

Non-Incineration Medical Waste Treatment Pilot Project at Bagamoyo District Hospital, Tanzania



Stringer, R., Kiama, J., Emmanuel, J., Chenya, E., Katima, J., & Magoma, F.
September 2010
Web Version



TABLE OF CONTENTS

| | |
|----------------------------------------------------------------|----|
| Acknowledgements..... | 1 |
| Notes On Products | 1 |
| Abbreviations | 2 |
| Executive Summary..... | 3 |
| Background | 4 |
| Project Description..... | 5 |
| Collaborating Partners And Roles | 6 |
| About Bagamoyo District Hospital..... | 7 |
| Baseline Assessment Of Health Care Waste Management | 7 |
| Sharps Box Integrity Testing | 11 |
| Site Preparation | 12 |
| Technology Procurement And Shipping | 12 |
| Training | 13 |
| Setting Up The Waste Management System | 14 |
| Shredder Installation..... | 14 |
| Autoclave Installation And Validation..... | 15 |
| Project Monitoring, Evaluation And Documentation | 16 |
| Segregation Practices..... | 17 |
| Autoclave And Shredder Operation..... | 18 |
| Estimated Reduction In Dioxin/Furan Releases At Bagamoyo | 20 |
| Lessons Learned For Treatment Technology Design | 20 |
| Conclusion..... | 21 |
| References | 22 |
| Appendix 1: Sharps Box Integrity Testing Procedure | 23 |
| Appendix 2: Test Protocol For Autoclaves..... | 27 |
| Appendix 3: Autoclave Validation Technical Note..... | 32 |

ACKNOWLEDGEMENTS

This authors wish to thank the following people for their efforts, which were instrumental in the success of this project: all the staff of Bagamoyo District Hospital; the Bagamoyo District leadership that is lead by the District Executive Director; The Chief Medical Officer of the Ministry of Health and Social welfare; the Directorate of Preventive Services; and Toxics Link in Delhi for assistance in the procurement of the autoclave and shredder.

NOTES ON PRODUCTS

Mention of a product in this report does not constitute an endorsement or recommendation by any of the organizations involved in this project.

ABBREVIATIONS

| | |
|--------|-------------------------------------------------------|
| AGENDA | AGENDA for Environment and Responsible Development |
| BDC | Bagamoyo District Council |
| BDH | Bagamoyo District Hospital |
| CMO | Chief Medical Officer |
| DHO | District Health Officer |
| DMO | District Medical Officer |
| GEF | Global Environmental Facility |
| HCWM | Health Care Waste Management |
| HCWMC | Health Care Waste Management Committee |
| HCWH | Health Care Without Harm |
| Hg | Mercury |
| HO | Health Officer |
| ICP-IS | Infection prevention and control and injection safety |
| JSI | John Snow Inc |
| MoHSW | Ministry of Health and Social Welfare |
| MSW | Municipal Solid Waste |
| NGO | Non-Governmental Organization |
| PCDDs | Polychlorinated dibenzo-p-dioxins |
| PCDFs | Polychlorinated dibenzofurans |
| POPs | Persistent Organic Pollutants |
| PPE | Personal Protective Equipment |
| PVC | Polyvinyl Chloride |
| UDSM | University of Dar es Salaam |
| UNDP | United Nations Development Programme |
| WHO | World Health Organization |

EXECUTIVE SUMMARY

Medical waste, if not treated properly, represents a hazard to healthcare workers, patients, the public and the environment. This is an increasing problem in low income countries, including those in Africa, where healthcare systems are improving but the medical waste management systems have not been strengthened to the same extent.

In the developed world, steam-based systems such as autoclaves are widely used to disinfect infectious waste. They are effective and also avoid the dioxin and furan emissions associated with medical waste incinerators. However, the technique is hardly used in Africa, partly because there is little experience with the technique.

This project was therefore intended to demonstrate how autoclaving could be employed in a typical Tanzanian District Hospital- that of Bagamoyo, on the Tanzanian coast an hour's drive north of Dar es Salaam.

The technology employed was a manually operated, gravity-fed vertical autoclave with a capacity of 167 litres. A shredder was also used to destroyed used syringes once they had been disinfected. This prevented them either being reused or becoming the cause of accidental injury. A small building was adapted to house the equipment, with the necessary services, a bin washing area, and separate storage areas for untreated and treated waste as well as clean supplies.

The hospital was provided with coloured bins to segregate waste according to the Tanzanian national guidelines and medical staff were trained in segregation and safe waste management. Machinery operators were trained in routine operation and basic maintenance of the autoclave and shredder and lab staff shown how to test autoclave disinfection efficacy.

Before inauguration, the autoclave was tested with a variety of cycle parameters to determine the most efficient method of disinfecting the waste. A mixture of steam flushes and pressure pulses were used to ensure that steam penetrated right through the waste to disinfect the whole load. Different cycles were developed for bags of infectious waste and sharps boxes. Effectiveness was proved using autoclave tape, steam integrators and biological indicators containing heat-resistant bacteria. Only when tests showed that the bacteria did not survive the process were the cycles approved.

A year of monitoring after the project initiation demonstrated that this technology can work well in the African context. Issues relating to adherence to segregation practices, and maintenance of the autoclave and shredder were addressed as they arose. Information was also gathered to assist in the development of a lower-cost and lower-maintenance version of the autoclave, which is being developed by the University of Dar es Salaam as part of a UNDP-GEF funded project. Prototypes are expected to be ready for testing by the end of 2010 or early 2011.

BACKGROUND

It is estimated that half the world's population is at occupational, environmental or public health risk from poorly treated medical waste. This problem is particularly serious in developing world, where improvements in healthcare services are not matched by strengthening of the waste management infrastructure (Harhay *et al.* 2009).

Tanzania is among the countries making efforts to tackle this problem. It is also a signatory to the Stockholm Convention on Persistent Organic Pollutants (POPs) (UNEP 2001), a global convention with the aim of eliminating some of the most long-lived anthropogenic pollutants. The Convention has listed polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) among initial 12 POPs and, under Annex C, cites incineration of medical waste as one of the major source of PCDDs and PCDFs.

The wastes that are treated in these incinerators include plastic materials, especially polyvinyl chloride (PVC), whose incineration is strongly associated with emissions of dioxins and furans. Incineration of medical waste can also lead to release of heavy metals (e.g. mercury, from broken thermometers, or lead or cadmium from plastics) and acid gases, such as sulphur oxides, hydrogen chloride, nitrogenous gases and particulates.

These toxins, if not trapped in pollution control devices, will be released into the air. Liquid effluent from air pollution devices can carry pollution into water bodies. Moreover, incineration ash needs to be disposed of as hazardous waste as it contains heavy metals and persistent organic pollutants. If it is not disposed of in secured landfills, it can contaminate soil and groundwater. These routes can all lead to food chain contamination.

It is estimated that half the world's population is at occupational, environmental or public health risk from poorly treated medical waste.

Article 5 of the POPs Convention urges countries to take measures to further reduce releases of POPs from unintended production "with the goal of their continuing minimization and, where feasible, ultimate elimination." Article 11 require parties within their capabilities, at the national and international levels, to encourage and/or undertake

appropriate research, development, monitoring and cooperation pertaining to persistent organic pollutants and, where relevant, to their alternatives including on their sources and releases into the environment; and release reduction and/or elimination.

Many African countries, including Tanzania, have ratified the Stockholm Convention on Persistent Organic Pollutants (POPs) and thus have obligations to implement the Convention including support for alternative technologies.

The WHO Policy Paper on safe healthcare waste management (WHO 2004) supports the Stockholm and Basel Conventions. It also directs countries to develop and implement plans, policies, legislation and manual on safe medical waste management; allocate human and financial resources for safe medical waste management and scale up the promotion of non-incineration treatment alternatives.

Many African countries have relied on incinerators as their only means of medical waste disposal, although alternative technologies have been used for decades in many industrialized countries in place of medical waste incinerators. During the 2006 WHO regional workshop on health-care waste management in Nairobi, Kenya, African delegates reported many problems with small-scale incinerators but little familiarity with alternative technologies. The problems reported include the poor physical state of small-scale incinerators constructed on-site in several countries, low capacity of incinerators, complaints from local communities about the smoke; and low efficiency in reaching the desired burning temperature.

In a separate project, the Global Environmental Facility (GEF), through the United Nations Development Programme (UNDP), World Health Organization and Health Care Without Harm, will develop low-cost, locally made alternative technologies at the University of Dar es Salaam. The component is under the global project of “Demonstrating and Promoting Best Techniques and Practices for Reducing Health Care Waste to Avoid Environmental Releases of Dioxins and Mercury”. It will take about a year and a half to design, construct, test, and evaluate the technologies.

