# A comparison of prognosis calculators for geriatric trauma: A Prognostic Assessment of Life and Limitations After Trauma in the Elderly consortium study

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BACKGROUND: The nine-center Prognostic Assessment of Life and Limitations After Trauma in the Elderly consortium has validated the Geriatric

Trauma Outcome Score (GTOS) as a prognosis calculator for injured elders. We compared GTOS' performance to that of the

Trauma Injury Severity Score (TRISS) in a multicenter sample.

METHODS: Three Prognostic Assessment of Life and Limitations After Trauma in the Elderly centers not submitting subjects to the GTOS validation study identified subjects aged 65 years to 102 years admitted from 2000 to 2013. GTOS was specified using the formula

[GTOS = age + (Injury Severity Score [ISS]  $\times$  2.5) + 22 (if transfused packed red cells (PRC) at 24 hours)]. TRISS uses the Revised Trauma Score (RTS), dichotomizes age (<55 years = 0 and  $\geq$ 55 years = 1), and was specified using the updated 1995 beta coefficients. TRISS Penetrating was specified as [TRISS<sub>P</sub> = -2.5355 + (0.9934  $\times$  RTS) + (-0.0651  $\times$  ISS) + (-1.1360  $\times$  Age)]. TRISS Blunt was specified as [TRISS<sub>B</sub> = -0.4499 + (0.8085  $\times$  RTS Total) + (-0.0835  $\times$  ISS) + (-1.7430  $\times$  Age)]. Each then became the sole predictor in a separate logistic regression model to estimate probability of mortality. Model performances were

evaluated using misclassification rate, Brier score, and area under the curve.

**RESULTS:** Demographics (mean + SD) of subjects with complete data (N = 10,894) were age, 78.3 years  $\pm 8.1$  years; ISS,  $10.9 \pm 8.4$ ;

 $RTS = 7.5 \pm 1.1$ ; mortality = 6.9%; blunt mechanism = 98.6%; 3.1% of subjects received PRCs. The penetrating trauma subsample (n = 150) had a higher mortality rate of 20.0%. The misclassification rates for the models were GTOS, 0.065;  $TRISS_B$ , 0.051; and  $TRISS_P$ , 0.120. Brier scores were GTOS, 0.052;  $TRISS_B$ , 0.041; and  $TRISS_B$  0.084. The area under the curves were GTOS, 0.844;

TRISS<sub>B</sub>, 0.889; and TRISS<sub>B</sub> 0.897.

CONCLUSION: GTOS and TRISS function similarly and accurately in predicting probability of death for injured elders. GTOS has the advantages

of a single formula, fewer variables, and no reliance on data collected in the emergency room or by other observers. (J Trauma

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LEVEL OF EVIDENCE: Prognostic, level II.

**KEY WORDS:** Geriatric; elderly; trauma; score; prognosis.

The rapid aging of the US population is well recognized. According to the United States Census Bureau, the population aged 65 years and older was roughly 43.1 million in 2012 and is expected to almost double to 83.7 million by 2050. Injuries in this population often result in increased morbidity and mortality. Multiple factors including frailty, decreased physiologic reserve, comorbidities, and malnutrition all contribute to worse outcomes for these patients compared to their younger peers<sup>3,4</sup> with a resultant increase in utilization of resources and length of hospitalization. Unfortunately, it is common for the most severely injured geriatric patients to experience a prolonged intensive care unit stay only to subsequently die, and survivors have an increased relative risk of death after their hospitalization without a return to their preinjury state of health.

Optimal care of the injured elder includes formally setting the goals of care early in these patients' hospital courses. In doing so, the doctor and patient or their surrogate decision maker craft a treatment plan aligned with the patient's goals, values, and preferences. The delivery of accurate prognostic expectations is a key part of these discussions, but these are frequently based on anecdote.

In an effort to address this clinical shortcoming, we have created the Prognostic Assessment of Life and Limitations After

Trauma in the Elderly [PALLIATE] consortium. This nine-center collective has multidisciplinary expertise in the fields of trauma care, geriatrics, palliative care, and biostatistics, and has concentrated its efforts to date on the creation and promulgation of prognosis calculators after geriatric injury. The first of these efforts, the Geriatric Trauma Outcome Score (GTOS), was derived through analysis of roughly 4,000 patients from a single center using logistic regression. Using the variables of Injury Severity Score (ISS), age, and performance of packed red blood cell (PRBC) transfusion within 24 hours of admission, GTOS was subsequently externally validated as an accurate and pragmatic predictor of in-hospital mortality for the injured elder. A free online calculator for the GTOS is available at www. palliateconsortium.com.

