of the vial. She therefore, threw away the saline in her syringe, withdrew the air and then rechecked the amount of saline to add and injected into the vial. At which point the solution in the vial was clear. With the vial in its current size, air needs to be removed to hold the 5 mls. An additional reminder: **Don't forget to withdraw air from vial before injecting saline solution.** Observing more nurses preparing the vials would be the best way to ensure that this note is incorporated into practice.

Still with regards to Dilution, one final suggestion was raised by a senior nurse, to reiterate the new concentration of the drug, so that the formula under Product Description would be well understood. Although, this may appear to be 'additional' information that may not be 'essential', this nurse, like others, emphasised that job aids are also ways of building capacity and understanding. She gave the example that this job aid is an opportunity to show how the dilution factor changes and that an IV route requires a less concentrated drug as compared to administering a drug into muscle (IM route). Her opinion was that simplicity is important but clarity is essential.

Artesunate strength	Intravenous route (IV)	Intramuscular route (IM)
30 mg	2.5 ml	1 ml
60 mg	5 ml	2 ml



Check dose

Flow of information: The 'Use IV route' statement was sometimes misread. Respondents jumped to the next line before completing the statement.

This reemphasised the importance of flow of information and why it is best to put the two statements under each other.

Weight bands and dosing: The need to alter the dosing table so that it could be interpreted up to 100 kilos came up persistently throughout the various stages of field testing.

With regards to the lower weight bands, five paediatricians were interviewed during the Validation stage and they considered the smaller decimals (no rounding up) appropriate for children less than 21 kilograms, in particular for severely malnourished children with severe malaria.

Example for (IV) for a 105 kg patient:

105 kg = 100 kg + 5 kg

	100 Kg	= 240 mg	24.0 ml
+	5 Kg	= 12 mg	1.5 ml
	105 Kg	**= 252 mg**	**25.5 ml**

For adults or those over 21 kilos, various different approaches were tested and these are illustrated below. Calculating for >51.5 kg using the formula or adding values, was understood by most, but was considered 'tedious'. Subsequent to testing, permission was obtained to round the dose up and this allowed weight bands to be collapsed and the table was extended to 100 kilos.

A request to include pregnancy precautions within the dosing table was highlighted by the labour ward nurses.

Different versions of dosing tables tested.

Intravenous route (IV)		
Weight kg	Dose	
	mg	ml
1.5 - 2.4	5	0.5
2.5 - 3.4	7	0.7
3.5 - 4.4	10	1.0
4.5 - 5.4	12	1.2
5.5 - 6.4	14	1.4
6.5 - 7.4	17	1.7
7.5 - 8.4	19	1.9
8.5 - 9.4	22	2.2
9.5 - 10.4	24	2.4
10.5 - 11.4	26	2.6
11.5 - 12.4	29	2.9
12.5 - 13.4	31	3.1
13.5 - 14.4	34	3.4
14.5 - 15.4	36	3.6
15.5 - 16.4	38	3.8
16.5 - 17.4	41	4.1
17.5 - 18.4	43	4.3
18.5 - 19.4	46	4.6
19.5 - 20.4	48	4.8
20.5 - 21.4	50	5.0
21.5 - 22.4	53	5.3
22.5 - 23.4	55	5.5
23.5 - 24.4	58	5.8
24.5 - 25.4	60	6.0
25.5 - 26.4	62	6.2
26.5 - 27.4	65	6.5
27.5 - 28.4	67	6.7
28.5 - 29.4	70	7.0
29.5 - 30.4	72	7.2
30.5 - 31.4	74	7.4
31.5 - 32.4	77	7.7
32.5 - 33.4	79	7.9
33.5 - 34.4	82	8.2
34.5 - 35.4	84	8.4
35.5 - 36.4	86	8.6
36.5 - 37.4	89	8.9
37.5 - 38.4	91	9.1
38.5 - 39.4	94	9.4
39.5 - 40.4	96	9.6
40.5 - 41.4	98	9.8
41.5 - 42.4	101	10.1
42.5 - 43.4	103	10.3
43.5 - 44.4	106	10.6
44.5 - 45.4	108	10.8
45.5 - 46.4	110	11.0
46.5 - 47.4	113	11.3
47.5 - 48.4	115	11.5
48.5 - 49.4	118	11.8
49.5 - 50.4	120	12.0
50.5 - 51.4	122	12.2

