International Journal of Environmental Research and Public Health

MDPI

Article

Quality of water for reprocessing of medical devices in healthcare facilities in Nepal

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Abstract: Reusable medical devices are decontaminated and sterilized often many times by healthcare facilities across the globe. Reprocessing of medical devices comprises several processes and water plays an important role in some of these, including cleaning and steam sterilization. The water used is required to have certain qualities to ensure the effectiveness of the processes. In this short communication, we report findings of our study which measured quality parameters (pH, total hardness) for water used for medical device reprocessing in 13 primary and secondary care public hospitals in Nepal. The mean pH of water used for reprocessing of medical devices varied from 6.48 to 8.05 across the hospitals whereas the mean total hardness of water varied from 5.93 to 402.50 mg/L $CaCO_3$. Although the range of the mean water pH across hospitals fell within the recommended range, many of the hospitals had mean total hardness higher than recommended for cleaning medical devices. None of the hospitals had mean total hardness suitable for using as feedwater for steam generation. Public hospitals in Nepal should have appropriate water treatment systems so that the recommended water quality can be achieved to ensure effective decontamination and reprocessing of medical devices.

Keywords: healthcare; medical devices; reprocessing; water quality

Citation: To be added by editorial staff during production.

Academic Editor: Firstname Lastname

Received: date
Accepted: date
Published: date

1. Introduction

Healthcare facilities across the globe reuse many medical devices several times by decontaminating and reprocessing them before each use. Some medical devices are used for invasive clinical procedures, such as surgery, and are classified as critical medical devices. Before each use, these medical devices are subjected to a reprocessing cycle, which includes processes including cleaning and sterilization. Sterilization is the process used to render the product free from viable microorganisms, including the most resistant spores. The denaturing of prions is considered in other processes. Among sterilization techniques, moist heat sterilization (also known as steam sterilization or autoclaving) is the most used in healthcare facilities across the globe.

pH and hardness are two important aspects of water quality. pH is a measure of acidity (pH < 7), alkalinity (pH > 7) or neutrality (pH 7), whereas hardness is determined by the concentrations of calcium (Ca^{2+}) and magnesium (Mg^{2+}) ions. In addition, other chemical contaminants also determine the quality of water. Poor water quality can cause corrosion of devices, hard-water deposits on devices, pitting of instruments, inactivation of detergents (and thus inadequate cleaning of devices), pyrogenic reactions in patients due to endotoxins and other pyrogenic agents, and infections in patients due to microbial contamination. Production of good quality steam is critical when sterilizing medical devices. Saturated steam (steam in a state of equilibrium between condensation and evaporation) releases the greatest amount of latent heat when it comes into contact with cooler surfaces, and thus is the most effective means of sterilizing medical devices. Superheated

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steam, wet steam (also known as supersaturated steam) and steam containing non-condensable gases are not good for this purpose [1]. High quality saturated steam can only be obtained if high quality water is used for generating the steam.

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The recommended pH of water for cleaning of medical devices is between 6 and 9 [1,2], and a total hardness level of less than 150 mg $CaCO_3$/L is considered the required hardness for cleaning medical devices [1–3]. Total hardness ≤2 mg $CaCo_3$/L is recommended for generating steam for sterilization [4]. However, the quality of water used for medical device reprocessing has not been well studied and documented, particularly in developing countries. In this short communication, we report findings of a study which assessed water quality (in terms of pH and hardness) used for medical device reprocessing in primary and secondary care public hospitals across Nepal. We also discuss the potential adverse effects of poor-quality water on medical device reprocessing.

2. Materials and Methods

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2.1. Water Samples

Waters used for medical device reprocessing in 13 primary and secondary care public hospitals across Nepal were tested for pH and hardness. The 13 hospitals included two zonal (secondary care) hospitals, nine district (primary care) hospitals and two district-level (primary care) hospitals [5]. The nine district hospitals covered all seven provinces of Nepal. Waters used for 12 consecutive medical device reprocessing cycles in each of the zonal hospitals, 15 consecutive cycles in each of the district hospitals and 15 consecutive cycles in each of the district-level hospitals were sampled and tested for total hardness and pH. Therefore, altogether 189 water samples were tested for pH and hardness. The calculation of sample size has been described in detail elsewhere [6] and was primarily carried out for measuring effectiveness of steam sterilization cycles in these hospitals.

2.2. Measurement of Water pH and Hardness

An HI 96735C Hardness meter (Hanna Instruments Inc., Woonsocket, USA) was used for measuring the hardness of the water used for reprocessing medical devices in the study hospitals. The meter measures the hardness content as Mg^{2+} and Ca^{2+} in water samples in the 0–750 mg/L (ppm) $CaCO_3$ range [7].

An FG2/EL2 Portable pH Meter (Mettler Toledo, Schwerzenbach, Switzerland) was used to measure the pH of water used for reprocessing of medical devices in the study hospitals. The meter had a capacity to measure water pH ranging from 0.00 to 14.00, a precision of 0.01 pH units and an accuracy of ±0.01 pH units.

The detailed manufacturer's instructions for testing water for hardness and pH were followed. The instruments used for testing water were calibrated once a day during the testing period, according to the manufacturer's instructions. Twelve water samples were tested at each zonal hospital and 15 water samples were tested at each of the district level and district hospitals. The mean pH and the mean total hardness results for each hospital were reported.

3. Results and Discussion

All 13 hospitals included in this study used tap water without any prior treatment for all steps (including cleaning and steam generation) of medical device reprocessing. Therefore, all the water samples tested for pH and total hardness were untreated water. The mean water pH across hospitals ranged from 6.48 (slightly acid) to 8.05 (basic). The mean total hardness of water ranged from 5.93 to 402.50 mg/L $CaCO_3$ (Table 1).

