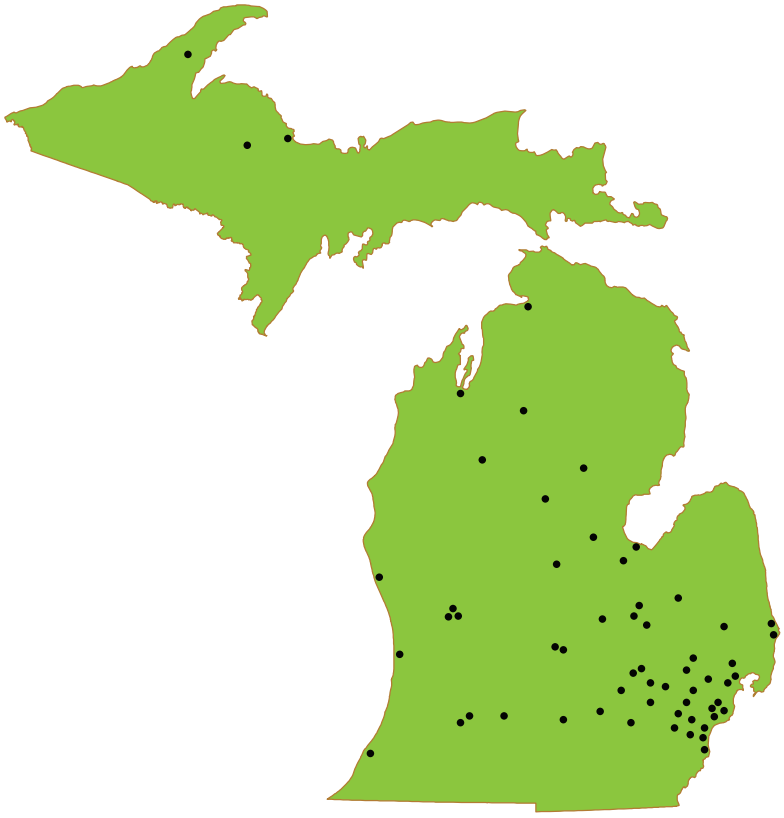
Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) Report: 2012 - 2016

November 2017

MARCQI Sites



Beaumont Hospital - Dearborn
Beaumont Hospital - Farmington Hills
Beaumont Hospital - Grosse Pointe
Beaumont Hospital - Royal Oak
Beaumont Hospital - Taylor
Beaumont Hospital - Trenton
Beaumont Hospital - Troy
Borgess Medical Center, Kalamazoo
Bronson-Battle Creek Health System, Battle Creek
Bronson Methodist Hospital, Kalamazoo
Covenant Medical Center, Saginaw
Crittenton Hospital Medical Center, Rochester
Garden City Hospital, Garden City
Genesys Regional Medical Center, Grand Blanc
Harper University Hospital, DMC, Detroit
Henry Ford Allegiance Health, Jackson
Henry Ford Health System, Detroit
Henry Ford Health-West Bloomfield, West Bloomfield
Henry Ford Health-Wyandotte Hospital, Wyandotte
Henry Ford Macomb Hospital, Clinton Township
Holland Hospital, Holland
Hurley Medical Center, Flint
Huron Valley-Sinai, DMC, Commerce Township
Lake Huron Medical Center, Port Huron
Lakeland Health, St. Joseph & Niles
McLaren Bay, Bay City
McLaren Flint
McLaren Greater Lansing
McLaren Lapeer Region, Lapeer
McLaren-Macomb, Mt. Clemens
McLaren-Northern Michigan, Petoskey
McLaren-Oakland, Pontiac
McLaren-Port Huron, Port Huron
Memorial Healthcare, Owosso
Mercy Health, Muskegon
Mercy Health, St. Mary's, Grand Rapids
MetroHealth Hospital, Wyoming
MidMichigan Medical Center, Midland
MidMichigan Medical Center, Clare
MidMichigan Medical Center, Gratiot
Munson Medical Center, Traverse City
Munson Healthcare, Cadillac
Munson Healthcare, Grayling
OrthoMichigan, Flint
Providence/Providence Park Hospitals, Southfield/Novi
Sinai Grace Hospital, DMC, Detroit
Sparrow Hospital, Lansing
Spectrum Health, Grand Rapids
St. John Hospital & Medical Center, Detroit
St. John Macomb Oakland Hospital, Warren
St. Joseph Mercy, Ann Arbor
St. Joseph Mercy, Chelsea
St. Joseph Mercy-Livingston, Howell
St. Joseph Mercy-Oakland, Pontiac
St. Mary Mercy Hospital, Livonia
University of Michigan Health System, Ann Arbor
UP Health - Marquette
UP Health, Bell - Ishpeming
UP Health, Portage - Houghton/Hancock
West Branch Regional Medical Center, West Branch

Suggested citation

Hughes, R.E., Hallstrom, B.R., Zheng, H., Kabara, J., Cowen, M., Igrisan, R., and Richmond, A. (2017) Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) Report: 2012-2016. University of Michigan, Ann Arbor.

Conflict of interest disclosure

None of the authors have financial relationships with the pharmaceutical or medical device industries.

Disclaimer

Although Blue Cross Blue Shield of Michigan and the Michigan Arthroplasty Registry Collaborative Quality Initiative work collaboratively, the opinions, beliefs and viewpoints expressed by the authors do not necessarily reflect the opinions, beliefs and viewpoints of BCBSM or any of its employees.

Preface

It is with great pleasure I write this foreword for the first annual report from Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI). I have been a registry nerd for many years and actively involved in the Swedish Hip Arthroplasty Register (SHAR) for more than 30 years.

One of the first fellows I was introduced to during my ten years at Massachusetts General Hospital and Harvard Medical School was Brian Hallstrom. Brian has been one of several key factors for initiating and getting the MARCQI registry up running. I have followed the development in Michigan and somehow feel I have a little responsibility for the project due to my influence on and interaction with Brian during his fellowship at MGH.

The basis for practicing medicine today is the principles of Evidence Based Medicine. A cornerstone in this concept is data collection, data mining and analyses of the data. From the mid 1970s until today there has been a global movement towards increasing use of regional and national registries. The hypothesis has been that feedback of analyzed data will result in use of proven concepts in the treatment we give our patients. In orthopaedics and specifically in joint replacement surgery we have unfortunately several examples in the past ten years with lack of compliance to the basics around evidence base practice.

The Nordic countries have been particular successful in starting national registries with high compliance from the surgical community. There have been several initiatives in the past 20 years to start joint replacement registries in USA, but the size of the project, legal and other issues have meant major difficulties for the initiative. Since a few years back the American Joint Replacement Registry (AJRR) has been more successful, working toward national coverage and expanding their initial dataset. An obvious alternative to a national registry in the United States is to start at the state level and thereafter aggregate data in a national database. The MARCQI registry is the role model for that type of implementation.

The current and first annual report from MARCQI is impressive and very informative. The results in Michigan are a perfect example of how structured reporting can result in improved quality and significant cost reduction. The collection of patient-reported outcome data will in next few years further improve the clinical results.

I congratulate the co-founders and co-directors Richard Hughes and Brian Hallstrom, the hard working group behind the MARCQI registry, the participating surgeons that allocate their valuable time to upload their data and all patients in Michigan that will benefit tremendously from this effort.

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Executive summary

The Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) is a collaborative dedicated to improving the quality of care for hip and knee replacement patients in Michigan. It has three goals: (1) improve patient safety in Michigan by promoting better outcomes, (2) enable surgeons and hospitals across the state to work together to improve quality, and (3) make Michigan the best place in the world to have a joint replacement. MARCQI is founded on the belief that health care quality is best improved by data-driven collaboration. These data can then be used for development, sharing, and learning of best practices in a non-competitive self-empowering framework. MARCQI started in 2012 and has grown rapidly. The Collaborative currently includes data from sixty-one hospitals and surgical centers across Michigan and it collects more than 95% of the hip and knee replacement cases done in the state. Funding is provided by Blue Cross Blue Shield of Michigan/Blue Care Network.

MARCQI is built on a patient registry that collects information on total hip and knee replacement cases performed in participating hospitals. As of the end of 2016, the registry contained 141,822 cases. The data are audited and linked across hospitals. Data elements include demographics, co-morbidities, outcomes, and implants. Outcomes such as infection, blood clots, and readmission are collected in a 90-day post-operative window. Re-operations required to remove or replace implants (“revision surgeries”) are tracked indefinitely. Risk-adjustment is performed to account for patient factors that affect outcomes, so comparisons between hospitals and between surgeons are not unduly affected by patient demographics.

Quality improvement opportunities are identified through analyses of registry data. The resulting quality improvement initiatives are prioritized by the leadership in close collaboration with the executive and medical advisory committees. Risk-adjusted data are provided to Collaborative members with overall rates and averages for comparison across institutions. Reports are provided to each hospital and dashboards are available online. The most important and powerful quality improvement tool is the Collaborative meeting. These meetings occur three to four times a year, and they involve members coming together to share project successes and challenges. Quality improvement activities have been conducted in the areas such as blood transfusion, nursing home discharges, infection prevention, dislocation reduction, and venothromboembolism prevention. The transfusion and tranexamic acid initiative, for example, reduced the risk of transfusion for total knee and hip replacement patients across the state from 7.0% to 1.4% and 14.2% to 3.4%, respectively.

MARCQI also conducts post-market surveillance of hip and knee implants, and this report provides implant-specific revision risks. Demographic and other relevant information (approach, head size, bearing, etc.) about the cases performed with each implant are provided. Reasons for revision are also captured and summarized for quality improvement.

Patient-reported outcome surveys (PROS) are also collected to characterize patient function and well being before and after surgery and to track improvement. PROS data collection started at a few hospitals and has grown across the Collaborative. The goal is to collect these data from patients being treated at all participating hospitals. Pain measured on a 10-point scale is shown to rapidly drop from an average of 6.4 pre-operatively to 2.1 by six to twelve weeks following surgery for hip replacements and from 6.1 to 2.8 for knee replacements. General health, as measured by the PROMIS-10 questionnaire, rapidly returns to the population mean.

Improving quality can also reduce costs by increasing appropriateness of care, reducing unnecessary utilization of resources, and reducing complications. For example, transfusion reduction has saved approximately $4 million annually. Reductions in readmissions and nursing home discharges have saved $1 million and $20 million annually, respectively. Quality improvement is a win-win activity for patients, providers, hospitals, and payers.

This document describes the origin, operation, and successes of MARCQI; it is intended to be used for quality improvement. It reports on data collected between February 15, 2012, and December 31, 2016.

Acknowledgements

We would like to acknowledge and thank Stan Mendenhall and Mendenhall Associates, Inc. for making their device library available for our data analysis, the California Joint Replacement Registry for early help, and the Michigan Health & Hospital Association for providing access to the Michigan Inpatient Data Base. Within the University of Michigan, we thank Sharon Vaassen of the Department of Orthopaedic Surgery for her instrumental contributions to creating MARCQI.

We are also grateful to the global community of arthroplasty registry directors and staff constituting the International Society of Arthroplasty Registries (ISAR) for mentorship and inspiration.

We appreciate the assistance in producing this report provided by Colleen McClorey (legal review), Camden Cheek and Owen Hughes (LaTeX programming), Mary Gumtow (proofreading), and Jasna Markovac (editing).

Support for the Michigan Arthroplasty Registry Collaborative Quality Initiative is provided by Blue Cross and Blue Shield of Michigan and Blue Care Network (BCBSM/BCN) as part of their Value Partnerships program. We express our gratitude to BCBSM/BCN staff who have pioneered the CQI model in Michigan and supported MARCQI (Marc Cohen, Rozanne Darland, Tom Leyden, David Share, Tom Simmer, and Monica Whitted) and the University of Michigan-BCBSM/BCN liaisons (John Billi, Joanne Kimata, and Carrie Miller).

Contents

1 Introduction **1**
1.1 Blue Cross Blue Shield of Michigan/Blue Care Network's Collaborative Quality Initiative program 1
1.2 Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) 2
1.3 MARCQI quality improvement philosophy 2
1.4 Organization 3
1.5 Collaborative meetings 5
1.6 Transparency 5
1.7 United States and international registries 6

2 Data quality and completeness **7**

3 Quality improvement initiatives **9**
3.1 Transfusion 9
3.2 Tranexamic acid 9
3.3 Nursing home discharges 10
3.4 Infection prevention 11
3.5 Venothromboembolism (VTE) prevention 13

4 Total hip arthroplasty statistics, devices, and revisions **15**
4.1 Descriptive statistics 15
4.2 Most commonly used implants 20
4.3 Revision risk summary 22
4.4 Revision risk for implant combinations 27

5 Total knee arthroplasty statistics, devices, and revisions **62**
5.1 TKA descriptive statistics 64
5.2 Most commonly used TKA implants 68
5.3 TKA revision risk summary 70
5.4 Revision risk for TKA implant combinations 75
5.5 UKA descriptive statistics 119
5.6 Most commonly used UKA implants 123
5.7 UKA revision risk summary 124
5.8 Revision risk for UKA implant combinations 129

6 Patient-reported outcomes **136**
6.1 Survey selection 136
6.2 Data collection 136
6.3 PROS scores 137
6.4 Appropriateness 138

7 Savings and value **140**
7.1 Reducing transfusions 141
7.2 Nursing home discharges 141
7.3 Preventing VTE 141
7.4 Readmission 142
7.5 Summary 142

Appendices

Appendix A Statistical methods **143**
A.1 Multi-level closed-loop data quality QC/QA 143
A.2 Time window, inclusion and exclusion criteria for the hip and knee chapters 144
A.3 Data structure for analytics 144

A.4 Definition of revision event for statistical modeling . . . 145
A.5 MARCQI cohort: Qualifying patients and events for descriptive statistics and implant survival analysis . . . 145
A.6 Descriptive statistics and visualization . . . 149
A.7 Kaplan-Meier: Unadjusted survival probabilities and cumulative percent revision rates (CPR) . . . 149
A.8 Cox's proportional hazards model . . . 149
A.9 Generalized linear mixed effect models (GLMM) . . . 150
A.10 Risk-standardized event rates (RSR) using registry database for performance profiling . . . 150
A.11 Database and software platform . . . 151

Appendix B Awards and publications **152**
B.1 Awards . . . 152
B.2 Journal publications . . . 152
B.3 Conference abstracts . . . 153

Appendix C Personnel and committees **155**
C.1 Personnel . . . 155
C.2 Committees . . . 155

List of Tables

1 Ten most commonly used femoral components in primary total conventional THA. . . . 20
2 Ten most commonly used acetabular components in primary total conventional THA. . . . 20
3 Ten most commonly used femoral/acetabular component combinations used in primary total conventional THA. 20
4 Most common reasons for revision following primary conventional THA. . . . 22
5 Most common reasons for revision following primary conventional THA in first year post-operatively. . . . 23
6 Most common reasons for revision following primary conventional THA in second year post-operatively. . . . 23
7 Most common reasons for revision following primary conventional THA in third year post-operatively. . . . 23
8 Cumulative percent revision for primary conventional THA (numerical values). . . . 24
9 Cumulative percent revision for primary conventional THA by diagnosis (numerical values). . . . 25
10 Cumulative percent revision for primary conventional THA by sex for osteoarthritis diagnosis (numerical values). 26
11 Summary of cumulative percent revision for stem/cup combinations having at least 500 cases, sorted alphabetically. . . . 27
12 Cumulative percent revision for Accolade II/Trident combination compared to all other conventional THA implants (numerical values). . . . 28
13 Descriptive statistics on cases receiving the Accolade II/Trident combination. . . . 28
14 Distribution of head size for Accolade II/Trident combination. . . . 29
15 Distribution of bearing surface for Accolade II/Trident combination. . . . 29
16 Distribution of approach used for Accolade II/Trident combination. . . . 29
17 Cumulative percent revision for Accolade TMZF/Trident combination compared to all other conventional THA implants (numerical values). . . . 30
18 Descriptive statistics on cases receiving the Accolade TMZF/Trident combination. . . . 30
19 Distribution of head size for Accolade TMZF/Trident combination. . . . 31
20 Distribution of bearing surface for Accolade TMZF/Trident combination. . . . 31
21 Distribution of approach used for Accolade TMZF/Trident combination. . . . 31
22 Cumulative percent revision for Anthology/Reflection 3 combination compared to all other conventional THA implants (numerical values). . . . 32
23 Descriptive statistics on cases receiving the Anthology/Reflection 3 combination. . . . 32
24 Distribution of head size for Anthology/Reflection 3 combination. . . . 33
25 Distribution of bearing surface for Anthology/Reflection 3 combination. . . . 33
26 Distribution of approach used for Anthology/Reflection 3 combination. . . . 33
27 Cumulative percent revision for Corail/Pinnacle combination compared to all other conventional THA implants (numerical values). . . . 34
28 Descriptive statistics on cases receiving the Corail/Pinnacle combination. . . . 34
29 Distribution of head size for Corail/Pinnacle combination. . . . 35
30 Distribution of bearing surface for Corail/Pinnacle combination. . . . 35
31 Distribution of approach used for Corail/Pinnacle combination. . . . 35
32 Cumulative percent revision for Fitmore/Continuum combination compared to all other conventional THA implants (numerical values). . . . 36
33 Descriptive statistics on cases receiving the Fitmore/Continuum combination. . . . 36
34 Distribution of head size for Fitmore/Continuum combination. . . . 37
35 Distribution of bearing surface for Fitmore/Continuum combination. . . . 37
36 Distribution of approach used for Fitmore/Continuum combination. . . . 37
37 Cumulative percent revision for M/L Taper/Continuum combination compared to all other conventional THA implants (numerical values). . . . 38
38 Descriptive statistics on cases receiving the M/L Taper/Continuum combination. . . . 38
39 Distribution of head size for M/L Taper/Continuum combination. . . . 39

40 Distribution of bearing surface for M/L Taper/Continuum combination. . . . 39
41 Distribution of approach used for M/L Taper/Continuum combination. . . . 39
42 Cumulative percent revision for M/L Taper/Trilogy combination compared to all other conventional THA implants (numerical values). . . . 40
43 Descriptive statistics on cases receiving the M/L Taper/Trilogy combination. . . . 40
44 Distribution of head size for M/L Taper/Trilogy combination. . . . 41
45 Distribution of bearing surface for M/L Taper/Trilogy combination. . . . 41
46 Distribution of approach used for M/L Taper/Trilogy combination. . . . 41
47 Cumulative percent revision for SROM/Pinnacle combination compared to all other conventional THA implants (numerical values). . . . 42
48 Descriptive statistics on cases receiving the SROM/Pinnacle combination. . . . 42
49 Distribution of head size for SROM/Pinnacle combination. . . . 43
50 Distribution of bearing surface for SROM/Pinnacle combination. . . . 43
51 Distribution of approach used for SROM/Pinnacle combination. . . . 43
52 Cumulative percent revision for Secur-Fit/Trident combination compared to all other conventional THA implants (numerical values). . . . 44
53 Descriptive statistics on cases receiving the Secur-Fit/Trident combination. . . . 44
54 Distribution of head size for Secur-Fit/Trident combination. . . . 45
55 Distribution of bearing surface for Secur-Fit/Trident combination. . . . 45
56 Distribution of approach used for Secur-Fit/Trident combination. . . . 45
57 Cumulative percent revision for Secur-Fit Max/Trident combination compared to all other conventional THA implants (numerical values). . . . 46
58 Descriptive statistics on cases receiving the Secur-Fit Max/Trident combination. . . . 46
59 Distribution of head size for Secur-Fit Max/Trident combination. . . . 47
60 Distribution of bearing surface for Secur-Fit Max/Trident combination. . . . 47
61 Distribution of approach used for Secur-Fit Max/Trident combination. . . . 47
62 Cumulative percent revision for Secur-Fit Plus Max/Trident combination compared to all other conventional THA implants (numerical values). . . . 48
63 Descriptive statistics on cases receiving the Secur-Fit Plus Max/Trident combination. . . . 48
64 Distribution of head size for Secur-Fit Plus Max/Trident combination. . . . 49
65 Distribution of bearing surface for Secur-Fit Plus Max/Trident combination. . . . 49
66 Distribution of approach used for Secur-Fit Plus Max/Trident combination. . . . 49
67 Cumulative percent revision for Summit/Pinnacle combination compared to all other conventional THA implants (numerical values). . . . 50
68 Descriptive statistics on cases receiving the Summit/Pinnacle combination. . . . 50
69 Distribution of head size for Summit/Pinnacle combination. . . . 51
70 Distribution of bearing surface for Summit/Pinnacle combination. . . . 51
71 Distribution of approach used for Summit/Pinnacle combination. . . . 51
72 Cumulative percent revision for Synergy/Reflection 3 combination compared to all other conventional THA implants (numerical values). . . . 52
73 Descriptive statistics on cases receiving the Synergy/Reflection 3 combination. . . . 52
74 Distribution of head size for Synergy/Reflection 3 combination. . . . 53
75 Distribution of bearing surface for Synergy/Reflection 3 combination. . . . 53
76 Distribution of approach used for Synergy/Reflection 3 combination. . . . 53
77 Cumulative percent revision for Taperloc 133/G7 combination compared to all other conventional THA implants (numerical values). . . . 54
78 Descriptive statistics on cases receiving the Taperloc 133/G7 combination. . . . 54
79 Distribution of head size for Taperloc 133/G7 combination. . . . 55
80 Distribution of bearing surface for Taperloc 133/G7 combination. . . . 55
81 Distribution of approach used for Taperloc 133/G7 combination. . . . 55
82 Cumulative percent revision for Taperloc 133/RingLoc+ combination compared to all other conventional THA implants (numerical values). . . . 56
83 Descriptive statistics on cases receiving the Taperloc 133/RingLoc+ combination. . . . 56
84 Distribution of head size for Taperloc 133/RingLoc+ combination. . . . 57
85 Distribution of bearing surface for Taperloc 133/RingLoc+ combination. . . . 57
86 Distribution of approach used for Taperloc 133/RingLoc+ combination. . . . 57

87 Cumulative percent revision for Trabecular Metal/Continuum combination compared to all other conventional THA implants (numerical values). . . . 58
88 Descriptive statistics on cases receiving the Trabecular Metal/Continuum combination. . . . 58
89 Distribution of head size for Trabecular Metal/Continuum combination. . . . 59
90 Distribution of bearing surface for Trabecular Metal/Continuum combination. . . . 59
91 Distribution of approach used for Trabecular Metal/Continuum combination. . . . 59
92 Cumulative percent revision for Trilock BPS/Pinnacle combination compared to all other conventional THA implants (numerical values). . . . 60
93 Descriptive statistics on cases receiving the Trilock BPS/Pinnacle combination. . . . 60
94 Distribution of head size for Trilock BPS/Pinnacle combination. . . . 61
95 Distribution of bearing surface for Trilock BPS/Pinnacle combination. . . . 61
96 Distribution of approach used for Trilock BPS/Pinnacle combination. . . . 61

97 Ten most commonly used femoral components in primary TKA. . . . 68
98 Ten most commonly used tibial components in primary TKA . . . 68
99 Ten most commonly used femoral/tibial component combinations in primary TKA. . . . 68
100 Most common reasons for first revision following TKA. . . . 70
101 Most common reasons for first revision following primary TKA in first year post-operatively. . . . 71
102 Most common reasons for first revision following primary TKA in second year post-operatively. . . . 71
103 Most common reasons for first revision following primary TKA in third year post-operatively. . . . 71
104 Cumulative percent revision for primary TKA (numerical values). . . . 72
105 Cumulative percent revision for primary TKA by diagnosis (numerical values). . . . 73
106 Cumulative percent revision for primary TKA by sex for osteoarthritis diagnosis (numerical values). . . . 74
107 Cumulative percent revision risk for femoral/tibial combinations having at least 500 primary cases, sorted alphabetically. . . . 75
108 Cumulative percent revision for Attune/Attune combination compared to all other TKA implants (numerical values). . . . 76
109 Descriptive statistics on cases using the Attune/Attune combination. . . . 77
110 Distribution of approach used for Attune/Attune combination. . . . 77
111 Cumulative percent revision for Evolution MP/Evolution MP combination compared to all other TKA implants (numerical values). . . . 78
112 Descriptive statistics on cases using the Evolution MP/Evolution MP combination. . . . 79
113 Distribution of approach used for Evolution MP/Evolution MP combination. . . . 79
114 Cumulative percent revision for Genesis II/Genesis II combination compared to all other TKA implants (numerical values). . . . 80
115 Descriptive statistics on cases using the Genesis II/Genesis II combination. . . . 81
116 Distribution of approach used for Genesis II/Genesis II combination. . . . 81
117 Cumulative percent revision for Journey II/Journey combination compared to all other TKA implants (numerical values). . . . 82
118 Descriptive statistics on cases using the Journey II/Journey combination. . . . 83
119 Distribution of approach used for Journey II/Journey combination. . . . 83
120 Cumulative percent revision for LCS Complete/M.B.T. combination compared to all other TKA implants (numerical values). . . . 84
121 Descriptive statistics on cases using the LCS Complete/M.B.T. combination. . . . 85
122 Distribution of approach used for LCS Complete/M.B.T. combination. . . . 85
123 Cumulative percent revision for Legion/Genesis II combination compared to all other TKA implants (numerical values). . . . 86
124 Descriptive statistics on cases using the Legion/Genesis II combination. . . . 87
125 Distribution of approach used for Legion/Genesis II combination. . . . 87
126 Cumulative percent revision for NexGen LPS GS/NexGen Precoat combination compared to all other TKA implants (numerical values). . . . 88
127 Descriptive statistics on cases using the NexGen LPS GS/NexGen Precoat combination. . . . 89
128 Distribution of approach used for NexGen LPS GS/NexGen Precoat combination. . . . 89
129 Cumulative percent revision for NexGen LPS Option/NexGen Precoat combination compared to all other TKA implants (numerical values). . . . 90
130 Descriptive statistics on cases using the NexGen LPS Option/NexGen Precoat combination. . . . 91
131 Distribution of approach used for NexGen LPS Option/NexGen Precoat combination. . . . 91

132 Cumulative percent revision for NexGen LPS Option/NexGen TM combination compared to all other TKA implants (numerical values). . . . 92
133 Descriptive statistics on cases using the NexGen LPS Option/NexGen TM combination. . . . 93
134 Distribution of approach used for NexGen LPS Option/NexGen TM combination. . . . 93
135 Cumulative percent revision for NexGen Option/NexGen Option combination compared to all other TKA implants (numerical values). . . . 94
136 Descriptive statistics on cases using the NexGen Option/NexGen Option combination. . . . 95
137 Distribution of approach used for NexGen Option/NexGen Option combination. . . . 95
138 Cumulative percent revision for NexGen Option/NexGen Pegged combination compared to all other TKA implants (numerical values). . . . 96
139 Descriptive statistics on cases using the NexGen Option/NexGen Pegged combination. . . . 97
140 Distribution of approach used for NexGen Option/NexGen Pegged combination. . . . 97
141 Cumulative percent revision for NK II/NK II combination compared to all other TKA implants (numerical values). 98
142 Descriptive statistics on cases using the NK II/NK II combination. . . . 99
143 Distribution of approach used for NK II/NK II combination. . . . 99
144 Cumulative percent revision for NK II GS/NK II combination compared to all other TKA implants (numerical values). . . . 100
145 Descriptive statistics on cases using the NK II GS/NK II combination. . . . 101
146 Distribution of approach used for NK II GS/NK II combination. . . . 101
147 Cumulative percent revision for Persona/Persona combination compared to all other TKA implants (numerical values). . . . 102
148 Descriptive statistics on cases using the Persona/Persona combination. . . . 103
149 Distribution of approach used for Persona/Persona combination. . . . 103
150 Cumulative percent revision for Sigma/M.B.T. combination compared to all other TKA implants (numerical values). . . . 104
151 Descriptive statistics on cases using the Sigma/M.B.T. combination. . . . 105
152 Distribution of approach used for Sigma/M.B.T. combination. . . . 105
153 Cumulative percent revision for Sigma/Sigma combination compared to all other TKA implants (numerical values). . . . 106
154 Descriptive statistics on cases using the Sigma/Sigma combination. . . . 107
155 Distribution of approach used for Sigma/Sigma combination. . . . 107
156 Cumulative percent revision for Sigma PFC/Sigma combination compared to all other TKA implants (numerical values). . . . 108
157 Descriptive statistics on cases using the Sigma PFC/Sigma combination. . . . 109
158 Distribution of approach used for Sigma PFC/Sigma combination. . . . 109
159 Cumulative percent revision for Triathlon/Triathlon combination compared to all other TKA implants (numerical values). . . . 110
160 Descriptive statistics on cases using the Triathlon/Triathlon combination. . . . 111
161 Distribution of approach used for Triathlon/Triathlon combination. . . . 111
162 Cumulative percent revision for Triathlon/Triathlon TS combination compared to all other TKA implants (numerical values). . . . 112
163 Descriptive statistics on cases using the Triathlon/Triathlon TS combination. . . . 113
164 Distribution of approach used for Triathlon/Triathlon TS combination. . . . 113
165 Cumulative percent revision for Vanguard/Maxim combination compared to all other TKA implants (numerical values). . . . 114
166 Descriptive statistics on cases using the Vanguard/Maxim combination. . . . 115
167 Distribution of approach used for Vanguard/Maxim combination. . . . 115
168 Cumulative percent revision for Vanguard/Maxim Mono-Lock combination compared to all other TKA implants (numerical values). . . . 116
169 Descriptive statistics on cases using the Vanguard/Maxim Mono-Lock combination. . . . 117
170 Distribution of approach used for Vanguard/Maxim Mono-Lock combination. . . . 117
171 Ten most commonly used femoral components in primary UKA. . . . 123
172 Ten most commonly used tibial components in primary UKA 123
173 Ten most commonly used femoral/tibial component combinations in primary UKA. . . . 123
174 Most common reasons for first revision following primary UKA. . . . 125
175 Most common reasons for first revision following primary UKA in first year post-operatively. . . . 125

176 Most common reasons for first revision following primary UKA in second year post-operatively. 125
177 Most common reasons for first revision following primary UKA in third year post-operatively. 126
178 Cumulative percent revision for primary UKA (numerical values). 127
179 Cumulative percent revision for primary UKA by sex for osteoarthritis diagnosis (numerical values). 128
180 Cumulative percent revision risk for femoral/tibial combinations having at least 500 primary cases, sorted alphabetically. 129
181 Cumulative percent revision for Oxford/Oxford combination compared to all other UKA implants (numerical values). 130
182 Descriptive statistics on cases using the Oxford/Oxford combination. 131
183 Distribution of approach used for Oxford/Oxford combination. 131
184 Cumulative percent revision for Restoris MCK/Restoris MCK combination compared to all other UKA implants (numerical values). 132
185 Descriptive statistics on cases using the Restoris MCK/Restoris MCK combination. 133
186 Distribution of approach used for Restoris MCK/Restoris MCK combination. 133
187 Cumulative percent revision for Zimmer High Flex/Zimmer High Flex combination compared to all other UKA implants (numerical values). 134
188 Descriptive statistics on cases using the Zimmer High Flex/Zimmer High Flex combination. 135
189 Distribution of approach used for Zimmer High Flex/Zimmer High Flex combination. 135

List of Figures

1 Structure of MARCQI. . . . 4
2 Collaborative meeting. . . . 5

3 Blood transfusion over time for elective primary hip and knee replacement in Michigan. . . . 10
4 MARCQI ten-step infection prevention protocol. . . . 11
5 Percent of MARCQI patients screened for *Staphylococcus aureus* prior to surgery. . . . 12
6 Percent of primary elective THA and TKA cases with deep infection within 90 days or surgery. . . . 12
7 Percent of cases with DVT or PE within 90 days of surgery. . . . 13

8 THA cases over time. . . . 15
9 Percent of THA arthroplasty cases by primary or revision. . . . 16
10 Percent of primary THA cases by sex. . . . 16
11 Age distribution of primary THA cases by sex. . . . 17
12 Percent of primary THA cases by approach. . . . 17
13 Percent of primary THA cases by diagnosis. . . . 18
14 Percent of primary THA cases by ASA class. . . . 18
15 Percent of primary THA patients (first case) by thrombosis prophylaxis between 10/1/2016 and 12/31/2016 (this time window is shorter than rest of figures because of significant change over time). . . . 19
16 Percent of primary THA cases by procedure. . . . 19
17 Percentage of polyethylene liners by type of polyethylene for primary conventional THA. . . . 21
18 Percentage by bearing surface couple for primary conventional THA. . . . 21
19 Distribution of head sizes for primary conventional THA, excluding dual mobility cases. . . . 22
20 Most common reasons for revision following primary conventional THA (Pareto chart). . . . 24
21 Cumulative percent revision for primary conventional THA. . . . 24
22 Cumulative percent revision for primary conventional THA by diagnosis. . . . 25
23 Cumulative percent revision for primary conventional THA by sex for osteoarthritis diagnosis. . . . 26
24 Cumulative percent revision curve for Accolade II/Trident combination compared to all other conventional THA implants. . . . 28
25 Cumulative percent revision curve for Accolade TMZF/Trident combination compared to all other conventional THA implants. . . . 30
26 Cumulative percent revision curve for Anthology/Reflection 3 combination compared to all other conventional THA implants. . . . 32
27 Cumulative percent revision curve for Corail/Pinnacle combination compared to all other conventional THA implants. . . . 34
28 Cumulative percent revision curve for Fitmore/Continuum combination compared to all other conventional THA implants. . . . 36
29 Cumulative percent revision curve for M/L Taper/Continuum combination compared to all other conventional THA implants. . . . 38
30 Cumulative percent revision curve for M/L Taper/Trilogy combination compared to all other conventional THA implants. . . . 40
31 Cumulative percent revision curve for SROM/Pinnacle combination compared to all other conventional THA implants. . . . 42
32 Cumulative percent revision curve for Secur-Fit/Trident combination compared to all other conventional THA implants. . . . 44
33 Cumulative percent revision curve for Secur-Fit Max/Trident combination compared to all other conventional THA implants. . . . 46

34 Cumulative percent revision curve for Secur-Fit Plus Max/Trident combination compared to all other conventional THA implants. . . . 48
35 Cumulative percent revision curve for Summit/Pinnacle combination compared to all other conventional THA implants. . . . 50
36 Cumulative percent revision curve for Synergy/Reflection 3 combination compared to all other conventional THA implants. . . . 52
37 Cumulative percent revision curve for Taperloc 133/G7 combination compared to all other conventional THA implants. . . . 54
38 Cumulative percent revision curve for Taperloc 133/RingLoc+ combination compared to all other conventional THA implants. . . . 56
39 Cumulative percent revision curve for Trabecular Metal/Continuum combination compared to all other conventional THA implants. . . . 58
40 Cumulative percent revision curve for Trilock BPS/Pinnacle combination compared to all other conventional THA implants. . . . 60

41 All knee cases over time. . . . 62
42 Percent of knee arthroplasty cases by primary or revision. . . . 63
43 Percent of primary TKA cases performed as TKA, UKA, and PFJ. . . . 63
44 Primary TKA cases over time. . . . 64
45 Percent of primary TKA cases by sex. . . . 64
46 Age distribution of primary TKA cases by sex. . . . 65
47 Percent of primary TKA cases by approach. . . . 65
48 Percent of primary TKA cases by diagnosis. . . . 66
49 Percent of primary TKA cases by ASA class. . . . 66
50 Percent of primary TKA patients (first case) by thrombosis pharmacoprophylaxis between 10/1/2016 and 12/31/2016 (this time window is shorter than rest of figures because of significant change over time). . . . 67
51 Percent of polyethylene inserts by type of polyethylene in primary TKA. . . . 69
52 Most common reasons for first revision following primary TKA (Pareto chart). . . . 72
53 Cumulative percent revision for primary TKA. . . . 72
54 Cumulative percent revision for primary TKA by diagnosis. . . . 73
55 Cumulative percent revision for primary TKA by sex for osteoarthritis diagnosis. . . . 74
56 Cumulative percent revision curve for Attune/Attune combination compared to all other TKA implants. . . . 76
57 Cumulative percent revision curve for Evolution MP/Evolution MP combination compared to all other TKA implants. . . . 78
58 Cumulative percent revision curve for Genesis II/Genesis II combination compared to all other TKA implants. . . . 80
59 Cumulative percent revision curve for Journey II/Journey combination compared to all other TKA implants. . . . 82
60 Cumulative percent revision curve for LCS Complete/M.B.T. combination compared to all other TKA implants. . . . 84
61 Cumulative percent revision curve for Legion/Genesis II combination compared to all other TKA implants. . . . 86
62 Cumulative percent revision curve for NexGen LPS GS/NexGen Precoat combination compared to all other TKA implants. . . . 88
63 Cumulative percent revision curve for NexGen LPS Option/NexGen Precoat combination compared to all other TKA implants. . . . 90
64 Cumulative percent revision curve for NexGen LPS Option/NexGen TM combination compared to all other TKA implants. . . . 92
65 Cumulative percent revision curve for NexGen Option/NexGen Option combination compared to all other TKA implants. . . . 94
66 Cumulative percent revision curve for NexGen Option/NexGen Pegged combination compared to all other TKA implants. . . . 96
67 Cumulative percent revision curve for NK II/NK II combination compared to all other TKA implants. . . . 98
68 Cumulative percent revision curve for NK II GS/NK II combination compared to all other TKA implants. . . . 100
69 Cumulative percent revision curve for Persona/Persona combination compared to all other TKA implants. . . . 102
70 Cumulative percent revision curve for Sigma/M.B.T. combination compared to all other TKA implants. . . . 104
71 Cumulative percent revision curve for Sigma/Sigma combination compared to all other TKA implants. . . . 106
72 Cumulative percent revision curve for Sigma PFC/Sigma combination compared to all other TKA implants. . . . 108
73 Cumulative percent revision curve for Triathlon/Triathlon combination compared to all other TKA implants. . . . 110
74 Cumulative percent revision curve for Triathlon/Triathlon TS combination compared to all other TKA implants. . . . 112
75 Cumulative percent revision curve for Vanguard/Maxim combination compared to all other TKA implants. . . . 114

76 Cumulative percent revision curve for Vanguard/Maxim Mono-Lock combination compared to all other TKA implants. . . . 116
77 Primary UKA cases over time. . . . 119
78 Percent of primary UKA cases by sex. . . . 119
79 Age distribution of primary UKA cases by sex. . . . 120
80 Percent of primary UKA cases by approach. . . . 120
81 Percent of primary UKA cases by diagnosis. . . . 121
82 Percent of primary UKA cases by ASA class. . . . 121
83 Percent of primary UKA patients (first case) by thombosis pharmacoprophylaxis between 10/1/2016 and 12/31/2016 (this time window is shorter than rest of figures because of significant change over time). . . . 122
84 Percentage of polyethylene inserts by type of polyethylene in primary UKA. . . . 124
85 Most common reasons for first revision following primary UKA (Pareto chart). . . . 127
86 Cumulative percent revision for primary UKA. . . . 127
87 Cumulative percent revision for primary UKA by sex for osteoarthritis diagnosis. . . . 128
88 Cumulative percent revision curve for Oxford/Oxford combination compared to all other UKA implants. . . . 130
89 Cumulative percent revision curve for Restoris MCK/Restoris MCK combination compared to all other UKA implants. . . . 132
90 Cumulative percent revision curve for Zimmer High Flex/Zimmer High Flex combination compared to all other UKA implants. . . . 134

91 PROMIS-10 Survey collection in 2016. . . . 137
92 Average pre-operative HOOS JR and KOOS JR for hospitals with more than 40 surveys. . . . 138
93 Percentage of patients with pre-op pain score $\leq$3 and PROMIS-10 physical health score $\geq$50 by hospital. . . . 139

94 Flowchart of MARCQI 4-level QC/QA process. . . . 143
95 Illustration of event flow and eight types of patients in MARCQI database. . . . 146
96 Flowchart of method used to identify revisions. . . . 148

Chapter 1

Introduction

The Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI, pronounced mar'ki) is a state-wide collaborative focused on improving the quality of care for hip and knee arthroplasty patients in Michigan. It is built on the CQI framework and philosophy, which emphasizes a non-punitive and collaborative approach to quality improvement. The foundation is high-quality data that is risk adjusted and provided back to hospitals and providers. The MARCQI mission has three components:

1. improve patient safety in Michigan by promoting better outcomes,

2. enable surgeons and hospitals across the state to work together to improve quality, and

3. make Michigan the best place in the world to have a joint replacement.

1.1 Blue Cross Blue Shield of Michigan/Blue Care Network's Collaborative Quality Initiative program

Inspired by the efforts to reduce mortality after cardiac procedures in the Northern New England Cardiovascular Disease Study Group (O'Connor *et al.*, 1996), a model of regional collaboration for quality improvement was implemented by Blue Cross Blue Shield of Michigan/Blue Care Network (BCBSM/BCN) in 1997 with the Percutaneous Coronary Interventions (PCI) project. The success of PCI led to the creation of the CQI program in 2004, which was conceived and championed by David Share, MD. He has overseen its growth to seventeen CQIs in multiple specialties. These encompass surgical and medical specialties and they are organized either around hospitals or physicians. This description focuses on the hospital-based CQI model. The programs have shown improvements in complications, mortality, and cost across the state of Michigan (Share *et al.*, 2011).

The CQI program organizes the Collaboratives in a unique way that is critical to their success. Each Collaborative requires an environment of trust and transparency that many providers, hospitals, and payers have not experienced before. The providers managing and participating in the CQI control the data and decide how to use it for improvement. BCBSM/BCN does not receive patient or provider level data from the CQIs, although Collaborative-wide data may be shared. The only hospital-level data shared with BCBSM/BCN is de-identified so BCBSM/BCN can see variation but not specific hospital performance values. Access to these data is limited to the coordinating center, with clinical sites having access to their own data.

Each hospital has at least one clinical data abstractor (CDA) and designated clinical champion. The CDA abstracts data from hospital records for each qualifying patient and enters them into an online database that constitutes the MARCQI patient registry. Each clinical champion is responsible for providing leadership for MARCQI activities at the hospital and within the community of physicians practicing at the hospital. Sharing Collaborative data with colleagues and leading quality

improvement efforts are important responsibilities for the clinical champion. CDAs support clinical champions in gathering and interpreting MARCQI data and conducting quality improvement activities. The CDAs are responsible for assuring the quality and completeness of the data entered into the registry.

In order to develop a collaborative environment between surgeons and/or hospitals, many of whom are business competitors, participants agree not to use the data for anything other than quality improvement. Data are not to be used for marketing purposes. The relative performance of sites is not shared beyond the participants. This allows for transparency and collaboration inside the project and significantly increases the effectiveness of improvement efforts.

The premise of collaborative quality improvement is that having a mechanism to collect robust, clinically meaningful data empowers providers and hospitals to improve quality. This can then occur at a more efficient and effective pace than would occur with isolated efforts within a single hospital. The large sample size resulting from multiple sites is especially beneficial to understanding the risk factors and best practices associated with significant yet infrequent complications such as venous thromboembolism (VTE) and infections. The projects are designed and led by experienced physicians who know the problems that need to be solved, the solutions that should be tried, and the data that should be collected. The CQI program requires that the Collaborative members meet three to four times a year as part of a typical quality improvement cycle to review the aggregated and site-specific data. These regular meetings allow clinical champions and quality improvement teams to work together, explore variations in care, and identify improvement projects. The representatives from each site then return to their respective hospitals, share the data with their entire provider group and develop and implement these projects in a way that works at their institution. The implementations are as varied as the sites. The hospital teams are encouraged to choose the projects that will be most impactful and will have the greatest opportunity for quality improvement.

Between Collaborative meetings, the MARCQI coordinating center helps to facilitate these quality improvement efforts by providing educational materials, organizing webinars and other forms of communication, and connecting sites with better performing sites they can learn from. Additional data and more detail is provided if possible.

BCBSM has a pay-for-performance program, which incorporates CQIs. By aligning incentives to quality improvement efforts, BCBSM/BCN has increased engagement with and support of CQI efforts by hospital administrators and surgeons. MARCQI has worked to emphasize Collaborative-wide rather than site-specific quality measures for this.

1.2 Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI)

MARCQI is part of the CQI program funded by the Value Partnerships program of Blue Cross Blue Shield of Michigan/Blue Care Network (BCBSM/BCN), and it is operated by the University of Michigan. The design of MARCQI was developed in 2010 to focus on total hip arthroplasty (THA), total knee arthroplasty (TKA), and unicondylar knee arthroplasty (UKA). The project proposal was accepted as a BCBSM/BCN CQI in 2011. The initial proposal called for recruitment of all hospitals in Michigan that performed at least 200 total hip or knee arthroplasties annually (hemiarthroplasty procedures were excluded). Data collection began in 2012 with two pilot sites and rapidly expanded to twelve sites by the end of the year. By year five, 2016, MARCQI had grown to include all but one hospital in the state performing more than 200 cases and was capturing $>$ 95% of the hip and knee arthroplasty cases performed in Michigan each year. Thus, sixty-one hospitals are represented in the database.

1.3 MARCQI quality improvement philosophy

The MARCQI approach is to provide the data and best practices necessary to drive quality improvement within a non-punitive and collaborative framework. The goals of MARCQI are to facilitate the collection, interpretation and dissemination of outcomes and process-of-care data in a way that hospitals, physicians and other providers can understand and act on. MARCQI does not focus only on single sites with poor performance, nor does it aim to divert patients to high performing sites. Instead, MARCQI seeks to improve the care across all sites. Our ultimate goal is to make Michigan the best place in the world to have a joint replacement.

The philosophy at MARCQI is based on the the healthcare improvement ideas of Ignaz Semmelweis, Florence Nightingale, Ernest Codman, Avedis Donabedian, and Don Berwick along with quality improvement methods developed in manufacturing by W. Edwards Deming, Walter Shewhart and others. We are pursuing the ideal, as Codman said in 1918, that hospitals should “follow up each patient they treat, long enough to determine whether the treatment given has permanently relieved the condition or symptoms complained of.” (Codman, 1918) The majority of clinical practice in the United States over the ensuing century has been to provide medical services with little to no knowledge of the ultimate outcome of these treatments. This reflects the lack of available clinical data and the challenges associated with obtaining outcomes information.

Any quality improvement process has potential risks. One pitfall is to assume that all favorable or unfavorable outcomes reflect only surgeon performance. Our analyses and experience indicate that some outcomes are influenced heavily by individual surgeons, but others, like readmissions, reflect multidisciplinary care. Quality improvement efforts need to be directed at the appropriate level. Another risk is to ignore the downstream, unintended effects of intended interventions. Behavioral and practice changes by providers or institutions can be designed to truly improve quality or to just improve performance on a given quality measure without improvement in the outcome.

