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Self-reported Financial Conflict of Interest in Nephrology Clinical Practice Guidelines

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Introduction: There is ongoing controversy concerning the potential influence of industry and financial conflict of interest (FCOI) in the development of clinical practice guidelines (CPG). The influence of industry in renal guideline development has been discussed in the past with emphasis on the National Kidney foundation (NKF) and Kidney and Dialysis Outcomes Quality Initiative guidelines. In this study we evaluate the self-reported FCOI among guideline panel members in Kidney Disease: Improving Global Outcomes (KDIGO) CPGs.

Methods: We examined 10 of the most recent KDIGO CPGs developed between 2009 and 2018. Using disclosure lists, we catalogued FCOIs for panelists for each individual CPG. The categories were Advisor/Consultant, Honoraria, Travel Stipend, Grant/Research Support, Speaker, Equity Interest, Employee, Board of Trustees, Royalties, Advisory Board, Employment, Ownership, Data Monitoring Committee, Expert Testimony, and Development of Education Materials. We also reviewed FCOIs for members of evidence review team (ERT). We also catalogued the company involved in each disclosure. One conflict describes 1 instance of participation of an individual in 1 category in each guideline. "Company" describes a commercial, industry, or institute affiliation reported in each episode.

Results: One hundred two (66.4%) of the total 151 panelists reported FCOI. A total of 662 conflicts were disclosed. Being a consultant or advisor was the most common category. One hundred fifty-one companies were associated with FCOI disclosure. One company was most frequently reported, involving 60 (9%) of 662 conflicts. Of the 52 members in the ERT, there was 1 instance of FCOI.

Conclusion: FCOI is prevalent in KDIGO guidelines with almost two thirds of the panelists self-reporting FCOI. The evidence review team had only 1 instance of FCOI.

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The National Academy of Medicine defines conflicts of interest (COIs) as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest. COIs have the potential to introduce bias into the development process of guidelines, thereby affecting the integrity of the guidelines. COI policies typically focus on financial gain because it is relatively more objective, fungible, and quantifiable.[1] Although there is limited evidence on the effects of financial conflicts of interest (FCOIs) on guideline recommendations, the process of guideline development can be theoretically influenced by implicit bias (attitudes that affect our understanding, actions, and decisions in an unconscious manner) amongst members with significant FCOIs. Some argue that the FCOI is driven by a powerful industry that systematically seeks to influence medical evidence production, publication, and dissemination for its advantage.[2] FCOIs in clinical practice guidelines (CPGs) have raised increasing concern as majority recommendations contained in most CPGs are derived from a lower level of evidence or expert opinion.[3–7]

Professional organizations such as Institute of Medicine (IOM) have responded by more rigorous regulation of FCOIs. Nevertheless, tension remains between the competing goals of optimizing guideline quality by using experience and insight of experts and ensuring that FCOIs do not influence recommendations.[6] The issue of FCOIs in renal guidelines was discussed

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extensively when the Kidney and Dialysis Outcomes Quality Initiative released their 2006 update for anemia guidelines wherein the target hemoglobin range was increased from 11 to 12 to 11 to 13 g/dl in patients with chronic kidney disease (CKD). Because of the tight relationship in patients with CKD between target hemoglobin and erythropoietin-stimulating protein (EPO), an increase in cost of health care by the use of EPO was expected.[8] More importantly, issues regarding FCOIs were raised as the guideline panel did not wait to consider the final results of the trials informing target hemoglobin levels for CKD patients before releasing their update. However, the trials concluded that aiming for a higher hemoglobin range was associated with increased frequency of cardiovascular events.[9,10]

Kidney Disease: Improving Global Outcome (KDIGO) is a global organization developing and implementing evidence-based clinical practice guidelines in kidney disease. It was originally established in 2003 by the National Kidney Foundation, an American foundation experienced in developing and implementing guidelines. In 2013, KDIGO became an independently incorporated nonprofit foundation and is governed by an international volunteer executive committee.[11]

The KDIGO global network is composed of experts from around the world who work to implement KDIGO guidelines in their respective countries or regions. Many experts are associated with local nephrology societies or guideline groups and help KDIGO to promote local adoption of guideline recommendations through clinical practice conferences. KDIGO is governed by a volunteer executive committee made up of leading nephrology experts throughout the world, who are also part of the global network. They make critical decisions about KDIGO's priorities, projects, and resource allocations.[11]

The KDIGO CPG panel has a relationship with industry, which includes acting as an advisor/consultant or speaker, receiving grants, and serving on the company's advisory board. Some of the panel members were principal investigators, lead investigators, and authors of trials considered for recommendations in KDIGO CPG. KDIGO has developed a policy in which the KDIGO guideline panelists (co-chairs and work group members) require disclosure of external relationships and potentially conflicting interests. This information is available to the public to safeguard the integrity of KDIGO guidelines and the guideline development process.

