THIRD PARTY REPROCESSING

A COLLABORATIVE INITIATIVE

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The reprocessing and reuse of single use medical devices (SUD's) as an alternative to disposing is a small but expanding industry in Canadian hospitals. The growth is a result of many hospitals continuing the practice of reprocessing single use medical devices in the institutions' central processing department; a practice that does not adhere to FDA standards. Many hospitals are using and/or considering third party reprocessing which is proven to be cost effective and provides and equivalent if not higher level of sterility assurance (Furman, 1998).

Third party reprocessors are defined as a facility that is regulated by an organization such as the Food and Drug Administration (FDA). They are not regulated by Health Canada but are registered with the FDA and therefore reprocess single use medical devices to the same quality system requirements as the original equipment manufacturer (OEM).

Health Canada has recognized four (4) classes of medical devices based on the level of control necessary to assure the devices safety and effectiveness (Wikipedia, 2008). Third party reprocessors reprocess single use medical devices, Class 1, Class 11 categories to the same quality systems requirements as the original equipment manufacturer and assures the devices remain safe and effective for the appropriate clinical uses.

Third party reprocessors have adopted rigorous and stringent practices to ensure the reprocessed devices perform as effective as original. One hundred percent (100%) of the devices are inspected to ensure functional testing and

undergo the same standard that leading medical device manufacturers are mandated to adhere to (SterilMed, 2007).

Currently there are no Canadian third party reprocessing facilities, however, there are Canadian based affiliates which are regulated by the US Food and Drug Administration. There are two (2) main affiliates that have a distinct variation in their operations. One ensures that there is no co-mingling of products and institutions are guaranteed return of their original devices. The alternate company boasts a rapid turnaround, however, items are pulled from a vast product inventory that directly contravenes Health Canada's regulations.

Provincial and territory governments (health regions) are responsible to develop the required policies, procedures, and recommendations for the re-use of reprocessed single use medical devices (OHS, 2004). Health Canada Scientific Advisory Panel has endorsed guidance to health care facilities on ways to minimize the risk to patients.

Third party reprocessors recognize that not every device is eligible for reprocessing, amounting to only a small percentage of the thousands of medical devices used. They do not take title to the device(s) but simply return the device(s) to the organizations that have requested their services. First and foremost, it is a way to maintain the highest quality of patient care while achieving significant cost savings. With respect to cost savings the benefits of third party reprocessing are clear- IT SAVES MONEY!

A conservative estimate cost savings for a hospital with 100%

compliance is targeted at $500/medical/surgical bed. For example a 400 bed facility would generate an annual savings of $200,000/year. These numbers, however, do not address disposal costs, which are currently absorbed by the facilities. A national survey reported statistically it offers a range of 30-50% cost savings as compared to purchasing new devices. Hospitals avoid considerable expense associated with establishing their own in house reprocessing facilities. Regulated third party reprocessors report lower operating costs that can offer hospitals services a significant cost savings, which provides the opportunities for reallocation of monies for staff education. A $100,000 cost savings can result in a minimum of 3000 pounds of medical waste eliminated annually from our landfills, significantly benefiting our environment.

The hospital's malpractice insurance will demonstrate a reduction as third party reprocessors are members of the Association of Medical Device Reprocessors (AMDR) and maintain a minimum of five million ($5,000,000) liability insurance. This coverage is substantially greater than any original manufacturer (OEM) and hospitals can have a greater level of assurance that third party reprocessors are held to the same manufacturers standards as OEM's (Williamson, May, 2007). In addition to regulatory compliance, third party reprocessors adhere to fundamental safety principles defining them as industry leaders (AMDR.org.,nd). To date, no liability claims have been made by any institution using third party reprocessing.

A custom business plan is offered to organizations by third party reprocessors verifying their effectiveness in generating the highest savings in the

industry. If this business plan is proven beneficial to both the organization and health care consumer, why is there resistance to its implementation?

The most significant misunderstanding relating to third party reprocessing by organizations is the integrity and safety of the reprocessed medical device(s) for patient use by healthcare professionals. We, as healthcare professionals, lack a clear and concise understanding on the quality assurance met by third party reprocessors on SUD's (Selvey, 2008). "Many also may not realize that labeling a device single use is sometimes simply a marketing strategy on the part of the OEM, since the identical or nearly identical device(s) may have been manufactured previously as a reuseable device"(Selvey, 2008 pg. 1).

When healthcare organizations support the implementation of third party reprocessing it concurs the savings of hundreds of thousands of healthcare dollars annually, demonstrates a national growth working cohesively with industry partners, reduces waste practices; sound management of a greener environment and most importantly assures healthcare consumers that reprocessed medical devices are clean, functional and sterile as when originally manufactured.

Third party reprocessors work independently with each healthcare facility to customize a reprocessing program individualized to their needs. The following steps outline a brief projection for implementation.

STEP ONE

Pick up at healthcare facility.

Devices are logged and prepped for pickup by onsite facility personnel.

STEP TWO

Sorting and logging of devices

Devices are labeled with barcodes and entered into a database for internal tracking to ensure ownership.

STEP THREE

Reprocessing

100% of devices are function tested and packaged all passing through three inspections (sterilized, quarantined, final inspection)

Devices that fail to meet the state of the art validation testing are rejected and reported to the institution and discarded with no cost incurred.

STEP FOUR

Pre-return inventory check

Shipping inventories are prepared for each container returning to the organization for tracking

STEP FIVE

On time shipping

Guaranteed return of sterile devices to the originating site

In the small but expanding market place of third party reprocessors, there is growing recognition in Canada with over 400 eastern hospitals utilizing this validated process (SterilMed, Inc., 2008).

Nationally, healthcare organizations are responsible in the delivery of safe and attainable healthcare to the population. Additionally, they must remain

vigilant in controlling escalating healthcare costs demonstrating transparency to the healthcare consumer.

Third party reprocessors initiatives should be embraced as an extension of the multidisciplinary healthcare team with a main focus of reducing costs associated with medical devices, medical wastes, and providing the gold standard of medical care. Organizations need to be acutely aware and compliant to the quality improvement programs that are available and successfully implemented throughout the healthcare industry. These product industries are continuously striving for improved delivery without compromising patient safety and healthcare organizations need to be educated in regards to the resources available for improved health services to the consumer.

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