Appropriate use of chemical indicators in the steam sterilization process: Assured sterility and economy

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To the Editor—Satisfactory quality monitoring of sterilization processes is of paramount importance in maintaining the reliability of sterile supplies to caregivers. The quality monitoring process of each sterilization technique depends on chemical, biological, and physical parameters, according to the recommendations of the Association for the Advancement of Medical Instrumentation (AAMI), the International Standards Organization (ISO), and the European Norms (EN).[1] The chemical monitoring system is composed of a set of indicators based on specific requirements: exposure monitoring (exposure control tape, type I), equipment monitoring (Bowie-Dick test pack, type II), and package monitoring (internal chemical indicators, types III and VI). All chemical indicators are tested in a chemical indicator evaluation resistometer (CIER vessel) according to the ISO 11140-1 standard. A validated chemical indicator can easily detect steam quality, noncondensable gases, and proper steam penetration inside the sterilizer.[1] The biological indicator system consists of viable nonpathogenic microorganisms, providing a defined resistance to a specified sterilization process. The biological indicators are prepared using a live bacterial spore containing a minimum of 1 million colony-forming units (CFU).

Biological indicators provide a direct measure of lethality. They are approved by the American Type Culture Collection (ATCC) and are also tested using the biological indicator evaluation resistometer (BIER vessel) according to ISO 11139.[2] All chemical and biological indicators are called process challenge devices (PCDs); they are used as a medical device simulator (MDSs) for sterility assurance. The physical monitoring system consists of all critical parameters: sterilization time, temperature, pressure, and saturated steam. The sterilization process for those physical monitoring systems has been standardized with a digital microprocessor or analog meter for real-time monitoring of the steam generator, door gasket, chamber, and/or jacket, which continuously monitors all critical parameters throughout the cycle. The chemical and biological monitoring systems are depend on the same physical parameters, but they also indicate the presence of saturated steam for sterility assurance not reported using parametric release only.[3,4]

The difficulty with the physical monitoring system is the detection of the presence of saturated steam (ie, water vapor in a state of equilibrium between condensation and evaporation) for sterility assurance because it is based on records demonstrating that the process parameters were delivered within specified tolerances (ISO/TS 11139:2006). However, the detection of only the saturated steam for sterility assurance (EN 556) but using chemical indicator in every set (ie, package monitoring) is meaningless when the sterilizer is under routine monitoring and control according to EN ISO 14937 or is validated by a third party according to EN ISO17665-1.[5] Although a process indicator (type I) is required to ensure that the goods have already been exposed to a sterilization process, this indicator does not provide any information about the efficacy of the sterilization process.

In general, the steam sterilization process depends on deep vacuum and proper steam penetration system. This can only be achieved by good vacuum pump, proper steam injection, rejection of noncondensable gases, saturated steam, and proper load configuration.[6]

According to the routine monitoring protocol, the sterilizer should run with diagnostic cycle first (ie, maximum leakage should be below 1.3 kpa as per EN 285) followed by an air removal test using a Bowie-Dick test pack (EN 285, part 17). If both cycles are passed satisfactorily, then a biological cycle should run for biological monitoring. The PCDs are kept in the most critical area of a sterilizer for the worst-case scenario (ie, lowest acceptable temperature or shortest acceptable exposure time). Thus, if a single Bowie-Dick or a biological indicator can monitor the entire load for sterility assurance, then there is no reason to keep an internal chemical indicator in every set. However, a normal PCD (ie, a dummy pack containing a type V or VI chemical indicator for surface sterilization purposes) does not assure the sterility of luminal or complex instruments because these instruments are more challenging with regard to air entrapment. To avoid these potential problems, a hollow-process–challenged device by Helix PCD (HPCD, according to EN 867-5 and EN 285) is used to simulate the luminal instruments by measuring their inner surfaces (ie, surface measurement by inner diameter × inner length with wall thickness and material of tubes). The indicator in the HPCD is a type II chemical indicator (EN ISO 11140-1) for detecting the noncondensable gases in every cycle.[1,8]

