

Saving more lives with artesunate injection

Injectable Artesunate Stakeholders' Meeting Report
Geneva, 11 November 2011



KEY FACTS

- In 2010, there were an estimated 216 million cases of malaria ¹
- Around 8 million cases of uncomplicated malaria will progress to severe malaria annually ²
- 86% of people who die of malaria are children under the age of 5
- Treating severe malaria with injectable artesunate reduces mortality by 35% in adults and 22% in children, compared to parenteral quinine.³

On 11 November 2011, convened by the Medicines for Malaria Venture (MMV), World Health Organization (WHO) and Medecins Sans Frontieres (MSF), 11 organisations from across the field of malaria came together to discuss the challenges relating to the treatment of severe malaria to agree on a way forward together and ultimately save more lives.

In April 2011, based on new scientific evidence, the WHO guidelines were revised to recommend artesunate, delivered intravenously, as the first-line treatment for severe malaria in both adults and children.

Since then, several African countries have revised their severe malaria treatment guidelines to reflect the WHO recommendation but to-date, not all countries affected by malaria have adopted the new policy.

MMV's goal is to work together with key partners to discover, develop and deliver new safe, effective and quality antimalarials to vulnerable populations at affordable prices with ultimate goal of eradicating this terrible disease.

MMV worked with Guilin Pharmaceuticals to achieve WHO prequalification for its injectable artesunate, which was granted in November 2010. The challenge now is to save lives by ensuring this treatment reaches patients in the shortest possible time frame.

The message for injectable artesunate is clear and compelling: 100% of people with severe malaria may die if they are not treated quickly and injectable artesunate is easier to use and will save more lives than the current treatment, parenteral quinine. But there are many other issues that are slowing down improvements in severe malaria management.

This report, based on the outcomes of the Malaria Stakeholder Meeting in November 2011, summarises the key issues relating to the adoption and implementation of injectable artesunate in malaria affected regions and outlines a set of recommended actions that this group believes will help speed up access to this life saving medicine.

References

1. World Malaria Report 2011
2. www.astmh.org/source/blog/post.cfm/trial-finds-artesunate-more-effective-in-africa-for-severe-malaria
3. Dondorp AM, Fanello CI, Hendriksen IC, Gomes E, Seni A, Chhaganlal KD, et al. Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open label, randomised trial. *Lancet* 2010;376:1647-57

ENCOURAGING POLICY

The need for Health Ministries to adopt injectable artesunate as part of their recommended treatment for severe malaria is absolute. If the drug is not registered and included on their lists of approved drugs, then it cannot be bought, distributed and used within that country.

The factors that influence decision-making are multiple, often complex and differ from country to country. They include established clinical practices, the views of key opinion leaders and the availability of antimalarials from local manufacturers, as well as clinical efficacy, safety, reputation and price differences between antimalarials.

The adoption decision depends not only on the clinical benefits of injectable artesunate, but also on the feasibility of deploying this treatment within the context of their national health care system.

As financing the purchase of injectable artesunate and its deployment remains a key issue for many governments, ways to reduce this barrier need to be sought. There is a need to define the financial requirements under real programmatic situations relating to the introduction of injectable artesunate, along with clear communications of its effectiveness and benefits. Ensuring that sources for financial support are available will also be a key factor in removing finance related barriers to policy adoption.

Recommended Actions ▼

Develop clear collective messages from the malaria community

- Disseminate WHO recommendations widely and clearly position injectable artesunate as the best treatment, without discrediting quinine
- Produce clear messages from all the key players and disseminate these to multiple stakeholders.

Build a deep understanding of the needs of each country and their decision-making framework

- Identify and fill gaps in our country-level understanding of health policies and severe malaria management
- Assess the current attitudes towards management of severe malaria and readiness for change
- Determine which messages will have the most resonance in which countries, and how to build on the impact of these.

Support governments in understanding the real financial implications and available support

- Finalise costing tools designed to assist in the calculation of projected national funding requirements when introducing injectable artesunate
- The funding for training, communication, supervision and monitoring should be considered as one with procurement costs.

Understand any regulatory issues

- Understand regulatory requirements for policy adoption of injectable artesunate
- Help manufacturers submit for registration and respond to regulatory requirements without delays.

Continue gaining the support of Key Opinion Leaders

- Key Opinion Leaders often have some influence on the decisions of health ministries. They can also help promote the adoption of injectable artesunate across the health profession and increase the demand by the consumers.
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SUPPORTING IMPLEMENTATION

There is a lag between the time when a Ministry of Health adopts a new antimalarial medicine in its national malaria treatment guidelines and when it is in large-scale use. From our experience with ACTs, we can expect this to vary from 6 months to two years.

