

Original article

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Total knee infection as a clinical quality indicator

La infección total de rodilla como indicador de calidad clínica

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ABSTRACT. Total knee arthroplasty infection (TKAI) is an important surgical outcome and quality indicator. We present a statistical method to analyze the rate of occurrence of TKAI based upon the binomial distribution. The rationale, process and interpretation are presented to obtaining the exact and cumulative probability of having k infections after n procedures with a predetermined health quality indicator goal. In other words, to find out in a scientific manner whether there are too many infections or not.

Keywords: total knee arthroplasty, joint replacement, prosthetic infection, epidemiology, indicator.

RESUMEN. La infección de artroplastia total de rodilla (IATR) es un importante indicador de resultados y calidad quirúrgica. Presentamos un método estadístico para analizar la tasa de incidencia de IATR según la distribución binomial. Se presentan la justificación, el proceso y la interpretación para obtener la probabilidad exacta y acumulada de k infecciones después de n procedimientos con un objetivo predeterminado de indicador de calidad de salud. En otras palabras, para determinar científicamente si hay demasiadas infecciones o no.

Palabras clave: artroplastia total de rodilla, reemplazo articular, infección protésica, epidemiología, indicador.

Abbreviations:

95% CI = 95% confidence interval.

k = Outcome, also called: success rate.

n = Sample (number of TKAs).

p = Observed rate of infection.

P = Probability.

q = (1-p).

TKA = Total Knee Arthroplasty.

TKAI = Total Knee Arthroplasty Infection.

X = Random variable.

Introduction

Quantification of the rate of total knee arthroplasty infection (TKAI) is an important surgical outcome and a clinical quality indicator.¹ Prosthetic infection can be

disabling, costly and devastating.² Proper antimicrobial prophylaxis programs are designed to reduce the incidence of TKAI.³ The incidence of TKAI is reported in percentage; as the rate of infections relative to the number of total knee arthroplasties (TKA) performed. Blanco, Díaz, Melchor, Da Casa and Pescador report ranges of infection from 0.29 to 2%; and the incidence at the Mayo Clinic of 1.2% of 3,000 primary TKAs.^{4,5} In 2022, Vaisman, Casas, Bianchi and Edwards, reported an infection rate of 1.47% after TKA.⁶

From a clinical quality standpoint, it seems reasonable to establish a target by defining a low infection rate and aim to keep the rate of infections equal or below that goal. However, several challenges arise. A critical one is that the

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confidence interval could be too wide, potentially leading to misleading conclusion.

Example 1.

The quality department of a given hospital established a goal of TKAI to 1.1% (a very low rate of infection, as reported by the Mayo Clinic). During the first quarter of the year, 35 TKAs were performed and 1 infection was identified. This yields a rate of 2.86% ($1/35 = 0.0286$). A superficial interpretation might suggest that the observed rate of infection is more than two times the goal (exactly: 2.6x). However, such interpretations are erroneous. Derived from the 95% confidence interval (95% CI) for a proportion.^{7,8} We obtain that such 95% CI ranges from 0 to 8.38%. Since the lower bound derived from the formula was -2.66%, a non-viable value, it is adjusted to 0.

$$CI_{95\%} = p \pm 1.96 \sqrt{\frac{pq}{n}} \quad \text{Equation (1)}$$

Where p is the observed rate of infection, or the proportion of infected patients; q is $(1-p)$ and n is the sample or number of TKAs performed.

Substituting with the values from the example:

$$CI_{95\%} = 0.0286 \pm 1.96 \sqrt{\frac{0.0286 \times 0.9714}{35}} = -0.0266 - 0.0838$$

Equation (2)

We can observe that the 95% CI «engulfs» the goal of 1.1%. We now see that the observed rate of infections at this hospital lies inside the «safe zone» defined by the 95% CI.

This example illustrates a simple method to determine whether the observed rate of TKAI falls within the confidence interval. However, it does not provide a precise measure of how well the hospital is performing in terms of TKAI prevention.

Another problem is that infections occur as discrete events. A discrete event or variable is one that takes whole-number values, can only obtain values from a finite state, and is obtained by counting. This means that we cannot observe «half an infected patient», «three quarters of an infected patient», or «10% of an infected patient». We can only observe zero, one, two, three (or more) infections. A discrete variable, therefore, is expressed as a sequence of successive integers that cannot be meaningfully subdivided into smaller units.^{9,10}

A robust strategy to assess the fulfillment of a clinical quality goal for a discrete variable such as the rate of TKAI is to analyze the event (infection) as a discrete variable. If we denote the number of infections as k and the number of TKAs performed as n , and base the analysis on a discrete probability distribution-specifically, the Binomial

Distribution-we apply the appropriate mathematical framework.

