

Safety-cost trade-offs in medical device reuse: a Markov decision process model

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Abstract Healthcare expenditures in the US are approaching \$2 trillion, and hospitals and other healthcare providers are under tremendous pressure to rein in costs. One cost-saving approach which is gaining popularity is the reuse of medical devices which were designed only for a single use. Device makers decry this practice as unsanitary and unsafe, but a growing number of third-party firms are willing to sterilize, refurbish, and/or remanufacture devices and resell them to hospitals at a fraction of the original price. Is this practice safe? Is reliance on single-use devices sustainable? A Markov decision process (MDP) model is formulated to study the trade-offs involved in these decisions. Several key parameters are examined: device costs, device failure probabilities, and failure penalty cost. For each of these parameters, expressions are developed which identify the indifference point between using new and reprocessed devices. The results can be used to inform the debate on the economic, ethical, legal, and environmental dimensions of this complex issue.

Keywords Medical devices · Reprocessing · Risk analysis · Cost-benefit study · Markov decision process

1 Introduction

1.1 Overview

Healthcare costs have risen dramatically in the United State in recent years, with total expenditures of nearly \$2 trillion in 2004 [1] and spending of \$4 trillion projected by 2015 [2]. Hospitals and other healthcare providers are under increasing pressure to keep costs down. Partly in response to this pressure, hospitals have begun sterilizing and reusing some devices designated as single-use devices (SUDs). Devices that are now sterilized and refurbished for further use include external-use items such as compression sleeves, but also include internal-use items such as cardiac catheters and arthroscopic shaver blades.

As the volume and complexity of single-use devices has increased, hospitals have increasingly relied upon third-party reprocessing firms. These firms collect, sterilize, refurbish, and repackage the devices and then resell them to hospitals at a fraction of the cost of the new device. Recent data from the US Food and Drug Administration (FDA) indicate that 45% of hospitals with more than 250 beds reuse devices labeled for one use [3]. With \$80 billion spent on medical devices annually in the US, \$3 billion of which is for SUDs [4], it is little wonder that reprocessing has blossomed into an industry with annual revenues exceeding \$125 million [3].

Original equipment manufacturers (OEMs) and other critics of reprocessing claim that the safety of patients is at stake. They argue that reprocessing may damage the devices, leading to malfunctions. In addition, it is difficult or impossible to remove all potential contaminants such as metal flakes and human tissue.

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In short, the devices are intended only for a single use and beyond that, their reliability and safety cannot be guaranteed.

Proponents of reprocessing argue that the refurbished devices are entirely safe. Some of the devices which they handle are those that were removed from the package but never actually used, perhaps due to a cancellation of surgery. Those devices that have actually been used are carefully inspected, and damaged devices are discarded. Judicious reuse of devices, the argument goes, is simply an efficient use of resources, which benefits healthcare providers and patients alike. In addition to saving money, reprocessing benefits the environment by reducing waste. In 2004, the major reprocessors refurbished about 4.6 million devices, eliminating 935 tons of medical waste [5]. Reprocessors and hospitals claim that the OEMs are using fear as a tool to protect their revenues.

Both sides rely on sweeping generalizations and appeals to emotion. As a result, the debate has deteriorated into a kind of “he-said, she-said” shouting match. Patients are left wondering, is medical device reuse safe? Society is left wondering, is it environmentally sustainable to depend so heavily on single-use devices? And hospital administrators are left wondering, what is the economic impact of *not* using reprocessed devices?

One impediment to systematic study of this issue is lack of data. Prior to 2002, the FDA did not require any certification of reprocessed devices. While reprocessors were required to follow good manufacturing practices and were subject to review if complaints were made, the devices were effectively treated as new. Currently, reprocessors are required to submit data to verify that the reconditioned instruments are safe and sterile. However, reporting of device malfunctions is voluntary, and even the doctors and nurses using the devices may not be aware that they are reprocessed [3].

Clearly, medical device reuse is a complex issue that has many different dimensions, including economic, ethical, legal, and environmental. To help shed light on these issues, this paper presents a Markov decision process (MDP) model of the healthcare provider’s decision problem: Given the device costs, the failure probabilities, and the failure cost, is it better to use new or reprocessed devices? Before presenting the details of the model, a discussion of previous research related to this problem is presented.

1.2 Relevant literature

Two broad areas of research are relevant to the study of reprocessing: medical/healthcare research and management science research. The medical research related

to device reprocessing can be divided into three categories, each focusing on a particular aspect of the practice: philosophical issues, administrative issues, and technical issues. Most of the papers in the first category include general discussions of the various “big picture” dimensions of reprocessing, including ethical, legal, and economic [6, 7]. Other works in this category are more editorial in nature, seeking to support a particular point of view [8, 9].

The second category of medical and healthcare research has to do with administrative issues. Some papers in this group summarize information about government regulations [10], while others discuss the legal implications of reprocessing [11, 12]. Other papers in this category report on current reuse and reprocessing practices in different medical facilities and regions [13–15], while others focus more on logistical and implementation aspects of reprocessing [16, 17]. Several studies have examined the costs and benefits of reusable devices versus disposable devices [18–20], and while they touch on some related issues, they do not directly address the question posed by this paper. First, they do not address the issue of *reprocessing*, which involves reusing devices which are labeled as disposable. In addition, the scope of these studies is very narrow—for example, looking at a single instrument type—whereas we seek to provide a more general framework.

The third category of medical research related to reprocessing is focused on the technical aspects of the practice. In some cases, clinical trials are performed to evaluate the safety and effectiveness of reusing SUDs [21, 22]. However, most studies involve laboratory experiments designed either to evaluate the efficacy of different sterilization methods [23–25] or to study the effects of reprocessing on the material properties (e.g., tensile strength) of devices [26–28].

In summary, the medical research related to device reprocessing tends to be either a very high-level discussion of ethics, a discussion of how to administer a reprocessing program, or a very low-level analysis of which materials or procedures are effective for specific device types. Research of the first variety, while clearly important, offers no clear cut answers about whether reprocessing makes sense for a particular healthcare provider or device type. Research of the second and third variety takes reprocessing as a given. There is a significant opportunity, therefore, for mid-level analysis of when and where reprocessing is viable. Such analysis can help provide guidance about how to allocate resources and direct future research with respect to different device types, procedures, materials, etc.