Our objective in this study was to describe the extent of self-reported FCOIs among CPG panelists in KDIGO, which has not been evaluated previously. We evaluated the FCOIs of authors related to the 10 available KDIGO guidelines and the respective evidence review team (ERT).

METHODS

We examined 10 of the most updated KDIGO CPGs, which were developed between 2009 and 2018. We reviewed the FCOIs of panelists in 10 CPGs, which were available as a part of the biographic and disclosure information of individual guideline document. The CPGs include Glomerulonephritis,[12] CKD–Mineral and Bone Disorder (BMD),[13] Acute Kidney Injury (AKI),[14] Anemia in Chronic Kidney Disease (CKD),[15] Blood Pressure in CKD,[16] Transplant Recipient,[17] CKD Evaluation and Management,[18] Lipids in CKD,[19] Hepatitis in CKD,[20] and Living Kidney Donor.[21]

Using disclosure lists, we catalogued FCOIs for each panelist of the individual CPG. The categories included were: Advisor/Consultant, Honoraria, Travel Stipend, Grant/Research Support, Speaker, Equity Interest, Employee, Board of Trustees, Royalties, Advisory Board, Employment, Ownership Interests, Data Monitoring Committee, Expert Testimony, and Development of Education Materials. We catalogued the companies/institutions involved in each disclosure. One "conflict" describes 1 instance of participation of an individual in 1 category in each guideline. Thus, a single reported conflict could be more than one talk or advisory payment, etc, for the corresponding company. "Company" describes a commercial, industry, or institute affiliation reported by an individual in each conflict. Our data on companies are complicated by mergers that took place between the writings of different guidelines, as KDIGO is an international organization with guideline writers from all over the world. Furthermore, companies may be known by different entities in different parts of the world, which was not verified. We also reviewed the FCOIs of the ERT, whose responsibility is to assemble evidence for consideration by the panelists.

RESULTS

We found a total of 151 panelists in the 10 CPGs reviewed from the 2019 version of the updated KDIGO CPG disclosure list. All 151 panelists (100%) completed their FCOI disclosures. We also reviewed the FCOIs of the ERT.

Among the 151 panelists, 131 were work group members and 20 were co-chairs. Each guideline has 2 co-chairs. Of the 131 work group members, 87 (66.4%) reported FCOIs. Of the 20 co-chairs, 15 (75%) reported FCOIs. Of the complete group of 151 panelists, 102 (two thirds) reported FCOIs.

A total of 662 conflicts were disclosed, with an average of 6.4 conflicts per panelist with FCOIs.

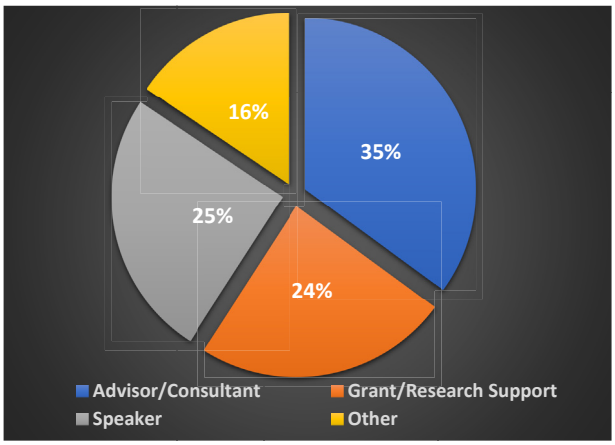

Figure 1. Prevalence of categories among self-reported FCOI in KDIGO CPG panelists. CPG, clinical practice guidelines; FCOI, financial conflict of interest. KDIGO, Kidney Disease: Improving Global Outcomes.

Advisor/Consultant was the most common category (35%), followed by Grant/Research Support (24%) and Speaker (25%), respectively (Figure 1).

A total of 151 companies were associated with FCOIs, with Amgen associated with nearly 60 conflicts (9%), followed by Merck, Sharp & Dohme (4.6%) and Roche (4.3%).

Among the 10 guidelines, the prevalence of panelists with FCOIs was: Anemia in CKD (88%), BMD (83%), Lipid Management in CKD (82%), Hepatitis in CKD (79%), AKI (67%), Living Kidney Donor (63%), Glomerulonephritis (61%), Care of Kidney Transplant Recipients (60%), CKD Evaluation and Management (56%), and Blood Pressure in CKD (43%) (Figure 2).