Example 2.

We will use the same numbers as in example 1, but make the analysis with the binomial distribution:⁷

$$P(X = k) = \binom{n}{k} p^k q^{n-k} \quad \text{Equation (3)}$$

Where $P(X = k)$ is read as «the probability of a random variable (X) to have the outcome (k)». n is the sample or number of TKAs performed; p is the goal (0.011), and q is defined as $(1-p)$. The term $\binom{n}{k}$ reads as « n choose k » and represent a combination which can be also expressed as ${}_nC_k$ and can be easily computed on a scientific calculator, smartphone, or computer.

Substituting with the values from the example:

$$P(X = k) = \binom{35}{1} \times 0.011^1 \times 0.989^{34} = 0.2643 = 26.43\%$$

Equation (4)

This result (26.43%), can be interpreted as: «The probability of having exactly one infection out of 35 TKAs is of 26.43%».

What would the result be if no infection was seen among the 35 TKAs?

$$P(X = k) = \binom{35}{0} \times 0.011^0 \times 0.989^{35} = 0.6790 = 67.90\%$$

Equation (5)

This means that the probability of not having any infections is 67.90%.

The different values for k (number of infections) are displayed from 0 to 5 in [Table 1](#). As we can see, the probability of having exactly 2 infections out of 35 TKAs is 0.05; this value lies outside the expected range and the rate of 2 infections can be considered as «significantly» high-suggesting that two infections were «too many». For many health managers, researchers, and policymakers, the conventional significance threshold of 0.05 is used to judge whether an event frequency is unusually high (or unusually low). Nonetheless, Feinstein emphasizes that the ultimate interpretation of these values depends «on how you interpret the results».⁹

In addition to the computation of exact probabilities, we can calculate the cumulative probability of having k or more events ($P(X \geq k)$). The results are displayed in [Table 2](#) and can be interpreted as follows: For $P(X \geq 0) > 0.9999$, the probability of having none or more infections (i.e., 0, 1, 2, 3 ... 35) is essentially 100%. For $P(X \geq 1) = 0.3210$, the probability of having at least one infection (i.e., 1, 2, 3 ... 35) is 32.10%. For $P(X \geq 2) = 0.0567$, the probability of having two or more infections (i.e., 2, 3 ... 35) is 5.67%.

Table 1: Probability of having k infections out of 35 TKAs.

k	0	1	2	3	4	5
$P(X = k)$	0.6790	0.2643	0.0500	0.0061	0.0005	< 0.0001
k = outcome, in this case: number of infected TKAs. $P(X = k)$ = the probability of having exactly k events.						

Table 2: Cumulative probability of having k infections out of 35 TKAs.

k	0	1	2	3	4	5
$P(X \geq k)$	> 0.9999	0.3210	0.0567	0.0067	0.0006	< 0.0001
k = outcome, in this case: number of infected TKAs. $P(X \geq k)$ = the probability of having k events or more.						

This value is very close to the conventional significance threshold of 0.05, indicating that from this point ($k = 2$), the number of infections may be considered excessive.

These analytical methods provide a more realistic view of how events occur in practice. The cumulative probability approach reflects the likelihood of observing not only an exact number of infections but also that number or more. As the sample size (n) increases, exact and cumulative probabilities tend to converge (or get closer). The choice and interpretation of either technique (exact vs. cumulative) should be guided by methodological rigor and the specific monitoring objectives of each health facility.

The goal of 1.1% used as an example was drawn from data by the Mayo Clinic; however, each facility can establish its own benchmark based on realistic expectations. Community hospitals, for instance, may choose rates reported on studies performed in comparable centers and avoid unrealistic targets. Quality departments should therefore define institutional goals using a balance of external evidence, internal performance data, and available resources, ensuring that targets are both ambitious and achievable.

There are several websites that provide binomial distribution calculators. Here are two useful links. Note that «success» refers to «outcome», and that notation can vary—for example, k represented sometimes represented as x .

1. <http://stattrek.com/online-calculator/binomial.aspx>
2. <http://vassarstats.net/binomialX.html>

Conclusion

We recommend analyzing discrete variables, such as number of TKAs, when the expected rate of infection is known or has been set as a goal to assess quality outcomes,

with the strategy of the binomial distribution described herein. The goal of 1.1% used in this manuscript was set for educational purposes, in this case drawn from the rate reported from the Mayo Clinic; each hospital or health service should determine its own targets based on local needs, resources, and patient population. Future work will address the appropriate methodology for analyzing quality indicators expressed as the number of events over a defined time-period.

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