In addition to healthcare and medical research, there is also a body of management science research relevant

to medical device reprocessing. Specifically, the question of whether or not to use reprocessed devices is similar to questions examined in the literature related to equipment maintenance and replacement. Models in this area address the question of when to inspect, replace, and/or repair systems (usually single pieces of equipment) whose condition deteriorates over time. Valdez-Flores and Feldman [29] and Dekker et al. [30] provide extensive reviews of this vast body of literature. Two pertinent, seminal works are discussed below.

Derman [31] models a system with deteriorating condition, denoted as discrete state $i = 0, 1, \dots, N$. The cost to operate the system increases as the condition gets worse. If the worst state (N) is reached, the equipment must be replaced. However, the equipment may be replaced preemptively at a lower cost. Sufficient conditions are identified that ensure that a control limit policy is optimal, i.e., if it is optimal to replace the equipment in some state j , then it will also be optimal to replace the equipment in worse states, $i > j$. The framework presented in [31] forms the basis of the model developed in Section 2.

Ross [32] presents a model of a production process that can be in any one of several discrete states. The process condition, however, is not known to the decision maker without inspection. The decision maker must decide whether to produce a unit, inspect a previously produced unit, or revise the process, thereby returning it to the best condition. This framework differs slightly from the model presented in the next section; however, the two-state model results in [32] have a very similar flavor to ours.

The scenario studied in this paper differs from the traditional maintenance environment in two ways. First, the decision maker chooses a different device at each decision epoch—one does not reuse the same exact device at that moment. So the state transition probabilities are “reset” at each epoch. Second, the notion of “failure” in a medical context includes device malfunction, but may also include post-operative infection or other harm to the patient.

The other body of management science literature that relates to this paper is the research on closed-loop supply chains. The concept of closed-loop supply chains incorporates the idea of collecting used products and reusing, recycling, or refurbishing them. The forward and reverse flows of products, components, and materials creates new challenges with respect to supply chain management. Fleischmann et al. [33] provide an extensive review of quantitative models in this area. Flapper et al. [34] report a number of industry case studies, and Dekker et al. [35] provide a wide-ranging collection of quantitative models relating to

closed-loop supply chains, addressing issues such as supply chain design [36], production planning [37], and inventory control [38]. Savaskan et al. [39] use a game-theoretic approach to examine different supply chain designs.

One particularly relevant model in this area is that of Flapper and Kiesmüller [40]. This paper examines distribution items (like pallets and boxes) and develops a model to estimate the cost of employing—purchasing, transporting, reconditioning, and disposing of—a particular item type. The approximate cost can then be used to determine which item type is appropriate for a particular application. There are two key differences between the scenario modeled in [40] and the scenario studied here. First, the model in [40] assumes a preset maximum number of uses. Second, there is no penalty for the failure of an item. That is, the quality of the item may deteriorate, and it may be discarded before it reaches the maximum usage; however, the item does not fail during use.

In summary, there is a clear need to examine the practice of reprocessing and to do so as objectively as possible. Toward that end, the goal of this paper is to apply some of the time-tested principles of maintenance decision models to the reuse of medical devices. The intention is that a systematic study of the problem can help facilitate the discussion of important medical, ethical, and economic issues related to this subject and provide concrete guidance about whether reprocessing is appropriate in a particular context.

2 Model

A healthcare provider can use a new device or a reprocessed device to perform a given medical procedure. Regardless of which type of device is used, there is a probability that it fails, meaning that it breaks, malfunctions, or causes some harm to the patient. Thus, the device state is characterized as either being “functional” or “non-functional.” If the device fails, then a penalty cost is incurred. Reprocessed devices cost less than new devices but may have higher failure probabilities and thus may incur greater penalty costs over the long run. The healthcare provider’s objective is to determine a use/reuse policy that minimizes the long-run expected average cost.

2.1 Basic model and notation

A medical device may be in one of two states—“functional” or “non-functional”—indicated as $i = 0$ or $i = 1$, respectively. At each decision epoch, the

healthcare provider decides whether to use a reprocessed device, denoted as action $a = r$, or to use a new device, denoted as action $a = n$. The cost of using a reprocessed device is C_r , and the cost of a new device is denoted as C_n . A functioning device—whether it is new or reprocessed—may fail during use. Let p_a denote the probability that a type a device fails, i.e., makes a transition from the functional to the non-functional state, where $a \in \{r, n\}$. If a device fails, a cost of C_f is incurred, and the device is replaced with a functional device, i.e., the process returns to state 0 with probability one. The notation is summarized below.

- a $\equiv$ index for action; $a = r$ refers to using a reprocessed device, and $a = n$ refers to using a new device.
- i $\equiv$ index for state; $i = 0$ refers to functional, and $i = 1$ refers to non-functional.
- C_r $\equiv$ cost of using a reprocessed device.
- C_n $\equiv$ cost of using a new device.
- C_f $\equiv$ penalty cost incurred for device failure, regardless of type.
- p_a $\equiv$ probability that a type a device fails (makes a transition from the functional state to the non-functional state).

Since expected costs and state transitions depend only on the current state and action taken, the problem can be modeled using a Markov decision process (MDP). An MDP is specified by five objects: a set of states, a set of possible actions, a definition of decision points, the expected costs (and/or rewards) associated with each state and action combination, and a set of probabilities defining the possible transitions which the process can make from one state to another. For the problem described above, these objects are defined as follows. The set of states is denoted by $\{0, 1\}$, the set of actions is denoted by $\{r, n\}$, and decision points occur just before each medical procedure is performed. Using the standard MDP notation, the expected cost of taking action a in state i is denoted as $C(i, a)$, so we have $C(0, a) = C_a$ and $C(1, a) = C_a + C_f$, for each $a \in \{r, n\}$. In addition, p_{ij}^a denotes the probability that the process makes a transition to state j when the current state is i and action a is taken. For example, when device type a is used in state 0 (functional), then the probability of making a transition to state 1 (non-functional) is $p_{01}^a = p_a$.

