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Quantification of Benefits for Medical Devices

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ABSTRACT

One of the most prominent challenges in safety risk management of medical devices is the Benefit-Risk Analysis. This paper proposes a methodology to quantify benefits, thereby creating more consistency, and explainability in the evaluation of benefits and the benefit/risk ratio.

Leveraging the guidance from the FDA, we define four Dimensions for appraising benefits. The product of the rankings of a benefit in all four Dimensions is used as a quantitative measure of a benefit.

The quantitative score for the overall benefit of a medical device would be the sum of the scores of the individual benefits.

INTRODUCTION

One of the most prominent challenges in safety risk management of medical devices is the Benefit-Risk Analysis. EU MDR refers to reducing risks as far as possible without adversely affecting the benefit/risk ratio. Computation of the benefit/risk ratio necessitates numerical values in the numerator and the denominator. We have techniques to quantitatively compute risks, but benefits are not typically quantified. Therefore, estimation of the benefit/risk ratio has been merely a subjective opinion.

This paper proposes a methodology to quantify benefits, thereby creating more consistency, and explainability in the evaluation of benefits and the benefit/risk ratio.

A further advantage of quantification of benefits is the ability to more objectively compare the benefits of two comparable products, which could be successive generations of the same product, or competitive products.

Leveraging the guidance from the FDA (2012), we define four Dimensions for appraising benefits. The product of the rankings of a benefit in all four

Dimensions is used as a quantitative measure of a benefit.

The quantitative score for the overall benefit of a medical device would be the sum of the scores of the individual benefits.

BACKGROUND

Benefit is defined in ISO 14971:2019 as: "positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health". There is also Note 1 to entry that says: "Benefits can include positive impact on clinical outcome, the patient's quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or positive impact on public health."

The FDA has released several guidances on Benefit-Risk analysis for PMA, De Novo, and 501(k) devices. In these guidances the FDA puts forth four factors for assessing the extent of a benefit:

A. Type of benefit
B. Magnitude of the benefit
C. Probability of the patient experiencing the benefit
D. Duration of the effect (benefit)

In this paper we leverage these four factors to quantify the extent of a benefit.

It is noteworthy that the perspective of the FDA guidances considers devices that provide therapeutic benefits to patients, while there are many other types of medical devices that do not provide therapeutic benefits, such as surgical tools and sterilizers. As such, in this paper the definitions of each FDA factor have been extended within the four specified Dimensions, to encompass the non-therapeutic medical devices as well.

SOLUTION DESCRIPTION

Using the 2-step method described below, we compute a numerical score for each benefit.

STEP 1

Leveraging the FDA Guidance, we define 4 Dimensions A-D for the evaluation of each benefit of a medical device.

Dimension A – Type of Benefit

Rank each benefit based on the type of benefit, as defined in Table 1 below. The rankings imply the degree of importance.

For accessories to a medical device, where the accessory makes it possible for the medical device to deliver its intended function, the accessory inherits the medical device's benefit type.

Table 1: Type of Benefit

Rank	Description of Benefit Type	Examples
1	Simplifying care Clinical Efficiency - Ease of Patient Care - Convenience | basic protection | Improved hygiene | Simple diagnostics	wound protection (bandages); maintaining antiseptic practices (surgical gloves); oral health (toothbrush); blood pressure measurement (sphygmomanometer)
2	Relief from symptoms (basic)| facilitating delivery of care to patients	pain reduction (Transcutaneous Electrical Nerve Stimulation); palliative care (pain pump); facilitating surgeries (reusable surgical instruments); medical imaging (diagnostic X-ray)
3	Relief from symptoms (advanced) | Improvement of impaired body function	infusion of analgesics (infusion pumps); pain relief (SCS); alignment of vertebrae (vertebral fixation)
4	Life-extending benefit – reduced probability of mortality| Restoration of body function | minimally invasive interventions | Advanced diagnostics	identification of the genes responsible for breast cancer; opening of arterial lesions (stents); minimally invasive surgery (surgical robot)
5	Life-Critical benefits – loss of benefit could cause serious injury or death	restoration of normal cardiac rhythm (ICD), cranial navigation (SW); breathing support (ventilator)
6	Sustaining life – loss of benefit would result in immediate death	circulating blood in the body (artificial heart), oxygenating and circulating blood (cardiopulmonary bypass machine)

Table 2: Magnitude of Benefit

Rank	Description	Examples
1	Small benefit | < 50% improvement | low impact on patient care	wound protection (bandages), maintaining antiseptic practices (surgical gloves), enabling mobility for handicapped persons (wheelchair)
2	Medium benefit | 50-80% improvement | moderate impact on patient care	stabilizing the knee (external knee joint brace), staples (Surgical staplers); cardiac mapping (electro anatomic mapping)
3	Large benefit | > 80% improvement | high impact on patient care	infusion of analgesics (infusion pumps); defibrillator; sterilization (autoclave);

Dimension B – Magnitude of Benefit

Rank each benefit on the scale in Table 2 above. Assume all the benefit is received, as intended. For example, a TENS (Transcutaneous Electrical Nerve Stimulation) device at best, offers temporary pain relief – it's not a cure. A clinician might rank the magnitude of its benefit a 1 or a 2.

