Appendix 1 – full summary of International Classification of Disease (ICD) -10 codes

|  |  |
| --- | --- |
| **ICD-10 code** | **Count** |
| Y75.8 - Neurological devices associated with adverse incidents - Miscellaneous devices, not elsewhere classified  | 295 |
| R52.9 Pain, unspecified | 110 |
| T85.7 Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts | 55 |
| T81.0 Haemorrhage and haematoma complicating a procedure, not elsewhere classified | 7 |
| R51 Headache | 6 |
| T81.2 Accidental puncture and laceration during a procedure, not elsewhere classified | 5 |
| Blank  | 4 |
| I64 Stroke, not specified as haemorrhage or infarction | 3 |
| R11 Nausea and vomiting | 3 |
| T80 Complications of surgical and medical care, not elsewhere classified | 3 |
| G41 Status epilepticus | 2 |
| G97.0 Cerebrospinal fluid leak from spinal puncture | 2 |
| R20.2 Paraesthesia of skin | 2 |
| R25.2 Cramp and spasm | 2 |
| R57.2 Septic shock | 2 |
| W19 Unspecified fall | 2 |
| W86 Exposure to other specified electric current | 2 |
| Y61.0 Foreign object accidentally left in body during surgical and medical care during surgical operation | 2 |
| A49.0 Staphylococcal infection, unspecified site | 1 |
| A49.9 Bacterial infection, unspecified | 1 |
| D34.9 Malignant neoplasm, primary site unspecifiedC80.9 Malignant neoplasm, primary site unspecified | 1 |
| F45.9 Somatoform disorder, unspecified | 1 |
| G82.2 Paraplegia, unspecified | 1 |
| G83.1 Monoplegia of lower limb | 1 |
| G83.2 Monoplegia of upper limb | 1 |
| I26 Pulmonary embolism | 1 |
| I15.8 Other secondary hypertension | 1 |
| I61.9 Intracerebral haemorrhage, unspecified | 1 |
| M54.5 Low back pain | 1 |
| Not enough information | 1 |
| R06.0 Dyspnoea | 1 |
| T09 Other injuries of spine and trunk, level unspecified | 1 |
| T81.9 Unspecified complication of procedure | 1 |
| W88 Exposure to ionizing radiation | 1 |
| Z42.2 Follow-up care involving plastic surgery of other parts of trunk | 1 |
|  | 524 |

Appendix 2 – Full summary of event subtypes

|  |  |  |  |
| --- | --- | --- | --- |
| **Subtype Device** | Count | **Subtype Patient** | Count |
| Lead migration | 59 | Pain at the implant site | 68 |
| Lead fracture | 28 | Infection - not specific | 52 |
| Device positioned poorly | 23 | Protrusion through skin | 30 |
| Device faulty - not specified | 21 | Stimulation ineffective | 25 |
| Lead issue - not specified | 18 | Painful overstimulation | 14 |
| Device malfunctioning | 17 | Painful burning sensation at implant site | 10 |
| High impedance | 17 | Headache | 7 |
| Pulse generator failure | 15 | Pain in other body part | 6 |
| Lead positioned poorly | 8 | Dural tear | 5 |
| Lead damaged during procedure | 5 | Haematoma | 5 |
| Lead damaged from a fall | 4 | Paraesthesia | 4 |
| Blank | 4 | Neurological deficit | 3 |
| Device damaged during other procedure | 3 | Numbness in body part | 3 |
| Difficult implant leading to prolonged procedure | 2 | Pain exacerbated | 3 |
| Lead disconnection | 2 | Infection - MRSA | 2 |
| No stimulation | 2 | Sepsis | 2 |
| Not enough information | 2 | Seizure | 2 |
| Part of device left insitu | 2 | Abdominal pain and autonomic dysfunction | 1 |
| Unable to turn device off | 2 | Cramping | 1 |
| Charger cannot connect to device | 1 | CSF leak | 1 |
| Device flipped inside pocket | 1 | CVA and incontinence | 1 |
| Device malfunctioning in certain environments | 1 | CVA during procedure | 1 |
| Device overheating | 1 | CVA shortly after procedure | 1 |
| Device turning off | 1 | CVA some time after | 1 |
| Difficult explant leading to parts being left inside the patient | 1 | Dural tear and incontinence | 1 |
| Exposed wires  | 1 | DVT | 1 |
| Extension lead ineffective | 1 | Epidural haematoma | 1 |
| IPG migration | 1 | Excessive bleeding post op | 1 |
| Lead failure (not specified) | 1 | Extreme pain and sensory loss in leg following implant | 1 |
| Lead fraying | 1 | Foreign body left in epidural space | 1 |
| Lead not inserted into IPG | 1 | Incontinence | 1 |
| Lead did not fit into splitters (discovered mid surgery) | 1 | Knees gave way causing a fall (now in coma) | 1 |
| Lead not secured properly | 1 | Leg spasms | 1 |
| Other fault | 1 | Nausea | 1 |
| Suspected lead fracture | 1 | Nausea and dizziness | 1 |
| Unclear | 1 | Pain not relieved | 1 |
|  |   | Pain when turning head | 1 |
|  |   | Patient dissatisfied - not specified | 1 |
|  |  | Persistent headaches | 1 |
|  |  | Removal of granuloma | 1 |
|  |  | Post op swelling | 1 |
|  |  | Psychosomatic paralysis | 1 |
|  |  | Pulmonary embolism | 1 |
|  |  | Sensation of electric shock | 1 |
|  |  | Seroma | 1 |
|  |  | Shortness of breath | 1 |
|  |  | Trauma to cervical spine | 1 |
|  |  | Tumour growth inside pocket | 1 |
|  |  | Vomiting | 1 |

