Reuse of SUDs: Using Evidence to Inform Policy

Implications for Health Policy

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CADTH Symposium
Edmonton, AB, April 28, 2008
NEW EVIDENCE TO INFORM POLICY DECISIONS

1. CADTH Survey and Technology Report (2008)
   • Updated information on current practices in Canada
   • Review of health risks
   • Detailed economic analysis
   • Experience with Third Party Reprocessing services

2. US experience with regulated reprocessing of SUDs
   • Regulations introduced in 2000
TRENDS IN HOSPITAL REUSE

Reuse of SUDs by hospitals has declined significantly in recent years.

- 1986: 66% of large hospitals (> 200 beds) reused SUDs
- 2001: 40% of surveyed hospitals reused some SUDs
- 2008: Only 28% of hospitals still reuse some SUDs (CADTH survey)
CURRENT ENVIRONMENT IN CANADA

• Many hospitals have adopted a “no reuse” policy.

• US-based third-party reproprocessors (TPRs) provide contract services to some Canadian hospitals. TPRs have US FDA authorization. Reprocessing is done in US.

• 15% of Canadian hospitals that reuse SUDs have them reprocessed by TPRs.

• Several Provincial or Territorial Ministries now have policies on reuse and some recommend using licensed TPRs.
THE ISSUES

Policy makers must consider a number of factors in deciding whether to allow reuse:

1. Safety concerns
2. Technical issues
3. Economic benefit
4. Legal liability
5. Ethical responsibility
6. Regulatory requirements
1. SAFETY CONCERNS

HOW SAFE DO REPROCESSED SUDs HAVE TO BE?

Reprocessed SUDs are in theory not as safe as new ones

BUT

No reprocessed device is as safe as a new one.

It is probably more realistic to compare the safety of reprocessed SUDs to the safety of reprocessed reusables.

Reprocessed reusables are a greater potential risk, since many more patients are exposed to them than to reused SUDs.
1. SAFETY CONCERNS

HOW SAFE ARE REPROCESSED SUDs?

• It is difficult to determine risk because incidents of adverse patient outcome are seldom linked to the specific device used in a procedure, or whether it was new or reused.

• Reused SUDs do not appear to be more hazardous in clinical use than other devices
  • (CADTH, 2008): “Insufficient evidence to suggest or rule out harm.”
  • US Government Accountability Office (2008): “Available information does not indicate that reuse of SUDs presents an elevated health risk.”
2. TECHNICAL ISSUES

HOW CAN STERILITY AND FUNCTION OF A REPROCESSED SUD BE ASSURED?

• There are no instructions for reprocessing SUDs
• Hospitals lack necessary equipment and training
• Many SUDs cannot be disassembled for proper cleaning
• Some plastic materials cannot withstand heat or chemicals
• Delicate mechanical and electronic components may fail
• Devices are hard to track to monitor number of reuses
3. ECONOMIC BENEFIT

DOES REUSE REALLY SAVE MONEY?

- Savings per procedure depends on cost of new device
- Reusing low-cost devices may not really save money

IS REUSE CHEAPER IF ALL HIDDEN COSTS ARE INCLUDED?

- CADTH report calculates break-even point at which increased liability cost of adverse events would erase purchase cost savings
4. LEGAL LIABILITY

• IS IT ILLEGAL TO USE A DEVICE CONTRARY TO THE MANUFACTURER’S INSTRUCTIONS?
  – No. There are no Federal or Provincial regulations governing “off-label use” of medical devices. Provincial Ministries may issue directives on specific cases.

• DOES REUSE OF AN SUD INCREASE THE RISK OF CIVIL LITIGATION FOR A HOSPITAL?
  – Perhaps. But hospitals must already manage liability for all their operations. Most civil suits have concerned alleged negligence in using reusable devices.
  – In any case, the hospital would have to show it had followed an ‘appropriate standard of care’. This ‘appropriate standard of care’ could include reusing SUDs, if hospital has a policy on it.
5. ETHICAL RESPONSIBILITY

SHOULD A HOSPITAL TELL PATIENTS THAT IT REUSES SUDS?
- Most experts suggest this is a level of detail that need not be mentioned.

SHOULD PATIENTS BE GIVEN THE CHOICE OF HAVING A NEW OR A REUSED SUD FOR THEIR PROCEDURE?
- Patients are usually given a choice of having the procedure or not having it. They don't have a choice of the devices to be used.
- Often, the care giver cannot know beforehand whether the SUD will be new or reprocessed.
- Most patients would want a new SUD, but they would probably want a new reusable device if they knew about problems in reprocessing reusables.
6. REGULATORY REQUIREMENTS

WHO HAS THE AUTHORITY TO REGULATE REUSE?
– Provincial and Territorial Health Ministries
– Under the current *Food and Drugs Act*, Health Canada has no authority to regulate the reuse of SUDs.

WHAT REGULATIONS OR DIRECTIVES EXIST?
– Six of 13 Canadian jurisdictions now have directives.
– No Health Canada regulations.
PROVINCIAL AND TERRITORIAL POLICIES

QUEBEC
(1996) Issued an advisory against reuse of cardiac catheters and pacemakers.
Quebec is currently drafting an updated policy on reuse

MANITOBA
(1999) Banned reuse of “critical contact” SUDs (those contacting blood or sterile body cavities)

NORTHWEST TERRITORIES
(2005) Banned reuse of any device labelled as single-use
PROVINCIAL AND TERRITORIAL POLICIES (continued)

BRITISH COLUMBIA
(2007) As of January 1, 2008, critical contact SUDs must not be reused unless reprocessed by a third-party reprocessor licensed by Health Canada or other regulator (e.g., USFDA)

NEW BRUNSWICK
(2007) As of October 31, 2008, hospitals must not reprocess critical or semi-critical contact SUDs. Hospitals must not reuse SUDs unless they are reprocessed by a third-party reprocessor licensed by a regulatory authority (e.g., USFDA)

ALBERTA
(2008) As of February 1, 2008, critical or semi-critical SUDs shall not be reused unless reprocessed by a third party reprocessor who ensures the device is safe and functional. (Exemption: Semi-critical SUD used on same patient in home care.)
F/P/T WORKING GROUP ON REUSE

- Federal, Provincial and Territorial Assistant Deputy Ministers of Health established a Working Group in 2007 to draft a pan-Canadian framework on the reuse of SUDs.

- Framework can be used by Provinces and Territories to develop policies in their own jurisdictions.

- F/P/T WG has drafted a consensus document with a recommendation to submit it to the Conference of Deputy Ministers of Health for endorsement.
CONCLUSIONS

- Reuse of SUDs in Canada is declining
- The consensus of advice is that hospitals should not reprocess SUDs themselves
- A consensus on reuse policy is emerging:
  - Several Provinces have issued directives on reuse, and more are expected in the near future
  - The pan-Canadian Framework on reuse may be endorsed by the Conference of Deputy Ministers of Health
RESOURCE DOCUMENTS ON REUSE POLICY