The pilot project at a hospital in one of the Sub-Saharan Africa country was therefore proposed in order to demonstrate an alternative non-incineration treatment technology so that it can be evaluated and the experience gained in an African setting can guide countries in developing their national plans as well as inform the GEF project and facilitate the rapid and successful deployment of the technologies it develops.

PROJECT DESCRIPTION

The main objective of the pilot project was to install, demonstrate and evaluate existing off-the-shelf non-incineration medical waste treatment technologies at Bagamoyo District Hospital in Tanzania.

The specific objectives of the project were

- To act as a showcase for best environmental technology to minimize or eliminate the release of dioxins and furans (PCDD/PCDF).
- To assist in improving the health-care waste management system of Bagamoyo District hospital.
- To identify design issues that could be incorporated into the UNDP GEF project designs.
- To facilitate the development of a recycling system for plastics and other recyclable waste.

COLLABORATING PARTNERS AND ROLES

Health Care Without Harm (HCWH): an international NGO. Provide overall coordination; technical support and technology selection; coordinate equipment procurement, installation and testing; conduct the evaluation; and disseminate results at various international conferences and networks. www.noharm.org

AGENDA for Environment and Responsible Development: a Tanzanian NGO. Provide technical and logistic support; collaborate in setting up materials recovery and recycling; assist in preparations and importation of technology; assist in installation, testing, and training; monitor operation for a year; compile data and participate in the evaluation. www.agenda-tz.org/

John Snow Inc. (JSI): an international NGO. Facilitate links to the hospital; assist in logistics and technical support; assist in importation of technology; incorporate the new technology into existing health-care waste management training for the hospital; participate in the evaluation and disseminate results. www.jsi.com

The United Nations Development Programme's Global Environmental Facility Project (UNDP GEF): provide technical support; assist in technology selection and installation; provide technical support on testing and monitoring; participate in the evaluation; share results with the Global Expert Team and UDSM Design Team; and disseminate results through the UNDP GEF network. www.gefmedwaste.org

Ministry of Health and Social Welfare: monitor the development of the pilot project; commit to sustain the system at Bagamoyo District Hospital for a minimum of four years after the initial pilot year of optimization, including allocation of the relevant funds; and consider the results when enhancing their national plans and policies related to health-care waste management; agree to the project being a showcase for international governmental and non-governmental organizations, donors, and other interested parties. www.moh.go.tz/

Vice President's Office, Department of the Environment: monitor the developments of the pilot project and consider the results in their national plans and policies. Ensure compliance with Environmental Management Act Cap 191. <http://www.tanzania.go.tz/environment.html>

Bagamoyo District Hospital (BDH): the site of the pilot project. Hospital administration to provide a site and utility connections for the new technology, provide personnel to run the technology, and commit to maintain a good health-care waste management system. The hospital staff to participate in the training and continuous improvement of the waste management system, and cooperate in the monitoring and evaluation; and admit visitors wishing to see the project.

Bagamoyo District Council (BDC): commit to a system of collection, transport, and disposal of treated health-care waste at a controlled landfill, and collaborate in setting up a system of materials recovery and recycling with local industry.

ABOUT BAGAMOYO DISTRICT HOSPITAL

Bagamoyo District Hospital was selected by the Ministry of Health and Social Welfare (MoHSW) for the project based on criteria developed by the project team. The criteria contained factors such as size of the hospital, its reputation and the existence of either a good HCWM system (minimization, segregation including for mercury, proper collection, transport, storage, etc.) or a high likelihood of improving the existing HCWM system to a high level (e.g., there are already plans to improve, or assessments have been made, or the hospital is committed to improve their system), availability of laboratory capable of processing microbiological test samples and an engineer/other staff capable of routine maintenance.

Other factors included a reliable electricity supply; local infrastructure (municipal waste disposal system) able to deal with sterilized waste- ideally recycling for paper and/or plastic possible. The hospital also needed to express commitment to work on the project and provide a contact personnel within the hospital, willingness to sustain the system after the project period (allocate yearly funds for maintenance, repair, training etc.). Lastly, its accessibility to international and regional travelers, and suitability to be a showcase to interested parties was also considered.

The hospital is a typical Tanzanian general hospital, with 125 beds, 5 wards (maternity, female, male, pediatric and isolation). Occupancy is usually 100% apart from the isolation ward which is reserved for patients suffering from tuberculosis or leprosy, and is usually not occupied. In addition, there are two operating theatres (major and minor); a dental surgery, eye department; and various out-patient departments. There is a staff of 183 including 72 non-medical attendants.

Finally, BDH is home to the Bagamoyo Research and Training Unit (BRTU) which is an extension of Ifakara Health and Research Development Centre (IHRDC) and conducts clinical trials, notably for malaria vaccines (http://brtu.ihrdc.or.tz/about_us/index.php). The many vaccinations provided by this research group mean that BDH generates more sharps waste than is typical for a hospital of its size.

BASELINE ASSESSMENT OF HEALTH CARE WASTE MANAGEMENT

After the introduction of the project to the Ministry of Health and Social Welfare, the project team visited BDH to introduce the project to the management and conduct the baseline assessment of HCWM.

The baseline assessment was conducted to provide a comprehensive understanding of:

- Hospital capacity in general eg number of beds and average occupancy rate etc;
- Hospital level policies and management/administrative practices on medical waste management and final disposal;
- Status of medical waste handling training;
- Awareness and attitudes about waste management at all levels in hospital;
- Medical waste handling, including segregation, transportation and storage;

- System for final disposal of medical waste (local MSW treatment, recycling);
- Amounts of overall health-care waste generated, estimated or measured amounts of infectious waste, pathological and sharps waste;
- Compliance with Ministry of Health and Social Welfare (MoHSW) guidelines;
- Existing waste-related equipment within the hospital;
- Hazards and risks from existing system;
- Possible location for an alternative technology;

The team conducted interviews with key personnel including the DMO, DHO, CMO, HO, Matron and the waste handler with the purpose of obtaining first hand information and a general overview on the hospital waste management system.

An in-depth walkthrough assessment was conducted to inspect waste generating areas, including wards, laboratories, operating theatres, main stores, outpatients departments, injection section etc. The inspections included taking pictures of the different departments, checking trash bins to assess segregation, checking the strategic location of the trash bins, looking for appropriate signs and posters, colour coding for bins and liners, cleanliness etc. Also short interviews were carried out with hospital staff during the walkthroughs.

Generally, the waste management at the hospital was not satisfactory and did not meet the criteria set out in the national guidelines (MoHSW 2006). There was no data on amount of waste generated at the hospital. From the estimation done by the team after the assessment it was found that 452 of 726 litres of waste from 21 service units were either infectious (ie infectious, pathological or sharps as defined by the national guidelines) or had been rendered infectious by mixing with one of these wastes. Thus 62% of the waste generated was considered infectious.



Poor hygiene observed during the baseline assessment

It is generally assumed that only 15-25% of the waste generated by a hospital is infectious (see eg WHO 2004); a figure as high as 62% indicates that a lot of non-infectious waste has been mixed in with the infectious waste.

Part of the problem was that a lot of the service units did not have the right colour-coded waste bins in each service unit. Also, it was discovered that only 60 staff (out of more than 180) were trained by JSI previously on HCWM hence there was a low level of awareness among the personnel.

The hospital had no Health Care Waste Management Committee or waste manager, and no specific internal policy relating to waste management.

The incinerator was not operated according to required standards. Whereas the incinerator should be brought to the recommended operating temperature with auxiliary fuel before adding the medical waste, it was instead completely filled with waste and then lit. When the team was onsite, neighbours from the community nearby the hospital came and complained that the smoke was drifting over their households and demanded the hospital stop incinerating their waste.

Ash from the incinerator was buried in shallow pits and chickens were observed scratching in it. This can represent a direct route for dioxins and other pollutants in the ash into the food chain, via eggs and chicken meat. Analysis of chicken eggs close to a small scale medical waste incinerator in India reported dioxin levels several-fold higher than internationally accepted limits (IPEN, TL & Arnika 2005).



The incinerator at BDH before its breakdown



Neighbours complaining to the project team about the smoke from the incinerator



Incinerator charged with waste before lighting



Chickens scratching in the ash pit



Incinerator with stack and roof burnt out

At the time of the project team's first visit to BDH in January 2007, the incinerator was reported to have a new flue. By the time of the installation of the autoclave and shredder in October 2008, the flue and protective roof of the incinerator and both burned through, rendering it inoperable.

