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RESEARCH ARTICLE

Challenges with Molecular Waste Management in sub-Saharan Africa – HIV Viral Load and COVID

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ABSTRACT

Introduction: Waste generated from HIV viral load testing and SARS CoV-2 for diagnosis of COVID-19 contains potentially hazardous guanidinium thiocyanate. Guanidinium thiocyanate may be toxic to humans and if not properly disposed of can pollute waters and harm aquatic life. Sub-Saharan African countries are particularly challenged by limited resources to suitably manage waste generated at health care facilities and laboratories. There is a need to identify waste management challenges and develop strategies to mitigate this type of laboratory testing waste in resource limited countries.

Methods: HIV viral load data used for this analysis were standardized monitoring evaluation and reporting Presidents Emergency Plan for AIDS Relief datasets for Malawi, Mozambique, South Africa, and Zimbabwe. COVID-19 data was obtained from the Johns Hopkins Coronavirus Resource Center.

Discussion: Inadequate management of HIV viral load and COVID-19 guanidinium thiocyanate waste due to lack of policy, guidelines and appropriate procedures for containment, poses a significant public health threat to the environment. Recognizing this gap, the United States Centers for Disease Control and Prevention has decided to provide technical expertise, raise awareness, and work with other international partners to disseminate knowledge and find solutions for the Presidents Emergency Plan for AIDS Relief supported countries in sub-Saharan Africa. The World Health Organization guidelines on safe management of waste from healthcare activities were proposed as a starting point to develop country specific guidelines.

Conclusions: The United States Centers for Disease Control and Prevention, in collaboration with other international partners, is diligently working to provide technical assistance to countries for training and development of mitigation strategies to appropriately manage guanidinium thiocyanate containing waste. Waste management is a growing problem as molecular testing for HIV, COVID-19, and other emerging diseases increase.

Introduction

Waste generation is on the rise globally due to rapid population growth, urbanization and industrialization. It is estimated that by the year 2050 global solid waste generation will reach 3.4 billion tons, a 70% increase from the 2016 level[1]. About 75-90% of health-care waste is non-hazardous with the remaining 10-25% regarded as hazardous and may create a variety of health risks[2]. Chemical waste consists of discarded solid, liquid, and gaseous chemicals. Resource limited countries may be impacted more severely in comparison to developed nations by unsustainably managed waste which may result in serious health, safety, and environmental consequences. One category of waste of concern is health-care-associated waste which includes all the waste generated by health-care facilities, research institutions and laboratories. In sub-Saharan Africa there has been an unprecedented scale-up in HIV viral load (VL) and early infant diagnosis (EID) testing services over the last 9 years, largely due to the ability to perform molecular testing at a reasonable cost and a shift in monitoring the success of treatment for HIV patients on anti-retroviral therapy (ART) using VL rather than CD4 counts[3]. There were approximately 39 million people diagnosed worldwide with HIV/AIDS in 2022 with 29.8 million accessing antiretroviral therapy (ART)[4]. Sub-Saharan Africa bears the largest burden of HIV disease with approximately 65% of the global epidemic[5]. In 2020, it was estimated that more than 30 million HIV viral load tests were performed globally generating approximately 924,000 liters of effluent chemical waste and 2.1 million kg annually[6].

During a meeting in Addis Ababa, Ethiopia (2017), organized by the United States Centers for Disease Control and Prevention (CDC) in support of the Presidents Emergency Plan for AIDS Relief (PEPFAR) laboratory activities, 23 sub-Saharan countries were brought together to share progress and challenges with scaling up HIV VL testing services. Multiple countries reported a challenge with accumulation of waste generated from HIV VL testing supported by international donors. Laboratories located in resource-limited settings with poor infrastructure and limited waste management practices must comply with biosafety requirements in an environment of increasing demand for laboratory testing often without additional financial resources allocated to manage the waste. To further compound the growing issue of laboratory waste, the response to the COVID-19 pandemic has utilized molecular diagnostics for testing. Manufacturers of molecular platforms used for HIV VL and Early Infant Diagnosis (EID) testing quickly developed assays for SARS CoV-2 to address the COVID-19 pandemic. Point of care (POC) PCR testing for SARS CoV-2 allowed testing to be expanded to small clinical and laboratory facilities or remote sites with less infrastructure than major medical facilities. These sites may have less waste management (WM) capability than large facilities in an urban environment. Of major concern is the fact that the molecular testing performed for HIV (both VL and EID) and SARS-CoV-2 produces mixed chemical waste which contains guanidinium thiocyanate (GTC). Guanidinium thiocyanate is considered to be corrosive and a health hazard, capable of causing skin burns and should not come into contact with the environment, due to its potential effects on humans and aquatic life[7]. Guanidinium thiocyanate should not come into contact with oxidizing agents