Intravenous route (IV)		
Weight kg	Dose	
	mg	ml
1.5 - 2.4	5	0.5
2.5 - 3.4	7	0.7
3.5 - 4.4	10	1.0
4.5 - 5.4	12	1.2
5.5 - 6.4	14	1.4
6.5 - 7.4	17	1.7
7.5 - 8.4	19	1.9
8.5 - 9.4	22	2.2
9.5 - 10.4	24	2.4
10.5 - 11.4	26	2.6
11.5 - 12.4	29	2.9
12.5 - 13.4	31	3.1
13.5 - 14.4	34	3.4
14.5 - 15.4	36	3.6
15.5 - 16.4	38	3.8
16.5 - 17.4	41	4.1
17.5 - 18.4	43	4.3
18.5 - 19.4	46	4.6
19.5 - 20.4	48	4.8
20.5 - 21.4	50	5.0
21.5 - 22.4	53	5.3
22.5 - 23.4	55	5.5
23.5 - 24.4	58	5.8
24.5 - 25.9	60	6.0
26.0 - 29.0	70	7.0
30.0 - 33.0	80	8.0
34.0 - 37.0	90	9.0
38.0 - 41.0	100	10.0
42.0 - 45.0	110	11.0
46.0 - 50.0	120	12.0
51.0 - 54.0	130	13.0
55.0 - 58.0	140	14.0
59.0 - 62.0	150	15.0
63.0 - 66.0	160	16.0
67.0 - 70.0	170	17.0
71.0 - 75.0	180	18.0
76.0 - 79.0	190	19.0
80.0 - 83.0	200	20.0
84.0 - 87.0	210	21.0
88.0 - 91.0	220	22.0
92.0 - 95.0	230	23.0
96.0 - 100.0	240	24.0

Intravenous route (IV)		
Weight kg	Dose	
	mg	ml
1.5 - 2.4	5	0.5
2.5 - 3.4	7	1.0
3.5 - 4.4	10	1.0
4.5 - 5.4	12	1.5
5.5 - 6.4	14	1.5
6.5 - 7.4	17	2
7.5 - 8.4	19	2
8.5 - 9.4	22	2.5
9.5 - 10.4	24	2.5
10.5 - 11.4	26	3.0
11.5 - 12.4	29	3.0
12.5 - 13.4	31	3.5
13.5 - 14.4	34	3.5
14.5 - 15.4	36	4.0
15.5 - 16.4	38	4.0
16.5 - 17.4	41	4.5
17.5 - 18.4	43	4.5
18.5 - 19.4	46	5.0
19.5 - 20.4	48	5.0
20.5 - 21.4	50	5.0
21.5 - 22.4	53	5.5
22.5 - 23.4	55	5.5
23.5 - 24.4	58	6.0
24.5 - 25.9	60	6.0
26.0 - 29.0	70	7.0
30.0 - 33.0	80	8.0
34.0 - 37.0	90	9.0
38.0 - 41.0	100	10.0
42.0 - 45.0	110	11.0
46.0 - 50.0	120	12.0
51.0 - 54.0	130	13.0
55.0 - 58.0	140	14.0
59.0 - 62.0	150	15.0
63.0 - 66.0	160	16.0
67.0 - 70.0	170	17.0
71.0 - 75.0	180	18.0
76.0 - 79.0	190	19.0
80.0 - 83.0	200	20.0
84.0 - 87.0	210	21.0
88.0 - 91.0	220	22.0
92.0 - 95.0	230	23.0
96.0 - 100.0	240	24.0

Administer

In general, this section was very well understood during the validation phase. However, the question about syringe sizes and how to withdraw and administer from multiple vials was raised. This was addressed by including the statement: **Prepare the correct size syringe to withdraw the correct mls from the vial/vials.**

