



## Using the modified frailty index as a predictor of complications in adults undergoing transforaminal interbody lumbar fusion

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### ABSTRACT

**Objective:** To correlate the operative characteristics and complications of transforaminal lumbar interbody fusion (TLIF) to patient frailty status for the first time in a multicenter study.

**Methods:** Using the American College of Surgeons National Surgical Quality Improvement (ACS-NSQIP) database, all patients who underwent TLIF in 2015–2020 were filtered for their demographics, operative characteristics, and 30-day complication outcomes. Patients were stratified into 2 cohorts, low and high frailty, based on their modified frailty index 5 score. Univariate analysis was performed between the 2 cohorts for each collected variable, and multivariable analysis was performed to observe adjusted odds ratios (OR).

**Results:** The frail cohort experienced more unplanned readmission (4.3 vs 6.6 %,  $p < 0.001$ ). During hospital stays, the frail cohort experienced more overall complications (9.8 vs 13.8 %,  $p < 0.001$ ). In contrast to the low frailty cohort, the high frailty patients saw longer hospital stays (3.27 vs. 3.69 days,  $p < 0.001$ ). The high frailty group saw more discharges to an institution beside their home (89.6 vs 77.9 %,  $p < 0.001$ ). Rates of superficial and deep surgical site infection, organ space infection, wound dehiscence, reintubation, renal insufficiency, urinary tract infection, stroke, cardiac arrest, DVT, sepsis, and septic shock were not significantly different. Multivariable analyses showed high frailty status as an independent predictor of unplanned readmissions, major complications, and preventing discharge to home.

**Conclusions:** mFI-5 serves as an effective predictor of surgical outcomes following TLIF and independently predicts unplanned readmission, discharge to home, and major complications. Noninfectious outcomes were more likely to be significantly different between the high- and low frailty groups, while all infectious outcomes apart from superficial surgical site infection and pneumonia were not significantly different between the cohorts.

### 1. Introduction

Transforaminal lumbar interbody fusion (TLIF) is a widely used procedure for treating degenerative disk disease, spinal stenosis, and spondylolisthesis, typically performed less invasively than anterior approaches.<sup>1</sup> Like other fusion approaches, the TLIF aims to decompress neural structures, stabilize the spine, and promote the fusion of vertebral segments. The lateral approach of the TLIF offers many advantages, including minimal neural retraction, lower vascular complications, and avoidance of the midline scar, which is useful for revision cases.<sup>2,3</sup> However, the approach requires significant paraspinal muscle retraction and dissection, which has been shown to increase postoperative pain

and delayed rehabilitation.<sup>4,5</sup>

Inter-rater reliability and granularity concerns in assessment among patients with mild comorbidity levels have led to the increased use of frailty to stratify perioperative risk.<sup>6,7</sup> The first frailty index was a 70 variable score originating from the Canada Study of Health and Aging based on history and physical examination. However, the extensive nature of the score precludes it from widespread use and cannot be used in large multicenter database analyses.<sup>8,9</sup> The Modified Frailty Index (mFI) is a tool with a limited number of variables that can help stratify patients at risk for perioperative complications while also being calculable from large multicenter quality improvement data. Given the less invasive nature of the TLIF surgery, there is opportunity to offer this

**Abbreviations:** TLIF, Transforaminal Lumbar Interbody Fusion; mFI, Modified Frailty Index; NSQIP, National Surgical Quality Improvement Project.

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surgery to a more frail patient population that may not be candidates for more invasive procedures. This in turn stresses the importance of looking at TLIF outcomes stratified by frailty. There are limited studies investigating the use of mFI in TLIF patients, with a 2021 study from Moses et al looking at the correlation of mFI with complication rates, length of stay (LOS), disposition following discharge, and health-related quality of life (HRQOL) outcomes in a single center retrospective review of 198 patients undergoing single-level TLIF procedures between 2013-2018.<sup>9</sup> Their study showed a significant difference in the length of stay, complication rates, and disposition status among frail and not frail patients. While the study showed a positive association between frailty and complications, limitations of a single center study as noted by the authors include a relatively small sample size. A study by Garcia et al<sup>10</sup> looked at 30-day readmission risk factors among TLIF patients using the American College of Surgeons National Surgical Quality Improvement (ACS-NSQIP) database from 2011 to 2013 which found risk factors for readmission in TLIF surgery to be similar to risk factors in other lumbar spinal procedures but did not look at the mFI as a predictor of outcomes. To our knowledge, studies that investigate mFI specifically as a predictor of complications in this population are limited to single center studies. We present a retrospective multicenter cohort study of the NSQIP database from 2015 to 2020 studying demographic and outcome differences among not frail and frail (defined as an mFI score  $\geq 2$ ) patients undergoing TLIF surgery.

