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How do you… decide which platelet bacterial risk mitigation strategy to select for your hospital-based transfusion service?

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Abstract

The United States Food and Drug Administration Final Guidance for Industry titled, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion" provides nine strategies for platelet bacterial risk mitigation. Even if it is assumed all strategies are comparable in terms of safety and efficacy, the decision of which to implement remains challenging. Some additional factors that warrant evaluation before selecting a strategy include the financial impact, process for implementation, logistics upon implementation, institutional acceptance by blood bank staff, administration and clinicians, and effect on platelet availability. To assist with this difficult choice, a panel of transfusion service physicians who have expertise on the topic and have already selected strategies for their transfusion services were recruited to provide varied perspectives. In addition, the use of a decision-making tool that objectively evaluates defined criteria for assessment of the nine strategies is described.

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CONFLICT OF INTEREST

Paul Ness is a consultant to Terumo BCT and Biomerieux.
Mark H. Yazer and Nancy M. Dunbar are on the scientific advisory board of Verax Biomedical.
Darrell J. Triulzi is on the medical advisory board for Fresenius Kabi and a grant recipient from Cerus Corporation.
Wen Lu, Meghan Delaney, Willy A. Flegel, Nora Ratcliffe, and Alyssa Ziman declare that they have no conflicts of interest relevant to this manuscript.

SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.
Appendix S1. Supplementary File.

BACKGROUND

Bacterial contamination, most notably of platelets, is the leading infectious risk to the United States (US) blood supply.[1] On September 30, 2019, the US Food and Drug Administration (FDA) published a Guidance for Industry titled "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion" to address this risk.[2]

This guidance offers nine strategies for mitigating the risk of bacterial contamination of platelets. Transfusion services must comply within 18 months from guidance publication. For the purposes of this project, it was assumed that all strategies offer comparable clinical efficacy and safety for all patient populations and clinical situations. The focus of this assessment, therefore, is on the impact each strategy will have on cost, operations (implementation, acceptance, and logistics), and platelet availability. This manuscript provides varied perspectives on each strategy and describes the use of a decision-making tool to help transfusion services select a risk mitigation strategy.

METHODS

A panel of eight transfusion service physicians (TSPs) completed a uniform questionnaire and solution selection matrix (matrix). These TSPs were selected to represent diverse perspectives based on size and type of practice, patient populations served, platelet transfusion volume, platelet availability, and current platelet manufacturing and testing practices.

The uniform questionnaire included nine questions to capture practice setting, demand and supply of platelets, current platelet testing and manufacturing practices, and preferred risk mitigation strategy. The matrix was developed by modifying a lean six sigma tool[3] to include the nine risk mitigation strategies offered by the FDA and five pre-defined criteria for assessment: cost, implementation, logistics, acceptance, and platelet availability (Fig. 1). The TSP were provided with the following definitions for the five criteria:

1. Financial **COST** per platelet unit acquisition and additional testing (1 = most expensive to 5 = least expensive).
2. **IMPLEMENTATION** process, i.e., how difficult this would be to implement at your facility only taking into consideration the actual steps of implementation and not acceptance of this choice (1 = most difficult to 5 = easiest; refer to the fourth criterion below regarding acceptance).
3. Process **LOGISTICS**, i.e., how difficult this option is for blood bank staff after implementation (1 = most difficult to 5 = easiest).
4. **ACCEPTANCE**, i.e., how people at your hospital (blood bank staff, administration, clinicians) would feel about implementation of this strategy (1 = least supportive to 5 = most supportive).

5. Platelet **AVAILABILITY**, i.e., how the strategy selected would influence the overall ability to have platelets on your shelf available for transfusion when needed (1 = least platelet availability to 5 = most platelet availability).

Instructions were provided for matrix completion as annotated in Fig. 1. Assignment of weight and score was at the discretion of the TSP based on their personal opinion and practice setting. Following assignment of criteria weight and determination of a score for each criterion and each strategy, the matrix automatically calculated a total score for each strategy. The TSP assumed availability of all strategies, even though a culture-based device labeled as a "safety measure" for large volume delayed sampling (LVDS) at ≥ 48 hours to extend the shelf-life of platelets up to 7 days is not currently available. The minimum possible total score, assuming all criteria are assigned a score of 1, is 100. The maximum possible total score, assuming all criteria are assigned a score of 5, is 500.