Incentivizing improvement is done in many ways. Financial incentives, both rewards and penalties, are one type but they must be designed and applied carefully. It is important not to undermine the goal of trust that was required to build the collaborative community of MARCQI. For example, pay-for-performance measures that are structured in a way that emphasizes hospital rankings can create a competitive environment that makes collaboration impossible. Caution is needed to avoid encouraging physicians and hospitals to limit care for patients at higher risk of having a complication, requiring complex care or needing prolonged management. This has been called “cherry picking,” or conversely “lemon dropping,” but these derogatory terms demean the affected patients and lay the blame on the physician or hospital. Socioeconomic effects on outcomes are difficult to control for, and may unfairly penalize so-called safety net hospitals that largely care for a more challenged population. For this reason we strive to risk adjust any comparisons and to benchmark our results against published national benchmarks, when available, so that our evaluation of sites rewards the significant improvements that most sites have made.

By working collaboratively to improve care across the state, MARCQI seeks to improve the quality, safety, and value of the care we provide for all patients in Michigan. This is done with robust attempts at risk adjustment, collaboration between higher and lower performing sites at Collaborative meetings, and incentives that are based on system wide improvements rather than just hospital rankings and individual improvement.

1.4 Organization

Organizationally, MARCQI is made up of four parts: coordinating center, data management center, committees, and hospitals (Figure 1). Data are housed at an independent vendor (Ortech, London, Ontario). All CQIs have physician project directors who are instrumental to providing leadership for the Collaborative. These directors provide clinical insight, leadership among their peers to move quality improvement initiatives, and leadership within the University of Michigan to manage the coordinating center. MARCQI is unique among the CQIs because it also has a non-physician co-director who is an engineer with expertise in bioengineering and industrial engineering disciplines. This co-director focuses on implant evaluation and analytical methods development using tools from quality engineering and operations research. Under the direction of the co-directors, the coordinating center is managed by a program manager whose role is to maintain communication and cooperation with the participating sites. The project manager also manages the pay-for-performance system, arranges the statewide Collaborative meetings and maintains all the paperwork related to participation and contracting. Four registered nurses serve as senior clinical analysts. They are assigned to support specific hospitals, teach training classes to the clinical data abstractors (CDAs) at each of the sites and maintain the data specifications manuals. Also located at the coordinating center in Ann Arbor is the statistician expert who develops the statistical models in support of the MARCQI quality initiatives. The statistician also works closely with the data center at the St. Joseph Mercy Quality Institute to develop risk adjustment models, select and implement data visualization tools, perform multivariable modeling, improve data quality, and prepare reports. The administrative assistant is responsible for the website, the quarterly newsletter, and works closely with the MARCQI team to coordinate activities. All members of the coordinating center staff serve on at least one of the committees.

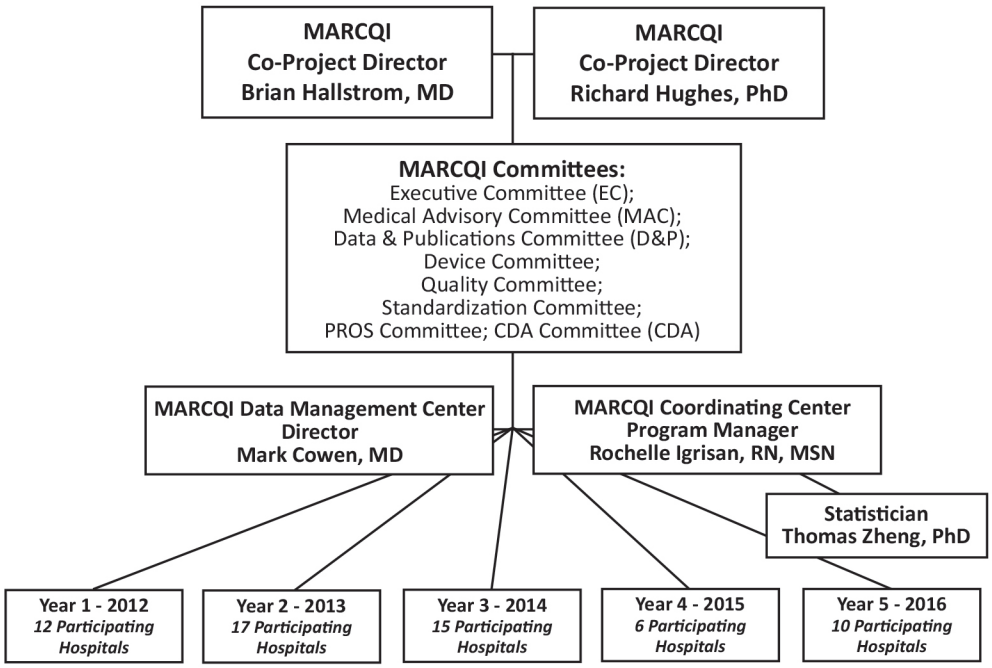

Figure 1: Structure of MARCQI.

Executive Committee. Serves as the oversight and advisory body to the co-directors of MARCQI. It is responsible for approving the governing rules of the MARCQI registry and provides strategic direction. It is composed of orthopaedic surgeons and co-directors.

Medical Advisory Committee. Obtains input from the surgeons and gives them a voice in the operations of the registry. It is chaired by a MARCQI co-director and all clinical champions are members.

Data and Publications Committee. Responsible for developing and implementing the policies and procedures for publishing the results of MARCQI quality improvement activities in a way that is in compliance with federal regulations. It consists of co-directors, surgeons, personnel at the data management center, and MARCQI's biostatistician. It has two co-chairs.

Device Committee. Responsible for overseeing the analysis of implant data collected by MARCQI. It consists of co-directors, surgeons, personnel at the data management center, and the coordinating center's biostatistician. It has two co-chairs.

Quality Committee. Works on in-depth quality improvement projects and looks for ways to continuously improve the quality of care delivered. It is co-chaired by two clinical champions and has CDA's, nurses, hospital quality directors, a patient representative, a nurse navigator, and physician assistant as members.

Standardization Committee. Responsible for standardizing documentation to improve data collection. It is chaired by a clinical champion and has two surgeons and three nurse/CDAs as members.

Patient-reported Outcome Committee. Focuses on increasing the collection of patient-reported outcome surveys (PROS) and refining the analysis of that data. It is chaired by a clinical champion and includes a co-director, project manager, nurse coordinator, several CDAs, a surgeon, the director of the data center and the vendor.

Clinical Data Abstractor Committee. Oversees the development and approval of the data specifications manual. The committee also monitors the CDA Forum to find out what topics are currently on the minds of the CDAs. The CDA

Committee also monitors the CDA Forum to find teaching opportunities to keep the CDAs current and up to date. The committee is made up of six CDAs and co-chaired by a CDA and a nurse coordinator,

1.5 Collaborative meetings

Figure 2: Collaborative meeting.

Central to MARCQI is the Collaborative meeting, which is a gathering of the consortium to review data, share best practices, and set priorities (Figure 2). Face-to-face meetings of the Collaborative are critical to quality improvement. Research has shown that merely providing data back to hospitals may not be very effective by itself (Osborne *et al.*, 2015); collaboration and sharing of best practices based on high-quality data is necessary. There have been 22 meetings since the beginning of MARCQI. The last Collaborative meeting in 2016 had an attendance of 196 people, including 44 clinical champions and 67 clinical data abstractors. The Collaborative meetings make a registry more than a data repository; they bring people from sites together to collaborate on quality improvement.

Device, Quality, Data and Publications, Patient-reported Outcomes, Medical Advisory, and Executive Committees also meet on the day of the Collaborative meeting, either before or after the main session. The meetings of the Executive and Medical Advisory Committees are especially useful for brainstorming and vetting potential quality improvement initiatives.

MARCQI uses the traditional plan-do-check-act (PDCA) cycle of quality improvement. At each meeting we check our results and develop a plan for action going forward. Each site takes their results back to their hospital and is asked to present the data to all the surgeons to ensure that the information is disseminated and that opportunities for improvement are pursued. Each site's progress on their chosen project is reviewed. The meetings are also opportunities to conduct participant surveys. For example, surveys about coordinating center performance are regularly collected at meetings so feedback can be provided to BCBSM/BCN.

1.6 Transparency

Transparency in healthcare can take many forms. In our current environment there is very little accurate and valid information that patients and families can use to make decisions about where to get their care. One model of transparency would place detailed information about outcomes at the hospital and physician level in the hands of patients so that they can make informed decisions about their care. While this may seem like the ideal situation, the unfortunate reality is much more complicated and fraught with unintended consequences. The inadequacies and limitations of risk adjustment, the subtleties

and implications of specific outcomes, the paucity of good benchmarks, the uncertain effect of variation and chance, and the effects this transparency might have on access to care are all issues that need to be addressed before this level of transparency should be implemented.

MARCQI has adopted a different model of transparency. Over the course of the Collaborative meetings, MARCQI has adopted a practice of presenting data transparently at the hospital level within the Collaborative. In order to work together to improve results it is essential to know who has the experience and outcomes to inform improvement. This allows for open discussions between sites that may be struggling with a particular measure and sites that are performing well. At our meetings, we assemble panels of representatives from high performing sites to lead the discussion on a particular topic. We ask sites that have made significant improvements present on their experience.

Transparency also extends to disclosure of conflicts of interest. MARCQI leaders and Clinical champions are required to disclose their conflicts annually. At the Collaborative meetings disclosure slides are shown concurrently for all talks on a screen adjacent to the main presentation (at left in Figure 2).

1.7 United States and international registries

Around the world, arthroplasty registries have a long history. MARCQI is a member of the International Society of Arthroplasty Registries (ISAR) that has forty-one members and meets annually to share methodology and results. The Swedish Knee Arthroplasty Registry (SKAR, est. 1975) and Hip Arthroplasty Registry (SHAR, est. 1978) are two of the oldest programs. Members also include the National Registry for England, Wales, Northern Ireland and the Isle of Man (NJR), the Australian Orthopaedic Association National Joints Replacement Registry (AOANJRR), nordic registries (Norway, Sweden, Denmark, and Finland), and many others.

In the US, there are other established registry projects that are housed in institutions or health care organizations. The Mayo Clinic, Massachusetts General Hospital and Health East are some examples that have resulted in local improvement and multiple publications. The Kaiser Permanente registry, started in 2001, has also been successful in implementing positive change in their system and sharing those results in the literature. ForceOrtho, which was formerly Force-TJR, focuses primarily on patient-reported outcome surveys. Force-TJR started in 2010 and was initially funded by the Agency for Healthcare Research and Quality.

MARCQI was developed as a combination of two models, the international arthroplasty registry and the quality improvement collaborative. By combining these two ideas, MARCQI is able to facilitate rapid cycle quality improvement and perform longer term tracking of survivorship and outcomes. The state of Michigan is very similar in size and arthroplasty volume to the nation of Sweden with populations of almost ten million people. As a state registry, the scale of MARCQI allows for in-person meetings and face-to-face collaboration with representatives from each site. MARCQI does not seek to become a national registry and encourages Michigan hospitals to participate in the American Joint Replacement Registry (AJRR). These two projects complement each other and have different goals and scope.

Chapter 2

Data quality and completeness

The MARCQI data model was developed to ensure valid and reliable data within the registry. There is a financial incentive for hospitals to achieve high levels of complete data. Hospitals must submit data for each registered case from each of nine categories in order for the record to be considered complete and to qualify for the incentive. There are nine required categories: (1) International Classification of Diseases (ICD) diagnosis for the procedure performed, (2) corresponding patient demographics, (3) pre-operative and post-operative laboratory values, (4) evidence the planned surgery actually occurred (confirmed with the surgical procedure file), (5) data about the procedure performed, for example, procedural approach, mode of anesthesia, intra-operative events, (6) information about the device(s) implanted, (7) perioperative information such as blood products given, return to the OR, (8) whether or not VTE prophylaxis was given, and (9) evidence that 90-day post-operative surveillance occurred and any events recorded. *For 2016, 46,625 cases (98.7%) met the definition of complete data out of a total of 47,245 eligible cases.*

Hospitals submit data through a secure web application hosted by Ortech. Ortech creates a unique case and patient identifier that links data from multiple sources and then warehouses the registry data. See Hughes *et al*. (2015) for more information on the MARCQI data model. There are four primary data sources for the registry:

1. *Manually abstraction from the medical record*. Medical record data are abstracted manually by trained clinical data abstractors, most of whom are nurses. Each participating site has at least one abstractor. Because MARCQI maintains that accurate ascertainment of critical data elements requires strict criteria and definitions, certain data elements may be submitted to the registry only manually. Examples include pre-operative risk factors and post-operative events.

2. *Batched or file-based acquisition mode*. The surgical procedure log from the hospital must be submitted into the registry through the file-based acquisition mode. This provides a safeguard to ensure all eligible cases are submitted to the registry. Other data elements may also be submitted through this route in order to streamline the data submission process. Examples are clinical laboratory values that do not require a clinical background to record and site-specific surgical site infection information downloaded from the National Healthcare Safety Network (NHSN). Usually the nurse abstractors work with their hospitals' information technology department to create these batched files for the registry.

3. *Hospital administrative data from the Michigan Inpatient Data Base (MIDB)*. These data are transferred directly from MIDB to the MARCQI registry on a quarterly basis; this contains encounter-level procedures, diagnoses, disposition and a unique patient identifier that permits multi-year, longitudinal tracking of subsequent hospitalizations across participating sites within Michigan.

4. *Patient-reported outcomes (PROS)*. PROS data that is collected through the vendor's clinic module is transferred to the registry in real time. Sites that choose to collect PROS data via other methods are able to enter the data manually or through the file-based acquisition process.

Quality improvement requires accurate, reliable, and completed data. Thus, MARCQi has multiple program elements focused on assuring high-quality data:

1. *Rigorous eight hour training program for the clinical data abstractors, followed by an examination with three test cases to abstract*. For ongoing education, the coordinating center hosts approximately seven webinars per year in which pertinent clinical scenarios are presented and discussed. The center distributes a periodic newsletter with frequently asked abstraction questions to promote a standard approach across sites.

2. *Specifications manual*. A specifications manual having detailed definitions, flow-charts and diagrams was developed. The manual is updated annually and reflects input and review from the chart abstraction community. At the end of 2016 it was 376 pages long.

3. *Data quality checks at the time data is submitted to the registry*. Field constraints are in place to prevent erroneous or incomplete data that is submitted manually (*e.g.*, out-of-range laboratory values and improper sequencing of dates). Electronic data submitted through the file-based acquisition mode must contain key fields to permit matching with other data sources, have a valid format, and be consistent with the procedure and laterality of registered cases. From the inception of the registry, the number of data quality checks has increased as out-of-range values and inconsistencies in the data were identified through analyses, leading to the creation of quality improvement reports.

4. *Short time period for submitting data on a given case to ensure the registry is timely, represents contemporaneous practice, and prevents modification of historical data*. Sites are allowed up to 150 days from the date of surgery to collect and submit data on a case. This includes 90 days from the surgery date (in order to ascertain 90-day events and outcomes), plus no more than an additional 60 days to complete the data collection and submission processes. Sites cannot make further changes to the case's data after 150 days from the surgery without the permission of the coordinating center.

5. *Site visits and audits by the coordinating center to review the workflow sequence and standardization of the abstraction process at each participating site*. Random checks for VTE events also occur. The coordinating center audits first year sites and sites with a new lead abstractor at approximately three, six and twelve months after data submission begins, and audits the longer participating sites every 18 to 24 months.

6. *Minimize the possibility that a site would bolster its performance measures by excluding cases with adverse events from the registry*. Case finding and submission practices are reviewed when hospitals have lower case matching rates with the procedures recorded in the MIDB than their peers. Of MIDB cases deemed eligible for the registry using administrative data, approximately 97% are also found within the clinical registry, and conversely, 95% of primary surgeries recorded in the registry are also found within the MIDB administrative data.

7. *Coordinating center reviews each site's quarterly quality improvement reports for unusual findings compared to peers*. The CDAs routinely review their individual reports and queries to identify potential data quality or completeness issues. In addition to the above hierarchical quality control process, data quality checking is also conducted dynamically and routinely as part of specific research projects to identify potential data quality issues. The data manager, statistician, project directors, professional nurses and site CDAs are involved in this cautious checking process. Once the issues are confirmed, the database is corrected.

Chapter 3

Quality improvement initiatives

Quality improvement projects have been chosen to address significant variability in care. Projects are selected and developed in conjunction with the Executive and Medical Advisory committees. This chapter describes the initiatives and their impact on the quality of care; chapter eight discusses the beneficial financial impacts resulting from these improvements.

3.1 Transfusion

When we first began to generate hospital level data it was clear that transfusion utilization varied widely between hospitals. Across MARCQI, 14.2% of hips and 7.0% of knees were being transfused when we first systematically scrutinized these data in 2013. The percentage of patients transfused after knee replacement at each hospital ranged from 1% to 25% and after hip replacement from 7% to 39%. In addition, 29.9% of these transfusions were administered to patients with a hemoglobin greater than 8 g/dL. Due to the strong evidence in the literature that the risks of these transfusions likely outweighed any benefit, these were termed “unnecessary transfusions” and targeted as a priority. In addition, the average number of units transfused in patients receiving blood was 1.9 units. Analysis of our data showed that transfusion was associated with an increased risk of readmission and infection. The coordinating center polled sites about the institutional use of transfusion protocols and found that there was significant variability across hospitals. Many did not have any organized plan to guide clinical decision making about transfusion. Also, despite a large body of literature recommending more restrictive transfusion practices, entrenched clinical practices encouraged transfusion in situations that did not support their administration.

At the Collaborative meeting in November of 2013, we introduced the MARCQI transfusion reduction program. This had four elements: (1) screening for and treating pre-operative anemia, (2) limiting blood loss through good operative hemostasis, (3) adopting a transfusion guideline such as the American Red Cross or American Association of Blood Banks, and (4) check post-transfusion hemoglobin results prior to ordering and administering a second unit.

In the first year after this initiative was established, transfusion rates dropped to 3.9% for TKA and 8.9% for THA resulting in an estimated 632 fewer patients receiving a transfusion and 1,370 fewer units of packed red blood cells being transfused in 2014. Moreover, we have not detected an increase in length-of-stay, readmission, emergency department (ED) visit, and deep infection during the period of decreasing transfusions. The MARCQI experience reducing transfusion has been published by Markel *et al.* (2016, 2017).

3.2 Tranexamic acid

As a follow-up to and an extension of the transfusion reduction project and at the recommendation of several MARCQI clinical champions, the MARCQI coordinating center began an analysis of the use of tranexamic acid (TXA) in Michigan. TXA is an established antithrombolytic agent that has been used in cardiothoracic surgery, trauma, and other clinical situations for years. There has been growing support for its use in total joint arthroplasty so in April of 2014 a data element was added to the MARCQI database to collect information on this practice.

For hip replacement, the use of TXA was associated, as expected, with fewer transfusions (odds ratio OR=0.72;

95% CI=0.60 - 0.86) and a smaller drop in hemoglobin (mean difference=-0.65 g/dL; 95% CI=-0.60 to -0.71 g/dL) after surgery. Unexpectedly, the analysis also found that the use of TXA was associated with a lower odds of readmission (*OR*=0.77; 95% CI=0.64 - 0.93).

In patients having a knee replacement, the use of TXA was again associated with significantly fewer transfusions (*OR*=0.26; 95% CI=0.21 - 0.31) and a smaller drop in hemoglobin (mean difference= -0.68g/dL; 95%CI=-0.64 to -0.71 g/dL) after surgery. In addition, TXA administration was also associated with a lower risk of VTE events (*HR*=0.56; 95% CI=0.42 - 0.73).

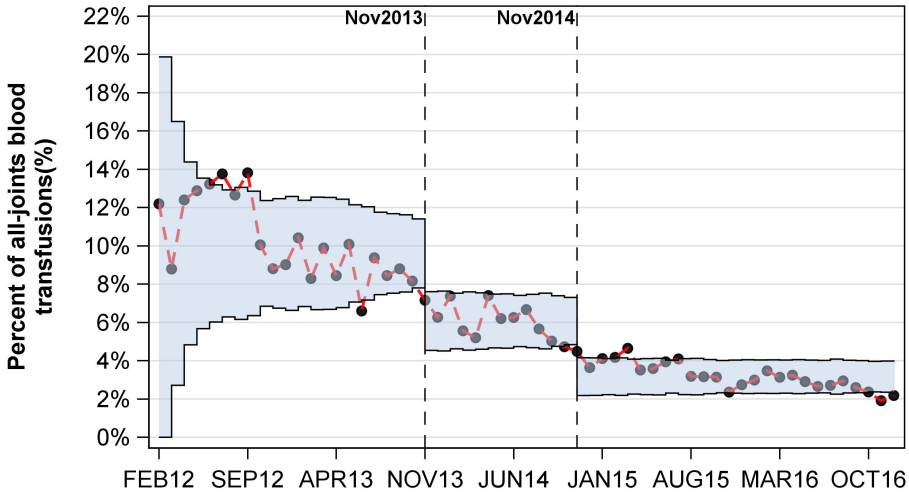

Figure 3: Blood transfusion over time for elective primary hip and knee replacement in Michigan.

There was no increase in complications such as cardiovascular, cerebrovascular or VTE events in either the hip or knee groups. This was presented at Collaborative meetings in 2015 and discussions led to addition of TXA to the recommendations for transfusion reduction. These results were reported in Hallstrom *et al*. (2016).

By the end of 2016, transfusion after knee replacement had dropped to 1.4% and after hip replacement to 3.4% with transfused patients receiving an average of 1.7 units of blood (Figure 3). In addition, unnecessary transfusion has been essentially eliminated with the rate now at 0.2%. When comparing actual transfusions with the estimated number of transfusions had the 2013 rate continued, over 3,000 patients avoided transfusion in Michigan and 5,800 fewer units were transfused in 2016.

3.3 Nursing home discharges

An early MARCQI measure that showed enormous variability between hospitals was the use of extended care facilities or skilled nursing facilities, hereafter called nursing homes, after discharge from the acute care hospital. For many hospitals and physicians, there was an expectation that patients would leave the hospital and spend several days to weeks recovering in a nursing home before going home. This was, in part, the result of the prolonged recovery necessary prior to the advent of less invasive surgery, improved pain management, wide use of regional anesthesia, and rapid mobilization protocols. While some patients with limited supports or other comorbidities may need a nursing home stay prior to living independently, much of this usage was based on habit. Established care pathways, discharge planning, hospital priorities, affiliations, and patient and family expectations all contributed to the continued use of nursing homes.

Patients were found to have a 50% higher risk of readmission when discharged to a nursing home after elective primary knee replacement (*HR* 1.51, 95% CI=1.3 - 1.73) and a 30% higher risk after hip replacement (*HR* 1.27, 95% CI=1.02 - 1.56). This trend held true even when patients were divided according to risk, with patients at the lowest risk of

needing a nursing home being at the highest relative risk for readmission ($RR > 4$).

The raw range of nursing home utilization varied from 9% to 35%. Variation was even larger when data were risk standardized. As a result of examining these variation data, outlier hospitals were encouraged to choose discharge disposition as a quality improvement project beginning in the spring of 2014. Hospitals used a variety of strategies to reduce nursing home utilization. (Charles *et al.*, 2016) Over the course of the next three years the use of nursing home as the discharge destination for hip and knee arthroplasty patients in Michigan dropped from 23.0% to 16.1%.

3.4 Infection prevention

Deep infection in a total knee or hip replacement is catastrophic for the patient and is extremely costly. The five-year mortality rate after a diagnosis of arthroplasty infection exceeds the Centers for Disease Control and Prevention reported mortality for a diagnosis of stage 2B colon cancer (Henley *et al.*, 2017)

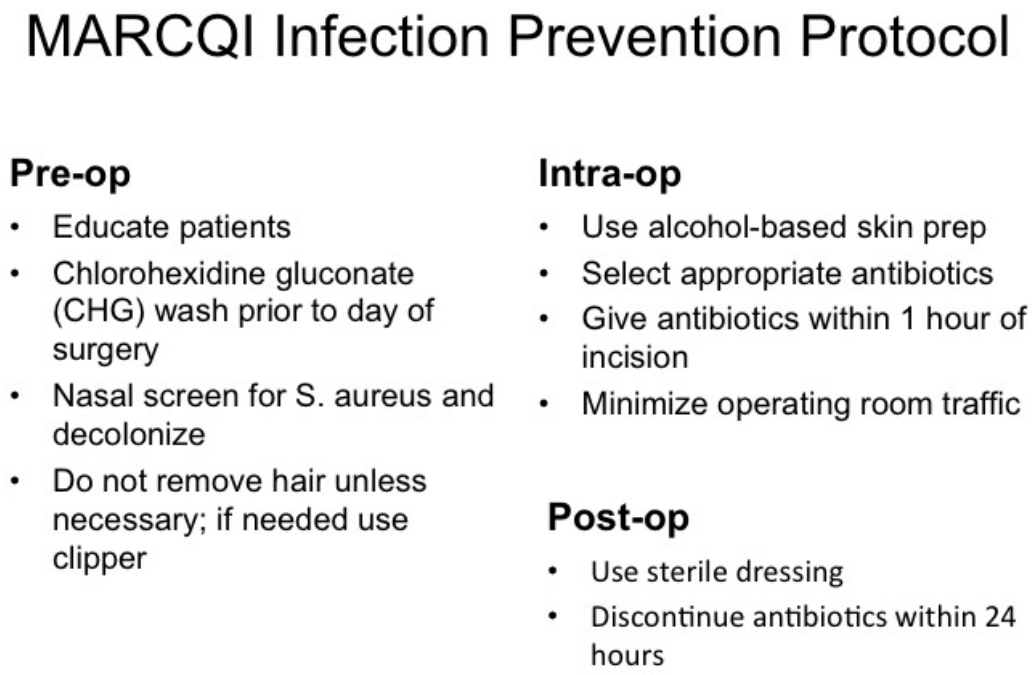

Figure 4: MARCQI ten-step infection prevention protocol.

MARCQI worked with infection control experts and our clinical champions to develop a series of evidence based recommendations for infection prevention. These 10 guidelines (Figure 4) were recommended to the Collaborative.

One component of these recommendations was screening patients for *Staphylococcus aureus* (SA). This is the most common bacteria to cause deep implant infections and patients who carry SA in their nares are at increased risk for infection after surgery with both SA and other bacteria. In the MARCQI patients, those that screen negative for SA colonization had a 0.49% infection risk, while those that screened positive for Methicillin-sensitive *Staphylococcus aureus* (MSSA) had a 0.60% risk. Methicillin-resistant *Staphylococcus aureus* (MRSA) carriers had triple the risk at 1.49%. Screening offers the opportunity to decolonize patients pre-operatively and make appropriate antibiotic selection by adding

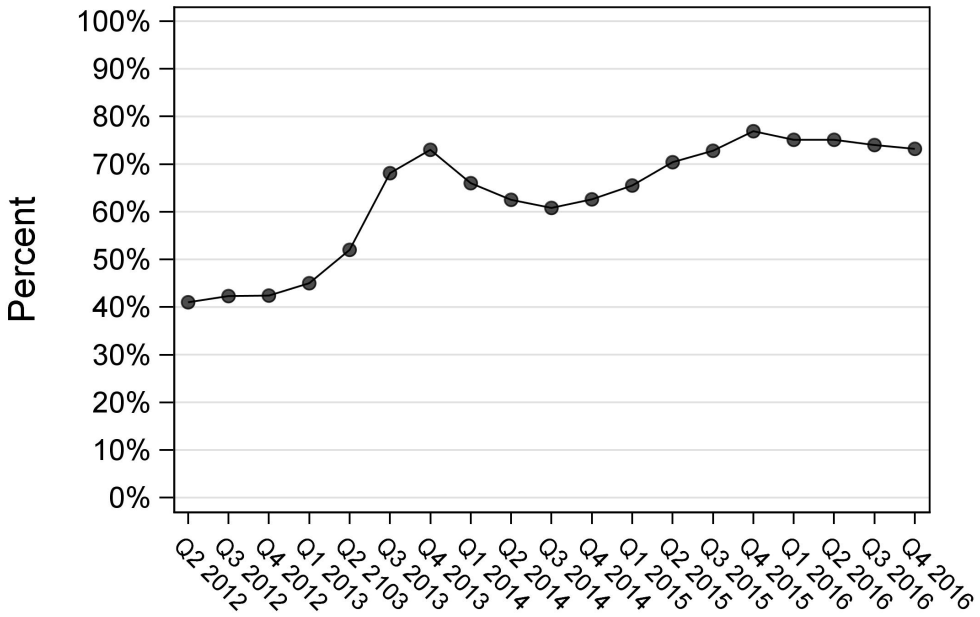

Figure 5: Percent of MARCQI patients screened for *Staphylococcus aureus* prior to surgery.

vancomycin to the pre-operative antibiotics for MRSA carriers.

Since MARCQI began, patient screening has improved from 40% of patients in 2012 to 74% of patients in 2016 (Figure 5). In 2016, 12.1% of patients were decolonized without screening. Of the 31,274 patients who were screened, 17.7% tested positive for SA, and 85.1% of those positive were decolonized.

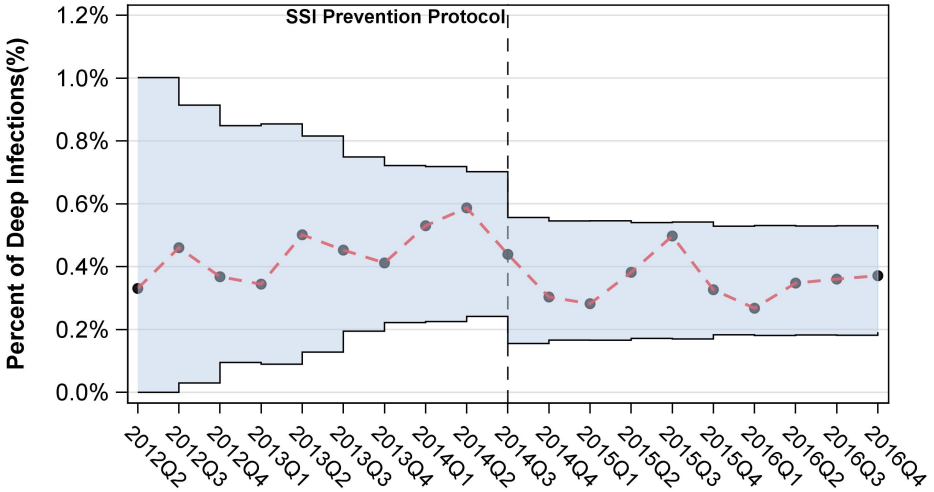

Figure 6: Percent of primary elective THA and TKA cases with deep infection within 90 days or surgery.

Overall, 90-day infection rates across MARCQI are low with a combined average of 0.40% (Figure 6). For TKA, 0.33% developed deep infection in the first 90 days. For THA the overall unadjusted 90-day infection rate has been 0.53%. This compares very favorably with reports from the National Healthcare Safety Network (NHSN). A study of national surveillance networks reported NHSN infection rates after TKA and THA of 1.0% and 1.4%, respectively.

3.5 Venothromboembolism (VTE) prevention

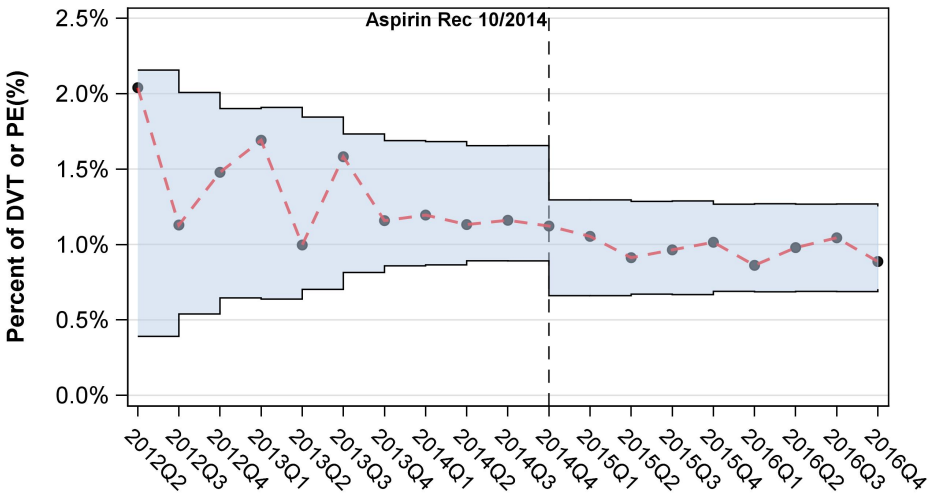

Figure 7: Percent of cases with DVT or PE within 90 days of surgery.

At the inception of MARCQI, the American College of Chest Physicians (ACCP) guidelines recommended low molecular weight heparins as a first line prophylaxis and specifically excluded aspirin. Likewise, the Centers for Medicare and Medicaid Services (CMS) Surgical Care Improvement Program (SCIP) excluded aspirin from accepted prophylaxis. However, the American Academy of Orthopaedic Surgeons (AAOS), using different goals and criteria, included aspirin in their guidelines. As a result of these conflicting guidelines and pressures from regulatory bodies, there was wide variety in practice between hospitals in MARCQI with 71.5% of patients receiving some form of pharmacologic prophylaxis other than aspirin.

Since that time, the ACCP guidelines and the SCIP measures have both added aspirin, bringing them into concordance with the AAOS guidelines. A major MARCQI quality improvement project was focused on tracking VTE rates and prevention. The overall rate of VTE events was 1.1% in THA patients and 1.4% after TKA. MARCQI encouraged participating sites to follow a multimodal VTE prevention strategy based on the AAOS guidelines, including aspirin for appropriately selected patients. This strategy includes screening patients for an increased personal risk for VTE, selecting pharmacologic prophylaxis based on patient and surgical characteristics (*i.e.*, patient's risk, magnitude of surgery, expected post-operative activity level), using regional anesthesia, TXA, intermittent calf compression devices or foot pumps, and rapidly mobilizing patients. The use of non-aspirin pharmaco-prophylaxis has decreased to 36.9% of patients, down from 71.4%, while the use of aspirin alone has increased to 50.0% of cases. Eleven percent received some combination of aspirin and another agent. In 2016, 50.6% received compression stockings, 89.8% had intermittent compression devices and 11.7% were prescribed venous foot pumps. TXA was administered to 88.5% of patients.

In 2016, 0.8% THA patients had a VTE event: 0.5% had a DVT and 0.4% had a PE. Twelve patients were diagnosed with both. For bleeding complications, 1.5% developed a hematoma and 1.3% of patients had a nadir hemoglobin of less than 7 g/dL. One third of the hematomas required a return to the OR for irrigation and debridement.

Over the life of MARCQI this switch to greater use of aspirin as the sole pharmacologic prophylaxis has not resulted in an increase in VTE events (Figure 7).

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Chapter 4

Total hip arthroplasty statistics, devices, and revisions

Selection of the most suitable implant is a critical component of providing high quality hip arthroplasty care. Since revision is an undesirable outcome and is widely reported across arthroplasty registries, we include a chapter on revision risk. These data are based on primary cases performed from 2/15/2015 to 12/31/2016. For detailed information on each figure and table (date ranges and inclusion/exclusion criteria), see the online supplement `http://marcqi.org/dev/wp-content/uploads/2017/10/MARCQI_2012-2016_report_chapter_4_and_5_specifications.pdf`. Apparent inconsistencies in sample sizes between tables can be resolved by examining the inclusion criteria listed for each table in the online supplement. The first section provides an overview of THA, primary and revision procedures combined. All revision risk in sections two through four are for primary conventional THA only.

4.1 Descriptive statistics

This section presents data on all THA cases, including primary and revision cases.

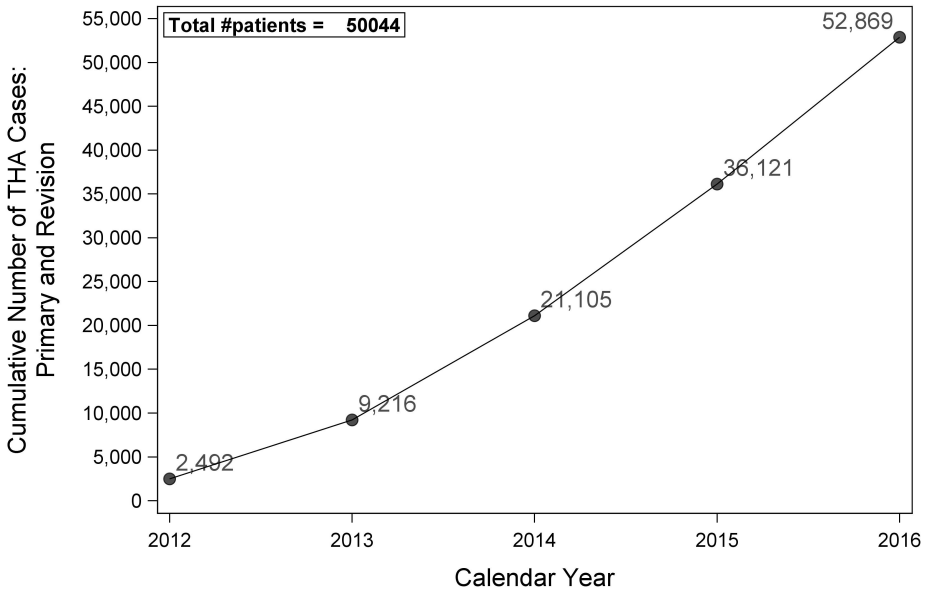

Figure 8: THA cases over time.

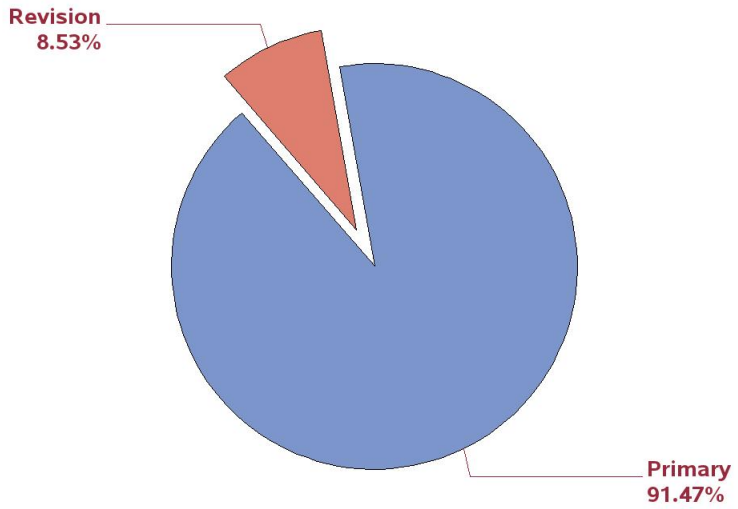

Figure 9: Percent of THA arthroplasty cases by primary or revision.

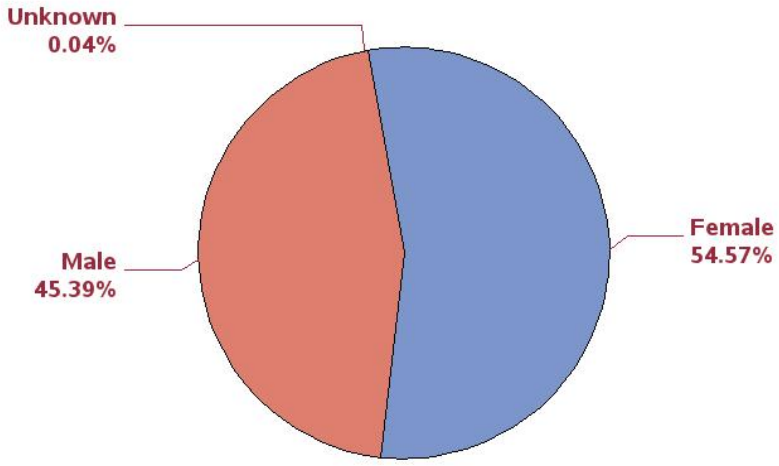

Figure 10: Percent of primary THA cases by sex.

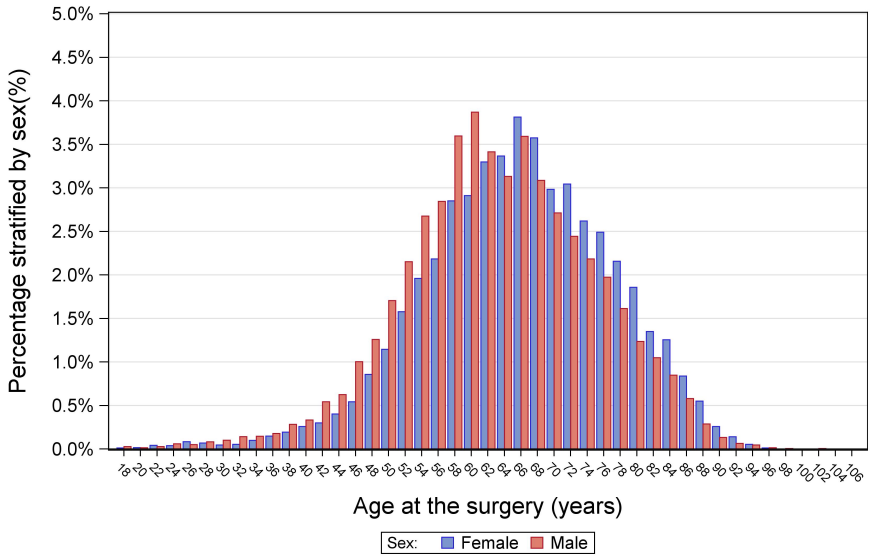

Figure 11: Age distribution of primary THA cases by sex.

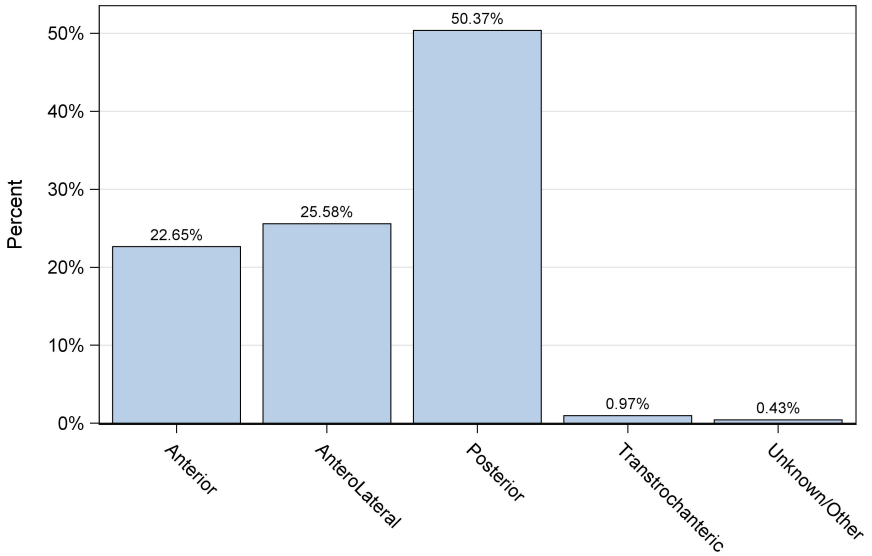

Figure 12: Percent of primary THA cases by approach.

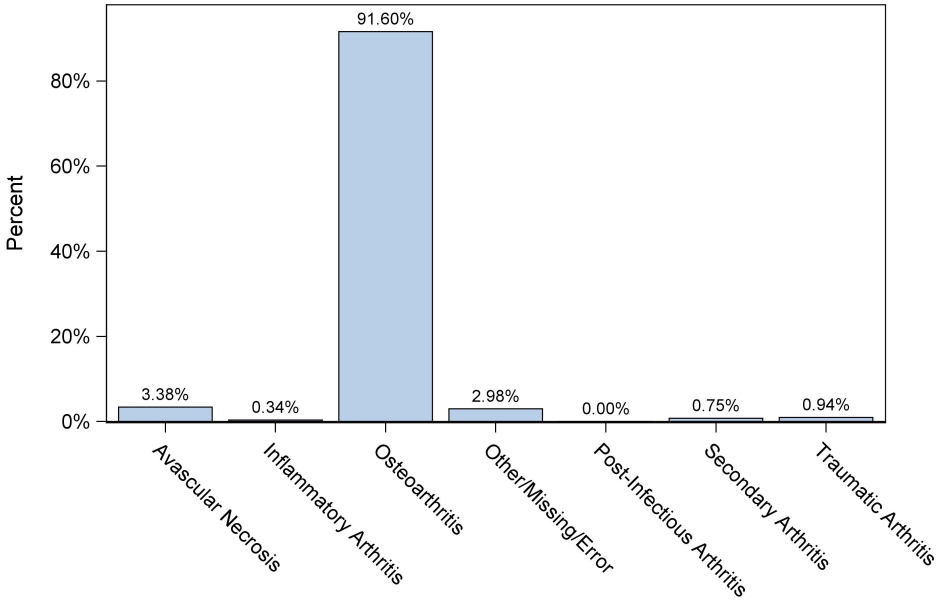

Figure 13: Percent of primary THA cases by diagnosis.

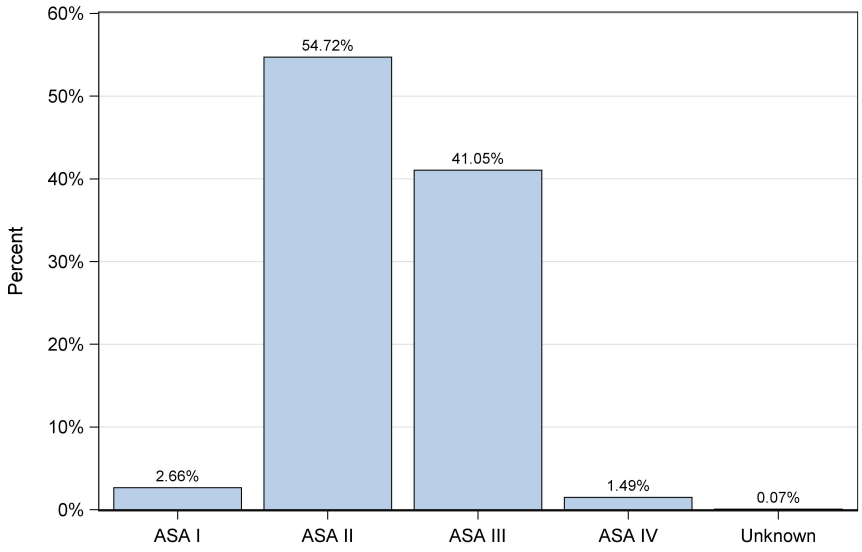

Figure 14: Percent of primary THA cases by ASA class.