## 2. Methods

The NSQIP database started as a Veteran's Administration project and expanded to over 700 hospitals from all sectors across the United States. The database collects the hospitalization course and 30-day outcomes from deidentified electronic health records using trained Surgical Clinical Reviewers. Data accuracy and consistency are maintained by audits from the American College of Surgeons and by avoiding using billing codes as a proxy for clinical courses.

This study comprised NSQIP years 2015–2020 with elective TLIF procedures identified using CPT code 22630. ICD 9 and 10 codes were used to verify that surgeries were done for spinal pathologies.

Patient demographics included the patient's age, sex, and BMI. Comorbidities analyzed included diabetes status with oral agents or insulin, smoker in the last year, dyspnea, independent functional health status, history of severe COPD, congestive heart failure 30 days before surgery, hypertension requiring medication, acute preoperative renal failure, current dialysis status 30 days pre-op, disseminated cancer status, chronic steroid use, weight loss of 20 pounds or greater, and ASA status  $>2$ . Operative characteristics included discharge to home, clean wound class status, mean operation time, and total length of stay. Complications within 30 days of surgery included unplanned readmission, reoperation, superficial surgical infection, deep surgical infection, organ space infection, wound dehiscence, pneumonia, inability to wean off the ventilator, renal insufficiency, acute renal failure, urinary tract infection, stroke, cardiac arrest, myocardial infarction, perioperative blood transfusion, deep venous thrombosis, sepsis, and septic shock. Complications were split as major and minor complications. Major complications included reoperation, unplanned readmission, deep surgical infection, organ space infection, pneumonia, sepsis, septic shock, cardiac arrest, stroke, myocardial infarction, deep venous thrombosis, pulmonary embolism, unable to wean off ventilator, reintubation, and acute renal failure. Minor complications included superficial surgical infection, urinary tract infection, renal insufficiency, wound dehiscence, and perioperative blood transfusion.

### 2.1. Modified 5-Items Frailty Index (mFI-5)

The Modified 5-Items Frailty Index classified the frailty of our study population based on five factors: diabetes mellitus, hypertension, congestive heart failure, severe chronic obstructive pulmonary disease,

and dependent functional status. The group having an mFI of 0 or 1 was designated as the low frailty population, and the other group having an mFI score greater than or equal to 2 was designated as the high frailty population. Given the goal of the study to identify the effect of frailty on TLIF patient outcomes, the decision was made to group nonfrail (mFI 0) and pre-frail (mFI 1) together separate from frail (mfi 2+).

### 2.2. Statistical analysis

Data was analyzed using IBM SPSS (Version 28.1) with a statistical significance to be  $p \leq 0.05$ . Unpaired *t*-test and Fisher's exact test were performed to assess outcome significance for continuous and categorical variables, respectively, between the high and low frailty cohorts. Continuous variables were reported as a mean with a standard deviation. Categorical variables were reported as a proportion. Multivariate analysis was conducted to find adjusted odds ratios (OR) with confidence intervals (CI) of mFI on the outcomes of the two cohorts.