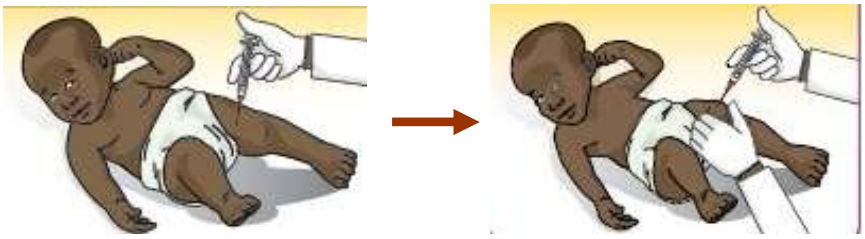
As outlined in the principal stage, a previous effort to address the misreading of 'ml' by using millilitres was not helpful and was changed back to the original. Questions as to whether the drug could be infused, like quinine were raised while others asked "what would happen if we infused this instead of doing IV bolus?" The consequences of administering the drug incorrectly could be made clear in the booklet.

An opportunity to recall the dose before administering was appreciated.

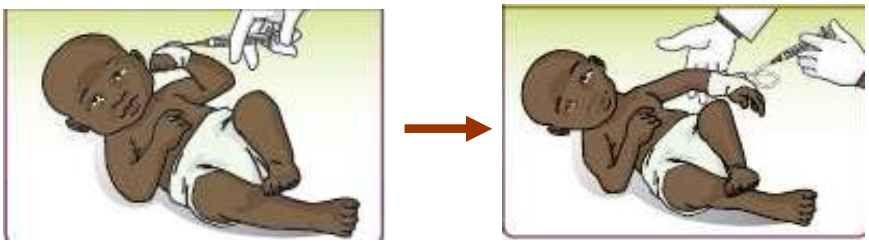
Double check dose and required (mls) for patient's weight (kg) before injecting.

Images

The picture of child getting injection had been changed to use the thigh instead of the buttock. Concerns about the unfriendliness of the new image were addressed and a hand was introduced to support the child's' leg. This change was requested since the start of field testing and was very well received.



The IV equivalent picture required changing too, as it was perceived as "cold" and "unfriendly" and the angle of the hand considered "impossible" for any effective bolus injection - the arm needed to be extended and supported.

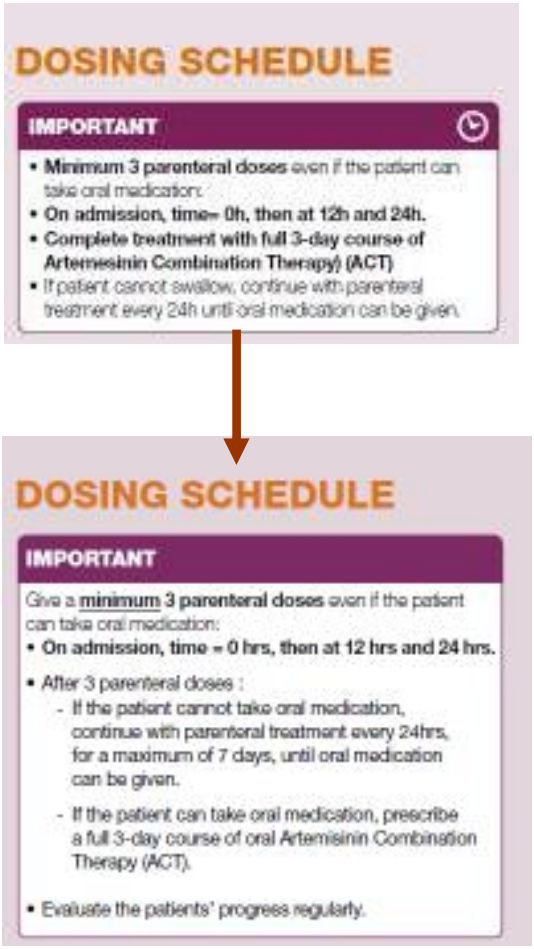


Best Practice Reminders: A concern was raised by one nurse that nurses need to be reminded to draw back the plunger and withdraw blood (to be sure the needle is in a vein), before administering the drug IV bolus. Although this is standard practice, the consultant had an opportunity to observe a nurse administering IV bolus and the nurse did not draw back the plunger first. For IM it is the opposite, nurses should draw back on plunger and should not draw blood, as the drug should enter into the muscle and

