Surgical Site Infection after Colon Surgery: National Healthcare Safety Network Risk Factors and Modeled Rates Compared with Published Risk Factors and Rates

Heather Young, MD, Bryan Knepper, MPH, MSc, Ernest E Moore, MD, FACS, Jeffrey L Johnson, MD, FACS, Phillip Mehler, MD, Connie S Price, MD

The Inpatient Prospective Payment System stipulates that hospitals must report rates of colon surgical site infection (SSI) to the National Healthcare Safety Network (NHSN) beginning in 2012, and colon SSI rates will be linked to reimbursement beginning in 2014. For the last decade, the use of pay-for-performance has been promoted in the belief that economic incentives and penalties can accelerate improvements in the quality and outcomes of care. Without an appropriate risk-stratification model, surgeons and hospitals would be penalized for performing operations on patients at higher risk for SSI developing, including those with more severe surgical disease or comorbid conditions. Therefore, pay-for-performance can result in unintended outcomes, such as the exclusion of severely ill patients from care.

NHSN used logistic regression to develop procedure-specific risk-adjustment models; this replaces the older National Nosocomial Infection Surveillance index system. This new tool is based largely on nonmodifiable patient and procedure factors and predicts the expected rate of SSI after various surgical procedures. The procedures and variables included in the model-building process were voluntarily reported from 2006 to 2008 in emergent, urgent, and elective settings. Formal assessment of data accuracy was not performed. Eight risk factors were found to be important in the development of colon SSI, including decreasing age (odds ratio [OR] = 0.98 for each 10-year increase; 95% CI, 0.96–1.00), general anesthesia (OR = 1.47; 95% CI, 1.02–2.12), American Society of Anesthesiologists (ASA) score >2 (OR = 1.35; 95% CI, 1.26–1.46), duration of surgery (OR = 1.03 for each 10-minute increase; 95% CI, 1.02–1.03), open procedure (OR = 1.14; 95% CI, 1.04–1.25), lack of medical school affiliation (OR = 1.15; 95% CI, 1.06–1.25), hospital bed size (OR = 1.30 for >500 beds; 95% CI, 1.19–1.41), and wound class (OR = 1.10 for contaminated or dirty procedures; 95% CI, 1.01–1.19). The c-statistic for this model was 0.59.

As the stakes of hospital reputation and financial reimbursement are both imminent and high, we sought to compare and contrast the NHSN risk-adjustment model for colon surgery with published rates and risk factors for colon SSI. Our hypothesis is that the database used by NHSN to develop the colon SSI risk-adjustment model is limited by the voluntary-reporting strategy and by the use of variables of convenience, making the risk factors for colon SSI and the expected rates of colon SSI generated by NHSN inaccurate for most surgical centers.

To test this hypothesis, we review the published rates of colon SSI in reputable high- and moderate-quality articles, calculate a weighted mean based on sample size, and compare these rates with expected SSI rates produced by NHSN models of highest- and lowest-risk patient populations. We also examine risk factors for colon SSI in the published literature and compare these with variables used in the risk-adjusted NHSN model.

METHODS

Quality measurement

The quality of literature was assessed using a modified Cochrane Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system. Studies earned points based on the following criteria: study design (randomized controlled trial, +4 points; prospective cohort, +2 points), adequate control of confounding (+1 point),
multicenter design (+1 point), and sample size (>250, +1 point; >500, +2 points). Points were removed for serious limitations to study quality (−1 point), lack of generalizability (−1 point), and imprecise or sparse data (−1 point). Studies that earned at least 4 points were deemed as high quality; 3 points were moderate quality; 1 to 2 points were low quality; and 0 points were very low quality. Multicenter design and sample size are not part of the original GRADE system; instead, dose-response gradient and magnitude of effect are the included variables. As this clinical review is not focused on the effect of a treatment or intervention, these modifications were made to ensure that the point system was pertinent to the review subject.