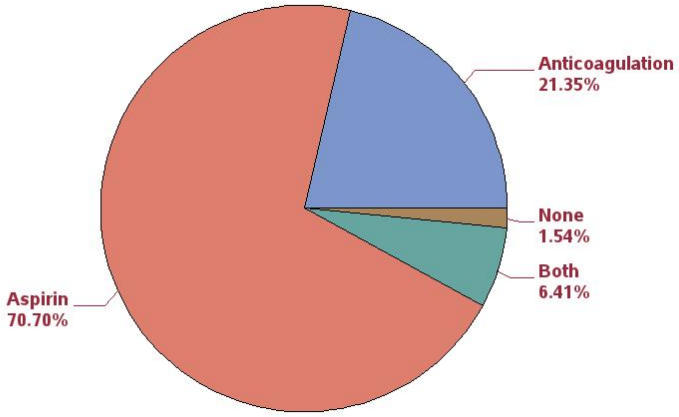

Figure 15: Percent of primary THA patients (first case) by thrombosis prophylaxis between 10/1/2016 and 12/31/2016 (this time window is shorter than rest of figures because of significant change over time).

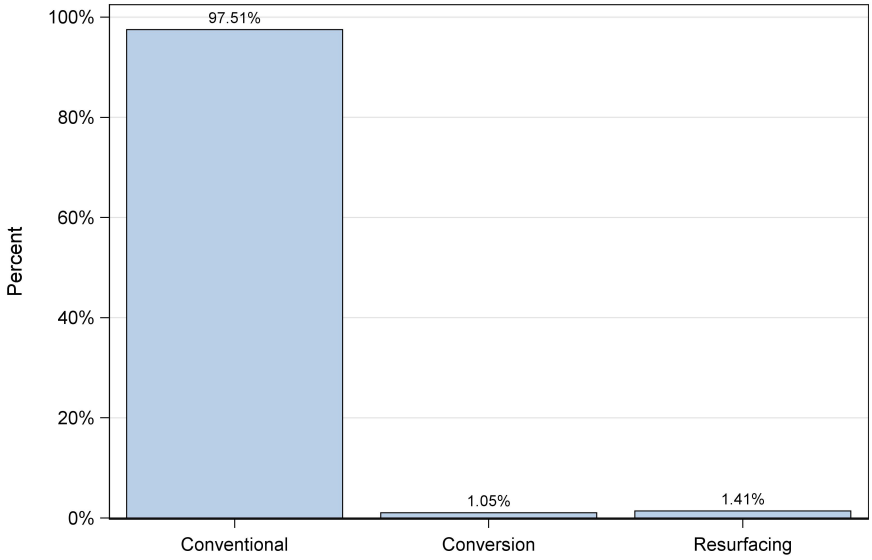

Figure 16: Percent of primary THA cases by procedure.

Note the data element for procedure, which was used to create the figure above, was changed in January of 2015 to include conversion.

4.2 Most commonly used implants

The following three tables provide utilization data of implants used in primary THA.

Table 1: Ten most commonly used femoral components in primary total conventional THA.

Rank	Stem	N	Percent
1	Accolade II	10425	21.9
2	M/L Taper	7221	15.2
3	Taperloc 133	4533	9.5
4	Summit	3831	8.0
5	Fitmore	2496	5.2
6	Secur-Fit Plus Max	1692	3.5
7	Anthology	1676	3.5
8	Secur-Fit Max	1506	3.2
9	Tri-Lock BPS	1468	3.1
10	Corail	1190	2.5
11	Others	11626	24.3

Table 2: Ten most commonly used acetabular components in primary total conventional THA.

Rank	Cup	N	Percent
1	Trident	15824	33.2
2	Continuum	9376	19.7
3	Pinnacle	7576	15.9
4	G7	3053	6.4
5	Reflection 3	2800	5.9
6	RingLoc+	1578	3.3
7	Trilogy	1404	3.0
8	Trabecular Metal	1183	2.5
9	Regenerex RingLoc	881	1.9
10	Reflection	471	1.0
11	Others	3518	7.4

Table 3: Ten most commonly used femoral/acetabular component combinations used in primary total conventional THA.

Rank	Stem/cup combination	N	Percent
1	Accolade II / Trident	9941	20.9
2	M/L Taper / Continuum	4987	10.5
3	Summit / Pinnacle	3783	7.9
4	Fitmore / Continuum	1889	4.0
5	Taperloc 133 / G7	1782	3.7
6	Secur-Fit Plus Max / Trident	1686	3.5
7	Secur-Fit Max / Trident	1500	3.1
8	Anthology / Reflection 3	1458	3.1
9	Taperloc 133 / RingLoc+	1267	2.7
10	Tri-Lock BPS / Pinnacle	1203	2.5
11	Others	18168	37.8

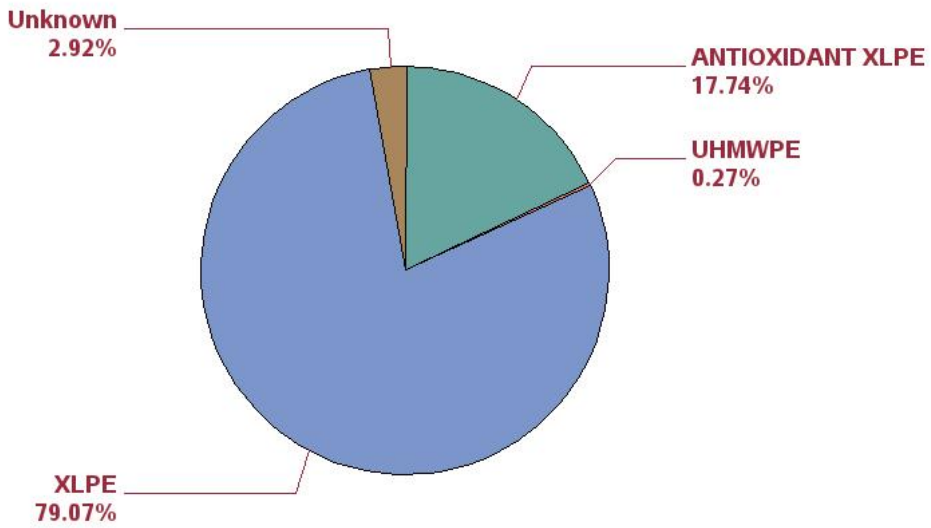

Figure 17: Percentage of polyethylene liners by type of polyethylene for primary conventional THA.

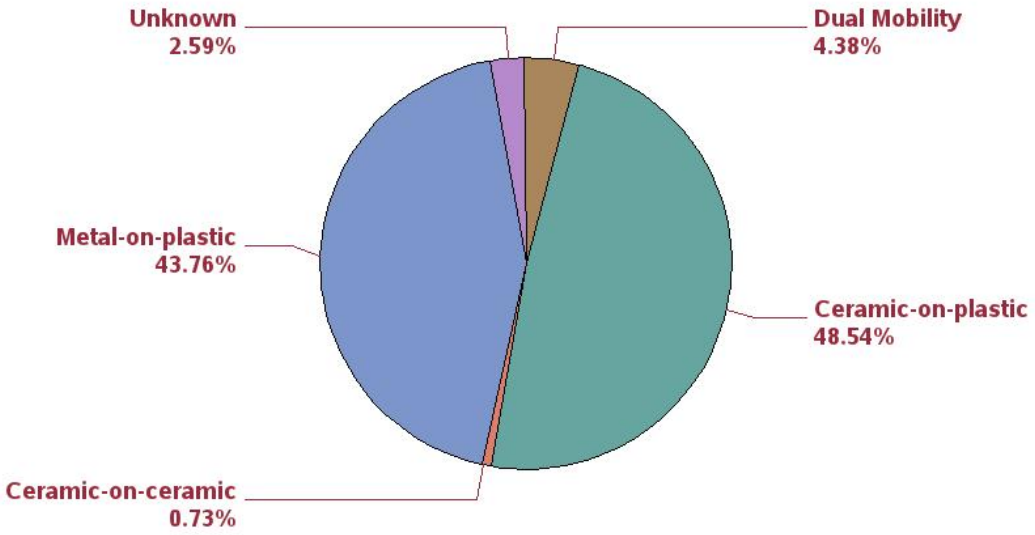

Figure 18: Percentage by bearing surface couple for primary conventional THA.

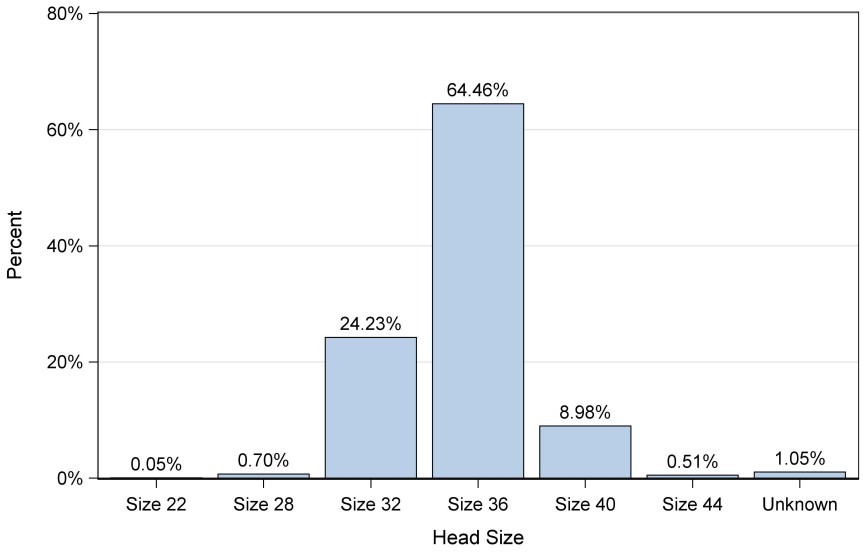

Figure 19: Distribution of head sizes for primary conventional THA, excluding dual mobility cases.

4.3 Revision risk summary

The reason for revision is of central importance to quality improvement because it helps focus attention on specific causes that may be addressed. Therefore, the data are presented in two formats below: tabular and Pareto chart. The tabular format is consistent with how other arthroplasty registries report cause of revision. The Pareto chart figure presents the same data in a format commonly used in quality improvement. The Pareto chart sorts the reasons for revision by frequency (bar chart on bottom, from left to right) and presents a cumulative percent using a line graph above. The causes corresponding to each bar are numbered and a key at the bottom links the numbers to text descriptions

Table 4: Most common reasons for revision following primary conventional THA.

Rank	Reason for revision	N	Percent
1	Instability/Dislocation	143	24.4
2	Peri-prosthetic fracture (Femur)	124	21.1
3	Joint Infection	106	18.1
4	Aseptic loosening	84	14.3
5	Pain	76	12.9
6	Component fracture/failure	25	4.3
7	Peri-prosthetic fracture (Acetabulum)	14	2.4
8	Malalignment	13	2.2
9	Poly liner wear	1	0.2
10	Metal reaction/Metallosis	1	0.2

Table 5: Most common reasons for revision following primary conventional THA in first year post-operatively.

Rank	Reason for revision	N	Percent
1	Peri-prosthetic fracture (Femur)	118	27.1
2	Instability/Dislocation	115	26.4
3	Joint Infection	83	19.0
4	Aseptic loosening	40	9.2
5	Pain	39	8.9
6	Component fracture/failure	21	4.8
7	Malalignment	10	2.3
8	Peri-prosthetic fracture (Acetabulum)	9	2.1
9	Poly liner wear	1	0.2

Table 6: Most common reasons for revision following primary conventional THA in second year post-operatively.

Rank	Reason for revision	N	Percent
1	Aseptic loosening	27	28.7
2	Pain	24	25.5
3	Instability/Dislocation	19	20.2
4	Joint Infection	16	17.0
5	Peri-prosthetic fracture (Acetabulum)	3	3.2
6	Component fracture/failure	2	2.1
7	Peri-prosthetic fracture (Femur)	2	2.1
8	Malalignment	1	1.1

Table 7: Most common reasons for revision following primary conventional THA in third year post-operatively.

Rank	Reason for revision	N	Percent
1	Aseptic loosening	14	35.0
2	Pain	10	25.0
3	Instability/Dislocation	5	12.5
4	Joint Infection	5	12.5
5	Component fracture/failure	2	5.0
6	Peri-prosthetic fracture (Femur)	2	5.0
7	Peri-prosthetic fracture (Acetabulum)	1	2.5
8	Malalignment	1	2.5

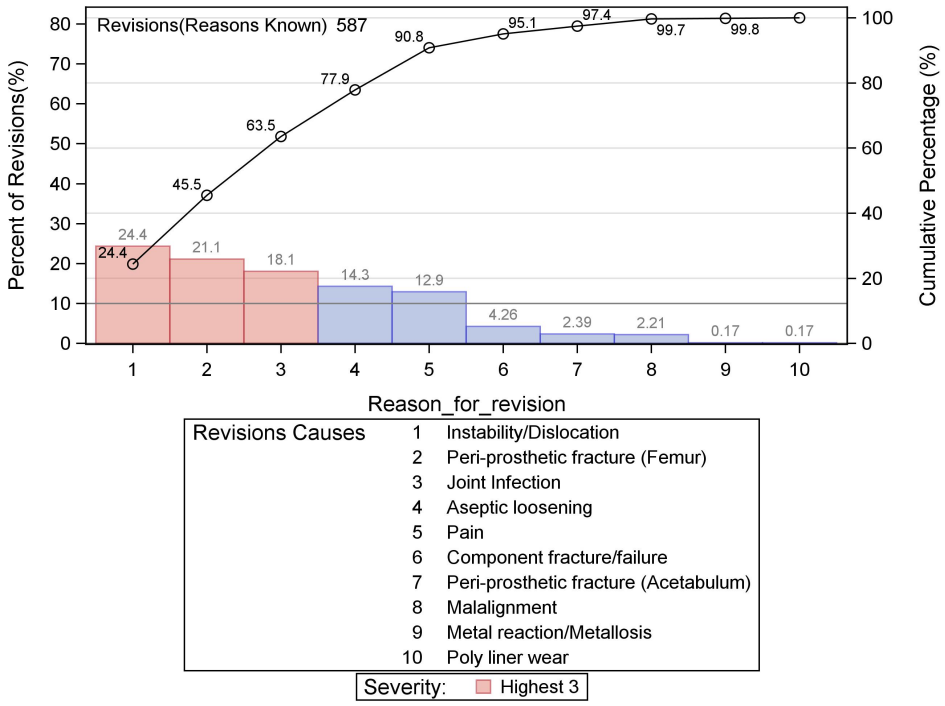

Figure 20: Most common reasons for revision following primary conventional THA (Pareto chart).

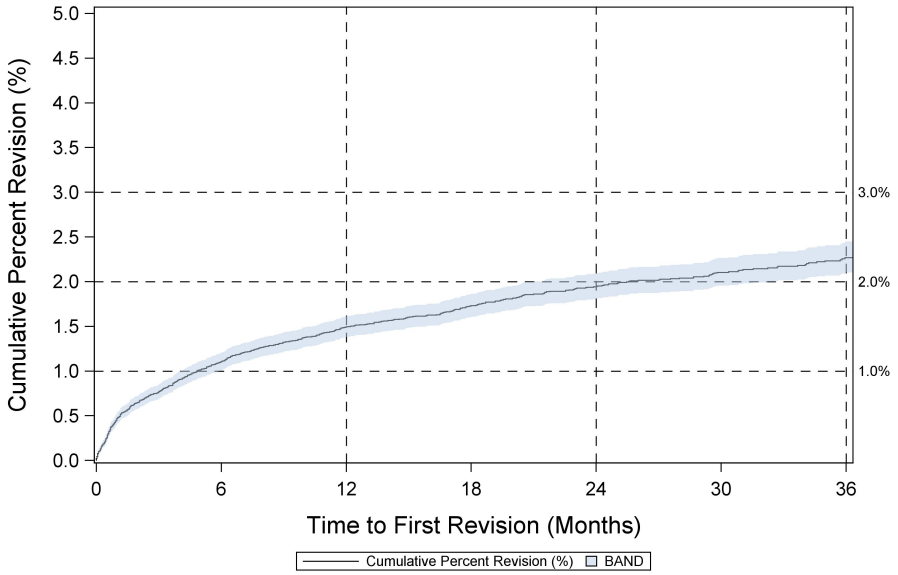

Figure 21: Cumulative percent revision for primary conventional THA.

Table 8: Cumulative percent revision for primary conventional THA (numerical values).

N	1 year	2 years	3 years
47576	1.49 (1.38,1.61)	1.94 (1.81,2.09)	2.27 (2.10,2.45)

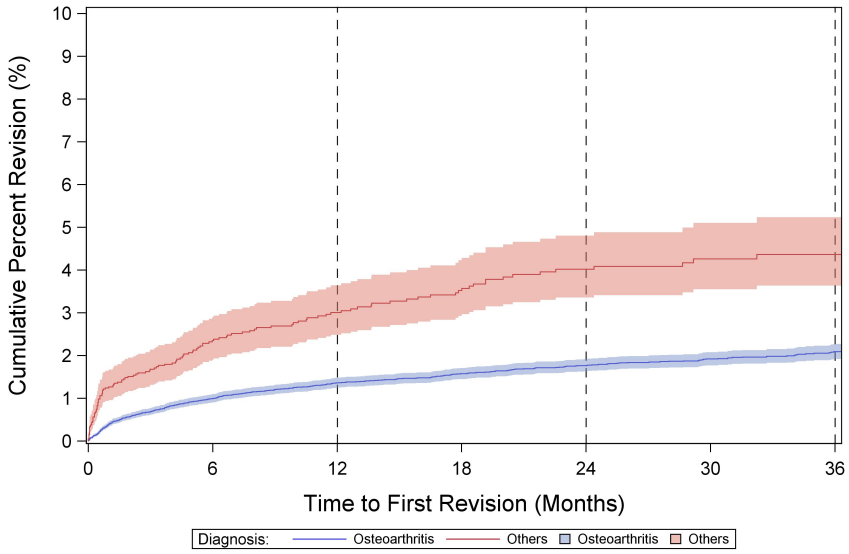

Figure 22: Cumulative percent revision for primary conventional THA by diagnosis.

Table 9: Cumulative percent revision for primary conventional THA by diagnosis (numerical values).

Diagnosis	N	1 year	2 years	3 years
Osteoarthritis	43563	1.36 (1.25,1.48)	1.77 (1.63,1.91)	2.09 (1.92,2.28)
Others	3913	3.01 (2.48,3.64)	4.02 (3.36,4.81)	4.37 (3.64,5.24)
Unknown/Missing	102			

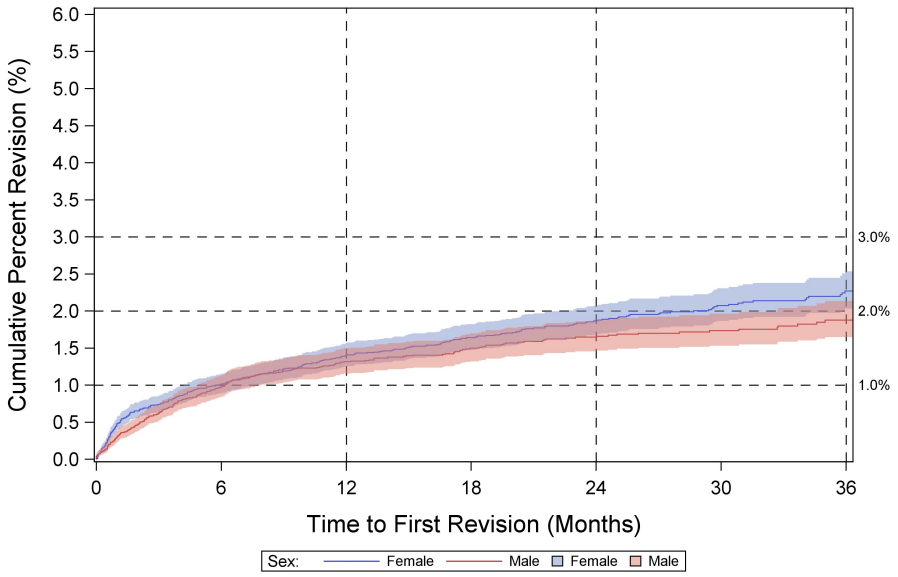

Figure 23: Cumulative percent revision for primary conventional THA by sex for osteoarthritis diagnosis.

Table 10: Cumulative percent revision for primary conventional THA by sex for osteoarthritis diagnosis (numerical values).

Sex	N	1 year	2 years	3 years
Female	24166	1.40 (1.25,1.57)	1.87 (1.68,2.07)	2.27 (2.03,2.53)
Male	19378	1.32 (1.16,1.50)	1.65 (1.46,1.86)	1.88 (1.65,2.13)
Unknown/Missing	19			

4.4 Revision risk for implant combinations

There is variation in revision risk across implants. The following section of this chapter provides revision risk data by stem/cup implant combination. The reader should be cautious in interpreting implant cumulative percent revision (CPR) data because there are many other factors that can affect CPR such as the characteristics of the patients who receive the implants, the volume of procedures done by the surgeons using the implant, and the volume of procedures done using that specific implant. Both mean and median volume numbers are provided for surgeons and hospitals because the distributions are skewed. Bearing surface couple, head size, and approach can also vary across implant combinations and affect CPR. Text and tables have been included to provide this information for each implant combination so the reader can make decisions based on a comprehensive view of how the implant combination is used. Note that sample size differs for CPR reporting and descriptive statistics provided in tables: the difference is due to excluding death from the CPR calculations. All implant combinations have a minimum follow up of at least three years. Therefore, if the red line and shaded confidence interval end prior to three years, this does not mean the longest follow up was less than three years. Instead, it means that no additional revisions occurred after the end of the red line and confidence interval band.

While the reader is encouraged to read the details of each stem/cup implant combination, the following table summarizes the three-year CPR values.

Table 11: Summary of cumulative percent revision for stem/cup combinations having at least 500 cases, sorted alphabetically.

Stem/cup combination	N	1 year	2 years	3 years
Accolade II / Trident	9929	1.02 (0.82,1.26)	1.56 (1.28,1.90)	2.27 (1.84,2.81)
Accolade TMZF / Trident	860	1.06 (0.56,2.04)	1.58 (0.89,2.79)	1.87 (1.06,3.31)
Anthology / Reflection 3	1452	2.51 (1.78,3.55)	*3.26 (2.36,4.50)*	*3.26 (2.36,4.50)*
Corail / Pinnacle	1182	1.08 (0.59,1.95)	*1.48 (0.83,2.63)*	*1.48 (0.83,2.63)*
Fitmore / Continuum	1888	1.40 (0.94,2.09)	*1.75 (1.20,2.54)*	*1.75 (1.20,2.54)*
M/L Taper* / Continuum	4983	1.73 (1.39,2.14)	2.00 (1.63,2.46)	2.42 (1.96,2.97)
M/L Taper* / Trilogy	1180	1.27 (0.75,2.14)	2.24 (1.47,3.41)	*2.67 (1.76,4.04)*
SROM / Pinnacle	794	0.67 (0.28,1.61)	*1.23 (0.61,2.48)*	*1.23 (0.61,2.48)*
Secur-Fit / Trident	696	2.83 (1.79,4.46)	3.63 (2.35,5.60)	*3.63 (2.35,5.60)*
Secur-Fit Max / Trident	1498	1.86 (1.27,2.73)	2.70 (1.88,3.86)	2.85 (2.00,4.07)
Secur-Fit Plus Max / Trident	1679	1.54 (1.03,2.29)	1.83 (1.25,2.68)	2.15 (1.47,3.15)
Summit / Pinnacle	3779	1.33 (1.00,1.78)	1.50 (1.13,1.98)	1.57 (1.19,2.08)
Synergy / Reflection 3	579	2.21 (1.26,3.87)	2.93 (1.77,4.84)	*2.93 (1.77,4.84)*
Taperloc 133 / G7	1779	1.69 (1.11,2.57)	*2.28 (1.41,3.69)*	*2.28 (1.41,3.69)*
Taperloc 133 / RingLoc+	1262	1.67 (1.08,2.59)	*2.10 (1.41,3.12)*	*2.10 (1.41,3.12)*
Trabecular Metal / Continuum	522	2.98 (1.81,4.90)	2.98 (1.81,4.90)	4.29 (2.15,8.47)
Tri-Lock BPS / Pinnacle	1201	*0.57 (0.25,1.26)*	*0.57 (0.25,1.26)*	*0.57 (0.25,1.26)*

Notes:

* M/L Taper does not include M/L Taper Kinectiv.

A revision risk in *italics* indicates it is the same as it was at the time of the last revision.

Accolade II/Trident
N=9929

This implant combination was used by 90 surgeons. The median number of cases for those surgeons using this implant combination was 20.5 (interquartile range 140). The mean was 110.5 and standard deviation was 184.3. This implant combination was used at 38 sites. The median number of cases using this implant combination per site was 82.5 (interquartile range 336). The mean was 261.6 and standard deviation was 411.4.

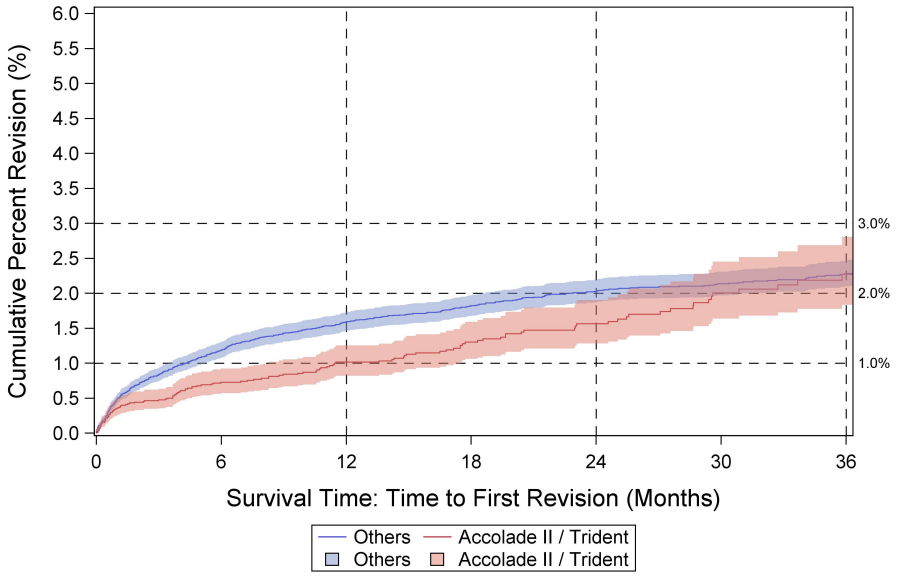

Figure 24: Cumulative percent revision curve for Accolade II/Trident combination compared to all other conventional THA implants.

Table 12: Cumulative percent revision for Accolade II/Trident combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years
9929	1.02 (0.82,1.26)	1.56 (1.28,1.90)	2.27 (1.84,2.81)

Table 13: Descriptive statistics on cases receiving the Accolade II/Trident combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	5390	54.22	
Age (yrs)	9941	63.99(11.17)	64.00(15.00)
Height (cm)	9941	169.71(10.23)	170.00(15.00)
Weight (kg)	9941	87.43(20.89)	86.00(28.00)
BMI(kg/m^2)	9941	30.25(6.28)	29.45(8.01)
Smoking - never (%)	4743	47.71	
Smoking - previous (%)	3808	38.31	
Smoking - current (%)	1319	13.27	
Smoking - unknown (%)	71	0.71	

Table 14: Distribution of head size for Accolade II/Trident combination.

Size (mm)	N	Percent
22	3	0.0
28	22	0.2
32	1973	21.8
36	6485	71.7
40	507	5.6
44	29	0.3
Other/unknown	28	0.3

Table 15: Distribution of bearing surface for Accolade II/Trident combination.

Bearing	N	Percent
Metal-on-plastic	2552	25.7
Ceramic-on-plastic	6457	65.0
Ceramic-on-ceramic	11	0.1
Metal-on-metal	0	0.0
Dual mobility	863	8.7
Other/unknown	58	0.6

Table 16: Distribution of approach used for Accolade II/Trident combination.

Approach	N	Percent
Anterior	3147	31.7
Anterolateral	1340	13.5
Posterior	5417	54.5
Transtrochanteric	16	0.2
Unknown/other	21	0.2

Accolade TMZF/Trident
N=860

This implant combination was used by 14 surgeons. The median number of cases for those surgeons using this implant combination was 8 (interquartile range 14). The mean was 61.5 and standard deviation was 136.9. This implant combination was used at 11 sites. The median number of cases using this implant combination per site was 22 (interquartile range 196). The mean was 78.3 and standard deviation was 105.2.

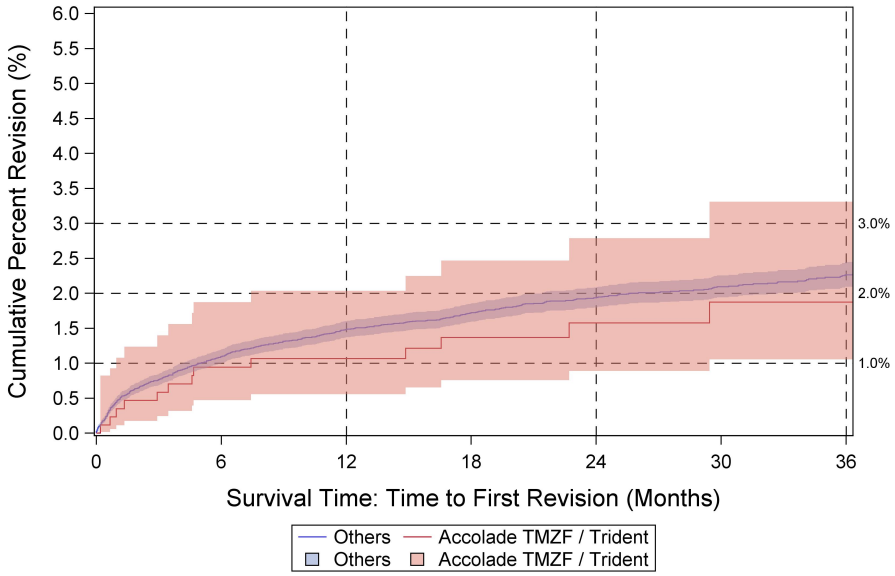

Figure 25: Cumulative percent revision curve for Accolade TMZF/Trident combination compared to all other conventional THA implants.

Table 17: Cumulative percent revision for Accolade TMZF/Trident combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years
860	1.06 (0.56,2.04)	1.58 (0.89,2.79)	1.87 (1.06,3.31)

Table 18: Descriptive statistics on cases receiving the Accolade TMZF/Trident combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	478	55.52	
Age (yrs)	861	63.11(11.23)	63.00(16.00)
Height (cm)	861	169.62(10.57)	168.00(15.00)
Weight (kg)	861	89.57(21.02)	89.00(29.00)
BMI(kg/m^2)	861	31.00(6.11)	30.43(8.14)
Smoking - never (%)	400	46.46	
Smoking - previous (%)	321	37.28	
Smoking - current (%)	123	14.29	
Smoking - unknown (%)	17	1.97	

Table 19: Distribution of head size for Accolade TMZF/Trident combination.

Size (mm)	N	Percent
28	1	0.1
32	89	10.6
36	651	77.6
40	91	10.8
Other/unknown	7	0.8

Table 20: Distribution of bearing surface for Accolade TMZF/Trident combination.

Bearing	N	Percent
Metal-on-plastic	478	55.5
Ceramic-on-plastic	352	40.9
Ceramic-on-ceramic	2	0.2
Metal-on-metal	0	0.0
Dual mobility	18	2.1
Other/unknown	11	1.3

Table 21: Distribution of approach used for Accolade TMZF/Trident combination.

Approach	N	Percent
Anterior	8	0.9
Anterolateral	113	13.1
Posterior	730	84.8
Transtrochanteric	3	0.3
Unknown/other	7	0.8

Anthology/Reflection 3
N=1452

This implant combination was used by 38 surgeons. The median number of cases for those surgeons using this implant combination was 11 (interquartile range 50). The mean was 38.4 and standard deviation was 60.6. This implant combination was used at 28 sites. The median number of cases using this implant combination per site was 20.5 (interquartile range 63.5). The mean was 52.1 and standard deviation was 69.7.

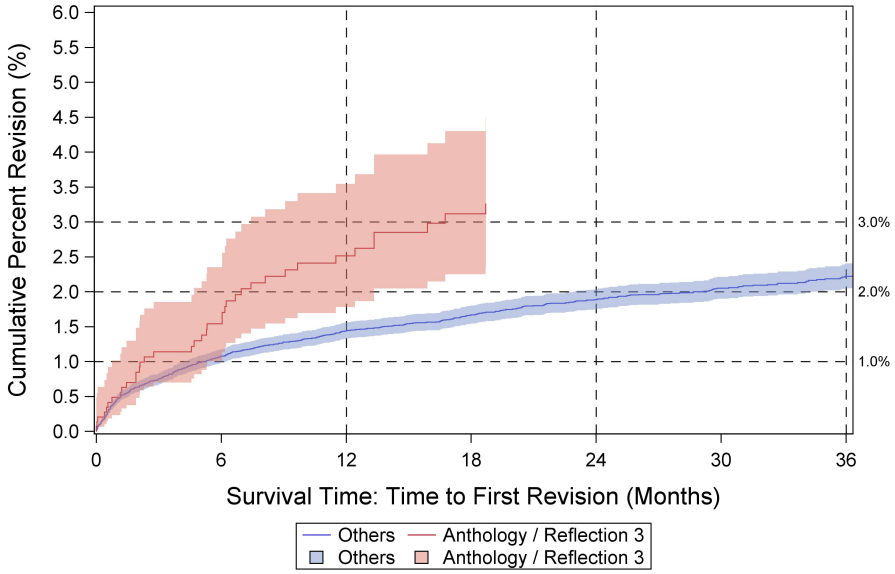

Figure 26: Cumulative percent revision curve for Anthology/Reflection 3 combination compared to all other conventional THA implants.

Table 22: Cumulative percent revision for Anthology/Reflection 3 combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years*	3 years*
1452	2.51 (1.78,3.55)	3.26 (2.36,4.50)	3.26 (2.36,4.50)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 23: Descriptive statistics on cases receiving the Anthology/Reflection 3 combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	783	53.7	
Age (yrs)	1458	64.02(11.44)	64.00(15.00)
Height (cm)	1458	169.14(10.36)	168.00(15.00)
Weight (kg)	1458	90.13(23.19)	88.00(29.00)
BMI(kg/m^2)	1458	31.40(7.05)	30.40(8.77)
Smoking - never (%)	697	47.81	
Smoking - previous (%)	516	35.39	
Smoking - current (%)	241	16.53	
Smoking - unknown (%)	4	0.27	

Table 24: Distribution of head size for Anthology/Reflection 3 combination.

Size (mm)	N	Percent
22	1	0.1
28	10	0.7
32	375	25.8
36	868	59.6
40	179	12.3
44	13	0.9
Other/unknown	10	0.7

Table 25: Distribution of bearing surface for Anthology/Reflection 3 combination.

Bearing	N	Percent
Metal-on-plastic	382	26.2
Ceramic-on-plastic	1063	72.9
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	13	0.9

Table 26: Distribution of approach used for Anthology/Reflection 3 combination.

Approach	N	Percent
Anterior	636	43.6
Anterolateral	325	22.3
Posterior	482	33.1
Transtrochanteric	11	0.8
Unknown/other	4	0.3

Corail/Pinnacle
N=1182

This implant combination was used by 28 surgeons. The median number of cases for those surgeons using this implant combination was 27 (interquartile range 60.5). The mean was 42.4 and standard deviation was 52.5. This implant combination was used at 16 sites. The median number of cases using this implant combination per site was 37.5 (interquartile range 113.5). The mean was 74.2 and standard deviation was 92.4.

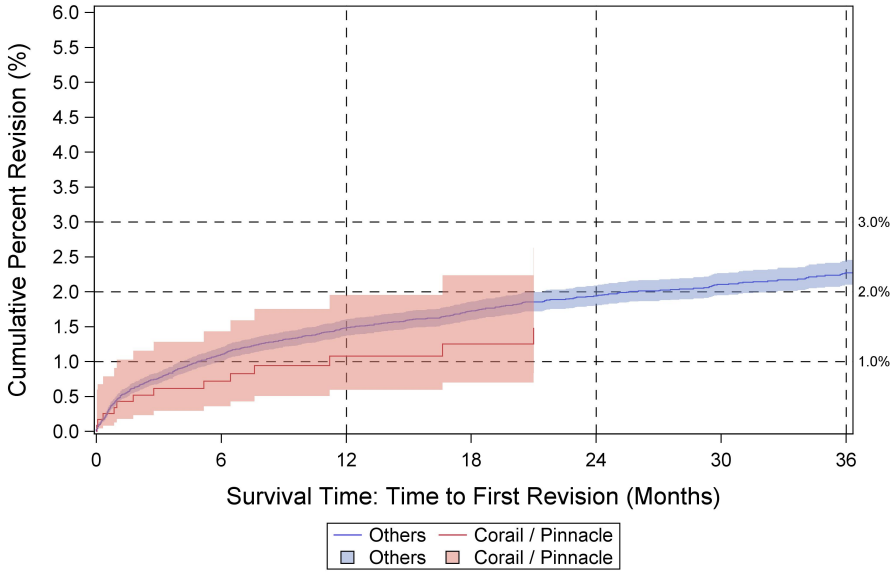

Figure 27: Cumulative percent revision curve for Corail/Pinnacle combination compared to all other conventional THA implants.

Table 27: Cumulative percent revision for Corail/Pinnacle combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years*	3 years*
1182	1.08 (0.59,1.95)	1.48 (0.83,2.63)	1.48 (0.83,2.63)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 28: Descriptive statistics on cases receiving the Corail/Pinnacle combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	696	58.64	
Age (yrs)	1187	65.68(10.66)	66.00(15.00)
Height (cm)	1187	168.96(10.23)	168.00(15.00)
Weight (kg)	1187	87.31(19.91)	85.00(26.00)
BMI(kg/m^2)	1187	30.50(5.96)	29.75(7.82)
Smoking - never (%)	529	44.57	
Smoking - previous (%)	450	37.91	
Smoking - current (%)	206	17.35	
Smoking - unknown (%)	2	0.17	

Table 29: Distribution of head size for Corail/Pinnacle combination.

Size (mm)	N	Percent
32	265	22.5
36	775	65.7
40	119	10.1
44	15	1.3
Other/unknown	5	0.4

Table 30: Distribution of bearing surface for Corail/Pinnacle combination.

Bearing	N	Percent
Metal-on-plastic	711	59.9
Ceramic-on-plastic	459	38.7
Ceramic-on-ceramic	5	0.4
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	12	1.0

Table 31: Distribution of approach used for Corail/Pinnacle combination.

Approach	N	Percent
Anterior	869	73.2
Anterolateral	221	18.6
Posterior	95	8.0
Transtrochanteric	2	0.2
Unknown/other	0	0.0

Fitmore/Continuum
N=1888

This implant combination was used by 35 surgeons. The median number of cases for those surgeons using this implant combination was 5 (interquartile range 23). The mean was 54.0 and standard deviation was 166.7. This implant combination was used at 16 sites. The median number of cases using this implant combination per site was 28 (interquartile range 143). The mean was 118.1 and standard deviation was 184.2.

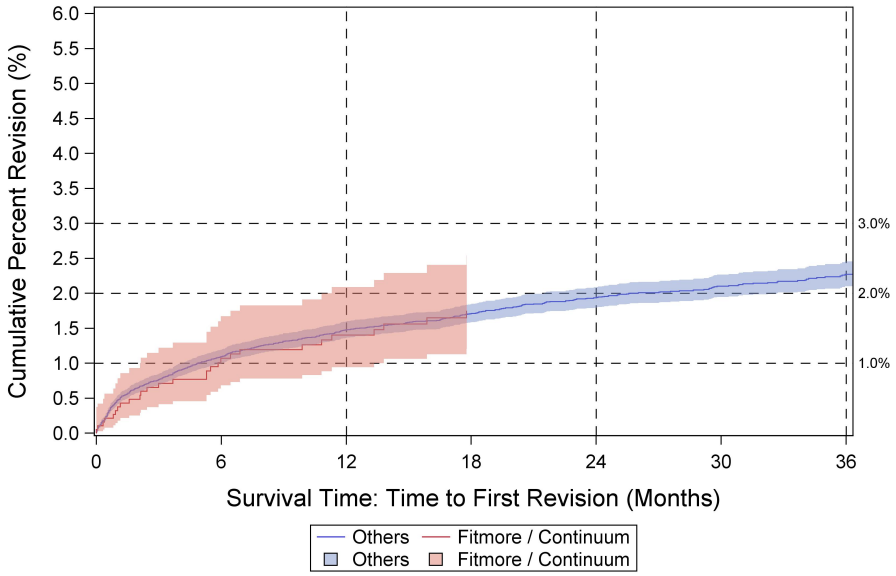

Figure 28: Cumulative percent revision curve for Fitmore/Continuum combination compared to all other conventional THA implants.

Table 32: Cumulative percent revision for Fitmore/Continuum combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years*	3 years*
1888	1.40 (0.94,2.09)	1.75 (1.20,2.54)	1.75 (1.20,2.54)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 33: Descriptive statistics on cases receiving the Fitmore/Continuum combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	925	48.97	
Age (yrs)	1889	63.80(10.41)	64.00(14.00)
Height (cm)	1889	170.57(10.30)	170.00(16.00)
Weight (kg)	1889	87.85(21.70)	86.00(30.00)
BMI(kg/m^2)	1889	30.03(6.18)	29.22(7.90)
Smoking - never (%)	896	47.43	
Smoking - previous (%)	741	39.23	
Smoking - current (%)	248	13.13	
Smoking - unknown (%)	4	0.21	

Table 34: Distribution of head size for Fitmore/Continuum combination.

Size (mm)	N	Percent
28	3	0.2
32	447	23.8
36	1238	66.0
40	172	9.2
Other/unknown	15	0.8

Table 35: Distribution of bearing surface for Fitmore/Continuum combination.

Bearing	N	Percent
Metal-on-plastic	456	24.1
Ceramic-on-plastic	1404	74.3
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	29	1.5

Table 36: Distribution of approach used for Fitmore/Continuum combination.

Approach	N	Percent
Anterior	1600	84.7
Anterolateral	20	1.1
Posterior	269	14.2
Transtrochanteric	0	0.0
Unknown/other	0	0.0

M/L Taper/Continuum
N=4983

This implant combination was used by 64 surgeons. The median number of cases for those surgeons using this implant combination was 26.5 (interquartile range 84). The mean was 77.9 and standard deviation was 155.3. This implant combination was used at 28 sites. The median number of cases using this implant combination per site was 54 (interquartile range 153). The mean was 178.1 and standard deviation was 378.6.

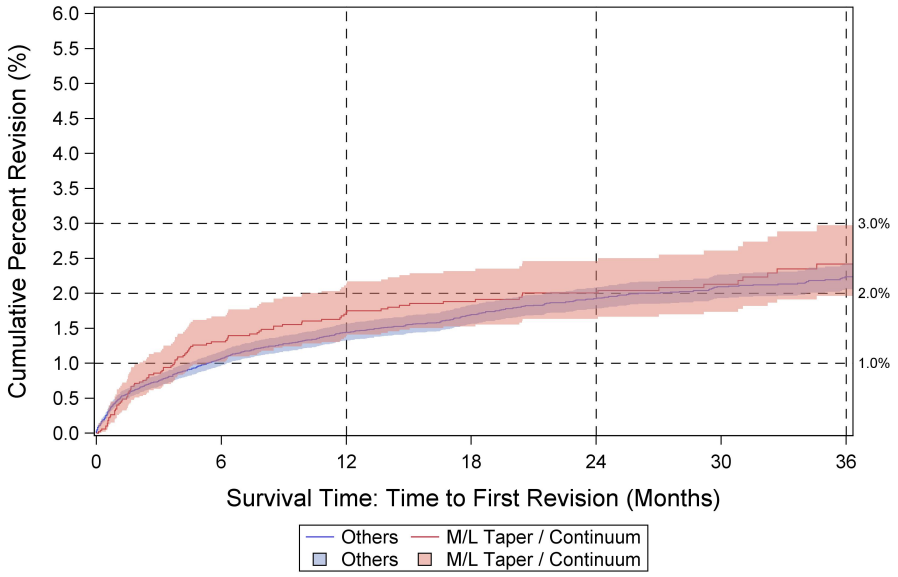

Figure 29: Cumulative percent revision curve for M/L Taper/Continuum combination compared to all other conventional THA implants.

Table 37: Cumulative percent revision for M/L Taper/Continuum combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years
4983	1.73 (1.39,2.14)	2.00 (1.63,2.46)	2.42 (1.96,2.97)

Table 38: Descriptive statistics on cases receiving the M/L Taper/Continuum combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	2671	53.56	
Age (yrs)	4987	64.56(10.90)	65.00(14.00)
Height (cm)	4979	169.77(10.41)	170.00(15.00)
Weight (kg)	4978	86.85(20.21)	85.00(28.00)
BMI(kg/m^2)	4978	30.02(5.91)	29.28(7.57)
Smoking - never (%)	2467	49.47	
Smoking - previous (%)	1913	38.36	
Smoking - current (%)	590	11.83	
Smoking - unknown (%)	17	0.34	

Table 39: Distribution of head size for M/L Taper/Continuum combination.

Size (mm)	N	Percent
28	17	0.3
32	1134	22.9
36	3362	68.0
40	362	7.3
Other/unknown	68	1.4

Table 40: Distribution of bearing surface for M/L Taper/Continuum combination.

Bearing	N	Percent
Metal-on-plastic	2126	42.6
Ceramic-on-plastic	2747	55.1
Ceramic-on-ceramic	2	0.0
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	112	2.3

Table 41: Distribution of approach used for M/L Taper/Continuum combination.

Approach	N	Percent
Anterior	1047	21.0
Anterolateral	912	18.3
Posterior	2948	59.1
Transtrochanteric	43	0.9
Unknown/other	37	0.7

Note M/L Taper does not include M/L Taper Kinectiv.

M/L Taper/Trilogy
N=1180

This implant combination was used by 17 surgeons. The median number of cases for those surgeons using this implant combination was 14 (interquartile range 95). The mean was 69.5 and standard deviation was 98.3. This implant combination was used at 11 sites. The median number of cases using this implant combination per site was 12 (interquartile range 258). The mean was 107.5 and standard deviation was 179.1.

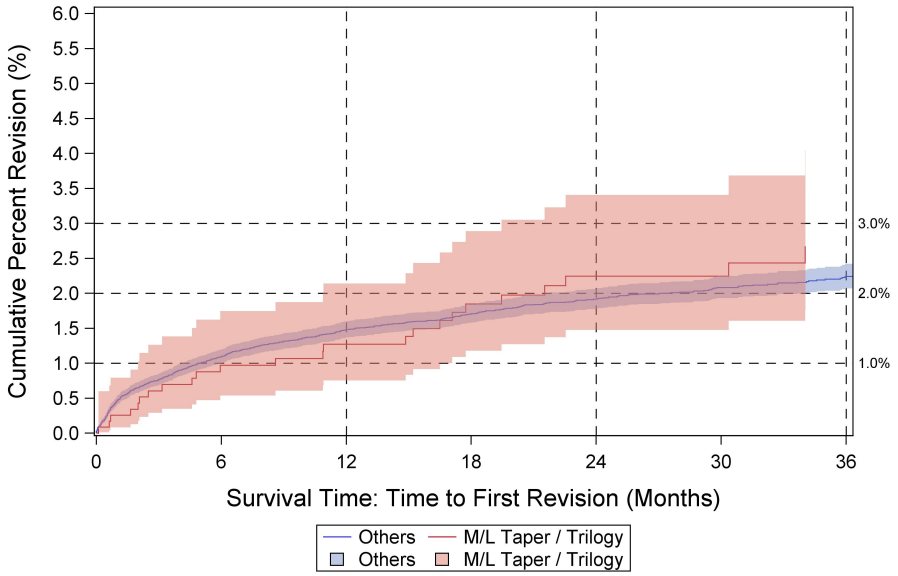

Figure 30: Cumulative percent revision curve for M/L Taper/Trilogy combination compared to all other conventional THA implants.