All expected costs are bounded, and according to basic MDP theory, a stationary (time-invariant) optimal

policy exists and the following recursion will be satisfied [41]:

$$g + h(i) = \min_a \left\{ C(i, a) + \sum_{j=0}^1 p_{ij}^a h(j) \right\}, \quad \text{for } i=0, 1, \quad (1)$$

where $h(i)$ is defined as the optimal cost function and g is a constant that equals the long-run expected average cost. In words, Eq. 1 simply means that the minimal cost can be expressed as a function of the expected cost for the current state and action plus the sum of expected costs in future states, weighted by the probability of reaching those states.

Denote $\theta = [a_0, a_1]$ as a *policy*, i.e., a decision rule, which specifies that devices of type a_i be used in state $i \in \{0, 1\}$, where $a_i \in \{r, n\}$. In other words, device type $a_0 \in \{r, n\}$ will be used in state 0, and device type $a_1 \in \{r, n\}$ be used in state 1. Using the policy $\theta = [a_0, a_1]$ induces a discrete-time Markov chain with the following state transition probabilities:

$$[p_{ij}^{a_i}] = \begin{bmatrix} 1 - p_{a_0} & p_{a_0} \\ 1 - p_{a_1} & p_{a_1} \end{bmatrix}, \quad (2)$$

where each element of the matrix indicates the probability of a transition from state i to state j when action a_i is taken. Specifically, when the policy $\theta = [a_0, a_1]$ is used and the process is in the functional state, then action a_0 is taken, and the probability of making a transition to the non-functional state is p_{a_0} ; the probability of remaining in the functional state is $1 - p_{a_0}$. The transition probabilities for action a_1 are interpreted similarly.

According to basic Markov chain theory (see [42], for example), the chain induced by a stationary policy can be characterized by a unique set of steady-state probabilities; specifically, when policy θ is employed, the stationary probability that the process is in state i is $\pi_i(\theta)$, regardless of the initial state. For policy $\theta = [a_0, a_1]$ the state transition probabilities in Eq. 2 can be used to derive the following steady-state probabilities:

$$\pi_0(\theta) = (1 - p_{a_1}) / [p_{a_0} + (1 - p_{a_1})], \quad \text{and} \quad (3)$$

$$\pi_1(\theta) = p_{a_0} / [p_{a_0} + (1 - p_{a_1})]. \quad (4)$$

These probabilities are useful in characterizing the long-run expected average cost of using a particular policy.

2.2 Cost functions

The decision maker's goal is to find the policy that minimizes the long-run expected average cost. Since there is a finite number of states and replacement is

required upon failure, then regardless of which state the process begins in, the long-run expected average cost can be expressed as a function of the steady-state probabilities:

$$g(\theta) = \sum_{i=0}^1 C(i, a_i) \pi_i(\theta), \quad (5)$$

where $C(i, a_i)$ indicates the expected cost of using a type a_i device in state i as specified by policy θ , and $\pi_i(\theta)$ denotes the stationary probability of being in state i when θ is used.

For a given set of parameters, it is straightforward to compute the expected average cost using Eq. 5. Since there are two states and two actions available in each state, four stationary policies are possible; they are $\theta_1 = [r, r]$, $\theta_2 = [r, n]$, $\theta_3 = [n, r]$, $\theta_4 = [n, n]$. Take policy $\theta_2 = [r, n]$, for example. In words, this policy specifies that reprocessed devices be used in state 0 (the functional state). When a failure occurs, i.e., the process makes a transition to the non-functional state, then a new device should be used. In contrast, policy $\theta_1 = [r, r]$ continues to use reprocessed devices even after a failure occurs (not the same, failed device but rather a “freshly” refurbished device). Substituting the appropriate parameters into Eq. 5 yields the expected cost function for a given policy. The expected cost functions for each of the four policies are reported in Table 1.

Although some of the cost functions may be further simplified, keeping them in a symmetric form will facilitate proof of the results that follow. To determine the optimal policy, one could easily compute the expected average cost for each policy and simply choose the policy with the lowest value. The purpose of the model, however, is to analyze trade-offs and to examine the impact of different parameters on the long-run cost. With this in mind, we examine how the optimal policy changes as a function of different model parameters.

2.3 The impact of device cost

Cost pressure is the primary impetus for reuse of medical devices. Reprocessed devices typically cost about half as much as a new device, but may cost as little as

10% of the original price [5]. This prompts the question: For a given set of parameters, how much less would a reprocessed device need to cost to make it preferable to a new device?

Although it is easy to determine the optimal policy for a given set of costs, it is not immediately obvious from inspection of the cost functions in Table 1 where the trade-off point is between new and reprocessed devices. To help determine this point, define α as the ratio of device costs: $\alpha \equiv C_r/C_n$. Reprocessed devices cost no more than new devices, so $0 < \alpha \leq 1$. Using an approach similar to that used in [43], the following proposition identifies the indifference point between new and reprocessed devices with respect to the device cost.

Proposition 2.1 *With respect to the cost of a reprocessed device, there is a single point, α^* , at which the decision maker is indifferent between new and reprocessed devices:*

$$\alpha^* = \frac{C_n + C_f(p_n - p_r)}{C_n}. \quad (6)$$

When $C_r/C_n > \alpha^$, a new device is preferred; when $C_r/C_n < \alpha^*$, a reprocessed device is preferred.*

Proof Choose two policies which differ by action in only one state—for example, $\theta_2 = [r, n]$ and $\theta_4 = [n, n]$. Equating the cost functions of these two policies (see Table 1) will indicate the point at which we are indifferent between a new device and a reprocessed device in state 0:

$$\begin{aligned} & [C_r(1 - p_n) + (C_n + C_f)p_r]/[(1 - p_n) + p_r] \\ & = [C_n(1 - p_n) + (C_n + C_f)p_n]/[(1 - p_n) + p_n]. \end{aligned}$$

Substituting $\alpha = C_r/C_n$ in the above equation and solving for the indifference point yields Eq. 6. A comparison of policies $\theta_1 = [r, r]$ and $\theta_3 = [n, r]$ produces exactly the same result. Similarly, comparing $\theta_3 = [n, r]$ and $\theta_4 = [n, n]$ or $\theta_2 = [r, n]$ and $\theta_1 = [r, r]$ yields the same expression for state 1. $\square$