In our 200-bed cancer center in eastern India, >200 surgical sets (minor and major sets) are packed every day, and 5 instrument cycles are run per day to sterilize them. We have provided a cost calculation (Table 1) as a reference; it shows a clear cost difference in between not using an internal chemical indicator versus using an internal chemical indicator, increases the cost of sterilized sets.[1]

According to the international standard, all type V or VI indicators are called 'integrating' or 'emulating' indicators, and they can only specify the constant concentration of steam with time and temperature. Only those indicators have defined sated value (SV) according to EN ISO 11140-1. Moreover, if an HPCD with a type II chemical indicator monitoring air removal, temperature-time-integral (F_0 value) and condensation of steam to water is added to the type V or VI chemical indicator (as a dummy pack) in every cycle, then this monitoring is a better alternative to releasing the sterile load than including the internal chemical indicator in every set. Ensuring quality in sterilization processes requires considerable. The challenge is to ensure that the sterilization indicators are used efficiently to prevent waste and maintain quality.[9]

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Table 1. Cost Differnce With or Without Internal Chemical Indicator Used in Every Set

Cost With Internal Chemical Indicator	Cost per Piece (INR)	Cost per Day (INR)	Cost per Year (INR)	Cost Without Internal Chemical Indicator	Cost per Piece (INR)	Cost per Day (INR)	Cost per Year (INR)
Bowie-Dick test Pack (1 per cycle)	Rs. 500 **$7.69**	Rs. 500 **$7.69**	Rs 180000 **$276.92**	Bowie-Dick test pack	Rs. 500 **$7.69**	Rs. 500 **$7.69**	Rs.180,000 **$276.92**
Expose control tape	Rs. 450 **$6.92**	Rs. 450 **$6.92**	Rs. 162,000 **$2492.30**	Expose control tape	Rs. 450 **$6.92**	Rs. 450 **$6.92**	Rs. 162000 **$2492.30**
Batch label	Rs. 1 **$0.01**	Rs. 200 **$3.07**	Rs. 72,000 **$1107.69**	Batch label	Rs. 1 **$0.01**	Rs. 200 **$3.07**	Rs. 72000 **$1107.69**
Biological Indicator	Rs.145 **$2.23**	Rs. 145 **$2.23**	Rs. 52,200 **$803.07**	Biological indicator	Rs.145 **$2.23**	Rs. 145 **$2.23**	Rs. 52200 **$803.07**
Internal chemical indicator (every set)	Rs. 15 **$0.23**	Rs. 3,000 **$46.15**	Rs. 1,080,000 **$16,615.38**	Batch monitoring by HPCD (every load)	Rs. 60 **$0.92**	Rs. 300 **$4.61**	Rs. 108,000 **$1,661.53**
Total cost with chemical indicator in a year		Rs. 4295 **$ 66.07**	Rs. 1,546,200 **$23,787.69**	Total cost without chemical indicator in a year		Rs. 1595 **$24.53**	Rs. 574200 **$8,833.84**

Note. Cost difference in INR per year: Rs. 1,546,200 − Rs. 574,200 = Rs. 972,000. Cost difference in USD per year: $23,787.69 − $8,833.84 = $14,953.85.

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Assessment of stool color in *Clostridioides difficile* infection: A pilot study

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To the Editor—Clostridioides difficile, formerly known as *Clostridium difficile*, is a spore-forming anaerobe that is believed to colonize ~5%–10% of healthy adults and is usually asymptomatic.[1] The toxin-producing strains of *Clostridioides difficile* can cause *Clostridioides difficile* infection (CDI), which is characterized by frequent diarrhea. CDI is the leading cause of infectious diarrhea in hospitalized patients, and some risk factors of CDI, such as old age, antibiotic use, and proton pump inhibitor (PPI) use have already been reported.[2,3] The incidence of CDI is 0.8–4.71 per 10,000 patient days in Japan.[4] *Clostridioides difficile* can be widely distributed in the environment as spores, which are extremely resistant to environmental changes including alcohol sterilization; therefore, prompt and appropriate diagnosis of CDI is important for the prevention of nosocomial spread of CDI.

A rapid stool test kit for detecting toxins and glutamate dehydrogenase (GDH) antigen is generally used to diagnose CDI.

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