To date, the criterion standard of prognosis calculators after injury has been the Trauma Injury Severity Score (TRISS). Originally created in late 1980s<sup>9</sup> and subsequently revised with updated coefficients, <sup>10–12</sup> the TRISS model uses the Revised Trauma Score (RTS). RTS, created in 1981, is a scoring system heavily based on the first physiologic data obtained from the patient, consisting of Glasgow Coma Scale (GCS) score, systolic blood pressure (SBP), and respiratory rate (RR). <sup>13</sup> Physiologic data, however, can often be found to

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This original work will be presented from the podium at the 2017 annual meeting of EAST and has not been submitted or published elsewhere.

be missing on retrospective review rendering subsequent calculations impossible. <sup>14</sup>

The objective of the present investigation was to compare the performance of the GTOS model to that of TRISS and its revisions utilizing a sample from multiple high volume trauma centers in the United States not previously used in the PALLIATE Consortium's GTOS validation study. We hypothesized that the GTOS model would perform favorably in comparison to TRISS in the prediction of index admission mortality after geriatric injury.

#### PATIENTS AND METHODS

## Study Settings and Data Retrieval

This study was approved by the institutional review boards of all centers that submitted data. The generation of the TRISS and GTOS models has been previously described. 7,9-12 All subjects between the ages of 65 years and 102 years admitted to the trauma services of three geographically diverse PALLIATE consortium centers (University of Florida-Gainesville; Oregon Health and Science University in Portland, Oregon; and Wright State Physicians in Dayton, Ohio) between January 1, 2000, and December 31, 2013, were identified. These centers were specifically chosen as they had not contributed subjects to the GTOS validation study.<sup>7</sup> The original and validation samples of the GTOS studies were based on patients aged 65 years to 102 years. Thus, for age comparability, we constrained the sample for this study to be of the same age range, 65 years to 102 years. Originally, our age cutoff was chosen to prevent age outliers that were felt to be misreported to be included in our data. Those covariates needed to calculate the GTOS and TRISS were retrieved, namely, age, GCS, SBP, RR, calculated ISS, calculated RTS, units of PRBCs transfused in the first 24 hours after admission (dichotomized as yes/no), mechanism of injury (penetrating versus blunt), and mortality status for the index admission. Intubation status on arrival and individual Abbreviated Injury Scale (AIS) scores were also collected in the data set. Regarding mortality, all subjects in whom care was withdrawn regardless of the reason were categorized as in-hospital deaths. All data were deidentified for name and medical record numbers before submission to the central data coordinating center at UT Southwestern.

#### **Analysis**

The GTOS as developed by our Parkland core incorporates age (continuously measured), ISS, and PRBC transfusion at 24 hours postinjury (dichotomized as yes = 1, no = 0). As a first step, the GTOS was specified using the formula validated in the PALLIATE Consortium's previous work [GTOS = age + (ISS  $\times$  2.5) + 22 (if transfused PRBCs at 24 hours)].

TRISS uses the RTS, ISS, dichotomizes age such that younger than 55 years is 0 and 55 years or older is 1, and considers mechanism of injury. Four different versions of each the TRISS Blunt and Penetrating models were used for analysis based on coefficient updates (Table 1):

- (1) 1990: TRISS coefficients derived from the American College of Surgeons Major Trauma Outcome Study (MTOS). 11,15
- (2) 1995: Updated TRISS coefficients, also derived from the MTOS, based on AIS-90 updates. This is the current gold standard.<sup>10</sup>
- (3) 2010: Recommended TRISS coefficient updates derived from National Trauma Data Bank (NTDB) imputed data.
- (4) 2010: Recommended coefficient updates derived from the National Sample Project (NSP) imputed data. <sup>12</sup>

For the purposes of this analysis, TRISS was specified separately using estimated beta coefficients from 1990, <sup>11</sup> 1995, <sup>10</sup> and imputed beta coefficients from 2010. <sup>12</sup> As a second step, each score (resulting from each equation listed in Table 1) then became the sole predictor in a separate logistic regression model to estimate the probability of mortality.