The average score, average weight, and deviation from the average weight by each TSP, and average total score for each strategy were calculated. The deviation from the average weight is the average difference between the weight assigned by each TSP and the average weight given by all TSPs for that criterion. The average weight and average score for each criterion were used to generate a unified average matrix with total scores automatically calculated by the matrix (Fig. 2).

After completing the uniform questionnaire and matrix, the TSP shared their expertise through free text comments as a way to provide opinions and nuanced details not captured by the matrix and offer insight into how the weights and scores were determined.

RESULTS

The TSPs who participated in this project practice in settings that range from rural to urban, and provide inpatient and outpatient platelet transfusion support for surgical, trauma, hematology/oncology, stem cell transplant, and solid organ transplant patients of all ages. TSP representing a standalone children's hospital and a Veterans' Affairs (VA) hospital were included. The TSPs represented a variety of transfusion services with different platelet manufacturing capabilities and transfusion volumes (Table 1). Platelet transfusion volumes ranged from a center that does not routinely stock platelets to one that transfuses approximately 90 units per day. The median number of platelets transfused per day at the seven centers that routinely stock platelets is 24 (standard deviation = 31, range < 1-90).

The weight assigned to each of the five criteria by each TSP (de-identified as A-H), the average weight of all TSPs and the deviation from the average weight for each TSP are presented in Table 2. The criterion with the highest average weight was platelet availability (30%), followed by logistics (23%), cost (19%), implementation (16%), and acceptance (12%). The deviation from the average weight ranged from 4 (TSP H) to 12 (TSP G), demonstrating the variability in the weights assigned to the five criteria by each TSP.

The total score calculated by the matrix for each risk mitigation strategy for each TSP and the average total score of all TSPs combined are also provided (Table 2). The strategies with the highest total scores (bold font) represent the preferred mitigation strategies according to

the matrix. For seven out of eight TSPs, the us of ‖ in Table 2 is to highlight this data. For the one TSP whose preferred risk mitigation strategy did not have the highest total score, the preferred strategy had the second highest total score.

The strategy with the highest average total score of all TSPs combined was LVDS ≥ 48 hours for up to 7 days of storage (average total score 422) followed by LVDS ≥ 36 hours for up to 5 days of storage (average total score 395).

In the unified average matrix (Fig. 2), average scores of “5” were noted for the two strategies with the highest total score (LVDS ≥ 48 hr for up to 7 days of storage and LVDS ≥ 36 hr for up to 5 days of storage). However, the average score for the majority of the criteria was “3” (31/45, 69%). This reflects that there may not be a strategy that is clearly the best or worst.

This observation is reflected in the free text comments from the TSP that demonstrate a wide range of opinions. Their remarks are summarized below under the following five general categories:

1. LVDS
2. Pathogen reduction (PR)
3. Secondary (2°) culture
4. 2° rapid testing
5. 7-day storage

LVDS

- LVDS ≥ 48 hours for up to 7 days of storage (average total score 422)
- LVDS ≥ 36 hours for up to 5 days of storage (average total score 395)
- LVDS ≥ 36 hours and 2° rapid testing for up to 7 days of storage (average total score 266)
- LVDS ≥ 36 hours and 2° culture ≥ 4 days for up to 7 days of storage (average total score 266)

For transfusion services that do not collect or manufacture their own platelets, LVDS ≥ 48 hours for up to 7 days of storage and LVDS ≥ 36 hours for up to 5 days of storage are appealing from the perspectives of implementation and logistics, as there is no further requirement for testing by the hospital transfusion service. However, it is not known at this point whether the blood supplier will adopt LVDS. Another unknown for LVDS is cost. It has been postulated that LVDS will increase cost to some extent since each split unit must be sampled, as opposed to primary (1°) culture at 24 hours, which only requires a single sample of the mother bag. In addition, the increase in sample volume requirement may decrease split rates and additionally contribute to increased cost. Transfusion services that collect and manufacture platelets will need an in-house microbiology laboratory that is using an FDA approved culture device to perform LVDS locally, which has implications for cost, implementation, and logistics.