Of the 662 conflicts, the highest number of conflicts was associated with Hepatitis in CKD (14.2%). The lowest number of conflicts was associated with Care of Kidney Transplant Recipients (4.5%) (Figure 3).

Although the average number of conflicts was 6.4 per panelist among all with FCOIs, the relative frequency of this differed with each guideline (Table 1). The average number of conflicts was highest at 12.2 per panelist in Blood Pressure in CKD and lowest at 3.3 per panelist for both Care of Kidney Transplant Recipients and Living Kidney Donor guidelines, respectively. The other FCOIs were: CKD Evaluation and Management (3.8), Glomerulonephritis (8), Lipids in CKD (7.4), Hepatitis in CKD (8.5), Anemia in CKD (4.1), AKI (7.7), and BMD (8.9). The ERT in all, except 1 member in 1 CPG (Hepatitis in CKD), had no FCOI disclosures.

DISCUSSION

FCOIs among CPGs has become a topic of debate in the scientific community. In a systematic review of the level of evidence underlying KDIGO CPGs in 2016, the authors concluded that KDIGO recommendations were based largely on weak evidence, reflecting expert opinion.[7] This does not mean that the high prevalence of FCOIs among the guideline panelists in KDIGO and the predominance of relatively weak evidence/expert opinion are related. There are no studies comprehensively evaluating the effects of FCOI on CPGs. Observational data can be used to explore relationships and to generate hypotheses on the extent and direction of the influences exerted by specific conflicts on recommendations in CPGs. The frequent lack of temporal data within financial disclosures also makes it difficult to explore associations between FCOIs and CPG recommendations.[22]

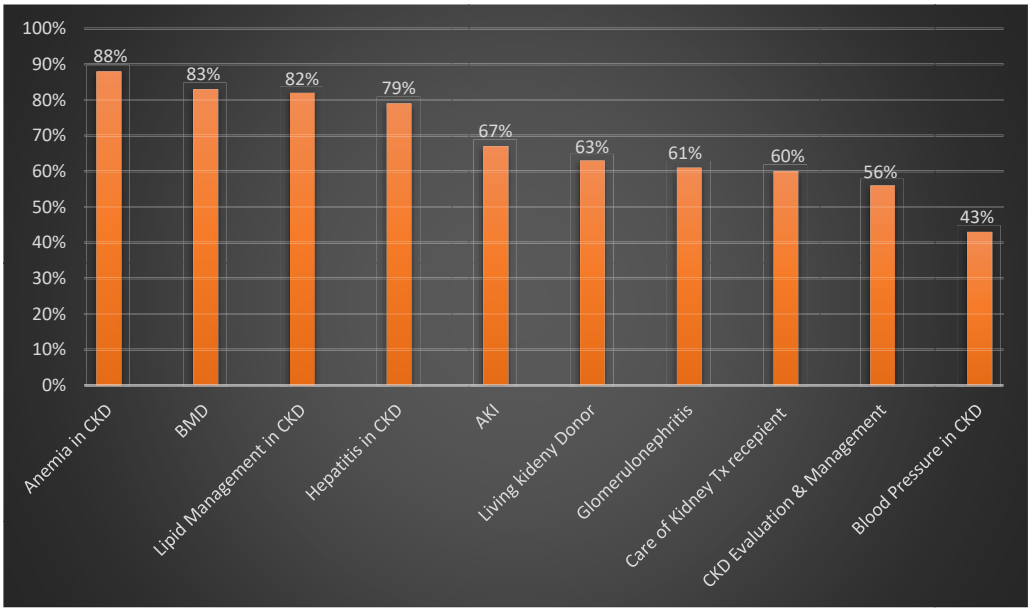

Figure 2. Percent of panelists reporting at least 1 conflict of interest among the 10 reviewed CPGs. AKI, acute kidney injury; BMD, bone mineral density; CKD, chronic kidney disease; CPG, clinical practice guidelines.