## 3. Results

### 3.1. Baseline demographic characteristics

10,587 patients who underwent TLIF surgery were identified from 2015 to 2020. 8574 patients fell into the low frailty group with mFI of 0 or 1; 2013 patients fell into the high frailty group with mFI  $\geq 2$  (Table 1)\*. The high frailty group had a statistically significant difference from the low frailty group with an older average age (64.8 vs. 58.6,  $p < 0.001$ ), higher BMI (33.1 vs. 30.3,  $p < 0.001$ ), and a higher proportion of male sex (48.8 vs. 45.9 %,  $p = 0.02$ ). The high frailty group also saw a greater prevalence of certain preoperative comorbidities than the non-frail cohort: diabetes requiring insulin or oral agents (84.9 vs. 3.5 %,  $p < 0.001$ ), dyspnea (10.2 vs. 3.6 %,  $p < 0.001$ ), independent functional status (92.3 vs. 99.4 %,  $p < 0.001$ ), COPD (17.0 vs. 1.4 %,  $p < 0.001$ ), CHF (1.6 vs. 0.0 %,  $p < 0.001$ ), hypertension (99.8 vs. 45.4 %,  $p < 0.001$ ), dialysis (0.5 vs. 0.1 %,  $p = 0.001$ ), chronic steroid use (6.2 vs. 4.1 %,  $p < 0.001$ ), and ASA status  $>2$  (79.1 vs. 44.2 %  $p < 0.001$ ). The two groups had no significant difference in smoking status ( $p = 0.61$ ), renal failure ( $p = 0.24$ ), cancer ( $p = 0.1$ ), and weight loss  $>20$  pounds ( $p = 0.24$ ).

**Table 1**

Patient and operative characteristics of the low and high frailty groups.

Patient Characteristics			
Variables	mFI = 0,1 (n = 8574)	mFI $\geq 2$ (n = 2013)	p-value
<b>Demographics</b>			
Age	58.6 $\pm$ 0.14	64.8 $\pm$ 0.22	<0.001
BMI	30.3 $\pm$ 0.07	33.1 $\pm$ 0.15	<0.001
Male sex	3936 (45.9 %)	982 (48.8 %)	0.02
<b>Comorbidities</b>			
Diabetes	301 (3.5 %)	1689 (84.9 %)	<0.001
Current smoker	1595 (18.6 %)	364 (18.1 %)	0.61
Dyspnea	309 (3.6 %)	206 (10.2 %)	<0.001
Independent status	8533 (99.4 %)	1857 (92.3 %)	<0.001
COPD	121 (1.4 %)	342 (17.0 %)	<0.001
CHF	4 (0.0 %)	33 (1.6 %)	<0.001
Hypertension	3897 (45.4 %)	1989 (99.8 %)	<0.001
Renal failure	3 (0.0 %)	2 (0.1 %)	0.24
Dialysis	11 (0.1 %)	11 (0.5 %)	0.001
Cancer	10 (0.1 %)	6 (0.3 %)	0.10
Chronic steroid use	353 (4.1 %)	124 (6.2 %)	<0.001
Weight loss $>20$ pounds	21 (0.2 %)	8 (0.4 %)	0.24
ASA $>2$	3784 (44.2 %)	1590 (79.1 %)	<0.001
<b>Operative Characteristics</b>			
Home discharge	7686 (89.6 %)	1568 (77.9 %)	<0.001
Clean wound class	8535 (99.5 %)	2002 (99.5 %)	1.00
Operation time	213.09 $\pm$ 1.06	213.99 $\pm$ 2.18	0.71
Total length of stay	3.27 $\pm$ 0.04	3.69 $\pm$ 0.12	<0.001

\*.

### 3.2. Operative characteristics

There was a significantly lower rate of home discharges in the high frailty group than in the low frailty group (77.9 vs. 89.6 %,  $p < 0.001$ ) and a longer length of stay (3.69 vs. 3.27 days,  $p < 0.001$ ). There was no significant difference between the groups in operation length ( $p = 0.71$ ) and proportion of clean wound class ( $p = 1.00$ ).

### 3.3. Outcome data

Among complications, the high frailty group had a statistically significant difference from the low frailty group with a higher rate of overall complications (13.8 vs. 9.8 %,  $p < 0.001$ , RR 1.41) and a higher rate of unplanned readmissions (6.6 vs. 4.3 %,  $p < 0.001$ , RR 1.53) (Table 2)†. Among specific complications, the high frailty group had a higher rate of pneumonia (1.2 vs. 0.5 %,  $p < 0.001$ , RR 2.40), pulmonary embolism (0.7 vs. 0.3 %,  $p = 0.003$ , RR 2.33), inability to wean off ventilator (0.3 vs. 0.1 %,  $p = 0.02$ , RR 3.0), acute renal failure (0.3 vs. 0.0 %,  $p < 0.001$ , Risk difference 0.3 %), myocardial infarction (0.8 vs. 0.2 %,  $p < 0.001$ , RR 4.0), and need for perioperative blood transfusion (7.6 vs. 5.5 %,  $p < 0.001$ , RR 1.38). Rates of superficial surgical site infection ( $p = 0.05$ ), deep surgical site infection ( $p = 0.6$ ), organ space infection ( $p = 0.11$ ), wound dehiscence ( $p = 0.37$ ), reintubation ( $p = 0.17$ ), renal insufficiency ( $p = 0.68$ ), urinary tract infection ( $p = 0.17$ ), stroke ( $p = 0.26$ ), cardiac arrest ( $p = 0.68$ ), DVT ( $p = 0.55$ ), sepsis ( $p = 0.28$ ), and septic shock ( $p = 0.53$ ) were not significantly different between the high and low frailty groups.