BDH used yellow cardboard sharps boxes for collection of used syringes and other sharps waste. These were designed to be incinerated, rather than autoclaved. If the hospital were to be able to continue using the same containers with the non-incineration technologies, it was important to ascertain whether they would still safely retain sharps after autoclaving. An experiment to test this was designed and is described below.

The team also conducted an assessment of the off-site disposal facility several kilometres from the hospital. The site was not fenced and there was stagnant water which makes the site not ideal for waste disposal. The District Council informed the project team that they were in the process of identifying a more appropriate site, but at the time of writing this has not happened yet.

The poor final disposal route meant that, even after disinfection, used syringes could still cause injury. In some countries there is a trade in used syringes. Rag pickers seek them out as they can be resold. Up to 10% of health facilities in India were estimated to sell used syringes to rag pickers; a practice that contributed to a recent outbreak of hepatitis B which claimed at least 60 lives (Solberg 2009). Using needle cutters that cut the hub off the syringe and make it impossible to reuse can prevent this happening, and produce a small volume of needles that could be buried in a sharps pit. However, because needle/hub cutters are not used in Tanzania, it was imperative to shred all syringes after autoclaving.



Bagamoyo dump

SHARPS BOX INTEGRITY TESTING

As described above, Bagamoyo District Hospital uses yellow cardboard sharps containers. They would be autoclaved before shredding the syringes for recycling or final disposal. Therefore, before the commencement of the project, experiments were conducted to determine whether they were able to withstand high-vacuum steam treatment and then be transferred from the autoclave to a shredder without breakage and accidental release of its contents.

Equipment used for the tests included a portable steam sterilizer with accessories; gas stove; two 5-liter sharps cardboard boxes representative of those used at Bagamoyo; surrogate sharps waste (clean syringes and other plastic material amounting to approx. 1 kg); watch; heat-resistant gloves, heavy-duty gloves, heavy-duty apron, and safety glasses; a small amount of vacuum grease.

The sharps boxes showed no signs of damage and retained their physical integrity after autoclaving and shaking tests in two separate experiments using first capped then uncapped syringes.

A sharps box containing 1 kg of surrogate sharps waste was placed in the steam sterilizer unit and treated for 45 minutes at that highest working pressure (about 21 psig, corresponding to a saturation temperature of about 127°C). The sterilizer was then depressurized and the sharps box was removed, examined and tested. The first test involved using capped syringes while the second test was conducted using uncapped syringes. The full experimental procedure is given in Appendix 1.

The sharps boxes showed no signs of damage and retained their physical integrity after autoclaving and shaking tests in two separate experiments using first capped then uncapped syringes. Minor wear was observed on joint where the box is glued as indicated in the photos below.



Sharps box after the experiment



Minor wear on the glued joint

SITE PREPARATION

BDH allocated an existing building for the project activities. A layout plan (see below) was prepared before renovation and expansion of the building. During renovation, all holes in the lower parts of the walls and floor were sealed to keep away rodents and other vectors. The floors were smoothed to ensure easy cleaning in case of spills. The layout had utility connections (electricity and water) for autoclave and shredder operation. A drain with a lock prevented gases from the condensate or from the septic tank from backing up and seeping into the rooms. All doors were lockable.

The main part of the building included separate, adjacent areas, the first for waste treatment and the second for cleaning of equipment and temporary storage of treated waste. The main waste treatment room contained an induced draft fan to bring fresh air into the rooms for heat and odor control. A domestic shower base was installed in the wash room as an economical and effective wash area. There were also two secure storage areas, one for untreated waste and one for supplies.



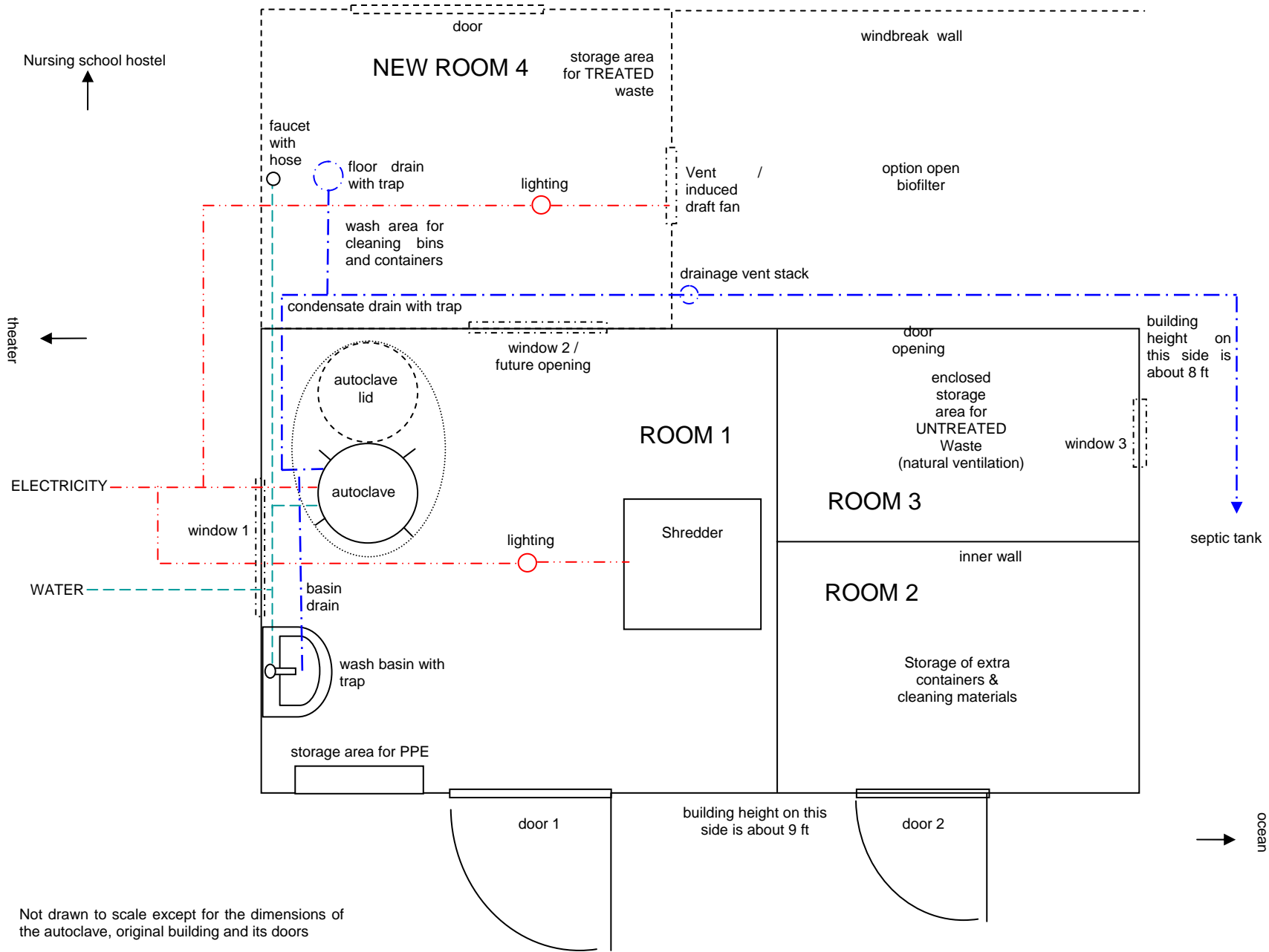
The autoclave and shredder building at BDH

TECHNOLOGY PROCUREMENT AND SHIPPING

HCWH publishes an inventory of global suppliers for non-incineration medical waste management (Emmanuel & Stringer 2007). Suppliers in India who could provide to equipment to the required specification at low cost were chosen and the equipment shipped by sea to Tanzania. The following are the specifications for the autoclave and shredder in use at BDH:

Autoclave: ACMAS vertical autoclave, inside chamber of 304 grade stainless steel, an inner volume of 167 liters, radial locking arrangement, pressure and temperature gauges, water level indicator, safety valves, electrical control box. A spare heating element and gasket were also purchased.

Shredder: PIMCO Plastic scrap granulator Model PR-200 with 3HP electric motor, 5 x 200mm blades installed. One set of spare blades was also purchased.



Not drawn to scale except for the dimensions of the autoclave, original building and its doors



Autoclave



Shredder and operator

TRAINING

Staff of Bagamoyo District Hospital were first trained in infection prevention and control and injection safety (ICP-IS) in 2008. Some staff were also trained in healthcare waste management.

The autoclave and shredder operators were trained by an experienced medical waste management engineer

Before the start of the project, JSI conducted refresher training for 150 staff, including nurses, waste handlers, attendants, and some doctors.

