Author’s response to reviews

Title: Mapping Standard Ophthalmic Outcome Sets to Metrics Currently Reported in Eight Eye Hospitals

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Author’s response to reviews:

To: Dr. Choul Yong Park, MD, PhD

BMC Ophthalmology

21 September 2017
Dear Dr. Choul,

Thank you for your letter dated 11 September 2017 with regard to our resubmitted manuscript ID BOPH-D-17-00416R1, entitled "Mapping Standard Ophthalmic Outcome Sets to Metrics Currently Reported in Eight Eye Hospitals".

We are grateful for the additional comments provided by the editor and the reviewers and have revised our manuscript accordingly. Please find the details below:

Q0: The manuscript is significantly improved with the authors' careful revision. However, there are still some points to be considered before reaching the final decision.

A: Thank you.

Q1. lines 175-180: The table in supplement 1 is about the refractive surgery, not corneal transplantation. The authors need to check this whole paragraph and to make correction.

A: We thank the Editor for highlighting this and have amended the manuscript as follows (line 175):

“Refractive surgery outcomes are presented in Supplement 1. Several hospitals report refractive outcomes in detail, which is useful for marketing purposes to potential customers/consumers for such procedures. However, there are many permutations and combinations of refractive treatments and preoperative refractive errors precluding easy comparison.”

The outcomes primarily focus on corneal transplant failure or rejection rate. The expected failure rate differs significantly based on which type of corneal graft, and some institutions differentiate their results based on corneal procedure type. Some hospitals report post-operative visual acuity or improvement following corneal transplant surgery.

We have replaced the above text to line 193:

Supplement 4 demonstrates glaucoma and corneal surgery outcome measures. The cornea outcomes primarily focus on corneal transplant failure or rejection rate. The expected failure rate differs significantly based on which type of corneal graft, and some institutions differentiate their
results based on corneal procedure type. Some hospitals report post-operative visual acuity or
improvement following corneal transplant surgery.

Q2. lines 188: 10-15 diopter should be re-written as "prism diopter".
A: We have added ‘prism’ accordingly (line 190):
“There are also two hospitals that measure the postoperative improvement in ocular alignment,
with success being defined as less than 10-15 prism diopter of residual eso- or exotropia.”

Q3: It is necessary to present the full terminology for "PROM" when it first came. I cannot find
this in the main manuscript or table although it is explained in 'Abstract'.
A: We agree with the Editor and have amended the text as follows:
“Despite the existence of two internationally agreed ICHOM standards for eye care, compliance
with the proposed measures is limited and especially measurement of recommended patient
reported visual functioning or vision-related quality of life (PROMS) is not yet taking place
systematically.” (line 227)

Q4: The discussion should be more shortened. It is too long and redundant. The authors can
summarize it and make it less than 6 pages.
A: We have substantially shortened the Discussion paragraph, and refer to the amended
manuscript (from line 210 onwards), and hereby reduced the Discussion to 5 and a half pages.
“We present the first review of ophthalmic outcome measures reported by eye hospitals in
diverse populations in various nations. The study is limited by the number of institutions who
publicly report outcomes and indicators, and a reluctance from a number of institutions to either
devote resource to gather regular indicator results to benchmark or, if gathered, to share or
publish indicator results. This rendered a comprehensive or global data gathering study
impractical at this time, but the use of a sample of leading institutions was possible and, although
by necessity only permitting descriptive statistics, does demonstrate both the utility and the
issues in attempting to use ophthalmic indicators to benchmark and compare performance across
institutions and countries. Although several hospitals report similar outcomes and targets or
benchmarks in each subspecialty, there is little congruence on which outcomes or benchmarks
should be reported, which methodologies should be used and how to address preoperative risk
and co-morbidity. Despite the existence of two internationally agreed ICHOM standards for eye
care, compliance with the proposed measures is limited and especially measurement of
recommended patient reported visual functioning or vision-related quality of life (PROMS) is not yet taking place systematically. While we realize that health care systems are complex and (large) differences between health systems could be barrier for valid comparisons, [8] other surgical specialties have long recorded outcomes and such reporting has improved clinical and cost effectiveness as well as patient safety [19, 27]. Initial fears of surgeon avoidance of high-risk cases or unfair reputational damage have proved largely unfounded [19]. In the U.K. many surgical specialties publish their outcomes, and in 2016 the first pilot with a national reporting on cataract surgery outcomes was done in a similar fashion [28]. Pay for performance tools have been instituted by Medicare in the US. The Physician Quality Reporting System (PQRS) was initially started as an incentive system to promote quality of care and outcome reporting. In 2017, ophthalmic practices who do not report three quality measures 50% of time will receive a two percent penalty on Medicare reimbursements two years down the road. Physicians who report nine measures in three of the new national quality strategy domains will receive a 0.5% bonus payment [29]. With the increasing prevalence of electronic record systems, quality-focused healthcare, rising patient expectations as well as increasing cost pressures, our expectation is that outcome reporting in ophthalmology will globally become the norm instead of the exception.