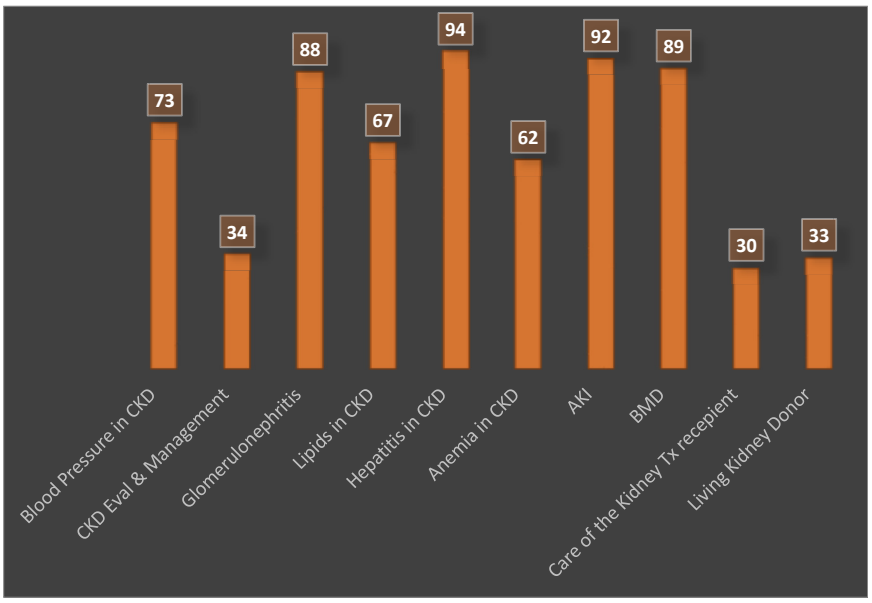

Figure 3. Total number of self-reported conflicts in each Kidney Disease: Improving Global Outcomes clinical practice guidelines. AKI, acute kidney injury; BMD, bone mineral density; CKD, chronic kidney disease; Tx, transplant.

A notable example relating to the influence of the pharmaceutical industry in CPGs involves the use of efalizumab in the treatment of psoriasis, and the differences in recommendations between the S3 guideline (Germany) and NICE guidelines (England). The recommendations from the S3 guidelines were found to be more favorable for use in the treatment of psoriasis than the NICE guidelines. Most authors of the S3 guidelines had extensive COIs, particularly through financial links to the manufacturer of efalizumab; in contrast, the authors with conflicts of interest were excluded from participation in the creation of the NICE guideline.[23] Similarly, guidelines for opioid prescribing for chronic noncancer pain from 2007 to 2013 were at risk of bias because of pervasive COIs with the pharmaceutical industry and the paucity of mechanisms to address bias.[24]

KDIGO states that it makes every effort to avoid any actual or reasonably perceived COI that may arise as a result of an outside relationship or a personal, professional, or business interest of a panelist. All panelists are required to complete, sign, and submit a disclosure and attestation form showing all such relationships that may be perceived as or are actually a COI. This document is updated annually and the information is adjusted accordingly. All reported information is published in its entirety at the end of the article in the Work Group Members' Biographic and Disclosure Information section and is kept on file at the National Kidney Foundation, which is the former managing agent for KDIGO.[17] Although it is understood that panelists with significant FCOIs are excluded from respective guideline development, there is no publicly available information on who was excluded.

KDIGO's comprehensive methodology of the guideline development process is explicitly outlined with each CPG. KDIGO has implemented several tools and checklists that have been developed to assess the methodologic process of systematic review and guideline development. These include Appraisal of Guidelines for Research and Evaluation criteria, The Conference of Guideline Standardization (COGS) checklist and the Institute of Medicine (IOM) standard for systematic reviews. Several of the KDIGO

Table 1. Distribution of episodes in the 10 guidelines

	Guideline[a]									
Characteristics	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
No. of conflicts	73	34	88	67	94	62	92	89	30	33
No. of panel members	14	16	18	11	14	17	18	12	15	16
No. of panel members with reported FCOI	6 (43%)	9 (56%)	11 (61%)	9 (82%)	11 (79%)	15 (88%)	12 (67%)	10 (83%)	9 (60%)	10 (63%)
Relative frequency of FCOI	12.1	3.8	8	7.4	8.5	4.1	7.7	8.9	3.3	3.3
No. of conflicts in ERT	0	0	0	0	1	0	0	0	0	0

ACI, acute kidney injury; CKD, chronic kidney disease; ERT, evidence review team; FCOI, financial conflict of interest.
[a]Index for guidelines: 1—Blood Pressure in CKD; 2—CKD Evaluation and Management; 3—Glomerulonephritis; 4—Lipids in CKD; 5—Hepatitis in CKD; 6—Anemia in CKD; 7—AKI; 8—CKD-Mineral Disorder and Bone Disorder; 9—Transplant Recipient; 10—Living Kidney Donor.

guidelines have comparative tables for both COGS and IOM standards.