Table 1. pH and hardness of water used for reprocessing medical devices in the study hospitals.

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Hospital type	Hospital code	Number of water samples tested	Mean pH	Mean total hardness (mg/L $CaCO_3$)
Zonal hospitals	02	12	7.73	402.50
	08	12	6.88	143.33
District hospitals	01	15	6.75	179.33
	03	15	8.05	167.00
	04	15	6.72	5.93
	06	15	6.48	51.93
	07	15	6.88	115.67
	09	15	6.52	99.67
	11	15	7.25	121.80
	12	15	7.27	152.33
	13	15	7.40	160.33
District-level hospitals	05	15	7.47	147.00
	10	15	6.60	104.13

The mean pH of water used for reprocessing medical devices in the study hospitals ranged from 6.52 to 8.05. This pH range falls within the typical pH range of potable water and is considered acceptable for cleaning medical devices [2]. Lyon [2] recommends a pH range (6.5–8.5) for cleaning medical devices whereas McDonnell & Sheard [1] recommend pH between 6.0 and 9.0 for cleaning, disinfection and rinsing of medical devices.

The mean total hardness of water varied considerably across the study hospitals, ranging from 5.93 to 402.50 mg/L $CaCO_3$. Most of the hospitals were supplied with 'hard' water, i.e. water having total hardness ≥120 mg/L $CaCO_3$. Recommendations made by different guidelines and authors for water hardness for cleaning medical devices also differ to some extent. The Australian/New Zealand Standard (AS/NZS 4187:2014) recommends using water with total hardness ≤60 mg/L $CaCO_3$ (Standards Australia & Standards New Zealand 2006), whereas some authors have recommended a threshold of 150 mg/L $CaCO_3$ [1,2]. More than 38% of the hospitals studied had a mean total hardness of water >150 mg/L $CaCO_3$. This indicates that water in those hospitals is not ideal for cleaning medical devices. Hard water causes white deposits or scale (e.g. calcium carbonate, $CaCO_3$) on medical devices. Such deposits are difficult to remove with water (because of their low solubility; $CaCO_3$ water solubility = 15 mg/L at 25 °C) and can cause clogging of devices, spotting on devices, and ultimately device damage; the deposits also provide a matrix for bacterial adhesion/growth. A study conducted in a tertiary care hospital in Nepal reported that stains/spots were the most commonly observed 'damages' on medical devices used for general- and neurosurgery [8]. In addition, hard water can also inactivate soaps/detergents (by forming inactive calcium salts which are water insoluble) used for cleaning, leading to poor cleaning of medical devices.

Water is not only required for the cleaning process of medical device reprocessing cycles; it is also needed for generating steam for steam sterilization (autoclaving) processes. As with the recommended water hardness for cleaning medical devices, the recommended hardness level for feed-water for generating steam also differs between guidelines/authors. [1] consider a water hardness of <20 mg/L $CaCO_3$ as acceptable for steam generation, whereas the Instrument Reprocessing Working Group [4] recommends ≤2 mg $CaCO_3$/L for steam generation. Some other documents recommend using only treated (i.e. to modify hardness) water for generation of steam [2,9]. None of the hospitals included in this study used treated water for their steam sterilizers (autoclaves), and only one hospital

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had a water supply with a mean total hardness <20 mg/L $CaCO_3$. Hard water, due to the presence of bicarbonate (HCO_3^-), when heated may produce non-condensable gases (e.g. CO_2) which reduce latent heat release when steam comes in contact with the surfaces of medical devices [4]. This can ultimately lead to inadequate inactivation or killing of microorganisms. We previously reported a high proportion of steam sterilization failures in these hospitals when the sterilization cycles were tested with biological indicators containing 10^6 spores of *Geobacillus stearothermophilus* [6]. Although there could be other factors associated with ineffective steam sterilization of medical devices, the effects of hard water cannot be overlooked. Hospitals with hard water should treat the water (e.g. by use of water softening devices) prior to its use in autoclaves. Larger hospitals, for example zonal hospitals, should have an appropriate water treatment plant to produce high quality water for steam generation. Typically, water treatment includes softening, purification (reverse osmosis, deionization or distillation), and degassing [10].

In addition to having damaging effects on medical devices, hard water can also cause damage to the electric heating systems of autoclaves. The hard water deposits accumulate on the surface of the electric heating coil and form a thick layer around it (Figure 1). Such deposits can significantly decrease the heating efficiency of the coil and thus significantly increase the length of an autoclave cycle [2].

Figure 1. An autoclave water-heating coil covered with a layer of deposits (most likely to be $CaCO_3$ from hard water) and a newly purchased heating coil (picture taken in one of the hospitals included in this study).

3.1. Strengths and Limitations of This Study

There are other aspects of water quality such as conductivity (e.g. due to high chloride concentration) which may also affect cleaning and sterilization efficiency [11]. However, total hardness and pH are arguably the two most important parameters for water quality measurement in a sterilization context. In this study, we measured and reported total hardness and pH of waters from different public hospitals which cover all geographical regions including mountains, hills and plains, and all seven provinces of the country. This may be the first study systematically measuring and reporting some quality parameters of waters from healthcare facilities across Nepal.

4. Conclusions

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Appendix A

The appendix is an optional section that can contain details and data supplemental to the main text—for example, explanations of experimental details that would disrupt the flow of the main text but nonetheless remain crucial to understanding and reproducing the research shown; figures of replicates for experiments of which representative data is shown in the main text can be added here if brief, or as Supplementary data. Mathematical proofs of results not central to the paper can be added as an appendix.

Appendix B

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