



## From Single-Use to Reuse: How AI is Shaping the Future of Single-Use Medical Devices Reprocessing

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### Abstract

There is no doubt that artificial intelligence (AI) is the revolution of this century and The upcoming leader of the whole world. Some may see that AI endangers human life and by time it will replace humans and take over their tasks and responsibilities and become the dominant species. Indeed, every detail in our life is now depending totally or partially on AI. It shapes and controls our future. The benefits originated from its application made it a choice of great importance when we face a problem where human power cannot deal with. In medicine, AI integration has achieved a lot of benefits in many aspects including clinical trials, drug discovery, health services and hospital administration. One aspect of great importance that can benefit from AI integration is infection control. Infection control is one of the pillars in any health care facility. It aims to protect health care givers and patients from getting infections through establishing barriers known as standard precautions. These barriers break down infection transmission cycle preventing microorganisms from reaching host that could be staff, patient, environment or even visitors. Reprocessing of instruments is one of these standard precautions that ensure safety of multiple use instruments before being used again on patients. Our review explains the role that AI can play in infection control specifically in reprocessing of instruments and more specifically reprocessing of single use devices (SUDs).

## من الإِستخدام الفردي إلى إعادة الإِستخدام: كيف يشكّل الذكاء الإِصطناعي مستقبل إعادة معالجة الأجهزة الطبية ذات الإِستخدام الواحد

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لا شك أن الذكاء الاصطناعي هو ثورة هذا القرن والقائد القادم للعالم أجمع. قد يرى البعض أن الذكاء الاصطناعي يعرض حياة الإنسان للخطر ويمرور الوقت سيحل محل البشر ويتولى مهامهم ومسؤولياتهم ويصبح النوع السائد. في الواقع، أصبحت كل تفاصيل حياتنا تعتمد كلياً أو جزئياً على الذكاء الاصطناعي. إنها تشكل مستقبلنا وتتحكم فيه. إن الفوائد الناجمة عن تطبيقه جعلته خياراً ذا أهمية كبيرة عندما نواجه مشكلة لا تستطيع القوة البشرية التعامل معها.

في الطب، حقق تكامل الذكاء الاصطناعي الكثير من الفوائد في العديد من الجوانب بما في ذلك التجارب السريرية واكتشاف الأدوية والخدمات الصحية وإدارة المستشفيات.

أحد الجوانب ذات الأهمية الكبيرة التي يمكن أن تستفيد من تكامل الذكاء الاصطناعي هو مكافحة العدوى. تعتبر مكافحة العدوى أحد الركائز الأساسية في أي منشأة رعاية صحية. ويهدف إلى حماية مقدمي الرعاية الصحية والمرضى من الإصابة بالعدوى من خلال وضع حواجز تعرف باسم الاحتياطات القياسية. تعمل هذه الحواجز على تحطيم دورة انتقال العدوى، مما يمنع الكائنات الحية الدقيقة من الوصول إلى المضيف الذي يمكن أن يكون موظفاً أو مريضاً أو بيئة أو حتى زواراً.

## 1. INTRODUCTION

There is no standard definition of Artificial Intelligence. AI can be simply defined as any task performed by a machine or a computer program, It is the science of making machines work smarter and demonstrate intelligence like humans, It may be defined as intelligent imitation of human behavior, Some researchers informally define AI as such a program that in an arbitrary world will not behave worse than human, Another definition of AI is that branch of computer science that is primarily concerned with automation of intelligent behavior, AI is also the creation of intelligent systems meaning systems having the ability to learn, think and solve problems.

AI aims to make computers behave as if they were humans but with more intelligence and less time than humans do.

AI offers us many advantages including finishing tasks faster than humans, ability to deal with complex situations, doing multiple functions at the same time and consuming less space. At the same time we may face some disadvantages like increasing the problem of unemployment and also cost.

AI can be used in many different disciplines in medicine to improve health services and achieve greater accuracy. The integration of AI in medicine has augmented the capabilities of clinicians through improving process of diagnosis and treatment of patients.