Inclusion and exclusion criteria
A PubMed literature review was performed to determine published rates and risk factors for SSI after colon surgery. Search terms were colon surgery and surgical site infection or SSI between January 1, 2001, and August 15, 2011. A second PubMed search using terms colon, surgery, and infection was performed for a 5-year period; no additional articles that met inclusion criteria were found. We believe that all pertinent articles were located; if an article were erroneously omitted, it was a chance, unintentional occurrence that was not meant to skew the results of this article.

Exclusion criteria were case reports or series, review articles or meta-analyses, non-English-language publications, and nonhuman studies. Additionally, publications were excluded if they did not use CDC criteria to define SSI, did not report either rates or risk factors for colon SSI, failed to separate rates and risk factors for colon SSI from other surgical procedures, and received a GRADE score <3 (i.e., low or very low quality).

Rate calculation
Rates of colon SSI were taken from all studies that met inclusion criteria. For studies that reported a range of SSI rates (e.g., control/intervention groups in randomized controlled trials, left vs right colon surgery, etc), the overall SSI rate was used. The largest study, Kao and colleagues, reported a risk-adjusted mean SSI rate; the actual SSI rate was equal to the risk-adjusted SSI rate in this particular study. We multiplied the SSI rate by the number of patients in each individual study. These calculated values for each study were added together and then divided by the total number of patients in all studies to produce a mean SSI rate in the published literature.

Colon SSI risk modeling through NHSN
Denver Health Medical Center performs routine colon SSI surveillance and voluntarily reports data to NHSN. To determine the colon SSI rate predicted by NHSN, a random sample of 100 patients who underwent colon surgery at this institution were modeled into highest- and lowest-risk cohorts. Procedures were de-identified and original values for the NHSN risk factors were modified to either maximize or minimize SSI risk. Variables included age, surgery duration, ASA score, laparoscope use, wound class, anesthesia type, number of beds in the hospital, and medical school affiliation; they were stratified according to the model for colon surgery outlined by Mu and colleagues.

A sensitivity analysis was performed to ascertain the range of SSI expected by NHSN modeling. Age and duration of surgery were chosen as variables to perform the sensitivity analysis because the expected SSI rate changes with each 10-unit increase or decrease of the variable. The lowest-risk colon SSI patients were modeled by age 65 or 75 years old, surgery duration of 34 and 54 minutes, laparoscopic procedure, ASA class 1, spinal anesthesia, wound class “clean-contaminated,” hospital bed size ≤500, and major medical school affiliation. Seventy-five years old was chosen as the highest age because it is the current mean life expectancy for an American male. The duration of lowest-risk operations was chosen based on the 10th and 25th percentiles of the original 100 randomly selected colon operations. The highest-risk SSI patients were modeled by age 18 or 28 years old, surgery duration of 187 and 219 minutes, open procedure, ASA class 5, general anesthesia, and wound class “dirty,” hospital bed size >500, and no medical school affiliation (Table 1). The duration of the highest-risk operations was chosen as the 75th and 90th percentile of the original 100 randomly selected colon surgery procedures. Four different risk profiles of 100 for the highest-risk and 4 different risk profiles of 100 procedures for the lowest-risk cohorts were uploaded into NHSN, and the number of expected SSI for each cohort and each risk profile was calculated using Standardized Infection Ratio—All SSI Data by Procedure in NHSN version 6.6 (CDC, Atlanta, GA).

Comparison of rates
Two separate comparisons of colon SSI rates were performed. Published rates were compared with NHSN-modeled SSI rates using bootstrap resampling analysis to reduce any bias that might have been caused by uneven sampling. Bootstrap resampling is performed by random
Monte-Carlo sampling of observations from the original dataset with replacement to construct a specified number of novel datasets, all of which are equal in size to the original dataset. For this analysis, 10,000 random bootstrap samples were drawn with replacement from the original dataset of published rates and the NHSN-modeled highest- and lowest-risk cohorts. These data were compared with the weighted mean of published colon SSI rates. The second comparison was between colon SSI rates reported in studies including elective procedures to studies, including all emergent, urgent, and elective procedures. Both comparisons were evaluated using a 2-tailed t-test of means. All analyses were conducted using SAS version 9.3 (SAS Institute).

