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POLICY BRIEF

Addressing Barriers to Medical Device Repair in Canada

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The Problem:

The repair and maintenance of medical devices are critical to ensuring the efficiency, affordability, and reliability of healthcare delivery in Canada. However, restrictive practices by medical device manufacturers and increasing sophistication of device design are limiting hospitals' ability to independently repair their equipment, creating challenges that undermine patient care, hospital operations, and broader healthcare system sustainability.

Drawing from interviews with biomedical engineering technologists, legal experts, and hospital administrators, as well as recent high-profile examples from the United States, this briefing highlights the key barriers to medical device repair in Canada and proposes preliminary recommendations for policy intervention.

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About the MacEachen Institute

The MacEachen Institute for Public Policy and Governance at Dalhousie University is a nationally focused, non-partisan, interdisciplinary institute designed to support the development of public policy and encourage greater citizen engagement.

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Barriers to Medical Device Repair

The barriers to repairing software-dependent medical devices can be grouped into three major categories:

1) Technical Barriers

Device vendors often restrict access to replacement parts, proprietary software, and service information, effectively monopolising the repair process. Many devices require specialised software updates, diagnostics, or replacement parts that are unavailable to hospital technicians.

Vendors also rely on digital service keys for access to repair and service information, which are often only made available to technicians who have completed costly certification training. In recent years, vendors have begun to limit or discontinue these certification programs altogether, forcing hospitals to rely exclusively on them for repair and servicing. When vendor technicians are unavailable or are required to travel long distances, this dependency can lead to treatment delays and rescheduling, jeopardising time-sensitive medical procedures while increasing costs.

2) Legal Barriers

Vendors' assertion of intellectual property rights, trade secrets, and restrictive contractual terms further entrench these challenges. Exclusivity clauses in procurement contracts, non-disclosure agreements, and end-user license agreements prevent hospitals and independent technicians from accessing repair resources in various ways.

In some cases, vendors will refuse to service or support medical devices if they have been repaired, modified, or touched by an independent or third-party technician. Misinterpretations of federal regulations also compound these issues, with some vendor spreading misinformation relating to the competence of in-house technicians, impacts on patient safety, privacy, or misconstruing whether certain repairs are permitted by Health Canada.

3) Economic Barriers

Vendor-controlled repair monopolies drive up costs. Multi-year exclusive service contracts from vendors can cost hospitals up to 10 times more than in-house repair options. Hospitals and health authorities often feel pressured to enter into these agreements out of fear that a lack of access to replacement parts and certification training may render in-house repair impossible regardless. Ultimately, these increased expenses, when multiplied across the diverse range of devices in a hospital, strain budgets and divert resources away from patient care.

Impact on Healthcare Delivery

Restrictive repair practices have direct and systemic consequences for Canadian healthcare:

- **Patient Safety and Care Delays:** Hospitals unable to perform immediate repairs face critical delays in patient care. For example, if a heart-lung machine breaks down and the hospital must wait for a vendor technician, patients requiring open-heart surgery may have their procedures postponed, with life-threatening consequences.
- **Increased Costs:** Mandatory vendor service contracts inflate costs for hospitals, contributing to Canada's rising healthcare expenses. This financial burden reduces funds available for other essential services and technologies.
- **Reducing the Value of In-House Expertise:** The expansion of vendors' role in providing exclusive repair and servicing of medical devices has come at the cost of in-house and independent technicians. Left unaddressed, these dynamics risk undermining and sidelining biomedical engineering technicians, wasting valuable expertise and reducing demand for independent expertise across the country. This has the potential to produce negative ripple effects into the future, where hospitals and health authorities become entirely dependent on device vendors for daily operations.

Comparative Insights from the U.S.

The situation in Canada mirrors troubling trends observed in the US, as highlighted by recent developments:

- The Federal Trade Commission (FTC) has cited monopolistic repair practices by companies like John Deere in the agricultural sector, which have forced farmers to wait weeks for authorized repairs. Similar dynamics are emerging in healthcare, as evidenced by Terumo Cardiovascular's decision to revoke certifications for hospital technicians, leaving hospitals dependent on the vendor's repair network.
- During the COVID-19 pandemic, some US hospitals resorted to pirating repair software from overseas and 3D printing replacement parts to address urgent needs when vendors could not meet repair demands. This resulted in calls for the federal Critical Medical Infrastructure Right-to-Repair Act of 2020, the first attempt to address right to repair legislation at the federal level in the United States. Organisations like iFixit, who sought to provide access to medical device repair information for free online, were also met with legal threats from device vendors. This underscores the risk of systemic failure during emergencies if independent repair options for critical medical infrastructure are blocked by vendors.

Preliminary Recommendations

While further research is needed to formulate comprehensive policy recommendations, the following areas warrant immediate attention:

1) Enhancing Cooperation with Vendors

Policymakers should promote partnerships between hospitals, vendors, manufacturers, and third-party providers through regulations requiring that repair processes are collaborative rather than monopolistic. Mandating vendor training and certification programs for hospital technicians could restore some of the balance between maintaining proprietary control and empowering in-house and third-party repairs.

2) Regulatory Clarifications and Amendments

Federal regulators should address ambiguities in the Medical Devices Regulations under the Food and Drugs Act. Health Canada must provide clear guidance on permissible repair activities and actively counter misinformation propagated by vendors. Legislative measures should ensure that intellectual property rights do not unjustly hinder lawful repairs by in-house technicians or suppress fair market competition from third parties.

3) Expanding Right-to-Repair Protections

Canada should explore adopting right-to-repair legislation specific to the healthcare sector, ensuring that hospitals have access to the tools, software, certification training, and resources needed to repair devices. Inspiration can be drawn from FTC recommendations and the broader movement advocating for repair rights in other industries in collaboration with device vendors and industry groups.

4) Strengthening Capabilities

Despite the enormous headwinds, investment in hospital biomedical engineering teams is essential. This includes ensuring access to training, spare parts, and service information, which will reduce reliance on OEM service contracts and mitigate repair delays. These technical capabilities must be accompanied by scrutiny and clarification from contracts and procurement departments working in health authorities and hospitals, who need to develop right to repair guidelines and requirements which all device vendors must meet at the time devices are being purchased.

Conclusion

The barriers to repairing software-dependent medical devices pose a critical challenge to the Canadian healthcare system. Restrictive vendor practices compromise patient care, inflate costs, and waste valuable technical expertise. Addressing these issues will require coordinated action from federal regulators, hospitals, vendors, and manufacturers, alongside the development of robust right-to-repair protections in law and through public health procurement policy.

The Unlocking Healthcare Research Team welcomes further insights and recommendations to advance this critical discussion. If you have expertise or perspectives to contribute, please contact us using the information below. Together, we can ensure that Canada's healthcare system remains resilient, efficient, and patient-focused.