not into a vessel. These practices are very standard but it appears that may be easily forgotten or overlooked. A section addressing best practice in the booklet could consider raising these reminders.

Dosing Schedule

By this stage of field testing, the dosing schedule section was well understood. Spacing the text to ensure each line is read may be helpful. Response to requests for an endpoint for treatment (established as 7 days) was included in the final stages and well received.



WHO Recommended Treatment?

MMV developed various different style icons to highlight that Artesunate was the 'WHO recommended treatment' for severe malaria. The preference was personal and ultimately using the WHO recognized colours of blue and white, seemed most appropriate.

Booklet requests

The booklet was not tested during this process. However, during the process, key 'ingredients' for the booklet were highlighted by respondents.

These suggestions are listed below:

- What does the drug do?
- Comparison chart with quinine and artemesinin
- Definition of severe malaria
- Research findings leading to the drug becoming WHO recommended treatment
- Cost per dose
- Manufacturers' address for reporting untoward effects
- Prescriber Leaflet information
    - side effects
    - contraindications
    - interactions
    - pregnancy safety
    - lactation safety
    - premature children
- Why can't you give IV infusion?
- Rationale for bicarbonate
- What is the purpose of reconstituting the drug, what are the consequences of administering undiluted artesunate?
- Why dextrose and saline and not water for injection, which is more readily available/cheaper?
- Trouble shooting
    In the case of overdose
    In the case of allergic reaction – antidote
- Oral ACT – what are they and what are their generic are and brand names.