like bleach, which is widely used in the laboratory setting for disinfection purposes, because this can lead to the release of toxic cyanide gas. Guanidinium thiocyanate is not just a component of HIV and SARS-CoV-2 molecular diagnostic and testing assays, as it is found in many other molecular assays used in the extraction of DNA and RNA for multiple pathogens such as hepatitis B virus, hepatitis C virus and human papilloma virus among others. Laboratories performing HIV VL/EID and SARS-CoV-2 testing should require guidance on proper considerations for the disposal of solid and liquid mixed waste generated from these testing platforms. The manufacturers of the platforms recommend that liquid waste should be disposed of according to country-specific regulations, guidelines, or policies, which in most cases are lacking or do not contain specific instructions for disposal of molecular waste containing GTC.

There is an urgency, particularly for resource limited countries in sub-Saharan Africa, to identify effective waste management options as testing for HIV VL/EID and COVID-19 continues to meet country needs. The CDC has been working with Global Fund and Ministries of Health in PEPFAR-supported countries in sub-Saharan Africa to identify critical gaps in waste management that can be targeted for intervention. Lessons learned in the management of HIV VL/EID and COVID-19 waste can then be extended to improving WM in the entire biomedical sector.

Methods

Gaps in waste management knowledge, disposition, and national policy have been identified in countries by a number of methods, including self-identification assessment, national surveys, and in-person meetings[8]. HIV viral load data used for this analysis were standardized monitoring evaluation and reporting PEFAR datasets for Malawi, Mozambique, South Africa, and Zimbabwe. Routine data are reported in aggregate at the facility level in countries and reviewed by the State Department Office of the Global AIDS Coordinator and are available online[9]. The reporting range was from July 1, 2023 to September 30, 2023 and represent the number of PEPFAR supported ART patients with a VL result documented in the medical or laboratory information system within the past 12 months. COVID-19 data was obtained from the Johns Hopkins Coronavirus Resource Center website as of March 2023.

Discussion

There are gaps in the laboratory WM sector for many countries in sub-Saharan Africa lacking waste management policy guidelines and the ability to adequately dispose of GTC containing waste. International donors have a responsibility apart from providing funding for testing a variety of pathogens including HIV, Hepatitis and COVID-19 to provide potential solutions to address the growing problem of managing waste products from molecular diagnostics. Due to lack of guidance, policies and standing operating procedures, many laboratories in sub-Saharan Africa countries pour the liquid waste down the drain as reported by attendees during the meeting in Addis Ababa and observed directly by the authors of this manuscript. Some countries have adopted overarching policy and strategies for chemical waste, however, specific waste management procedures for molecular testing laboratories are often lacking[8,10].

To address the gaps in the management of laboratory waste, a group of international donors and partners including PEPFAR, the Global Fund to fight HIV, TB and Malaria, World Health Organization (WHO), the African Society for Laboratory Medicine, Clinton HIV/AIDS Initiative, and manufacturers of molecular diagnostics used in sub-Saharan Africa have embarked on a collaboration (The Integrated Diagnostics Consortium) to develop waste mitigation strategies, and promote sharing of best practices with the goal to prevent toxic waste from entering the environment. Global Fund and PEPFAR are providing synergistic technical assistance for policy development and procedures to appropriately manage GTC containing waste, in addition to financial resources. The CDC is also working with manufacturers and the private sector to develop innovative and sustainable solutions for the challenges low- and middle-income countries face within the healthcare sector with waste management.

Although formal international guidance on the management of molecular waste containing GTC has not been developed, the WHO Blue Book (WHO Publication: Safe Management of Wastes from Health-Care Activities, 2nd Ed, 2014) is a good resource for countries that are planning to develop national regulations and policies[2]. The WHO Blue Book covers a variety of topics helpful with WM including legislative, and policy issues, training and guidance on safe WM practices as well as healthcare WM planning at national and facility levels. Information on cost estimation and WM equipment considerations are useful for countries developing WM mitigation strategies.