The training focused mainly on waste segregation, which is an important aspect of proper waste treatment and mandated in Tanzania's guidelines on medical waste management (MoHSW 2006). Staff were also trained on safe handling of syringes after use and given an insight on the autoclave as the alternative treatment of HCW.

The autoclave and shredder operators were trained by an experienced medical waste management engineer. Local technicians were orientated by the project staff on the technology as a whole and specific maintenance issues as they arose.

SETTING UP THE WASTE MANAGEMENT SYSTEM

BDH was supplied with waste bins, liners, personal protective equipment (PPE) for waste handlers and operators, posters, waste audit forms, good practice forms, ward feedback forms and accident reporting forms for use in healthcare waste management at the beginning of the project. The forms provided were used for both internal and external monitoring and evaluation of the waste management practices.

A Healthcare Waste Management Committee (HCWMC) was established at the beginning of the project, and a Health Officer appointed as contact person for the project.



Waste bins supplied to BDH



Segregation poster supplied to BDH

SHREDDER INSTALLATION



Shredded syringes

The shredder was connected to the three (3) phase electric line. It was then tested to evaluate the shredding of sharp wastes and proved effective. As the main plastic in syringes is high density polyethylene, it can be recycled. Unfortunately, it was not possible to identify a suitable recycler who could take this waste. The search for a recycler is ongoing.

AUTOCLAVE INSTALLATION AND VALIDATION

The autoclave was installed with both the steam and water outlet pipes channeled to the drainage system to prevent any emissions to the working area. The autoclave was connected water and to the single phase electric line.

As well as plumbing in the autoclave, it was tested to find the most effective operating cycle. This is an essential part of the installation procedure and was carried out by experienced engineers. The combination of equipment and waste in every facility will be different, so it is not sufficient to use the manufacturer's recommended operational parameters without further validation. This is true both where the autoclave is a general purpose design, as in this case, and where it has been marketed specifically for medical waste treatment.

The autoclave was tested to find the most effective operating cycle. The combination of equipment and waste in every facility will be different, so it is not sufficient to use the manufacturer's recommended operational parameters without further validation.

The autoclave being tested here was a gravity-fed model, without a vacuum cycle to remove air from the system before the steam is fed in. Therefore, to ensure that the steam penetrated all the way into the waste bags, pressure was allowed to build up and then released. 14 experimental runs were conducted using different combinations of steam flushes, pressure pulses, and exposure times. The primary purpose was to ensure that waste is being properly disinfected, but by starting with a shorter run time and gradually increasing it, facilities also identify the most rapid and economical method of doing so.

Three methods of measurement were used to validate disinfection: steam integrators (autoclave tape and Steam *Plus* Sterilization) and biological indicators (3M Attest 1292 self-contained biological indicators for steam at 250°F/121°C corresponding to 10⁵ concentration of *Geobacillus stearothermophilus*).

Autoclave tape is adhesive tape with diagonal stripes that turn black on exposure to high temperature. It does not provide any indication of how long the temperature exposure has been, so it will not alone provide proof of disinfection. However, it is cheap and can be used every day as an easy way to tell whether or not a bag or box has been autoclaved.

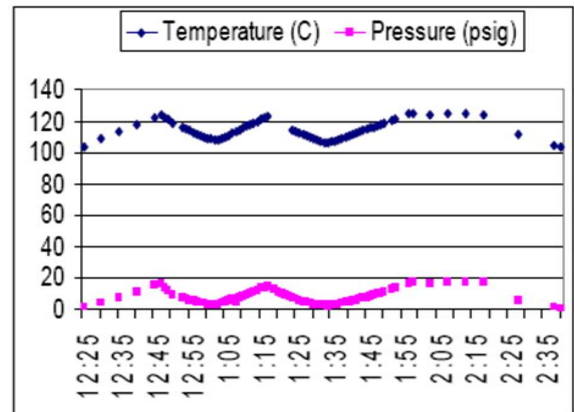
Integrators are also heat-sensitive indicators, but also provide an indication of the time that the indicator has been at high temperature. These are often used as a surrogate for sterilization, but should only be relied upon if it has not been established that the conditions they indicate do indeed disinfect the waste.

Biological indicators (also called SCBIs or self contained biological indicators) are small plastic vials with two compartments. One contains bacterial spores, the other a nutrient broth incorporating a colour indicator. After the SCBIs have been through the autoclaving process, they are compressed to break the seal between the spores and the broth, shaken

to mix and then placed in an incubator which maintains an ideal growth temperature for the spores. If any have survived and grow, they will induce a colour change in the broth that can be read by eye or a colorimeter, depending on the brand in question.

Initially, the test bags were filled with crumpled newspapers and about 150 ml of water. An Attest biological indicator and integrator were fixed to the bottom end of a PTFE tube using autoclave tape. The tube was then inserted into the middle of the test bag with the top of the tube protruding above the bag; the bag was then tied. The test bags were placed at the bottom of the autoclave basket, which was then filled to capacity with six more bags of surrogate waste.

Several runs were conducted using different purge cycles and final exposure times. Once a cycle had been found after which the biological indicators showed sterility, the test waste bag was replaced with real hospital waste. Tests were also run using sharps containers, where the indicators were placed in the bottom-most box. It was found that the sharps containers could be disinfected with a shorter cycle time than the waste bags.



Temperature and pressure variations during one test

The Attest Auto-reader, 12-well, 3-Hour Rapid Readout Incubator was used during the testing and was later donated to BDH to enable monthly verification test of the autoclave.

The tests show that at least Level III disinfection or higher can be achieved in the gravity-fed autoclave as long as at least two deep pulses (15 minutes each) are used followed by a 20 minutes exposure at 124°C or four shallow pulses (5, 4, 3 and 2 minutes respectively) followed by a 30 minutes exposure at 124°C.

Detailed experimental procedures are given in Appendix 2 and a technical brief of the experiments (Emmanuel 2008), which was published at the time, is attached as Appendix 3.

PROJECT MONITORING, EVALUATION AND DOCUMENTATION

The project was officially launched on 9th October 2009 in an event attended by various stakeholders including representatives from the Ministry of Health and Social Welfare (MoHSW), Bagamoyo District Council, the hospital administration and staff, and the project team (HCWH, UDSM, UNDP/GEF, JSI and AGENDA). During the launch, autoclave and shredder operation was demonstrated.

During the launch, the project received high praise from hospital staff and administration and the district's Executive Director, whereby commitment to ensure successful implementation of the project in collaboration with the project team was given.

Monitoring was conducted both internally and externally. The BDH-HCWMC conducted the supervision internally to oversee the implementation of the HCWM system and seek technical support from the project team. The hospital gathered data on average amount of waste treated per day or week, record average amount of sharps waste treated per day or week, document microbial inactivation test results, record maintenance and repair.

To monitor HCWM practices at the hospital, for the first three months, AGENDA and JSI conducted weekly supervision, followed by monthly supervision for the rest of the project period. The observations of the supervision were communicated to the project contact person and hospital management for discussion and improvements.

SEGREGATION PRACTICES

During the initial baseline assessment, 62% of the waste was either infectious or mixed with infectious waste so that it needed to be treated as infectious. Afterwards, this was reduced to 25%. The proportion of infectious waste that is generated by hospitals is often quoted as 10-25%, so the figures here are at the high end of the usual range. Two factors explain this: hospitals in low income countries do not always produce the same level of general (non-infectious) waste as in richer countries and second; segregation was not carried out perfectly, so some non-infectious waste was mixed into the infectious waste. However, the amount of infectious waste generated remained steady over the course of the year of monitoring, which indicates that the situation did not deteriorate.

Two main issues were identified regarding segregation. First was a general disinclination to change practices. Some nurses felt that segregation was an extra and unnecessary burden on them. Follow-up training and further reinforcement on the importance of segregation were necessary to raise the standard of segregation.

During the initial baseline assessment, 62% of the waste was either infectious or mixed with infectious waste so that it needed to be treated as infectious. Afterwards, this was reduced to 25%.

The other issue, identified in the early stages of the project, was that nurses were putting gloves, swabs etc in the sharps boxes, which could clog the shredder. It was ascertained that nurses were putting the non-sharps waste into the sharps box when they were using a treatment trolley at the bedside and had no other waste receptacle at hand. The project offered small colour-coded containers that could be emptied into the relevant bins back at the nurses' station, but this was rejected as regulations specified that containers on the trolley should be sterile. Finally, it was agreed that sterile kidney dishes would be used and the problem abated.

These two issues underline the need for any system to be set up in a way that is sensitive to the needs of the medical staff, and for the waste management team to be vigilant and make sure that any bad practices are corrected as soon as possible. Refresher training should also be conducted on a regular basis. This can be carried out by outside agencies, but may more simply and economically be undertaken by members of the waste management team or other appropriate staff members. Regular inspection by the appropriate regulatory authorities is also important.

