An exploration of the role of religion/spirituality in the promotion of physicians' wellbeing in Emergency Medicine

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Keywords
Burnout, Emergency medicine, Prevention, Religion, Spirituality

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An exploration of the role of religion/spirituality in the promotion of physicians' wellbeing in Emergency Medicine

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ABSTRACT
Background: Burnout is highly prevalent among Emergency Medicine (EM) physicians and has significant impact on quality of care and workforce retention. The objective of this study was to determine whether higher religion/spirituality (R/S) is associated with a lower prevalence of burnout among EM physicians (primary outcome). A history of malpractice lawsuits and maladaptive behaviors were the secondary outcomes. Methods: This was a cross-sectional, survey-based study conducted among a random sample of physicians from the Massachusetts College of Emergency Physicians mailing list. Burnout was measured using a validated 2-item version of the Maslach Burnout Inventory. Maladaptive behaviors (smoking, drinking, and substance use) and medical malpractice were self-reported. R/S measures included organized religiosity, religious affiliation, private R/S practice, self-rated spirituality, religious rest, and religious commitment. Logistic regression was used to model study outcomes as a function of R/S predictors. Results: Of 422 EM physicians who received the invitation to participate, 138 completed the survey (32.7%). The prevalence of burnout was 27%. No significant associations were observed between burnout and R/S indicators. Maladaptive behaviors (adjusted OR = 0.42, CI: 0.19 to 0.96; p = 0.039) and history of medical malpractice (adjusted OR = 0.32; CI: 0.11 to 0.93; p = 0.037) were less likely among physicians reporting to be more involved in organized religious activity and to observe a day of rest for religious reasons, respectively. Conclusion: This study provides preliminary evidence for a possible protective association of certain dimensions of R/S on maladaptive behaviors and medical malpractice among EM physicians.

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Introduction

According to a recent survey conducted by the Physicians’ Foundation, more than half of physicians in the United States are pessimistic about the future of the medical profession, about one third report feeling “overextended and overworked”, and almost half plan to retire or take various steps to reduce patient load—such as cutting back on hours or reducing the number of patients they see (Anon., 2014). The proportion of physicians abandoning the medical profession is particularly high among doctors working at the very “frontline” of medical practice, i.e., Emergency Medicine (EM) (Doan-Wiggins et al., 1995; Goldberg et al., 1996; Kelley et al., 2004), where the number of physicians planning to retire is greater than the number that will be replaced through residency training (Gallery et al., 1992; Goh et al., 1999).

Evidence indicates that burnout, a syndrome characterized by emotional exhaustion, depersonalization, and reduced personal accomplishment (Maslach et al., 1998) is an important determinant of physicians’ departure and has reached epidemic levels among EM physicians’ workforce (Goldberg et al., 1996; Goh et al., 1999; Curtis and Puntillo, 2007; Shanafelt et al., 2012). About a third of EM physicians present signs of psychological distress and burnout (Goh et al., 1999), with over 70% showing significant levels of emotional exhaustion and depersonalization and about half reporting low to moderate perception of personal accomplishment (Goldberg et al., 1996; Goh et al., 1999). Similar high burnout levels have been detected among EM physicians in Europe and Turkey (Embricaco et al., 2007a; Heinke et al. 2011; Lederer et al., 2008; Erdur et al., 2006).

The most important consequence of burnout is a decline in the quality of care offered to patients (Dyrbye et al., 2010; Shanafelt et al., 2010; Simmons and Leung, 2011; Shanafelt et al., 2011). The objective of this study was to determine whether higher religion/spirituality (R/S) is associated with a lower prevalence of burnout among EM physicians (primary outcome). An exploration of the role of religion/spirituality in the promotion of physicians’ wellbeing in Emergency Medicine.

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West et al., 2006; Shanafelt et al., 2002; Firth-Cozens and Greenhalgh, 1997). Second, burnout takes a toll on physicians’ health, as indicated by associations between burnout, substance use, and depression (Gallery et al., 1992; Erdur et al., 2006; Burbeck et al., 2002; Lloyd et al., 1994; Oreskovich et al., 2015). A third important consequence is the impact of burnout on EM staffing. Given the predicted increase in demand for critical care services due to the aging of the US population and the stable supply of physicians, it has been estimated that by 2020 the deficit of physicians working in EM and intensive care will reach approximately 20% of demand, and by 2030 it will approach 35% (Kelley et al., 2004).