Table 42: Cumulative percent revision for M/L Taper/Trilogy combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years*
1180	1.27 (0.75,2.14)	2.24 (1.47,3.41)	2.67 (1.76,4.04)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 43: Descriptive statistics on cases receiving the M/L Taper/Trilogy combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	614	51.95	
Age (yrs)	1182	67.37(9.98)	67.00(15.00)
Height (cm)	1182	169.42(10.45)	169.00(15.00)
Weight (kg)	1182	86.92(19.82)	85.00(27.00)
BMI(kg/m^2)	1182	30.18(5.82)	29.62(7.50)
Smoking - never (%)	528	44.67	
Smoking - previous (%)	501	42.39	
Smoking - current (%)	152	12.86	
Smoking - unknown (%)	1	0.08	

Table 44: Distribution of head size for M/L Taper/Trilogy combination.

Size (mm)	N	Percent
28	37	3.1
32	760	64.5
36	359	30.5
40	13	1.1
Other/unknown	9	0.8

Table 45: Distribution of bearing surface for M/L Taper/Trilogy combination.

Bearing	N	Percent
Metal-on-plastic	1005	85.0
Ceramic-on-plastic	164	13.9
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	13	1.1

Table 46: Distribution of approach used for M/L Taper/Trilogy combination.

Approach	N	Percent
Anterior	15	1.3
Anterolateral	696	58.9
Posterior	447	37.8
Transtrochanteric	24	2.0
Unknown/other	0	0.0

Note M/L Taper does not include M/L Taper Kinectiv.

SROM/Pinnacle
N=794

This implant combination was used by 35 surgeons. The median number of cases for those surgeons using this implant combination was 3 (interquartile range 26). The mean was 22.7 and standard deviation was 38.3. This implant combination was used at 19 sites. The median number of cases using this implant combination per site was 5 (interquartile range 19). The mean was 41.8 and standard deviation was 110.6.

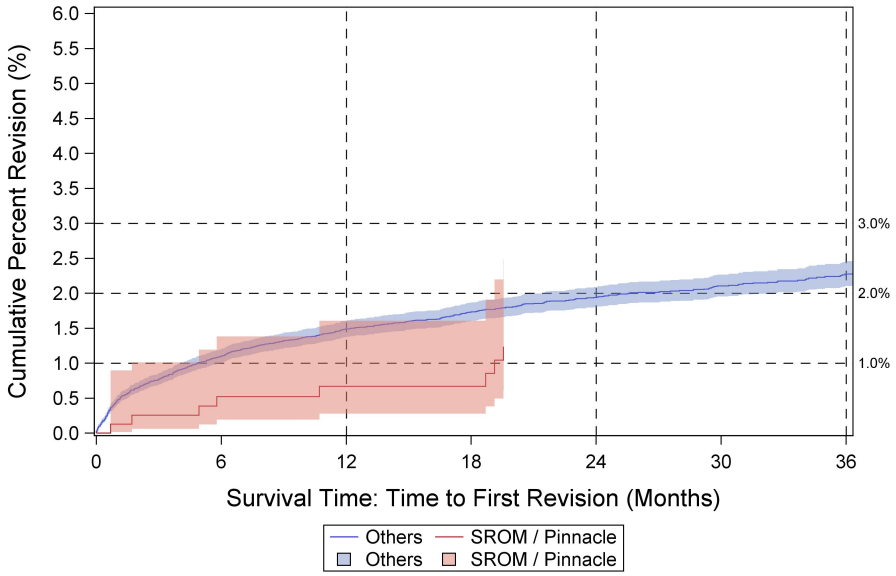

Figure 31: Cumulative percent revision curve for SROM/Pinnacle combination compared to all other conventional THA implants.

Table 47: Cumulative percent revision for SROM/Pinnacle combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years*	3 years*
794	0.67 (0.28,1.61)	1.23 (0.61,2.48)	1.23 (0.61,2.48)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 48: Descriptive statistics on cases receiving the SROM/Pinnacle combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	404	50.88	
Age (yrs)	794	61.31(11.66)	62.00(15.00)
Height (cm)	794	170.95(10.85)	170.00(18.00)
Weight (kg)	794	90.24(22.06)	88.00(30.00)
BMI(kg/m^2)	794	30.78(6.50)	30.05(8.53)
Smoking - never (%)	378	47.61	
Smoking - previous (%)	282	35.52	
Smoking - current (%)	132	16.62	
Smoking - unknown (%)	2	0.25	

Table 49: Distribution of head size for SROM/Pinnacle combination.

Size (mm)	N	Percent
28	4	0.5
32	186	23.5
36	573	72.3
40	24	3.0
44	2	0.3
Other/unknown	3	0.4

Table 50: Distribution of bearing surface for SROM/Pinnacle combination.

Bearing	N	Percent
Metal-on-plastic	285	35.9
Ceramic-on-plastic	503	63.4
Ceramic-on-ceramic	1	0.1
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	5	0.6

Table 51: Distribution of approach used for SROM/Pinnacle combination.

Approach	N	Percent
Anterior	9	1.1
Anterolateral	463	58.3
Posterior	306	38.5
Transtrochanteric	10	1.3
Unknown/other	6	0.8

Secur-Fit/Trident
N=696

This implant combination was used by 28 surgeons. The median number of cases for those surgeons using this implant combination was 4 (interquartile range 16.5). The mean was 25 and standard deviation was 54.5. This implant combination was used at 16 sites. The median number of cases using this implant combination per site was 12.5 (interquartile range 33.5). The mean was 43.8 and standard deviation was 71.9.

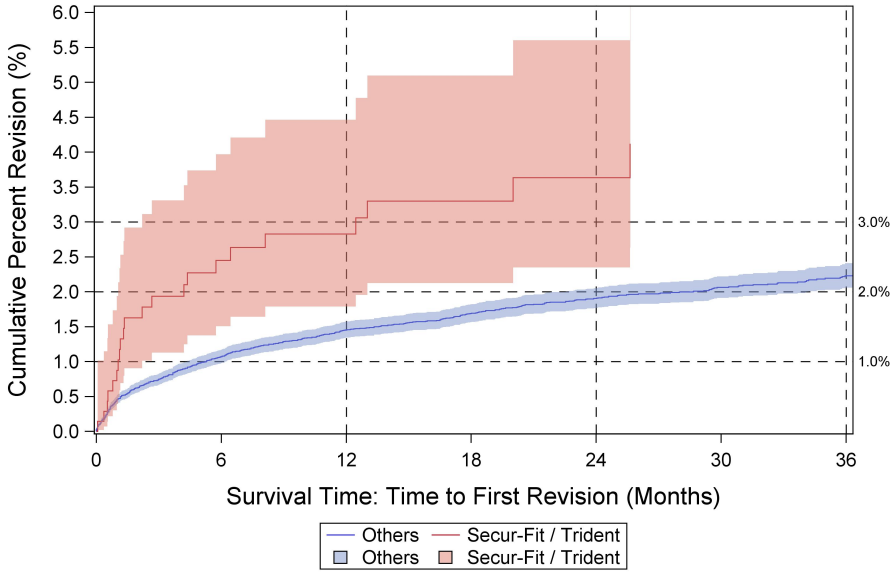

Figure 32: Cumulative percent revision curve for Secur-Fit/Trident combination compared to all other conventional THA implants.

Table 52: Cumulative percent revision for Secur-Fit/Trident combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years*
696	2.83 (1.79,4.46)	3.63 (2.35,5.60)	3.63 (2.35,5.60)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 53: Descriptive statistics on cases receiving the Secur-Fit/Trident combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	431	61.57	
Age (yrs)	700	64.57(10.74)	65.00(14.00)
Height (cm)	700	168.62(10.06)	167.00(17.00)
Weight (kg)	700	89.50(21.68)	87.00(30.00)
BMI(kg/m^2)	700	31.35(6.56)	30.70(9.36)
Smoking - never (%)	324	46.29	
Smoking - previous (%)	251	35.86	
Smoking - current (%)	117	16.71	
Smoking - unknown (%)	8	1.14	

Table 54: Distribution of head size for Secur-Fit/Trident combination.

Size (mm)	N	Percent
28	1	0.2
32	105	16.9
36	347	55.8
40	162	26.1
Other/unknown	7	1.1

Table 55: Distribution of bearing surface for Secur-Fit/Trident combination.

Bearing	N	Percent
Metal-on-plastic	224	32.0
Ceramic-on-plastic	391	55.9
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	75	10.7
Other/unknown	10	1.4

Table 56: Distribution of approach used for Secur-Fit/Trident combination.

Approach	N	Percent
Anterior	1	0.1
Anterolateral	331	47.3
Posterior	364	52.0
Transtrochanteric	1	0.1
Unknown/other	3	0.4

Secur-Fit Max/Trident
N=1498

This implant combination was used by 51 surgeons. The median number of cases for those surgeons using this implant combination was 9 (interquartile range 33). The mean was 29.4 and standard deviation was 55.5. This implant combination was used at 20 sites. The median number of cases using this implant combination per site was 32.5 (interquartile range 89). The mean was 75 and standard deviation was 95.8.

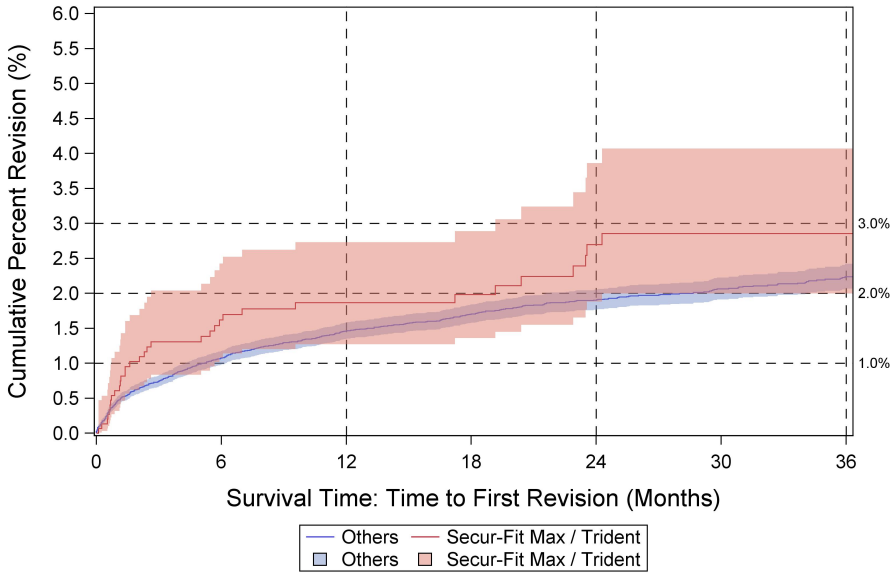

Figure 33: Cumulative percent revision curve for Secur-Fit Max/Trident combination compared to all other conventional THA implants.

Table 57: Cumulative percent revision for Secur-Fit Max/Trident combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years
1498	1.86 (1.27,2.73)	2.70 (1.88,3.86)	2.85 (2.00,4.07)

Table 58: Descriptive statistics on cases receiving the Secur-Fit Max/Trident combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	764	50.93	
Age (yrs)	1500	64.37(11.50)	65.00(15.00)
Height (cm)	1500	169.64(10.35)	170.00(15.00)
Weight (kg)	1500	90.46(21.09)	89.00(27.00)
BMI(kg/m^2)	1500	31.34(6.34)	30.72(8.41)
Smoking - never (%)	683	45.53	
Smoking - previous (%)	608	40.53	
Smoking - current (%)	202	13.47	
Smoking - unknown (%)	7	0.47	

Table 59: Distribution of head size for Secur-Fit Max/Trident combination.

Size (mm)	N	Percent
22	3	0.2
28	16	1.2
32	274	20.4
36	942	70.3
40	98	7.3
Other/unknown	8	0.6

Table 60: Distribution of bearing surface for Secur-Fit Max/Trident combination.

Bearing	N	Percent
Metal-on-plastic	754	50.3
Ceramic-on-plastic	329	21.9
Ceramic-on-ceramic	250	16.7
Metal-on-metal	0	0.0
Dual mobility	118	7.9
Other/unknown	49	3.3

Table 61: Distribution of approach used for Secur-Fit Max/Trident combination.

Approach	N	Percent
Anterior	12	0.8
Anterolateral	540	36.0
Posterior	915	61.0
Transtrochanteric	22	1.5
Unknown/other	11	0.7

Secur-Fit Plus Max/Trident
N=1679

This implant combination was used by 29 surgeons. The median number of cases for those surgeons using this implant combination was 7 (interquartile range 36). The mean was 58.1 and standard deviation was 181.4. This implant combination was used at 17 sites. The median number of cases using this implant combination per site was 14 (interquartile range 91). The mean was 99.2 and standard deviation was 255.9.

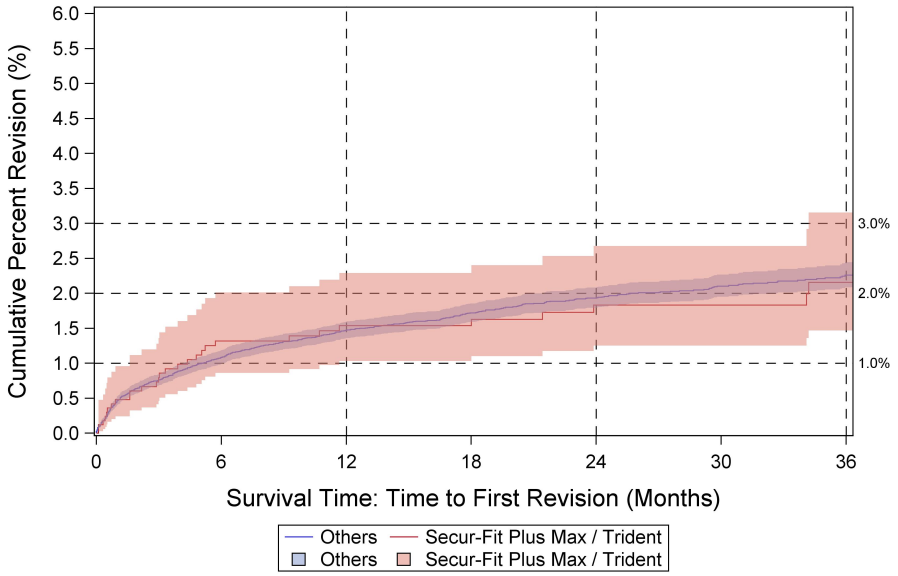

Figure 34: Cumulative percent revision curve for Secur-Fit Plus Max/Trident combination compared to all other conventional THA implants.

Table 62: Cumulative percent revision for Secur-Fit Plus Max/Trident combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years
1679	1.54 (1.03,2.29)	1.83 (1.25,2.68)	2.15 (1.47,3.15)

Table 63: Descriptive statistics on cases receiving the Secur-Fit Plus Max/Trident combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	843	50	
Age (yrs)	1686	61.53(13.34)	62.00(17.00)
Height (cm)	1686	169.55(10.73)	170.00(15.00)
Weight (kg)	1686	86.87(19.92)	86.00(27.00)
BMI(kg/m^2)	1686	30.11(6.24)	29.51(7.15)
Smoking - never (%)	788	46.74	
Smoking - previous (%)	630	37.37	
Smoking - current (%)	226	13.4	
Smoking - unknown (%)	42	2.49	

Table 64: Distribution of head size for Secur-Fit Plus Max/Trident combination.

Size (mm)	N	Percent
28	1	0.1
32	140	8.6
36	1257	76.8
40	206	12.6
44	29	1.8
Other/unknown	4	0.2

Table 65: Distribution of bearing surface for Secur-Fit Plus Max/Trident combination.

Bearing	N	Percent
Metal-on-plastic	1096	65.0
Ceramic-on-plastic	537	31.9
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	41	2.4
Other/unknown	12	0.7

Table 66: Distribution of approach used for Secur-Fit Plus Max/Trident combination.

Approach	N	Percent
Anterior	2	0.1
Anterolateral	55	3.3
Posterior	1622	96.2
Transtrochanteric	4	0.2
Unknown/other	3	0.2

Summit/Pinnacle
N=3779

This implant combination was used by 56 surgeons. The median number of cases for those surgeons using this implant combination was 13 (interquartile range 91.5). The mean was 67.6 and standard deviation was 131.6. This implant combination was used at 26 sites. The median number of cases using this implant combination per site was 46.5 (interquartile range 211). The mean was 145.5 and standard deviation was 204.3.

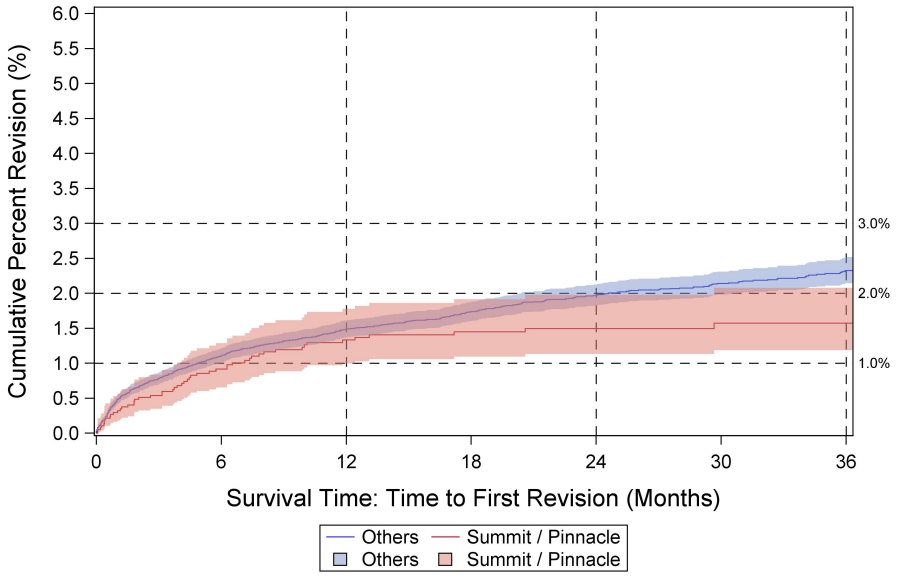

Figure 35: Cumulative percent revision curve for Summit/Pinnacle combination compared to all other conventional THA implants.

Table 67: Cumulative percent revision for Summit/Pinnacle combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years
3779	1.33 (1.00,1.78)	1.50 (1.13,1.98)	1.57 (1.19,2.08)

Table 68: Descriptive statistics on cases receiving the Summit/Pinnacle combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	2133	56.38	
Age (yrs)	3783	65.38(11.13)	66.00(15.00)
Height (cm)	3782	169.22(10.31)	170.00(15.00)
Weight (kg)	3783	88.85(21.80)	87.00(29.00)
BMI(kg/m^2)	3782	30.90(6.55)	29.95(8.38)
Smoking - never (%)	1692	44.73	
Smoking - previous (%)	1523	40.26	
Smoking - current (%)	551	14.57	
Smoking - unknown (%)	17	0.45	

Table 69: Distribution of head size for Summit/Pinnacle combination.

Size (mm)	N	Percent
28	10	0.3
32	920	24.4
36	2629	69.8
40	168	4.5
44	24	0.6
Other/unknown	16	0.4

Table 70: Distribution of bearing surface for Summit/Pinnacle combination.

Bearing	N	Percent
Metal-on-plastic	2116	55.9
Ceramic-on-plastic	1601	42.3
Ceramic-on-ceramic	35	0.9
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	31	0.8

Table 71: Distribution of approach used for Summit/Pinnacle combination.

Approach	N	Percent
Anterior	134	3.5
Anterolateral	1586	41.9
Posterior	2012	53.2
Transtrochanteric	28	0.7
Unknown/other	23	0.6

Synergy/Reflection 3
N=579

This implant combination was used by 23 surgeons. The median number of cases for those surgeons using this implant combination was 5 (interquartile range 40). The mean was 25.2 and standard deviation was 42.8. This implant combination was used at 20 sites. The median number of cases using this implant combination per site was 5 (interquartile range 21). The mean was 29 and standard deviation was 59.9.

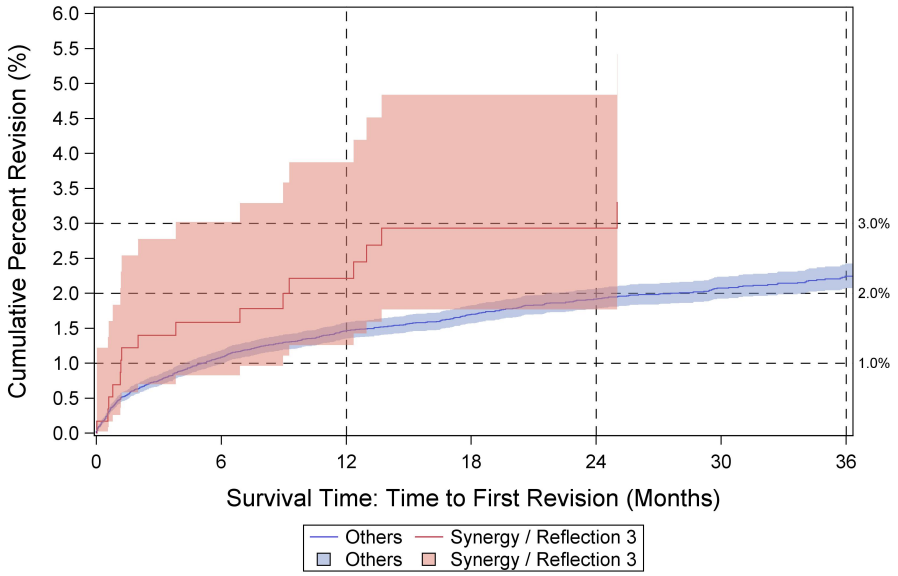

Figure 36: Cumulative percent revision curve for Synergy/Reflection 3 combination compared to all other conventional THA implants.

Table 72: Cumulative percent revision for Synergy/Reflection 3 combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years*
579	2.21 (1.26,3.87)	2.93 (1.77,4.84)	2.93 (1.77,4.84)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 73: Descriptive statistics on cases receiving the Synergy/Reflection 3 combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	315	54.31	
Age (yrs)	580	67.85(10.41)	68.00(15.50)
Height (cm)	580	168.94(10.59)	168.00(15.00)
Weight (kg)	580	88.51(21.23)	88.00(29.50)
BMI(kg/m^2)	580	30.85(6.17)	30.41(8.35)
Smoking - never (%)	250	43.1	
Smoking - previous (%)	252	43.45	
Smoking - current (%)	75	12.93	
Smoking - unknown (%)	3	0.52	

Table 74: Distribution of head size for Synergy/Reflection 3 combination.

Size (mm)	N	Percent
22	1	0.2
28	7	1.2
32	130	22.4
36	381	65.8
40	54	9.3
44	4	0.7
Other/unknown	2	0.3

Table 75: Distribution of bearing surface for Synergy/Reflection 3 combination.

Bearing	N	Percent
Metal-on-plastic	277	47.8
Ceramic-on-plastic	300	51.7
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	3	0.5

Table 76: Distribution of approach used for Synergy/Reflection 3 combination.

Approach	N	Percent
Anterior	11	1.9
Anterolateral	155	26.7
Posterior	409	70.5
Transtrochanteric	3	0.5
Unknown/other	2	0.3

Taperloc 133/G7
N=1779

This implant combination was used by 48 surgeons. The median number of cases for those surgeons using this implant combination was 11 (interquartile range 27.5). The mean was 37.1 and standard deviation was 74.9. This implant combination was used at 29 sites. The median number of cases using this implant combination per site was 26 (interquartile range 61). The mean was 61.5 and standard deviation was 93.0.

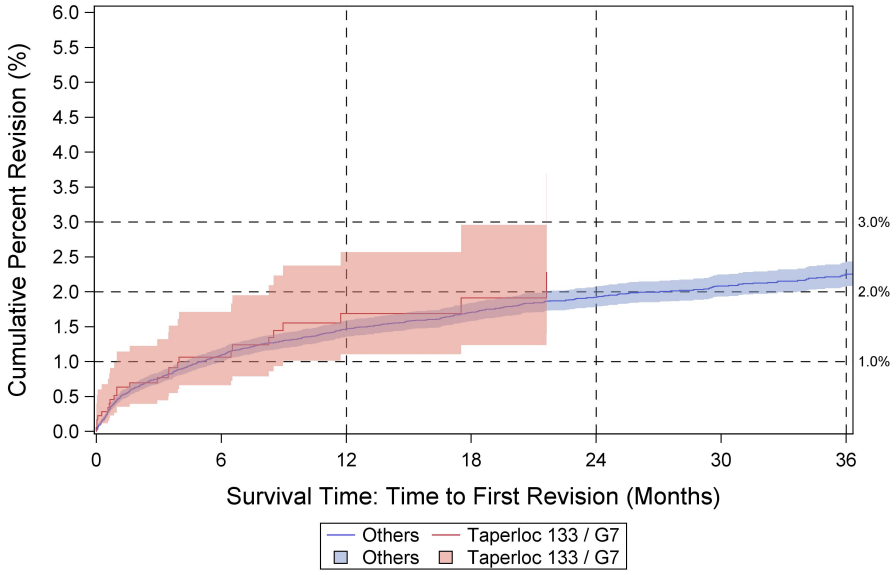

Figure 37: Cumulative percent revision curve for Taperloc 133/G7 combination compared to all other conventional THA implants.

Table 77: Cumulative percent revision for Taperloc 133/G7 combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years*	3 years*
1779	1.69 (1.11,2.57)	2.28 (1.41,3.69)	2.28 (1.41,3.69)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 78: Descriptive statistics on cases receiving the Taperloc 133/G7 combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	948	53.2	
Age (yrs)	1782	62.91(11.15)	63.00(14.00)
Height (cm)	1782	169.68(10.34)	170.00(15.00)
Weight (kg)	1782	89.27(20.09)	88.00(27.00)
BMI(kg/m^2)	1782	30.92(6.08)	30.42(7.85)
Smoking - never (%)	833	46.75	
Smoking - previous (%)	672	37.71	
Smoking - current (%)	260	14.59	
Smoking - unknown (%)	17	0.95	

Table 79: Distribution of head size for Taperloc 133/G7 combination.

Size (mm)	N	Percent
28	3	0.2
32	224	12.8
36	1189	67.7
40	325	18.5
44	1	0.1
Other/unknown	14	0.8

Table 80: Distribution of bearing surface for Taperloc 133/G7 combination.

Bearing	N	Percent
Metal-on-plastic	538	30.2
Ceramic-on-plastic	1204	67.6
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	8	0.5
Other/unknown	32	1.8

Table 81: Distribution of approach used for Taperloc 133/G7 combination.

Approach	N	Percent
Anterior	620	34.8
Anterolateral	414	23.2
Posterior	743	41.7
Transtrochanteric	0	0.0
Unknown/other	5	0.3

Taperloc 133/RingLoc+
N=1262

This implant combination was used by 22 surgeons. The median number of cases for those surgeons using this implant combination was 9 (interquartile range 122). The mean was 57.6 and standard deviation was 83.5. This implant combination was used at 17 sites. The median number of cases using this implant combination per site was 11 (interquartile range 123). The mean was 74.5 and standard deviation was 111.0.

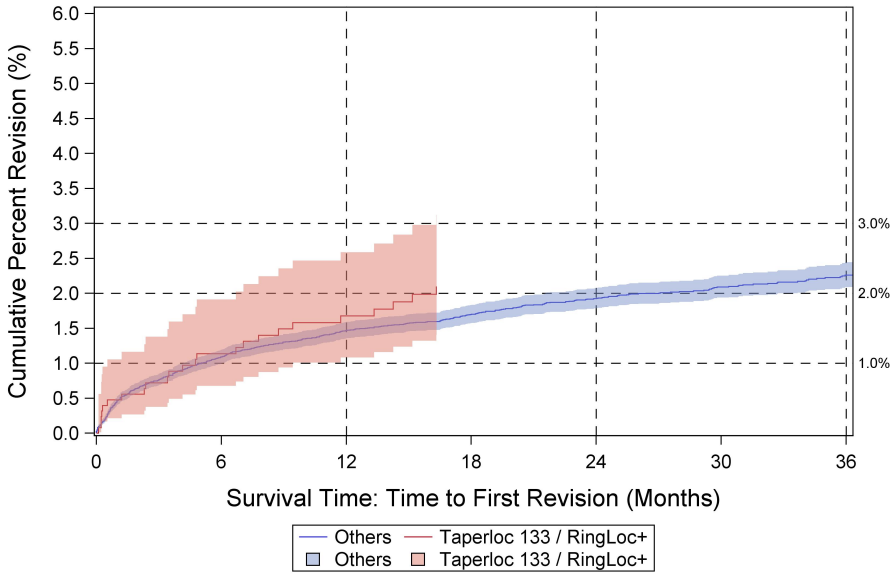

Figure 38: Cumulative percent revision curve for Taperloc 133/RingLoc+ combination compared to all other conventional THA implants.

Table 82: Cumulative percent revision for Taperloc 133/RingLoc+ combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years*	3 years*
1262	1.67 (1.08,2.59)	2.10 (1.41,3.12)	2.10 (1.41,3.12)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 83: Descriptive statistics on cases receiving the Taperloc 133/RingLoc+ combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	675	53.28	
Age (yrs)	1267	65.24(10.37)	66.00(14.00)
Height (cm)	1267	169.60(10.40)	170.00(15.00)
Weight (kg)	1267	90.12(21.76)	88.00(28.00)
BMI(kg/m^2)	1267	31.20(6.46)	30.46(8.45)
Smoking - never (%)	569	44.91	
Smoking - previous (%)	508	40.09	
Smoking - current (%)	169	13.34	
Smoking - unknown (%)	21	1.66	

Table 84: Distribution of head size for Taperloc 133/RingLoc+ combination.

Size (mm)	N	Percent
32	71	5.7
36	745	59.3
40	359	28.6
44	64	5.1
Other/unknown	18	1.4

Table 85: Distribution of bearing surface for Taperloc 133/RingLoc+ combination.

Bearing	N	Percent
Metal-on-plastic	690	54.5
Ceramic-on-plastic	549	43.3
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	28	2.2

Table 86: Distribution of approach used for Taperloc 133/RingLoc+ combination.

Approach	N	Percent
Anterior	151	11.9
Anterolateral	544	42.9
Posterior	559	44.1
Transtrochanteric	7	0.6
Unknown/other	6	0.5

Trabecular Metal/Continuum
N=522

This implant combination was used by 12 surgeons. The median number of cases for those surgeons using this implant combination was 9 (interquartile range 79). The mean was 43.6 and standard deviation was 54.8. This implant combination was used at 12 sites. The median number of cases using this implant combination per site was 7.5 (interquartile range 69.5). The mean was 43.6 and standard deviation was 63.5.

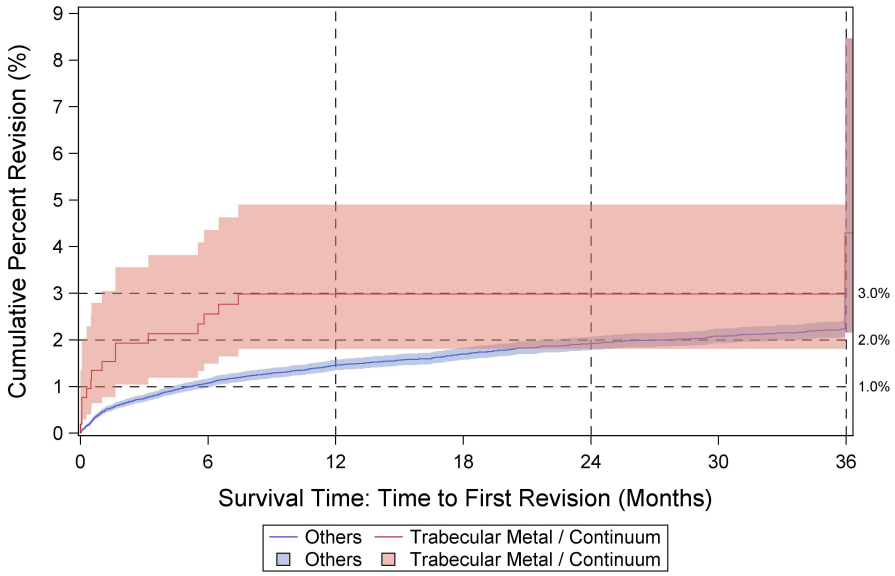

Figure 39: Cumulative percent revision curve for Trabecular Metal/Continuum combination compared to all other conventional THA implants.

Table 87: Cumulative percent revision for Trabecular Metal/Continuum combination compared to all other conventional THA implants (numerical values).

N	1 year	2 years	3 years
522	2.98 (1.81,4.90)	2.98 (1.81,4.90)	4.29 (2.15,8.47)

Table 88: Descriptive statistics on cases receiving the Trabecular Metal/Continuum combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	289	55.26	
Age (yrs)	523	65.76(11.11)	66.00(16.00)
Height (cm)	523	169.40(10.71)	170.00(15.00)
Weight (kg)	523	89.55(21.80)	88.00(28.00)
BMI(kg/m^2)	523	31.07(6.50)	29.98(8.80)
Smoking - never (%)	226	43.21	
Smoking - previous (%)	216	41.3	
Smoking - current (%)	81	15.49	
Smoking - unknown (%)	0	0.0	

Table 89: Distribution of head size for Trabecular Metal/Continuum combination.

Size (mm)	N	Percent
28	8	1.5
32	218	41.8
36	275	52.7
40	19	3.6
Other/unknown	2	0.4

Table 90: Distribution of bearing surface for Trabecular Metal/Continuum combination.

Bearing	N	Percent
Metal-on-plastic	256	49.0
Ceramic-on-plastic	264	50.5
Ceramic-on-ceramic	0	0.0
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	3	0.6

Table 91: Distribution of approach used for Trabecular Metal/Continuum combination.

Approach	N	Percent
Anterior	1	0.2
Anterolateral	439	83.9
Posterior	81	15.5
Transtrochanteric	1	0.2
Unknown/other	1	0.2

Trilock BPS/Pinnacle
N=1201

This implant combination was used by 36 surgeons. The median number of cases for those surgeons using this implant combination was 8 (interquartile range 26.5). The mean was 33.4 and standard deviation was 74.5. This implant combination was used at 20 sites. The median number of cases using this implant combination per site was 14.5 (interquartile range 49.5). The mean was 60.2 and standard deviation was 117.3.

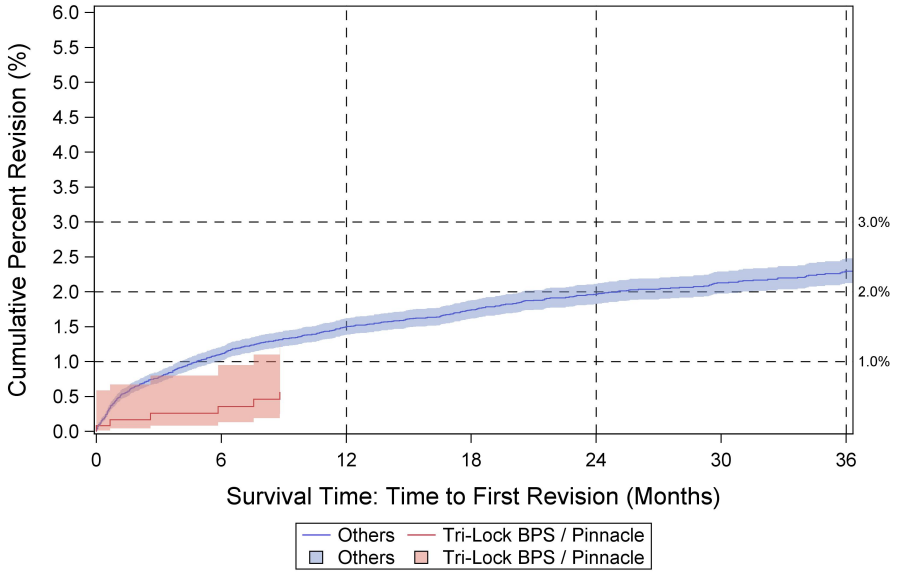

Figure 40: Cumulative percent revision curve for Trilock BPS/Pinnacle combination compared to all other conventional THA implants.

Table 92: Cumulative percent revision for Trilock BPS/Pinnacle combination compared to all other conventional THA implants (numerical values).

N	1 year*	2 years*	3 years*
1201	0.57 (0.25,1.26)	0.57 (0.25,1.26)	0.57 (0.25,1.26)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 93: Descriptive statistics on cases receiving the Trilock BPS/Pinnacle combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	685	56.94	
Age (yrs)	1203	64.90(10.44)	65.00(14.00)
Height (cm)	1202	169.57(10.03)	170.00(14.00)
Weight (kg)	1203	85.49(19.16)	84.00(26.00)
BMI(kg/m^2)	1202	29.62(5.56)	29.05(7.34)
Smoking - never (%)	570	47.38	
Smoking - previous (%)	484	40.23	
Smoking - current (%)	138	11.47	
Smoking - unknown (%)	11	0.91	

Table 94: Distribution of head size for Trilock BPS/Pinnacle combination.

Size (mm)	N	Percent
28	3	0.3
32	505	42.1
36	664	55.4
40	20	1.7
Other/unknown	6	0.5

Table 95: Distribution of bearing surface for Trilock BPS/Pinnacle combination.

Bearing	N	Percent
Metal-on-plastic	696	57.9
Ceramic-on-plastic	455	37.8
Ceramic-on-ceramic	41	3.4
Metal-on-metal	0	0.0
Dual mobility	0	0.0
Other/unknown	11	0.9

Table 96: Distribution of approach used for Trilock BPS/Pinnacle combination.

Approach	N	Percent
Anterior	713	59.3
Anterolateral	182	15.1
Posterior	307	25.5
Transtrochanteric	1	0.1
Unknown/other	0	0.0

Chapter 5

Total knee arthroplasty statistics, devices, and revisions

Selection of the most suitable implant is a critical component of providing high quality knee arthroplasty care. Since revision is an undesirable outcome and is widely reported across arthroplasty registries, we include a chapter on revision risk. These data are based on primary cases performed from 2/15/2015 to 12/31/2016. For detailed information on each figure and table (date ranges and inclusion/exclusion criteria), see the online supplement `http://marcqi.org/dev/wp-content/uploads/2017/10/MARCQI_2012-2016_report_chapter_4_and_5_specifications.pdf`.

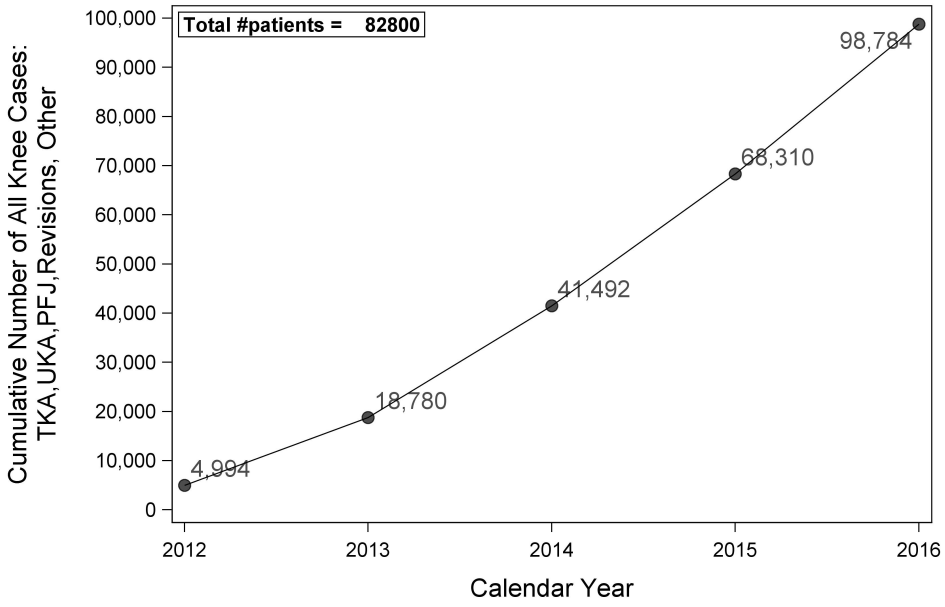

Figure 41: All knee cases over time.

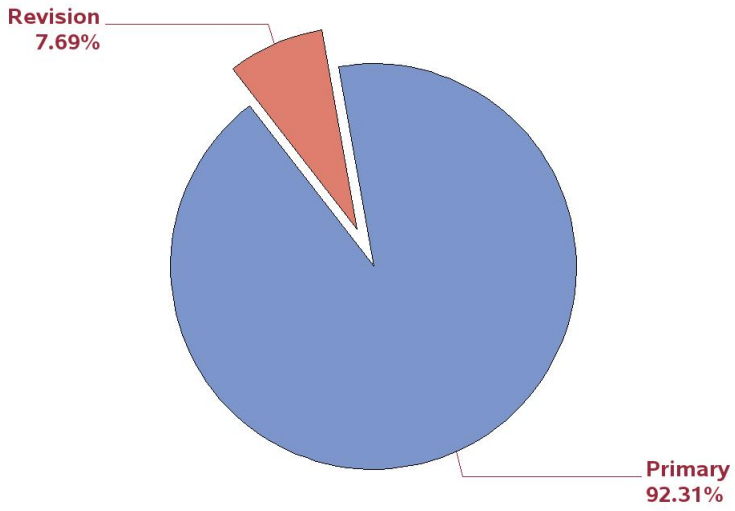

Figure 42: Percent of knee arthroplasty cases by primary or revision.

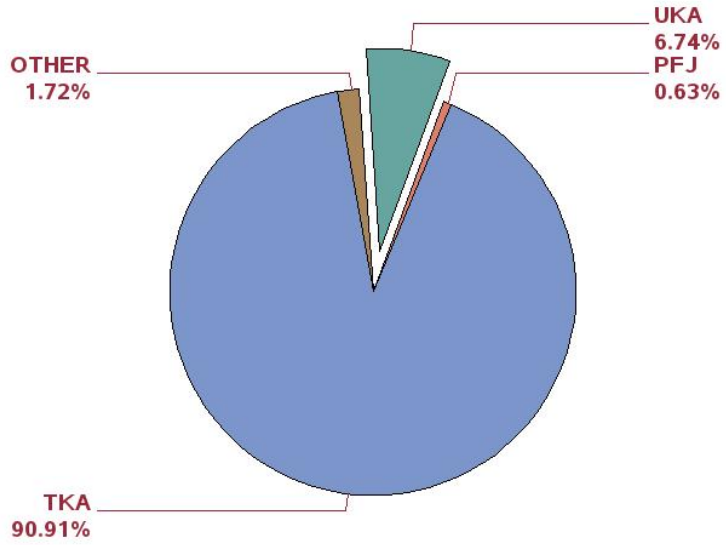

Figure 43: Percent of primary TKA cases performed as TKA, UKA, and PFJ.

5.1 TKA descriptive statistics

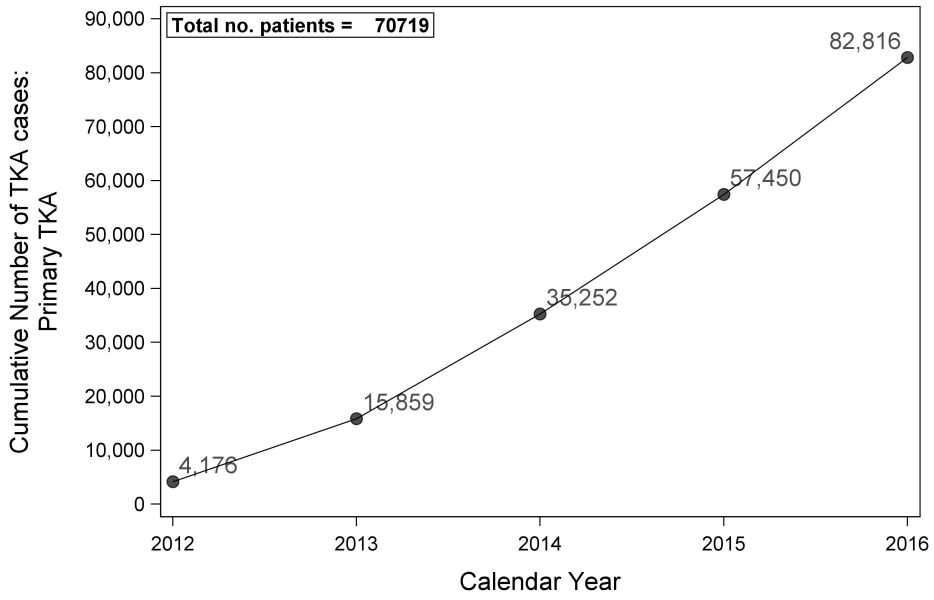

Figure 44: Primary TKA cases over time.

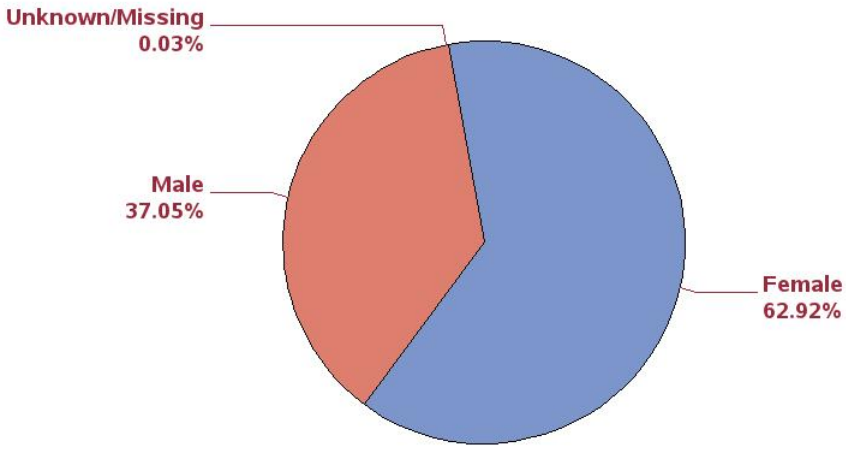

Figure 45: Percent of primary TKA cases by sex.