Figure 1 illustrates how the ratio of the costs and the indifference point, α^* , change as a function of the cost

Table 1 The four possible policies and their cost functions

Policy No.	a_0	a_1	Expected Cost Function
1	r	r	$[C_r(1 - p_r) + (C_r + C_f)p_r]/[(1 - p_r) + p_r]$
2	r	n	$[C_r(1 - p_n) + (C_n + C_f)p_r]/[(1 - p_n) + p_r]$
3	n	r	$[C_n(1 - p_r) + (C_r + C_f)p_n]/[(1 - p_r) + p_n]$
4	n	n	$[C_n(1 - p_n) + (C_n + C_f)p_n]/[(1 - p_n) + p_n]$

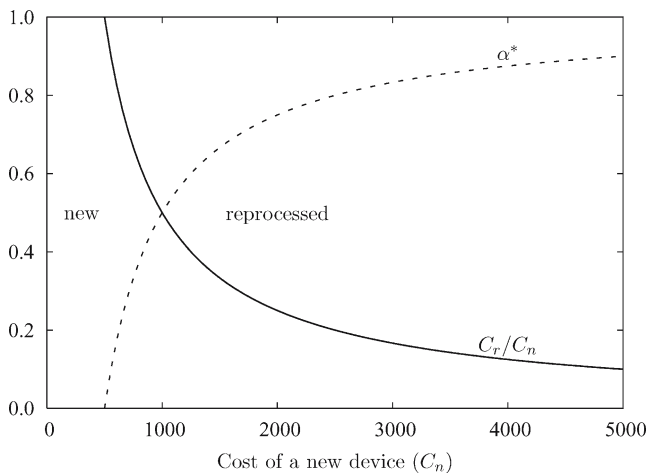


Fig. 1 α^* and C_r/C_n as a function of C_n

of a new device, C_n . When $C_r/C_n > \alpha^*$, a new device is preferred; otherwise, a reprocessed device is preferred. Note that there is a single crossing point.

This result allows a healthcare provider to answer questions like: How *low* would the cost of a reprocessed device need to be to make it preferable to a new device? As evident from the graph above, as the cost of a new device (C_n) increases, α^* increases, and using a reprocessed device becomes more attractive. Note that since $p_n \leq p_r$, the second term in the numerator of Eq. 6 is non-positive. Thus, as the failure probability of a reprocessed device (p_r) increases, the value of α^* decreases, meaning that new devices are more attractive. For the same reason, an increase in the failure cost (C_f) makes new devices more desirable. Increasing the failure probability of a new device (p_n) decreases α^* , making reprocessed devices more attractive.

2.4 The impact of failure probabilities

In addition to cost differences, there may be differences between new and reprocessed devices with respect to their failure probabilities. OEMs would have us believe that reprocessed devices are more likely to fail (i.e., malfunction, cause infections, etc.), while device reprocessors argue the contrary.

Define β as the ratio of failure probabilities of the different device types: $\beta \equiv p_n/p_r$. Assuming that new devices have some positive probability of failure but are not more likely to fail than reprocessed devices means that $0 < \beta \leq 1$. Using this definition of β , we can express the cost functions of all different policies in terms of p_n . Doing so allows us to find the point at which are indifferent between various policies, as shown in the following proposition.

Proposition 2.2 *With respect to the failure probability of a reprocessed device, there is a single point, β^* , at which the decision maker is indifferent between new and reprocessed devices:*

$$\beta^* = \frac{C_f p_n}{C_n - C_r + C_f p_n}. \quad (7)$$

If $p_n/p_r < \beta^$, then it is optimal to choose a new device, and if $p_n/p_r > \beta^*$, then it is optimal to choose a reprocessed device.*

Proof Choose two policies which differ by action in only one state—for example, $\theta_2 = [r, n]$ and $\theta_4 = [n, n]$. Equating the cost functions of these two policies (see Table 1) will indicate the point at which we are indifferent between a new device and a reprocessed device in state 0:

$$\begin{aligned} & [C_r(1 - p_n) + (C_n + C_f)p_r]/[(1 - p_n) + p_r] \\ & = [C_n(1 - p_n) + (C_n + C_f)p_n]/[(1 - p_n) + p_n]. \end{aligned}$$

Substituting $p_r = \beta p_n$ in the above equation and solving for the indifference point yields Eq. 7. A comparison of policies $\theta_1 = [r, r]$ and $\theta_3 = [n, r]$ yields the same result. Similarly, comparing $\theta_3 = [n, r]$ and $\theta_4 = [n, n]$ or $\theta_2 = [r, n]$ and $\theta_1 = [r, r]$ produces the same expression for state 1. $\square$

According to Proposition 2.2, if the failure probability of a reprocessed device is more than $1/\beta^*$ times greater than the failure probability of a new device, then the new device is preferred. The figure below illustrates how the ratio of the failure probabilities and the indifference point, β^* , change as a function of the failure probability of a new device, p_n . When $p_n/p_r < \beta^*$ it is optimal to choose a new device; otherwise, a reprocessed device is optimal.

This result enables the decision maker to answer such questions as: How much *more* likely to fail would a reprocessed device need to be to make a new device preferable? As shown in Figure 2, as the failure probability of a new device (p_n) increases, the value of β^* also increases, i.e., using a reprocessed device becomes more favorable. If the cost of a new device (C_n) increases, then the denominator of Eq. 7 increases, so reprocessed devices become more attractive. Increasing the failure cost (C_f) or the cost of a reprocessed device (C_r) causes β^* to increase, meaning that new devices are more attractive.