Pathogen reduction (PR)

- PR up to 5 days of storage (average total score 311)

PR is generally regarded as the costliest strategy.[4] However, like LVDS, PR platelets (PRPs) require no additional testing by the hospital transfusion service, making this an attractive option from a logistical perspective. PR decreases the risk for bacterial contamination, and also decreases the risk of non-bacterial infectious agents.[5] Therefore, some of the cost may be offset by not needing to test for *Babesia* (where performed),[6] Zika Virus,[7] CMV,[8] and potentially other not yet identified infectious risks that may threaten the platelet supply.[9]

Additionally, irradiation is not required to prevent transfusion-associated graft-versus-host disease (TA GVHD) for platelets that have undergone PR.[9,10] However, for transfusion services that irradiate their own blood products, an irradiator would still be required for red blood cells.

Nonetheless, PR is the only bacterial risk mitigation strategy offered by the FDA that reduces the risk of transmitting non-bacterial infectious agents and is approved for the indication of preventing TA GVHD.[11]

The availability of PRPs is difficult to predict and may be dictated by the transfusion service's platelet supplier. As PRPs are available for distribution at 24 hours after collection, this may increase the platelet unit's overall shelf-life and thus availability, thereby perhaps even decreasing the rate of outdate and wastage. Additional strategies that could improve the availability of PRPs include prompt availability of pre-donation platelet counts and optimizing apheresis collections to meet platelet concentration and volume restrictions for PR treatment, also known as guard-band limitations.[12]

Concerns expressed regarding the use of PRPs include the potential need for maintaining a dual inventory of platelets due to supply limitations, decreased platelet count increments (PCIs),[13] risk of human leukocyte antigen (HLA) alloimmunization,[14] and the effect of psoralen on neonatal, pediatric, and obstetric patients.[15–17] Even with noninferior hemostatic function in hematology oncology patients,[18,19] decreased PCIs may result in increased platelet utilization and reduced platelet inventory. Increased HLA alloimmunization[14] may make finding suitable platelet products more difficult, an additional challenge for TSPs and clinicians.

Secondary (2°) culture

- 1° culture ≥ 24 hours and 2° culture ≥ Day 3 for up to 5 days of storage (average total score 294)
- 1° culture ≥ 24 hours and 2° culture ≥ 4 days for up to 7 days of storage (average total score 294)
- LVDS ≥ 36 hours and 2° culture ≥ 4 days for up to 7 days of storage (average total score 266)

Secondary culture involves a single additional test for the transfusion service, as opposed to potentially performing 2° rapid testing multiple times. Secondary culture also allows the

shelf-life of platelets to be extended to up to 7 days. If an FDA approved culture device were not available in-house, this strategy would require significant upfront investment of resources including time, personnel, and financial cost for implementation. If an FDA approved culture device is available and has been validated, this strategy may be the simplest logistically.[20]

However, not all TSPs were in agreement. TSPs from centers that collect and manufacture platelets regarded 2° culture to involve substantial hands-on time, especially when additional aerobic and anaerobic cultures are required for split units. Another consideration is the 12-hour hold time, which effectively shortens the available shelf-life of the product if tested on Day 4. However, this is not an issue if the culture is performed on Day 3.

Secondary (2°) rapid testing

- 1° culture ≥ 24 hours and 2° rapid testing for up to 7 days of storage (average total score 302)
- 1° culture ≥ 24 hours and 2° rapid testing for up to 5 days of storage (average total score 286)
- LVDS ≥ 36 hours and 2° rapid testing for up to 7 days of storage (average total score 266)

Secondary rapid testing is one of two strategies currently available that allows the shelf-life of platelets to be extended from 5 days to up to 7 days. Appealing aspects of 2° rapid testing include the ability to increase platelet availability during times of platelet shortages and the flexibility to fulfill ad hoc orders as soon as nonreactive results are obtained. Some TSPs regard time of issue testing as the simplest strategy with regard to logistics since the test can be performed within the transfusion service with a rapid turnaround time and immediately available results. Concerns with 2° rapid testing include false negative[21] and false positive[22] test results. The latter is especially problematic for small rural centers where patients travel considerable distances for platelet transfusion, as well as HLA-matched and cross-matched platelets ordered for a specific patient. In addition, units with repeat reactive results (due to true and false positives) cannot be transfused and may contribute to increased inventory requirements and costs. The need for quality control, proficiency testing, and competency also make this strategy less attractive, especially for transfusion services with low volume platelet transfusions.