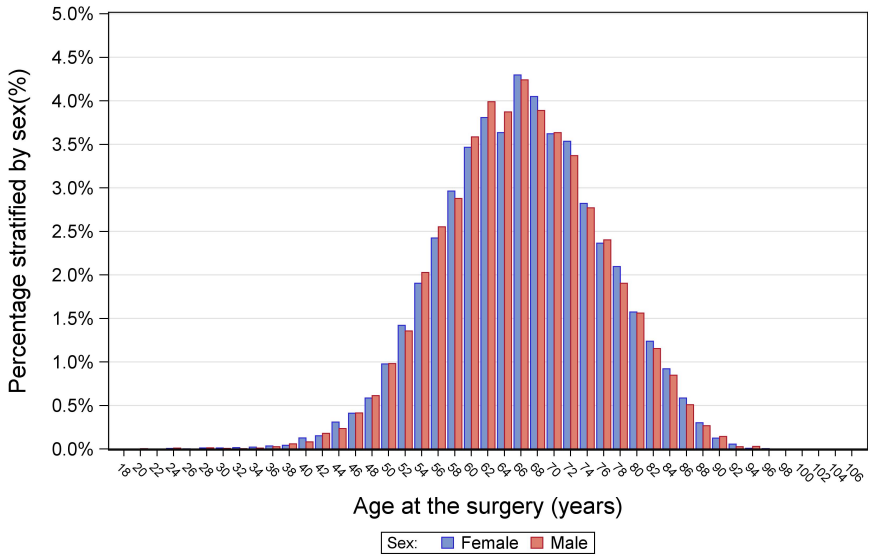

Figure 46: Age distribution of primary TKA cases by sex.

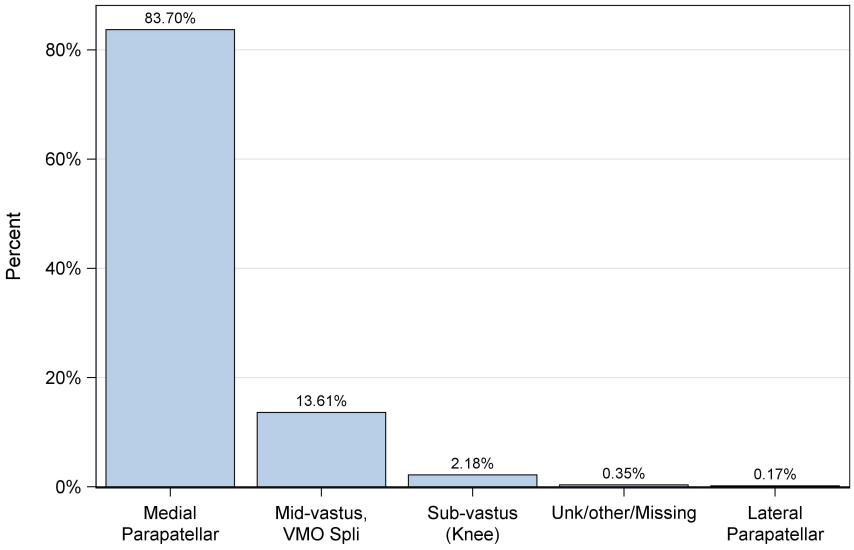

Figure 47: Percent of primary TKA cases by approach.

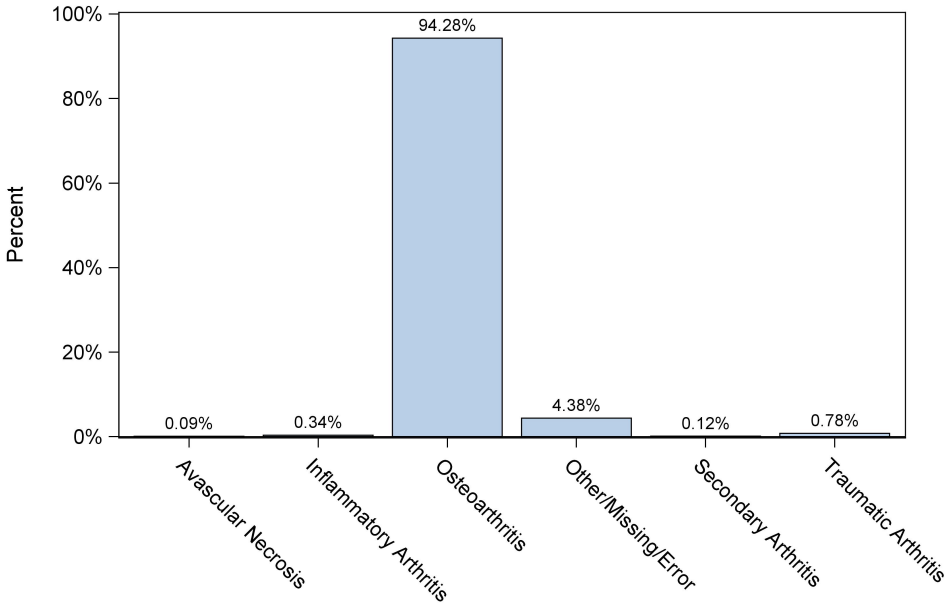

Figure 48: Percent of primary TKA cases by diagnosis.

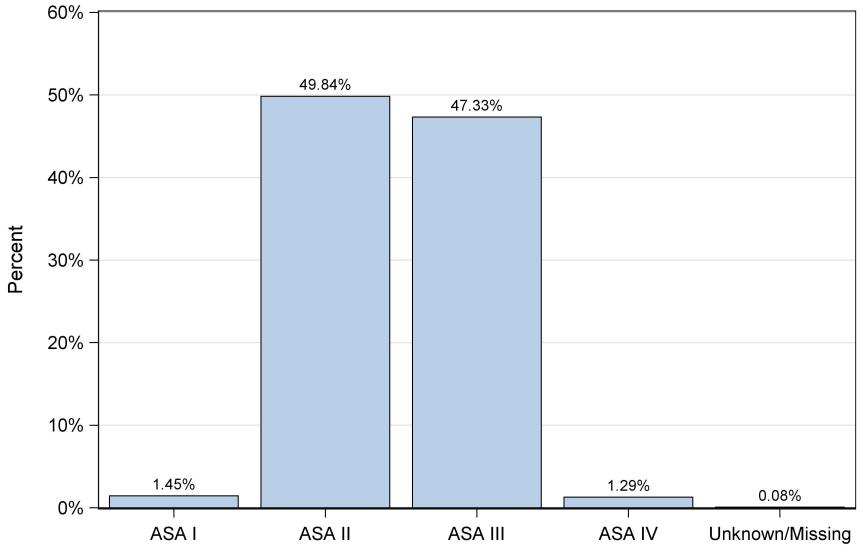

Figure 49: Percent of primary TKA cases by ASA class.

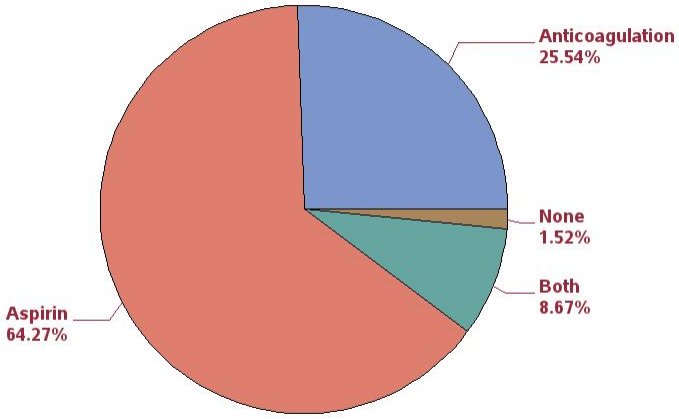

Figure 50: Percent of primary TKA patients (first case) by thrombosis pharmacoprophylaxis between 10/1/2016 and 12/31/2016 (this time window is shorter than rest of figures because of significant change over time).

5.2 Most commonly used TKA implants

The following three tables provide utilization data of implants used in primary TKA.

Table 97: Ten most commonly used femoral components in primary TKA.

Rank	Femoral component	N	Percent
1	Triathlon	20871	25.2
2	Persona	18885	22.8
3	Vanguard	12909	15.6
4	Genesis II	5016	6.1
5	Attune	4884	5.9
6	Sigma PFC	3046	3.7
7	NexGen LPS Option	1932	2.3
8	Sigma	1871	2.3
9	NexGen Option	1667	2.0
10	Journey II	1619	1.9
11	Others	10116	12.2

Table 98: Ten most commonly used tibial components in primary TKA

Rank	Tibial component	N	Percent
1	Persona	18666	22.5
2	Maxim	12138	14.7
3	Triathlon	10567	12.8
4	Triathlon TS	10409	12.6
5	Genesis II	5707	6.9
6	Attune	4877	5.9
7	Sigma	3642	4.4
8	NK II	2481	3.0
9	NexGen Precoat	2254	2.7
10	M.B.T.	1725	2.1
11	Others	10350	12.5

Table 99: Ten most commonly used femoral/tibial component combinations in primary TKA.

Rank	Femural/tibial component combination	N	Percent
1	Persona / Persona	18661	22.5
2	Vanguard / Maxim	12119	14.6
3	Triathlon / Triathlon	10558	12.8
4	Triathlon / Triathlon TS	10266	12.4
5	Genesis II / Genesis II	4959	6.0
6	Attune / Attune	4877	5.9
7	Sigma PFC / Sigma	2381	2.9
8	Journey II / Journey	1585	1.9
9	NK II GS / NK II	1577	1.9
10	Sigma / Sigma	1251	1.5
11	Others	14582	17.5

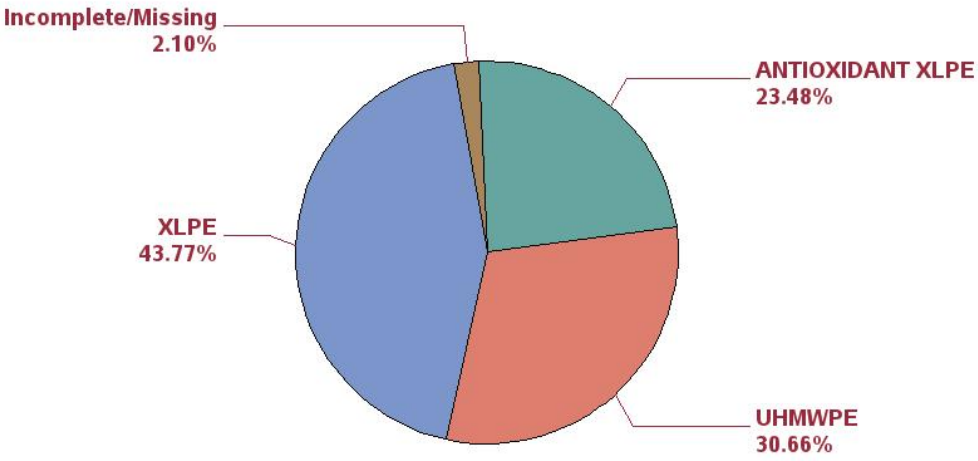

Figure 51: Percent of polyethylene inserts by type of polyethylene in primary TKA.

5.3 TKA revision risk summary

Reason for revision is of central importance to quality improvement because it helps focus attention on specific causes that may be addressed. Therefore, the data are presented in two formats below: tabular and Pareto chart. The tabular format is consistent with how other arthroplasty registries report cause of revision. The Pareto chart figure presents the same data in a format commonly used in quality improvement. The Pareto chart sorts the reasons for revision by frequency (bar chart on bottom, from left to right) and presents a cumulative percent using a line graph above. The causes corresponding to each bar are numbered and a key at the bottom links the numbers to text descriptions. In addition to an overall summary of reason for revision, tables showing reason for revision for the first, second, and third year post-operatively are provided because the reasons change over this time horizon. It is important to note that the time window for the cases reported in reasons for revision tables and figures differ from the time window used for other figures because reason for revision was added to the database on 1/1/14. While these data capture revisions for primaries performed back to 2/15/2015, only revisions occurring on or after 1/1/2014 are included in the reasons for revision figure and tables. Also note that for knees instability/dislocation should be interpreted as instability.

Table 100: Most common reasons for first revision following TKA.

Rank	Reason for revision	N	Percent
1	Instability/Dislocation	259	27.1
2	Joint Infection	221	23.1
3	Pain	205	21.4
4	Aseptic loosening	119	12.4
5	Arthrofibrosis	65	6.8
6	Component fracture/failure	33	3.4
7	Malalignment	13	1.4
8	Peri-prosthetic fracture (Femur)	12	1.3
9	Extensor mechanism failure	8	0.8
10	Metal reaction/Metallosis	7	0.7
11	Peri-prosthetic fracture (Tibia)	7	0.7
12	Poly liner wear	6	0.6
13	Osteolysis	1	0.1
14	Patellofemoral joint	1	0.1

Table 101: Most common reasons for first revision following primary TKA in first year post-operatively.

Rank	Reason for revision	N	Percent
1	Joint Infection	122	28.7
2	Instability/Dislocation	112	26.4
3	Pain	74	17.4
4	Arthrofibrosis	42	9.9
5	Aseptic loosening	29	6.8
6	Component fracture/failure	12	2.8
7	Malalignment	9	2.1
8	Peri-prosthetic fracture (Femur)	8	1.9
9	Peri-prosthetic fracture (Tibia)	6	1.4
10	Extensor mechanism failure	5	1.2
11	Poly liner wear	3	0.7
12	Metal reaction/Metallosis	3	0.7

Table 102: Most common reasons for first revision following primary TKA in second year post-operatively.

Rank	Reason for revision	N	Percent
1	Instability/Dislocation	101	28.5
2	Pain	93	26.3
3	Joint Infection	69	19.5
4	Aseptic loosening	50	14.1
5	Arthrofibrosis	15	4.2
6	Component fracture/failure	11	3.1
7	Metal reaction/Metallosis	4	1.1
8	Peri-prosthetic fracture (Femur)	3	0.8
9	Extensor mechanism failure	3	0.8
10	Poly liner wear	2	0.6
11	Malalignment	2	0.6
12	Peri-prosthetic fracture (Tibia)	1	0.3

Table 103: Most common reasons for first revision following primary TKA in third year post-operatively.

Rank	Reason for revision	N	Percent
1	Instability/Dislocation	35	24.6
2	Aseptic loosening	32	22.5
3	Pain	31	21.8
4	Joint Infection	26	18.3
5	Arthrofibrosis	8	5.6
6	Component fracture/failure	7	4.9
7	Poly liner wear	1	0.7
8	Malalignment	1	0.7
9	Patellofemoral joint	1	0.7

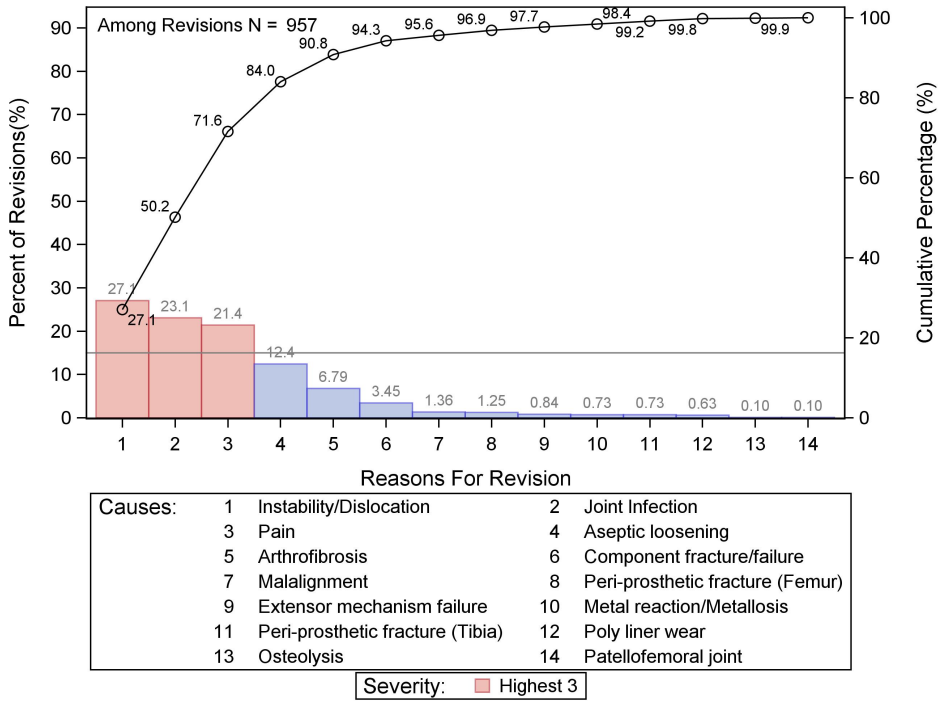

Figure 52: Most common reasons for first revision following primary TKA (Pareto chart).

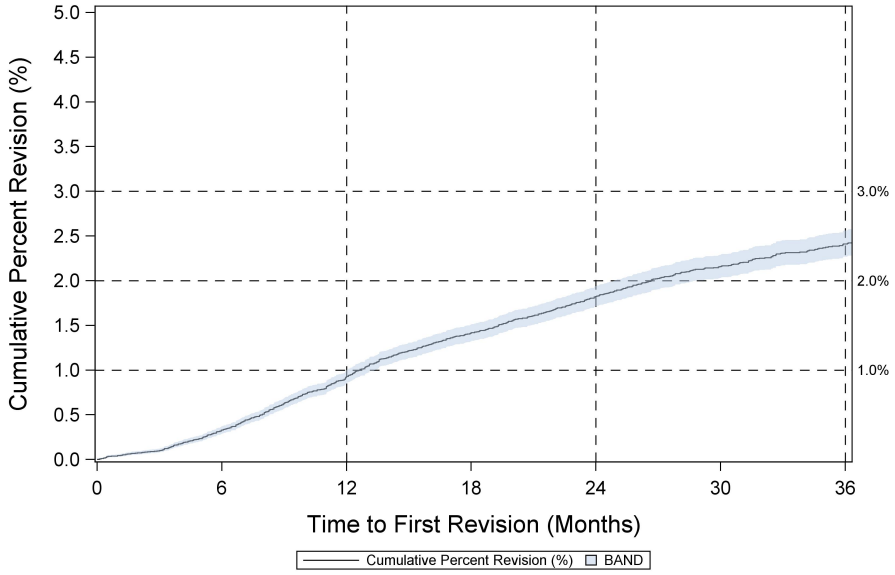

Figure 53: Cumulative percent revision for primary TKA.

Table 104: Cumulative percent revision for primary TKA (numerical values).

N	1 year	2 years	3 years
82816	0.93 (0.86,1.00)	1.82 (1.71,1.94)	2.41 (2.27,2.56)

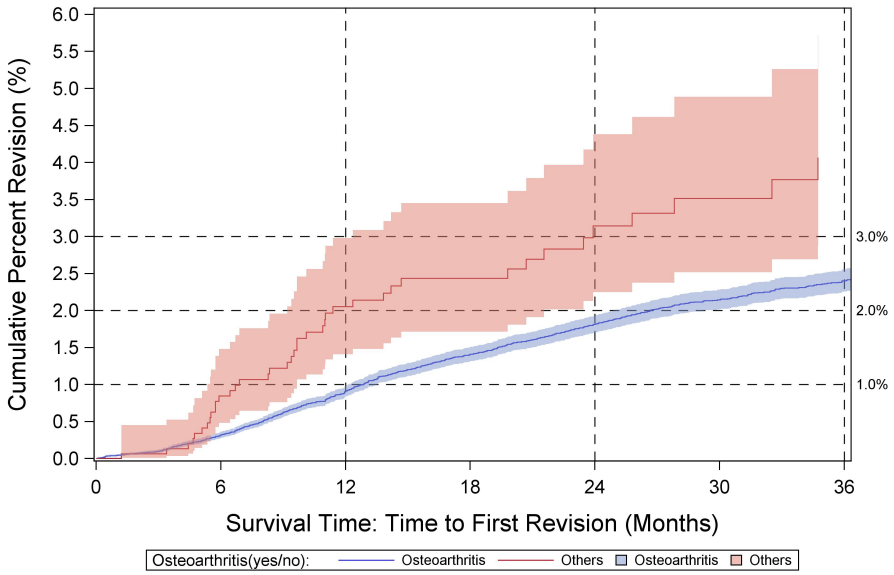

Figure 54: Cumulative percent revision for primary TKA by diagnosis.

Table 105: Cumulative percent revision for primary TKA by diagnosis (numerical values).

Diagnosis	N	1 year	2 years	3 years
Osteoarthritis	77964	0.91 (0.84,0.99)	1.81 (1.70,1.93)	2.40 (2.25,2.56)
Others	1608	2.05 (1.41,2.98)	3.14 (2.25,4.38)	4.07 (2.89,5.72)
Unknown/Missing	3121			

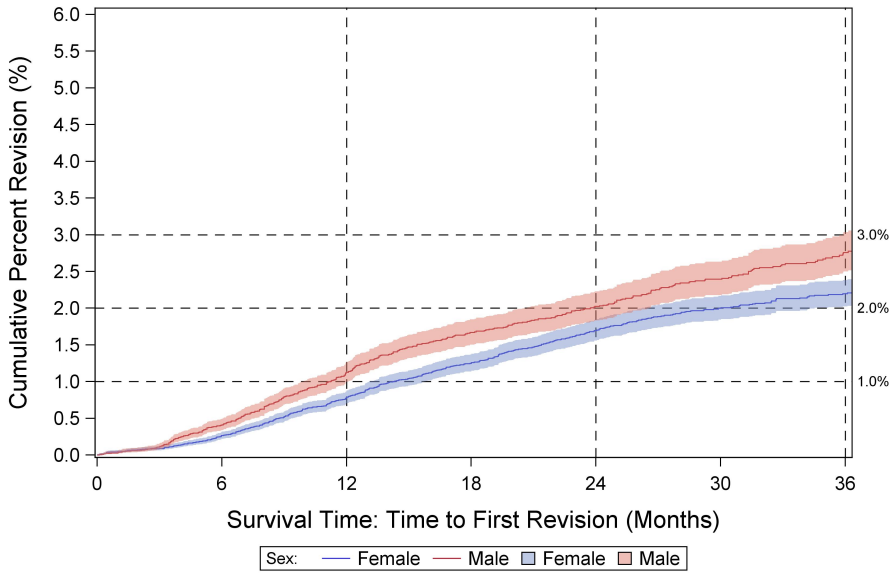

Figure 55: Cumulative percent revision for primary TKA by sex for osteoarthritis diagnosis.

Table 106: Cumulative percent revision for primary TKA by sex for osteoarthritis diagnosis (numerical values).

Sex	N	1 year	2 years	3 years
Female	49278	0.79 (0.70,0.88)	1.69 (1.56,1.84)	2.20 (2.02,2.38)
Male	28662	1.13 (1.00,1.27)	2.02 (1.83,2.23)	2.76 (2.50,3.04)
Unknown/Missing	24			

5.4 Revision risk for TKA implant combinations

As with hip implants, there is substantial variation in revision risk across TKA implants. The same caveats about interpreting CPR data provided in chapter 5 also apply to the interpretation of CPR data for knees. Specifically, note that all implant combinations have a minimum follow up of at least three years. Therefore, if the red line and shaded confidence interval end prior to three years, this does not mean the longest follow up was less than three years. Instead, it means that no additional revisions occurred after the end of the red line and confidence interval band.

While the reader is encouraged to read the details of each femur/tibia implant combination, the following table summarizes the three-year CPR values.

Table 107: Cumulative percent revision risk for femoral/tibial combinations having at least 500 primary cases, sorted alphabetically.

Femur/Tibia combination	N	1 year	2 years	3 years
Attune / Attune	4870	0.68 (0.47,1.01)	1.72 (1.26,2.34)	*2.42 (1.60,3.66)*
Evolution MP / Evolution MP	548	0.72 (0.23,2.25)	1.32 (0.55,3.19)	*2.16 (1.01,4.58)*
Genesis II / Genesis II	4944	1.42 (1.10,1.83)	2.85 (2.33,3.48)	3.99 (3.26,4.87)
Journey II / Journey	1581	2.03 (1.29,3.20)	3.83 (2.47,5.90)	*5.07 (3.30,7.73)*
LCS Complete / M.B.T.	665	1.20 (0.54,2.67)	3.89 (2.37,6.33)	5.42 (3.19,9.13)
Legion / Genesis II	747	1.32 (0.63,2.78)	*2.92 (1.54,5.50)*	*2.92 (1.54,5.50)*
NexGen LPS GS / NexGen Precoat	505	0.40 (0.10,1.61)	1.44 (0.69,2.99)	2.08 (1.12,3.83)
NexGen LPS Option / NexGen Precoat	583	0.57 (0.18,1.75)	1.41 (0.67,2.93)	1.65 (0.83,3.29)
NexGen LPS Option / NexGen TM	983	0.42 (0.16,1.13)	0.42 (0.16,1.13)	0.84 (0.40,1.77)
NexGen Option / NexGen Option	860	0.55 (0.21,1.45)	0.97 (0.43,2.19)	*1.23 (0.57,2.64)*
NexGen Option / NexGen Pegged	527	1.02 (0.42,2.43)	1.82 (0.91,3.63)	2.25 (1.15,4.39)
NK II / NK II	903	0.11 (0.02,0.81)	0.29 (0.07,1.17)	*0.87 (0.36,2.10)*
NK II GS / NK II	1574	0.38 (0.16,0.92)	0.68 (0.34,1.37)	1.43 (0.78,2.64)
Persona / Persona	18633	0.76 (0.63,0.92)	1.86 (1.62,2.14)	2.29 (2.00,2.63)
Sigma / M.B.T.	600	2.28 (1.30,3.99)	3.00 (1.81,4.94)	3.54 (2.20,5.67)
Sigma / Sigma	1249	1.88 (1.23,2.87)	2.94 (2.07,4.16)	*3.17 (2.23,4.51)*
Sigma PFC / Sigma	2377	0.37 (0.18,0.74)	0.90 (0.56,1.42)	1.38 (0.93,2.04)
Triathlon / Triathlon	10536	0.93 (0.74,1.16)	1.44 (1.19,1.75)	2.02 (1.64,2.49)
Triathlon / Triathlon TS	10261	0.91 (0.73,1.14)	1.67 (1.39,2.00)	2.22 (1.85,2.66)
Vanguard / Maxim	12110	0.90 (0.73,1.10)	1.74 (1.48,2.05)	2.41 (2.06,2.82)
Vanguard / Maxim Mono-Lock	576	0.75 (0.28,2.00)	2.23 (1.20,4.12)	*3.09 (1.70,5.56)*

Note:

A revision risk in *italics* indicates it is the same as it was at the time of the last revision.

Attune/Attune
N=4870

This implant combination was used by 64 surgeons. The median number of cases for those surgeons using this implant combination was 21 (interquartile range 121). The mean was 76.2 and standard deviation was 112.8. This implant combination was used at 29 sites. The median number of cases using this implant combination per site was 44 (interquartile range 291). The mean was 168.2 and standard deviation was 229.8.

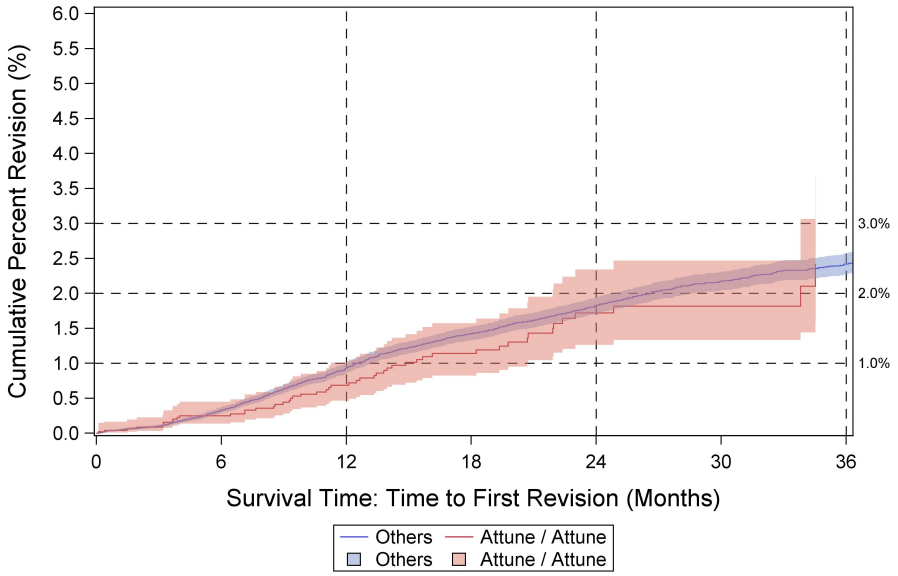

Figure 56: Cumulative percent revision curve for Attune/Attune combination compared to all other TKA implants.

Table 108: Cumulative percent revision for Attune/Attune combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years*
4870	0.68 (0.47,1.01)	1.72 (1.26,2.34)	2.42 (1.60,3.66)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 109: Descriptive statistics on cases using the Attune/Attune combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	2964	60.8	
Age (yrs)	4877	65.6(9.3)	66(13)
Height (cm)	4877	95.6(21.4)	94(27)
Weight (kg)	4877	168.5(10.5)	168(17)
BMI(kg/m^2)	4877	33.7(6.8)	32.9(9)
Smoking - never (%)	2434	49.9	
Smoking - previous (%)	1879	38.5	
Smoking - current (%)	523	10.7	
Smoking - unknown (%)	41	0.8	

Table 110: Distribution of approach used for Attune/Attune combination.

Approach	N	Percent
Medial parapatellar	4300	88.2
Mid-vastus	558	11.4
Sub-vastus	9	0.2
Lateral parapatellar	4	0.1
Unknown/missing/other	6	0.1

Evolution MP/Evolution MP
N=548

Fewer than 10 surgeons and 10 sites used this implant combination.

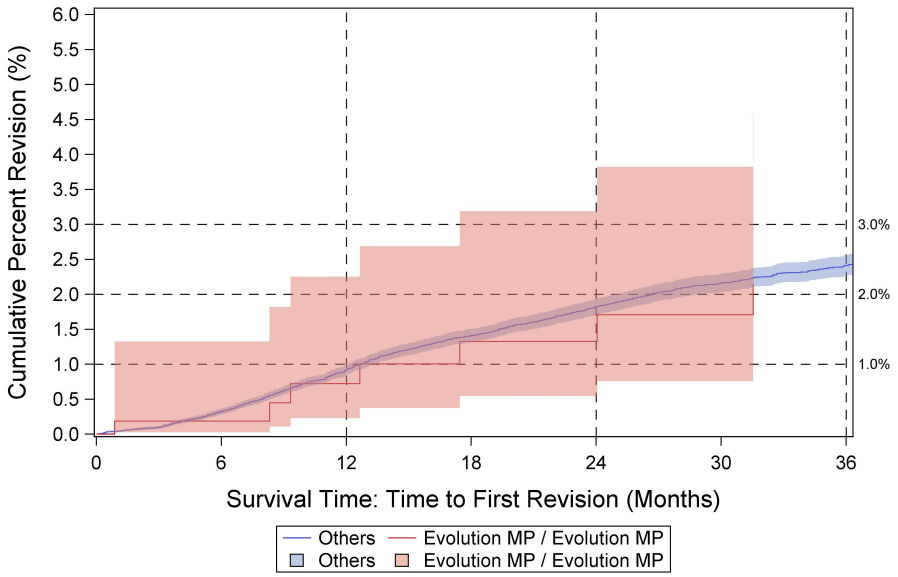

Figure 57: Cumulative percent revision curve for Evolution MP/Evolution MP combination compared to all other TKA implants.

Table 111: Cumulative percent revision for Evolution MP/Evolution MP combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years*
548	0.72 (0.23,2.25)	1.32 (0.55,3.19)	2.16 (1.01,4.58)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 112: Descriptive statistics on cases using the Evolution MP/Evolution MP combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	340	62	
Age (yrs)	548	65.3(9.9)	65(13)
Height (cm)	548	93.8(22.3)	91.5(27)
Weight (kg)	548	168.3(11.2)	167(15)
BMI(kg/m^2)	548	33(6.6)	32.4(8.8)
Smoking - never (%)	310	56.6	
Smoking - previous (%)	207	37.8	
Smoking - current (%)	27	4.9	
Smoking - unknown (%)	4	0.7	

Table 113: Distribution of approach used for Evolution MP/Evolution MP combination.

Approach	N	Percent
Medial parapatellar	545	99.5
Mid-vastus	3	0.5
Sub-vastus	0	0.0
Lateral parapatellar	0	0.0
Unknown/missing/other	0	0.0

Genesis II/Genesis II
N=4944

This implant combination was used by 152 surgeons. The median number of cases for those surgeons using this implant combination was 6 (interquartile range 32.5). The mean was 32.6 and standard deviation was 61.2. This implant combination was used at 49 sites. The median number of cases using this implant combination per site was 43 (interquartile range 142). The mean was 101.2 and standard deviation was 123.9.

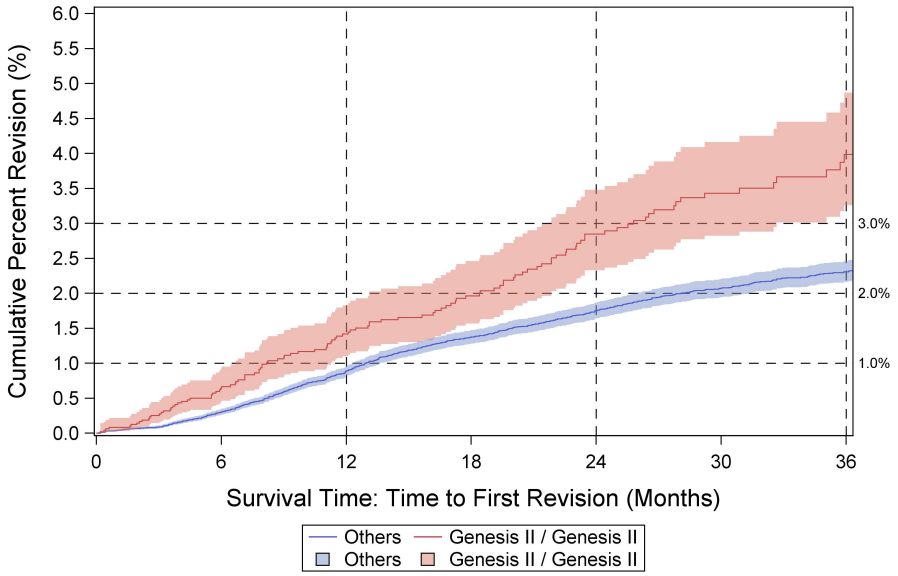

Figure 58: Cumulative percent revision curve for Genesis II/Genesis II combination compared to all other TKA implants.

Table 114: Cumulative percent revision for Genesis II/Genesis II combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
4944	1.42 (1.10,1.83)	2.85 (2.33,3.48)	3.99 (3.26,4.87)

Table 115: Descriptive statistics on cases using the Genesis II/Genesis II combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	3094	62.4	
Age (yrs)	4959	65.5(9.7)	66(13)
Height (cm)	4959	96.1(22.2)	94(28)
Weight (kg)	4959	168.3(10.4)	167(17)
BMI(kg/m^2)	4959	33.9(7.3)	33(9.9)
Smoking - never (%)	2453	49.5	
Smoking - previous (%)	1988	40.1	
Smoking - current (%)	492	9.9	
Smoking - unknown (%)	26	0.5	

Table 116: Distribution of approach used for Genesis II/Genesis II combination.

Approach	N	Percent
Medial parapatellar	4183	84.4
Mid-vastus	747	15.1
Sub-vastus	8	0.2
Lateral parapatellar	6	0.1
Unknown/missing/other	15	0.3

Journey II/Journey
N=1581

This implant combination was used by 65 surgeons. The median number of cases for those surgeons using this implant combination was 7 (interquartile range 33). The mean was 24.4 and standard deviation was 36.5. This implant combination was used at 28 sites. The median number of cases using this implant combination per site was 42.5 (interquartile range 72). The mean was 56.6 and standard deviation was 55.4.

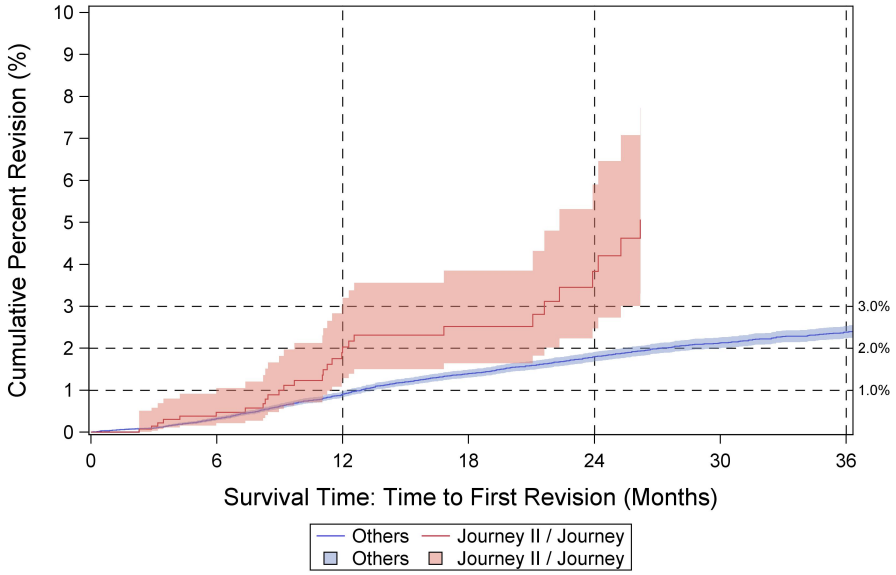

Figure 59: Cumulative percent revision curve for Journey II/Journey combination compared to all other TKA implants.

Table 117: Cumulative percent revision for Journey II/Journey combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years*
1581	2.03 (1.29,3.20)	3.83 (2.47,5.90)	5.07 (3.30,7.73)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 118: Descriptive statistics on cases using the Journey II/Journey combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	986	62.2	
Age (yrs)	1585	63.9(9.4)	64(13)
Height (cm)	1585	95.6(21.9)	95(29)
Weight (kg)	1585	168.2(10.6)	167(15)
BMI(kg/m^2)	1585	33.8(7)	33.1(9.7)
Smoking - never (%)	800	50.5	
Smoking - previous (%)	586	37	
Smoking - current (%)	196	12.4	
Smoking - unknown (%)	3	0.2	

Table 119: Distribution of approach used for Journey II/Journey combination.

Approach	N	Percent
Medial parapatellar	1323	83.5
Mid-vastus	255	16.1
Sub-vastus	1	0.1
Lateral parapatellar	2	0.1
Unknown/missing/other	4	0.3

LCS Complete/M.B.T.
N=665

Fewer than 10 surgeons and 10 sites used this implant combination.

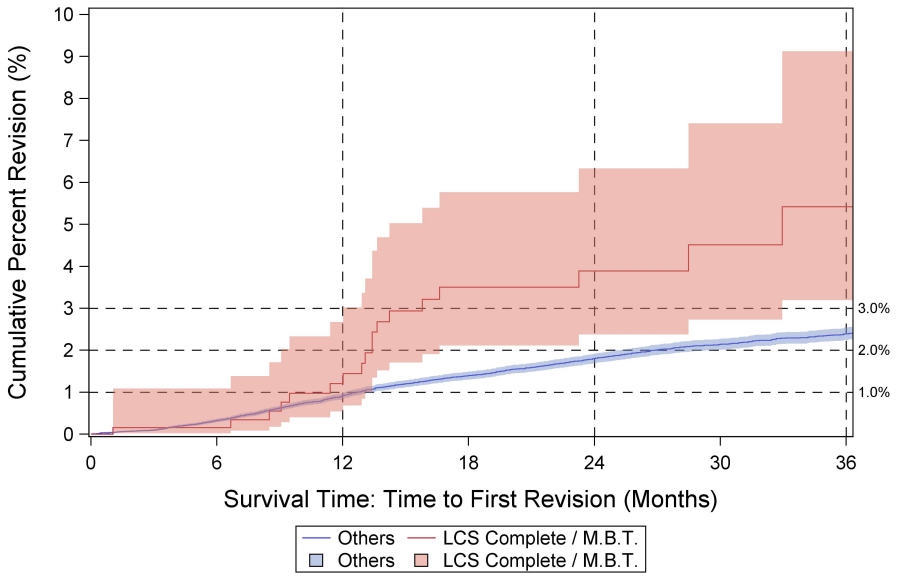

Figure 60: Cumulative percent revision curve for LCS Complete/M.B.T. combination compared to all other TKA implants.

Table 120: Cumulative percent revision for LCS Complete/M.B.T. combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
665	1.20 (0.54,2.67)	3.89 (2.37,6.33)	5.42 (3.19,9.13)

Table 121: Descriptive statistics on cases using the LCS Complete/M.B.T. combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	401	60.2	
Age (yrs)	666	67.3(9.7)	67(15)
Height (cm)	666	94.4(19.9)	92(26)
Weight (kg)	666	168(10)	168(15)
BMI(kg/m^2)	666	33.4(6.2)	33(8.8)
Smoking - never (%)	349	52.4	
Smoking - previous (%)	201	30.2	
Smoking - current (%)	65	9.8	
Smoking - unknown (%)	51	7.7	

Table 122: Distribution of approach used for LCS Complete/M.B.T. combination.

Approach	N	Percent
Medial parapatellar	664	99.7
Mid-vastus	1	0.2
Sub-vastus	0	0.0
Lateral parapatellar	0	0.0
Unknown/missing/other	1	0.2

Legion/Genesis II
N=747

This implant combination was used by 56 surgeons. The median number of cases for those surgeons using this implant combination was 4.5 (interquartile range 14.5). The mean was 13.3 and standard deviation was 21. This implant combination was used at 28 sites. The median number of cases using this implant combination per site was 8.5 (interquartile range 25.5). The mean was 26.7 and standard deviation was 53.4.

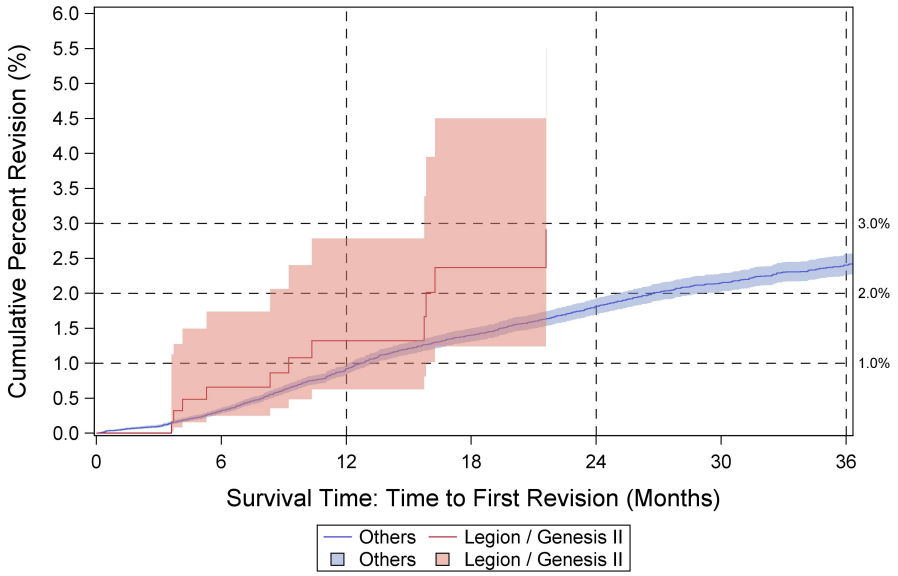

Figure 61: Cumulative percent revision curve for Legion/Genesis II combination compared to all other TKA implants.

Table 123: Cumulative percent revision for Legion/Genesis II combination compared to all other TKA implants (numerical values).

N	1 year	2 years*	3 years*
747	1.32 (0.63,2.78)	2.92 (1.54,5.50)	2.92 (1.54,5.50)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 124: Descriptive statistics on cases using the Legion/Genesis II combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	720	96.4	
Age (yrs)	747	65.4(9.2)	65(12)
Height (cm)	747	89.4(19.9)	88(27)
Weight (kg)	747	162(7.5)	162(10)
BMI(kg/m^2)	747	34.1(7)	33.8(9.6)
Smoking - never (%)	433	58	
Smoking - previous (%)	247	33.1	
Smoking - current (%)	61	8.2	
Smoking - unknown (%)	6	0.8	

Table 125: Distribution of approach used for Legion/Genesis II combination.

Approach	N	Percent
Medial parapatellar	530	71.0
Mid-vastus	210	28.1
Sub-vastus	1	0.1
Lateral parapatellar	3	0.4
Unknown/missing/other	3	0.4

NexGen LPS GS/NexGen Precoat
N=505

This implant combination was used by 38 surgeons. The median number of cases for those surgeons using this implant combination was 6 (interquartile range 15). The mean was 13.3 and standard deviation was 18.9. This implant combination was used at 18 sites. The median number of cases using this implant combination per site was 4.5 (interquartile range 15). The mean was 28.1 and standard deviation was 76.5.

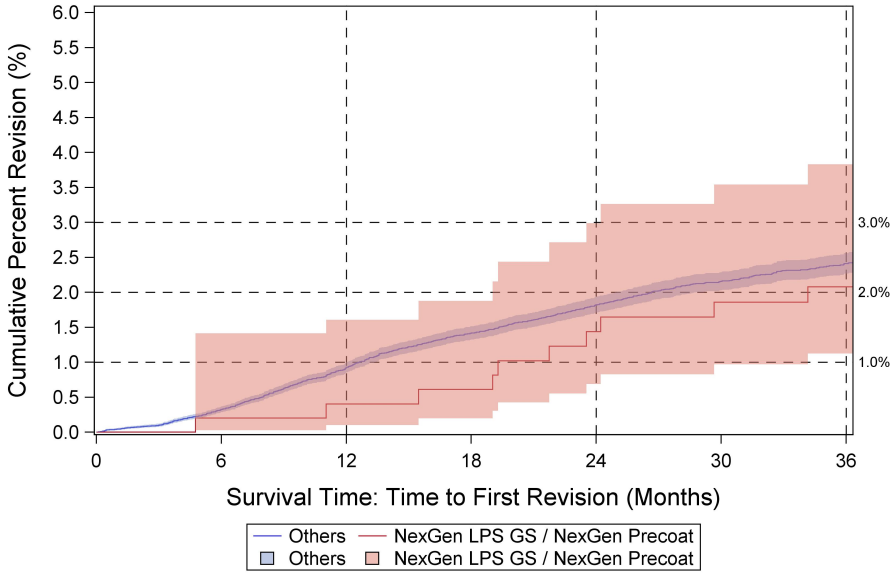

Figure 62: Cumulative percent revision curve for NexGen LPS GS/NexGen Precoat combination compared to all other TKA implants.