We estimated the misclassification (error) rate, Brier score, <sup>16</sup> and area under the curve (AUC) in evaluating the predictive performance of GTOS versus all TRISS derivations as predictors of patient mortality in our sample. The misclassification (error) rate is the proportion of observations over the sample for which the predicted mortality and actual mortality disagree (hence, the correct classification rate or accuracy rate = 1 – misclassification rate). The Brier score is the weighted squared difference between the predicted probabilities and their observed response levels of mortality over all observations in the sample. The Brier score measures the accuracy of probabilistic predictions and ranges from 0 (perfect agreement in prediction) to 1 (perfect disagreement in prediction). The 95% binomial exact confidence

TABLE 1. Model Equations for GTOS and TRISS With Updated Beta Coefficients by Year and Database Used

Score	Model Equations		
GTOS	$Age + (2.5 \times ISS) + (22 \times PRBC)$		
TRISS <sub>B</sub> (1990), MTOS	$-1.3054 + (0.9756 \times RTS) + (-0.0807 \times ISS) + (-1.9829 \times age)$		
TRISS <sub>P</sub> (1990), MTOS	$-1.8973 + (1.0069 \times RTS) + (-0.0885 \times ISS) + (-1.1422 \times age)$		
TRISS <sub>B</sub> (1995), MTOS	$-0.4499 + (0.8085 \times RTS) + (-0.0835 \times ISS) + (-1.7430 \times age)$		
TRISS <sub>P</sub> (1995), MTOS	$-2.5355 + (0.9934 \times RTS) + (-0.0651 \times ISS) + (-1.1360 \times age)$		
$TRISS_B$ (2010), NTDB	$1.6494 + (0.0095 \times RR) + (0.4260 \times SBP) + (0.6307 \times GCS) + (-0.0795 \times ISS) + (-1.6216 \times age)$		
TRISS <sub>P</sub> (2010), NTDB	$-0.5757 + (0.1517 \times RR) + (0.5237 \times SBP) + (0.8310 \times GCS) + (-0.0872 \times ISS) + (-0.8714 \times age)$		
TRISS <sub>B</sub> (2010), NSP	$2.0281 + (-0.0691 \times RR) + (0.2470 \times SBP) + (0.6965 \times GCS) + (-0.0748 \times ISS) + (-1.6924 \times age)$		
TRISS <sub>P</sub> (2010), NSP	$0.3409 + (0.0615 \times RR) + (0.3397 \times SBP) + (0.8634 \times GCS) + (-0.0805 \times ISS) + (-1.2477 \times age)$		

GTOS used continuously measured age; TRISS models used a dichotomized age, which was operationalized as <55 years (coded 0) and  $\geq55$  years (coded 1); PRBC transfusion by 24 hours postinjury (dichotomized as yes = 1, no = 0); RTS given by  $\rightarrow$  RTS =  $(b1 \times RR) + (b2 \times SBP) + (b3 \times GCS)$ .

intervals were calculated for the AUC. All statistical analyses were carried out using SAS software, version 9.4 (SAS Institute, Inc., Cary, NC).

#### **RESULTS**

A total of 16,147 subjects met the initial inclusion criteria between the three centers, with 10,894 constituting the final study cohort as shown in the CONSORT diagram in Figure 1. A total of 4,304 patients were excluded for missing PRBC data at one single center, whereas a total of 393 patients from all centers were excluded for missing physiologic data. Many of our exclusions were in actuality missing more than one item of data, thus our diagram serves only as a visual estimation. Demographic data for the final sample both overall and by blunt and penetrating trauma subtypes can be found in Table 2. Comparison of misclassification rates, Brier scores, and AUCs for GTOS and all TRISS derivations are seen in Table 3.

#### **DISCUSSION**

GTOS and TRISS were found to perform similarly and accurately in predicting the probability of death for injured elders. GTOS has the advantage of having fewer variables to be collected, and no reliance on data collected in the emergency room (ER) or by other observers, such as physiologic data. Although a large volume of subjects were excluded at one center for a lack of data on PRC transfusion within 24 hours of admission, this is a data point that many centers have only recently begun to track in their trauma registries. Importantly, it is a data point that is not "lost" if not captured immediately and thus would not preclude calculation of the GTOS in real time on a given patient.