Appendix 3 – Full summary of actions taken in response to events.

|  |  |
| --- | --- |
| **Action taken** | Count |
| Single surgical intervention | 383 |
| Single surgical intervention and IV antibiotics | 21 |
| Multiple surgical intervention | 16 |
| Admitted to hospital for medical management including IV antibiotics | 13 |
| Single surgical intervention and antibiotics | 12 |
| Admitted to hospital for medical management | 9 |
| Not stated | 9 |
| Single surgical intervention (planned) | 9 |
| None | 7 |
| Medical management | 5 |
| Reprogramming of device | 5 |
| Blank | 4 |
| Hospital admission for rehabilitation | 3 |
| None - patient died | 3 |
| Prolonged surgery | 3 |
| Antibiotics | 2 |
| Hospital admission for blood patch | 2 |
| None - issue resolved | 2 |
| Conservative management of stroke | 1 |
| Epidural injection | 1 |
| Extended hospital admission for medical management | 1 |
| Induced coma | 1 |
| Intubation | 1 |
| Referral to a Neurologist | 1 |
| Multiple surgical intervention and IVABS | 1 |
| None - device left insitu but not usable | 1 |
| Prolonged hospital admission | 1 |
| Referral to a Cardiologist | 1 |
| Referral to a Pain Specialist | 1 |
| Referral to Surgeon | 1 |
| Part of bone removed | 1 |
| Prescribed rest and fluids | 1 |
| Referral to specialist (not specified) | 1 |
| Single surgical intervention and rehabilitation | 1 |

Appendix 4: Verbatim copies of the reports of the 5 events rated as Grade 5 (Death)

1) “A report was received that the patient will be undergoing palliative radiation therapy

for a large tumor located in the IPG pocket. The IPG pocket is located in the subclavicular

region of the chest. It was noted that a large dose of radiation is expected to

be directed to the IPG site. An explant was ruled out by the treating physician due to

the risk of the cancer spreading. The tumor was assessed as being unrelated to the

device. Additional information was received that the patient is now deceased. No

further information can be obtained regarding the patient's tumor.

Additional information was received that the patient's death was not device related.”

2) “A report was received that the patient was hospitalized 2 weeks post implant due to

suspected infection at the midline incision. The patient complained of not feeling

well. The patient’s wounds were checked and revealed one site having surface area

oozing, with no significant pus at the incision sites. Both incision sites were cleaned,

new dressings were placed and antibiotics were administered. The patient became

very unwell in the next 48 hours and was transferred to another facility. She was

explanted, intubated and required medication to stabilize her blood pressure. There is

no evidence to suggest the infection was device or procedure related. The physician

assessed the patient to have critical condition sepsis and he does not expect the patient

to survive.

Additional information was received that the patient passed away due to multiple

organ failure due to sepsis.

Sponsor update received 13/03/2018:

Additional information was received that the cultures taken in an effort to identify the

cause of the infection failed to grow, and the source of the infection was not

identified. It is unknown if the source was bacterial or fungal.”

3) “It was reported the patient experienced loss of sensation in their left leg following an

SCS implant procedure on 17 July 2018. CT scan revealed some air/fluid in the

subarachnoid space. Subsequently the patient regained sensation and mobility in the

leg. The physician stated the nerve fibers may have been irritated while gaining

access to the epidural space during the implant and the patient's symptoms were

improving. No further action taken at the time as the patient’s symptoms were

improving.

However, the patient passed away on 20 July 2018 due to Deep Vein Thrombosis

leading to a Pulmonary Embolism. The patient had co morbidities and the death was a

result of these co morbidities. The reason stated was the time spent on the table during

the procedure. Reportedly the issue was not related to the device.

24 August 2018: No additional information received”

4) “A patient was implanted on 24 Aug 2018 and was admitted for two days following

surgery as part of standard protocol. The final wound check prior to discharge was

unremarkable. On 27 Sep 2018 that patient died as an inpatient in Canberra Hospital

in Canberra, ACT due to septic shock, apparently secondary to infection of the IPG.

Upon follow up with physician's assistant, the patient began experiencing pain in the

right leg, approximately within the past 1-2 weeks prior to date of death. The patient

checked into the emergency department of Canberra Hospital on 23 Sep 2018 with

pain in right leg, radiating to right low back at the IPG pocket site. The physician was

notified of the patient's admission on 25 Sep 2018. Patient had an explant of the SCS

system on 25 Sep 2018 and died on 27 Sep 2018 due to sepsis.”

5) “It was reported to Nevro that the patient passed away. There were no reports of

device-related issues from the patient prior to the passing and the patient had been

receiving effective pain relief while using the device. Follow-up indicated that the

physician believes the patientâ€™s death was not related to the device.

Update 14/01/2019. The patient was implanted for back and leg pain. A review of the

complaint history record shows no reported issues from the patient prior to the

patientâ€™s death. The device diagnostic data shows the patient was regularly using

stimulation and charging the device since implant.”