Note that magnitude of a benefit is independent of its type. For example, a bandage that is used on a wound to prevent bleeding and infection maybe a type 1 but have a magnitude 3 benefit.

For devices that do not directly provide a therapeutic benefit, e.g., surgical instruments, navigation, or diagnostic devices, estimate the impact of the benefit on patient care.

Dimension C – Probability of Receiving the Benefit

Rank each benefit on the scale in Table 3 below.

Guidance

For therapeutic benefits, the Clinical Evaluation would be a good source of information for Dimension C ranking.

The probability of receiving benefit for an individual can be computed as the ratio of A/B, where A = the number of people who have received the benefit, and B = the number of people who have received the therapy. In many cases the decision as to who received the benefit is not so clear. For example, a Spinal Cord Stimulator (SCS) may provide significant pain relief to some, but moderate/low pain relief to others. In such cases, a threshold of benefit can be defined and thus people who receive at least that much benefit would be counted in the A group.

In some cases, the probability of receiving the benefit could be estimated for a whole population, as the ratio of C/D, where C = the estimated number of people in a population (e.g., a country) who would receive the therapy, and D = the estimated number of the people in that population who could benefit from the therapy (e.g., people with the relevant medical condition). This would treat the accessibility of a therapy in a given population as a public health benefit.

For devices that do not directly provide a therapeutic benefit, e.g., surgical instruments, navigation, or diagnostic devices, use the reliability/specificity estimates.

Table 3: Probability of Receiving the Benefit

Rank	Description
1	Small | < 50% of the users/patients are expected to receive the benefit | reliability <80%
2	Medium | 50-80% of the users/patients are expected to receive the benefit | reliability 80-95%
3	Large | > 80% of the users/patients are expected to receive the benefit | reliability > 95%

Table 4: Duration of the Benefit

Rank	Description
1	Short duration of benefit | Short device lifetime
2	Medium duration of benefit | Medium device lifetime
3	Long duration of benefit | Long device lifetime

Dimension D – Duration of the Benefit

Rank each benefit on the scale in Table 4 above, based on the expected duration of the benefit.

Guidance

For therapeutic benefits, the Clinical Evaluation would be a good source of this information.

For devices that do not directly provide a therapeutic benefit, e.g., surgical instruments, navigation, or diagnostic devices, use the device lifetime as compared to the user need. For example, if three models of a reusable medical device can be used 5, 20, and 50 times, they would be ranked 1, 2, and 3 respectively.

STEP 2

Compute the benefit score by multiplying the rankings of each benefit along the four Dimensions. Example:

Device X has the following ranking:

- Dimension A – 5
- Dimension B – 3
- Dimension C – 2
- Dimension D – 3

The benefit score = 5 x 3 x 2 x 3 = 90

DISCUSSION

Although the rankings in the four Dimensions are mostly subjective, and partially based on factual clinical data, this method yields a more objective way of appraising a benefit. This method is especially beneficial when comparing the relative value of the same benefit over the progressive iterations of the same device. Or, when comparing the benefits of competitive devices.

The quantitative score for the overall benefit of a medical device would be the sum of the scores of the individual benefits, as identified in the Clinical Evaluation Report.

It should be noted that this whitepaper presents a framework for the quantification of benefits of medical devices. This framework can be adapted to best suit the needs of the manufacturers. For instance, by modifying the descriptions in the tables provided for each Dimension, or by increasing/decreasing the granularity of the rankings in each Dimension.

NORMALIZATION OF BENEFITS

There have been attempts, e.g., by Chung, et. al. (2022) to normalize the quantified values of benefits vs. the quantified values of risks. Normalization of benefits vs. risks affords the ability to compute a benefit/risk ratio where if value of the fraction is > 1, one could claim that the benefits outweigh the risks. No attempt is made in this paper, to normalize benefits vs. risks. The presented approach computes a score for benefits, independent of risks. Therefore, the ratio of benefit/risk would result in a value that would be compared against predetermined acceptance criteria. This is very similar to RPN computation and usage in Failure Modes and Effects Analyses (FMEA).

FUTURE WORK

REFINEMENT

Depending on the uncertainty on the estimates in rankings withing the four Dimensions, we may assign a correction factor to attenuate a computed benefit score.

Conversely, if a benefit meets an important unmet need, we may assign a correction factor to amplify a computed benefit score.

REFERENCES

[1] US Food and Drug Administration. Factors to consider when making benefit-risk determinations in medical device premarket approval and de novo classifications. Issued March. 2012.

[2] Chung, B., Kutty, J., Benefit-Risk Determination: A Quantitative Approach, March 2022, , RQM+, Retrieved from www.rqmplus.com