Goals in clinical outcome reporting include encouraging quality improvement, creating a minimum standard for providers, driving innovation in care, performance management of units and individual surgeons, distributing pay incentives, increasing informed decision making for patients as well as promoting public confidence in healthcare providers, and contributing to research [30, 31]. Reporting outcomes data to the public may promote greater scrutiny of health care and reduce variations in the quality of care, thereby making physicians more accountable [32]. For example, one study in vitreoretinal surgery demonstrated that reporting patient safety incidents resulted in a change in clinical practice and an accompanying increase in patient safety [33]. However, strategic and shared planning regarding what outcomes are reported and how risk adjustment is included will increase the utility of published outcomes [34].

One potentially straightforward method of outcome reporting is to indicate ophthalmic quality and safety by measurement of the rate of serious adverse healthcare associated events such as postoperative infections, unplanned reoperations, and so called ‘never events’. ‘Never events’ are serious, potentially preventable errors in healthcare, for example in cataract care these may include operating on the wrong patient, on the wrong eye, or inserting the incorrect (unplanned) intraocular lens [35]. ‘Never events’ are taken seriously and investigated with root cause analysis, and actions should be taken to prevent error recurring with a culture of fair blame. Unplanned or return surgeries or reoperations are sometimes unavoidable, but are relatively easy to measure by providers. However this number can be skewed by clinical conditions and eye hospitals with a large retina service may skew rates compared to a center undertaking low risk cataract surgery only. Ideally reoperation rates or returns to surgery should be reported by
ophthalmic subspecialty. There was significant consensus in this area, with all institutions reporting similar values; however some institutions reported only subspecialty-specific data.

In cataract surgery, many institutions report visual acuity – the most common target was best-corrected visual acuity of 20/40 or better, however another strategy is to consider improvement in visual acuity. We found that timing of follow-up for outcome reporting following cataract surgery may be influenced by particular health system or hospital’s practice patterns. For example if post-operative cataract patients are discharged from ophthalmic care or followed up in the community the return of outcome data may be problematic.

Refractive surgery lends itself to outcome measures as the primary goal is improved uncorrected visual acuity without loss of best-corrected visual acuity. Several hospitals report refractive outcomes in detail and which is useful for marketing purposes to potential customers/consumers for such procedures. However there are many permutations and combinations of refractive treatments and preoperative refractive errors precluding easy comparison.

In medical retinal care, clinical measures, such as visual improvement and stability of vision following treatment for medical retinal conditions such as neovascular age-related macular degeneration or diabetic macular edema are more difficult to extract or compare. Pivotal clinical trials may provide benchmark data [36] but real world outcomes may not meet these benchmarks. Retina surgical outcomes vary significantly based on the pre-operative condition and the complexity of the case. Some institutions account for this by making specific sub-categories, while others look only at primary retinal detachment surgery or reattachment for all cases. This is an area where risk adjustment is extremely important to allow accurate comparisons of outcomes between institutions.

It is notable that there is a lack of hospitals using patient-reported measures, while patient satisfaction and experience rates are commonly used measure by payers and state agencies. In contrast, while a variety of instruments have been employed in research studies for assessing the impacts of cataract (and other ocular) surgery on patients’ symptoms, functional ability, wellbeing and health, these are not yet generally publicly reported in clinical care. These PROM’s can be divided into generic assessments that have been designed to apply across a range of different health conditions (for example, the EuroQol EQ-5D and SF-36) and instruments that focus specifically on vision-related conditions (for example, the VF-14). Properly developed PROMs are valid and reliable research tools but they can be cumbersome for patients to use routinely on a large-scale basis [37]. The RCOphth resisted the use of the VF-14 PROM metrics for routine use in NHS cataract surgery for referral or reimbursement purposes, as the College was of the opinion that it added no value in routine NHS care in the UK [1]. Subsequent research confirmed the College’s concerns about the VF-14 tool [38, 39]. PROMs tools are increasingly being tied to reimbursement and their use is likely to be an area of growth in ophthalmic care the future.
Limitations of current ophthalmic indicator use