Table 126: Cumulative percent revision for NexGen LPS GS/NexGen Precoat combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
505	0.40 (0.10,1.61)	1.44 (0.69,2.99)	2.08 (1.12,3.83)

Table 127: Descriptive statistics on cases using the NexGen LPS GS/NexGen Precoat combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	497	98.2	
Age (yrs)	506	65.4(9.6)	64(14)
Height (cm)	506	90.2(21.4)	88(29)
Weight (kg)	505	161.9(7.5)	162(10)
BMI(kg/m^2)	505	34.4(7.5)	34(11.1)
Smoking - never (%)	299	59.1	
Smoking - previous (%)	173	34.2	
Smoking - current (%)	33	6.5	
Smoking - unknown (%)	1	0.2	

Table 128: Distribution of approach used for NexGen LPS GS/NexGen Precoat combination.

Approach	N	Percent
Medial parapatellar	490	96.8
Mid-vastus	5	1.0
Sub-vastus	0	0.0
Lateral parapatellar	4	0.8
Unknown/missing/other	7	1.4

NexGen LPS Option/NexGen Precoat
N=583

This implant combination was used by 58 surgeons. The median number of cases for those surgeons using this implant combination was 4.5 (interquartile range 11). The mean was 10.1 and standard deviation was 12.7. This implant combination was used at 27 sites. The median number of cases using this implant combination per site was 12 (interquartile range 28). The mean was 21.7 and standard deviation was 33.3.

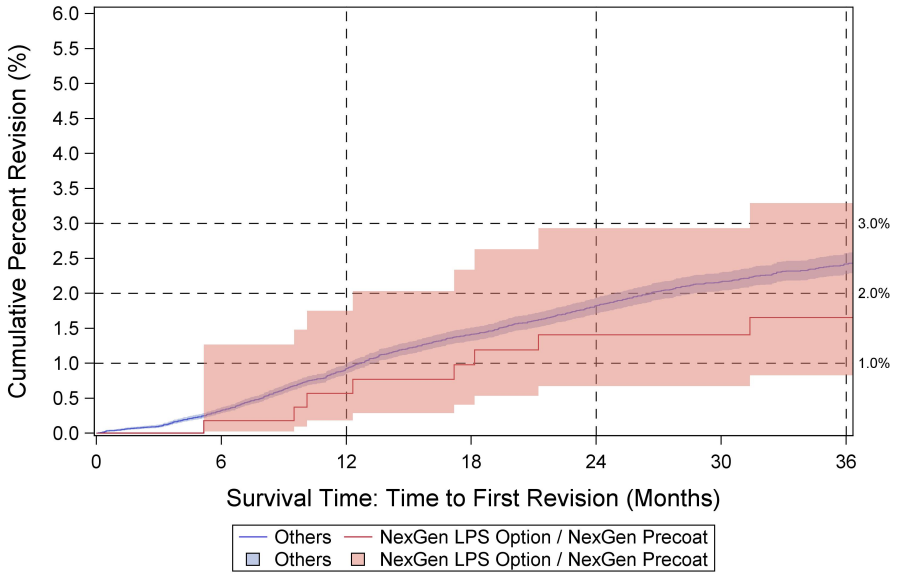

Figure 63: Cumulative percent revision curve for NexGen LPS Option/NexGen Precoat combination compared to all other TKA implants.

Table 129: Cumulative percent revision for NexGen LPS Option/NexGen Precoat combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
583	0.57 (0.18,1.75)	1.41 (0.67,2.93)	1.65 (0.83,3.29)

Table 130: Descriptive statistics on cases using the NexGen LPS Option/NexGen Precoat combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	233	39.8	
Age (yrs)	585	66.6(10.2)	67(14)
Height (cm)	585	95.7(20)	94(27)
Weight (kg)	585	170.7(10.6)	172(18)
BMI(kg/m^2)	585	32.9(6.7)	32(8.9)
Smoking - never (%)	257	43.9	
Smoking - previous (%)	264	45.1	
Smoking - current (%)	63	10.8	
Smoking - unknown (%)	1	0.2	

Table 131: Distribution of approach used for NexGen LPS Option/NexGen Precoat combination.

Approach	N	Percent
Medial parapatellar	560	95.7
Mid-vastus	18	3.1
Sub-vastus	1	0.2
Lateral parapatellar	2	0.3
Unknown/missing/other	4	0.7

NexGen LPS Option/NexGen TM
N=983

Fewer than 10 surgeons and 10 sites used this implant combination.

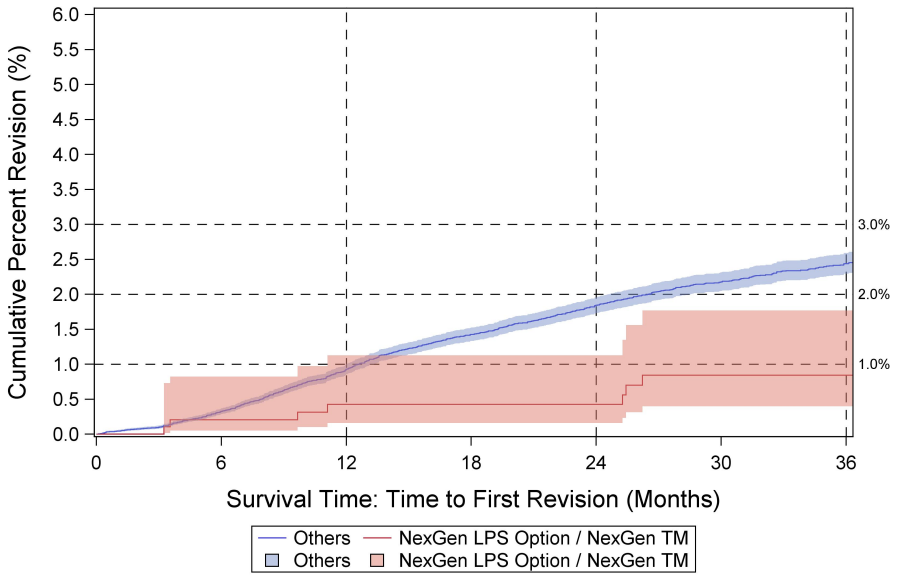

Figure 64: Cumulative percent revision curve for NexGen LPS Option/NexGen TM combination compared to all other TKA implants.

Table 132: Cumulative percent revision for NexGen LPS Option/NexGen TM combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
983	0.42 (0.16,1.13)	0.42 (0.16,1.13)	0.84 (0.40,1.77)

Table 133: Descriptive statistics on cases using the NexGen LPS Option/NexGen TM combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	514	52.2	
Age (yrs)	984	66.6(8.4)	67(11)
Height (cm)	984	93.1(19.7)	92(26)
Weight (kg)	984	169.6(10.2)	170(15)
BMI(kg/m^2)	984	32.3(6.2)	31.6(7.8)
Smoking - never (%)	543	55.2	
Smoking - previous (%)	397	40.4	
Smoking - current (%)	42	4.3	
Smoking - unknown (%)	2	0.2	

Table 134: Distribution of approach used for NexGen LPS Option/NexGen TM combination.

Approach	N	Percent
Medial parapatellar	341	34.7
Mid-vastus	633	64.3
Sub-vastus	4	0.4
Lateral parapatellar	1	0.1
Unknown/missing/other	5	0.5

NexGen Option/NexGen Option
N=860

This implant combination was used by 10 surgeons. The median number of cases for those surgeons using this implant combination was 59.5 (interquartile range 109). The mean was 86.1 and standard deviation was 69.0. Fewer than 10 sites used this implant combination.

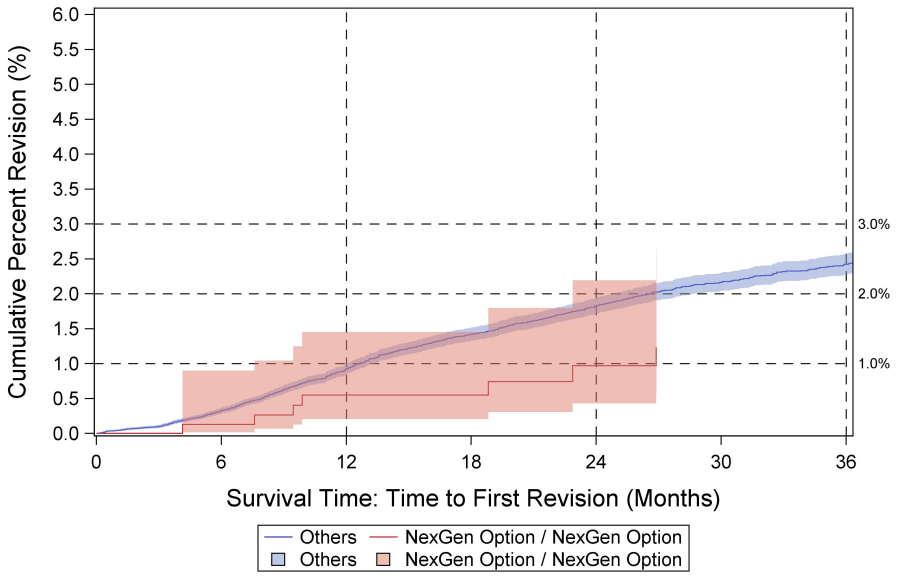

Figure 65: Cumulative percent revision curve for NexGen Option/NexGen Option combination compared to all other TKA implants.

Table 135: Cumulative percent revision for NexGen Option/NexGen Option combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years*
860	0.55 (0.21,1.45)	0.97 (0.43,2.19)	1.23 (0.57,2.64)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 136: Descriptive statistics on cases using the NexGen Option/NexGen Option combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	449	52.2	
Age (yrs)	861	69.3(8.7)	70(12)
Height (cm)	861	92.4(19.4)	92(25)
Weight (kg)	861	169.1(10.1)	170(16)
BMI(kg/m^2)	861	32.3(6.2)	31.6(8.4)
Smoking - never (%)	395	45.9	
Smoking - previous (%)	395	45.9	
Smoking - current (%)	71	8.3	
Smoking - unknown (%)	0	0.0	

Table 137: Distribution of approach used for NexGen Option/NexGen Option combination.

Approach	N	Percent
Medial parapatellar	846	98.3
Mid-vastus	12	1.4
Sub-vastus	0	0.0
Lateral parapatellar	3	0.3
Unknown/missing/other	0	0.0

NexGen Option/NexGen Pegged
N=527

Fewer than 10 surgeons and 10 sites used this implant combination.

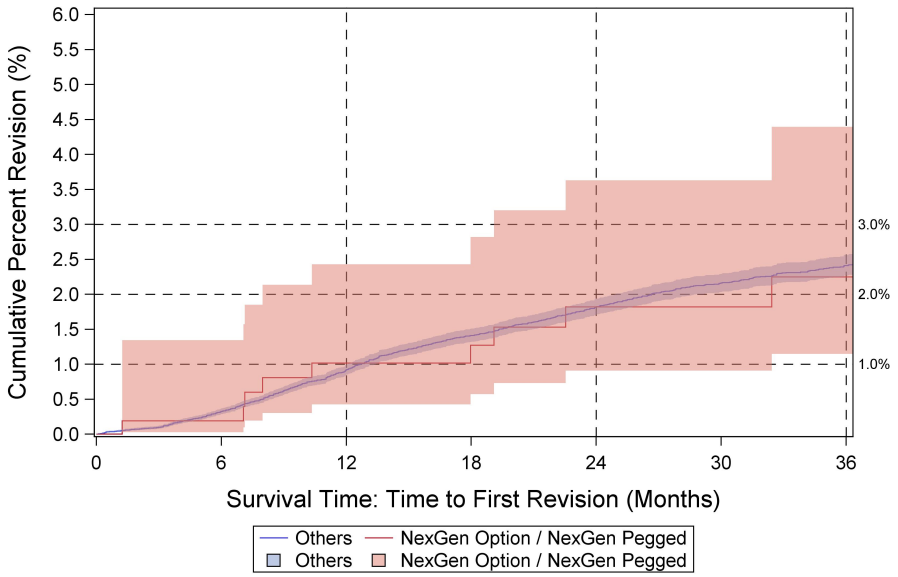

Figure 66: Cumulative percent revision curve for NexGen Option/NexGen Pegged combination compared to all other TKA implants.

Table 138: Cumulative percent revision for NexGen Option/NexGen Pegged combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
527	1.02 (0.42,2.43)	1.82 (0.91,3.63)	2.25 (1.15,4.39)

Table 139: Descriptive statistics on cases using the NexGen Option/NexGen Pegged combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	271	51.1	
Age (yrs)	530	66.5(8.9)	66(13)
Height (cm)	530	95.8(20.3)	94.5(29)
Weight (kg)	530	169.9(10.4)	169.5(16)
BMI(kg/m^2)	530	33.1(6)	32.4(9.2)
Smoking - never (%)	230	43.4	
Smoking - previous (%)	235	44.3	
Smoking - current (%)	63	11.9	
Smoking - unknown (%)	2	0.4	

Table 140: Distribution of approach used for NexGen Option/NexGen Pegged combination.

Approach	N	Percent
Medial parapatellar	518	97.7
Mid-vastus	2	0.4
Sub-vastus	0	0.0
Lateral parapatellar	10	1.9
Unknown/missing/other	0	0.0

NK II/NK II
N=903

This implant combination was used by 10 surgeons. The median number of cases for those surgeons using this implant combination was 6.5 (interquartile range 99). The mean was 90.3 and standard deviation was 162.3. Fewer than 10 sites used this implant combination.

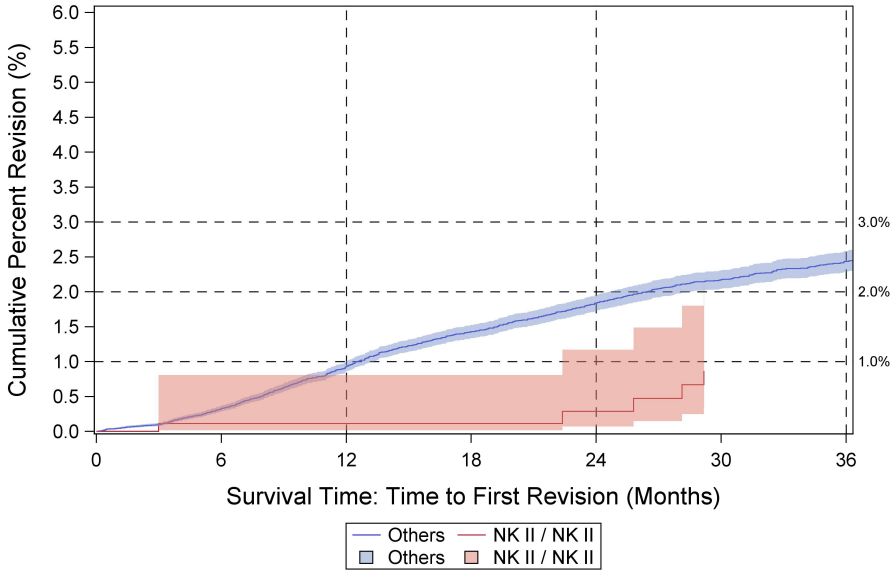

Figure 67: Cumulative percent revision curve for NK II/NK II combination compared to all other TKA implants.

Table 141: Cumulative percent revision for NK II/NK II combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years*
903	0.11 (0.02,0.81)	0.29 (0.07,1.17)	0.87 (0.36,2.10)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 142: Descriptive statistics on cases using the NK II/NK II combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	584	64.7	
Age (yrs)	903	66.8(9.3)	67(13)
Height (cm)	903	93.5(21.6)	90(28)
Weight (kg)	903	167.8(10.1)	167(15)
BMI(kg/m^2)	903	33.2(6.9)	32.1(8.7)
Smoking - never (%)	487	53.9	
Smoking - previous (%)	347	38.4	
Smoking - current (%)	65	7.2	
Smoking - unknown (%)	4	0.4	

Table 143: Distribution of approach used for NK II/NK II combination.

Approach	N	Percent
Medial parapatellar	836	92.6
Mid-vastus	39	4.3
Sub-vastus	12	1.3
Lateral parapatellar	5	0.6
Unknown/missing/other	11	1.2

NK II GS/NK II
N=1574

Fewer than 10 surgeons and 10 sites used this implant combination.

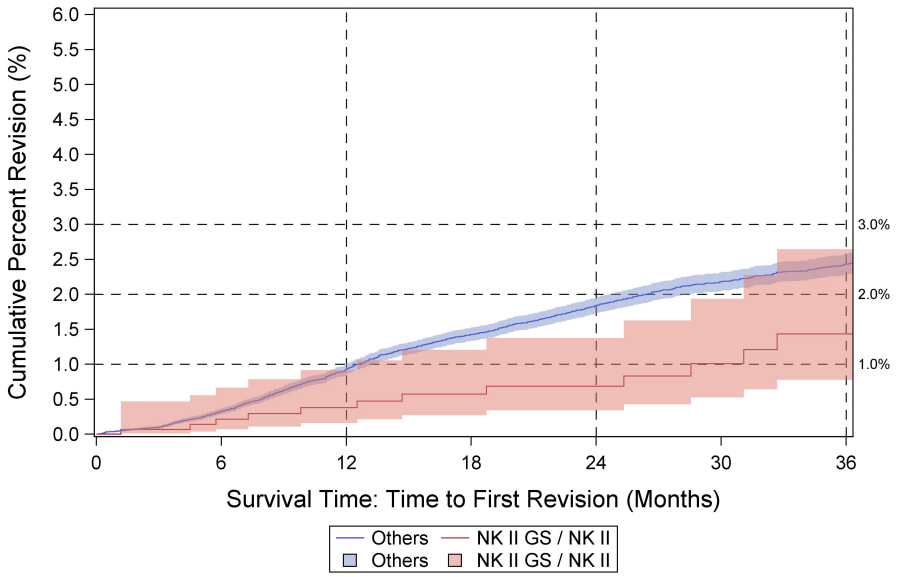

Figure 68: Cumulative percent revision curve for NK II GS/NK II combination compared to all other TKA implants.

Table 144: Cumulative percent revision for NK II GS/NK II combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
1574	0.38 (0.16,0.92)	0.68 (0.34,1.37)	1.43 (0.78,2.64)

Table 145: Descriptive statistics on cases using the NK II GS/NK II combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	963	61.1	
Age (yrs)	1577	67.6(9.2)	68(13)
Height (cm)	1575	92.4(21.9)	90(29)
Weight (kg)	1576	168.3(10.7)	167(17)
BMI(kg/m^2)	1575	32.5(6.5)	31.8(9)
Smoking - never (%)	826	52.4	
Smoking - previous (%)	638	40.5	
Smoking - current (%)	112	7.1	
Smoking - unknown (%)	1	0.1	

Table 146: Distribution of approach used for NK II GS/NK II combination.

Approach	N	Percent
Medial parapatellar	1394	88.4
Mid-vastus	65	4.1
Sub-vastus	108	6.8
Lateral parapatellar	3	0.2
Unknown/missing/other	7	0.4

Persona/Persona
N=18633

This implant combination was used by 149 surgeons. The median number of cases for those surgeons using this implant combination was 52 (interquartile range 133). The mean was 125.2 and standard deviation was 211.8. This implant combination was used at 49 sites. The median number of cases using this implant combination per site was 208 (interquartile range 482). The mean was 380.8 and standard deviation was 538.1.

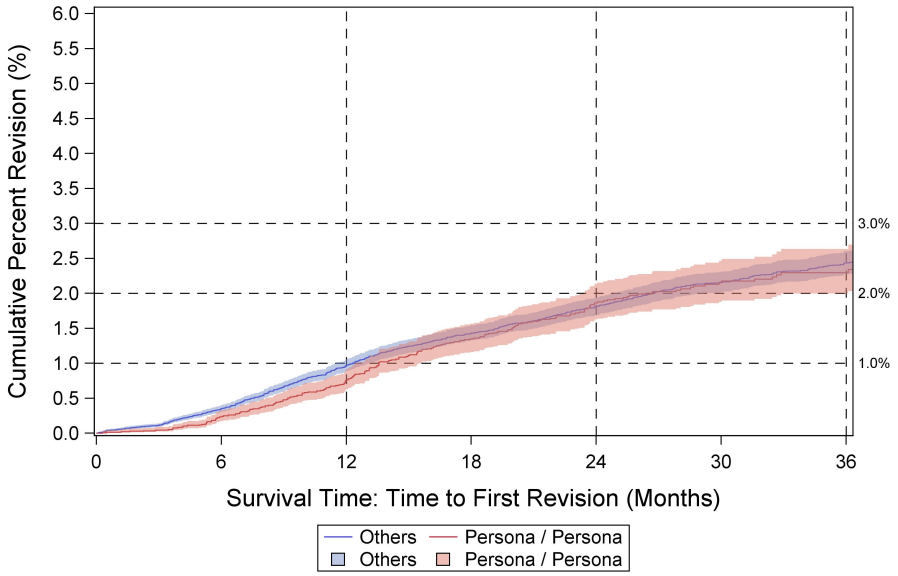

Figure 69: Cumulative percent revision curve for Persona/Persona combination compared to all other TKA implants.

Table 147: Cumulative percent revision for Persona/Persona combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
18633	0.76 (0.63,0.92)	1.86 (1.62,2.14)	2.29 (2.00,2.63)

Table 148: Descriptive statistics on cases using the Persona/Persona combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	11788	63.2	
Age (yrs)	18661	65.9(9.2)	66(12)
Height (cm)	18657	94.1(21.5)	92(28)
Weight (kg)	18657	168.1(10.5)	167(15)
BMI(kg/m^2)	18657	33.3(6.8)	32.4(9.1)
Smoking - never (%)	9571	51.3	
Smoking - previous (%)	7402	39.7	
Smoking - current (%)	1563	8.4	
Smoking - unknown (%)	125	0.7	

Table 149: Distribution of approach used for Persona/Persona combination.

Approach	N	Percent
Medial parapatellar	16322	87.5
Mid-vastus	1666	8.9
Sub-vastus	601	3.2
Lateral parapatellar	22	0.1
Unknown/missing/other	50	0.3

Sigma/M.B.T.
N=600

This implant combination was used by 37 surgeons. The median number of cases for those surgeons using this implant combination was 4 (interquartile range 20). The mean was 16.2 and standard deviation was 23.9. This implant combination was used at 26 sites. The median number of cases using this implant combination per site was 16 (interquartile range 26). The mean was 23.1 and standard deviation was 26.3.

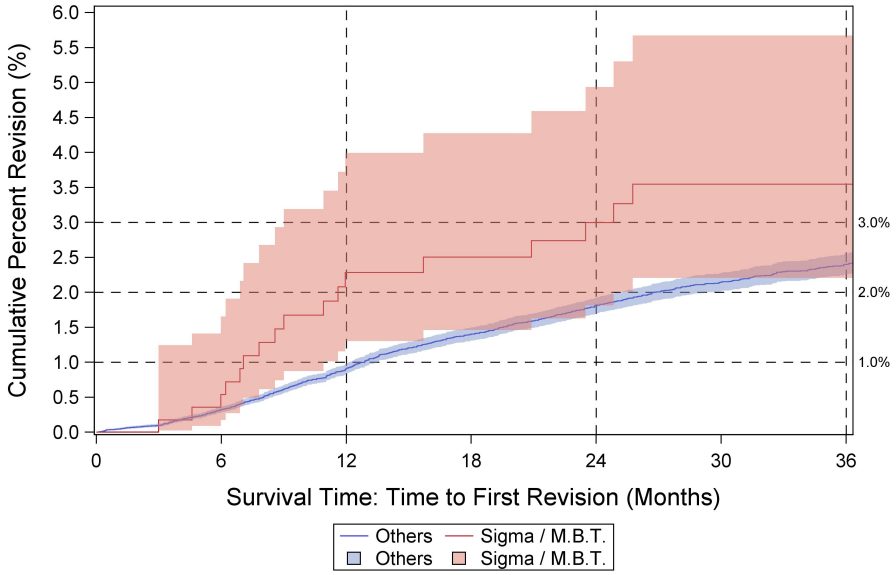

Figure 70: Cumulative percent revision curve for Sigma/M.B.T. combination compared to all other TKA implants.

Table 150: Cumulative percent revision for Sigma/M.B.T. combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
600	2.28 (1.30,3.99)	3.00 (1.81,4.94)	3.54 (2.20,5.67)

Table 151: Descriptive statistics on cases using the Sigma/M.B.T. combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	390	65	
Age (yrs)	600	64(10.1)	63(13)
Height (cm)	600	98.2(22.3)	97(31)
Weight (kg)	600	168.1(10.8)	167(16)
BMI(kg/m^2)	600	34.7(7.2)	34.3(9.4)
Smoking - never (%)	289	48.2	
Smoking - previous (%)	212	35.3	
Smoking - current (%)	63	10.5	
Smoking - unknown (%)	36	6	

Table 152: Distribution of approach used for Sigma/M.B.T. combination.

Approach	N	Percent
Medial parapatellar	564	94.0
Mid-vastus	27	4.5
Sub-vastus	1	0.2
Lateral parapatellar	1	0.2
Unknown/missing/other	7	1.2

Sigma/Sigma
N=1249

This implant combination was used by 35 surgeons. The median number of cases for those surgeons using this implant combination was 4 (interquartile range 37). The mean was 35.7 and standard deviation was 67.5. This implant combination was used at 20 sites. The median number of cases using this implant combination per site was 12 (interquartile range 37.5). The mean was 62.6 and standard deviation was 132.6.

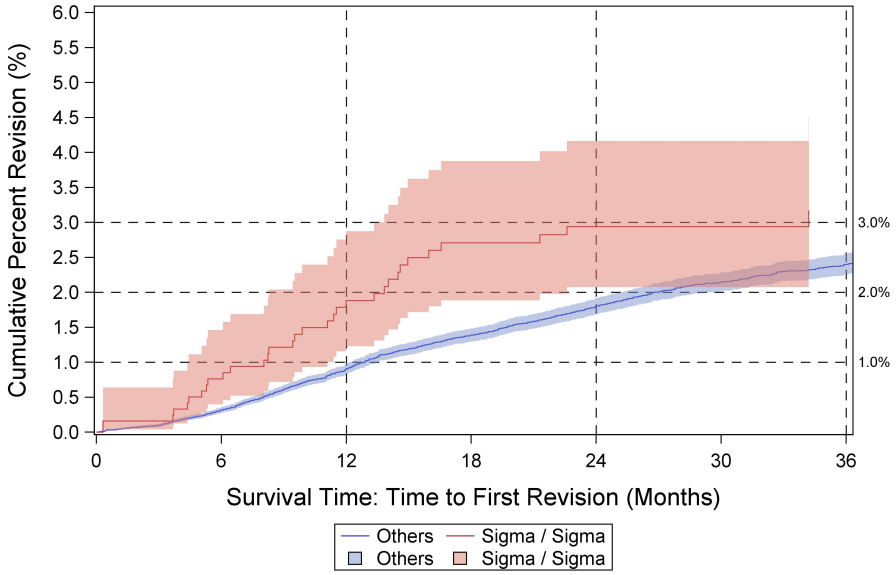

Figure 71: Cumulative percent revision curve for Sigma/Sigma combination compared to all other TKA implants.

Table 153: Cumulative percent revision for Sigma/Sigma combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years*
1249	1.88 (1.23,2.87)	2.94 (2.07,4.16)	3.17 (2.23,4.51)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 154: Descriptive statistics on cases using the Sigma/Sigma combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	800	64	
Age (yrs)	1251	67.4(10.1)	68(15)
Height (cm)	1251	89.8(20.5)	88(27)
Weight (kg)	1251	167.3(10.4)	167(15)
BMI(kg/m^2)	1251	32(6.3)	31.2(8.8)
Smoking - never (%)	660	52.8	
Smoking - previous (%)	495	39.6	
Smoking - current (%)	92	7.4	
Smoking - unknown (%)	4	0.3	

Table 155: Distribution of approach used for Sigma/Sigma combination.

Approach	N	Percent
Medial parapatellar	1209	96.6
Mid-vastus	27	2.2
Sub-vastus	0	0.0
Lateral parapatellar	1	0.1
Unknown/missing/other	14	1.1

Sigma PFC/Sigma
N=2377

This implant combination was used by 48 surgeons. The median number of cases for those surgeons using this implant combination was 15 (interquartile range 60). The mean was 49.6 and standard deviation was 82.3. This implant combination was used at 24 sites. The median number of cases using this implant combination per site was 28.5 (interquartile range 85). The mean was 99.2 and standard deviation was 159.7.

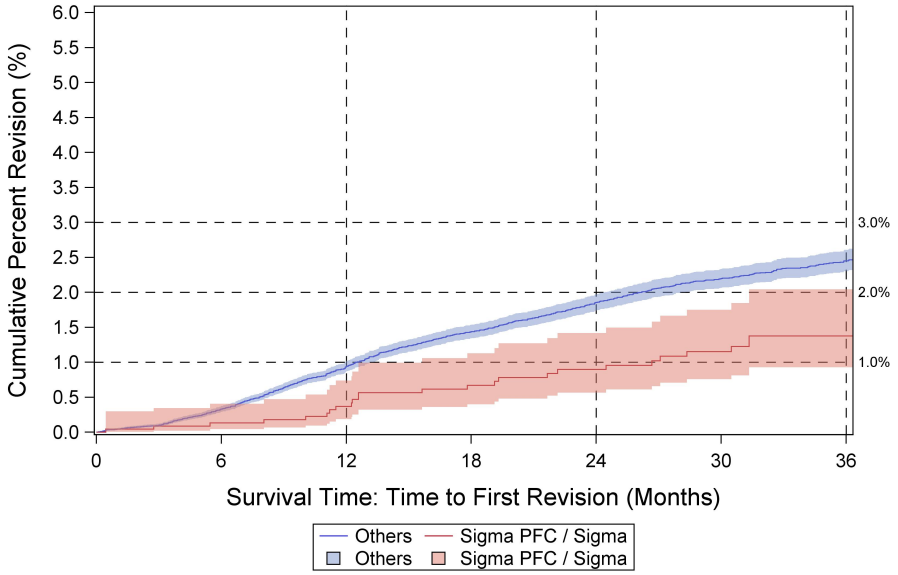

Figure 72: Cumulative percent revision curve for Sigma PFC/Sigma combination compared to all other TKA implants.

Table 156: Cumulative percent revision for Sigma PFC/Sigma combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
2377	0.37 (0.18,0.74)	0.90 (0.56,1.42)	1.38 (0.93,2.04)

Table 157: Descriptive statistics on cases using the Sigma PFC/Sigma combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	1465	61.5	
Age (yrs)	2381	66.9(9.3)	67(14)
Height (cm)	2379	93.1(21)	91(28)
Weight (kg)	2380	167.9(10.5)	167(15)
BMI(kg/m^2)	2379	33(6.7)	32(8.6)
Smoking - never (%)	1170	49.1	
Smoking - previous (%)	972	40.8	
Smoking - current (%)	227	9.5	
Smoking - unknown (%)	12	0.5	

Table 158: Distribution of approach used for Sigma PFC/Sigma combination.

Approach	N	Percent
Medial parapatellar	2250	94.5
Mid-vastus	122	5.1
Sub-vastus	1	0.0
Lateral parapatellar	2	0.1
Unknown/missing/other	6	0.3

Triathlon/Triathlon
N=10536

This implant combination was used by 99 surgeons. The median number of cases for those surgeons using this implant combination was 29 (interquartile range 154). The mean was 106.7 and standard deviation was 169.9. This implant combination was used at 39 sites. The median number of cases using this implant combination per site was 85 (interquartile range 342). The mean was 270.7 and standard deviation was 428.7.

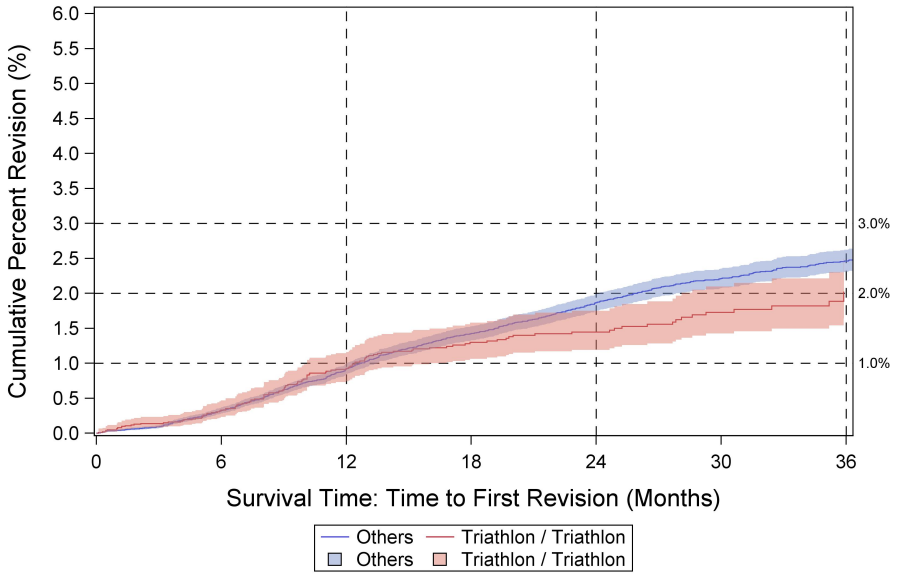

Figure 73: Cumulative percent revision curve for Triathlon/Triathlon combination compared to all other TKA implants.

Table 159: Cumulative percent revision for Triathlon/Triathlon combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
10536	0.93 (0.74,1.16)	1.44 (1.19,1.75)	2.02 (1.64,2.49)

Table 160: Descriptive statistics on cases using the Triathlon/Triathlon combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	6319	59.9	
Age (yrs)	10558	65.4(9.7)	65(13)
Height (cm)	10558	95.6(21.8)	93(29)
Weight (kg)	10558	168.5(10.5)	167(17)
BMI(kg/m^2)	10558	33.7(7)	32.8(9.3)
Smoking - never (%)	5326	50.5	
Smoking - previous (%)	4084	38.7	
Smoking - current (%)	1064	10.1	
Smoking - unknown (%)	84	0.8	

Table 161: Distribution of approach used for Triathlon/Triathlon combination.

Approach	N	Percent
Medial parapatellar	8418	79.7
Mid-vastus	1351	12.8
Sub-vastus	753	7.1
Lateral parapatellar	14	0.1
Unknown/missing/other	22	0.2

Triathlon/Triathlon TS
N=10261

This implant combination was used by 118 surgeons. The median number of cases for those surgeons using this implant combination was 14 (interquartile range 73). The mean was 87 and standard deviation was 193.1. This implant combination was used at 40 sites. The median number of cases using this implant combination per site was 42 (interquartile range 128). The mean was 256.7 and standard deviation was 612.3.

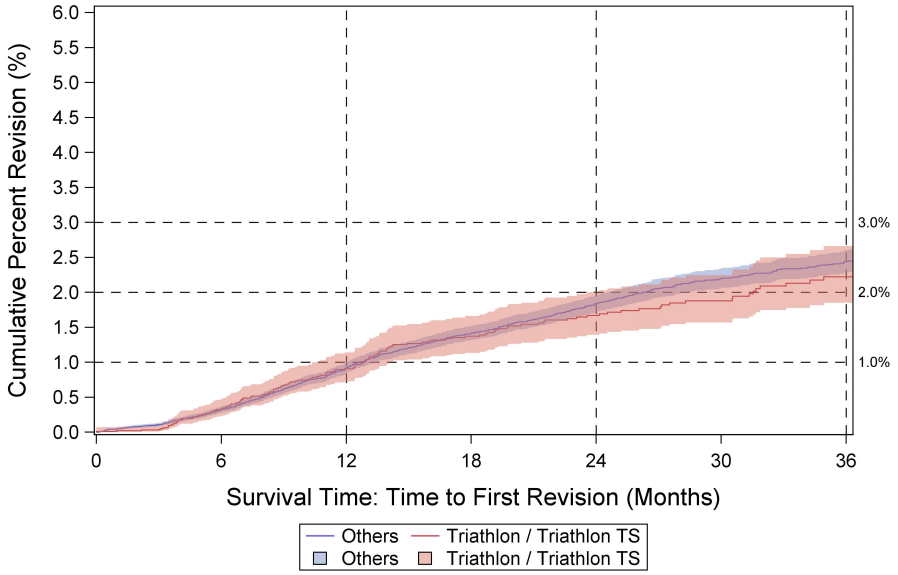

Figure 74: Cumulative percent revision curve for Triathlon/Triathlon TS combination compared to all other TKA implants.

Table 162: Cumulative percent revision for Triathlon/Triathlon TS combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
10261	0.91 (0.73,1.14)	1.67 (1.39,2.00)	2.22 (1.85,2.66)

Table 163: Descriptive statistics on cases using the Triathlon/Triathlon TS combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	6680	65.1	
Age (yrs)	10266	66.8(9.7)	67(13)
Height (cm)	10265	93.1(22.2)	91(30)
Weight (kg)	10265	167.5(10.7)	167(15)
BMI(kg/m^2)	10265	33.1(7.1)	32.3(9.5)
Smoking - never (%)	5619	54.7	
Smoking - previous (%)	3854	37.5	
Smoking - current (%)	767	7.5	
Smoking - unknown (%)	26	0.3	

Table 164: Distribution of approach used for Triathlon/Triathlon TS combination.

Approach	N	Percent
Medial parapatellar	7232	70.4
Mid-vastus	2917	28.4
Sub-vastus	67	0.7
Lateral parapatellar	10	0.1
Unknown/missing/other	40	0.4

Vanguard/Maxim
N=12110

This implant combination was used by 93 surgeons. The median number of cases for those surgeons using this implant combination was 39 (interquartile range 174). The mean was 130.3 and standard deviation was 218.8. This implant combination was used at 44 sites. The median number of cases using this implant combination per site was 95.5 (interquartile range 365.5). The mean was 275.4 and standard deviation was 394.2.

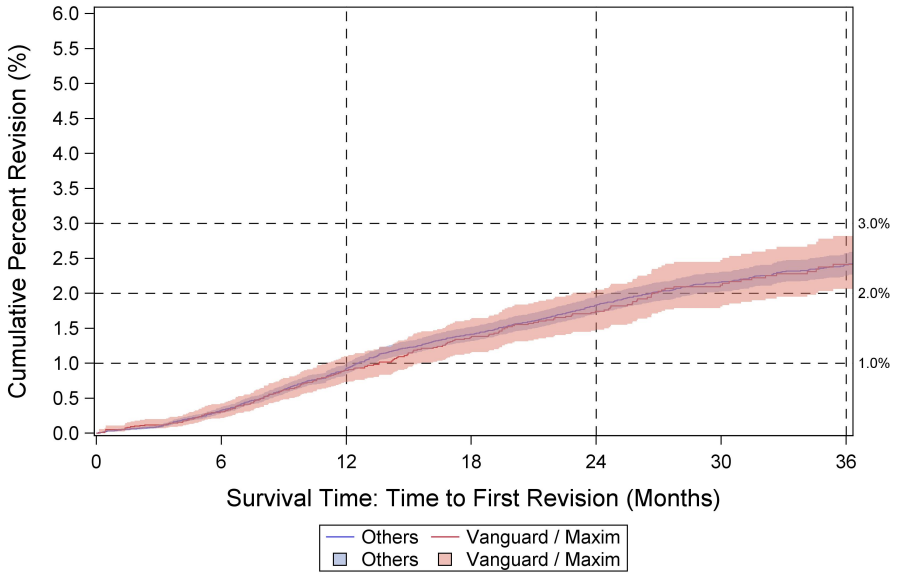

Figure 75: Cumulative percent revision curve for Vanguard/Maxim combination compared to all other TKA implants.

Table 165: Cumulative percent revision for Vanguard/Maxim combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years
12110	0.90 (0.73,1.10)	1.74 (1.48,2.05)	2.41 (2.06,2.82)

Table 166: Descriptive statistics on cases using the Vanguard/Maxim combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	7613	62.8	
Age (yrs)	12119	66.2(9.6)	66(13)
Height (cm)	12117	94.6(22.3)	92(29)
Weight (kg)	12117	168(10.6)	167(15)
BMI(kg/m^2)	12119	33.5(7.3)	32.5(9.6)
Smoking - never (%)	6168	50.9	
Smoking - previous (%)	4631	38.2	
Smoking - current (%)	1127	9.3	
Smoking - unknown (%)	193	1.6	

Table 167: Distribution of approach used for Vanguard/Maxim combination.

Approach	N	Percent
Medial parapatellar	11159	92.1
Mid-vastus	765	6.3
Sub-vastus	129	1.1
Lateral parapatellar	27	0.2
Unknown/missing/other	39	0.3

Vanguard/Maxim Mono-Lock
N=576

This implant combination was used by 47 surgeons. The median number of cases for those surgeons using this implant combination was 3 (interquartile range 4). The mean was 12.3 and standard deviation was 25. This implant combination was used at 26 sites. The median number of cases using this implant combination per site was 4 (interquartile range 9). The mean was 22.2 and standard deviation was 40.6.

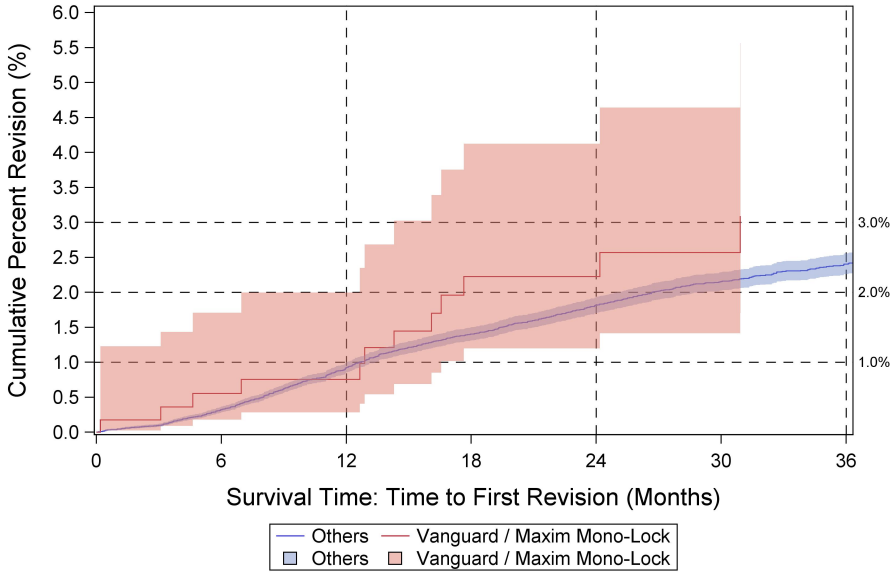

Figure 76: Cumulative percent revision curve for Vanguard/Maxim Mono-Lock combination compared to all other TKA implants.

Table 168: Cumulative percent revision for Vanguard/Maxim Mono-Lock combination compared to all other TKA implants (numerical values).

N	1 year	2 years	3 years*
576	0.75 (0.28,2.00)	2.23 (1.20,4.12)	3.09 (1.70,5.56)

* No revision occurred after the termination of the red curve in figure above; therefore, numerical revision risk at this time point is the same as it was at the time of the last revision.

Table 169: Descriptive statistics on cases using the Vanguard/Maxim Mono-Lock combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	496	86	
Age (yrs)	577	64.8(9.4)	65(12)
Height (cm)	577	93.4(23.2)	90(30)
Weight (kg)	577	164.7(8.8)	163(10)
BMI(kg/m^2)	577	34.4(7.6)	33.7(9.9)
Smoking - never (%)	276	47.8	
Smoking - previous (%)	219	38	
Smoking - current (%)	80	13.9	
Smoking - unknown (%)	2	0.4	

Table 170: Distribution of approach used for Vanguard/Maxim Mono-Lock combination.

Approach	N	Percent
Medial parapatellar	501	86.8
Mid-vastus	75	13.0
Sub-vastus	0	0.0
Lateral parapatellar	1	0.2
Unknown/missing/other	0	0.0

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5.5 UKA descriptive statistics

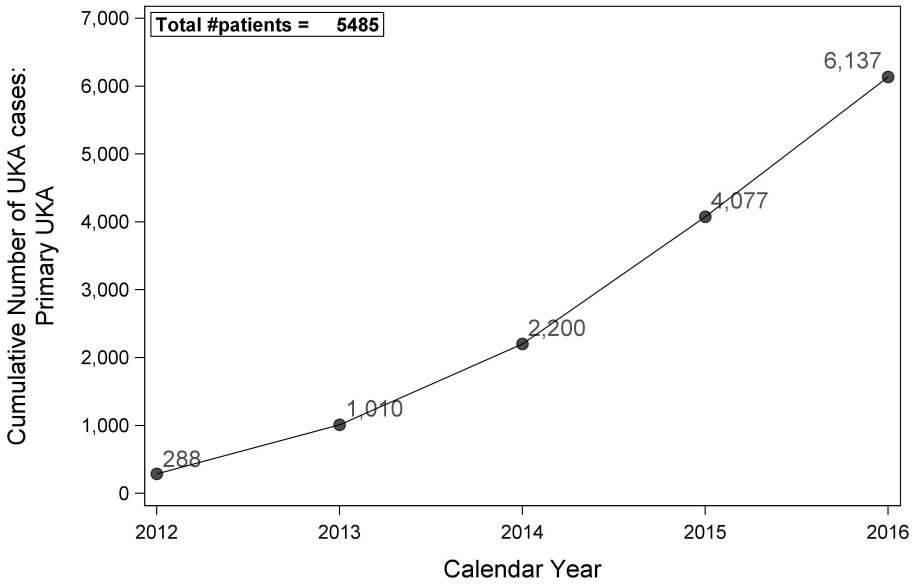

Figure 77: Primary UKA cases over time.

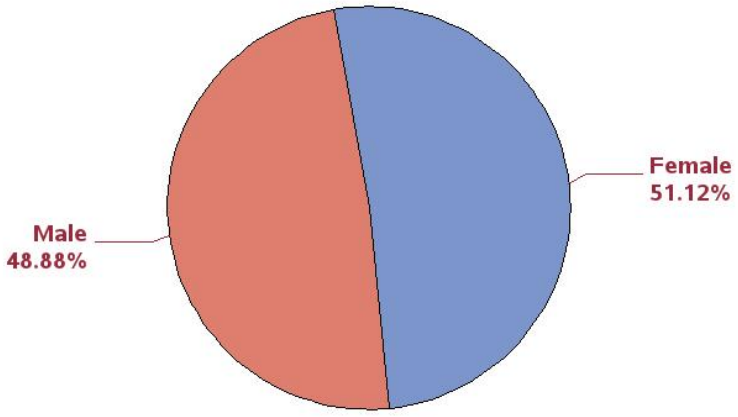

Figure 78: Percent of primary UKA cases by sex.