AUTOCLAVE AND SHREDDER OPERATION

Over the course of the project, the hospital reported producing an average of 22kg infectious waste per day, 23 full sharps containers and 15kg of highly infectious waste (primarily placenta waste resulting from the 6-7 daily deliveries). The average medical waste generation of in Tanzania is estimated to be 0.41 kg/occupied bed/day by the Secretariat of the Basel Convention and the World Health Organisation (SBC/WHO 2005). Bearing in mind that, since BDH is home to Bagamoyo Research and Training Unit, an extension of Ifakara Health and Research Development Centre (IHRDC)(see http://brtu.ihrdc.or.tz/about_us/index.php) which conducts malaria vaccine trials, and therefore generates more sharps waste than is typical for a facility of its size, Bagamoyo's figures would be in line with the official estimates.

The autoclave could hold up to 20 bags of waste (approximately 55-60 kg total weight) or 14 sharps containers. It was usually run 5 times a week, 3 times to treat infectious waste and twice for sharps boxes.

Pit disposal is recommended for the disposal of placenta in hospitals of this type, and they do not require autoclaving. Therefore the infectious waste and sharps boxes were autoclaved,

using separate runs for the two types of waste. The autoclave could hold up to 20 bags of waste (approximately 55-60 kg total weight) or 14 sharps containers. This means that the autoclave was usually run 5 times a week, 3 times to treat infectious waste and twice for sharps boxes. The shredder was operated almost every working day, though not for extended periods.

The autoclave was conservatively sized and proved more than adequate for the treatment of the waste produced at Bagamoyo District Hospital with 5 runs a week. The average cycle time was between 2 and 3 hours (the infectious waste requiring a longer cycle time than the sharps boxes), so when necessary, the operators were able to conduct 3 runs in a day. This would imply a maximum of 15 runs over a 5-day working week or 21 over a 7-day working week. In theory, therefore, an autoclave of this specification could treat the waste from a hospital three or four times as large. In practice, it is rarely possible to operate at maximum capacity and it is always best to retain some spare capacity, as there will inevitably be periods when it is needed, for example during a disease outbreak, or if a machine has been out of operation for a while, perhaps as a result of power failure, maintenance or staff absence.

Purchasing an autoclave capable of treating more waste than the hospital produces also allows for future expansion and means that one hospital could treat not only its own waste but that of smaller facilities in the vicinity. This “cluster” model is very cost-effective as it avoids the need for every facility to have full waste treatment infrastructure and is particularly suited to areas where there are a number of healthcare facilities in proximity.

Another strategy which would reduce down-time to purchase two smaller machines, which would allow one to be taken out service temporarily without leaving the hospital completely without waste treatment capability.

Both autoclave and shredder are still operating to the required standard, demonstrating that these two technologies can easily be maintained in African settings.

is

Disinfection verification tests conducted during routine operation of the autoclave showed that the operation cycle set was still working. Level III disinfection was achieved in all cases.

During the implementation of the project minor maintenance problems were experienced with the shredder and autoclave. These included breakage of the autoclave water inlet and outlet pipes. There was also leakage at the welded area of the bottom of the autoclave. The hospital had been using borehole water, rather than the piped supply for the autoclave, and corrosion of the welds at the bottom of the unit caused by salt in the water was the main cause of the corrosion. The problems were rectified by installing new pipes and welding the leaking area, which was done by local welders; thereafter the hospital ceased using salt water for the autoclave. The salinity of the borehole water was a result of Bagamoyo’s location on the coast, and so may not be expected to occur in other locations. However, the quality of water should always be checked.

Also the shredder experienced two minor problems. First, the blades, which were primarily designed to shred plastic materials, were blunted by the stainless steel of the syringe needles. This problem was exacerbated by the fact that, at the time of project launch, the incinerator was not working and there was a backlog of safety boxes that needed to be disinfected and shredded.

This had been anticipated and spare blades had been bought at the time the shredder was procured, so they were installed and the blunt ones were re-sharpened at the University of Dar es Salaam.

The second problem was a motor failure due to unbalanced voltage, which happened on one occasion and resulted in coil shorting. A local motor repair shop rewound the coils, which rectified the problem. All the maintenance costs were covered by the project.

Apart from the minor problems above both autoclave and shredder are still operating as per the required standard, demonstrating that these two technologies required minimal normal maintenance and can be easily maintained in African settings.

ESTIMATED REDUCTION IN DIOXIN/FURAN RELEASES AT BAGAMOYO

Prior to the installation of the autoclave and shredder, Bagamoyo District Hospital was using a De Montfort incinerator with a broken door, a chimney that later became corroded, and bricks and mortar that were cracked. The De Montfort incinerator in effect operated like a small box-type batch incinerator with no afterburner of the type that is not considered Best Available Techniques under the Stockholm Convention guidelines (Guidelines on Best Available Techniques and Provisional Guidance on Best Environmental Practices, Geneva, Switzerland, December 2006).

The replacement of the incinerator with an autoclave-shredder resulted in the elimination of approximately 3.8 g I-TEQ dioxins and furans per year.

The hospital burned mixed healthcare waste including non-infectious waste and PVC waste. In both the UNEP Dioxin Toolkit (Standardized Toolkit for Identification and Quantification of Dioxin and Furan Releases,

UNEP, Geneva, Switzerland, February 2005) and the UNDP GEF Project Dioxin Guidance (Guidance on Estimating Baseline Dioxin Releases for the UNDP GEF Global Healthcare Waste Project, July 2009), the emission factor for this type of incinerator is 40,200 ug I-TEQ per tonne (40,000 ug I-TEQ in air per tonne of waste burned and 200 ug I-TEQ in residue per tonne of waste burned).

Based on assessments conducted in 2007, the total amount of waste burned daily was estimated to be about 260 kg/day or 94,900 kg/year or 95 tonnes per year. The replacement of the incinerator with an autoclave-shredder resulted in the elimination of approximately 3.8 g I-TEQ per year.

LESSONS LEARNED FOR TREATMENT TECHNOLOGY DESIGN

The project has proved that steam-based medical waste treatment can work well in the Tanzanian district hospital. Moreover, a number of technical points have been identified that will be considered in the design of the technology being designed by the University of Dar as Salaam as part of the UNDP/GEF project.

These include:

- The steam exhaust pipe is not ideally designed resulting in very inefficient air removal
- Because it was not designed for air purging, the air removal line must be redesigned to ensure no release of pathogenic aerosols;
- The process cycle takes too long (about 3 hours) thereby reducing the treatment capacity of the autoclave;
- The long cycle times also means higher energy costs;
- The autoclave is not ergonomically designed; requires a lot of heavy lifting and extension to put in waste;
- Some locally purchased flexible tubing and fittings were not strong enough;

- The autoclave drains the condensate too slowly (a problem in the design of the drain pipe and valve);
- Since the hospital used salty water, some parts of the autoclave corroded;
- Soft waste such as gloves cause the shredder to jam;
- The shredder cannot handle cardboard safety boxes due to the hopper design;
- Not all needles are destroyed due to the blade design and screen size.

The UDSM/UNDP/GEF team continue to work on their designs and prototypes should be ready by late 2010/early 2011.

CONCLUSION

The pilot project at Bagamoyo District Hospital has been successfully implemented and shows that the alternative treatment of healthcare waste is the concept that could work in an African setting.

Regular oversight, equipment maintenance and regular refresher training is necessary to ensure the proper operating of any waste management system and should be incorporated into plans for whatever system is envisaged.

Though shredders are not usually present in hospitals, autoclaves are used in all hospitals to sterilize medical equipment, so the general concept is well understood. Where technical capacities to maintain and repair the technology are not available in the hospital, local staff can easily be trained to ensure the sustainability of the treatment technology.

The technological aspect of treatment of healthcare waste should not be regarded in isolation, as it requires good HCWM practices at all levels in order to function properly. This has been the key of successful implementation of the pilot project at Bagamoyo hospital. Regular oversight, equipment maintenance and regular refresher training is necessary to ensure the proper operating of any waste management system and should be incorporated into plans for whatever system is envisaged.

At Bagamoyo, the project has resulted in increasing capacity of local personnel in innovative non-incineration solutions for final disposal of medical waste and can act as the model for replication in other places.

As the success of the project, the Ministry of Health and Social Welfare (MoHSW) has expressed its interest in scaling up non-incineration technology in other district hospitals across the country. The Ministry has been working closely with the pilot project team to develop a plan for the replication.