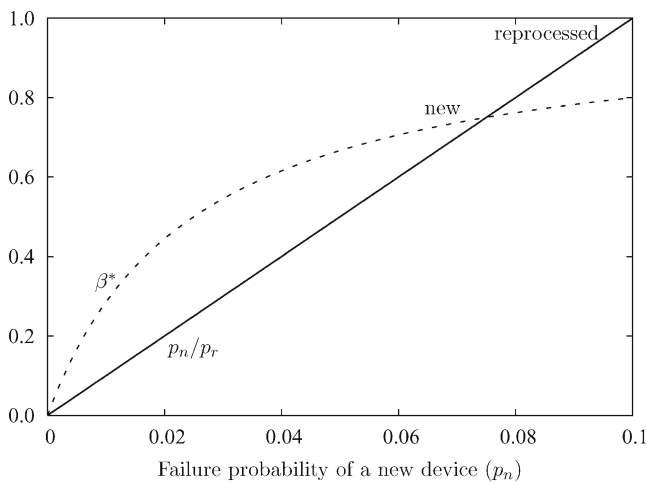


Fig. 2 β^* and p_n/p_r as a function of p_n

2.5 The impact of failure penalty cost

The other key model parameter to consider is the failure penalty cost, C_f . Provided that new devices have higher cost but lower failure probability as compared to reprocessed devices, one might wonder how high the penalty cost would have to be for new devices to be preferred over reprocessed devices. Following the same pattern as above, the following proposition indicates the indifference point between new and reprocessed devices.

Proposition 2.3 *With respect to the device failure cost, there is a single point, C_f^* , at which the decision maker is indifferent between new and reprocessed devices:*

$$C_f^* = \frac{C_n - C_r}{p_r - p_n}. \quad (8)$$

If $C_f > C_f^*$, then it is optimal to choose a new device, and if $C_f < C_f^*$, then it is optimal to choose a reprocessed device.

Proof Choose two policies which differ by action in only one state—say, $\theta_2 = [r, n]$ and $\theta_4 = [n, n]$. Equating the cost functions of these two policies (see Table 1) will indicate the point at which we are indifferent between a new device and a reprocessed device in state 0:

$$\begin{aligned} & [C_r(1 - p_n) + (C_n + C_f)p_r]/[(1 - p_n) + p_r] \\ &= [C_n(1 - p_n) + (C_n + C_f)p_n]/[(1 - p_n) + p_n]. \end{aligned}$$

Solving the above equation for C_f yields Eq. 8, indicating the indifference point. Similarly, comparing policies $\theta_1 = [r, r]$ and $\theta_3 = [n, r]$ will produce the same result,

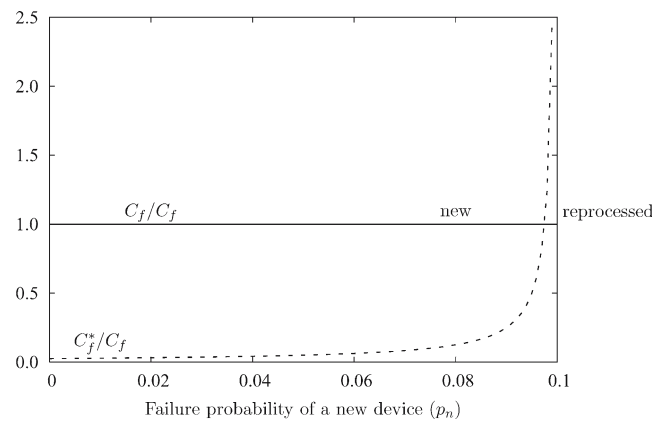


Fig. 3 C_f^*/C_f and C_f/C_f as a function of p_n

and comparing $\theta_3 = [n, r]$ and $\theta_4 = [n, n]$ or $\theta_2 = [r, n]$ and $\theta_1 = [r, r]$ will produce the same result for state 1. $\square$

Figure 3 illustrates how the indifference point, C_f^* , changes as a function of the failure probability of a new device, p_n . The value of C_f is also plotted, and the C_f^* function is normalized by C_f . If $C_f^*/C_f < 1$, then using a new device is optimal; otherwise, using a reprocessed device is optimal.

The impact of the other model parameters on C_f^* is fairly straightforward. As evident from the figure, an increase in the failure probability of a new device (p_n) causes C_f^* to increase, making reprocessed devices more desirable. As the cost of a new device (C_n) increases, the numerator of Eq. 8 also increases; thus, reprocessed devices become more attractive. An increase in the cost of a reprocessed device (C_r) causes C_f^* to decrease, making the use of new devices preferable. Similarly, an increase in the failure probability of a reprocessed device (p_r) causes C_f^* to decrease, also making the use of new devices preferable.

2.6 Optimality of “pure” policies

This model differs from the traditional maintenance model in that the decision maker is not really deciding whether or not to maintain a specific device; that is, a different device is used each period, but one must decide whether the device is new or reprocessed. Thus, the transition probabilities are “reset” at each decision epoch. Intuitively, we would expect that if action a^* is optimal in state 0, then it must also be optimal in state 1, since the transition probabilities and expected costs are the same. The following proposition confirms this intuition.

Proposition 2.4 *The optimal policy is a “pure” policy; that is, if action a^* is optimal for state 0, then it is also optimal for state 1.*

Proof The proof is by contradiction. Suppose that a “mixed” policy is optimal, say $\theta_3 = [n, r]$. Therefore, the expected cost of θ_3 must be less than that of θ_4 :

$$[C_n(1 - p_r) + (C_r + C_f)p_n]/[(1 - p_r) + p_n] < [C_n(1 - p_n) + (C_n + C_f)p_n]/[(1 - p_n) + p_n].$$

Simplifying the expression above, we see that for the inequality to hold we must have

$$C_f < (C_n - C_r)/(p_r - p_n). \quad (9)$$

For θ_3 to be optimal, its expected cost must also must be less than that of θ_1 :

$$[C_n(1 - p_r) + (C_r + C_f)p_n]/[(1 - p_r) + p_n] < [C_r(1 - p_r) + (C_r + C_f)p_r]/[(1 - p_r) + p_r].$$

Simplifying this expression yields

$$C_f > (C_n - C_r)/(p_r - p_n). \quad (10)$$

Clearly, both Eqs. 9 and 10 cannot hold. If Eq. 9 holds, then by Proposition 2.3 a reprocessed device is preferred, and $\theta_1 = [r, r]$ is optimal. If Eq. 10 holds, then a new device is preferred, and $\theta_4 = [n, n]$ is optimal. Thus, only a “pure” policy can be optimal. $\square$

2.7 Device-dependent failure costs

Up to this point, the failure penalty cost parameter has been assumed to be independent of device type. However, one can imagine circumstances for which this

would not be the case—for example a patient harmed by the use of a reprocessed device might choose to sue the reprocessor in addition to the other entities involved. To examine this possibility, several modifications are required. First, we modify our notation slightly by defining C_{fa} as the failure penalty cost of device type a , where $a \in \{r, n\}$. Define the ratio of the two penalty costs as $\gamma \equiv C_{fn}/C_{fr}$.

