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Room Upper 9

## Injury and Liability Associated With Implantable Devices for Chronic Pain

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**Background:** Implantable drug delivery systems (IDDS) and other implantable devices for the management of chronic pain have been used since the early 1990s. Morbidity and mortality from IDDS and spinal cord stimulators typically result during surgical phases (implantation or removal of devices) or during maintenance (1,2) with higher mortalities particularly associated with intrathecal drug (opioid) delivery (3). We investigated liability associated with devices used to manage chronic pain.

**Methods:** After IRB approval, we identified 941 chronic pain claims of which 142 were related to devices and care that occurred in the year 1990 or later from the Anesthesia Closed Claims Project Database of 10,367 claims. Fisher's exact test, chi-square analysis, and Independent Samples Mann-Whitney U Test were used to analyze differences in device claims with  $P < 0.05$  for statistical significance.

**Results:** The most common devices were IDDS ( $n=90$ , 63%) of which 38 claims were for maintenance of IDDS. Although 64% of all patients with device-related claims experienced temporary or minor injuries, 57% of IDDS maintenance claims ( $p < 0.001$ ) experienced either death (18%) or severe permanent injuries (39%) with 13% of claims resulting in severe permanent brain damage. Death and brain damage in maintenance claims resulted from medication administration errors, e.g., pocket and side port-fills ( $n=7$ ), programming errors ( $N=6$ ), and wrong drugs ( $N=3$ ), while spinal cord injury was the result of delayed recognition of granuloma formation ( $n=9$ ).

One hundred and four claims were for surgical events: 41 (29%) were for spinal cord stimulators (39 for implantation and 2 for removal), 52 (50%) for IDDS (44 for implantation and 8 for removal), and 11% for other devices (tunneled catheters = 8 and peripheral stimulators = 3). Permanent severe injury occurred in 24% of claims related to nerve stimulators. Claims for implantation or replacement of IDDS resulted in death (12%) and permanent severe injury (24%). The most common damaging events for implantation and replacement of all devices were infections ( $n=24$ ) and needle trauma to cord or cauda equina ( $n=10$ ) and for removal of devices was retained catheter fragments ( $n=6$ ).

Care was assessed as less than appropriate in 76% of IDDS maintenance claims, compared to 43% of all other device claims ( $p=0.001$ ). Payment was made in 62% of the IDDS maintenance claims compared to 34% of all other device claims ( $p=0.003$ ). The median payment was highest for claims for IDDS maintenance (\$334,526) and lowest for the removal of IDDS (\$67,304).

**Conclusions:** The maintenance of IDDS was associated with death, permanent brain damage, or permanent neurological injury from granuloma and was largely associated with substandard care resulting in payment. The majority of the substandard care associated with maintenance of these pumps involved medication administration errors and failure to recognize progressive neurological deterioration. Surgical phases of device implantation were associated with infections or permanent neurological injury from poor surgical technique involving needle trauma to cord or cauda equina. These findings demonstrate the need for providers to exercise caution in these areas in order to avoid potential severe complications.

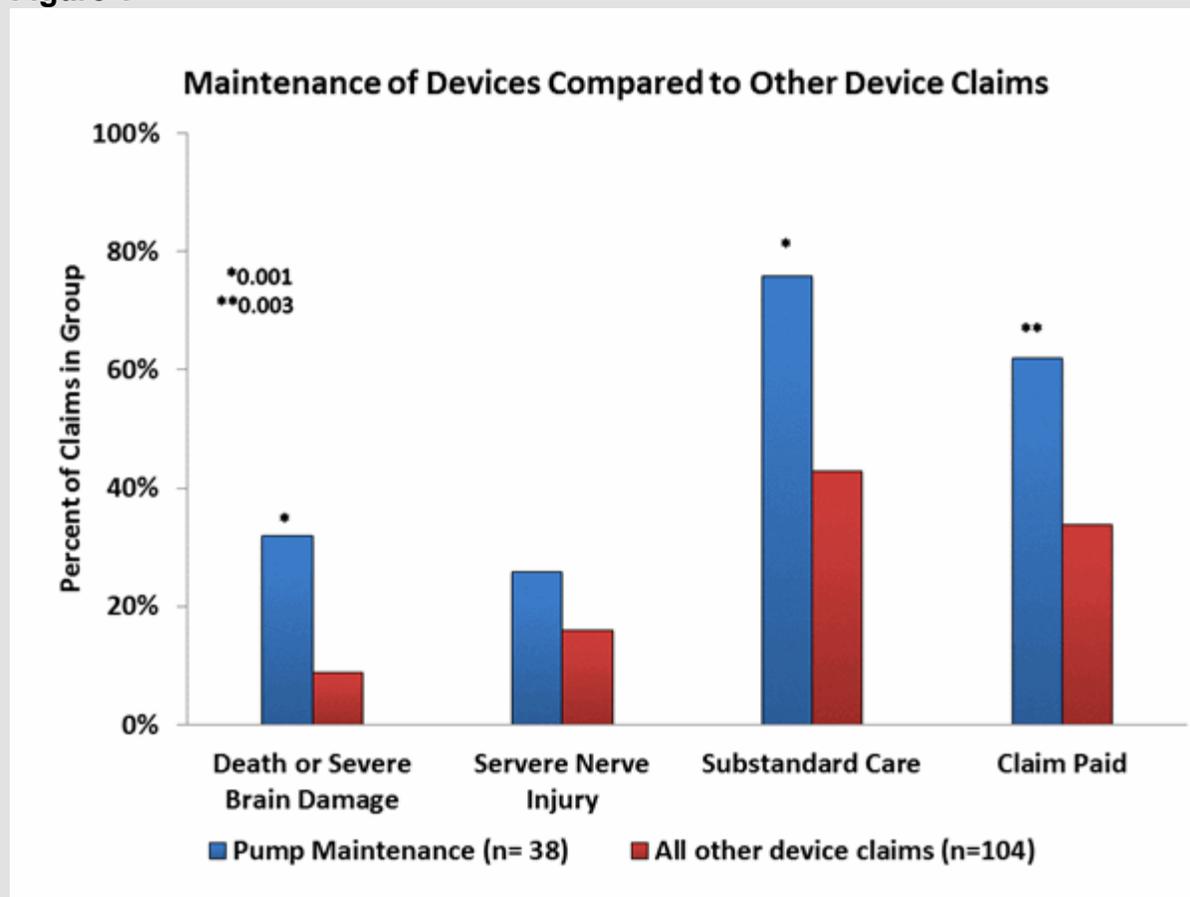
References:

1 Deer TR: Neuromodulation 2012 15(5) 467-82

2 Turner JA, Clin J Pain 2007 23 180-195

3 Coffey RJ: Anesthesiology 2009 111(4) 881-891

**Figure 1**



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