Seven-day storage

- LVDS ≥ 48 hours for up to 7 days of storage (average total score 422)
- 1° culture ≥ 24 hours and 2° rapid testing for up to 7 days of storage (average total score 302)
- 1° culture ≥ 24 hours and 2° culture ≥ 4 day for up to 7 days of storage (average total score 294)
- LVDS ≥ 36 hours and 2° rapid testing for up to 7 days of storage (average total score 266)

- LVDS ≥ 36 hours and 2° culture ≥ 4 days for up to 7 days of storage (average total score 266)

Currently, 2° culture and 2° rapid testing are both strategies that allows the shelf-life of platelets to be extended from 5 days to up to 7 days. The ability to extend the self-life of platelets to up to 7 days is extremely appealing and necessary for transfusion services with limited platelet availability, geographically distant from their blood supplier, or with a high outdate rate.[23] However, the ability to store platelets in platelet additive solution beyond Day 5 is limited by storage containers approved for 7 days of storage.[2] For transfusion services that are close to their platelet suppliers and with a low outdate rate, this option is less appealing due to concerns over decreased proven efficacy with extended storage and due to the risk that > 5 days platelet units could be issued not having undergone the necessary 2° testing. PR has the potential for > 5-day shelf-life, although it has not been approved by the FDA in the US.[24]

DISCUSSION

Deciding which platelet bacterial risk mitigation strategy to implement is complicated, not only because there are many factors to consider, but also due to the large number of unknowns, such as availability and cost of different platelet product types and FDA approval of test devices. In addition, opinions on this topic are strong and diverse. The lack of a simple “right” choice is reflected by the average score of “3” for most criteria in the matrix, the wide range in deviation from the average weight, as well as the varied perspectives expressed by the TSPs in their comments.

We were able to demonstrate through its application that the matrix tool provides useful information. The participating TSPs had already identified the preferred strategy for their transfusion services prior to starting this project. The matrix was developed to be a tool for the TSPs such that based on the assigned weight and score, the total score should reflect each user’s preference. For seven out of eight TSPs, the preferred strategy was indeed the option with the highest total score. This suggests that the matrix is a useful tool with good predictive value.

The main limitations of this project are in the assumptions that were made. First, although a LVDS culture-based device labeled as a “safety measure” for extending the dating of platelets to up to 7 days is not currently available, the TSPs were asked to assume that all strategies are viable options. Additionally, TSPs made the assumption that their blood center/s would be able to provide them with their preferred strategy or strategies, which may not necessarily be true. Further, clinical efficacy and safety for therapeutic and prophylactic transfusions for all patient populations were assumed to be comparable for all strategies. In addition, since efficacy and safety were assumed to be comparable, the five criteria regarded as most important and selected for the TSPs to weigh and score were cost, implementation, logistics, acceptance, and platelet availability. Some TSPs may regard other factors as more critical. However, the matrix can be customized by the user to reflect the factors they deem most important (Appendix S1). Finally, these eight TSPs may not necessarily represent all

transfusion services and the scope of this project did not include the perspective from a blood center.