REFERENCES

Emmanuel, J.E., Kiama, J. & Heekin, K. (2008) Testing a waste treatment autoclave at a hospital in Tanzania: a technical brief. Publ: UNDP GEF Healthcare Waste Project, AGENDA, 2pp. <http://www.noharm.org/details.cfm?ID=2071&type=document>.

Emmanuel, J. & Stringer, R. (2007) FOR PROPER DISPOSAL: A Global Inventory of Alternative Medical Waste Treatment Technologies. Publ: Health Care Without Harm, 52pp. http://www.noharm.org/lib/downloads/waste/For_Proper_Disposal.pdf

Harhay, M.O., Halpern, S.D., Harhay, J.S. & Oliaro, P.L. (2009) Health care waste management: a neglected and growing public health problem worldwide. *Tropical Medicine and International Health* 14(11): 1414-1417

IPEN, TL & Arnika (2005) Contamination of chicken eggs near the Queen Mary's Hospital, Lucknow medical waste incinerator in Uttar Pradesh (India) by dioxins, PCBs and hexachlorobenzene. Prepared by Dioxin, PCBs and Waste Working Group of the International POPs Elimination Network (IPEN) Secretariat, Friends of the Earth (Slovakia) and Arnika Association (Czech Republic), 25pp. http://www.noharm.org/lib/downloads/waste/Contamination_of_Eggs_in_India.pdf

MoHSW (2006) standards and procedures for healthcare waste management in Tanzania. Published, Ministry of Health and Social Welfare, United Republic of Tanzania, 38pp

SBC/WHO (2005) Preparation of national health-care waste management plans in sub-Saharan countries: Guidance manual. Publ: Secretariat of the Basel Convention/World Health Organisation, Geneva, ISBN 92 4 154 662 X, UNEP ISBN 91-2-158657-7, 88pp, http://www.who.int/water_sanitation_health/medicalwaste/en/guidancemanual.pdf

Solberg, K.E. (2009) Trade in medical waste causes deaths in India. *The Lancet*, 373, issue 9669: 1067.

UNEP (2001) The Stockholm Convention on Persistent Organic Pollutants (POPs). <http://chm.pops.int/default.aspx>

WHO (2004) Policy paper: safe healthcare waste management. Publ, WHO, Geneva, 2pp. http://www.who.int/water_sanitation_health/medicalwaste/en/hcwmpolicye.pdf

Appendix 1: Sharps Box Integrity Testing Procedure

SHARPS BOXES EXPERIMENTAL PROCEDURE

Background:

The cardboard sharps box currently in use at Bagamoyo hospital may be an adequate option as a single-use container. (Sharps boxes used for the measles immunization campaign in the Philippines in 2004 were able to withstand high-vacuum steam sterilization.) The goal of this experiment is to determine if cardboard sharps boxes used in Bagamoyo can be sterilized and then transported from the autoclave to a shredder without breakage and accidental release of its contents.

Objective:

To test whether the cardboard sharps boxes used at Bagamoyo hospital retain their physical integrity after autoclave treatment

Equipment:

- Portable steam sterilizer with accessories
- Electric stove or other heat source
- At least two 5-liter sharps cardboard boxes representative of those used at Bagamoyo (if more than one type is used, a sample of each should be tested)
- Surrogate sharps waste (clean syringes and other plastic material amounting to approx. 1 kg)
- Watch or timer
- Heat-resistant gloves, heavy-duty gloves, heavy-duty apron, and safety glasses
- A small amount of vacuum grease or other high-temperature lubricant
- Metal pan or thick plastic sheet (to collect any needles that may fall out during testing)
- Camera (optional)

Summary:

A sharps box containing 1 kg of surrogate sharps waste is placed in the steam sterilizer unit and treated for 45 minutes at that highest working pressure (about 21 psig, corresponding to a saturation temperature of about 127C). The sterilizer is then depressurized and the sharps box is removed, examined and tested. The first test involves using capped syringes. If the sharps box withstands sterilization, a second test is conducted using uncapped syringes (that is, with needles exposed).

Procedure:

A: Preparation

- Fill the sample sharps box with about 1 kg of surrogate sharps waste to simulate a full sharps container.
- Apply a thin film of high-temperature lubricant (such as vacuum seal grease) around the outside edge of the cover where the bevel meets the sterilizer wall to ensure a tight metal-to-metal seal.
- Place the filled sharps box in the aluminum rack and place the rack with the box inside the sterilizer.

- Add enough clean water to fill the bottom of the sterilizer to a depth of between 0.75 to 1 inch.
- Place the sterilizer cover on the unit making sure that the index alignment arrow on the cover aligns with the marking on the side.
- Hand-tighten the wing nuts on the cover of the unit evenly; always tighten two opposite wing nuts at the same time. (NOTE: Do not use a wrench.)

B: Sterilization

- Place the sterilizer on a stove or other heat source, making sure the steam control valve and overpressure plug are facing away from people in the area.
- Apply heat to the sterilizer.
- Once steam is released through the control valve, check the time and allow steam to continue escaping through the valve for at least seven minutes or until steam is released continuously.
- Place the weight on top of the control valve to achieve the highest operating pressure.
- Once the pressure reaches the highest operating pressure as indicated by the pressure gauge, begin timing the sterilization cycle.
- Adjust the heat as necessary to maintain as constant a pressure as possible.
- At the end of the sterilization cycle (45 minutes), remove the weight and allow the steam to escape. (NOTE: Use heat-resistant gloves when touching any hot surfaces.)
- When the pressure gauge indicates zero pressure, loosen the wing nuts by turning two opposite wing nuts counter-clockwise simultaneously. (NOTES: Allow the unit to cool down if time permits. Use heat-resistant gloves to loosen the wing nuts. Never loosen the wing nuts until the pressure gauge registers zero pressure. Do not subject the sterilizer to sudden extreme changes in temperature, such as pouring cold water or wrapping cold towels around a hot sterilizer.)
- Remove the cover by slightly tilting the cover (angling the cover away from the operator and other people in the area) and turning the cover counter-clockwise.

C: Testing the treated sharps box

- Take out the aluminum rack from the sterilizer unit and carefully remove the treated sharps box from the rack.
- Examine the sharps box for any perforations or cracks that could result in potential release of its contents.
- If there are no signs of perforations or cracks, lift the sharps box using its regular handle and shake the box vigorously for about 30 seconds and note if this action results in any serious damage. (NOTE: This is an attempt to simulate the worst-case condition as an operator removes a treated sharps box from an autoclave and transfers it to a nearby shredder.)
- Report the results of the test. Include before and after photos of the box if a camera is available.

D: Repeat the test with uncapped syringes

- If the sharps box shows no signs of damage and retains its physical integrity after the shaking test, repeat the above test using uncapped syringes. If using a combination of syringes and extra plastic material, carefully place the syringes such that the

- needles are at the bottom and against sides of the box. (NOTE: Use heavy-duty gloves, heavy-duty apron and safety glasses to avoid needle-stick injuries.)
- After the sterilization cycle, carefully examine the sharps box for punctures and protruding needles. (NOTE: Place a metal pan, tarpaulin or puncture-resistant plastic sheet under the box during examination or shaking to contain any needles that may fall out.)
 - If there are no signs of perforations or punctures, carefully shake the box for about 15 seconds and note if this action results in punctures or perforations. (NOTE: Use heavy-duty gloves, heavy-duty apron and safety glasses to avoid needle-stick injuries.)
 - Report the results of the test. Include before and after photos of the box if a camera is available.

Appendix 2: Test protocol for autoclaves

REVISED TEST PROTOCOL FOR THE AUTOCLAVE

Objective:

To conduct preliminary tests to ensure that the autoclave will be able to adequately disinfect medical waste within a reasonable time when operated as a gravity-displacement autoclave with or without steam flushing.

Materials:

- 3M Attest biological indicators (10e5) for 270°F/132°C Gravity Steam Sterilizers [RRBI]
- 3M Attest auto-reader Rapid Readout incubator for 1 hour incubation Raven Labs ProSpore ampoules (10e4 and 10e5) for 48 hour incubation [PS1-4 and PS1-5 respectively]
- Dry block 55°C incubator
- Teflon tube (permanently closed at one end; removable plug at the other end; with holes drilled along the sides near the bottom and at various locations along the tube to allow steam penetration); length of tube depends on size of bags (tube should be long enough such that when the bags are sealed, about 10 cm of the tube extends outside the bag [The tube will help protect the biological indicators, position them in place and make it easier to retrieve them for incubation.]
- Integrator and autoclave tapes
- Accurate weighing scale that can measure fractions of a kilogram up to 4 kilograms
- Simulated/surrogate medical waste (uncontaminated materials) – see below
- An accurate weighing scale that can measure fractions of a kilogram up to 4 kilograms
- 40-liter plastic bags (or bags closest to 40 liters in capacity).
- Simulated waste (newspaper, clothing, towels, cotton balls, pieces of cardboard, soft PVC plastic pieces, plastic wrap, HDPE or PP plastic bottles, latex or nitrile gloves, and small glass bottles or glass tubes) to be able to conduct the experiments
- Enough plastic bags, sharps and safety boxes to be able to conduct the experiments

NOTE: This test protocol assumes that 40-liter plastic bags will be used.