To ensure that injectable artesunate is introduced over a well-defined time period and delays are minimised, clear transition plans are recommended. These should cover regulatory approval, development of training materials and communication tools and resource mobilisation to enable the ready deployment of the new medicines.

To speed up the acceptance of the new treatment and its implementation, it is important to use local experience to help promote an understanding of the benefits of injectable artesunate in relation to the local context.

Communication and engagement with the private sector will help create good harmonisation between their products and those available in the public sector.

Recommended Actions ▼

Work with governments to develop comprehensive transition plans

- These should include:
 - policy adoption
 - training and communication to overcome resistance to change
 - a focus on timing to ensure the implications of delays are clear.
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Promote benefits to the clinicians

- Key Opinion Leaders to address and discuss the advantages of injectable artesunate at key conferences and meetings
 - Show the difference it will make to them – easier to manage, less time, higher impact on mortality
 - Illustrate the difference it will make to patients and their families
 - Develop and use clear communication materials.
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Raise public awareness of injectable artesunate

- Help them understand the difference from current treatments and what they can expect
 - Use local success stories where possible
 - Improve public awareness to support early identification and prompt referral of severe malaria
 - Deploy professional communication teams to spread the message.
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Understand and address concerns

- Delays can come from resistance to change: it will be important to understand the sources of concerns and address them
 - A care giver support and information centre needs to be made available so people can get answers to questions and concerns.
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Work with suppliers to simplify the product

- Work with suppliers to seek ways to develop a simple and easy-to-use treatment
 - Once several suppliers are validated, request standardisation to avoid confusion when using artesunate from different sources
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Work together across the malaria community

- Clearly position injectable artesunate as the best treatment for severe malaria and make WHO recommendations clear
 - Develop a forum for sharing knowledge, experience and lessons learned.
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TRAINING

Linked to implementation is the need for the effective training of healthcare professionals. For healthcare professionals, the opportunity to become familiarized with the practical aspects of the treatment during training will be important to encourage the needed change in attitudes and behaviours.

The introduction of injectable artesunate as a first-line treatment for severe malaria presents an opportunity to give doctors updated training on treating all forms of malaria, including diagnostic approaches. To be effective and feasible, the training of healthcare providers should be remunerated and require as little time away from patients as possible.

When a comprehensive training program is difficult to deliver within a reasonable time, this should not delay the introduction on artesunate, but a more focused training option should be considered.

Recommended Actions ▼

Identify and develop the tools needed to support new knowledge requirements

- Develop clear job aids and guidelines
 - Carefully assess the minimal tools and time requirements for injectable artesunate in the management of severe malaria.
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Look for ways to boost attendance at training courses

- Determine what incentives are attractive to doctors
 - Find ways to shorten the time required for training
 - Use Key Opinion Leaders from the medical schools and include lectures on injectable artesunate as part of accreditation schemes for the medical profession.
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Assess the best training approach

- Investigate training options that can be used to reduce 'classroom' time and add flexibility
 - Find a feasible way to regularly update health professionals' malaria case-management knowledge.
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Engage with medical and nursing schools

- Work with educational establishments to include injectable artesunate in the clinical curriculum.
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Look for ways to strengthen case management of malaria

- Look at possible synergies and collaboration opportunities with training programs on case management
 - Seek other initiatives that will improve the management of severe malaria.
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MONITORING

The number of cases with uncomplicated and severe malaria are recorded and reported by the national health information system of all malaria endemic countries. Since severe malaria is regularly misreported in peripheral health care settings, the number of hospital patients admitted for malaria is often used as a proxy.

Changes of case fatality rates in severe malaria cases (hospital patients admitted for malaria), can be used to monitor the programmatic effectiveness of deploying injectable artesunate.

Recommended Actions ▼

Find and agree a way to monitor uptake and implementation

- Need to monitor case fatality rates of hospitalised patients admitted for malaria, following the introduction of parenteral artesunate
 - Develop a tool for monitoring implementation including problems encountered
 - Assess if the reliability of data relating to the number of cases of severe malaria can be improved.
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YOU CAN HELP

The benefits of injectable artesunate are not in doubt. The only issue is time. The sooner injectable artesunate is in use, the more lives will be saved. You can help us speed up access by spreading the message.

Help us to encourage policy adoption and implementation by spreading the word that for severe malaria, Injectable artesunate is the WHO-recommended treatment. It is proven to save more lives than other available treatments for severe malaria and is fully supported by the Roll-Back Malaria partnership's Case Management Working Group.

SAVING MORE LIVES WITH ARTESUNATE INJECTION

