# Random Sampling Improves Precision and Reduces Burden in Patient Reported Outcome Collection for Arthroplasty Quality Measurement

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INTRODUCTION:

Over 740,000 Medicare beneficiaries undergo primary total hip or knee arthroplasty (THA and TKA, respectively) annually, with the number expected to increase to 1.2 million by 2030. The Centers for Medicare & Medicaid Services (CMS) has introduced mandatory reporting of the HOOS JR and KOOS JR for to support a hospital-level, patient reported outcome performance measure (PRO-PM) beginning in 2024. For inpatient reporting, CMS requires matching pre- and post- data for at least 50% of all eligible patients, regardless of volume. This is burdensome for high volume hospitals and may not produce an estimate of quality representative of the care provided at low-volume hospitals.

METHODS:

We calculated the minimum necessary number of completed PROMs in order to achieve a 95% confidence interval with the required precision of 10% (±5%) for hospitals with 5, 50, 500 and 5,000 combined eligible THA and TKA cases per year, assuming a 100% patient response rate and a conservative SCB (substantial clinical benefit) achievement of 50%. This was presented alongside the number of patients that would be required by the current CMS rules. Additional sensitivity analyses were performed to further explore the effects of CI width, hospital volume, and frequency of SCB attainment on required sample sizes.

RESULTS:

The current CMS methodology results in sample size requirements that scale linearly with case volume – 3, 25, 250, and 2500 patients for hospitals with 5, 50, 500, and 5,000 cases, respectively (Table 1). In contrast, a statistically-grounded random sampling strategy would require 5, 45, 218, and 357 patients, respectively. Additional sensitivity analyses demonstrate the potential effects of CI and frequency of SCB attainment (Table 2) and hospital case volume and frequency of SCB attainment (Table 3).

DISCUSSION AND CONCLUSION:

The current approach may significantly overburden high-volume hospitals while offering limited gains in precision, and may be inadequate for accurate measurement at low-volume sites. Sample size calculations provide thresholds for achieving suitably precise measurements of hospital performance. Although the sample sizes shown will need to be expanded in practice to account for patient non-response, random sampling would still allow CMS to achieve its goal of precise estimates while greatly reducing hospital burden, especially among the hospitals performing 500 or more THA/TKA per year that comprise ~35% of all THAs and TKAs annually. Furthermore, by focusing on a smaller pool of cases, these hospitals with large caseloads can achieve higher response rates among their random samples and thus reduce sampling bias and achieve more representative estimates. It is concerning that the currently required sample size for many low volume hospitals is unlikely to produce an accurate estimate of quality. Given that CMS already requires a random sample of just 300 patients for an information transfer PRO-PM, the Centers should consider allowing this alternative sampling rubric for the THA/TKA PRO-PM requirement.

Table 1. CMS-Required vs Statistically-Grounded Sample Sizes for Different Case Volumes

| Hospital Volume | Required minimal sample size with current CMS methodology | Required sample size to achieve 95% CI of 10% |
|---|---|---|
| 5 | 3 | 5 |
| 50 | 25 | 45 |
| 500 | 250 | 218 |
| 5,000 | 2500 | 357 |

Table 2. Effects of Varying Frequency of SCB Attainment and Confidence Interval Width on the Statistically-Grounded Sample Size for Hypothetical Hospital Performing 1,000 THA and TKA Annually

| % meeting SCB | CI width | | | | |
|---|---|---|---|---|---|
| | 2% | 5% | 10% | 15% | 20% |
| 50% | 906 | 607 | 278 | 146 | 88 |
| 55% | 905 | 604 | 276 | 145 | 87 |
| 60% | 903 | 597 | 270 | 141 | 85 |
| 65% | 898 | 584 | 260 | 135 | 81 |
| 70% | 890 | 564 | 245 | 126 | 75 |
| 75% | 879 | 536 | 224 | 114 | 68 |
| 80% | 861 | 497 | 198 | 99 | 58 |

Table 3. Effects of Hospital Case Volume and Varying Frequency of SCB Attainment on the Statistically-Grounded Sample Size, Assuming 10% Confidence Interval Width

| Pop N | Proportion meeting SCB | | | | |
|---|---|---|---|---|---|
| | 50% | 60% | 70% | 80% | 90% |
| 10 | 10 | 10 | 10 | 10 | 10 |
| 30 | 28 | 28 | 28 | 27 | 25 |
| 50 | 45 | 45 | 44 | 42 | 37 |
| 100 | 80 | 79 | 77 | 72 | 59 |
| 200 | 132 | 130 | 124 | 111 | 83 |
| 500 | 218 | 213 | 197 | 166 | 109 |
| 1000 | 278 | 270 | 245 | 198 | 122 |
| 3000 | 341 | 329 | 292 | 228 | 133 |
| 5000 | 357 | 344 | 304 | 235 | 135 |