Risk factors

Studies that met inclusion criteria were assessed for their report of independent nonmodifiable risk factors associated with SSI. Those that provided a multivariate analysis of colon SSI alone were included in the analysis.

RESULTS

The PubMed search yielded 173 articles; 16 articles were included in the literature review (Fig. 1). After assessing the quality of each study, 5 additional studies with either low or very low evidence quality were excluded. Of the final 11 articles, 2 studies were randomized controlled trials, 7 were prospective cohort studies, and 2 were retrospective cohort studies. All articles published rates and 5 published multivariate analysis of risk factors for colon SSI. Six studies included only elective, lower-risk patients, and 5 studies included all patients undergoing colon surgery.

The weighted mean colon SSI rate for all included articles was 11.4% (95% CI, 9.1–13.6%) (Table 2). There were no identifiable trends in colon SSI rates over time in the published literature (Fig. 2). Modeled rates of SSI predicted by NHSN ranged from 1.9% in the lowest-risk cohort to 11.7% in the highest-risk cohort (weighted mean 5.5%; 95% CI, 2.8–8.3%) (Table 1). There was a significant difference in the bootstrap analysis between the mean of the NHSN-modeled and the weighted mean of the published SSI rates (p = 0.008). Studies that included all colon operations had a weighted mean of 11.7% (95% CI, 7.9–15.4%), 5-9 and those that included only elective procedures had a weighted mean of 9.4% (95% CI, 3.6–15.3%).10-15 In the bootstrap analysis, the difference between colon SSI in all operations vs elective operations was nonsignificant (p = 0.20).

High- and moderate-quality studies supported 4 of the 8 NHSN risk factors (Table 3): increasing wound class,6,11 increasing operative time,6,7,11 open vs laparoscopic procedure,6,7,10 and increasing ASA score.6,11 Serra-Aracil and colleagues10 found that National Nosocomial Infection Surveillance risk index to be a risk factor for SSI after colon surgery. National Nosocomial Infection Surveillance is a simple risk-stratification tool that accounts for ASA class, wound class, operative time, and use of a laparoscope. In addition, high-quality studies identified emergent procedures,6 male sex,6 specific surgeons or hospitals,6 creation of an ostomy,10 and total/subtotal colectomy10 as risk factors for colon SSI. Studies of moderate quality found closure of an ostomy,12 higher body mass index,7 and transverse colectomy7 to be risk factors for colon SSI.

Of the remaining 4 NHSN risk factors, 2 are contradicted by the published literature. A high-quality study showed that increasing age (rather than decreasing) was a risk factor for colon SSI.6 In addition, smaller hospital size (rather than larger) was associated with an increase in colon SSI in the bivariate analysis of a high-quality study.10 The remaining 2 risk factors (ie, medical school affiliation and

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### Table 1. Expected Risk of Colon Surgical Site Infection Predicted by the National Healthcare Safety Network Risk-Adjustment Model

<table>
<thead>
<tr>
<th>NHSN risk factors</th>
<th>Lowest risk</th>
<th>Highest risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentile*</td>
<td>10th</td>
<td>25th</td>
</tr>
<tr>
<td>Age, y</td>
<td>65</td>
<td>75</td>
</tr>
<tr>
<td>Duration, min</td>
<td>34</td>
<td>34</td>
</tr>
<tr>
<td>Modeled SSI rate</td>
<td>2.1%</td>
<td>1.9%</td>
</tr>
<tr>
<td>ASA class</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Wound class</td>
<td>Clean-contaminated</td>
<td></td>
</tr>
<tr>
<td>Anesthesia</td>
<td>Spinal</td>
<td></td>
</tr>
<tr>
<td>Laparoscope</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Medical school affiliation</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Hospital bed size</td>
<td>≤500</td>
<td></td>
</tr>
</tbody>
</table>

*Percentile of 100 randomly selected procedures performed at our institution.

ASA, American Society of Anesthesiologists; NHSN, National Healthcare Safety Network; SSI, surgical site infection.
general anesthesia) were neither supported nor contradicted by the published literature.