Several factors have been linked with lower burnout among EM clinicians. System-level factors that have been studied include the quality of organizational leadership (Shanafelt et al., 2015), guaranteeing time away from clinical practice (Lloyd et al., 1994), a reduced workload (Embiaco et al., 2012; Embiaco et al., 2007b), the development of palliative care protocols (Treese et al., 2004), and offering clinicians the opportunity to share the experience of caring for severely ill patients (Smith and Hough, 2011; Hough et al., 2005). Individual-level factors include being in a committed relationship or cultivating a hobby (Doan-Wiggins et al., 1995). Among such factors, the study of the possible association between religion/spirituality (R/S) and burnout has received limited attention, despite evidence indicating that R/S plays an important role in the life of medical professionals (e.g., religious beliefs affect physicians’ practice and attitudes toward end-of-life decisions (Curlin et al., 2005; Chan et al., 2003) and more than 50% of physicians report being involved in various forms of private spiritual practice) (Cattin et al., 2008).

Malpractice litigation and maladaptive coping behaviors (i.e., smoking and substance use) are also fairly prevalent among EM physicians (Oreskovich et al., 2015; Studdert et al., 2006; Hull et al., 2008). While no study has so far attempted to evaluate the possible role of R/S in the prevention of these factors among physicians, the literature has shown robust associations between specific religious characteristics (i.e., worship attendance) and reduced alcohol intake, cigarette smoking, and substance use in a variety of populations (Gillum, 2005; Whooley et al., 2002; Salmoirago-Blotcher et al., 2011; Rasic et al., 2011; Robinson et al., 2012).

This study was a preliminary exploration of the possible role of R/S in the promotion of EM physicians’ wellbeing. The purpose of this study was to determine the relationship between markers of R/S and prevalence of burnout (primary outcome), malpractice lawsuits and maladaptive coping behaviors (secondary outcomes) among EM physicians.

Methods

Design and study participants

This was a cross-sectional, survey-based study. In 2014, 683 physicians randomly selected from the Massachusetts College of Emergency Physicians mailing list received three email messages describing the scope of the study and inviting them to participate, along with a link to a confidential on-line survey. Messages were followed by one paper copy of the survey by mail. Participants who preferred to complete the paper version were instructed to complete the questionnaire without checking a “yes” or “no” bullet point to survey completion. For those completing paper surveys, survey return was considered proof of consent. Participants were offered a $20 gift card as a compensation for their time.

The study and all study related materials received Institutional Review Board (IRB) approval at the University of Massachusetts Medical School.

Study assessments

The study survey was pilot-tested among a group of EM physicians prior to posting or mailing for verbiage, participant burden, and acceptability. Physicians’ suggestions were used to generate the final version of the study questionnaire. To respect individual feelings and perceptions about R/S and based on the feedback we received from physicians during the pilot-testing of this survey, we did not explicitly mention R/S in the survey; rather, questions about R/S attitudes and practices were embedded under the heading “Thoughts and Feelings”. All information was collected using the REDCap electronic data capture system hosted at the University of Massachusetts Medical School (Harris et al., 2009).

For paper and pencil surveys, a research assistant blinded to the study outcomes manually entered the data into REDCap. Data were then imported into analytical datasets.

Primary outcome

To assess burnout we used a 2-item validated version (West et al., 2009, 2012) of the Maslach Burnout Inventory (Maslach et al., 1998) used in a previous large survey-based study of physician burnout (Shanafelt et al., 2012). Physicians were asked to indicate how often the following two statements applied to them: “I feel burned out from my work” and “I have become more callous toward people since I took this job” (never, a few times a year, once a month or less, a few times a month, once a week, a few times a week, every day).

Secondary outcomes

Secondary outcomes were the prevalence of maladaptive behaviors and of previous malpractice lawsuits. Maladaptive behaviors included self-reported smoking status (never, current, ex-smoker); number of alcoholic drinks consumed per week; and previous or current substance use (cocaïne, painkillers, or marijuana for non-medical reasons). History of involvement in a medical malpractice lawsuit was assessed using a single question (“Have you ever been involved in a medical malpractice lawsuit?”) with 3 possible answers (yes, no, prefers not to answer).