One of the goals of Sustainable Development is providing health for all population. That's why all health care facilities nowadays focus on allocating resources to the most cost effective health protection programs including infection control. Infection control is one of the health pillars in all health systems that ensure safe health services for both patients and care givers.

It is estimated that about 2 million patients have hospital acquired infections (HAIs) each year and about 100,000 of them die(8). These hospital acquired infections result in \$4.5 billion annual expenses.

This economic burden comes from increased length of hospital stay, cost of treatment and supplies.

Avoiding hospital acquired infections will help improving the financial picture as patients without HAIs will not need additional treatment and will discharged sooner allowing beds for other patients.

One major risk of all interventions performed in hospitals is transmission of infection via medical devices.

The original equipment manufacturer (OEM) may provide a guidance for reuse of certain devices called reusable or multiple use devices or may provide us with items labeled as single use

only and those called disposable items or single use devices (SUD).

Ensuring that reusable or multiple use instruments are properly disinfected or sterilized is essential to prevent introduction of infectious microorganisms to patients.

For single use devices, although evidence suggests that reprocessing of certain types can be achieved safely and effectively, but still there are controversial issues regarding reuse of these devices.

One study showed that reprocessed SUDs are difficult to be completely cleaned and disinfected than reusable devices and those SUDs have suffered of material destruction during the reprocessing cycle.

In 1980 the Center for Disease Control and prevention (CDC) has released its guideline for prevention of nosocomial infections that provided a clear statement against reprocessing of SUDs(14). Few years later CDC removed this recommendation and stated that there is no evidence indicating increased risk of nosocomial infections as a result of reusing SUDs.

Reusing of SUDs is a controversial matter.

The health care centers started to reprocess SUDs without knowing their safety or the implicated cost.

The necessity of cost cutting pushed many countries to start reusing expensive SUDs, Reuse of disposable or single use instruments raises a number of concerns including the legal issue especially who will be responsible for any harm caused by such instruments.

That's why the process should be regulated and done under the supervision of third party rather than onsite hospital reprocessing or original equipment manufacturer reprocessing.

The Food and Drug Administration has approved reprocessing of certain SUDs provided that these devices meet safety and performance criteria and that the reprocessing is performed by a well regulated setting.

In August 2000 FDA released A guidance on reprocessing of SUDs by well regulated hospitals or third parties (19). The FDA stated that both hospitals and Third parties will be considered as manufacturers and should comply with the same regulations and requirements as the OEM.

Because the reprocessed SUD must have the same quality assurance and safety requirements as that produced by the OEM, the FDA's new policy is to stop reuse of SUDs in hospitals unless they rely on a third party in the reprocessing of such devices..

Canadian Agency for Drugs and Technologies in Health (CADTH) regulates third party re-processors that are required to meet the same requirements as the manufacturers.

Indeed, reprocessing of SUDs reflects environmental and economic benefits since it will decrease the bio-burden but we still need to determine the clinical safety of these devices.

## **2. SPECIFIC AIMS**

We mainly aim to clarify the role of AI in reprocessing of single use medical devices and exploring how AI technologies can be integrated into the reprocessing cycle to improve safety, efficiency and sustainability. We will explain contribution of AI to automating process, enhancing quality control and reducing cost transforming health system from disposing single use devices to managing single use devices.

## **3. WHY THIRD PARTY?**

Bias can occur if the original equipment manufacturer of SUDs takes on the responsibility for their reprocessing. The manufacturer may favor the reprocessing of the SUD as a cost saving measure resulting in compromising safety so as to meet economic goals.

There may be also a risk of reduced adherence to safety standards especially if there was a financial issue.

The manufacturer also may use quality indicators in favor of its down devices over others or it may exert pressure on the regulatory bodies to change standards in favor of their reprocessed devices.

Bias can also originate if the health care facility which uses the SUDs is responsible for their reprocessing which may impact safety and effectiveness.