In addition, we must modify the expected cost functions to account for device-dependent failure costs. At first glance, simply replacing C_f with either C_{fn} or C_{fr} in the cost functions listed in Table 1 would appear to be sufficient. However, consider a policy like $[r, n]$, where a reprocessed device (action r) is used in state 0. If the device fails, then we would expect to incur a cost of C_{fr} , and we would proceed to use a new device (action n). But what if the new device fails? There is no mechanism to include both C_{fn} and C_{fr} using the existing cost functions.

Before the cost functions can be modified, it is useful to augment the definition of the state. Specifically, let $(i, \hat{a})$ be the new state definition, where as before i indicates the current device state (“functional” or “non-functional”) and $\hat{a}$ indicates the device type employed at the last decision epoch. This expanded state definition allows us to address the issue of which failure penalty to assess: in state $(1, r)$, the penalty C_{fr} is incurred, and in state $(1, n)$, the penalty C_{fn} is incurred.

Using this expanded state definition, the transition probability matrix for the $[r, n]$ policy becomes

$$[p_{ij}^{a_i}] = \begin{bmatrix} 0 & 0 & 1 - p_r & p_r \\ 1 - p_n & p_n & 0 & 0 \\ 0 & 0 & 1 - p_r & p_r \\ 1 - p_n & p_n & 0 & 0 \end{bmatrix},$$

and the expected cost function for policy $[r, n]$ is

$$\frac{C_r p_r (1 - p_n) + (C_n + C_{fn}) p_r p_n + C_r (1 - p_r) (1 - p_n) + (C_n + C_{fr}) p_r (1 - p_n)}{(1 - p_n) + p_r}. \quad (11)$$

Note that the denominator of Eq. 11 is the same as the corresponding equation in Table 1, but the numerator has changed substantially to reflect the device-dependent failure penalties. The expected cost function of policy $[n, r]$ is similar to Eq. 11, while the cost functions for policies $[r, r]$ and $[n, n]$ are unchanged from the expressions in Table 1.

The following proposition identifies the indifference point between new and reprocessed devices with respect to the failure penalty cost.

Proposition 2.5 *With respect to the failure penalty cost, there is a single point, γ^* , at which the decision maker is indifferent between new and reprocessed devices:*

$$\gamma^* = \frac{C_{fn} p_r}{C_n - C_r + C_{fn} p_n}. \quad (12)$$

When $C_{fn}/C_{fr} < \gamma^$, a new device is preferred; when $C_{fn}/C_{fr} > \gamma^*$, a reprocessed device is preferred.*

Proof Choose two policies which differ by action in only one state—for example, $\theta_2 = [r, n]$ and $\theta_4 = [n, n]$. Equating the cost functions of these two policies will indicate the point at which we are indifferent between a new device and a reprocessed device in state 0 (see Eq. 11 and Table 1). Substituting $\gamma = C_{fn}/C_{fr}$ and solving for the indifference point yields Eq. 12. A comparison of any two policies that differ only by the action specified in state 0 will produce the same expression. Similarly, comparing any two policies that differ only by the action specified in state 1 will yield the same expression for state 1. $\square$

Note that the policy definition specifies the action for both state (i, r) and (i, n) . For example, $[r, n]$ requires that action r be taken in both state $(0, r)$ and $(0, n)$. The policy definition could be modified to allow a different action in each of the four states. But as long as the two policies being compared differ by only one action in one state, then the results do not change: there is a single switching point, and γ^* has the same form as Eq. 12.

Figure 4 illustrates how the indifference point, γ^* , changes as a function of the failure penalty cost of a new device, C_{fn} . If $C_{fn}/C_{fr} < \gamma^*$, then a new device is optimal; otherwise, a reprocessed device is optimal.

This result allows a healthcare provider to answer questions like: How much *more* would the failure penalty cost of a reprocessed device need to be to make a new device preferable? As evident from the graph, as the failure cost of a new device (C_{fn}) increases, γ^* increases. For a given value of C_{fr} , reprocessed devices become more desirable as C_{fn} increases. An increase in the failure probability of a new device makes γ^* smaller, and, other things being equal, makes

reprocessed devices more attractive. Similarly, an increase in the failure probability of a reprocessed device makes γ^* larger, making new devices more desirable. As the cost difference between new and reprocessed devices increases, the denominator of Eq. 12 increases and therefore γ^* decreases. Other things being equal, this makes reprocessed devices more desirable.

The indifference point expressions derived earlier change only slightly as a result of the device-dependent failure penalty. Using the modified cost expressions, and following the same approach outlined in Proposition 2.1, the indifference point regarding product cost becomes:

$$\alpha^* = \frac{C_n + C_{fn}p_n - C_{fr}p_r}{C_n}. \quad (13)$$

If $C_{fn} = C_{fr}$, then the above equation becomes Eq. 6. Similarly, using the same approach used in Proposition 2.2 with the modified cost expressions yields

$$\beta^* = \frac{C_{fr}p_n}{C_n - C_r + C_{fn}p_n}, \quad (14)$$

the indifference point with respect to the failure probabilities. As one might expect, the above equation becomes Eq. 7 when $C_{fn} = C_{fr}$. Finally, we observe that the conclusion of Proposition 2.4 still holds: only “pure” policies are optimal, i.e., $[n, n]$ or $[r, r]$.

2.8 Numerical examples

As discussed previously, medical device reuse is a complex ethical, economic, and legal issue. Currently, the data necessary to implement the model are not collected—at least systematically. However, one need not know the exact parameter values to make use of the model for rough-cut analysis. The following examples illustrate how the model can be used to help guide the study of this complex problem.