DISCUSSION
A significant difference was found between the published rates of colon SSI and the modeled expected rates from NHSN. Although SSI rates in the studies included in this review ranged from 5.4%\textsuperscript{15} to 23.2%,\textsuperscript{10} the highest-risk modeled colon SSI rates could not be driven higher than 11.7%. This review is not the first to suggest that NHSN underestimates the expected rate of colon SSI. Despite an intensive hospital-wide intervention to improve surgical

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{flowchart.png}
\caption{Flowchart for colon surgical site infection literature search.}
\end{figure}
core measures compliance, Wick and colleagues\textsuperscript{16} found their rates of SSI after small and large bowel operations to be higher than the nationally reported rates. Similarly, Kobayashi and colleagues\textsuperscript{17} reported that their rates of SSI in the first 6 days after colon surgery were equal to the nationally reported rates of SSI in the 30 days after colon surgery.

Four of the 8 risk factors for colon SSI in NHSN had high-quality evidence to support them. Two risk factors, general anesthesia and medical school affiliation, lacked support in the published literature, and 2 risk factors (ie, age and hospital size) were contradicted by the literature. In the NHSN model for colon surgery SSI risk, a 10-year increase in age is associated with a decrease in overall SSI risk (OR = 0.98; 95% CI, 0.96–1.00).\textsuperscript{3} For example, the NHSN model considers a 28-year-old patient to have a higher risk of colon SSI than an 85-year-old patient. In contrast, increasing age has been cited as a risk factor for SSI in numerous other types of operation in the published literature, including spine surgery,\textsuperscript{18,19} total hip arthroplasty,\textsuperscript{20,21} inguinal node dissection,\textsuperscript{22} and general surgery.\textsuperscript{23,24} Age can predispose patients to SSI because of comorbid medical conditions, nutritional deficiencies, physiologic changes in the cardiovascular or pulmonary systems, or alterations in the immune response.\textsuperscript{23,25}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure2.png}
\caption{Data collection periods and colon surgical site infection rates in high- and moderate-quality published literature, 1995–2011. Note that Shimizu 2010\textsuperscript{14} did not report data collection period.}
\end{figure}

\begin{table}
\centering
\caption{Published Rates of Colon Surgical Site Infection, Weighted by Number of Subjects}
\begin{tabular}{lllll}
\hline
First author & Year & Quality of evidence & n        & Study type         & SSI, %  \\
\hline
Hübner\textsuperscript{c} & 2011 & High       & 2,393 & Prospective cohort & 17.9  \\
Kao\textsuperscript{1} & 2011 & High       & 18,455 & Prospective cohort & 10.5  \\
Serra-Aracil\textsuperscript{10} & 2011 & High       & 383  & Prospective cohort & 23.2  \\
Degrate\textsuperscript{8} & 2010 & Moderate   & 233  & Prospective cohort & 13.3  \\
Englesbe\textsuperscript{13} & 2010 & High       & 1,553 & Prospective cohort & 9.1   \\
Shimizu\textsuperscript{14} & 2010 & High       & 91   & Randomized controlled trial & 7.7  \\
Ishibashi\textsuperscript{11} & 2009 & High       & 275  & Randomized controlled trial & 5.8  \\
Hawn\textsuperscript{7} & 2008 & High       & 1966 & Retrospective cohort & 12.0  \\
Imai\textsuperscript{7} & 2008 & Moderate   & 571  & Retrospective cohort & 21.2  \\
Konishi\textsuperscript{12} & 2006 & Moderate   & 339  & Prospective cohort & 9.4   \\
Tang\textsuperscript{15} & 2001 & Moderate   & 883  & Prospective cohort & 5.4   \\
\hline
Weighted mean SSI & — & —         & 27,142 & — & 11.4  \\
\hline
\end{tabular}
\textsuperscript{SSI, surgical site infection.}
\end{table}
The NHSN logistic regression model is a statistically rigorous method based on data from >62,000 patients, which is certainly more patients than we could obtain from moderate- and high-quality studies using CDC methods in the published literature. However, there are inherent flaws in the algorithm, which in turn might explain the discrepancy between published and expected SSI rates and risk factors. The NHSN models were developed from data reported voluntarily from 2006 to 2008. They are admittedly variables of convenience; colon surgery was not one of the 5 procedures for which procedure-specific supplemental variables were reported. Entry of variables can be biased by both the voluntary reporting strategy, as well as the ease of data capture. Accuracy of the data entry into NHSN has never been confirmed. In addition, Mu and colleagues published c-statistics to describe how well the logistic regressions predict SSI in each of the surgical procedures. Interestingly, colon surgery is among the poorest predictive validity, with c-score of 0.59. This indicates a model fit only somewhat better than chance.

