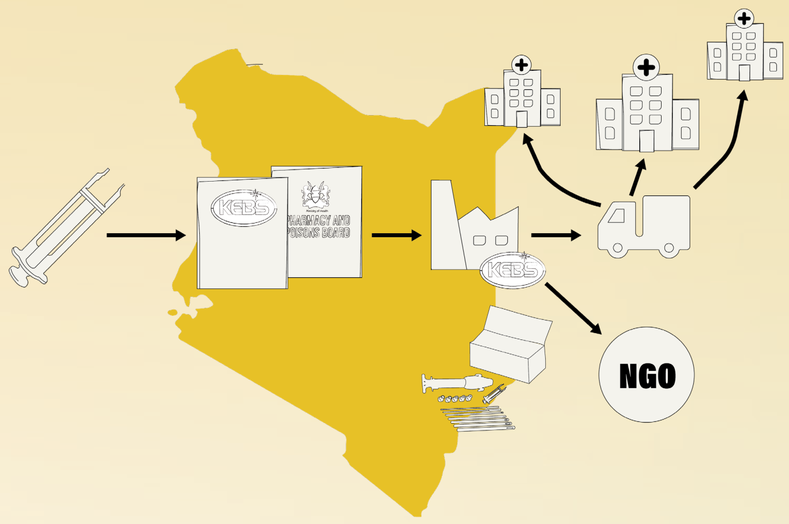
How to bring the Chloe SED a step closer to Kenyan women?

Recommendations for introducing a reusable medical device to the Kenyan market: certification, procurement and reprocessing

This study is a contribution to the existing Chloe SED project. Currently, the Chloe SED is an initiative that focuses on the Kenyan market. The device can be used for procedures related to pregnancy issues, such as Manual Vacuum Aspiration (MVA), where uterine contents are removed with the help of a vacuum suction device. The embodiment design of Chloe SED is nearly ready.

Certification

1

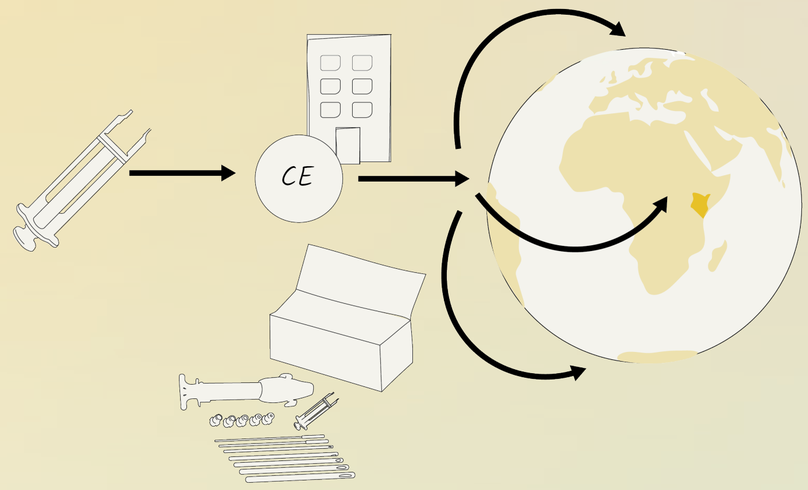


Keep it local

This research has shown that obtaining local Kenyan certification for medical devices without prior approval from abroad e.g., the CE-mark is possible, albeit challenging. The PPB and KEBS, two bodies involved in medical device certification in Kenya, are still in a learning environment and the certification process is still in development. The next steps for the Chloe SED project to obtain certification is to continue investing their time and resources into completing the Keyan national certification process to obtain the PPB DPER Registration Certificate. Reasons for this are the Chloe SED can reduce costs and aim for offering their device more affordably and can collect data more efficiently while the device is still under development

One key condition, however, is that the Chloe SED project must find a local subcontractor to manufacture the device locally. This manufacturer must hold an SM Permit (Kenyan approved QMS system for their production plant, which includes ISO 13485) to be authorised to produce the device.

