Investigation of sterilization processes in healthcare institutions in Ulaanbaatar, Mongolia

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Abstract

The high prevalence of hepatitis B and C in the Mongolian population is imputed not least to inadequate reprocessing of the medical devices used.

For the purpose of the current study conducted in 77 healthcare institutions in Mongolia, 105 autoclaves, three ethylene oxide (EO) sterilizers, one formaldehyde (FO) and one plasma (H_2O_2) sterilizer were investigated with biological indicators. 8% of the autoclaves and two of the three EO sterilizers showed unsatisfactory performance. The H_2O_2 and FO sterilizers tested inactivated the biological indicators.

Of the autoclaves, the older Russian models produced better results than the modern sterilizers from China and Korea. That may be due to the long experience with the old Russian appliances, which have no pre-vacuum, unlike with the more complex modern sterilizers.

Thermologgers were used for the first time (in Mongolia) for measurement of physical parameters such as pressure, holding time and temperature.

The findings indicate that inadequate reprocessing of medical devices may impact the high colonization rates with hepatitis viruses in Mongolia.

Key Words
- Mongolia
- CSSD
- Sterilisers

Introduction

Mongolia is the second largest landlocked country on earth and is situated between Russia and China. Half of the three million inhabitants live in the capital city Ulaanbaatar. In total, in Ulaanbaatar there are 42 public hospitals, 280 dental practices and more than 1,500 private clinics. The clinics and hospitals have between 10 and 720 beds.

Mongolia still experiences diseases that are now rare, or no longer occur, in Europe, e.g. plague, anthrax and brucellosis. Tuberculosis, which continues to spread, is a major problem. However, the real challenge is the high prevalence of hepatitis B and C viruses estimated to be 15–25% [1, 2, and 3]. A screening project carried out in 2017 among 230,000 of Ulaanbaatar inhabitants revealed that 17.5% of the screened population were carriers of hepatitis B and/or C viruses [4]. Accordingly, primary liver cancer is the leading cause of death among cancer diseases [5]. It is thought that 77% of Mongolians will at some time in their life have suffered from hepatitis B infection [6]. The problem is compounded by the high alcohol consumption, in particular of vodka [7, 2, 8].

Since 2010 the MeshHp Project (Mongolian Emergency Service Hospital Hygiene Project – www.meshhp.mn) has been implemented in Mongolia to improve hygiene (infection control) practices in pilot hospitals and emergency services of the city of Ulaanbaatar. To date, certain improvements have been made, e.g. in hand hygiene or immunization of healthcare workers against hepatitis B (rise from 10% to 60 – 80% at present). However, it is essentially more difficult to effect changes in settings that require more financial investment, e.g. in Central Sterile Supply Departments (CSSDs) or in microbiology laboratories [9, 10, 11, 12]. Within the project framework, through an analysis of the literature as well as many inspections of premises and discussions – also in all provinces of Mongolia – various risks were identified which are thought to explain the high prevalence of hepatitis viruses:

- Blood products were not properly tested in the past; this is still the case in rural areas.

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- Traditional medicine (e.g. bloodletting), acupuncture, tattooing.
- Injections were administered in the past with a glass syringe, which had been (just) boiled in water, and used for several persons.
- Pregnancy and birth, possibly with use of unsterile instruments.
- While since 1991 children have been vaccinated against hepatitis B, it is thought that early on this was often done with expired or no longer effective vaccines (e.g. vaccines becoming frozen during transportation in rural areas in winter).
- Sexual transmission may also play a role since especially at present the sexually transmitted disease rate is increasing [11, 10].

There is no doubt that inadequate reprocessing of medical instruments also plays a pivotal role [3]; poor reprocessing practices are imputed, in particular, to rural dentists. But even in the large public hospitals in Ulaanbaatar manual reprocessing is the current standard, the majority of autoclaves are decades old, instrument containers have holes that have to be plugged after sterilization [9].

This was the reason for investigating the quality of sterilization. To that effect, for the purpose of the study presented here the sterilization processes used to reprocess medical instruments in a number of hospitals and other healthcare institutions in Ulaanbaatar were investigated. Ulaanbaatar hospitals usually use autoclaves. Very few additionally have plasma (H_2O_2), formaldehyde (FO) or ethylene oxide (EO) sterilizers for reprocessing heat-sensitive instruments.

Based on the Mongolian Infection Protection Act, sterilizers must be routinely tested with both chemical and biological indicators. In reality most autoclaves are tested only with chemical indicators in the form of treatment indicators, and this is generally done on a daily basis.

Routine technical inspection of the sterilizers is not performed. However, the hospitals are obliged to have the autoclave pressure gauges tested once annually by the standardization authorities.

The aim of this study was to test with biological indicators sterilizers in Ulaanbaatar which are used predominantly for reprocessing medical instruments. In addition, temperature and pressure measurements were also carried out with thermologgers in a few sterilizers, as a prelude to any further studies.