As electronic records become standardized and more patient specific data is readily available, ophthalmic outcome measures will become easier to obtain and potentially more meaningful. The merit of quality reporting depends on data quality, risk adjustment, sample size, and the specification of quality measures themselves [40]. Current ophthalmic outcomes reporting methods do not usually take into account the complicated statistical methods for risk adjustment used in other healthcare fields and hence we have not applied any quantitative comparison or statistical tests in this study. The issue of case mix adjustments is a critical topic in other specialties that publicly report outcomes. Failure to adjust for such may discourage surgeons from treating high-risk patients and therefore deny high-risk patients the opportunity of benefiting from surgery, while appropriate risk adjustment can do much to allay these concerns. There has been reported reluctance of some cardiac surgeons to operate on high-risk patients for these reasons [41, 42] and, without appropriate risk adjustment, unintended distortions of appropriate surgical care may thus arise to the ultimate detriment of the public [43]. Efforts should be made to regain the focus on quality of care rather than punitive profiling [44, 45]. It is important to include other measures of quality such as structure and process as they are more easily interpreted, require shorter reporting periods, can be improved more readily, and may be better at measuring some differences in quality of care [10].

At present, hierarchical regression is the gold standard for risk adjustment of outcomes and for producing provider report cards; however this gold standard is rarely used [45] and no equivalent modeling has been developed in ophthalmology to date. The National Ophthalmic Database (NOD) in the UK has compiled a national cataract data set, and participating cataract surgeons have the ability to compare their individual surgical data to others in a risk-adjusted manner [28]. A new American registry [46] may have the ability to risk stratify eye surgeons’ case mix, while previous groups have either excluded any patients with comorbidities or not performed case mix analysis.

It is important to ensure that the outcomes metrics have the statistical power to detect differences in quality, which is difficult in outcomes that are rare, such as postoperative endophthalmitis, particularly for lower-volume surgeons. This data can help to identify outliers. The serious consequences for patients of these rare complications mean that it is important to identify these outliers accurately and promptly.

Next steps

Increasingly, there are national and multi-national collaborations that are collecting large quantities of data on structures, processes, and outcomes of care, and this is facilitated by increasing use of electronic health records which removes many previous barriers to large scale
data gathering. These databases will become more prominent and powerful with their ability to retrieve data directly from electronic medical records.

The European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) was initiated in 2008 by 11 European countries to improve treatment and standards of care for cataract and refractive surgery and to develop evidence based guidelines [47]. As of mid-2016, more than 2 million cataract operations were included in the database and specific guidelines were established regarding cataract surgery. These guidelines, in addition to the benchmark set by Hahn and colleagues [48] for cataract surgery, may be useful benchmarks for other organizations to use.

The Intelligent Research in Sight (IRIS) registry is a clinical data registry designed by the American Academy of Ophthalmology (AAO) that opened to all AAO member physicians since 2014. This registry automatically collects data from participating electronic health record systems and provide benchmark reports for participating practitioners. This fulfills parts of the federal U.S. Physician Quality Reporting System (PQRS) requirements, meaningful use, and value based modifiers, will avoid financial PQRS penalties, and can help ophthalmologists meet maintenance of certification requirements. As of 1 January 2016, the IRIS registry included 11,739 physicians, and registered 72.05 million visits representing 20.5 million patients presumably [49, 50].

Finally, ICHOM’s standard guideline sets for cataract surgery [13] and macular degeneration [15] have been rigorously developed with the goal of improving quality of health care, reducing health care costs, and supporting informed decision-making. As the currently reported outcomes were found to be only partially in line with the standards, in some instances the ICHOM sets might need to shift to align with what is currently done. In most instances, however, institutions might opt to align their reporting with the standard sets, which is the direction the institutions participating in our study are currently taking.

Our study shows that much more alignment on the concept of value based eye care will be needed to implement the standards in the day-to-day hospital practice and gives suggestions for future metrics in other subspecialties to be developed. Practice-based knowledge on outcome measures, as provided in this paper, should form part of the input of the international standardization process to assure implementation.”

We again thank the Editor and the Reviewers for your valuable comments, and trust the above clarifications and the amended manuscript improves the value of this work.

We look forward to your favourable follow-up, and are more than happy to provide any additional clarifications if useful.
Yours sincerely,

On behalf of the co-authors,

Dirk de Korne