In 2015, You et al.<sup>17</sup> demonstrated that one of the main barriers in communication with families was their difficulty in accepting poor prognoses. Family members frequently overestimate their loved one's chance of survival or recovery, and it can be challenging for a physician to guide a family through the

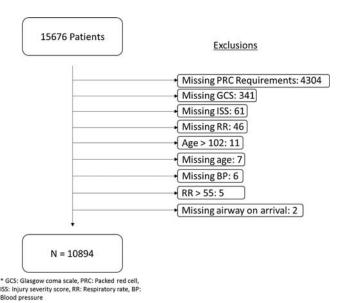


Figure 1. Consort diagram.

**TABLE 2.** Demographics

Demographics	Blunt	Penetrating	Overall
Total patients	10,744	150	10,894
Age (mean $\pm$ SD)	$78.4 \pm 8.1$	$74.7 \pm 7$	$78.3 \pm 8.1$
ISS (mean $\pm$ SD)	$11 \pm 8.4$	$10 \pm 9.8$	$11 \pm 8.4$
GCS (mean $\pm$ SD)	$14 \pm 2.8$	$12.4 \pm 4.7$	$14 \pm 2.8$
SBP (mean $\pm$ SD)	149.4 + 32	$128.6 \pm 46.2$	$149.1 \pm 33.3$
RR (mean $\pm$ SD)	$17.9 \pm 5$	$15.5 \pm 8.4$	$17.9 \pm 5.1$
No. intubated on arrival	864	35	899
No. receiving PRBC	329	15	344
No. deaths	725	30	755

decision-making process with anecdotal data alone. This is especially important because in the face of uncertainty, families and surrogate decision makers will often default to an aggressive treatment plan. Aggressive care does not always equal "better care," however, because patients and families often prefer palliative treatments once the burdens of care are clearly understood especially in the context of a poor prognosis. <sup>18</sup> Although GTOS is not meant to replace a goals of care discussion, it can be used as an important adjunct during conversation with patients and/or their family. Through the combination of both anecdotal experience and objective data, the physician can reinforce a potential poor outcome for the patient, which may limit unnecessary, aggressive care. In light of this hunger for accurate, objective prognostic information on the part of family members facing decisions with frequently irreversible consequences, the need for highperforming prognosis calculators is clear. The field of trauma care has a storied history of attempts to create injury severity and prognostic scoring systems in this vein.

# Historical Development of Injury Severity and Prognostic Scoring Systems

Baker et al. first developed the ISS, a score based on the AIS, in 1974. A new ISS (NISS) was later developed as a result of the many criticisms and drawbacks of the ISS. Using the top three most severe AIS injuries regardless of body region, the NISS has been found to be a superior predictor of mortality

**TABLE 3.** Comparison of Predictive Performance

Misclassification (Error) Rate	Brier Score	AUC (SE)	95% CI for AUC
0.065	0.0519	0.8440 (0.0079)	0.837 to 0.851
0.0515	0.042	0.8889 (0.0072)	0.883 to 0.895
0.1133	0.0832	0.8972 (0.0385)	0.837 to 0.941
0.0512	0.0414	0.8895 (0.0072)	0.883 to 0.895
0.12	0.0847	0.8969 (0.0385)	0.837 to 0.941
0.0629	0.0558	0.6861 (0.0118)	0.677 to 0.695
0.14	0.0937	0.8922 (0.0339)	0.831 to 0.937
0.062	0.0538	0.7243 (0.0113)	0.716 to 0.733
0.1467	0.0911	0.9025 (0.0308)	0.843 to 0.945
	0.065 0.0515 0.1133 0.0512 0.12 0.0629 0.14 0.062	(Error) Rate         Score           0.065         0.0519           0.0515         0.042           0.1133         0.0832           0.0512         0.0414           0.12         0.0847           0.0629         0.0558           0.14         0.0937           0.062         0.0538	(Error) Rate         Score         AUC (SE)           0.065         0.0519         0.8440 (0.0079)           0.0515         0.042         0.8889 (0.0072)           0.1133         0.0832         0.8972 (0.0385)           0.0512         0.0414         0.8895 (0.0072)           0.12         0.0847         0.8969 (0.0385)           0.0629         0.0558         0.6861 (0.0118)           0.14         0.0937         0.8922 (0.0339)           0.062         0.0538         0.7243 (0.0113)

compared with ISS. <sup>21,22</sup> Despite its superior performance, however, it has failed to be as widely embraced as the ISS. <sup>23</sup>

