Outcome-Based Agreements in Medical Devices: A Multidisciplinary Framework for Risk Evaluation and Deployment

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STUDY OBJECTIVE

Outcome-based agreements (OBAs) between providers, payers and medical device industry are increasingly seen as a tool to address uncertainties related to the value they may bring from the perspective of varying stakeholders and outcomes. Such agreements involve measurement of performance for a surgical intervention in a specified population, wherein net price or reimbursement is linked to outcomes achieved.[1]

As OBAs have become more commonplace, the need for a systematic, multidisciplinary approach to OBA deployment and risk quantification has become evident".

METHODS

A multi-disciplinary approach was set up to address the complexity of OBAs.

Figure 1: OBA multi-disciplinary team

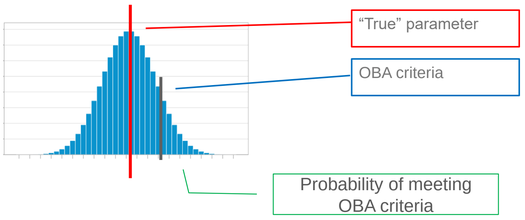
A key first step for the multi-disciplinary team is to determine the appropriate OBA outcome, for example hospital length of stay (LOS) reduction. As mentioned in the ISPOR Good Practices Report [1], outcomes should be clinically robust, clinically plausible, appropriate, and monitorable. OBA targets for the identified outcome then will be defined based on prior knowledge and available data about the outcome.

Once OBA outcome and targets are specified, probability of achieving targets for the specific patient population can be quantified. For example, statistical distributions for the OBA outcome could be defined through a priori knowledge of:

- Patient and provider characteristics (e.g., patient severity, procedure types, and baseline performance);
- The inferred true (population) mean/rate improvement achievable with the intervention, as informed by published literature or provider/payer data; and
- Observed or predicted temporal trends that may affect outcome performance over time.

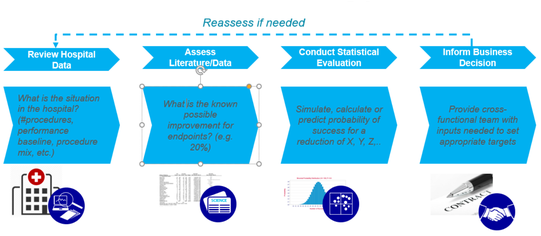
An example is illustrated in **Figure 2**

Figure 2 Statistical distribution for risk assessment



Finally, the cross-functional team must evaluate results of the statistical risk assessment together with the overarching implementation risk.

Figure 3 Risk assessment process



RESULTS

Two hypothetical examples highlight potential approaches to OBA risk assessment:

Example 1:

1. A device is designed to prevent surgical site infections (SSI).
2. The hospital performs 200 procedures/year.
3. Baseline SSI rate is 10%.
4. True SSI rate reduction is anticipated to be 40% from literature review.
5. OBA target reduction options are 20%, 30% and 40%.

The probability of achieving each target can then be quantified with information from the binomial distribution for the true (population) device effect. Results for each target are presented in **Table 1:**

Table 1: Probabilities of meeting SSI OBA targets

OBA targets (SSI reduction)	Probability to achieve targets
20%	90.5%
30%	77.8%
40%	50.0%

Based on these probabilities and acceptable implementation risks, the OBA target can be set at 20% under assumption that >90% probability to achieve OBA target is desired by parties involved.

Example 2:

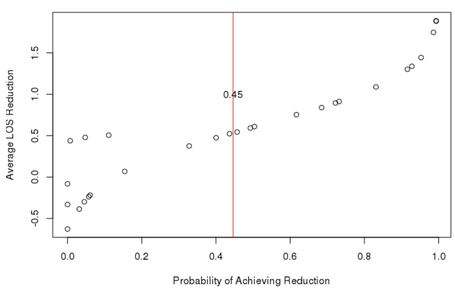
1. A post-operation enhanced recovery program (ERP) is designed to improve recovery time and therefore reducing hospital LOS.
2. ~30 hospitals from a hospital system are included.
3. From 2016-2018 data, we observed a temporal trend for mean LOS. Predicted net mean LOS= (baseline mean LOS – predicted mean LOS in 2019) + ERP effect
4. The ERP effect on LOS is estimated by prior data from 3 other hospitals: pooled average LOS reduction (days) is 0.8 day with pooled standard deviation 0.1.
5. Predicted mean and standard deviation for LOS in 2019 were estimated at each hospital based on linear regression.
6. Based on steps 4 and 5, predicted mean LOS in 2019 and ERP effect were randomly simulated using Monte Carlo simulations (n=1000) from respective statistical distributions (Gamma for predicted mean LOS and normal for ERP effect).

Two measures were calculated for each hospital as shown in **Figure 4**:

1. Predicated mean LOS change: (baseline mean LOS – predicted mean LOS in 2019) + ERP effect
2. Probability of mean LOS reduction meeting OBA criteria (0.6 day or higher)

Across all hospitals, the average probability of meeting OBA criteria is 45%, as indicated by the red line.

Figure 4
Probability of meeting OBA target at each hospital



CONCLUSIONS

We have described and implemented a systematic, multi-disciplinary approach to evaluate risk as a means to address complexity and increased interest in OBAs for surgical interventions. The examples reflect the use of baseline data derived from hospitals and/or literature, as well as different statistical approaches to quantify the probability of achieving outcome targets.

References

1. Garrison, L. P., Towse, A., Briggs, A., Pouvourville, G. D., Grueger, J., Mohr, P. E., … Sleeper, M. (2013). Performance-Based Risk-Sharing Arrangements—Good Practices for Design, Implementation, and Evaluation: Report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force. Value in Health, 16(5), 703–719.