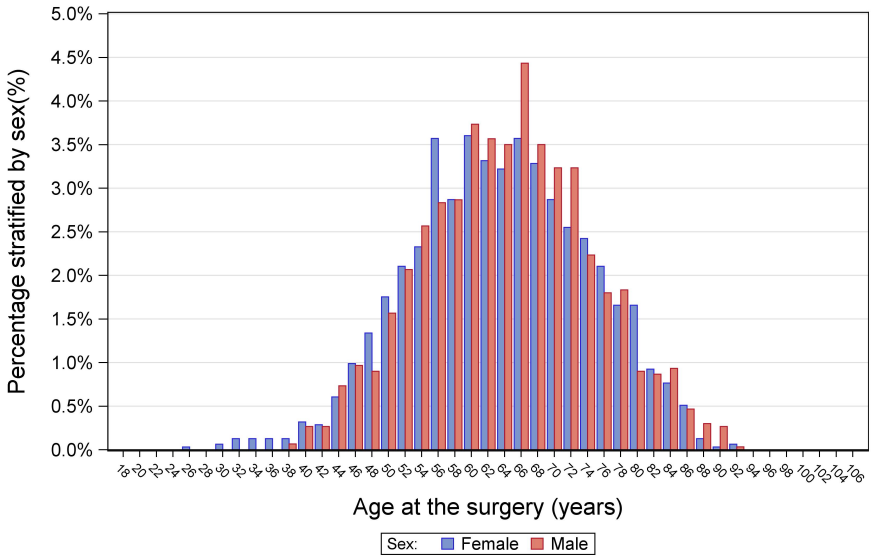

Figure 79: Age distribution of primary UKA cases by sex.

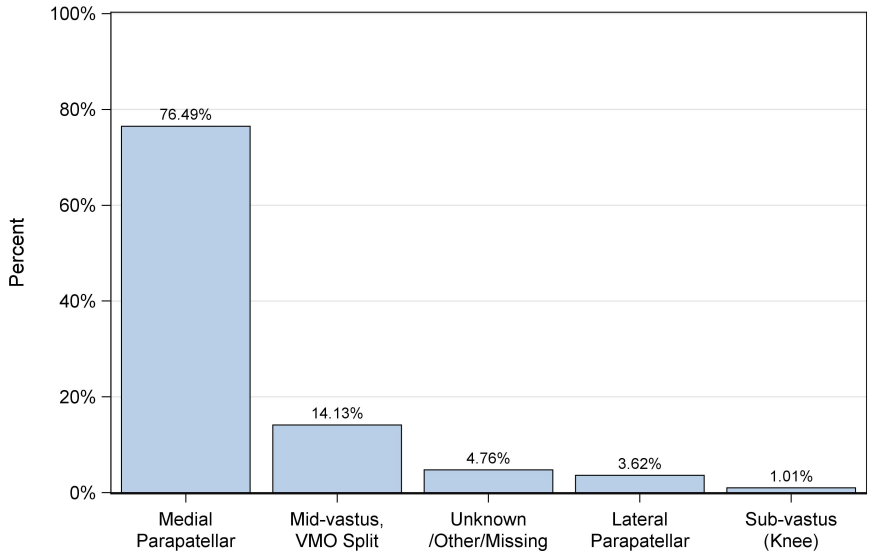

Figure 80: Percent of primary UKA cases by approach.

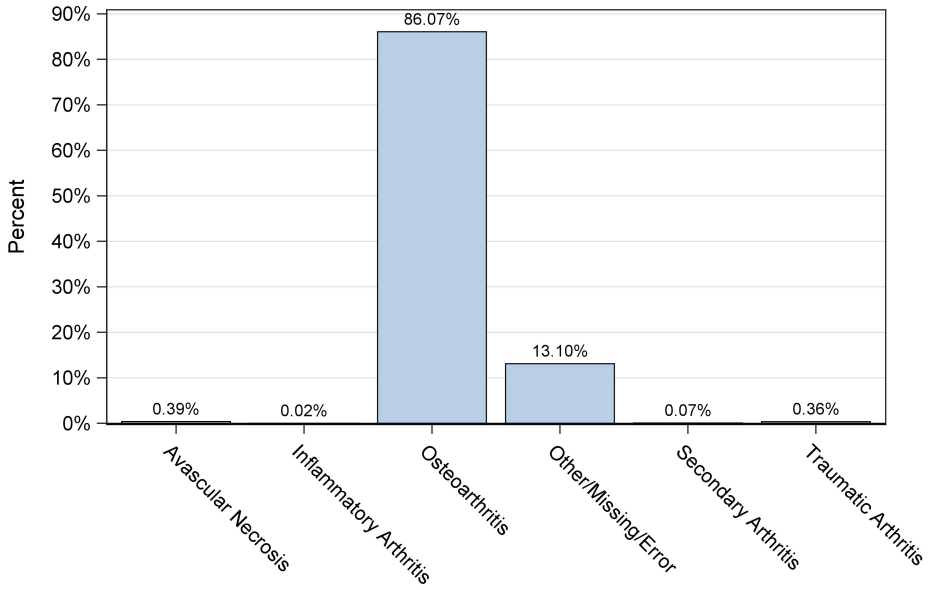

Figure 81: Percent of primary UKA cases by diagnosis.

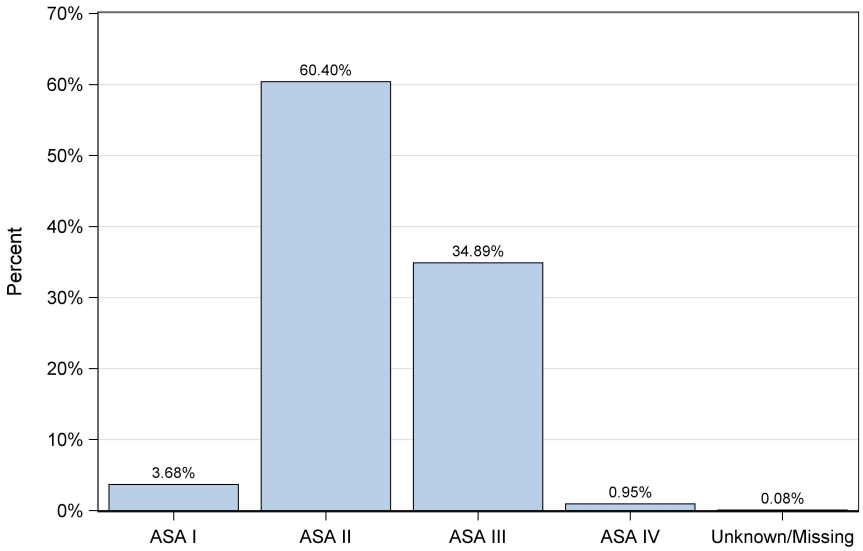

Figure 82: Percent of primary UKA cases by ASA class.

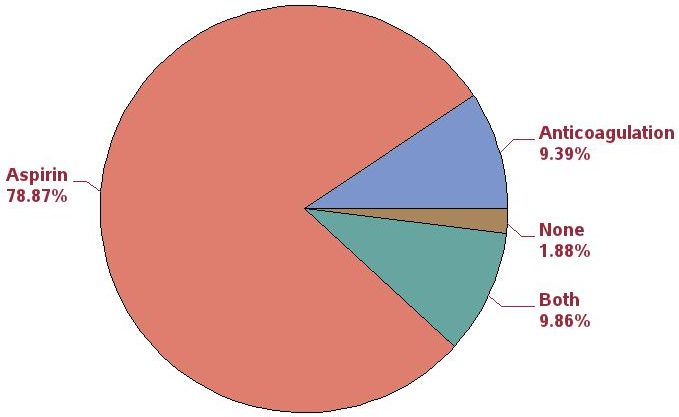

Figure 83: Percent of primary UKA patients (first case) by thombosis pharmacoprophylaxis between 10/1/2016 and 12/31/2016 (this time window is shorter than rest of figures because of significant change over time).

5.6 Most commonly used UKA implants

The following three tables provide utilization data of implants used in primary UKA.

Table 171: Ten most commonly used femoral components in primary UKA.

Rank	Femoral component	N	Percent
1	Zimmer High Flex	1995	32.5
2	Oxford	1731	28.2
3	Restoris MCK	1730	28.2
4	Triathlon PKR	213	3.5
5	iBalance	144	2.4
6	Journey	115	1.9
7	Sigma HP	83	1.4
8	Stride	75	1.2
9	Mirror	24	0.4
10	MG	18	0.3
11	Others	9	0.1

Table 172: Ten most commonly used tibial components in primary UKA

Rank	Tibial component	N	Percent
1	Zimmer High Flex	1990	32.4
2	Restoris MCK	1721	28.0
3	Oxford	1665	27.1
4	Triathlon PKR	212	3.5
5	iBalance	143	2.3
6	Journey	95	1.6
7	Sigma HP	82	1.3
8	Stride	75	1.2
9	Vanguard M	57	0.9
10	Mirror	24	0.4
11	Others	73	1.2

Table 173: Ten most commonly used femoral/tibial component combinations in primary UKA.

Rank	Femural/tibial component combination	N	Percent
1	Zimmer High Flex / Zimmer High Flex	1971	32.1
2	Restoris MCK / Restoris MCK	1721	28.0
3	Oxford / Oxford	1665	27.1
4	Triathlon PKR / Triathlon PKR	212	3.5
5	iBalance / iBalance	143	2.3
6	Journey / Journey	95	1.6
7	Sigma HP / Sigma HP	82	1.3
8	Stride / Stride	75	1.2
9	Oxford / Vanguard M	57	0.9
10	Mirror / Mirror	24	0.4
11	Others	92	1.5

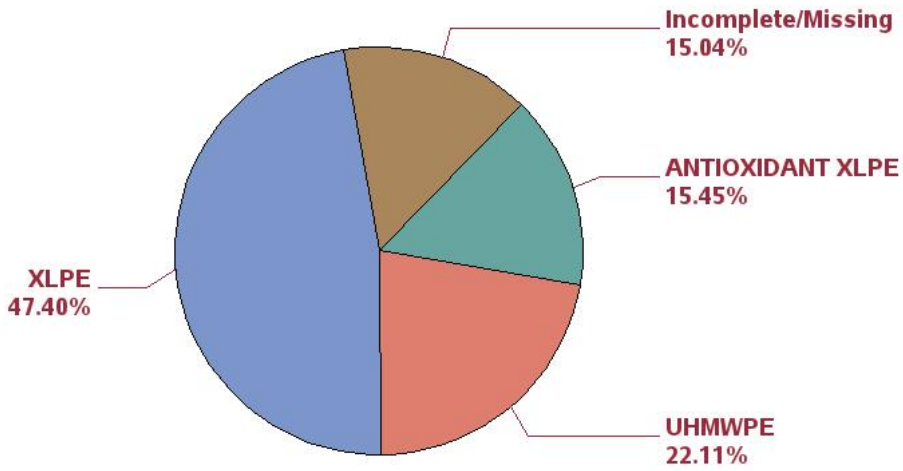

Figure 84: Percentage of polyethylene inserts by type of polyethylene in primary UKA.

5.7 UKA revision risk summary

Reason for revision is of central importance to quality improvement because it helps focus attention on specific causes that may be addressed. Therefore, the data are presented in two formats below: tabular and Pareto chart. The tabular format is consistent with how other arthroplasty registries report cause of revision. The Pareto chart figure presents the same data in a format commonly used in quality improvement. The Pareto chart sorts the reasons for revision by frequency (bar chart on bottom, from left to right) and presents a cumulative percent using a line graph above. The causes corresponding to each bar are numbered and a key at the bottom links the numbers to text descriptions. In addition to an overall summary of reason for revision, tables showing reason for revision for the first, second, and third year post-operatively are provided because the reasons change over this time horizon. It is important to note that the time window for the cases reported in reasons for revision tables and figures differ from the time window used for other figures because reason for revision was added to the database on 1/1/14. While these data capture revisions for primaries performed back to 2/15/2015, only revisions occurring on or after 1/1/2014 are included in the reasons for revision figure and tables. Also note that for knees instability/dislocation should be interpreted as instability.

Table 174: Most common reasons for first revision following primary UKA.

Rank	Reason for revision	N	Percent
1	Pain	31	26.5
2	Conversion of UKA	30	25.6
3	Aseptic loosening	19	16.2
4	Instability/Dislocation	10	8.5
5	Joint Infection	9	7.7
6	Component fracture/failure	6	5.1
7	Peri-prosthetic fracture (Tibia)	4	3.4
8	Osteolysis	3	2.6
9	Patellofemoral joint	2	1.7
10	Peri-prosthetic fracture (Femur)	1	0.9
11	Arthrofibrosis	1	0.9
12	Extensor mechanism failure	1	0.9

Table 175: Most common reasons for first revision following primary UKA in first year post-operatively.

Rank	Reason for revision	N	Percent
1	Pain	11	22.9
2	Joint Infection	8	16.7
3	Instability/Dislocation	6	12.5
4	Aseptic loosening	5	10.4
5	Conversion of UKA	5	10.4
6	Peri-prosthetic fracture (Tibia)	4	8.3
7	Osteolysis	2	4.2
8	Component fracture/failure	2	4.2
9	Patellofemoral joint	2	4.2
10	Peri-prosthetic fracture (Femur)	1	2.1
11	Arthrofibrosis	1	2.1
12	Extensor mechanism failure	1	2.1

Table 176: Most common reasons for first revision following primary UKA in second year post-operatively.

Rank	Reason for revision	N	Percent
1	Conversion of UKA	13	31.7
2	Pain	12	29.3
3	Aseptic loosening	9	22.0
4	Instability/Dislocation	3	7.3
5	Component fracture/failure	3	7.3
6	Osteolysis	1	2.4

Table 177: Most common reasons for first revision following primary UKA in third year post-operatively.

Rank	Reason for revision	N	Percent
1	Pain	7	41.2
2	Conversion of UKA	6	35.3
3	Aseptic loosening	1	5.9
4	Instability/Dislocation	1	5.9
5	Joint Infection	1	5.9
6	Component fracture/failure	1	5.9

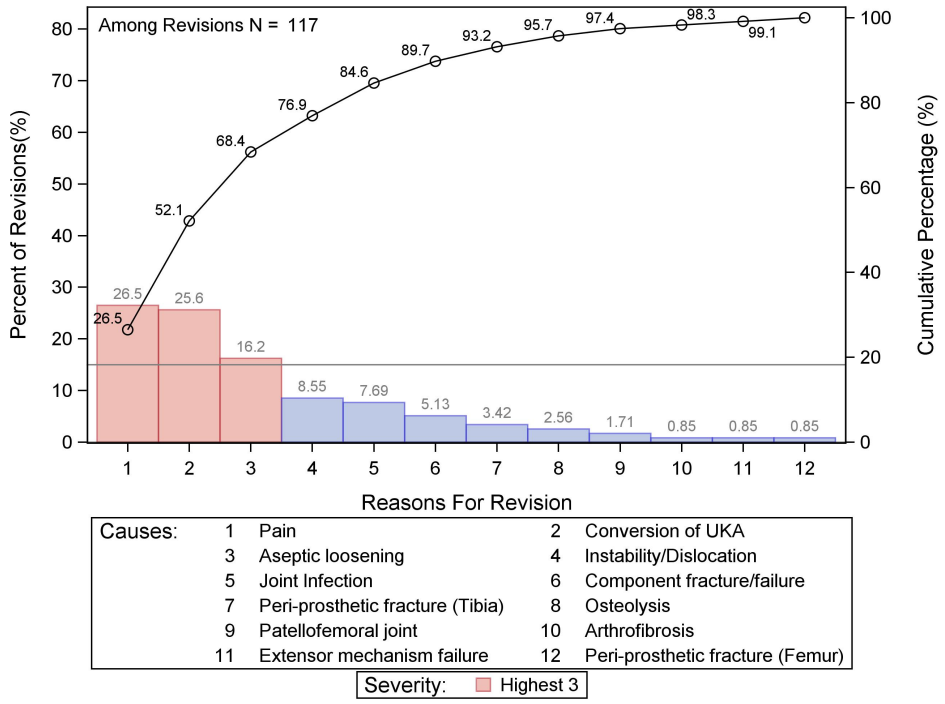

Figure 85: Most common reasons for first revision following primary UKA (Pareto chart).

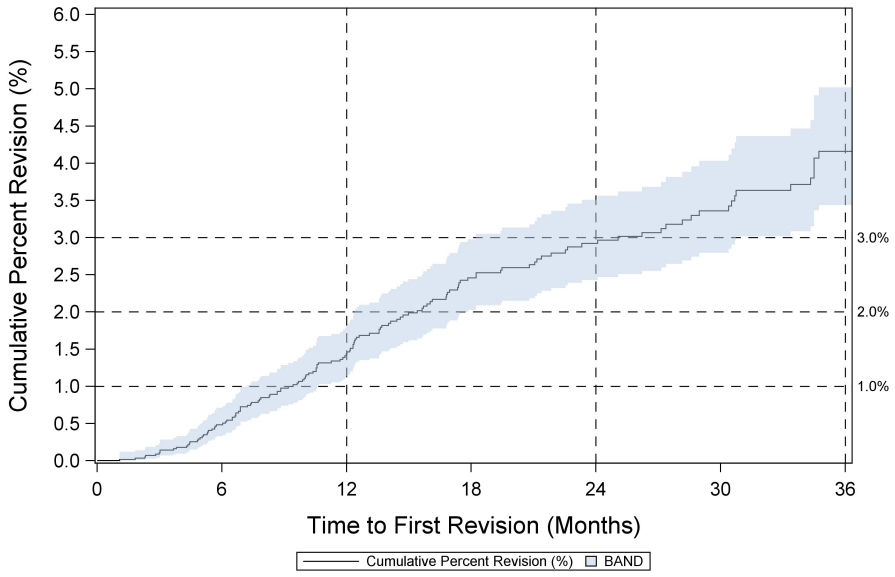

Figure 86: Cumulative percent revision for primary UKA.

Table 178: Cumulative percent revision for primary UKA (numerical values).

N	1 year	2 years	3 years
6135	1.44 (1.14,1.81)	2.92 (2.43,3.51)	4.16 (3.44,5.02)

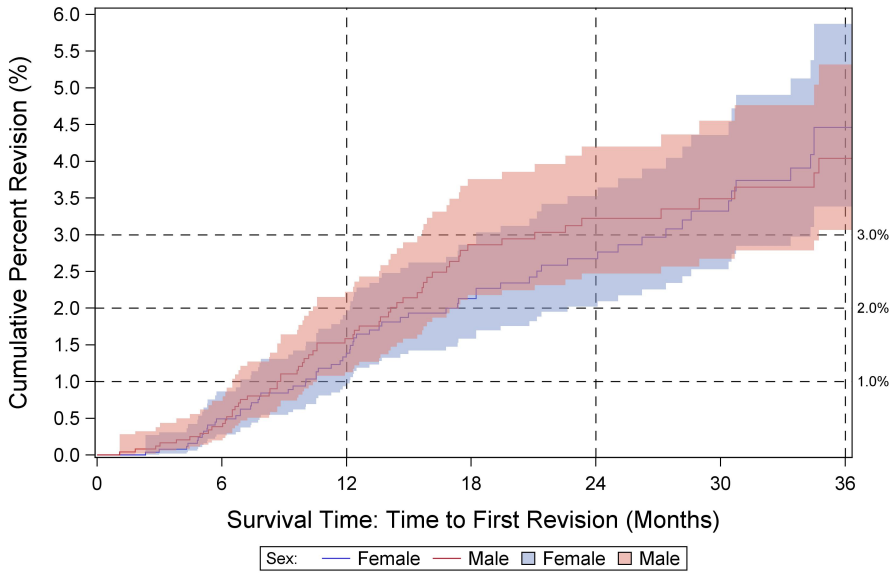

Figure 87: Cumulative percent revision for primary UKA by sex for osteoarthritis diagnosis.

Table 179: Cumulative percent revision for primary UKA by sex for osteoarthritis diagnosis (numerical values).

Sex	N	1 year	2 years	3 years
Female	2729	1.39 (0.98,1.97)	2.67 (2.02,3.53)	4.46 (3.38,5.87)
Male	2551	1.58 (1.13,2.22)	3.22 (2.47,4.20)	4.04 (3.06,5.32)
Unknown/Missing	0			

5.8 Revision risk for UKA implant combinations

In interpreting CPR curves, the reader should remember that all implant combinations have a minimum follow up of at least three years. Therefore, if the red line and shaded confidence interval end prior to three years, this does not mean the longest follow up was less than three years. Instead, it means that no additional revisions occurred after the end of the red line and confidence interval band.

While the reader is encouraged to read the details of each femur/tibia implant combination, the following table summarizes the three-year CPR values.

Table 180: Cumulative percent revision risk for femoral/tibial combinations having at least 500 primary cases, sorted alphabetically.

Femur/Tibia combination	N	1 year	2 years	3 years
Oxford / Oxford	1664	1.81 (1.22,2.69)	3.40 (2.46,4.69)	4.33 (3.11,6.02)
Restoris MCK / Restoris MCK	1721	0.96 (0.54,1.68)	2.18 (1.35,3.49)	4.04 (2.26,7.16)
Zimmer High Flex / Zimmer High Flex	1970	1.26 (0.82,1.93)	2.24 (1.60,3.14)	2.95 (2.12,4.11)

Oxford/Oxford
N=1664

This implant combination was used by 70 surgeons. The median number of cases for those surgeons using this implant combination was 11 (interquartile range 25). The mean was 23.8 and standard deviation was 51.7. This implant combination was used at 39 sites. The median number of cases using this implant combination per site was 18 (interquartile range 40). The mean was 42.7 and standard deviation was 83.5.

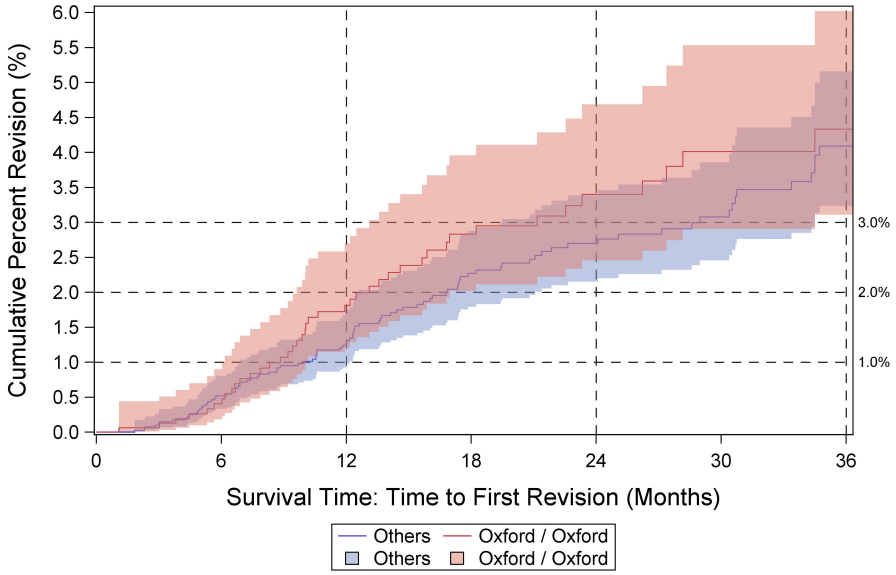

Figure 88: Cumulative percent revision curve for Oxford/Oxford combination compared to all other UKA implants.

Table 181: Cumulative percent revision for Oxford/Oxford combination compared to all other UKA implants (numerical values).

N	1 year	2 years	3 years
1664	1.81 (1.22,2.69)	3.40 (2.46,4.69)	4.33 (3.11,6.02)

Table 182: Descriptive statistics on cases using the Oxford/Oxford combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	825	49.6	
Age (yrs)	1665	64.1(10.2)	64(14)
Height (cm)	1665	91.4(19.9)	90(26)
Weight (kg)	1665	170(10.3)	170(16)
BMI(kg/m^2)	1665	31.6(5.9)	30.8(7.5)
Smoking - never (%)	789	47.4	
Smoking - previous (%)	693	41.6	
Smoking - current (%)	171	10.3	
Smoking - unknown (%)	12	0.7	

Table 183: Distribution of approach used for Oxford/Oxford combination.

Approach	N	Percent
Medial parapatellar	1489	89.4
Mid-vastus	100	6.0
Sub-vastus	12	0.7
Lateral parapatellar	4	0.2
Unknown/missing/other	60	3.6

Restoris MCK/Restoris MCK
N=1721

This implant combination was used by 40 surgeons. The median number of cases for those surgeons using this implant combination was 18 (interquartile range 30.5). The mean was 43.0 and standard deviation was 73. This implant combination was used at 10 sites. The median number of cases using this implant combination per site was 80.5 (interquartile range 213). The mean was 172.1 and standard deviation was 236.3.

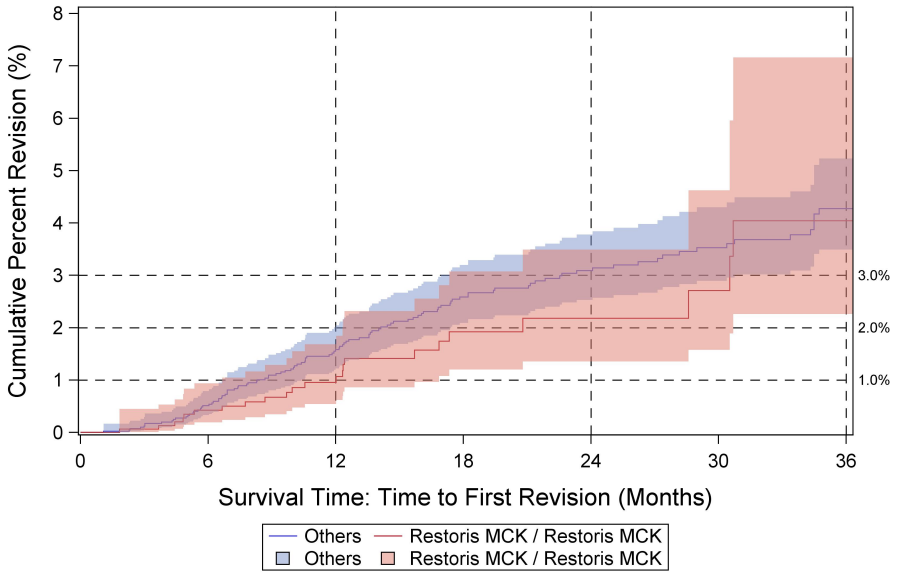

Figure 89: Cumulative percent revision curve for Restoris MCK/Restoris MCK combination compared to all other UKA implants.

Table 184: Cumulative percent revision for Restoris MCK/Restoris MCK combination compared to all other UKA implants (numerical values).

N	1 year	2 years	3 years
1721	0.96 (0.54,1.68)	2.18 (1.35,3.49)	4.04 (2.26,7.16)

Table 185: Descriptive statistics on cases using the Restoris MCK/Restoris MCK combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	873	50.7	
Age (yrs)	1721	64.1(9.5)	64(14)
Height (cm)	1721	91.4(19.5)	90(27)
Weight (kg)	1721	170.1(10.6)	170(16)
BMI(kg/m^2)	1721	31.6(5.8)	30.8(7.3)
Smoking - never (%)	851	49.5	
Smoking - previous (%)	731	42.5	
Smoking - current (%)	136	7.9	
Smoking - unknown (%)	3	0.2	

Table 186: Distribution of approach used for Restoris MCK/Restoris MCK combination.

Approach	N	Percent
Medial parapatellar	1369	79.5
Mid-vastus	80	4.6
Sub-vastus	1	0.1
Lateral parapatellar	100	5.8
Unknown/missing/other	171	9.9

Zimmer High Flex/Zimmer High Flex
N=1970

This implant combination was used by 104 surgeons. The median number of cases for those surgeons using this implant combination was 5 (interquartile range 14.5). The mean was 19.0 and standard deviation was 36.9. This implant combination was used at 37 sites. The median number of cases using this implant combination per site was 21 (interquartile range 70). The mean was 53.3 and standard deviation was 67.8.

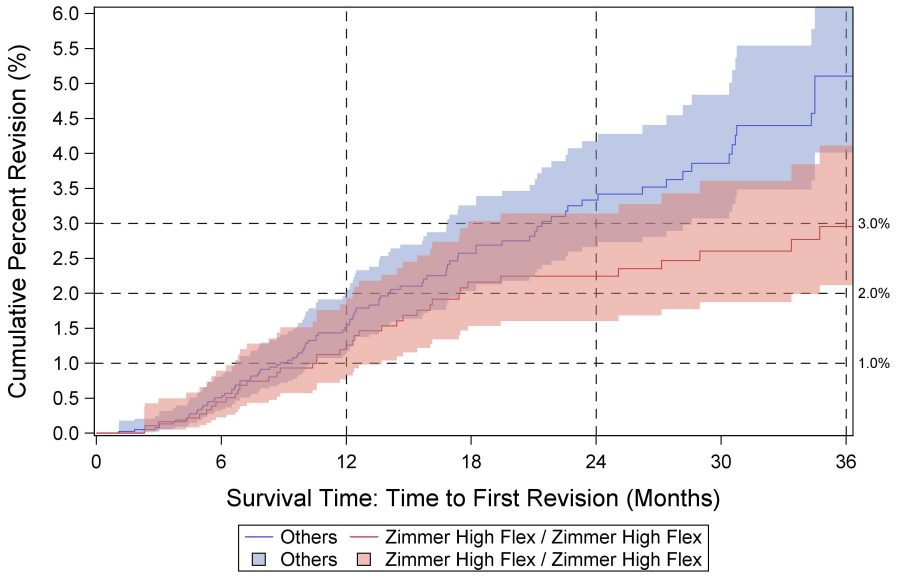

Figure 90: Cumulative percent revision curve for Zimmer High Flex/Zimmer High Flex combination compared to all other UKA implants.

Table 187: Cumulative percent revision for Zimmer High Flex/Zimmer High Flex combination compared to all other UKA implants (numerical values).

N	1 year	2 years	3 years
1970	1.26 (0.82,1.93)	2.24 (1.60,3.14)	2.95 (2.12,4.11)

Table 188: Descriptive statistics on cases using the Zimmer High Flex/Zimmer High Flex combination.

Quantity	N	Mean (SD)	Median (IQR)
Female (%)	1002	50.8	
Age (yrs)	1971	64.3(10.7)	64(16)
Height (cm)	1970	88.5(19)	87(26)
Weight (kg)	1969	169.5(10.4)	170(15)
BMI(kg/m^2)	1969	30.7(5.8)	30(7.5)
Smoking - never (%)	924	46.9	
Smoking - previous (%)	821	41.7	
Smoking - current (%)	204	10.4	
Smoking - unknown (%)	22	1.1	

Table 189: Distribution of approach used for Zimmer High Flex/Zimmer High Flex combination.

Approach	N	Percent
Medial parapatellar	1285	65.2
Mid-vastus	536	27.2
Sub-vastus	45	2.3
Lateral parapatellar	77	3.9
Unknown/missing/other	28	1.4

Chapter 6

Patient-reported outcomes

As part of our commitment to improving patient outcomes, MARCQI encourages participating sites to collect Patient-Reported Outcome Surveys (PROS). PROS collection is a powerful tool that helps providers improve care for both the individual patient completing the PRO survey, as well as other patients across Michigan who will be having joint replacements in the future. The surveys provide measurable data from the patient's perspective related to outcomes after surgery. PROS can be used at the point of care to assist with shared decision making, post-operatively to follow improvement, and to inform appropriateness and quality of care delivery across the course of care.

6.1 Survey selection

In 2015, MARCQI came to consensus on the recommended collection timeline and the best orthopaedic survey tools to utilize for the arthroplasty population. Considerable effort was put into balancing the competing desires to collect comprehensive questionnaires with the burden this places on patients and caregivers. The decision was made to avoid proprietary surveys, limit the number of questions and to harmonize efforts with national PROS collection and regulatory requirements. The final recommendations were to collect NIH's static ten-question implementation of the Patient-Reported Outcomes Measurement Information System (PROMIS-10)[1] and the Hip, and Knee, disability and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR.[2] or KOOS, JR.[3]) instruments. While surveys can be collected and will be accepted at any time point, a standard timeline was endorsed as follows:

1. pre-op survey - within 90 days prior to the date of surgery,
2. initial post-operative survey - 5-13 weeks,
3. follow-up survey - 5-13 months (selected to accommodate 6 month visits), and
4. late follow-up surveys - 2, 5, and 10 years.

6.2 Data collection

MARCQI has set a short-term goal that 50% of all THA and TKA cases will have at least a pre-operative and an initial post-operative survey. The ultimate Collaborative goal is 80% PROS collection for all elective THA and TKA cases. MARCQI supports sites in reaching this goal by providing a user friendly platform which assists in collection efforts. The database offers several options for PROS collection:

[1] PROMIS v.1.0/1.1-Global. PROMIS Health Organization and PROMIS Cooperative Group, 2012.

[2] Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR.), English Version 1.0. Hospital for Special Surgery, 2016., English Version 1.0. Hospital for Special Surgery, 2016.

[3] and Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR.), English Version 1.0. Hospital for Special Surgery, 2016., English Version 1.0. Hospital for Special Surgery, 2016.

1. *Clinic module*. A web based application allows the patient to answer the questionnaires on a tablet or computer kiosk at the time of their clinic appointment. Patient responses are immediately transferred to the MARCQI database and survey scores are generated at the time of completion. This provides real-time scoring which is ideal for shared decision making.
2. *Auto generated email*. The database sends a secure email to patients due for a survey. The email contains a link to the surveys, enabling the patient to complete the survey prior to a scheduled clinic appointment. The patient responses are immediately transferred to the MARCQI database and survey scores are generated at the time of completion.
3. *File based acquisition*. MARCQI sites may choose to utilize other tools to collect PRO surveys and can batch upload PROS results through the FBA option.
4. *Manual*. This method allows manual data entry for sites that collect the PROS on paper via the telephone.

The collection of PROS has historically only been done for research studies. It has not been a part of most clinical practices. With the adoption of PROS as a clinical tool for patient care and quality improvement, new protocols and workflows need to be developed in each surgeon's practice. When captured in the clinic, PROS can be integrated into the front desk check-in process or added to the intake process like a vital sign. However, this can add time to each patient encounter and many patients require assistance using technology such as touchscreen tablets or computer kiosks. Once this process is incorporated into the clinic setting, it can be the most effective way to have high capture rates. Email survey collection is not as productive due to much lower response rates. Some sites have improved this with reminder phone calls and support. There are also multiple vendors offering services to assist with PROS collection. Some MARCQI sites have used third party services to obtain higher PROS collection rates.

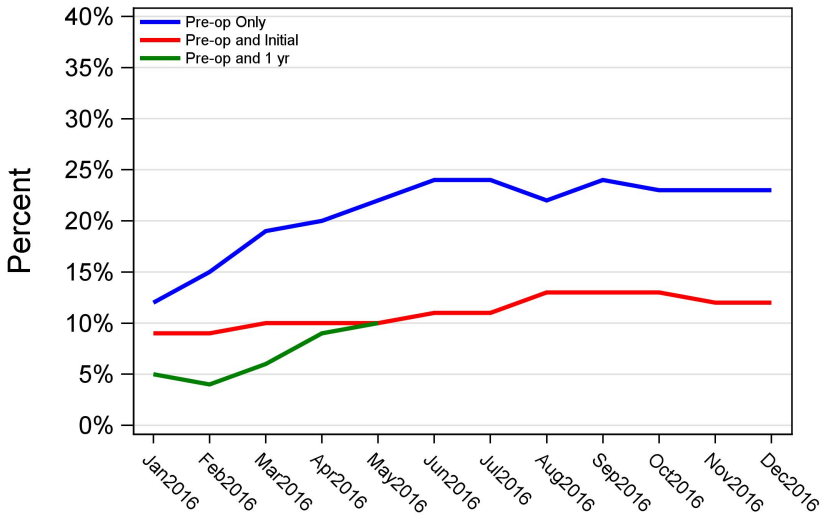

Figure 91: PROMIS-10 Survey collection in 2016.

PROS collection has been ongoing for the entire history of MARCQI. Some early sites were already collecting surveys from patients when they joined MARCQI. Currently 27 of the 60 MARCQI sites (45%) are collecting PROS surveys from their patients. Figure 91 shows the percent collection of PROMIS-10 surveys in 2016-2017 for all MARCQI cases.

6.3 PROS scores

There is little literature on the use and outcomes of PRO surveys used in clinical practice outside of a research setting. The PROMIS question bank was developed with funding from the National Institutes of Health and has been

normalized to the US population with a mean of 50 and a standard deviation of 10. MARCQI uses the PROMIS version which includes physical function and mental subscores. The HOOS JR and KOOS JR scores are on a 100-point scale.

For pre-operative scores in MARCQI patients, the average reported PROMIS-10 physical health score for hips was 39.2 (SD 7.1), more than one standard deviation below the population mean. At initial follow-up (5-13 weeks) physical health score for THAs had risen to an average of 48.9 (*SD*=8.2), returning rapidly to the population's average physical health. The pre-op mental health score averaged 48.4 (*SD*=8.8) and at initial follow-up had risen above the population mean to 53.2 (*SD*=8.5). Pain scores, on a 10-point scale, decreased from 6.4 (*SD*=2.1) to 2.1 (*SD*=2.0).

For knee replacement patients, the mean pre-op physical score was 39.9 (*SD*=6.5) and post-op score averaged 46.4 (*SD*=7.1). Mental health average score rose from 49.3 (*SD*=8.1) to 51.7 (*SD*=8.1). The mean pain score improved from 6.1 (*SD*=2.1) pre-op to 2.8 (*SD*=2.0) post-op.

Figure 92 shows there is considerable variability between hospitals in pre-op joint specific scores and in pain scores (hospitals are de-identified in the figure).

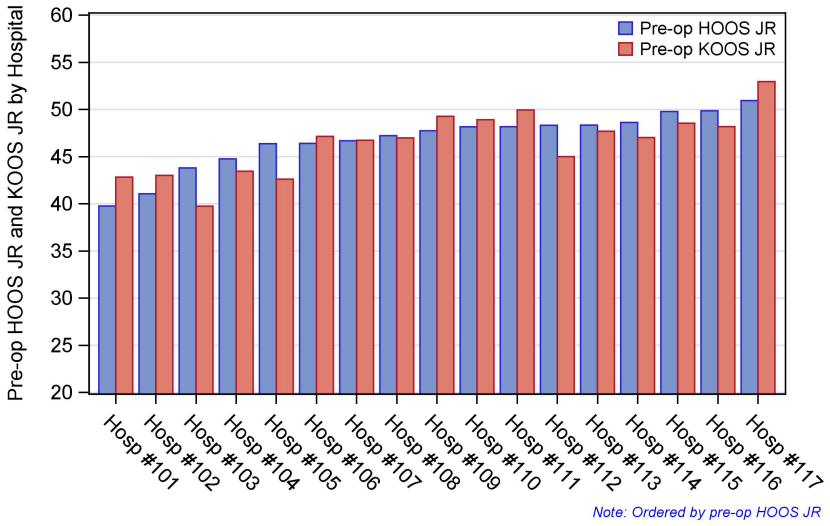

Figure 92: Average pre-operative HOOS JR and KOOS JR for hospitals with more than 40 surveys.

As PROS collection increases in MARCQI, we will be able to track longer term trends in patient's function and pain. Historically it has been recommended that arthroplasty patients be seen back in clinic at regular intervals, such as every two or five years. These surveys may be valuable in tracking patients over time and could potentially be used as an alternative to regular clinic visits, saving patients and clinicians time and saving the health care system the cost of these visits as well as the costs associated with imaging.

6.4 Appropriateness

The primary reasons to perform hip and knee replacements are to reduce pain and to improve function. There have been attempts to define appropriateness for surgery based on the extent or duration of non-operative treatments, the radiographic severity of disease, or other indirect measures of care. Directly measuring the patient's subjective pain and function with PROS provides a potential alternative to the question of appropriateness. Patients who have little pain and/or better than average function preoperatively raise the question of whether they should be having a procedure to reduce pain and improve function. There are many issues with this premise given the limited experience with and literature on the use of these tools. It is too early to say if they will truly provide meaningful information about the appropriateness of patient selection and indications. Others are studying PROS in shared decision making. PROS can potentially provide information to

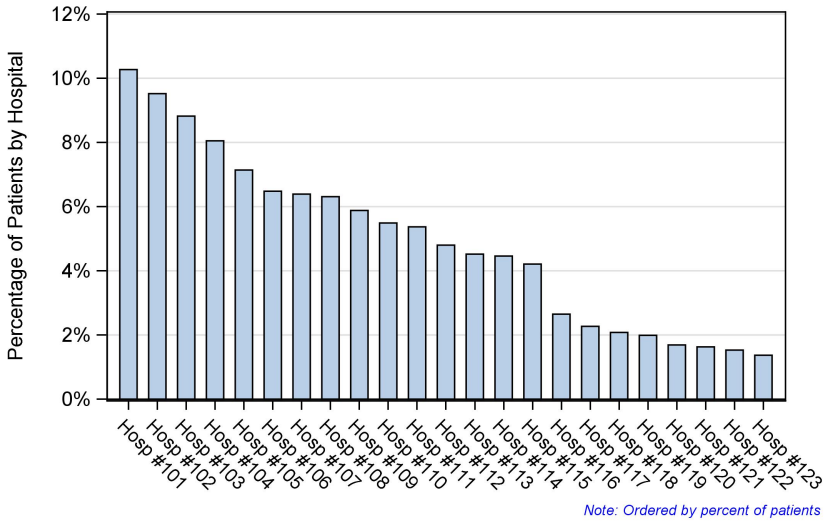

Figure 93: Percentage of patients with pre-op pain score $\leq$3 and PROMIS-10 physical health score $\geq$50 by hospital.

patients and providers when making a decision about surgery.

Figure 93 demonstrates the proportion of patients with low pain scores ($\leq$3) and higher than average function (PROMIS-10 physical health score $\geq$50) varied from 1.5% to over 10% across hospitals collecting PROS (hospitals de-identified). Overall 2.2% of the patients with PROS surveys met these criteria. The usefulness of PROS as a measure of appropriateness is yet to be determined and depends on a number of issues including the accuracy of the score, the timing of collection, and correct attribution of the score to the joint in question. This variability offers and opportunity for quality improvement.

Chapter 7

Savings and value

For its first 5 years, MARCQI has focused on quality improvement efforts to decrease complications around the time of surgery such as blood clots, infections, readmissions, bleeding, emergency department visits, and dislocations. This has been accomplished by identifying and reducing variations in care, providing quality data to hospitals and providers, encouraging the use of established guidelines, developing new protocols based on our collective experiences, and improving the appropriateness of the care provided through patient optimization.

All of these efforts have obvious benefits to patients and families. In addition, reducing problems and complications allow providers to spend their time providing care and improving the health of more patients rather than treating problems created by previous procedures.

These efforts come at a cost. The expense of administering the project includes the coordinating center, supporting the data collection process at each hospital and incentivizing improvement with pay-for-performance payments. Ideally, these costs should be exceeded or at least be balanced by the savings achieved by reducing unnecessary care, avoiding costly complications and improving the longevity of the procedures performed. These fiscal savings also ignore the less tangible benefits to patients, families, and providers of the reduced risks of complications.

The work of quality improvement can lead to reduced cost and better quality, resulting in improved value. Additionally, unnecessary surgery contributes no value. Therefore, improving the appropriateness of care provided will reduce cost of surgery. This can be summarized as:

$$Value = Appropriateness \times \frac{Quality}{Cost}$$

In addition to improving care, each of our quality improvement efforts has also reduced the cost of providing hip and knee replacements to the patients of Michigan. The beneficiary of these saving varies depending on the aspect of care being considered. Most of the savings benefit payers, but projects also benefit pharmaceutical plans, self-funded employers, hospitals, providers, or the patients themselves. For patients over 65 years old, the majority of savings will be realized by CMS; for those under 65, private healthcare payers will see the savings. Some projects reduce costs that are borne by the hospital and have to be covered under a diagnosis-related group payment. Patients will also see savings because of co-payments and deductibles.

As new episode of care models and value based payments become more common, the beneficiaries of these savings may shift. One example is the cost of a complication. Under fee for service, payers see the cost of that care and hospitals and providers benefit financially from providing the added care. In contrast, in an episode of care model the payer would not bear the cost of the complication and it would instead be reflected in the bottom line of the hospital that provided the original bundled service. The cost of post-discharge care such as nursing facilities would also shift in a similar way. This scenario would describe the “bundled payment” Comprehensive Care for Joint Replacement program developed by the Centers for Medicare and Medicaid Services.

Several examples of the impact and estimated savings of some of MARCQI's major quality improvement projects are detailed below.

7.1 Reducing transfusions

As detailed in chapter four, we first presented the MARCQI transfusion reduction program at the last Collaborative meeting of 2013. Recommendations included treating pre-operative anemia, following the American Red Cross guidelines, not transfusing blood unless the hemoglobin was below 8g/dL (in most cases), and checking post-transfusion hemoglobin results prior to ordering and administering a second unit. We also encouraged the use of TXA to reduce blood loss and transfusion requirements and we included transfusion as a pay-for-performance metric to further encourage the reduction efforts.

The savings associated with the transfusion project are significant. The costs of giving a transfusion are not just the cost of giving blood. In addition to the $300 - $400 cost of a unit of blood, there are the laboratory costs of storage, typing and crossmatching, the equipment costs and the nursing costs to deliver, administer, and monitor patients after a transfusion. The total cost of administering a single unit of blood is approximately $700 - $900 dollars. Given the estimated 5,800 fewer units transfused in 2016, this represents an annual savings of over four million dollars in Michigan and does not include the savings from avoiding the complications associated with transfusion such as infection and transfusion reactions.

7.2 Nursing home discharges

The greatest variation in cost between hospitals providing hip and knee replacement is in the post-acute care including physical and occupational therapy, emergency department visits, and the costs of extended care facilities (Miller *et al.*, 2011). Of these, discharge to an extended care nursing facility represents one of the largest expenses. In Michigan, the average cost of a discharge to a nursing facility is $7,800. For hospitals participating in the Comprehensive Care for Joint Replacement program of CMS, this represents about one third of the allotted episode payment after an uncomplicated arthroplasty.

In the past, total joint arthroplasty has required a prolonged hospitalization and rehabilitation. Patients typically spent several weeks in nursing homes before finally going to their own residences. In a MARCQI analysis, nursing home discharge was associated with a 30%-50% increased risk of readmission, even when risk stratified by comorbidities.

Improvements in technique, pain management, anesthesia, and post-operative rehabilitation protocols have shifted the patient experience. Rather than needing to recover from a large physiologic insult, a well-managed patient can now leave the operative room, in many ways, in better condition than they were in when they entered. As a result, the majority of total joint replacement patients can and should go home to recover, where bathing, ambulation, and self-care is a part of their recovery. Families do not have the inconvenience of visiting a nursing home and the patient avoids the risks and discomforts of being institutionalized. Through a program of anticipating patient's needs, pre-operative preparation, improving pre-operative education and setting the expectation for home discharge, the percent of Michigan patients that went to a nursing home after primary hip or knee arthroplasty has dropped from 23.0% to 16.1%. For the more than 42,000 patients who had these procedures in 2016, this saved the health care system in Michigan more than $20 million annually and enabled about 2,900 additional patients to recover at home or with family rather than in an institution.