CONCLUSIONS

The decision of which bacteria mitigation strategy or strategies to implement to comply with guidance is complex and requires coordination between transfusion services and blood centers. There is no right or wrong answer, nor does one size fit all. Given there is not a consensus on the optimal bacterial risk mitigation strategy for every transfusion service, this manuscript provides blended perspectives on different options from different practice settings. The matrix presented may be a helpful tool to break down the decision making into distinct steps so separate components can be evaluated independently. This matrix is also dynamic and can be modified as new strategies are approved by the FDA and become available (Appendix S1). Its output can help identify viable bacterial contamination risk strategies that are feasible for different institutions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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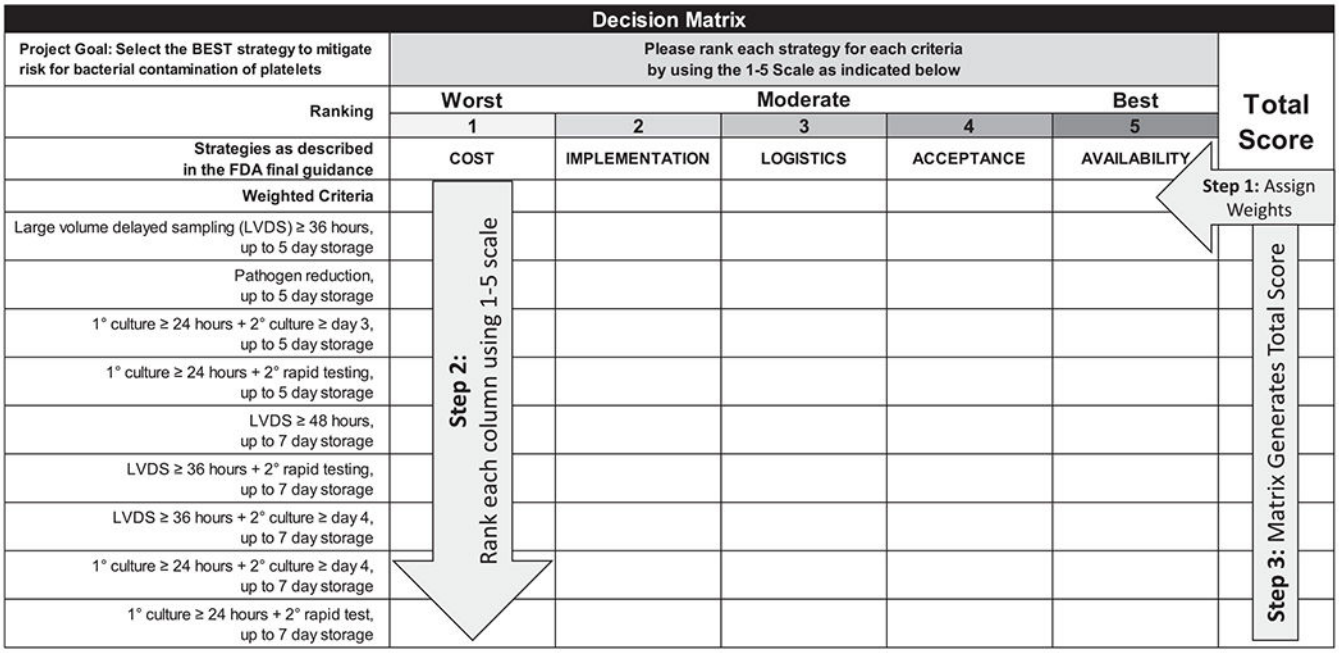

Fig. 1.

Solution selection matrix (matrix) with the nine risk mitigation strategies provided by the FDA and five pre-defined criteria for consideration. Instructions for matrix completion: Step 1: Assign a weight to each criterion, such that the total weight adds up to 100%. The most important criteria should be given the highest weight, but if two or more criteria are regarded to be of equivalent importance they may be given the same weight. Step 2: For each risk mitigation option, designate a score on a scale of 1-5, where 1 is the worst and 5 is the best (see definitions). Step 3: The total score for each option is automatically calculated by the matrix. The option(s) with the highest total score(s) warrant further consideration.

Decision Matrix						
Project Goal: Select the BEST strategy to mitigate risk for bacterial contamination of platelets	Please rank each strategy for each criteria by using the 1-5 Scale as indicated below					Total Score
Ranking	Worst		Moderate		Best	
	1	2	3	4	5	
Strategies as described in the FDA final guidance	COST	IMPLEMENTATION	LOGISTICS	ACCEPTANCE	AVAILABILITY	
Weighted Criteria	19	16	23	12	30	
Large volume delayed sampling (LVDS) ≥ 36 hours, up to 5 day storage	4	5	5	5	3	421
Pathogen reduction, up to 5 day storage	2	3	4	3	3	304
1° culture ≥ 24 hours + 2° culture ≥ day 3, up to 5 day storage	3	3	3	4	3	312
1° culture ≥ 24 hours + 2° rapid testing, up to 5 day storage	3	3	3	3	3	300
LVDS ≥ 48 hours, up to 7 day storage	4	5	5	4	4	439
LVDS ≥ 36 hours + 2° rapid testing, up to 7 day storage	3	3	3	3	3	300
LVDS ≥ 36 hours + 2° culture ≥ day 4, up to 7 day storage	3	3	2	3	3	277
1° culture ≥ 24 hours + 2° culture ≥ day 4, up to 7 day storage	3	3	3	3	3	300
1° culture ≥ 24 hours + 2° rapid test, up to 7 day storage	3	3	3	3	4	330