Materials and Methods

1. Testing the sterilization processes with biological indicators

To test the microbicidal action of steam, EO and H_2O_2 sterilizers in hospitals, the following biological indicators were used:

- BAG-BioCheck Steam *Geobacillus stearothermophilus*,
- BAG-BioCheck EO *Bacillus atrophaeus*,
- BAG-BioCheck H_2O_2 *Geobacillus stearothermophilus*,
- gke Steri-Record FO *Geobacillus stearothermophilus*.

To that end, the biological indicator ampullas were sterilized with the instruments during the daily reprocessing cycles, while placing two to five ampullas at the most unfavourable sites within the autoclaves. Afterwards, the biological indicators were incubated for 24 – 48 hours at 55 – 60 °C or at 37 °C under the conditions recommended by the manufacturer. An unsterilized ampulla was incubated as a positive control. Next, the biological indicator ampullas were evaluated on the basis of a colour change.

2. Testing the physical parameters during sterilization

An EBI-100 temperature/pressure logger from the firm Ebro Electronic GmbH was used to check the pressure, temperature and time course of the sterilization process. To that effect, the data logger was programmed and placed in the autoclaves with the instruments to be sterilized during routine daily cycles. On cycle termination the thermologger data were read out on a laptop using the software program Winlog.med V3.2.

Results

Seventy-seven medical establishments participated in the study: 44 dental clinics, 26 public and private hospitals, three instrument reprocessing centres, three birthing centres and one disposal plant for hospital waste. All institutions used between one and three autoclaves to reprocess medical instruments. Apart from the total of 105 autoclaves, three hospitals each used one EO sterilizer, one hospital an FO sterilizer, and one hospital an H_2O_2 sterilizer for heat-sensitive instruments. In total, 187 steam and 15 EO sterilization cycles as well as one FO and one H_2O_2 sterilization cycle were subjected to biological testing.

The autoclaves investigated were commissioned between 1980 and 2016 (Table 1) and originated from China (44%), Russia (24%) as well as South Korea, Germany, Japan, Taiwan and USA (Table 2).

In the study a total of 105 autoclaves were tested during daily routine sterilization cycles with biological indicators (Table 3), and in some cases retested at the request of the users. In the first test run four autoclaves (4%) were unable to inactivate the test spores. These hospitals were recommended to take these autoclaves out of service and repair them. Following repair, the autoclaves were retested with biological indicators. Only after a successful test result were the autoclaves placed in service again. Subsequent tests performed at the request of certain institutions demonstrated unsatisfactory biological indicator results for four other autoclaves that had produced satisfactory results in the first test run (Table 3).

As such, a total of eight of the 105 the autoclaves tested (8%) demonstrated an unsatisfactory sterilization performance based on the biological indicator results.

In terms of the year and country of manufacture, the majority of autoclaves with unsatisfactory results tended to be of more recent manufacture and originated from China and Korea, whereas only once did the often older Russian autoclaves produce unsatisfactory results (Table 4).

For two of three hospitals with an EO sterilizer the initial test results were unsatisfactory (Table 5). The two implicated EO sterilizers were subjected to further checks and repeatedly repaired. Finally, one EO sterilizer continued to show an unsatisfactory sterilization performance.

In the study only one FO and one H_2O_2 sterilizer were tested with biological indicators and both were satisfactory.

The majority of autoclaves investigated have no display or printer for

verifying and documenting the process sequences. Therefore, temperature/pressure loggers were used for the first time ever in Mongolia to measure the pressure and temperature course. In the pilot study five autoclaves with thermologgers were tested in parallel to the biological indicators. The results are presented in Table 6.

Discussion

Within the framework of this current study the sterilization processes of a number of hospitals in Ulaanbaatar were tested with biological indicators for a total of 105 autoclaves and retested, in some cases, repeatedly. 8% of autoclaves produced unsatisfactory results, showing inadequate inactivation of the test organisms. In the light of the seven-year experience gathered during the MeshHp Project, even higher error rates had been expected. Noteworthy is, however, the fact that autoclaves that in the first test round produced satisfactory results, failed to inactivate the test organisms in a subsequent test. That attests to the limited power of biological indicator tests, which for that reason have been replaced with validation processes in, for example, Germany.

Overall, it can be noted that it was not necessarily the oldest autoclaves (mainly from Russia) that had proved unsatisfactory. That may be due to the fact that the engineers and technicians have vast experience with the old Russian autoclaves, which have no pre-vacuum. By contrast, the engineers have difficulty understanding the operating instructions (poor knowledge of English) supplied for autoclaves with pre-vacuum processes as well as difficulty with the use of replacement parts and repairs. The repair services for autoclaves in Mongolia face many problems. Large hospitals have their own engineers but for small private clinics no such specialist services are available. The situation is compounded by the fact that there are several autoclaves from various countries with different standards in use. In Mongolia there is a continual flow of projects organized by the most diverse countries and groups from the healthcare sector for which, in some cases, autoclaves are also procured. In most cases the sponsor decides which autoclaves are to be purchased. In practice this means that the engineers are unable to build up their knowledge since they continually have to deal with other models. Experience also shows that there is a lack of resources to assure regular maintenance and in most cases also to have an engineer flown in from abroad to attend to faults. In reality this usually means that the autoclaves are no longer operated once they develop faults and recourse is had instead to the old Russian models, with which the engineers are, at least, familiar.