R/S predictors

We chose measures that have been included in validated R/S assessment batteries (the Fetzer Institute Multidimensional Measurement of Religiousness/Spirituality for Use in Health Research) (The Fetzer Institute, 2003). Organized religiosity was measured as frequency of attendance at religious services (never, less than once a year, several times a year, about once a month, 2 to 3 times/month, nearly every week, every week, several times a week). Religious affiliation was measured as none, Buddhist, Hindu, Jewish, Muslim, Roman Catholic, Eastern Orthodox, Protestant, other Christian, and other. Private religious/spiritual practice was assessed with the questions “How often do you pray privately in places other than at church, synagogue or other place of worship?” and “How often do you meditate?” (Never, less than once a month, once a month, a few times a month, once a week, a few times a week, once a day, several times a day). To capture individuals who would not identify with any organized religious system and yet still consider themselves “spiritual” we included assessments of self-rated spirituality “To what extent do you consider yourself a spiritual person?” (Very spiritual, moderately spiritual, slightly spiritual, not spiritual at all, prefer not to answer).

Religious commitment (the extent to which an individual considers religion as the guiding principle of one’s life) was measured using one statement derived from Hoge’s Intrinsic Religious Motivation Scale: “I try hard to carry my religious beliefs over into all my other dealings in life” (Agree strongly, agree somewhat, disagree somewhat, disagree strongly (The Fetzer Institute, 2003; Roge, 1972; Koenig et al., 1997)).
Finally, we incorporated two measures of R/S that were not included in the original Fetzer assessment battery. Religious rest was measured by asking how often the participant observed a day of rest for religious reasons during the previous year (never, less once a year, about 1–2 times/year, several times/year, about once/month, 2–3 times/month, nearly every week, every week, not applicable). Spiritual counsel was measured by asking whether the physician had seen a chaplain or other spiritual counselor during the previous month (yes, no, prefer not to answer).

Covariates

Covariates of interest included age; gender; race/ethnicity (American Indian or Alaskan native, Asian, Black or African American, Native Hawaiian or Pacific Islander, White/Caucasian, Hispanic or Latino); marital status (single, never married, currently married or living as if married, separated, widowed, divorced); number of children; and family income (<$100,000, $100,001–$125,000, $125,001–$150,000, $150,001–$175,000, $175,001–$200,000, $200,001–$250,000, $250,001–$300,000, $300,001–$500,000, over $500,000). In addition, we collected information about important confounders such as type of working environment (academic vs. community hospital), number of years working in EM, average number of hours dedicated to direct patient care each week, average number of hours on call per week, and number of shifts per month.

Statistical analysis

Consistent with previous work we categorized burnout as high if participants reported that either statement was true once a week or more often (West et al., 2009, 2012). For sensitivity analyses, we created a continuous burnout score by summing scores for the 2 items. For maladaptive behaviors, each behavior was treated as a yes/no dichotomous variable (smoking; current or ex-smoker vs. never; substance use ever; and drinking 8 or more alcoholic drinks/week vs. 7 or fewer). Maladaptive behavior was defined as the presence of at least one of the behaviors noted above.

Distributions and cross-tabulations were used to inform the treatment of the different R/S variables in the analysis. Organized religion, religious affiliation and private religious spiritual practice (prayer and meditation) were categorized as any vs. none. Religious rest was categorized as any vs. never. Religious commitment was categorized as high (agree somewhat to strongly agree) vs. low (disagree somewhat to strongly disagree). Consistent with prior studies we categorized self-rated spirituality as high if the physician answered “highly spiritual,” moderate if the physician answered “moderately spiritual,” and low if the physician answered “slightly” or “not at all spiritual” (Curlin et al., 2005, 2006).