Fig. 2.

Unified average matrix generated using the transfusion service physicians' (TSPs') average weight and score.

TABLE 1.

Participating transfusion service demographic data, platelet manufacturing capabilities, and volume of platelet transfusions

Transfusion service practice type			Number of platelets transfused per day
Centralized transfusion service serving more than one hospital		n = 1	90
Hospital based blood bank serving one or more hospitals	Collects and manufactures platelets, * routinely stocks platelets	n = 4	4
			7
			12
			35
	Does not collect and manufacture platelets, routinely stocks platelets	n = 2	40
			55
	Does not collect and manufacture platelets, does not routinely stock platelets	n = 1	<1

* No transfusion service that collects and manufactures platelets is 100% self-sufficient.

TABLE 2.

Solution selection matrix summary data

Transfusion service physician (TSP): A-H

Current manufacturing and testing practices: *, †, ‡, §

Preferred strategy not with highest total score: //

"Safety measure" device for large volume delayed sampling (LVDS) at ≥ 48 hours for up to 7 days storage not currently available in the US: ¶

Weight		**A** †	**B** ‡	**C** §	**D** *,§	**E** *,†	**F** *	**G** *	**H** *	**Average weight**
	Cost	30	30	10	20	30	15	5	10	19
	Implementation	10	20	10	5	10	30	25	15	16
	Logistics	10	20	25	25	10	20	35	40	23
	Acceptance	5	10	25	20	5	10	20	5	12
	Availability	45	20	30	30	45	25	15	30	30
	Deviation from the average weight	10	6	6	4	10	6	12	7	n/a
Mitigation strategy		**A** †	**B** ‡	**C** §	**D** *,§	**E** *,†	**F** *	**G** *	**H** *	**Average total score**
	LVDS ≥ 36 hours, up to 5 days of storage	320	460	225	**470**//	410	405	450	420	395
	Pathogen reduction, up to 5 days of storage	195	190	**420**	445	185	170	450	**435**	311
	1° culture ≥ 24 hours +2°culture ≥ Day 3, up to 5 days of storage	285	**470**	280	325	290	245	255	205	294
	1° culture ≥ 24 hours +2° rapid testing, up to 5 days of storage	310	330	**420**	255	325	285	145	220	286
	LVDS ≥ 48 hours, up to 7 days of storage¶	410	**470**	305	430	**500**	**445**	**455**	360	422
	LVDS ≥ 36 hours +2° rapid testing, up to 7 days of storage	325	330	235	260	370	310	140	160	266
	LVDS > 36 hours +2° culture ≥ Day 4, up to 7 days of storage	285	410	145	305	290	245	270	175	266
	1° culture ≥ 24 hours +2° culture ≥ Day 4, up to 7 days of storage	375	410	260	305	290	270	270	175	294
	1° culture ≥ 24 hours +2° rapid testing, up to 7 days of storage	**415**	340	395	255	325	325	140	220	302

*Pre-storage 1° culture, up to 5 days of storage.

†Pre-storage 1° culture + 2° rapid test, up to 7 days of storage.

‡Pre-storage 1° culture + 2° culture, up to 5 days of storage.

§Pathogen reduction.

//is associated with the total score of 470 in table 2. This is to highlight the single occurrence when the highest total score was not the preferred strategy for a TSP.

¶should follow "LVDS ≥ 48 hours, up to 7 day storage" to highlight the fact that this option is NOT currently available in the US, which is very important as to not mislead readers, especially since it has the highest average total score.