2



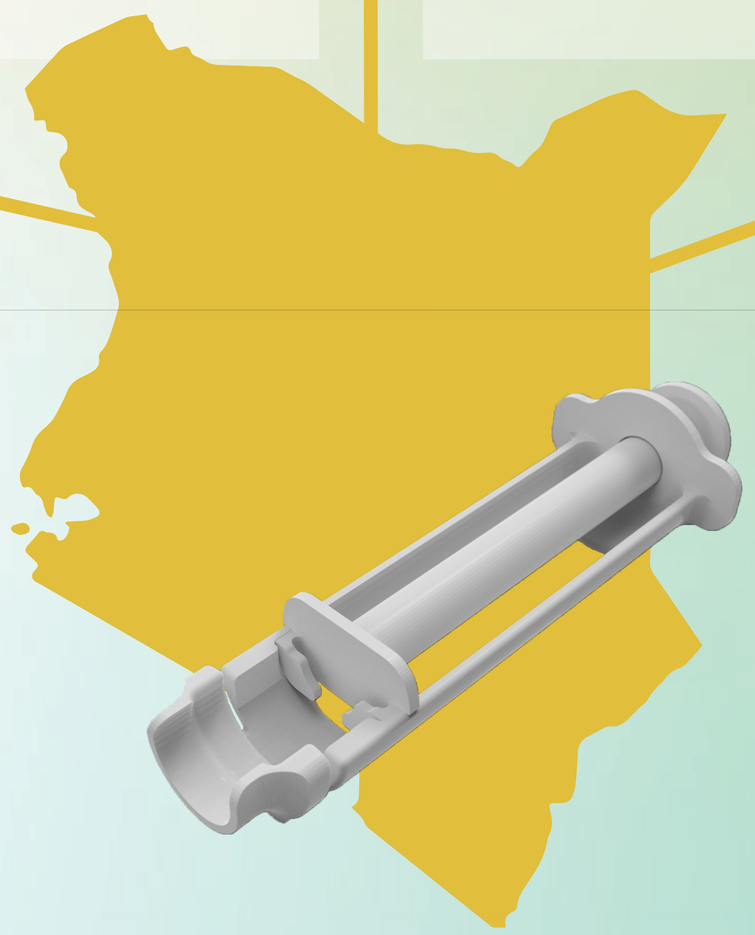
The power of the EU certiication

This research has found that medical device manufacturers from the Global North opt for the CE-mark from the EU because this certification is widely accepted by LMIC. Since, the Chloe SEDs market is not limited to Kenyan women but can be of use to many women on this planet, this research recommends that the Chloe SED project eventually obtains the CE mark. With this certification, the Chloe SED can enter markets in multiple countries and reach as many patients as possible. Therefore, it is recommended that the Chloe SED project obtains EU certification in the future by partnering with an established organisation that is experienced in certifying their medical equipment though the EU process. Suggestions are large global MVA kit suppliers or other large medical companies.

Reprocessing

Testing on reprocessing deviations

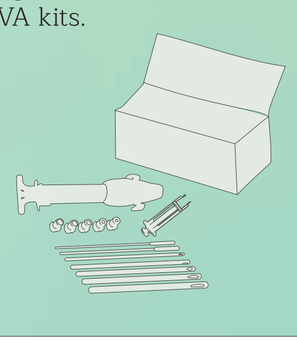
Research found that reprocessing methods in Kenyan healthcare facilities deviate from what is recommended by WHO protocols. They lack the resources to follow WHO practices and reprocess based on available materials. Therefore, this research recommends testing the device with the reprocessing method used in Kenya to ensure device safety, with a special attention to the influence of decontamination, the effectiveness of high-level disinfection and incorporating longer soaking times. This may lead to modifications. It is also recommended to test the device on longer soaking times and if applicable, adjust the life cycles and incorporate this information into the instructions.



Procurement

Chloe SED as part of an MVA kit

Hospitals procure MVA equipment as a kit. In order to reach the Kenyan market, the Chloe SED must become a standard component of an MVA kit. An interesting stakeholder, IPAS, is a large MVA kit supplier both in Kenya and globally. Another interesting stakeholder for the Chloe SED project is Marie Stopes, an international NGO located in Kenya that provides MVA procedures in their own clinics. They have their own brand of MVA kits. Both IPAS and Marie Stopes have CE certified and ISO 13485 compliant MVA kits.



Floor Burgers
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