Demographic characteristics were compared between high and low burnout categories using T-test or Wilcoxon rank sum test for continuous variables and chi-square test or Fisher’s exact test for categorical variables. Univariate and multivariate logistic regression models were used to assess the association between primary and secondary outcomes and the R/S predictors described above. Multivariate analyses for these models included all covariates that were associated with the outcome with p ≤ 0.1. If collinearity was found, the variable most strongly associated with the outcome was included in the analysis. We also conducted sensitivity analyses using linear regression to model continuous burnout scores as a function of the different R/S predictors. Results are presented as adjusted odds ratios (OR) with 95% confidence intervals. P values < 0.05 were considered significant. All analyses were conducted using Stata/MP 13.1 (Stata Statistical Software: Release 13. College Station, TX: StataCorp. LP, 2013).

Results

Among the 422 EM physicians who received the invitation to participate, 138 completed the surveys (cooperation rate, 32.7%). As seen in Table 1, the average age of survey responders was 48 years (range: 32–83); more than 70% of participants were male; 90% were married, 84% had at least one child and 88% were white. The average duration of work in EM was 16 years. Ninety-nine (72.8%) of participants reported low/average burnout, while 37 (27.2%) reported high burnout. As for religious affiliations, 25% of physicians reported no affiliation; 26% were Catholic, 21% Jewish, 14% Protestant, and 15% other religion. Overall, this was a very secular population: 50% of physicians reported they never prayed; 70% never meditated; 56% attended religious services less than once a year; 80% never observed a day of rest for religious reasons; 48% disagreed strongly with the statement “I try hard to carry my religious beliefs over into all my other dealings in life” and 0 doctors had consulted a chaplain or other spiritual counselor over the previous month. About 40% of physicians, however, reported to be “moderately or very spiritual”.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Characteristics of the study population.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>Low burnout</td>
</tr>
<tr>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Age (mean, SD)</td>
<td>47.8 (10.5)</td>
</tr>
<tr>
<td>Female</td>
<td>38 (28.6)</td>
</tr>
<tr>
<td>Marital status</td>
<td>14 (10.4)</td>
</tr>
<tr>
<td>Single/divorced</td>
<td>121 (89.6)</td>
</tr>
<tr>
<td>Married or living as if married</td>
<td>22 (16.4)</td>
</tr>
<tr>
<td>Number of children</td>
<td>55 (41.0)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>36 (26.9)</td>
</tr>
<tr>
<td>White</td>
<td>113 (83.8)</td>
</tr>
<tr>
<td>African American</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>Asian</td>
<td>11 (8.6)</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>3 (2.3)</td>
</tr>
<tr>
<td>Income before taxes</td>
<td>$100,001–$150,000</td>
</tr>
<tr>
<td>$150,001–$200,000</td>
<td>12 (9.8)</td>
</tr>
<tr>
<td>$200,001–$250,000</td>
<td>27 (20.9)</td>
</tr>
<tr>
<td>$250,001–$300,000</td>
<td>39 (31.7)</td>
</tr>
<tr>
<td>$300,001 and over</td>
<td>38 (29.0)</td>
</tr>
<tr>
<td>Institution type</td>
<td>0.673</td>
</tr>
<tr>
<td>Teaching/academic hospital</td>
<td>55 (40.4)</td>
</tr>
<tr>
<td>Community hospital</td>
<td>74 (54.4)</td>
</tr>
<tr>
<td>Years in EM (mean, SD)</td>
<td>16.0 (9.8)</td>
</tr>
<tr>
<td>Hours in direct patient care/week (mean, SD)</td>
<td>25.2 (10.0)</td>
</tr>
<tr>
<td>Number of shifts/month (mean, SD)</td>
<td>5.1 (18.3)</td>
</tr>
</tbody>
</table>

Numbers are n (%) unless otherwise specified.

Table 1, the average age of survey responders was 48 years (range: 32–83); more than 70% of participants were male; 90% were married, 84% had at least one child and 88% were white. The average duration of work in EM was 16 years. Ninety-nine (72.8%) of participants reported low/average burnout, while 37 (27.2%) reported high burnout. As for religious affiliations, 25% of physicians reported no affiliation; 26% were Catholic, 21% Jewish, 14% Protestant, and 15% other religion. Overall, this was a very secular population: 50% of physicians reported they never prayed; 70% never meditated; 56% attended religious services less than once a year; 80% never observed a day of rest for religious reasons; 48% disagreed strongly with the statement “I try hard to carry my religious beliefs over into all my other dealings in life” and 0 doctors had consulted a chaplain or other spiritual counselor over the previous month. About 40% of physicians, however, reported to be “moderately or very spiritual”.