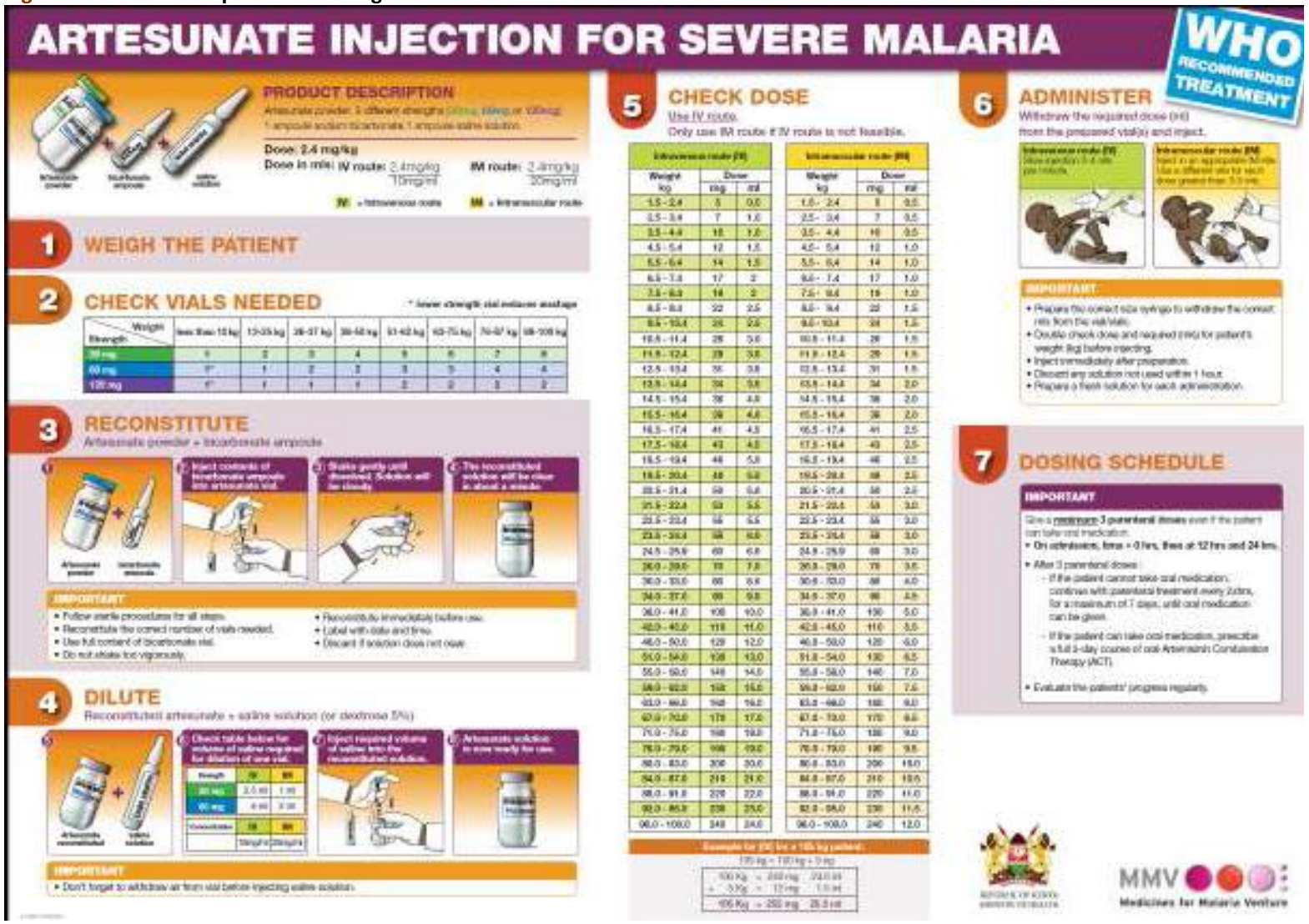
Conclusion

In order to ensure that the job aid for Artesunate Injection is responsive to the needs of the health personnel who will be treating patients with severe malaria, a disciplined qualitative field research was conducted. The fundamental aspect of this approach was to place the enquiry as close to the users of the job aid as possible so as to capture the 'insiders' views" and allow the respondents/informants to feel at ease to share their experience and interpretation of the guide, without fear of judgement or failure. The prolonged nature of the field study and the regular checking and cross checking that took place through out, illustrated by the evolution of the guide, suggests that the methodology was sound and the findings representative of health worker perceptions of the job aid. In addition, the participatory process of testing the job aid was appreciated by health workers interviewed, who were not used to being included in the field testing process. Some shared their frustration with previous job aids that they received that were sometimes 'irrelevant to our situation', 'too theoretical – not user friendly' or 'left many questions unanswered.'

The final version of the job aid can be seen below. It is our hope that the process has resulted in a job aid where the steps are clear and the information flows logically; best practice is consistently emphasised; the information presented is appropriate to the health worker cadres who will use the guide; all non-essential information has been removed and key safety requirements are included. The guide is attractive and engaging.

This carefully-designed job-aid can now assist and remind health workers to carry out their task of treating severe malaria in accordance with well-defined guidelines. The guide will effectively complement training and will offer significant advantages over stand-alone training, since it will be visible in the workplace. Although skills will improve during training, this job aid has the potential to reinforce and consolidate skills.

Figure 7: Final Version post field testing



Annex 1 – Permission from the Ministry of Public Health and Sanitation

MINISTRY OF PUBLIC HEALTH AND SANITATION
DIVISION OF MALARIA CONTROL

Telephone: Nairobi 2716934/5 Fax 2716935
E-Mail: head@nmcp.doherkenya.or.ke
All correspondence should be addressed to the Head, DOMC
When replying please quote:

KENYATTA HOSPITAL GROUNDS
P. O. BOX 19982 – 00202
KNH NAIROBI

REF: REF: MAL/DC/11/4/ VOL.III/ (54)

DATE: 3rd August 2011

To whom it may concern

Re: Permission to conduct field interviews on Parenteral Artesunate training materials

The DOMC in collaboration with the Medicines for Malaria Venture (MMV) is working with Dr Monique Oliff to field test different training materials for artesunate injection.