The Trauma Score (TS) was then developed by Champion et al.<sup>24</sup> in 1981 to be a scoring system based on physiologic data to aid in field triage either alone or in combination with the originally developed ISS. In 1989, the TS was revised (RTS) to improve outcome predictions, using only GCS, SBP, and RR as respiratory expansion, and capillary refill was removed from the original TS due to unreliability of their assessments.<sup>13</sup>

The next iteration in this effort to create an accurate prognostic model after trauma was the TRISS. Developed from the MTOS database, the TRISS method used ISS and added age and physiologic data via the TS to help with its predictive capabilities. TRISS was later modified replacing the TS with the RTS. The TRISS model used logistic regression to develop its beta coefficients which give weight to each of its specific variables. When originally developed, the TRISS coefficients were expected to continue to change over time as trauma care continued to evolve and (presumably) improve. 9 As the MTOS database grew and matured, the TRISS coefficients were revised in subsequent iterations with the most-recent 1995 values<sup>10</sup> generally serving as the criterion standard when performing TRISS calculations. In 2010, Schluter et al. 12 argued that updates to the beta coefficients could and should be based on the NTDB over the MTOS. In their analysis, they noted a divergence in performance of the TRISS model when comparing beta coefficients developed from imputed NTDB and NSP data sets versus those derived from the MTOS, concluding the coefficients should be updated based on imputed NTDB data. Although this work is intriguing, these 2010 TRISS coefficients do not seem to have been widely adopted thus driving our decision to use the 1995 "gold standard" beta coefficients as the basis for our primary comparison.

Another iteration in the quest for an improved prognostic model for trauma patients was A Severity Characterization of Trauma (ASCOT). Developed by Champion et al.<sup>11</sup> in 1990, ASCOT uses AIS scores, RTS, age, and penetrating versus blunt coefficients similar to TRISS. ASCOT, however, incorporates all AIS scores per body region, not just the maximum score as required for the ISS calculation, which can be cumbersome to collect and can lead to increased variability among observers. ASCOT also requires a much more complex mathematical calculation. As an aside, we attempted to retrospectively collect data for ASCOT calculations in the context of the present investigation, but we were disappointed to find that it was impossible after finding the additional AIS data to frequently be missing, and when present, difficult to sort for the required calculation. Although the ASCOT score has been found to be an improved predictor of outcome when compared with TRISS, 25 its complexity may have limited its widespread use.

The GTOS was developed from the perceived need for a reliable geriatric trauma prognosis calculator derived from a modern, exclusively geriatric data set. These efforts began with the Parkland group's demonstration that ISS and preinjury comorbidities alone were poor predictors of futility of care after geriatric trauma. <sup>26</sup> This work was followed by the creation of an actual scoring system, the GTOS, based on data from a single Level I academic trauma center. <sup>7</sup> After its development, the GTOS underwent external validation by Cook et al. <sup>8</sup> in the first

collaborative project from the newly created PALLIATE Consortium using data sets from the registries of four Level I trauma centers around the country. The GTOS was found to be an accurate predictor of mortality after geriatric trauma in the validation sample of over 18,000 patients.

#### **TRISS Versus GTOS**

The performances of both TRISS and the GTOS should be viewed in the context of their strengths and weaknesses. TRISS has the primary advantage of durability as it still constitutes the most well-known and well-accepted prognosis calculator for general trauma patients since its creation almost 30 years ago. As our results show, in a geriatric-specific cohort, the 1995 beta coefficients still perform very well with AUCs ranging from 0.8895 to 0.8869. Even with older beta coefficients or those developed from other data sets, the AUCs still performed respectably overall with a range from 0.6861 to 0.9025. Our results therefore suggest that TRISS has withstood the test of time, mitigating a criticism that it is based on data and outcomes from the 1980s and 1990s. 12,14 Additionally, although TRISS was derived from a data set inclusive of all ages in which age was just dichotomized at 55 years, it does not appear that the lack of a more nuanced approach to age or the inclusion of nongeriatric patients in the generation of its age coefficients hurt its performance for injured elders. These findings are in contradistinction to other work which has suggested that TRISS has high misclassification rates in those with severe trauma (ISS  $\geq$  20), patients with severe head injuries, and in patients older than 54 years.<sup>2</sup> Another potential advantage of TRISS is its ability to be calculated earlier than GTOS. GTOS requires knowledge of PRC transfusion by 24 hours, which could delay an accurate prognostic calculation for the provider to share until after the first day. Further, prospective assessment is required to determine TRISS's ability to provide an earlier and comparable prediction of mortality.

