Slides generously shared by Tom Sandora from his presentation at the 2/20/14 case conference.
Artesunate is available to treat severe malaria in the United States

Currently, only one non-oral drug is FDA-approved and available to treat severe malaria cases in the United States. However, the drug can harm the heart and is often not available. An investigational new drug protocol makes intravenous artesunate available for the treatment of patients with severe malaria.

**Treatment of Severe Malaria in the United States**

Approximately 1,500 cases of malaria are diagnosed in the United States each year. Approximately 10% of them are cases of severe malaria, which have a significantly higher chance of death.

Intravenous quinidine gluconate had been the only parenteral (administered by a non-oral route such as by injection) drug available in the United States for the treatment of severe malaria. However, quinidine, an antiarrhythmic drug with antimalarial action, can be harmful to the heart and has become less and less available in U.S. hospitals with the advent of newer antimalarial drugs.

**Artesunate and the New IND**

Artesunate is recommended by the World Health Organization (WHO) in preference to quinidine for the treatment of severe malaria and has been used worldwide for many years. Artesunate is in the class of medications known as artemisinins, which are derivatives from the "qinghaosu" or sweet wormwood plant (Artemisia annua).

On June 21, 2007, the Food and Drug Administration (FDA) approved investigational new drug (IND) protocol # 76,725, entitled Intravenous Artesunate for Treatment of Severe Malaria in the United States. This IND makes a new class of antimalarial medication, artemisinins, available in the United States for the first time.

The Walter Reed Army Institute of Research (WRAIR) has been conducting studies in several countries using artemesinin, and has agreed to provide a supply of this medication to CDC.

High quality-intravenous artesunate is available only to malaria patients hospitalized in the United States who need intravenous treatment because of:

- severe malaria disease
- high levels of malarias are parasites in the blood
- inability to take oral medications
- lack of timely access to intravenous quinidine
- quinidine intolerance or contraindications
- quinidine failure

The drug will be provided to the hospitals upon request and on an emergency basis by the CDC Drug Service or by one of the CDC Quarantine Stations located around the country.
CDC Quarantine Stations w/ Artesunate
Steps in Using Artesunate

• Obtain IND protocol and FDA form 1572: [http://www.cdc.gov/malaria/artesunate.html](http://www.cdc.gov/malaria/artesunate.html)
• Call BCH IRB to notify you will seek approval for Single Patient Emergency protocol
• Obtain BCH consent template from IRB
• Cut and paste CDC consent language into BCH consent template
• Fill out 1572 and demographics/eligibility part of protocol
  – This step can be deferred if immediate use necessary
Steps (cont’d)

• Submit new protocol request (Single Patient Emergency) in CHERP
  – Attach BCH consent form and completed protocol forms
• IRB will review, seek edits if needed, and approve
  – Provide finalized consent form
• Obtain patient/family consent
• Signed copy of consent to family and another to be placed in medical record
• Notify pharmacy to prepare artesunate: only stable for 1 hour
After Use

• No further data to IRB (unless adverse event)
• Fill out all pages of the CDC paperwork (~20 pages)
  – Dosing schedule (doses received, times)
  – Follow-up doses of oral antimalarial
  – Malaria microscopy results (date/time, parasitemia)
  – Serious adverse events
    • Report by phone to CDC within 24 hrs, by form within 10 days
  – Fax all paperwork to CDC: 404-718-4815