Example 1: orthopedic blades

A variety of blades are used in orthopedic surgery to cut tissue and bone. According to available data, the cost of a new blade is typically about \$30, and a reprocessed blade costs roughly \$15 [5]. Using the notation above, this means that $C_n = \$30$ and $C_r = \$15$. Suppose that the probability that the new device fails is $p_n = 0.000001$, i.e., there is a one-in-a-million chance of malfunction, infection, etc. Suppose further that the failure penalty cost is $C_f = \$1$ million. Employing Eq. 7 we see that the failure probability indifference point is $\beta^* = 0.0625$. Thus, according to the model, the reprocessed device would have to be more than 16 times

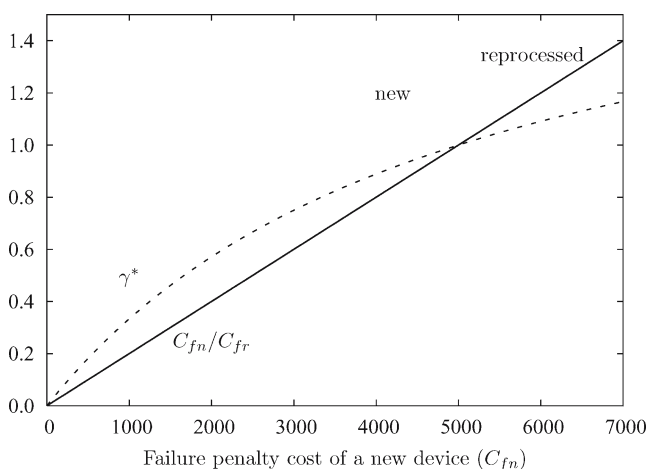


Fig. 4 γ^* and C_{fn}/C_{fr} as a function of C_{fn}

more likely to fail than the new device in order to make the new device optimal (since $1/0.0625 = 16$). Given that such a large increase in failure probability is unlikely, there is a strong argument in favor of reuse, especially if doing so allows the healthcare provider to treat more patients.

Example 2: cardiac catheter

Cardiac catheters are thin plastic tubes which are inserted into a patient's heart to diagnose various functions. A new catheter costs about \$280, and a reprocessed catheter costs approximately \$60—clearly, a significant cost savings [5]. In the model notation, we have $C_n = \$280$ and $C_r = \$60$. Suppose that the failure probability of the new device is $p_n = 0.001$ and that the reprocessed device is 10 times more likely to fail, so $p_r = 0.01$. Using Eq. 8 to compute the failure penalty cost indifference point yields $C_f^* = \$24,444$. In other words, if the actual penalty cost is less than \$24,444, then a reprocessed device is preferred to a new device. The nature of the procedure, however, is such that any malfunction could have catastrophic consequences. Thus, it may not be worth the additional risk to use a reprocessed device in this context, despite the significant cost savings.

Example 3: compression sleeve

Compression sleeves are worn on a patient's arm or leg to improve blood circulation. New sleeves cost approximately \$120 [5]. Suppose that the risk of failure (in this case probably an infection) is very small, say $p_n = 0.0000001$, and suppose that the failure penalty cost is $C_f = \$1$ million. Suppose that a reprocessed device is 10 times as likely to fail, so $p_r = 0.000001$. Making use of Eq. 6 to compute the device cost indifference point yields $\alpha^* = 0.9925$. This means that as long as the reprocessed device cost is less than \$119.10 ($= 0.9925 \times \120), then the reprocessed device is preferred. In fact, reprocessed sleeves can cost as little as \$11 [5], suggesting that reuse is worth considering in this context.

Example 4: trocar

A trocar is a sharp instrument used to create an opening in the body for endoscopic or laparoscopic procedures. New trocars cost about \$115, while reprocessed units cost only about \$30 [5]. Thus, we have $C_n = \$115$ and $C_r = \$30$. If the failure probability of the new device is $p_n = 0.001$, and the reprocessed device is 10 times more likely to fail, then $p_r = 0.01$. Suppose that the failure

penalty cost for a new device is $C_{fn} = \$10,000$. The indifference point with respect to the failure penalty cost can be determined using Eq. 12, which yields $\gamma^* = 1.053$. This result means that the failure penalty for a new device would have to be *greater* than the failure penalty for a reprocessed device in order to prefer the reprocessed device. Put differently, as long as $C_{fn} \leq C_{fr}$, then $C_{fn}/C_{fr} < \gamma^*$, and using a new device is optimal. Intuitively it seems likely that this condition will be met, which means that new devices are preferable even accounting for the tremendous cost savings provided by the reprocessed devices.

3 Discussion and conclusions

Reprocessing of single-use medical devices is an increasingly popular practice to help reduce healthcare costs. This paper has presented a Markov decision process model examining the choice between using new and reprocessed medical devices. The goal of the decision maker is to minimize the long-run expected average cost, given the key parameters of device costs, device failure probabilities, and failure penalty costs. For each of these parameters, expressions were developed which identify the indifference point between new and reprocessed devices, and it was shown that there is a unique switching point for each.

As stated previously, the purpose of the model is to shed light on the discussion about using reprocessed devices. Clearly, some costs are difficult to estimate, especially the failure costs, so exact analysis is difficult. However, healthcare providers can use the model for rough-cut analysis of different scenarios, and it may be used to confirm intuition about different kinds of devices. For example, one may be able to see a clear distinction between Class III items such as angioplasty catheters that are high risk or difficult to sterilize and Class I items such as saw blades that are easier to reprocess. The numerical examples in Section 2.8, which rely on actual cost data and estimated failure probabilities, illustrate how the model could be used for this purpose. In addition, the model could be useful in terms of decisions about pricing, i.e., how much one is willing to pay for certain devices.

Device reprocessing also involves important policy issues. Specifically, reimbursement to hospitals from Medicare and insurance companies is based on pre-determined rates for different procedures. Thus, the reimbursement for a particular procedure is not tied directly to the actual cost. This creates an incentive for hospitals to pursue ways to save money on devices, because these savings go directly into their pockets.