Multivariate analysis was performed to observe adjusted odds ratios (OR) of outcomes among the two cohorts (Table 3)‡. Adjusting for age, sex, BMI, dialysis, chronic steroid use, ASA class >2, mFI>2 had an adjusted OR for any complication: 1.08 (CI:0.93–1.26,  $p = 0.33$ ), major complication: 1.32 (CI:1.10–1.58,  $p = 0.003$ ), minor complication: 1.02 (CI: 0.76–1.35,  $p = 0.92$ ), home discharge: 0.66 (CI: 0.58–0.76,  $p < 0.001$ ), and readmission: 1.29 (CI:1.04–1.60,  $p = 0.02$ ).

## 4. Discussion

We present a 5-year retrospective multicenter cohort study of TLIF patients, looking at the demographic and outcome differences in low

**Table 2**  
Complications between the low and high frailty groups.

Variables	mFI = 0,1 (n = 8574)	mFI ≥ 2 (n = 2013)	p-value
Unplanned readmission	365 (4.3 %)	132 (6.6 %)	<0.001
Reoperation	257 (3.0 %)	71 (3.5 %)	0.22
Any complication	838 (9.8 %)	278 (13.8 %)	<0.001
Superficial surgical infection	95 (1.1 %)	33 (1.6 %)	0.05
Deep surgical infection	44 (0.5 %)	8 (0.4 %)	0.60
Organ space infection	36 (0.4 %)	14 (0.7 %)	0.11
Wound dehiscence	24 (0.3 %)	8 (0.4 %)	0.37
Pneumonia	41 (0.5 %)	25 (1.2 %)	<0.001
Reintubation	15 (0.2 %)	7 (0.3 %)	0.17
Pulmonary embolism	23 (0.3 %)	15 (0.7 %)	0.003
Unable to wean off ventilator	7 (0.1 %)	6 (0.3 %)	0.02
Renal insufficiency	7 (0.1 %)	2 (0.1 %)	0.68
Acute renal failure	1 (0.0 %)	6 (0.3 %)	<0.001
Urinary tract infection	111 (1.3 %)	34 (1.7 %)	0.17
Stroke	8 (0.1 %)	4 (0.2 %)	0.26
Cardiac arrest	7 (0.1 %)	2 (0.1 %)	0.68
Myocardial infarction	20 (0.2 %)	17 (0.8 %)	<0.001
Perioperative blood transfusion	469 (5.5 %)	153 (7.6 %)	<0.001
Deep venous thrombosis	31 (0.4 %)	9 (0.4 %)	0.55
Sepsis	38 (0.4 %)	13 (0.6 %)	0.28
Septic shock	12 (0.1 %)	4 (0.2 %)	0.53

†

**Table 3**  
Multivariate outcomes analysis.

Outcome	Adjusted Odds Ratio
Any complication	1.08 (CI:0.93–1.26, $p = 0.33$ )
Major complication	1.32 (CI:1.10–1.58, $p = 0.003$ )
Minor complication	1.02 (CI: 0.76–1.35, $p = 0.92$ )
Home discharge	0.66 (CI: 0.58–0.76, $p < 0.001$ )
Readmission	1.29 (CI:1.04–1.60, $p = 0.02$ )

\*Adjusted for age, BMI, bleeding disorder, and ASA Class >2.

