THE INFECTION RATE AND RISK FACTORS FOR PATIENTS EXPERIENCING AN INFECTION FOLLOWING DEEP BRAIN STIMULATION IMPLANTATION: EVIDENCE FROM A LARGE US PAYER DATABASE

BACKGROUND
Deep Brain Stimulation (DBS) can be an effective treatment for patients suffering from a number of diseases that are resistant to medical management, such as Parkinson’s Disease and essential tremor.1,2 DBS uses a surgically implanted medical device to deliver carefully controlled electrical stimulation to precisely targeted areas in the brain. A retrospective single-center study focusing on infection rates reported overall infection rates between 2.8% and 9.1%,3 while prospective multi-center studies report infection rates between 4% and 9.9%, depending on study conditions and follow-up timeframe.1,2

OBJECTIVE
The objective of this study is to estimate the infection rate for all DBS-implanted patients and identify the risk factors associated with infection based on baseline characteristics.

METHODOLOGY

Data source
The Truven MarketScan® Commercial Claims (2009–2014) and Medicare Supplemental (2011–2014) databases were used for this study.

Study design

Inclusion criteria
• Patients with a claim for a DBS generator implant or replacement (at least one of the following ICD-9 or CPT codes: 96.94, 86.95, 86.98, 68185, 68866) during the study period. The date of the first observed DBS generator implant defined the index date for each patient.

• Patients were continuously enrolled for at least 24 months (12 months before and 12 months after the index date).

Exclusion criteria
Patients were excluded if they had an epilepsy diagnosis or had a diagnosis code indicating a neurostimulation therapy (ICD-9 code 946.32) during study period. This is because the CPT procedure code for DBS generator implant is also used to indicate a generator replacement for other cranial neurostimulation therapies, including VNS.

DBS infection definition
• All-cause infection list was developed through consultation with the Medtronic Neuromodulation Medical Safety team, starting with the conditions for which a medical safety investigation would be initiated.

• While these infections are not necessarily related to the implantation of a device (or the associated surgical procedure), this list was chosen as a comprehensive list to ensure consistency across review and reporting of infection.

The list of infections is shown in Table 1.

Table 1. List of infections for study

RESULTS

Overall, 5.48% of DBS patients had any infection of interest (Table 1), within 90 days after index date. The infection rate difference between the initial group (4.40%) and the replacement group (6.32%) is not statistically significant (P-value=0.0984).

Specifically, 1.68% of DBS patients had a diagnosis code indicating a neuro-device specific infection (ICD-9 code: 996.63) within 90 days after index date. The neuro-device specific infection rate difference between the initial group (1.32%) and the replacement group (1.95%) is not statistically significant (P-value=0.3338).

Using logistic regression to examine patients with all-cause infection, patients with musculoskeletal pain (OR, 1.841; 95% CI 1.128–3.024; P-value=0.0146), and previous infection in the 12-month period before index date (OR, 2.406; 95% CI 1.137–4.216; P-value=0.0022) are more likely to have any type of infection within 90 days after index date (Table 3).

Table 3. The result of logistic regression for any infection within 90 days of index

CONCLUSION
Using a large administrative dataset, 5.48% of DBS-implanted patients were found to have any type of infection within 90 days following implant. Factors identified that increased the risk of infection include musculoskeletal pain and prior evidence of infection. This analysis highlights an ongoing need for infection control practices when performing DBS implants. Future research is needed to guide clinical decision making.

REFERENCES