Re-use of Single Use Devices
Implications for Hospitals

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Sudha Kutty,
Director, Patient Safety and Clinical Best Practice
Ontario Hospital Association
Agenda

• About OHA
• Current Drivers against re-use:
  – Data
  – Policies
  – Media/Public
• Implications
• Moving forward
About the OHA

• We are a hospital association of health care providers dedicated to the continuing improvement of health services in Ontario, through leadership, advocacy, education, communication and service.

• Our membership includes:
  – All the public hospitals in Ontario
  – Approximately 200 associate and affiliate members, such as:
    • Community Care Access Centres
    • Association of Health Care Centres
    • Organizations responsible for Women’s Health, AIDS, youth support services and senior citizen centres
    • Several health research organizations and for-profit health care providers and companies
Drivers

- Data
- Re-use of SUDs
- Policies/Guidelines
- The media/public
Data
• Only 28% of hospitals re-process SUDs
• Of those, 85% do so internally (as opposed to going to a third party)
• Of those who do not re-process SUDs, 81% had done so in the past
• The budgetary impact of moving to SUDs is minimal when the probability of adverse events is factored into the analysis
What the data doesn’t tell us

- Whether SUDs can be safely reprocessed
- The cost of using a third party reprocessor versus the cost of moving to single use devices
Policies
• OHA Position paper on the Re-use of Single Use Medical Devices (January 2004) recommended:

• That within a two year time frame, hospitals stop internally reprocessing critical and semi-critical Single Use Medical Devices (SUDs)
Recommendations

- The OHA supported the external reprocessing of SUDs by specialized third party reprocessors regulated by Health Canada
- The OHA recognized that Third Party Reprocessors were not currently regulated in Canada
- In the current absence of Canadian regulation of Third Party Reprocessors, the OHA recommended that hospitals should show due diligence in researching Third Party Reprocessors that are regulated by the United States Food and Drug Administration (FDA) and whose reprocessing procedures for the device have received FDA approval
Recommendations

• OHA supported the reprocessing of critical and semi-critical SUDs by regulated Third Party Reprocessors provided that the following criteria were met:
  • Device tracking and labeling
  • The ability to recall reprocessed devices
  • Proof of sterility or high level disinfection
  • Pyrogenicity testing
  • Maintenance of device functionality and integrity
  • The presence of quality assurance and quality control programs
  • The ability to report adverse events
  • Proof of good manufacturing procedures
2008 Standards for Reprocessing and Sterilization of Re-usable Medical Devices

- 8.1 The Team prevents the on-site reprocessing or sterilization of single use devices

CCHSA standards for reprocessing and sterilizing reusable medical devices will be available in April 2008 for organizations being surveyed in 2009. CCHSA Board approval on these standards is expected in April 2008.
• Ontario Provincial Infectious Diseases’ Committee’s Best Practice Manual- Cleaning, Disinfection and Sterilization in all Health Care Settings (April 2006)
• Guidelines on Single-Use Medical Equipment/Devices
  – Critical and semi-critical medical equipment/devices labeled as single-use must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor.
  – Needles must be single-use and must not be reprocessed.
– It is strongly recommended that catheters, drains and other medical equipment/devices with small lumens (excluding endoscopy equipment) be designated single-use and not be reprocessed and reused.

– The health care setting must have written policies regarding single use medical devices

• Other provinces have similar policies/regulation
Media and Public
Media and the Public

  – “Alberta health authorities have closed a Vegreville hospital to new admissions and most visitors after the spread of a bacterial-resistant superbug and the discovery that some patients may have been exposed to HIV and hepatitis during surgeries performed with dirty tools. The equipment sterilization room at St. Joseph's General Hospital was shut down Friday -- though it was first directed to do so more than one month ago -- after a recent audit found bits of flesh and blood left on tools and inside scopes used to examine patients and take tissue samples. Those tools weren't properly scrubbed and brushed inside and out before being sterilized, and were then used on other patients, inspectors discovered. "We believe the risk is very low," said Dr. Gerhard Benade, the medical health officer for the East Central Health Region. At worst, fewer than one per cent of patients who had certain surgeries are at risk of having been infected by a blood-borne pathogen, he said.”
  – “How on earth is it possible that it took a month -- an entire month! -- for St. Joseph's General Hospital in Vegreville to comply with orders to close a facility that was failing to properly clean and sterilize surgical tools? And for that matter, how is it possible in an era of "superbugs" - - decades after it became universally understood that hygiene is key to preventing the transmission of infections -- that such a closure order could ever become necessary? Bits of human flesh left on tools, for heaven's sake! Even if one has never been under the knife, the skin crawls at the thought of being subjected to hospital standards that sound more in keeping with our image of rural Africa than one of the richest, proudest, most medically sophisticated jurisdictions on the planet.
Implications
Implications of the CADTH report for hospitals

• Do not internally reprocess critical and semi-critical Single Use Medical Devices.

• If you are currently internally reprocessing SUDs, start figuring out how to stop:
  – Use this data as a driver for change
  – Use infection control to champion the issue
  – Use the increasing focus on transparency and accountability as a driver for change

• Go there before you are led there
But our work is not yet finished
Moving Forward

• March 2004 Federal Auditor General’s Report reviewed the regulation of medical devices
• AG fairly critical of Health Canada’s regulation of medical devices and on the issue of re-use found:
  – “Health Canada is taking only limited action to address the risks posed by the reuse of single-use devices. As one of the entities responsible for protecting the health and safety of Canadians, it must take action immediately.”
AG noted that in the US, reprocessors of SUDs are subject to the same regulatory requirements as the original device manufacturers:
- “...it is important that Health Canada as the federal regulator take action to manage the health and safety risk related to the re-use of single use medical devices.”

→ Recommendation: Health Canada should take action, such as **regulating reprocessed single use devices**, to manage the health and safety risks related to the reuse of single use medical devices.
Moving Forward

• More than ¼ of the country continues to re-use SUDs
• If we really want to move the entire country away from re-use of single use devices, we need federal regulation of reprocessing
• This will prevent hospitals from reprocessing these devices themselves
• It will bring federal oversight and regulation to the third party reprocessors who are currently reprocessing devices
Contact Information

Sudha Kutty
Director, Patient Safety and Clinical Best Practice

Phone: 416-205-1415
Fax: 416-205-1337
Email: skutty@oha.com