‡

versus high frailty patient populations. As expected, there was a significant difference between the two groups in complications, unplanned readmission, total length of stay, and discharge to home. Despite a significant difference in COPD status, dyspnea, and hypertension between the two groups, there was no significant difference in smoking status. This may be since hypertension and COPD status were part of the mFI score, placing patients with two or more comorbidities in the high frailty group. Alternatively, this may be due to the high prevalence of smoking as compared to COPD and other comorbidities associated with smoking. Congestive heart failure, diabetes mellitus, and independent functional status were characteristics used in the 5-item mFI and were also significantly higher in the high frailty group. Dyspnea, dialysis, chronic steroid use, and ASA status>2 were the new comorbidities not in the mFI-5 found to be of significant difference between the high and low frailty groups. By magnitude the largest comorbidity difference between the two groups was the prevalence of diabetes, with 3.5 % in the low frailty group and 84.9 % in the high frailty group. However, flipping the analysis looking for comorbidities as a predictor of frailty may yield more granular insights into the drivers of frailty and as a result complication. Further avenues for analysis could involve performing independent analysis of specific variables within the mFI, as well as different combinations of 4/5 of the mFI variables to identify the strongest and weakest predictors of individual complications within the mFI.

There was no significant difference in the low and high frailty groups in superficial surgical infections, deep surgical infections, organ space infections, postoperative urinary tract infections, sepsis, and septic shock, suggesting little to no relationship between frailty and infectious outcomes. There was, however, a significant difference in the populations' incidence of pneumonia. Significant differences were found in the incidence of pulmonary embolism, acute renal failure, and myocardial infarction, suggesting that while there were not as many differences in infectious outcomes between the populations, the high frailty group's incidence of noninfectious postoperative complications was the larger driver of the difference in overall complication and unplanned readmission rates between the two groups. Multivariate analysis of the two cohorts showed no significant difference in overall complication or minor complication rates. However, it did show high frailty status as an independent predictor of major complications, unplanned readmission, and preventing discharge to home.

Studies looking at the clinical significance of frailty as a preoperative stratification tool have had varied conclusions. In large database center studies such as this one, the statistical significance of a difference in length of stay (3.69 vs. 3.27 days,  $p < 0.001$ ), a difference of 10 h, is of limited clinical significance. However, the difference in the low frailty and high frailty groups' home discharge rates (77.9 vs. 89.6 %,  $p < 0.001$ ) can have clinical implications. Existing literature has shown a positive relationship between complications and increased frailty scores in spine surgery patients overall, however such studies look at a heterogeneous population with different risk profiles and baseline complication rates. In our review of the literature, the only studies looking at TLIF outcomes as they related to frailty were single center studies with limited sample sizes. Furthermore, the multivariate analysis

performed in this study is the first to separate high and low frailty TLIF patients, rather than use the mFI as a continuous variable. Analyses that use the mFI as a linear variable may provide less useful clinical value as it is less clear what value the score provides at middle ranges of the scale. Findings that show large differences between completely healthy and severely frail patient populations may not provide additional value in clinical decision making as the decision is already heuristically clear. Results of this study found frailty as an independent predictor of adverse outcomes while defining high frailty patients with an mFI of  $\geq 2$ , which was a substantial 19 % of the study population, leaving 81 % of patients as nonfrail or prefrail. Finding positive results in a cutoff value encompassing such a large amount of the study population may prove to be useful in stratifying an equivocal zone of patients with several comorbidities where decision making is not as clear and is doubly important in a less invasive procedure such as the TLIF where additional emphasis to avoid adverse outcomes is in part why the procedure was selected originally.

Methods used to quantify frailty vary significantly between studies, even within the field of spine surgery. Studies have used pathology-specific indices, including the Adult Spinal Deformity Frailty Index (ASD-FI), the Cervical Deformity Frailty Index, the Spinal Frailty Index, and the Metastatic Spinal Tumor Frailty Index.<sup>11–14</sup> Other generalized frailty scales used include the five and 11-item Modified Frailty Indices, the FRAIL scale, the Risk Analysis Index, and the Hopkins Frailty Index.<sup>15–18</sup> The heterogeneity in the indices used and outcomes of various surgical procedures makes it difficult to compare across specialties or even across procedures to measure the impact frailty has as an outcome predictor. However, in the systematic review of frailty tools used in neurosurgical procedures by Paznoikas et al, the mFI was the most used, being the frailty index of choice in 13/25 of the papers included in the systematic review.<sup>13</sup> In multiple neurosurgical studies, the mFI predicts frailty independent of age and comorbidity indices. A study by Cloney et al found the mFI to be an independent predictor of overall complication in geriatric patients undergoing glioblastoma resection.<sup>6,19</sup> The strength of the mFI as a tool for frailty in both clinical and academic settings cannot be understated. Unlike other tools, which require long questionnaires and have upwards of 40 variables, the streamlined nature of the mFI allows it to be recommended for use in clinical practice more easily. It is more readily used in academic studies, strengthening the evidence for the mFI as an independent predictor of complications in various surgical settings.