As mentioned previously, physicians are not always involved in the decision about whether or not to use reprocessed devices, but new “gainsharing” programs may change this situation. Gainsharing allow physicians to share in any cost savings achieved for a particular procedure, creating an incentive to give cost considerations more weight [44]. A surgeon participating in such a program can benefit financially by choosing less expensive devices and may therefore favor using reprocessed SUDs. In this situation, the physicians and hospitals both need to evaluate the costs and benefits of reprocessing.

The model can also be used to study device reuse issues from the device makers’ perspective. The OEMs obviously have an incentive to encourage healthcare providers to buy new devices. The device makers’ primary use of the model would be to examine pricing questions: How much lower would the cost of a new device need to be in order to make it preferable to the reprocessed device? In fact, there is evidence that reprocessing already influences the prices charged by device makers [45]. A systematic study of the problem would enable OEMs to be more proactive with respect to pricing. The model could also be used to study the impact of improved reliability, e.g., how much more reliable does the new device need to be as compared to a reprocessed device?

The reprocessing firms would also benefit from objective analysis of the issues. Reprocessors clearly have an incentive to encourage the use of reprocessed devices, so they can use the model to answer questions like: Given the failure probability trade-off point, what is the maximum failure probability such that it is still optimal to use a reprocessed device? By framing the debate in terms of risk relative to the original device, reprocessors may be able to persuade key decision makers. The model could also provide guidance in terms of pricing for the reprocessed devices.

In addition, government agencies, politicians, and concerned citizens will also benefit from a systematic analysis of medical device reuse. Sponsors of research could use the model to identify areas of study most likely to produce useful results. Currently, there is a great deal of medical research focused on the details of reprocessing for specific devices—e.g., sterilization procedures, material properties, etc. However, if certain device categories are deemed to be too risky to reprocess (i.e., the potential costs far outweigh the benefits), then resources can be shifted to studying device categories that will provide more value for patients and healthcare providers. While some questions regarding reprocessing may be studied effectively by individual firms, partnerships between medical research institu-

tions, the device makers, and the reprocessors may create synergies that produce more insight and benefit to all parties. Furthermore, regulatory agencies and research institutions may be the only parties with the necessary objectivity to evaluate the safety of device reprocessing. Insights gleaned from using the proposed framework would better enable regulators to impose standards on the industry—for example, by specifying reliability data requirements for device makers and reprocessors.

The model developed in this paper represents a first step in the exploration of a complex issue; however, there are many other questions and issues related to decision support for device reuse that deserve attention but that are beyond the scope of the current study or require additional tools. For example, the current model could be extended to include more than two states by expanding the non-functional state to include outcomes like mild infection, severe infection, and major catastrophe. Assigning appropriate likelihoods and penalties to these different outcomes would allow healthcare providers to perform more refined analyses.

Other decision support tools can be brought to bear on other aspects of the problem. For example, decision trees could be used to evaluate various alternatives—not only the question of whether or not to reprocess, but also the question of which supplier(s) to use. Simulation models would be effective in studying different reuse strategies. For a given device type or design, how many times could each device be refurbished and reused safely? Computer simulations would allow more detailed examination of specific devices and provide the ability to perform “what-if” analysis at a much lower cost than physical tests in a laboratory.

Beyond the question of whether or not reprocessing should be pursued, there are many questions about how to make the practice work effectively. For all of the decision makers, the issue of supply chain design is critical. Is it possible to structure win-win partnerships between the different links in the chain? For example, rather than simply criticizing reprocessing, perhaps device makers could think about how they might participate in the process. This could involve partnerships between device makers and hospitals or between device makers and reprocessors. Alliance Medical, a major reprocessor, has teamed up with Nellcor, an OEM of pulse oximetry equipment, to refurbish certain devices [45]. The results of this partnership will be an important indicator of the benefits and viability of cooperation. Perhaps hospitals should reclaim some portion of the sterilization and reprocessing efforts that have been outsourced to third parties. For example, what about those devices that have been opened but not actually

Table 2 Data for figures

Parameter	Figure 1 Value(s)	Figure 2 Value(s)	Figure 3 Value(s)	Figure 4 Value(s)
p_n	0.1	[0, 0.1]	[0, 0.1]	0.1
p_r	0.2	0.1	0.1	0.2
C_n	[0, 5,000]	1,000	100	1,000
C_r	500	750	75	500
C_f	5,000	10,000	10,000	n/a
C_{fn}	n/a	n/a	n/a	[0, 7,000]
C_{fr}	n/a	n/a	n/a	5,000

used? Perhaps reprocessors could handle different devices differently. There is typically a single stream of incoming devices, but perhaps a binning and sorting process would help assure better quality and help allay the concerns of patients and healthcare providers. Vanguard Medical Concepts, another major reprocessing firm, has partnered with some hospitals and persuaded them to pre-sort used devices in order to facilitate reprocessing [45]. The management science field has much to contribute in this area, and the existing research on design and operation of closed-loop supply chains is particularly relevant. Game-theoretic models, such as those mentioned in Section 1.2, can help identify situations that make partnerships advantageous. In addition, once a relationship is established, firms must cope with the details of operating the supply chain. Network optimization models using integer programming and other techniques can be used to manage the complex flows of new, used, and refurbished devices in the expanded supply chain [46].

Decision support for reprocessing also extends to the fields of engineering, materials science, and manufacturing system design. Device makers may pursue designs that facilitate reprocessing, for example by using stainless steel rather than plastic. On the other hand, some applications may require the flexibility of plastic, making reprocessing more challenging. Thus, the design question is not simply about which material is best for a given procedure but also involves the expectations regarding reprocessing and reuse. Furthermore, device makers may choose to discourage reprocessing by designing devices that are difficult or impossible to reprocess. Design specifications, including the materials used, will undoubtedly have a major impact on the manufacturing processes.

Clearly, patient safety is of paramount importance, but the growing cost of healthcare raises serious questions about the economic sustainability of our current practices. In addition, the enormous amounts of waste generated by our healthcare system raises questions about its environmental sustainability. What role can

reprocessing play in addressing these issues? No model can provide the definitive answer for such a complex issue. However, systematic analysis of the trade-offs involved can help shed light on different aspects of the problem and help inform the debate about medical device reuse.

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Appendix

Table 2 reports the parameter values used to generate the figures in the paper. Numbers in square brackets indicate a range of values.

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