This will ensure that the instructions for preparation and administration are clear and easy to follow. The field-testing will be conducted from August 29th to September 16th 2011 and will target health care workers and nursing staff in public and private hospitals and health facilities who administer artesunate by intravenous or intramuscular routes. This will ensure that the final training materials facilitate the correct usage of the treatment.

Please assist the bearer of this letter in conducting the interviews within your facility.

Your assistance will be much appreciated.

Yours sincerely,

Dr Elizabeth Juma
Head
Division of Malaria Control

Annex 2 – Informed Consent

wellsense

International Public Health Consultants

MMV - Individual Interview Guide (IDI) for field testing of
Artesunate for Injection Instructions

Introduction

Good day, my name is Dr Monique Oliff, I am a public health specialist and a nurse practitioner. I am here to speak to you on behalf of Medicine for Malaria Venture, known as MMV. MMV, is a non-profit foundation based in Geneva Switzerland, created to discover, develop and deliver new, affordable antimalarial drugs. We are here to speak to you today, so that the work MMV is doing to treat severe malaria effectively can incorporate the opinions and experiences of health workers in Kenya. I will now read through the consent form.

Informed Consent

As you know well, severe malaria is a medical emergency. After rapid clinical assessment and confirmed diagnosis, full doses of parenteral antimalarial treatment should be started without delay. WHO recommends parenteral artesunate over quinine for the treatment of severe *P. Falciparum* malaria in adults and children[1]. Intravenous injection is the preferred route of administration although intramuscular can also be given. Parenteral artesunate has been the treatment of choice for adults with severe malaria since 2006. The AQUAMAT trial[2] in 2010, a multi-centre study conducted in 5,425 children < 15 years of age across Africa, hospitalized with severe malaria, has provided the evidence needed to recommend artesunate above treatment with either artemether or quinine in children. The trial showed a significant drop in deaths (by 22.5%) in the group of children receiving artesunate when compared to the group receiving quinine. The incidence of convulsions, coma, and hypoglycaemia developing after hospitalization also dropped significantly.

Parenteral artesunate will soon be available in 3 different strengths: 30 mg/ 60 mg/ 120 mg. It has several advantages over quinine and artemether. It is more effective, it is easier to prepare and administer. The absorption is rapid and predictable, it kills all stages of the parasite's asexual cycle and it is also well tolerated by the patients. The next stage is to ensure that healthcare providers who treat severe malaria fully understand how to prepare and administer the product. MMV has developed training materials to illustrate these steps and support you as a health worker to correctly use the product.

We would like to speak with you as you have been chosen as a member of health worker staff at this health centre/hospital who regularly treats severe malaria. You can assist us to look at these instruction materials and determine if they will be understood and acceptable to you and your colleagues across Kenya who will use this drug to treat severe malaria. We would like your honest and open views of these instructions. There is no right and wrong answers. We simply want to know if these instructions work for you in your setting. We will take your opinions very seriously and the design will be revised in response to your views and those of other health workers across Mombasa.

Your interview will be confidential and anonymous. We will record the interview on this voice recorder so that we can record your suggestions – however at no point will your name be linked with your interview and only the MMV team and I will have access to this recording. We have permission from your health centre/hospital Director or In-charge as well as from the National Malaria Control Programme to speak with you and to take you from your duties for approximately 45 minutes. Although all your views are important to us, if at any point you wish to end this interview, you are free to leave.
Do you have any questions? If so, please feel free to ask me. Do you agree to be interviewed?

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[1] World Health Organization, Guidelines for the treatment of malaria, Second edition, Geneva, 2010; http://www.who.int/malaria/publications/atoz/mal_treatchild_revised.pdf

[2] Dondorp A *et al.* Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial; *The Lancet*, Vol. 376, Issue 9753, Pages 1647-1657, 13 November 2010