1. Preparations:

1.1 – Insert an RRBI or ampoule at the bottom of the Teflon tube and close the bottom. Attach an integrator at the side of the Teflon tube using autoclave tape. Be sure not to cover any holes along the tube.

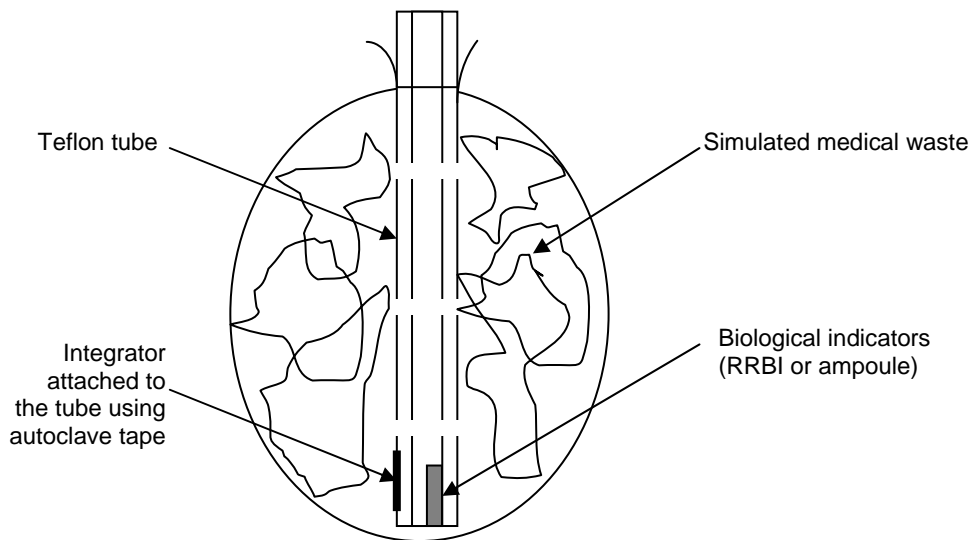
1.2 – Insert the tube into a bag with simulated waste as described as described in the first table (the amounts needed are shown in the second table):

| TYPE OF WASTE | SIMULATED WASTE MATERIALS |
|------------------|--------------------------------------------------------------------------------------------|
| Cellulosic waste | Newspaper, clothing, towels, cotton balls, pieces of cardboard |
| Plastic waste | Soft PVC plastic pieces, plastic wrap, HDPE or PP plastic bottles, latex or nitrile gloves |
| Glass | Small glass bottles or glass tubes |
| Liquid | Water (let the water absorb on the cellulosic waste) |

Approximate weights of samples for different container volumes:

| | 40 liter bag | 50 liter bag |
|------------------|--------------|--------------|
| Cellulosic waste | 3 kg | 3.7 kg |
| Plastic waste | 2.4 kg | 3.0 kg |
| Glass | 0.3 kg | 0.4 kg |
| Water | 0.3 kg | 0.4 kg |
| Total weight | 6.0 kg | 7.5 kg |

NOTE: When filling up the plastic bags with simulated waste, keep the waste well mixed inside each bag. Seal the bags by tying the ends around the tube or using any “twist ties” provided with the bags.



2. Test procedure:

2.1 – Place the plastic bags inside the screen basket in the autoclave such that the test bag is at the bottom. Fill the autoclave with other bags of surrogate waste. Turn on the incubator to allow for a 30-minute warm-up. Prepare a 10e5 ampoule (PS1-5) as a control test and include with the first RRBI.

2.2 – TEST A1 (Use RRBI, 134C for 30 minutes) - Start of the cycle: Make note of the time. Use PPE (gloves, safety glasses and/or face shield). Operate the autoclave as follows:

- Add water (about 6-8 liters) until the water gauge shows the right minimum water level.
- Depresses the foot paddle, swing the lid to its normal position to sit within the groove, then tighten the radial lock. Check the lock lever to ensure that the autoclave is properly sealed.
- Turns on the switch. The green light should turn on.
- Leave open the control valve. Once the temperature reaches 100C, wait for 10 minutes, after which close the valve for the first time.
- Allow the pressure to build up and watch the temperature panel. Once the temperature reaches 134C (about 29 psig), make note of the time.
- Allow steam exposure for 30 minutes.
- Switch off the heater and open the valve to release the pressure.
- After the steam is released, open the valve at the bottom to drain out the condensate.

- i) Rotate the locking wheel, step on the foot paddle to lift the lid, and swing the lid to the side. [Take precautions to prevent burns.]
- j) Remove the wire basket and take out the treated waste.
- k) Record the total length of time from when the cycle started until when the autoclave was opened.
- l) Pull out the Teflon tube, retrieve the RRBI and mark it as A1. Record the results of the integrator and autoclave tape.
- m) Wait for 10 minutes to cool the RRBI.
- n) Press the RRBI cap down. Holding the RRBI vial by the cap, open the auto-reader cover lid and use the Crusher Well to crush the glass ampoule inside the RRBI. Holding the RRBI vial by the cap, tap the bottom of the vial on a counter top until the purple media wets the spore strip at the bottom of the vial.
- o) Repeat the same procedure with a control BI.
- p) Place the RRBI and control BI into the incubation well corresponding to the type of biological indicator. Watch for the yellow light to appear. Do not remove the RRBI during incubation.
- q) Wait until either a Red (+) or Green (-) light appears and record the results.
- r) Discard the RRBI. Continue to incubate the control BI for visual pH color change. Record results and discard the control BI.
- s) Also incubate the 10e5 ampoule as a comparative test (48 hour incubation).

2.3 – If the RRBI shows a positive (Red, +) reading, repeat 2.2 but extend the steam exposure time to 45 minutes and 1 hour and mark the RRBI as appropriate. Once the RRBI shows a negative (Green, -) reading, repeat the experiment at the new exposure time but insert Teflon tubes in all the waste bags and record the results. If any of the RRBI's show a positive result, increase exposure times up to 1 hour.

2.4 – TEST B1 [Use RRBI and PS1-4 ampoules]. If one or more RRBI's show a positive (Red, +) reading after 1 hour, conduct a series of tests involving steam flushing as follows. Start of the cycle: Make note of the time. Operate the autoclave as follows:

- a) Add water (about 6-8 liters) until the water gauge shows the right minimum water level.
- b) Depresses the foot paddle, swing the lid to its normal position to sit within the groove, then tighten the radial lock. Check the lock lever to ensure that the autoclave is properly sealed.
- c) Turns on the switch. The green light should turn on.
- d) Leave open the control valve. Once the temperature reaches 100C, wait for 10 minutes, after which close the valve for the first time.
- e) Allow the pressure to build up and watch the temperature panel. Once the temperature reaches 134C (about 29 psig), open the valve and allow steam to be released until the temperature drops down to 100C (about 3 minutes). Then close the valve for the second time.
- f) Allow the pressure to build up again while monitoring the temperature. Once the temperature reaches 121C, open the valve again and allow steam to be released until the temperature drops down to 100C (about 3 minutes). Then close the valve for the third time.
- g) Allows the pressure to build up again while monitoring the temperature. Once the temperature reaches 134C (29 psig), wait for 10 minutes and then switch off the heater and open the valve to release the pressure.

- h) After the steam is released, open the valve at the bottom to drain out the condensate.
- i) Rotate the locking wheel, step on the foot paddle to lift the lid, and swing the lid to the side.
- j) Remove the wire basket and take out the treated waste.
- k) Record the total length of time from when the cycle started until when the autoclave was opened.
- l) Pull out the Teflon tube, retrieve the RRBI and mark it as B1. Record the results of the integrator and autoclave tape.
- m) Wait for 10 minutes to cool the RRBI.
- n) Press the RRBI cap down. Holding the RRBI vial by the cap, open the auto-reader cover lid and use the Crusher Well to crush the glass ampoule inside the RRBI. Holding the RRBI vial by the cap, tap the bottom of the vial on a counter top until the purple media wets the spore strip at the bottom of the vial.
- o) Place the RRBI into the incubation well corresponding to the type of biological indicator. Watch for the yellow light to appear. Do not remove the RRBI during incubation.
- p) Wait until either a Red (+) or Green (-) light appears and record the results. Discard the RRBI.