Effective treatments are included in the WHO Blue Book for management of infectious waste, inclusive of thermal, chemical, irradiation, biological and mechanical methods. The most commonly used effective methods for managing GTC containing hazardous waste are high-temperature incineration, and encapsulation. The high temperature incineration method requires specially designed incinerators capable of temperatures $\geq$1000^{o} C. Many sub-Saharan African countries have incinerators which do not have the capability of reaching the high temperature required to inactivate GTC. High temperature incinerators are expensive, must be monitored and properly maintained for emissions and equipped for chemical disposal. Centralized placement of disposal facilities and high-temperature incinerators could offset expenses in resource-constrained countries. The other method, using encapsulation, followed by landfill deposition, requires land with correctly erected barriers and probes to monitor for leakage. Encapsulation is a waste disposal method that sequesters hazardous materials in containers composed of impervious and non-reactive materials. The containers are secured with concrete, plastic, or steel for storage and burial. Due to the requirements including infrastructure and lack of availability, only a few countries in sub-Saharan Africa are using this method for chemical waste containment.

The acquisition of molecular diagnostic equipment for HIV VL and EID provided a platform that can be utilized for emerging pathogens. At the start of the COVID-19 epidemic, manufacturers of the majority of VL/EID platforms used in sub-Saharan Africa including Abbott, Roche, and Cepheid quickly developed assays for COVID-19. Sub-Saharan countries now have the added responsibility of scaling up testing for COVID-19 utilizing the

same platforms for HIV and Hepatitis molecular testing. GTC is identified as a major component of molecular waste from HIV (VL/EID) and SARS-CoV-2 waste. Manufacturers of molecular diagnostics recommend that waste be managed as per country regulations. However, many resource-limited countries including sub-Saharan Africa countries do not have such regulations in place. While manufacturers are committed to meeting environmental standards, direct engagement with countries on proper waste management is lacking.

The volume of GTC containing waste has increased considerably as the scale-up for HIV VL has progressed. A few country examples include: Malawi which has scaled up VL testing from 166,652 tests in 2019 to 800,588 in 2023, VL tests conducted in Mozambique has increased from 843 tests in 2015 to 1,318,544 tests in 2023, Zimbabwe has experienced over 10-fold increase in VL testing volumes over the last 5 years with approximately 3,991 tests in 2015 compared to 903,652 tests in 2023, and South Africa performed VL tests for 3,506,237 million persons in 2023[9].

Molecular laboratories in some countries are continuing SARS-CoV-2 testing for COVID-19. The number of cases for these countries as of March 10, 2023 are: Malawi 88,707, Mozambique 233,214, Zimbabwe 264,276 and South Africa which has confirmed 4,067,067 COVID-19 cases[11]. The numbers of tests for SARS-CoV-2 will continue to increase as testing for COVID-19 continues. Currently, the total reported cumulative cases globally, exceeds 700 million[12].

There is an essential need for a holistic plan to address management of health care associated waste generated from molecular diagnostics of current pathogens such as HIV and SARS CoV-2 and future emerging infectious diseases.

Conclusions

The problem of waste generation and uncoordinated waste management will continue to be a concern for our foreseeable future. The particular concerns of hazardous molecular waste, which has become a major part of the overall volume of healthcare-related waste, is also likely to increase due to greater reliance on molecular-based diagnostics. Continuing scale-up and high annual testing volumes, and more frequent outbreaks of other infectious diseases like COVID-19 will contribute to the growing WM problem. The environmental and public health impact from all types of healthcare-related waste being produced in situations without proper infrastructure and technical knowledge of WM will likely affect millions more globally.

The COVID-19 pandemic increased biomedical waste globally and has been recognized as a challenge requiring systemized effort and innovations that would be helpful for future pandemic preparedness[13-17]. The aspect of hazardous test components, such as GTC, is but one of the issues that will need to be addressed. Knowledgeable and experienced technical assistance and coordinated resources (both monetary and personnel) will continue to be needed. To be effective, a comprehensive, and collaborative approach is necessary to bring together country governments, international donors, manufacturers, and environmental stakeholders in the public and private sector to devise feasible, sustainable solutions to protect the environment and reduce this burgeoning public health threat.

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