Health care facilities may prioritize cost saving over patient safety and tend to process SUDs even if they are not save any more due to limited budget or resources.

Health care facilities may also use suboptimal methods or accelerate the steps of the reprocessing methods to improve sterilizer efficiency and avoid cost of maintenance which may lead to compromising safety and quality of the reprocessed devices.

Bias also may be due to self-auditing as the facilities will perform their own audits and over rate the evaluation of the reprocessing cycle.

Selective reprocessing is also one major factor where the facility may favor reprocessing of certain SUDs over others for the ease of reprocessing or for the seek of cost saving leading to reprocessing devices that are less suitable for reuse.

Among factors that may affect the reprocessing of SUDs is lack of expertise as the HCFs may lack the knowledge or the trained staff required to properly handle the whole reprocessing cycle.

We seek to introduce AI in the process of reprocessing of SUDs to act as the third party to enhance efficiency, accuracy, safety, consistency and compliance with regulatory standards.

AI can play a very important role in such process through enhancing automation, monitoring

and decision making throughout the reprocessing cycle.

AI can be integrated into a broader system of human oversight to ensure proper reprocessing via several aspects including:

#### **4. REUSABILITY PREDICTION**

AI can be used to track each SUD life cycle based on analyzing reprocessing history so we can detect number of times SUDs can be reprocessed which is an important step in reprocessing decision making avoiding any bias that might be originated if reprocessing performed from manufacturer perspective or consumer perspective.

By using certain AI models, it will be easy to detect the number of times that the device can be reused. AI can analyze factors like reprocessing conditions and device material to put a limit for reuse. This ensures that the device will not be reused beyond safety threshold.

#### **5. AUTOMATED INSPECTION**

We can use AI-powered visual recognition systems to inspect devices for cleanliness, damage or wear. This is a critical step in reprocessing any device especially when we talk about reprocessing of SUDs. We have to be very accurate in detecting if these SUDs are still safe and suitable for reuse.

Certain models can be used to analyze images of the device and detect any defects that may not be visible to human eye.

These computer vision systems also can be used to inspect the inside of complex instruments and narrow lumens to see if there is any damage that can cause harm to patients if reprocessed and reused.

Some SUDs are very critical and very expensive like cardiac catheters and some ocular devices that if we decided to reuse them we have to be sure that they are still suitable and will not cause any complications to patients and AI can help in making this decision accurately.

#### **6. MACHINE LEARNING BASED QUALITY ASSURANCE**

AI systems can use data to build models and pattern to recognize the presence of damage or contaminants allowing for more accurate and standardized quality control throughout the reprocessing cycle.

#### **7. FORECASTING EQUIPMENT FAILURE**

Reprocessing equipments need regular monitoring and maintenance to ensure they are operating on the required conditions. AI can monitor them and predict exactly when they are likely to fail. This can help in proactive maintenance before they are out of service.

#### **8. CONTINUOUS MONITORING**

AI can be integrated in the system to analyze data from previous cycles to identify any anomalies that may originate in the SUDs making them unsuitable for further reprocessing.

AI also can monitor the reprocessing devices to ensure that they are operating within the required parameters and detect any defects in the cycle.

### 9. REGULATION

AI can act as a regulatory support tool. It can provide us with real-time reports and generate documents that can be used for continuous auditing. This will not only reduce the cost burden on health care systems but also enhance regulatory accountability.

### 10. CONCLUSION

Despite being debatable, reprocessing of SUDs has economic, environmental and operational benefits.

AI integration in SUDs reprocessing can result in great advancement in both patient safety and cost effectiveness. It can help in overcoming controversial issues that health sectors face when they decide to reprocess single use devices.

AI will cause a great shift in how institutions think about reprocessing of SUDs. Instead of treating them as disposable items, health care systems will start to view SUDs as assets with longer life cycle. They will think about cost saving and waste reduction without being worried about safety or quality. This makes AI an area of interest regarding sustainable health care system.

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