

Securing consistent, reliable wound documentation in the assessment of remote patients

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Background

Buruli ulcer is a debilitating chronic skin and soft tissue infection caused by the *Mycobacterium ulcerans* bacterium, from the same bacteria family as tuberculosis and leprosy. Most patients are children under 15.

The ulcer, recorded by the World Health Organization (WHO) as an official neglected tropical disease, has been reported in at least 33 countries with tropical, subtropical and temperate climates in Africa, South America and Western Pacific regions.

Eighty per cent of cases detected early can be cured with a combination of antibiotics. If left untreated, infection leads to destruction of skin and soft tissue with large ulcers usually on the legs or arms, with long-term functional disability.

The standard treatment has been a combination of streptomycin and rifampicin. Although the current treatment is effective, intramuscular injection with streptomycin includes challenging logistical, operational and safety disadvantages.

A fully oral treatment has been trialled, with promising results observed in several small observational studies.

A WHO-sponsored study is underway to develop a fully oral treatment for the disease. This randomized, controlled open label non-inferiority phase II/III, multi-centre trial (1 center in Benin and 4 centers in Ghana), has two parallel treatment groups.

The primary outcome in the 332-subject trial is the achievement of healing without recurrence and without excision surgery within 12 months after start of treatment. Lesions are measured at the start of treatment and 12 months later.

Wound Assessment

Wound assessment is an important part of the trial. It is essential that wound dimensions and images supplied by the sites are reliable and consistent to ensure the treatments can be objectively evaluated. Because sites are scattered around the world, with stakeholders in Ghana, Benin, The Netherlands, France, Switzerland and the United States, timely communication is important.

- 1. At commencement of treatment, the lesion sites are examined by inspection and palpation, and documented by digital wound camera.**
- 2. Digital images are examined by a panel of wound experts in other parts of the world who are unaware of treatment allocation.**

Aim

To validate a digital wound assessment system's efficacy in documenting and securing reliable, real-time data for clinical trials in remote sites where trial stakeholders are accessing information from a range of locations elsewhere in the world.

Method

A World Health Organization study of the efficacy of treatments for Buruli ulcer in Africa is taking place at four sites in Ghana, and one in Benin, with the target set at a total of 332 study subjects with PCR-confirmed disease. The data is being analyzed by key researchers in France, The Netherlands, Switzerland and the USA. Study organizers recognized that undertaking wound assessments in such remote areas would introduce the risk of inconsistent assessment information and the loss of critical data.

The sponsors therefore implemented a digital wound assessment system to gather accurate data (wound area) and images. Researchers were interviewed to gauge the reliability and security of the wound assessment information, to validate the efficacy of the tool in capturing, storing, and securely sharing the required data.

Results / Discussion

The investigators reported that the use of digital wound assessment provided reliable, consistent wound status information and images. This supported their ability to effectively monitor the study's progress, obtain clinically meaningful information, obtain data instantly, and document the evidence required to publish repeatable study findings.

Conclusion

Digital wound assessment data centralized on a secure Internet server ensures that a reliable, timely record of wound status is available to stakeholders of clinical trials, even when the sites are in remote parts of the world.

At Agogo Presbyterian Hospital in Ghana, Dr Albert Paintsil, plastic surgeon from the Korle-Bu Teaching Hospital, Accra, conducts an assessment on a young Buruli ulcer patient. Looking on is Dr Richard Phillips, co-principal investigator of the study and physician specialist at the Komfo Anokye Teaching Hospital, Kumasi.