Bodies of work including this study that show frailty as an independent predictor of outcomes strengthen the literature and recommendation around a formal evaluation of frailty status in the clinical setting. Currently heuristic evaluation including age, BMI, a number of comorbidities, and “the eyeball test” is used in practice to evaluate surgical candidates. The introduction of a standardized, data supported metric like the mFI may better help stratify operative and nonoperative cases, including in older adults that have good functional status and excluding younger adults with poor status. However, while studies like the retrospective database review shown here show a clear relationship between frailty and complication among patients undergoing surgery, it is unclear the direction of effect the use of a frailty indicator in practice would have on surgical patient selection.

In summary, the mFI is a widely used frailty index that predicts outcomes, including complication, mortality, and readmission, among others, in the existing literature. Our study looking at the role of the mFI in TLIF procedures has shown that the mFI is an important predictor of complications and an independent predictor of major complications, unplanned readmissions, and preventing discharge to home.

#### 4.1. Limitations

The strength of the NSQIP database comes from its large size and dedicated data collectors. While it has been used in many neurosurgical studies, findings from Rolston et al<sup>20</sup> showed that there may be

inconsistencies between procedure and postoperative diagnosis coding that cannot exist in the same case, suggesting inaccuracies not accounted for in studies looking at the NSQIP. Furthermore, measuring outcomes for only 30 days may significantly limit the insight drawn from the study of spinal recovery since some measures, such as pain and functional status, may take longer to improve.

The mFI has been used in several neurosurgical studies, showing a general relationship between increased frailty and increased complication rates.<sup>21–24</sup> Studies have shown frailty indexes are stronger predictors of 30-day postoperative mortality, 1-year mortality, and discharge to a nursing facility than the ASA classification.<sup>25–27</sup> However, literature has also shown conflicting results regarding the predictive power of the mFI for individual complication risk among specific types of spine surgery.<sup>28</sup> To our knowledge, no prospective studies examine the relationship between frailty and major and minor complications in patients undergoing spine surgery.<sup>29</sup>

A relatively unique limitation to the field of spine surgery is over the relationship between frailty and the need for spine surgery, including less invasive procedures like the TLIF. Frailty broadly is defined as a reduction in physiologic function, and independent functional status is an important marker used in many frailty indices, including the mFI. The need for surgery in degenerative spine disease is often defined as a reduced functional status that can be improved by surgery.<sup>30</sup> A potential avenue for further investigation would be to control for functional status when comparing frail patients undergoing spine surgery, specifically given the direct interaction between the pathology and the variable that diabetes mellitus, hypertension, COPD, and CHF do not have.

## 5. Conclusions

This 5-year multicenter retrospective NSQIP database study showed the impact of the mFI-5 score as a predictor of complication and other adverse outcome variables in the TLIF surgery population. As mFI becomes a more widely studied tool for stratifying perioperative risk among patients, more large multicenter database analyses like the one presented here will prove useful to achieve greater granularity in analysis. Furthermore, the TLIF procedure is increasing in popularity, and demand for outcome data around perioperative complications will prove useful in patient education. This study shows the independent predictive value of frailty status for home discharge, readmission, and major complications which suggests it may serve as a useful metric clinicians can use in preoperative ambulatory and inpatient settings. With increasing literature and bodies of work like this study showing frailty as a significant predictor of postoperative complications, methods to improve frailty status, such as “prehabilitation,” may be more important in the surgeon’s preoperative plan.

## CRedit authorship contribution statement

**Momin M. Mohis:** Writing – review & editing, Writing – original draft, Validation. **Simon G. Ammanuel:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Cuong P. Luu:** Writing – review & editing, Writing – original draft, Validation. **James A. Stadler:** Writing – review & editing, Supervision, Project administration.

## Declaration of Competing interest

There are no declarations of interest to disclose.

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