The primary limitation of TRISS is its reliance on first recorded physiologic data, because it can vary widely based on out of hospital care before arrival. <sup>14</sup> For example, first recorded GCS may differ depending on whether it was recorded before intubation in the field or upon arrival to the ER. A literature review of GCS by Gabbe et al.<sup>28</sup> in 2003 illustrated the poor predictability of GCS in a trauma setting; one of its major limitations being the inability of a provider to determine an accurate GCS in a patient who was intubated or sedated before arrival. In an effort to assess the uncertainty surrounding the interplay of prehospital intubation and first recorded GCS on the TRISS calculation, we performed a separate sensitivity analysis by replicating our logistic regression models excluding the 899 patients who arrived to the ER intubated. The results revealed that our basic pattern of findings regarding the predictive performance of the GTOS and all TRISS derivation models persisted (results not reported).

This reliance on the efforts of field and ER personnel to accurately and completely capture multiple variables is even more problematic because this data is subject to being missing-not-at-random in the sickest of patients as charting can be haphazard when caring for moribund patients. In our sample, about 400 patients were excluded from our analysis given incomplete physiologic data.

What this means for the caregiver approaching the bedside of an injured geriatric trauma patient wishing to calculate their probability of mortality using TRISS is that (a) they are reliant on the accuracy of other providers' reporting, and (b) if any of that reporting is absent, it is not recoverable and TRISS is therefore incalculable.

When compared with TRISS, GTOS has the primary advantage of being a single, quick formula which can be calculated within 24 hours of presentation. Additionally, given the free calculator available at www.palliateconsortium.com, it can be done easily and rapidly through an online platform. GTOS also has the major advantage of not being reliant on other providers' data collection efforts as the age, ISS, and transfusion variables can be easily obtained from information available in the chart at any point in the hospitalization once all of the injuries have been identified. Although many patients had to be excluded from the analysis due to the lack of information at one institution regarding transfusion at 24 hours after injury, this is an artifact of a retrospective review and would not be applicable to a provider seeking to calculate the GTOS in real time.

In the past, the Consortium has had to defend our a priori decision to choose the covariates of age, ISS, and a transfusion rather than utilize the process of a traditional stepwise logistic regression for covariate selection. This choice was pragmatic in nature, because these were covariates which would be universally available on all patients at 24 hours after injury. The high performance of the model, both here and in our previous work, bespeaks to the fact that this should not be viewed as a limitation. A further criticism has been our use of ISS versus NISS to augment the discriminatory ability of the model's ability to assess injury severity. As mentioned in prior work, there was concern that using a less familiar scoring system may affect widespread use of our developed model.

We freely concede that one primary limitation to the GTOS is the scope of information within its purview. Most notably, the GTOS is a measure of mortality risk only and can yield no prognostic information about predicted functional status, expected quality of life, or postdischarge mortality. These are key weaknesses because these endpoints are of great importance to family members making decisions about treatment regimens. This is an area of future work for our coalition.

#### **CONCLUSION**

In conclusion, we have found that the GTOS is an accurate prognosis calculator which performs comparably with the gold standard of TRISS. In doing so, it relies on fewer variables and no upstream providers. As such, it is a worthwhile tool to aid in physician-family discussions on geriatric trauma prognosis.

## **AUTHORSHIP**

T.D.M. participated in the literature search, study design, data interpretation, writing. A.P.E. participated in the study design, data collection, critical revision. S.C.B. participated in the study design, data interpretation, critical revision. K.J.B. participated in the study design, data interpretation, critical revision. B.J. participated in the study design, data collection, and critical revision. B.R.B. participated in the study design, data collection, and critical revision. B.R.B. participated in the study design, data collection, and critical revision. J.D.K. participated in the study design, data interpretation, and critical revision. M.J.M. participated in the study design, data interpretation, and critical revision. P.A.N. participated in the study design, data interpretation, and critical revision. P.A.N. participated in the study design, data interpretation, and critical revision. A.C. participated in the literature

search, data interpretation, and critical revision. J.I. participated in the literature search, data interpretation, and critical revision. S.E.W. participated in the study design, data interpretation, and critical revision. M.E.P. participated in the data interpretation and critical revision. R.L.R. participated in the data interpretation and critical revision. H.A.P. participated in the study design, data interpretation, and writing.

#### DISCLOSURE

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