One example of the organizational problems is borne out by a World Health Organization (WHO) programme: some years ago advisers recommended that critical biological waste should be sterilized before disposal. The waste consisted of, for example, needles, peripheral venous line which were collect-

Table 1: Autoclaves based on year of manufacture

Year commissioned	Number	%
1980 - 1990	7	7
1991 - 2000	10	9
2001 - 2010	46	44
2011 - 2016	40	38
Unknown	2	2
Total	105	100

Table 2: Autoclaves based on country of manufacture

Country of manufacture	Number	%
China	46	44
Russia	25	24
Korea	19	18
Germany	5	5
Japan	6	5
Taiwan	3	3
USA	1	1
Total	105	100

Table 3: Autoclaves tested and results of biological indicator testing

Unsatisfactory results in	Number of autoclaves tested				
	105	56	20	15	7
1st Test	4				
2nd Test		0			
3rd Test			2		
4th Test				0	
5th Test					2

Table 4: Country and year of manufacture of autoclaves with unsatisfactory results

Country of manufacture	Defective autoclaves	Year of manufacture
China/SHINVA	5	2009 - 2014
Korea/Deltaclave	2	2008 and 2016
Russia/BK75	1	1995

ed in safety boxes. Even large hospitals produce less than 10 kg of such waste per day and, accordingly, it would have also been possible to discard that waste in a secure domestic waste dump. With WHO financial resources around 50 autoclaves were purchased and distributed among hospitals, with no attention paid to their installation. Hence, only some of the autoclaves were placed in service, while the remainder are still to be found on transport pallets and wrapped in plastic in the hospitals. However, where these autoclaves are in operation the waste is generally being sterilized more effectively than are the instruments in the CSSD, which continue to use the old Russian autoclaves. It would no doubt have been better to have exchanged these autoclaves.

There have also apparently been problems with the EO sterilizers operated by three hospitals. Two proved defective during the first biological test. One EO sterilizer continued to produce unsatisfactory results despite having been repaired several times. In fact EO sterilizers were banned some years ago – not least thanks to insights passed on by the MeshHp Project to the deputy health minister. Nonetheless, because of the enforcement deficits in Mongolia, they continue to be operated, in most cases with no awareness of the risks they present (e.g. carcinogenicity). In the Second National (Public) Hospital we witnessed a situation whereby a doctor who worked there brought back with him a second-hand EO sterilizer from abroad and requested the CSSD to place it in operation. That was done and at the end of the first cycle the EO canister was empty.

For the first time ever temperature/pressure loggers were also used in Mongolia. Of the five autoclaves tested, only two (Numbers 2 and 5 in Table 6) showed no growth of the biological indicators. That can be explained by the fact that for these autoclaves the sterilization time allowed had been sufficiently long. Overall, the results indicate that some of the sterilizers were not tight, thus giving rise to fluctuations in the pressure and, in some cases, temperature. It is possible that they had often been repaired, with individual parameter settings made. That means that the CSSDs no longer know with what temperature, with what pressure or what holding time the autoclaves operate; nor do they have details of the constancy of an autoclave. Therefore as a minimum requirement regular monitoring with biological indicators is currently indicated as the easiest solution. These tests should soon be supplemented with monitoring of the physical parameters.

Table 5: EO sterilizer test results

EO sterilizer	In 1st test	In subsequent tests	After multiple repairs
Inactivation of all test spores	1	2	2
Growth of test spores	2	1	1

Table 6: Results after testing with temperature/pressure loggers

Sterilizer	Temperature holding time	Pressure	Biological indicator
1	120 °C - 17 minutes	2.1 bar Recurrent drops in pressure to 1.9 bar	Growth
2	121 °C - 32 minutes	2.4 bar Recurrent drops in pressure to 2.1 bar	No growth
3	129 °C - 12 minutes	2.6 bar	Growth
4	125 °C - 17 minutes	2.2 bar	Growth
5	125 - 129 °C Continuous fluctuation 60 minutes	2.6 bar Recurrent drops in pressure to 2.3 bar	No growth

The results demonstrate that sterilization too – in addition to other reprocessing shortcomings – may play a role in the high prevalence of hepatitis B and C viruses in the Mongolian population. Accordingly, the MeshHp Project organizers will urged those responsible (health ministry, State Inspection Agency) about the need for action.

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