Strengths of this review are the use of only moderate- and high-quality studies as measured by the modified GRADE quality score and the inclusion of only those studies that define SSI and colon surgery by CDC definitions. However, given the strict inclusion criteria, only 11 studies could be included for colon SSI rates and risk factors. Several well-designed, multicenter studies either used nonstandard definitions or combined colon with rectal or small bowel operations and so their results were ineligible for this analysis. The NHSN risk factors of open procedures, increasing surgery duration, increasing wound class, and increasing ASA score were supported by some of these studies. Other risk factors found in these studies included obesity, early reintervention for a noninfectious complication of surgery, perioperative blood transfusion, smoking, diabetes, and inflammatory/infectious surgical indications.

A limitation of this review is that risk factors in specific subcategories of colon surgery are not explored; the category of colon surgery encompasses a wide variation in incisions, procedures, and extent of disease. Some authors have distinguished differing risk factors associated with right vs left hemicolectomy or with surgery for adenocarcinoma vs for diverticular disease. This might explain, in part, why risk factors in the published literature differ from each other. An additional limitation of this study is that our calculation of the published colon SSI rate is an underestimate; the largest study included in this review reported rates of superficial incisional SSI only, and another reported superficial and deep incisional, but not organ/space, SSI. It is likely that the actual rate of colon SSI is higher.

Table 3. Risk Factors for Colon Surgical Site Infection, National Healthcare Safety Network Procedure-Specific Variables, and Supporting Published Literature

<table>
<thead>
<tr>
<th>SSI risk factor</th>
<th>NHSN</th>
<th>High- and moderate-quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound class (increasing)</td>
<td>X</td>
<td>Hübner, 2011&lt;sup&gt;6&lt;/sup&gt; Serra-Aracil, 2011&lt;sup&gt;10&lt;/sup&gt;</td>
</tr>
<tr>
<td>Operative time (increasing)</td>
<td>X</td>
<td>Hübner, 2011&lt;sup&gt;6&lt;/sup&gt; Serra-Aracil, 2011&lt;sup&gt;10&lt;/sup&gt; Ishibashi, 2009&lt;sup&gt;11&lt;/sup&gt; Imai, 2008&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td>Open procedure (vs laparoscopic)</td>
<td>X</td>
<td>Hübner, 2011&lt;sup&gt;6&lt;/sup&gt; Serra-Aracil, 2011&lt;sup&gt;10&lt;/sup&gt; Imai, 2008&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td>ASA class (increasing)</td>
<td>X</td>
<td>Serra-Aracil, 2011&lt;sup&gt;10&lt;/sup&gt; Ishibashi, 2009&lt;sup&gt;11&lt;/sup&gt;</td>
</tr>
<tr>
<td>Medical school affiliation</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>General anesthesia</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>No. of hospital beds (more beds is higher risk)</td>
<td>X</td>
<td>Contradicted by Serra-Aracil, 2011&lt;sup&gt;10&lt;/sup&gt;*</td>
</tr>
<tr>
<td>Age (decreasing)</td>
<td>X</td>
<td>Contradicted by Hübner, 2011&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td>Emergent procedure</td>
<td></td>
<td>Hübner, 2011&lt;sup&gt;8&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sex (male)</td>
<td></td>
<td>Hübner, 2011&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td>Specific surgeon or hospital</td>
<td></td>
<td>Hübner, 2011&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td>BMI (increasing)</td>
<td></td>
<td>Imai, 2008&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td>Extent of colon resection</td>
<td></td>
<td>Serra-Aracil, 2011&lt;sup&gt;10&lt;/sup&gt; Imai, 2008&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td>Ostomy creation or closure</td>
<td></td>
<td>Serra-Aracil, 2011&lt;sup&gt;10&lt;/sup&gt; Konishi, 2006&lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

*Smaller hospitals had a higher rate of SSI after colon surgery on bivariate, but not multivariate, analysis.