R/S and burnout

Among demographic and work characteristics, being single or divorced, the number of hours the physician reported to be directly involved in patients’ care each week, the number of hours each physician was on call each week, and the number of shifts per month were associated with burnout. We did not find associations between burnout and age, gender, race/ethnicity, family income, type of institution (community vs. teaching hospital), and duration (years) of work in EM. No significant associations were observed between burnout and any of the R/S predictors in adjusted logistic or linear regressions analyses, although for most R/S predictors (with the exception of self-reported spirituality) point estimates showed a non-significant inverse association with burnout (Table 2 and Fig. 1a).
Almost 50% of physicians reported to have been involved in malpractice lawsuits in the past. As seen in Fig. 1b and Table 3, doctors who reported the religious observance of a day of rest, compared with those never observing religious rest, had lower odds of reporting a history of involvement in malpractice lawsuits (adjusted OR = 0.32; CI: 0.11 to 0.93; p = 0.037).

RS and maladaptive behaviors

Ten per cent of doctors reported to be smokers or ex-smokers and 10% reported marijuana (Erdur et al., 2006) or cocaine (Anon., 2014) use ever, while on average physicians reported consuming 4.1 (SD: 4.4) alcoholic drinks/week. As shown in Fig. 1c and Table 4, doctors who attended worship services during the past year, compared to those who never attended, had lower odds of reporting a history of involvement in malpractice lawsuits (adjusted OR = 0.42; CI: 0.11 to 0.93; p = 0.037).

Discussion

The purpose of this study was to conduct a preliminary exploration of the possible association between different indicators of R/S and burnout, maladaptive behaviors, and the likelihood of being involved in a previous malpractice lawsuit among EM physicians. In this study, no R/S indicator was significantly associated with burnout. Doctors who observed a day of rest for religious reasons were less likely to report involvement in previous malpractice claims and those who attended organized religious services were less likely to report maladaptive coping behaviors.

Both theoretical work and experimental evidence suggest that R/S might mitigate burnout and promote physicians’ wellbeing. R/S could reduce burnout by offering physicians a meaningful framework within which doctors can make sense of the stressful and dramatic events they face during the practice of medicine in emergency situations. Such meaningful framework has been only relatively recently lost in the history of medicine. Until at least the 17th century medicine and religion were closely intertwined and the roles of priests and physicians often overlapped. In the Pentateuch, for example, priests are responsible for the “diagnosis” of certain diseases (Leviticus 13:1–59) and God is called “your healer” (Exodus 15:26).
Frankl’s work posits that the presence of a meaningful context is essential for coping with the tragedies of life (Frankl, 1984). Second, certain forms of private spiritual practice might protect against burnout by promoting relaxation and reducing stress. Experimental studies of mindfulness meditation (a form of individual spiritual practice) have indeed shown promising results on physicians’ burnout (Krasner et al., 2009; Koenig et al., 2001).

In general, the medical literature has been relatively silent about the relationship between different markers of R/S and burnout among physicians. Studies conducted among medical students (Wachholz and Rogoff, 2013) and palliative care workers (Holland and Neimeyer, 2005) reported an inverse association between self-reported spirituality and burnout, while research conducted among primary care house officers has shown an inverse association between spiritual well-being and depression (Yi et al., 2007) and a positive association with self-reported health (Yi et al., 2007). These studies, however, measured constructs such as “spiritual well-being” that are highly correlated with measures of mental health and well-being (Koenig et al., 2001).

While in the present study we did not find statistically significant associations between R/S and burnout, point estimates indicated inverse associations of considerable magnitude between most R/S predictors and burnout, but with wide confidence intervals. This could be due to small cell numbers for high R/S categories for all the religious domains considered, as well as to the relatively small study sample size and suggests that this association should be explored in a larger and more religiously diverse population.