2.4 – If the RRBI shows a positive (Red, +) reading, repeat 2.3 but extend the final steam exposure time to 20 or 30 minutes and mark the RRBI as appropriate. Once the RRBI shows a negative (Green, -) reading, repeat the experiment at the new final steam exposure time but insert Teflon tubes in all the waste bags and record the results. If any of the RBIs show a positive result, increase exposure times up to 30 minutes.

2.5 – If any RRBI shows a positive reading after 30 minutes of final steam exposure, repeat 2.3 using 10e4 ampoules (PS1-4) and increase final exposure times as needed until all ampoules show no positive readings. Note that ampoules require 48 hour incubation periods so conduct experiments at different final exposure times to save time.

2.6 – Once all RBIs show negative readings, with or without steam flushing, repeat the experiment using 10e4 ampoules (PS1-4) at the conditions that resulted in all negative readings. After the 48 hour incubation, record results for comparison.

Appendix 3: Autoclave validation technical note

TESTING A WASTE TREATMENT AUTOCLAVE AT A HOSPITAL IN TANZANIA: A TECHNICAL BRIEF

INTRODUCTION AND OBJECTIVES

The United Nations Development Programme's Global Environment Facility (GEF) project on healthcare waste and the NGO Health Care Without Harm, in collaboration with AGENDA and John Snow, Inc., are conducting a pilot project to demonstrate proper healthcare waste management and the use of an autoclave and shredder imported from India to disinfect healthcare waste in the context of sub-Saharan Africa. This technical brief summarizes the results of microbial inactivation testing of the healthcare waste treatment autoclave at the 98-bed Bagamoyo District Hospital in Tanzania.

The objectives of the testing were to determine proper operating conditions for the autoclave that correspond at least to Level III disinfection and to test the use of a shredder for sharps waste.

MATERIALS

- Obromax autoclave (Acmas): vertical cylindrical vessel with internal dimensions of 550 mm diameter and 750 mm height; working pressure set to 17 psig; a thermocouple was added at 66 cm below the top of the internal vessel to measure steam temperatures
- Removable, perforated, stainless steel container that fits inside the autoclave to serve as a basket to hold waste bags and safety boxes
- 3M Attest 1292 self-contained biological indicators for steam at 250°F/121°C corresponding to 10⁵ concentration of *Geobacillus stearothermophilus* (donated to Bagamoyo District Hospital by 3M)
- Attest Auto-reader, 12-well, 3-Hour Rapid Readout Incubator (donated to Bagamoyo District Hospital by 3M)
- Autoclave Tape and SteamPlus Sterilization Integrators (SPS Medical)
- 1 ml *Geobacillus stearothermophilus* ampoules with 10⁴ and 10⁵ concentrations (PolySpore PS1-4-100 and PS1-5-15, Raven Labs) and a 15-well dry block 56°C incubator
- PTFE tubes for affixing the biological indicators and integrators, with wooden plugs to seal the tops of the tubes
- 20-liter infectious waste bags containing surrogate waste (crumpled newspapers) or actual hospital waste
- 5-liter safety boxes for sharps (Kojak Safety Box, Hindustan Syringes & Medical Devices) and unused 10 ml syringes (VanishPoint Syringes, Retractable Technologies, Inc.)
- Shredder (Pimco Manufacturing Corp., India) with a 3 HP motor (1420 rpm)

PROCEDURE

Fourteen experimental runs were conducted using different combinations of steam flushes, pressure pulses, and exposure times, using both surrogate and actual hospital waste. Initially, the test bags were filled with crumpled newspapers and about 150 ml of water. An Attest biological indicator and integrator were affixed to the bottom end of a PTFE tube using autoclave tape. The tube was then inserted into the middle of the test bag with the top of the tube protruding above the bag; the bag was then tied. The test bags were placed at the bottom of the autoclave basket, which was then filled to capacity with six bags of surrogate waste.

Once the biological indicators showed sterility, the test waste bag was replaced with real hospital waste. PTFE tubes with biological indicators and integrators were additionally inserted into safety boxes filled with syringes and into extra surrogate waste bags. For a few runs, 1 ml ampoules of *Geobacillus stearothermophilus* at 10⁴ and 10⁵ concentrations were also attached by autoclave tape to the tube. Table 1 below shows the experimental conditions for two successful runs using real hospital waste as the main test bag, one test sharps safety box, and one test surrogate waste bag. The safety boxes and surrogate waste bags were placed at different locations in the autoclave for testing. The table also shows a test run wherein 14 safety boxes (the autoclave's capacity) were treated and then shredded in a Pimco shredder.

RESULTS

The results of the autoclave tape, integrators and biological indicators are summarized in Table 1 below. Figures A, B and C are plots showing the temperature and pressure variations with time corresponding to runs A, B and C in Table 1. Figures D and E show photographs of sharps after steam treatment and then after shredding.

TABLE 1

| Run | Test Waste and Location in the Autoclave Basket | Operating Parameters | Steam Tape | Integrator | Biological Indicator |
|-----|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------|------------|--------------------------------------------------------------------------------------------------------|
| A | Hospital waste bag, bottom Sharps safety box, top Surrogate waste bag, top | Four pressure pulses at 5, 4, 3 and 2 minutes respectively, plus 30-minute exposure at 124°C | Passed | All passed | Attest – all passed Ampoules – all passed (both 10 ⁴ and 10 ⁵ concentrations) |
| B | Hospital waste bag, bottom Sharps safety box, middle Surrogate waste bag, top | Two pressure pulses for 15 minutes each, plus 20-minute exposure at 124°C | Passed | All passed | Attest – all passed |
| C | 14 sharps safety boxes (test safety box at the bottom) | One pressure pulse for 15 minutes, plus 20-minute exposure at 124°C | Passed | Passed | |

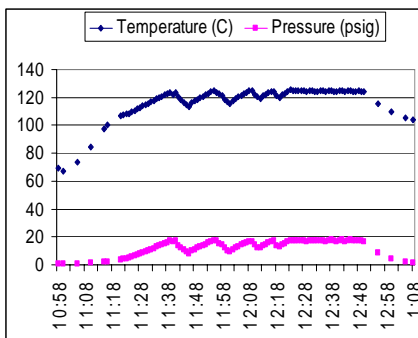


Figure A. Run A

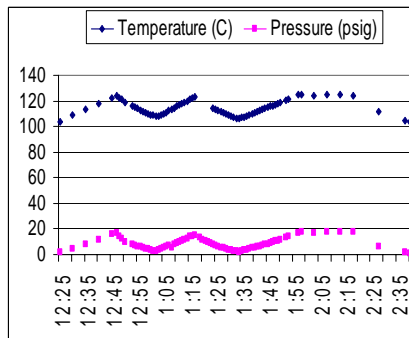


Figure B. Run B

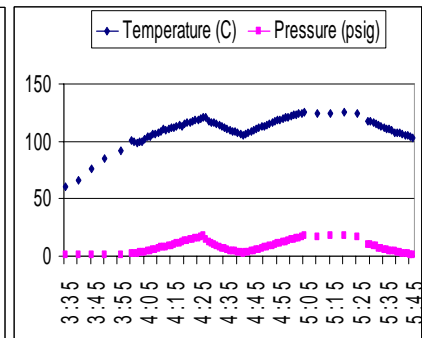


Figure C. Run C



Fig. D. Contents of a safety box after autoclaving



Fig. E. Close-up of shredded waste

DISCUSSION AND CONCLUSIONS

The tests show that at least Level III disinfection or higher can be achieved in the gravity-fed autoclave as long as at least two deep pulses are used followed by a 20-minute exposure at 124°C or four shallow pulses followed by a 30-minute exposure at 124°C. Since conditions are site specific, steam integrators and biological indicators should be used to validate disinfection levels. The autoclave tape only shows that the desired temperature was reached but provides no additional information. Integrators and biological indicators are more useful tools and were found to correlate well with each other. Residual air in the autoclave chamber and in the bags is a major factor in the failure to achieve proper disinfection. The reduction in air concentration is dependent on the ratio of absolute pressure in the chamber before evacuation divided by the absolute pressure of the chamber at the end of the evacuation. Thus, deeper pressure pulses are more effective than shallow pulses. The study shows that a relatively inexpensive gravity-fed autoclave and a shredder can be used effectively for treating healthcare waste including sharps in a small hospital in a developing country. For more information, see www.gefmedwaste.org.

Jorge Emmanuel, PhD¹; Jamal Kiama²; Kelly Heekin¹
¹UNDP GEF Healthcare Waste Project; ²AGENDA
 13 October 2008