ASA, American Society of Anesthesiologists; BMI, body mass index; NHSN, National Healthcare Safety Network; SSI, surgical site infection.
than our calculated value and that there is a larger discrepancy between the NHSN expected rate and the actual rate of colon SSI.

Although the importance of preventing health care-associated infections is irrefutable, there must be efforts to realign incentives and penalties in health care. The NHSN risk adjustment model is a methodologically rigorous approach for comparing observed and expected SSI rates, but expected rates need to be accurately assessed for this measure to be meaningful. Mu and colleagues’ plan to continually revise the procedure-specific risk-adjustment models as more data are reported to NHSN. However, even a short-term underestimation of SSI rates by NHSN could have a large impact on both a hospital’s public image and financial sustainability, especially safety-net hospitals that operate in a competitive market with precariously thin financial margins. Inaccurate benchmarking data will prompt many hospitals to shed high-risk and unprofitable patients, further challenging the viability of safety-net hospitals. Proper risk adjustment will help prevent hospitals from choosing to treat only low-risk patients.

In addition to the issues associated with risk adjustment for colon surgery, equitable hospital comparison is affected by the methods of postdischarge SSI surveillance. Superficial incisional SSI is both the most common type of SSI and the most subjective to diagnose. Surgeons could potentially prevent superficial SSI and “game the system” by allowing skin and subcutaneous tissue to heal by secondary intention in high-risk patients. Superficial incisional SSI is also the least likely to require rehospitalization. Hospital-based SSI surveillance by infection control practitioners has been repeatedly shown to underestimate the true incidence of SSI; as many as two thirds of SSI can be detected as an outpatient. Out of necessity, infection control practitioners will be increasingly using electronically available data and algorithms to diagnose SSI, as the number of publicly reported benchmarks increases. Electronically available data includes ICD-9 codes and commercial data mining tools, such as the Nosocomial Infection Marker. Using National Surgical Quality Improvement Project data as a gold standard in an academic medical center, Hollenbeak and colleagues reported that the sensitivity of ICD-9 codes and Nosocomial Infection Marker for detection of SSI after general or vascular procedures were both 20%. Similarly, Huang and colleagues compared Medicare claims data to hospital-based SSI surveillance at 5 Massachusetts hospitals and found the sensitivity of hospital-based surveillance for detecting SSI to be 48%. A method to “level the playing field” might involve proscribing a uniform method of SSI surveillance; alternatively, Mu and colleagues suggest reporting only deep incisional and organ/space SSI during initial hospitalization and rehospitalization at the same hospital.

CONCLUSIONS
Given these shortcomings, the risk-adjustment model for colon surgery and the methods of postdischarge SSI surveillance seem in need of refinement before colon SSI can be used as part of the Centers for Medicare and Medicaid Services Inpatient Prospective Payment System. A model with poor predictive validity should not be used to define a hospital’s performance and to determine financial penalties. Continued revisions, iterations, and applications of NHSN risk methodology to external datasets will identify strengths and weaknesses of the model; these should be addressed before implementation of financial incentives and penalties. The addition of literature-based non-modifiable patient and hospital variables to future risk-adjustment models is necessary to further improve this process.

Author Contributions
Study conception and design: Young, Knepper, Moore, Johnson, Mehler, Price.
Acquisition of data: Young, Knepper, Moore, Johnson, Mehler.
Analysis and interpretation of data: Young, Knepper.
Drafting of manuscript: Young, Knepper, Price.
Critical revision: Young, Knepper, Moore, Johnson, Mehler, Price.

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