7.3 Preventing VTE

The Collaborative focused on tracking and reducing VTE events due to the risks that blood clots and pulmonary emboli can pose to patients. There are many common prophylactic regimens for preventing VTE and there was wide variation in practice across the state. There is also little consensus in guidelines or the medical literature about the best prophylaxis. Over the last three years there has been a dramatic shift in the choice of medications used to prophylax for VTE. Currently in Michigan, the majority of patients are receiving aspirin as their sole pharmacologic prophylaxis. This has been driven by secular changes in practice nationally, the addition of aspirin to national guidelines and protocols, and growing evidence in the MARCQI data for the safety of aspirin.

Aspirin costs about $2 per month and requires no monitoring. Dosing is simple for patients, does not require

adjustment and does not require an injection. In contrast, low molecular weight heparin is estimated to cost between $450-$890 per month, factor-Xa inhibitors between $380-$450 per month. While the cost of warfarin itself is relatively low, the laboratory and nursing costs of monitoring and adjusting dosing approaches the cost of these other medications. (Kwong, 2011, Duran *et al.*, 2012) In an internal analysis by a single payer of savings from MARCQI in 2015, it was estimated that they realized a $281,596 savings from the shift to using aspirin for VTE prophylaxis. This likely represents only a fraction of the overall savings seen by all payers, including CMS. This also results in significant improvements in patient satisfaction by simplifying post-operative management.

7.4 Readmission

The cost of readmissions is significant to hospitals and disruptive to patient's and family's lives. Hospitals also face penalties from CMS if readmission rates exceed predicted rates.

As part of the efforts to reduce readmission MARCQI members have encouraged pre-habilitation protocols, care coordination, pathways for patient optimization, and communication protocols for patients presenting to the emergency department. Post-operative assessment of patient needs and understanding of discharge instructions was enhanced. Attention was paid to pre-emptively addressing common problems after discharge such as constipation, pain, stiffness, and wound issues. A protocol for emergency department work-up of joints was shared with members. The same internal payer analysis that measured cost savings for VTE prophylaxis estimated a $1,051,422 in cost avoidance from decreased readmissions across the MARCQI hospitals.

7.5 Summary

MARCQI initiatives save money by improving the quality of care. A reduction in the frequency of expensive complications avoids expenditures. Changing clinical practice to use resources more wisely without increasing adverse events or impairing outcomes can also substantially reduce costs. Moreover, reducing costs by increasing quality is a powerful way to enhance health care value. MARCQI has beneficial impact beyond hip and knee arthroplasty services lines because a MARCQI hospital builds infrastructure for quality improvement and clinical transformation that can affect patient care and costs across the institution.

Appendix A

Statistical methods

This appendix is intended to provide a clear and precise description of the analytical methods used to generate figures, tables, and text in this report. It is written primarily for registry methodologists. It can be used as a reference for readers most interested in clinical aspects of arthroplasty.

A.1 Multi-level closed-loop data quality QC/QA

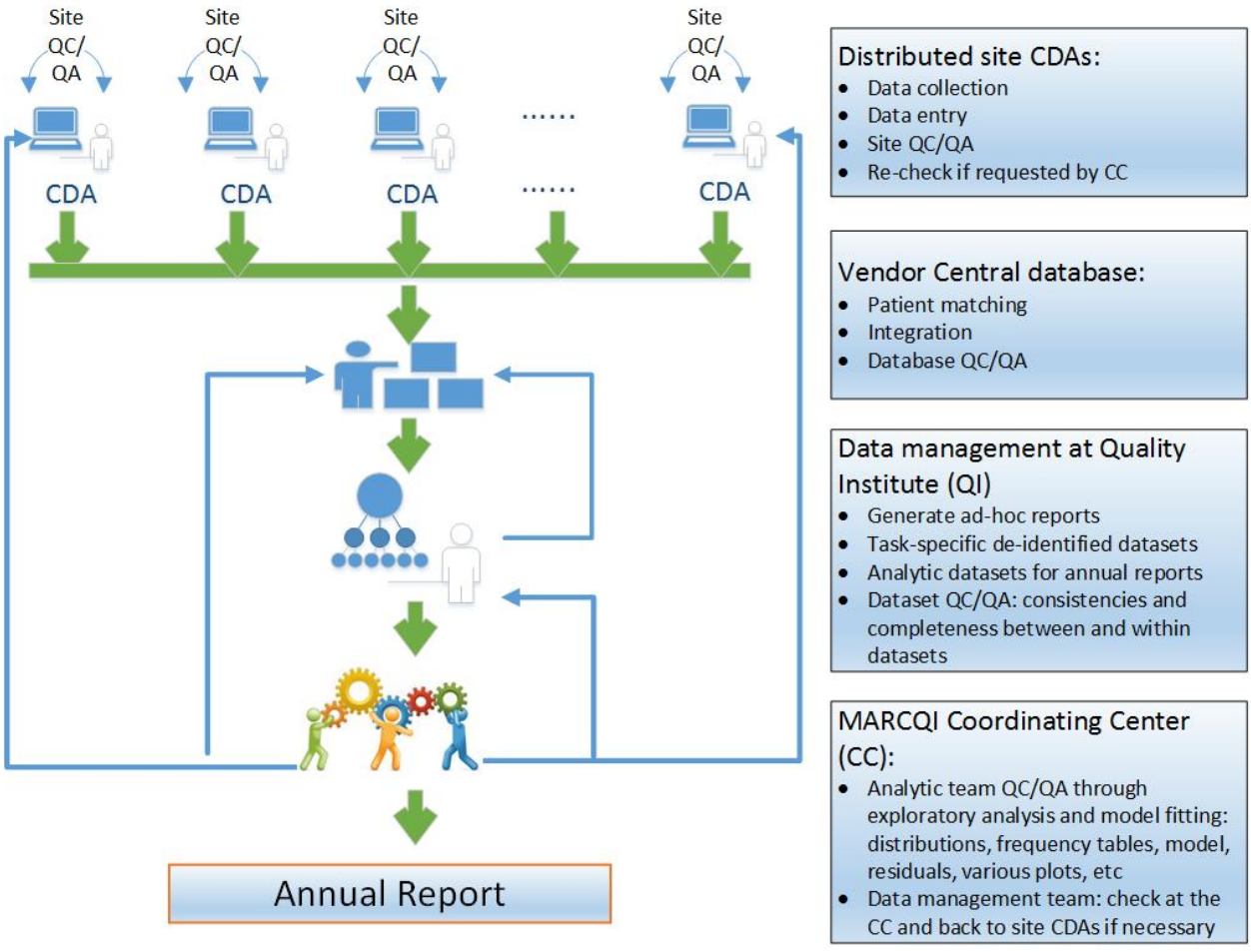

Figure 94: Flowchart of MARCQI 4-level QC/QA process.

Data quality is critical in MARCQI. In order to meet quality dimensions, including accuracy/validity, reliability/consistency, completeness, precision, timeliness, confidentiality, and integrity (Sheppard and Terveen, 2011), MARCQI data has been checked and validated on four levels: (1) hospital, (2) vendor database, (3) data management, and (4) analytical. The first three levels were addressed in chapter two. At the analytical level, the measures were further checked through distributions, frequency tables, model fittings, residuals, and other visualization tools. The questionable measures were directed to the coordinating center data management team and then returned to site CDAs if necessary. The CDAs validated data and made necessary corrections in the database if a measure was found to be in error. Figure 94 is the flowchart of four-level QC/QA process.

The following goals are the focus of data quality in MARCQI:

1. *Accuracy/validity*. MARCQI data accuracy is validated based on the definitions and medical domain knowledge to ensure that data is entered correctly and appropriately into the domain. At the MARCQI data entry stage, validation messages are created and a warning message window will pop-up if a value is out of normal range as pre-defined by the domain experts. This helps filter out potential data collection errors and allows confirmation of out-of-range but accurate values.

2. *Reliability/consistency*. The coordinating center staff ensures that the definition of measures is consistent over time and across sites. They assure data collection processes are consistent over time, across distributed hospital sites, and between collection systems through MARCQI CDA training, Collaborative meetings, and consultation with the sites.

3. *Completeness*. Data are fully inclusive, *e.g.*, complete list of eligible implant names, device materials, patient demographics, etc. Missing data, invalid data, and/or incomplete data are checked.

4. *Precision*. MARCQI data are detailed and includes demographics, lab, OR log, implant, etc.

5. *Timeliness*. MARCQI data are up-to-date and available quickly and frequently. Data reports are updated monthly, and the analytical datasets are updated quarterly.

6. *Integrity*. MARCQI maintains the accuracy, validity, and consistency of data over whole data lifecycle, within and between data tables so that data is recoverable, searchable, traceable, and stable.

7. *Confidentiality*. MARCQI data are maintained according to national/international standards for data. All MARCQI data are protected and used appropriately.

This entire process guarantees the MARCQI data quality ranging from protocol, data collection, data entry, patient matching, data merging, data transfer, data storage, and data analysis to decision making.

A.2 Time window, inclusion and exclusion criteria for the hip and knee chapters

This report covers MARCQI activities from 02/15/2012 to 12/31/2016, and included both primary and revision(s) cases. The inclusion and exclusion criteria for each table and figure in the hip and knee chapters are provided in an online supplement (`http://marcqi.org/dev/wp-content/uploads/2017/10/MARCQI_2012-2016_report_chapter_4_and_5_specifications.pdf`.).

A.3 Data structure for analytics

Two formats of data sets are used for this report, called “long” format and “wide” format.

1. The “long” format has a record (or row) for each case, *i.e.*, an individual record for each primary and revision case. Some patients may have multiple records indicating they have had multiple hip or knee replacement procedures over time. There may be a few patients with primary cases before 02/15/2012, and revision after 02/15/2012 (but before the end of the study 12/31/2016). This dataset is used to calculate statistics for total number of performed cases, overall and per calendar year.

2. In contrast, the “wide” format has one record (or row) for each primary case because a patient can only have one primary surgery per joint; subsequent procedures on the same joint would indicate revisions. There are no stand-alone records dedicated to revision(s). Rather, in the wide format the existence of a first revision is indicated as a dummy variable (1 means having a revision, 0 means not having a revision). Time to first revision in days was calculated for implant survival analysis. No revisions beyond first revision are coded in the wide data format. Some patients may have multiple records (or rows) if this patient had more than one primary surgery on different joints and/or lateralities. In this report, each primary surgery was treated as a new case. The date of primary cases must fall within the study window. This dataset is used to calculate descriptive statistics for primary cases, overall and breakdown by sex, diagnosis, and type of implant. It is also used for implant survival analysis.

A.4 Definition of revision event for statistical modeling

Total hip arthroplasty and total knee arthroplasty are surgical procedures in which a prosthesis is implanted to replace an arthritic or damaged joint to relieve pain and to improve patient function and quality of life. Joint replacements may require a revision surgery for various reasons. *The definition of revision used by MARCQI is a procedure that involves removing and replacing some, or all, of the hip or knee replacement components*. This report focuses on the time-to-first revision.

A.5 MARCQI cohort: Qualifying patients and events for descriptive statistics and implant survival analysis

MARCQI was designed to improve quality of care for elective primary total hip and knee arthroplasty and associated revisions, excluding treatment for trauma cases. CDAs review each case for admission type and uses the following criteria to determine if the case qualifies for inclusion in MARCQI:

1. *Elective*. All primary and revision hip and knee joint replacement cases qualify that meet three requirements: (1) a surgical procedure has been planned, (2) screening and optimization have been completed, and (3) the patient presented at a pre-planned appointment (surgical date) for treatment of a non-emergent condition.

2. *Urgent/emergent*. The only urgent/emergent cases that quality are revisions. This means that (1) a surgical procedure that has not been planned (screening and optimization have not been completed), and (2) the patient presents for care in a stable medical condition without an appointment. The patient may be admitted from an outpatient clinic or surgeon office.

3. *Trauma*. Primary trauma cases do not qualify. The CDA reviews the case to determine if an urgent/emergent qualifying revision of a knee or hip was performed.

There are many different combination of events that can occur for each patient within and outside the 2/15/2012 - 12/31/2016 time window. For example, a patient could have a primary and revision, have a primary and then die, or have a primary and have no revision before 12/31/2016 but remain alive. It is important to understand each when interpreting data in this report, especially time-to-revision and the resulting cumulative percent revision curves and numbers. Figure 95 illustrates the possible events (*e.g.*, revision) for the report window using eight types of patients. Symbols in the figure represent start of a primary surgery (S), single event (E_1) and/or multiple events (E_n), death (D), and censoring (C). The figure helps define important concepts used in MARCQI analyses:

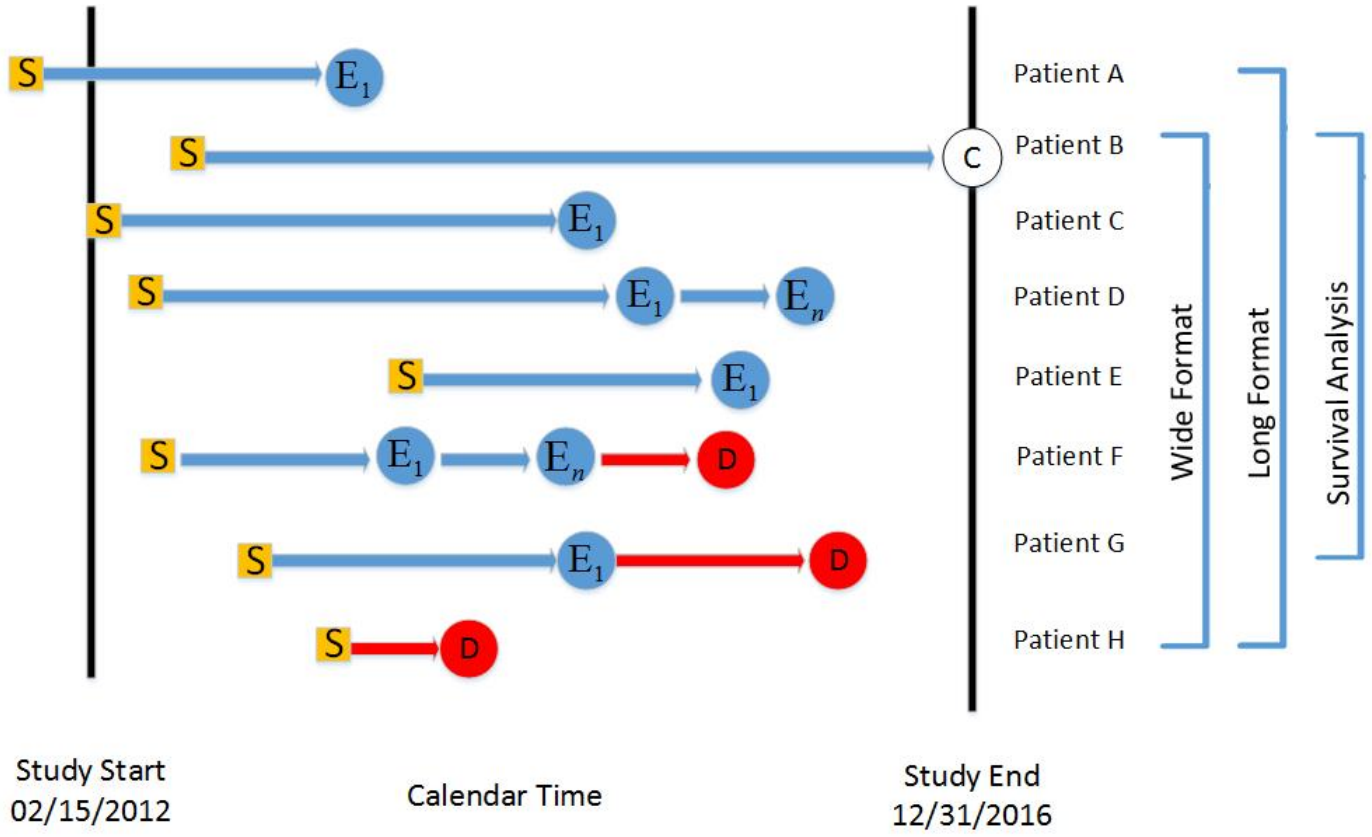

Figure 95: Illustration of event flow and eight types of patients in MARCQI database.

1. *Study time window*. All primary and revision surgeries performed between 02/15/2012 to 12/31/2016 are included. The revision event might be registered after 12/31/2016 in the database, but those post-study end event(s) do NOT qualify for implant survival analysis and were censored at the end of the study. In addition, primary surgeries performed prior to 02/15/2012 are not included in the revision analysis.

2. *Qualified patients*. All eight types of patients qualify for volume reporting, including patient A and patient H. Patient B through patient G qualified for implant survival analysis (thus patients A and H are disqualified). Patient C and patient E are of same type, even though starting time varies. Deaths are addressed in (7) below. Patient type A included in long format dataset is only qualified to calculate total volumes over time (Figures 8, 9, 41, and 42). Patient types B through H are included in the wide format dataset as primary surgery cases.

3. *Censoring*. The patients who did not have the event as of the end of the study end are considered right-censored. These patients provide some information, but not complete information, *e.g.*, Patient B. Patient A is excluded in implant survival analysis because the surgery occurred prior to the onset of the MARCQI registry; thus no left-censoring is considered in this report.

4. *Time-to-event*. Number of days elapsed from primary surgery to the event of interest (*e.g.* first revision following surgery).

5. *Qualified revision events for implant survival analysis*. First event E_1 after primary surgery (thus events E_2, E_3, ..., E_n disqualified). However, E_2, E_3, ..., E_n are counted in the total volume calculations.

6. *Lost-to-follow-up (LTFU)*. This report does not consider LTFU (*e.g.*, due to geographical relocation of patient) as an event of interest. Instead, if MARCQI has no follow-up or death information until study-end, that patient is treated as a right-censoring at the study-end.

7. *Handling of deaths*. In the MARCQI five-year report window, the death rate after primary THA surgeries is about 0.2%, including patient types F, G, and H. The death rate without any event(s) after primary surgery is approximately 0.19%, like patient type H. Following primary TKA cases, death rate is 0.15% without any revision event(s). Patients A and H are treated as qualified patients (in the denominator) in calculating descriptive statistics, implant combinations, surgeon and site volumes, but are excluded in implant survival analysis. Patients that die after a revision event (like patient F and G) are included in the implant survival analysis since those patients contributed information of time-to-first revision. This strategy ensures a minimal information loss. Kandala *et al.* (2015) showed that low death rate does not substantially affect the implant survival analysis. Thus in the report, the patient type A and H are excluded in the implant survival analysis without conducting competing risk analysis and left censoring.

Finally, for purposes of this report, “unit” is a general term and context specific and may refer to the surgeon, hospital, or implant that a patient is embedded.

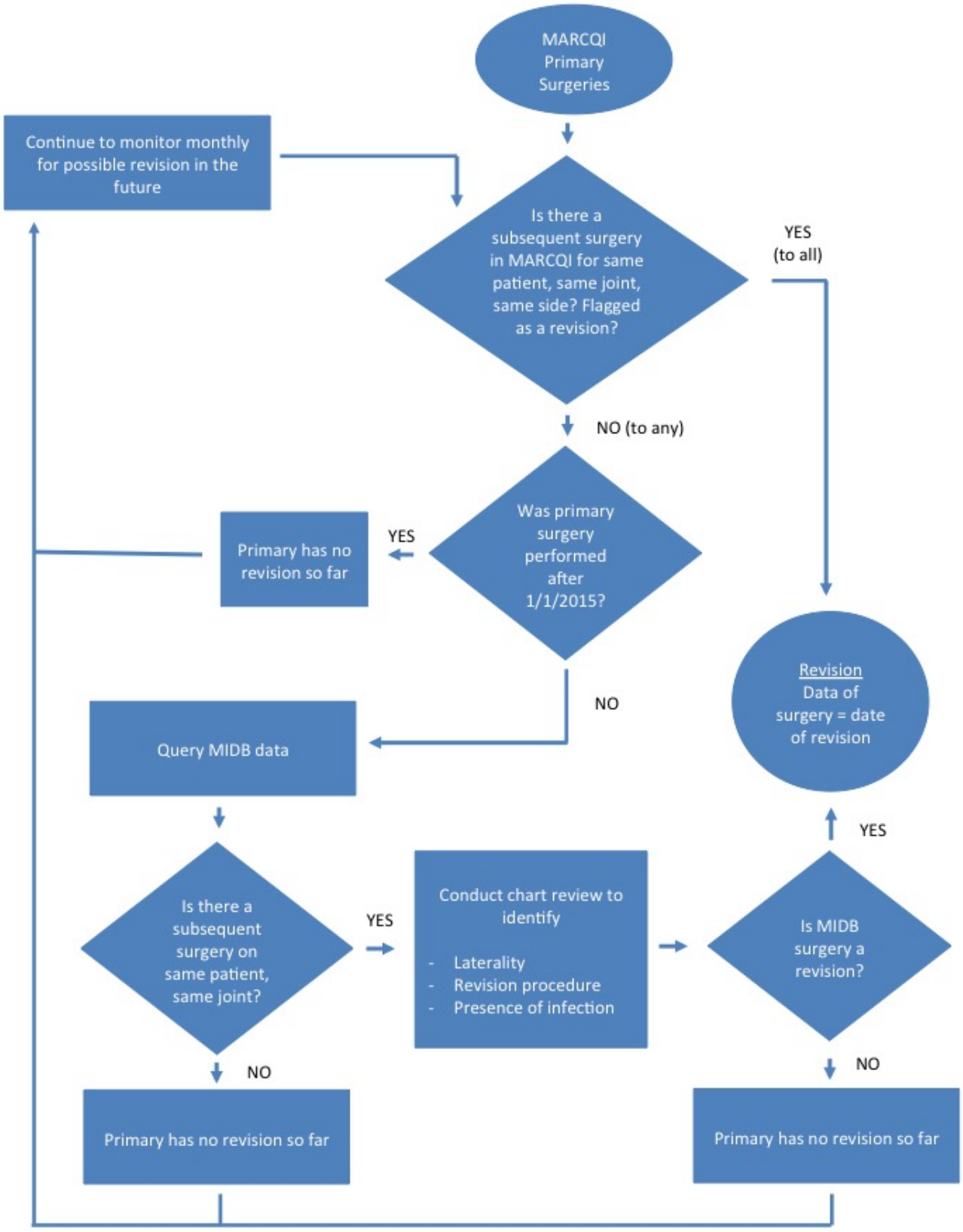

Figure 96: Flowchart of method used to identify revisions.

MARCQI uses a multi-faceted method for identifying revisions for two reasons: (1) revision data comes from both abstracted and administrative data sources, and (2) hospitals switched from ICD-9 to ICD-10 coding in 2015. Figure 96 illustrates the process used to identify revisions for this report. For surgeries occurring on or after October 1, 2015, a registry-based MARCQI revision is a case identified by the CDAs. For surgeries occurring prior to October 1, 2015, a revision surgery was identified by the ICD-9 procedure recorded for the case. Codes for primary procedures were: 81.51 (hip), 00.85 (hip), and 81.54 (knee). Hip revision codes were: 81.53, 00.70, 00.71, 00.72, and 00.73. Knee revision codes were: 81.55, 00.80, 00.81, 00.82, 00.83, and 00.84.

A.6 Descriptive statistics and visualization

For this report continuous measures were checked for normality and skewness. Categorical variables were checked for cell sizes and questionable categories values. If any potential issues were found and confirmed by the MARCQI data management team, then the data quality checking/correction was directed to a different level accordingly.

Univariate variate analyses are performed to compute descriptive statistics for this report, including frequency tables for smoking, both mean and standard deviation (SD), median and interquartile range (IQR) for age, weight, height, body mass index (BMI), and surgeon volumes (overall and device-specific). Frequency tables and various visualization tools, including pie charts, bar charts, Pareto charts (Montgomery, 2009; Tague, 2004), and line plots are employed to present data for sex, approach, diagnosis, distribution of primary vs. revision cases, venous thrombosis prophylaxis, polyethylene type, procedure type, bearing surface couple, head size, reason for revision, and American Society of Anesthesiologists (ASA) class.

A.7 Kaplan-Meier: Unadjusted survival probabilities and cumulative percent revision rates (CPR)

MARCQI presents revision risk for implants using a curve called the “cumulative percent revision,” which is abbreviated CPR and inspired by the Australian Orthopaedic Association National Joint Replacement Registry. Obviously, lower revision risk is preferred to higher risk.

The CPR is constructed starting with the time a primary joint replacement is performed, with the endpoint of interest being revision surgery on that joint. MARCQI computes the time to first revision since the primary procedure for those patients having revision surgery, which is the X-axis in the CPR curve. The Y-axis is the percent of patients who have had a revision among patients with the joint replacement by the corresponding X-axis time.

Computationally, the CPR curve is derived from unadjusted survival probabilities, $\hat{S}(t)$, which is calculated using the Kaplan-Meier product-limit estimator (Kaplan and Meier, 1958; Rich *et al.*, 2010) , and corresponding standard errors are calculated with Greenwood's formula (Kalbfleisch and Prentice, 2002). Then the overall, stratified, and implant-specific CPRs are expressed as percentages and calculated by $C\hat{P}R = (1 - \hat{S}(t)) \times 100$. The log-rank test is used to compare survival curves between groups at the $\alpha = 0.05$. There is a significant difference in the survival time between groups if the *p*-value is less than 0.05.

A.8 Cox's proportional hazards model

In survival analysis, the hazard function $h(t)$ describes the concept of the risk of an outcome (*e.g.*, revision, death, hospitalization, etc.) in an interval after time t, conditional on the subject having survived to time t. Thus it quantifies the instantaneous risk that an event will take place at time t given that the subject survived to time t. For most of this report, the event of interest is revision. In this case we use the term “implant survival analysis” to emphasize that it is the survival of a functioning implant rather than survival of the patient (as opposed to death) that is being analyzed. There are a few places where the event of interest is something other than revision (readmission, for example).

The Cox proportional hazards model (Cox, 1972) has been broadly used to predict the survival time in individual subjects by only utilizing variables co-varying with survival and ignoring the baseline hazard of individuals. Cox proportional hazard model makes no assumptions about the functional form of baseline hazard and only assumes that the hazard functions of different individuals remained proportional and constant over time. In this report, the measures of association given by the Cox model as hazard ratio (*HR* is used to explain the risk of event for certain categories of covariates or exposures of interest. Parameters in Cox model and *HR* are estimated using partial likelihood (Cox, 1975; Verweij and Van Houwelingen, 1994). The proportionality assumption can be checked by graphics, Schoenfeld residuals (Xue *et al.*, 2013; Grambsch and Therneau, 1994), and Martingale-based residuals (Lin *et al.*, 1993). Cox model can be extended to include random effects to account for within-unit correlation of the observed outcomes (Zhao, 2005).

As an example of interpretation of HR, fix other covariates, only consider $x_1 = 1$ if treatment and 0 if control. Then we have $HR = e^{\beta_1}$, indicating by what factor the hazard is multiplied for individuals in the treatment group relative to the control group while holding everything else constant. For instance, if $\beta_1 = 1.03$, then $HR = 2.8$ and it can be interpreted that the subjects labeled with a 1 (treatment) are 2.8 times more likely to have an event than the subjects labeled with a 0 (control). In this way we have a measure of association that gives insight into the strength and direction of the relationship between our exposure and outcome.

A.9 Generalized linear mixed effect models (GLMM)

Generalized linear models (GLMs) are a class of fixed effects regression models for several types of dependent variables (*i.e.*, continuous, dichotomous, counts) and has been well discussed in details (McCullagh and Nelder, 1989; Nelder and Wedderburn, 1972). However, these fixed effect models, which assume that all observations are independent of each other, are not appropriate for analysis of correlated data structures, including clustered data and repeated measures. For MARCQI registry data, patients (generally called subjects in the domain) are observed nested within larger units, including surgeons, hospitals, etc. These are often referred to as multilevel (Goldstein, 1995) or hierarchical (Raudenbush and Bryk, 2002) data, in which the level-1 observations or subjects are nested within the higher level-2 clusters or surgeons), who are nested within level-3 units or hospitals. Failure to account properly for the clustering within a dataset can lead to erroneous conclusions (inference).

Generalized linear mixed models (GLMMs) including both fixed and random cluster/and or subject effects are effective analysis tools for these multilevel or hierarchical data to account for the correlation of the data. Parameter estimation in GLMMs typically involves maximum likelihood or variants of it. Integration over the random-effects distribution (Rodriguez and Goldman, 1995) can be based on first- or second order Taylor expansions, a fully multivariate Taylor expansion and a Laplace approximation, Gauss-Hermite quadrature, and Markov chain Monte Carlo (MCMC) methods.

More specifically for dichotomous outcomes (*e.g.*, yes/no for infections, revisions), the mixed-effects logistic regression model uses logit link function to estimate odds ratio (*OR*), which is a measure of association between an exposure and an outcome. When a logistic regression model is fitted, the regression coefficient (*e.g.*, β_1, sex = 1 for male vs sex = 0 for female) is the estimated change in the log-odds of the outcome per unit increase in the value of the exposure or risk factor. The exponential function of the regression coefficient is the odds ratio associated with a one-unit increase (or a specified increment for continuous covariates) or a category in the exposure, holding other factors fixed.

A.10 Risk-standardized event rates (RSR) using registry database for performance profiling

Risk standardization is a statistical process to identify and adjust for variation in patient outcomes that stem from differences in patient characteristics (or risk factors, including patient demographic and clinical characteristics) across units (Taylor, 2013; Hom, 2016). The goal of risk standardization is to account for these differences across units that might be related to the outcome, and thus comparable across units by multiplying a population-level scale factor. The risk factors (*e.g.*, age, sex, BMI, race/ethnicity and/or selected clinical covariates, lab tests, etc.) are determined by clinical relevance and/or publications, as well as statistical relevance.

Hierarchical logistic regression models (as described in GLMM using logit link function) are commonly used tools to estimate unit level (*e.g.*, surgeons, hospitals, implants, etc.) risk-standardized event rates ($RSRs$) for each condition. This approach takes into account the hierarchical structure of the data to account for patient clustering within units (*e.g.*, surgeons, hospital, implant, etc.). Each model includes risk factors and a unit-specific random effect, accounting for within-unit correlation of the observed outcomes. Specifically, the RSR for each unit is calculated as the ratio of the number of "predicted" outcomes (revision, infection, transfusion, etc.) that reflect the influence of a particular hospital or surgeon to the number of "expected" outcomes that would occur for the "average" surgeon or hospital, multiplied by the registry-wide unadjusted rate of the given outcome (Ash *et al.*, 2012; CMS, 2007; Drye *et al.*, 2012), *i.e.*,

$$RSR = \frac{\#Predicted}{\#Expected} \times Raw\ MARCQI\ wide\ average\ rate$$

The numerator is the total number of predicted events of interest within a time window, and the denominator is the number of events expected on the basis of performance of the state's average unit adjusting for this unit's risk factors. Both measures are estimated from the hierarchical logistic regression model taking the hospital's performance with its observed case mix into account. The raw state wide average rate (scaling factor) is obtained from the registry samples and serves as the reference for comparison, allowing for each units' RSR comparable to the observed state-wide rate, instead of other individual units' $RSRs$. The statistical preference for using the predicted-to-expected ratio has been discussed in detail (CMS, 2007; Drye *et al.*, 2012).

A wide range in RSR differences suggests quality assessments based on the outcome measures differ. For performance comparison and quality improvement, RSR can be visualized by using funnel plots (Spiegelhalter, 2002, 2005) or forest plots (Lewis and Clarke, 2001) to categorize units as better, worse, or no different than the registry average rate.

A.11 Database and software platform

The raw data sources are securely transported to MARCQI by the data vendor (Ortech) in MS SQL format. All the data management, exploratory data analysis, descriptive statistics, graphs, statistical modeling are performed using SAS 9.4 (SAS® Institute Inc., Cary, North Carolina)[1], SAS / Interactive Matrix Language (IML)[2], and SAS Macro Language [3].

[1] SAS® 9.4 Product Documentation, http://support.sas.com/documentation/94/

[2] SAS/IML® 14.2: User's Guide, Copyright © 2016, SAS Institute Inc., Cary, NC, USA. http://support.sas.com/documentation/onlinedoc/iml/142/imlug.pdf

[3] SAS® 9.4 Macro Language: Reference, Fifth Edition. http://support.sas.com/documentation/cdl/en/mcrolref/69726/PDF/ default/mcrolref.pdf

Appendix B

Awards and publications

B.1 Awards

2016 Current Concepts in Joint Replacement/Orthopaedic Research and Education Foundation - Clinical Practice Award Paper, *No difference in dislocation seen in anterior vs posterior approach total hip arthroplasty* by J.D. Maratt, J.J. Gagnier, P.D. Butler, B.R. Hallstrom, A.G. Urquhart, and K.C. Roberts.

B.2 Journal publications

Franklin, P.D., Lewallen, D., Bozic, K., Hallstrom, B., Jiranek, W., and Ayers, D.C. (2014) Implementation of patient-reported outcome measures in U.S. Total joint replacement registries: rationale, status, and plans. *Journal of Bone and Joint Surgery - American Volume*, 96 Suppl 1:104-109.

Hughes, R.E. Hallstrom, B.R., Cowen, M.E., Igrisan, R.M., Singal, B.M., and Share, D.A. (2015) Michigan Arthroplasty Collaborative Quality Initiative (MARCQI) as a model for regional registries in the United States. *Orthopaedic Research and Reviews*, 7:47-56. Available online at `https://www.dovepress.com/michigan-arthroplasty-registry-collaborative-quality-initiative-marcqi-peer-reviewed-article-ORR`

Ellimoottil, C., Ryan, A.M., Hou, H., Dupree, J., Hallstrom, B., and Miller, D.C. (2016) Medicare's new bundled payment for joint replacement may penalize hospitals that treat medically complex patients. *Health Affairs*, 35(9):1651-1657.

Hallstrom, B.R., Singal, B., Cowen, M.E., Roberts, K.C., and Hughes, R.E. (2016) The Michigan experience with safety and effectiveness of tranexamic acid use in hip and knee arthroplasty. *Journal of Bone and Joint Surgery - American Volume*, 98:1646-1655.

Maratt, J.D., Gagnier, J.J., Butler, P.D., Hallstrom, B.R., Urquhart, A.G., and Roberts, K.C. (2016) No difference in dislocation seen in anterior vs posterior approach total hip arthroplasty. *Journal of Arthroplasty*, 31(9 Suppl):S127-S130.

Markel, D.C., Allen, M.W., and Zappa, N.M. (2016) Can an arthroplasty registry help decrease transfusions in primary total joint replacement? A quality initiative. *Clinical Orthopaedics and Related Research*, 474:126-131.

Hughes, R.E., Batra, A., and Hallstrom, B.R. (2017) Arthroplasty registries around the world: valuable sources of hip implant revision risk data. *Current Reviews in Musculoskeletal Medicine*, 10:240-252.

Courtney, P.M., Huddleston, J.I., Iorio, R., and Markel, D.C. (2017) Socioeconomic risk adjustment models for reimbursement are necessary in primary total joint arthroplasty. *Journal of Arthroplasty*, 32:1-5.

Courtney, P.M. and Markel, D.C. (2017) Arthroplasty registries: Improving clinical and economic outcomes. *Journal of Knee Surgery*, 30(1):7-11.

Omari. A., Hughes, R.E., Hallstrom, B.R., Singal, B.M., Igrisan, R.M., and McCardel, B.R. (2017) Using device data to

improve identification of intraoperative femur fractures in total hip arthroplasty. *Michigan Journal of Medicine*, 2(1). For full text see `http://quod.lib.umich.edu/m/mjm/13761231.0002.111/--using-device-data-to-improve-identification?rgn=main;view=fulltext`

Charles, R.J., Singal, B.M., Urquhart, A.G., Masini, M.A., and Hallstrom, B.R. (2017) Data sharing between providers and quality initiatives eliminate unnecessary nursing home admissions. *Journal of Arthroplasty*, 32(5):1418-1425.

Markel, D.C., Allen, M., Hughes, R., Singal, B., and Hallstrom, B. (2017) Quality initiative programs can decrease total joint arthroplasty transfusion rates - A multicenter study utilizing the MARCQI total joint registry database. *Journal of Arthroplasty*, 32(11):3292-3297.

B.3 Conference abstracts

Hughes, R.E., Igrisan, R., and Hallstrom, B. (2014) Designing pay-for-performance incentives for an arthroplasty quality improvement collaborative. *3rd International Congress of Arthroplasty Registeries*, May 31-June 2, Cambridge, MA, 2014.

Hughes, R. (2015) Development and operation of a regional arthroplasty quality improvement collaborative. *Healthcare Systems Process Improvement Conference 2015*, February 18-20, Orlando, FL, 2015.

Maratt, J.D., Gagnier, J., Butler, P., Hallstrom, B.R., Urquhart, A.G., and Roberts, K. (2015) Direct anterior approach does not reduce dislocation risk. *American Association of Hip and Knee Surgeons*, November 5-8, Dallas, TX, USA, 2015.

Hallstrom, B.R., Hughes, R., Igrisan, R., Cowen, M., and Singal, B. (2015) Dramatic reduction in blood transfusion through a quality improvement project in the Michigan arthroplasty registry. *4th International Congress of Arthroplasty Registries*, Gothenburg, Sweden, May 23-25, 2015.

Hughes, R.E., Singal, B., Hallstrom, B., Cowen, M., and McCardel, B. (2015) Using device data to improve detection of intra-operative femur fractures in total hip arthroplasty. *4th International Congress of Arthroplasty Registries*, Gothenburg, Sweden, May 23-25, 2015.

Hallstrom, B., Hughes, R., Singal, B., and Cowen, M. (2016) Primary and revision case capture in the Michigan arthroplasty registry. *5th International Congress of Arthroplasty Registries*, Manchester, England, May 28-30, 2016.

Zarling, B.J., Sikora-Klak, J., Bergum, C., and Markel, D.C. (2016) How do pre-operative medications influence outcomes in total joint arthroplasty? *34th annual meeting of the mid-America orthopaedic association*, Bonita Springs, FL, USA, April 13-17, 2016.

Maratt, J.D., Gagnier, J.J., Butler, P.D., Hallstrom, B.R., Urquhart, A.G., and Roberts, K.C. (2016) No difference in dislocation in anterior versus posterior approach total hip arthroplasty. *American Orthopaedic Association*, June 24-27, Seattle, WA, USA, 2016.

Hughes, R.E., Chan, M.Y.H., and Hallstrom, B.R. (2016) A Bayesian network model for hip implant outlier detection in post-market surveillance. *2016 BMES/FDA Frontiers in Medical Devices Conference*, College Park, MD, USA, May 23-25, 2016.

Zheng, H., Hughes, R.E., Kabara, J., Cowen, M.E., and Hallsrom, B.R. (2017) A multi-stage modeling framework to analyze discrete events with applications to venous thromboembolism (VTE) prophylaxis following total knee arthroplasty (TKA) within MARCQI. *6th International Congress of Arthroplasty Registries*, San Francisco, CA, USA, May 20-22, 2017.

Hughes, R.E., Batra, A., Pack, B.J., and Hallstrom, B.R. (2017) Translating registry data into clinical practice: Summary of arthroplasty registry reports of revision risk for hips. *6th International Congress of Arthroplasty Registries*, San Francisco, CA, USA, May 20-22, 2017.

Hughes, R.E., Zheng, H., Kabara, J., Mendenhall, S., Pack, B.J., and Hallstrom, B.R. (2017) Variation in bearing surface

couples in conventional total hip arthroplasty within Michigan. *6th International Congress of Arthroplasty Registries*, San Francisco, CA, USA, May 20-22, 2017.

Hood, B., Singal, B., Zheng, H., Hughes, R., Cowen, M., and Hallstrom, B. (2017) Aspirin for venous thromboembolism prophylaxis after primary total knee arthroplasty: An analysis of 41,537 cases in the Michigan arthroplasty registry. *6th International Congress of Arthroplasty Registries*, San Francisco, CA, USA, May 20-22, 2017.

Hughes, R.E., Batra, A., Pack, B.J., and Hallstrom, B.R. (2017) Translating registry data into clinical practice: Summary of arthroplasty registry reports of revision risk for hips. *2017 Michigan Orthopaedic Society Annual Scientific Meeting*, Mackinac Island, MI, USA, June 16-18, 2017.

Appendix C

Personnel and committees

C.1 Personnel

Co-Directors. Brian R. Hallstrom and Richard E. Hughes.

Coordinating center. Rebecca Fleckenstein, Mary Gumtow, Rochelle Igrisan, Anne Kagay-Lidster, Sherri McPhail, April Richmond, Thomas (Huiyong) Zheng.

Data management center. Mark Cowen and Jared Kabara.

Clinical Data Abstractors. Kelly Adomeit-Evans, Catherine Ashlin, Heather Behring, Margaret Biasutto, Jane Brinkman, Jennifer Chadwick, Karla Cleveland, Kim Cook, Denise Coons, John Cunningham, Rachel Deichelbohrer, Kristie Dennett, Melanie Deron, Audra Eller, Brynn Fields, Susan Galaska, Susan Glover, Susan Gressa, Heather Haener-Svoboda, Traci Hall, Alyssa Hakala, Amy Harshberger, Tricia Harvey, Michelle Hastings, Mary Hawk, Cynthia Hawkins, Denise Hnilica, Julie Hooker, Kathleen James-Berg, Stephanie Jenkins, Sharon Karam, Rong Ke, Bonnie Keller, Jori Kennedy, Darla Kethe, Susan Kilbourn, Ruth Knevel, Chelsea Knuth, Patricia Kokx, Julie Kolis, Lenna Krueger, Michelle Laverty, Crystal Lawrin, Erica Lemons, Dawn Light, Linda Linari, Dawn Litfin, Nadia McCann, Sherry McDermott, Mary McKinney Bobbi McLean, Samantha Moore, Phoebe Omolo, Sandra Osterland, Brooke Ostrander, Erin Owens, Shawn Panek, Fran Parrish, Alison Picot, Jennifer Pietsch, Stacie Poquette, Helen Roffle, Diane Roosenberg, Amy Sams, Margaret Santiviago, Marian Scanlon, Megan Secondi, Tonya Shufelt, Vicki Simpson, Jill Skrzypczak, Kristine Steenbergh, Jorgieann Stoneham, Stephanie Swindall, Lorelei Thayer, Lori Thomas, Carol Trapp, Julie Valeri, Jennifer VanRiette, Karen Wilde, Lizabeth Wisner, Paula Wisniewski, and Mary Young.

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Quality committee. Rebecca Bollinger, Sherry Bowman, Jim Crean, Kristie Dennett, Ken Edwards, Eileen Fatell, Mary Gumtow, Brian Hallstrom, Mary Hawk, Michele Hastings, Rochelle Igrisan, Kory Johnson, Chris Lee, Linda Mader, Bernard Roehr, Fred Schreiber, Ajay Srivastava, Mary Young, and Thomas (Huiyong) Zheng.

Executive committee. Mark Cowen, Susan Galaska, Brian Hallstrom, Richard Hughes, Rochelle Igrisan, Jori Kennedy, David Markel, Michael Masini, Brian McCardel, Bryan Pack, Karl Roberts, Andrew Urquhart, and Jay Verner.

Data and publications committee. Mark Cowen, Brian Hallstrom, Richard Hughes, David Markel, Michael Masini, and Thomas Zheng.

Patient-reported outcomes survey (PROS) committee. Mark Cowen, Brian Hallstrom, Denise Hnilica, Rochelle Igrisan, Jori Kennedy, Jared Kabara, Julie Kolis, Brian McCardel, April Richmond, Ajay Srivastava, and Paula Wisniewski.

Device committee. Creg Carpenter, Michael Charters, Mark Cowen, Brian Hallstrom, Richard Hughes, Jared Kabara, Sherri McPhail, Bryan Pack, Karl Roberts, and Thomas Zheng.

Medical advisory committee. Andrew Ajluni, Paul Bizzigotti, Kyle Bohm, James Bookout, W. John Bruder, Joseph Burkhardt, Michael Callan, Creg Carpenter, Michael Charters, David Christ, Matthew Colligan, Mark Cowen, Hussein Darwiche, Brian deBeaubien, Jeffrey DeClaire, Mark Dwyer, Kenneth Edwards, Timothy Ekpo, Eddie El-Yussif, Joseph Finch, Todd Galdes, G. Victor Gibson, Brian Hallstrom, Derek Hill, Daniel Hoard, Jon Hop, Richard Hughes, Rochelle Igrisan, Gerald Jerry, Derick Johnson, Kory Johnson, Leonard Karadimas, Safa Kassab, Donald Knapke, David Knesek, Jeffrey Krusniak, Christopher Lee, Homer Linard, Colleen Linehan, Bryan Little, David Markel, Sidney Martin, Michael Masini, Brian McCardel, Mark McMurray, Stephen Mendelson, J. Wesley Mesko, Daniel Middleton, Patrick Morse, Shivajee Nallamothu, Sam Nasser, Mark Noffsinger, John Olenyn, Bryan Pack, Martin Pallante, Wallace Pearson, Henri Pierre-Jacques, Aaron Potts, Emily Ren, Robert Render, Karl Roberts, Vani Sabesan, Michael Schmidt, Fred Schreiber, Eric Silberg, Craig Silverton, Daniel Sohn, Michael Sorscher, Kevin Sprague, Ajay Srivastava, Andrew Urquhart, James Verner, Joseph Walkiewicz, Robb Weir, and Michael Wind.

Standardization committee. Susan Galaska, Safa Kassab, Bobbi McLean, Brian McCardel, Sherri McPhail, Karl Roberts, and Andrew Urquhart.

Former members

Project Manager: Kerri Kwapis. *Biostatistician*: Bonita Singal, *Executive and Medical Advisory Committee*: Greg Golladay. *Epidemiologist*: Hal Morgenstern. *Nurse consultant*: Mickie Speers. *Administration*: Barb Benedetti. *Data manager*: Steve Coon. *Clinical data abstractors*: Crystal Andree, Tracey Attard, Kelly Bourn, Rob Behrendt, Diane Cox-Romel, MaryJo DeBono, Amanda Donnelly, Jennifer Emmert, Shirley Evoe, Angela Hasenfratz, Elizabeth Heighes, Debra Hischke, Brenda Hitchcock, Priscilla Jimenez, Debra Koats, Wendy Kunath, Jennifer LaMay, Billie Martin, Linda McIntosh, Becky McNew, Rachel Mitteer, Christine Ochmanek, Lauren Ramoie, Lisa Rockwell, Kathy Scranton, Kathryn Snyder, Gail Tack, Mary Ann Taylor, Donna Vinson, Annette Wilson, and Kym Wright.

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Support for MARCQI is provided by Blue Cross and Blue Shield of Michigan and Blue Care Network as part of the BCBSM Value Partnerships program.