This study also examined whether R/S could be associated with medical malpractice and maladaptive coping behaviors (smoking, excessive drinking and substance use). Although not all malpractice claims are attributable to medical mistakes (Studdert et al., 2006), we used malpractice lawsuits as a crude proxy of medical errors and of detached relationships with patients. Among the R/S domains examined, we found that the observance of a day of rest for religious reasons during the previous year was associated with decreased odds of a previous involvement in medical malpractice claims. A possible explanation for this finding is that “taking time off” for religious reasons could increase attention, improve cognitive work performance and reduce errors similar to other forms of mental breaks such as naps (Garbarino et al., 2004; Smith-Coggins et al., 2006) or nature walks (Berman et al., 2008, 2012). Since religious rest is a “commandment” in many religious traditions, it is possible that individuals who do so for religious reasons are particularly diligent in resting (i.e., by not using emails or social media) and therefore reap the most benefit. The impact of this association, if confirmed, could be relevant considering that based on recent estimates preventable medical errors account for more than 400,000 deaths a year (James, 2013).

Our finding that involvement in organizational religious activity (worship attendance) was associated with decreased odds of maladaptive coping behaviors such as smoking, drinking and substance use is consistent with robust epidemiological evidence indicating that worship attendance is associated with reduced intake of alcoholic beverages as well as reduced cigarette smoking and substance use in a variety of populations (Gillum, 2005; Whooley et al., 2002; Salmoirago-Blotcher et al., 2011; Rasic et al., 2011; Robinson et al., 2012). Possible mechanisms by which worship attendance could improve these behaviors involve peer pressure from the congregation and the belief, held by many religious traditions, that the body is holy and consequently should not be harmed by using intoxicating substances.

**Strengths**

The most notable strength of this work is its novelty: to the best of our knowledge, there are no published studies exploring the possible association between R/S and burnout, malpractice claims and maladaptive behaviors among physicians. Another important strength is the assessment of multiple validated domains of R/S. Studies in this field have often focused only on one aspect of R/S (i.e., organized religiosity) or have used constructs that are highly correlated with psychological measures, thus limiting the validity of their findings (Yi et al., 2007).
Limitations

This study also has a number of limitations. First, due to its exploratory nature, this study was not powered to detect meaningful differences in the outcomes of interest. Due to the small sample size associations were mostly non-significant and should be reproduced in a larger and more religiously diverse population. Second, information was self-reported and although the survey was strictly confidential we cannot exclude the presence of social acceptability bias, especially for sensitive items like alcohol intake and substance use. We also cannot make inferences about the characteristics of non-responders; for example, we cannot exclude that the prevalence of burnout could be higher (or lower) among non-responders. Third, cooperation rates were relatively low; however, similar rates have been reported in larger studies of physician burnout (Shanafelt et al., 2012). Fourth, while the prevalence of burnout in our population was fairly similar to that reported in other studies (Shanafelt et al., 2012), the religious characteristics of physicians living in the North-East and in Massachusetts in particular are different from those of doctors practicing in other areas of the US (Curlin et al., 2008), thereby limiting the generalizability of our findings. Finally, due to the cross-sectional nature of this study, no causal inference is possible with regard to the possible role of R/S in the prevention of burnout, maladaptive behaviors or malpractice claims; this question can only be answered using a prospective design.

Conclusion

In sum, while we did not find a statistically significant association between R/S and burnout, this study suggests that the religious observance of a day of rest may play a role in reducing medical errors and malpractice lawsuits and provides preliminary evidence for a role of organizational religiosity in reducing maladaptive coping behaviors like smoking, alcohol consumption and substance use. These promising findings need to be reproduced in larger survey-based studies involving a religiously diverse population of EM physicians. In order to determine the existence of a possible protective association, and to avoid reverse causality bias, such studies should use a prospective design. The finding of a possible protective role of R/S in the prevention of burnout, maladaptive behaviors and medical errors could result, for example, in policy changes at the hospital level, such as offering options for spiritual assistance to interested medical professionals and may provide a solid foundation for offering spiritual training in medical schools, residency and fellowship programs.

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Conflict of interest

All authors have completed the Unified Competing Interest form at www.icmje.org/col_disclosure.pdf (available on request from the corresponding author) and declare the following: Dr. Salmoirago-Blotcher reports grants from the University of Chicago, Program on Medicine and Religion, during the conduct of the study; Ms. Leung reports statistical consulting fees from the University of Chicago, Program on Medicine and Religion, during the conduct of the study; GF, GV, EB, SC, IO and FC have no competing interests to declare.

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