The COGS statement includes 18 items that are critical for understanding a guideline's development process, its recommendation statements, and potential issues in its application. The checklist includes key elements that should be present in guidelines to enhance validity and usability.[25] COGS asks to identify the funding source/sponsor and describe its role in developing and/or reporting the guideline as well as disclose potential conflict of interest. KDIGO explicitly names several companies that have supported the development of guidelines, but not the extent and role played by each company.

The IOM standards, on the other hand, are more explicit regarding advice on basic criteria for inclusion of panel members and aim to understand the nature of FCOIs in greater detail.

The IOM standards for panel composition with regard to FCOI include areas of scrutiny under comprehensive disclosure, divestment, and specific exclusions before selection of a guideline development group.[26] Although KDIGO has attempted to describe its adherence to IOM standards, a few deviations were noted. All KDIGO panelists completed their FCOI disclosures, but it is unclear whether the FCOIs are discussed by the prospective development group before the onset of his or her work. Although individuals with clear financial FCOIs are excluded, the process of discussion and decision is unclear. Similarly, there is no explicit explanation provided for whether each member describes how their conflict may affect the guideline development process or if the panelists have been asked to divest their investments before serving on a guideline panel. Finally, the number of panelists and co-chairs with FCOIs exceeded the minimum allowable number according to IOM recommendations. Nevertheless, KDIGO's ERT had only 1 member with an FCOI.

Although KDIGO CPG panelists are only required to self-report FCOIs, it is unclear whether they are verified for completeness. A study from Denmark, which reviewed 45 clinical guidelines across specialties after cross-checking reported FCOIs versus publicly available information, showed that there was significant underreporting of FCOIs. The authors recommended that publicly available, law-enforced disclosure lists could assist guideline-issuing bodies in ensuring that all conflicts are disclosed.[27]

To continuously assess COI declaration and management in German guidelines, a public database, LeitlinienWatch (GuidelineWatch), was created, which provides an immediate source of verification for COIs for the guideline executive committee.[28]

A notable example where significant revisions were made to their existing policy on management of FCOIs is the US Preventive Services Task Force (USPSTF), which provides independent, objective, and scientifically rigorous recommendations for clinical preventive services. As part of the general FCOI process, all disclosures are reviewed by the USPSTF chairs to determine whether they are actual FCOIs, based on the nature of the disclosure. For each USPSTF member, the disclosures are reviewed and then assigned 1 of 3 levels of potential conflict, each with a set of possible consequences (level 1 = no relevant FCOI; level 2 = disclosure of a potential bias; level 3 = mitigation required). Task Force chairs adjudicate the potential FCOI and make a determination of possible actions to mitigate the potential conflict on a case-by-case basis in accordance with USPSTF policies.[29] The key areas of scrutiny include: (i) attaching a total dollar amount to financial disclosure; (ii) inclusion of disclosures for immediate family members and close personal relationships; and (iii) a stronger definition of nonfinancial COI and a longer lookback period.

The American College of Chest Physicians made major changes to their ninth iteration of their antithrombotic guideline, designed to involve experts with FCOIs without developing recommendations affected by those conflicts. In the new guideline, the Health Science and Policy committee is responsible for deciding the conditions under which individuals can and cannot participate in guideline development. Accepted candidates must disclose all remunerated industry activities and must, for the duration of guideline development, divest themselves of direct financial interests in relevant companies. Furthermore, methodologists free of financial or intellectual FCOIs bear primary responsibility (chapter editors) for each chapter of the antithrombotic guideline. Each chapter may have a deputy editor with an FCOI, who may have input into preparing, summarizing, and interpreting the evidence, but is excluded from the deliberations that ultimately determine the direction and strength of the recommendations on which they have conflicts.[30]

The presence of FCOIs amongst guideline panelists is not unique to KDIGO CPGs. In 2011, the cardiovascular clinical practice guidelines had almost 56% of the 498 individuals reporting FCOI.[31] In 2019, The National Comprehensive Cancer Network guidelines had 46% of the guideline panelists reporting at least 1 FCOI.[32] FCOI is considered by some as an unavoidable byproduct of the partnership between the clinicians (with knowledge in patient care) and industry (with resources to address the clinical needs of the patients).[33] Subject experts are routinely asked to be consultants in pharmaceutical companies pursuing a drug study, which

may ultimately contribute to the general good of the society. One would argue that the most important aspect is the impact of the guideline on patient care, and if there has been an improvement in their health over time. Another point to consider is if the guideline caused more harm than good to patients. Some leaders admit the challenges of finding qualified experts without relationships with industry. They feel that strictly following IOM recommendations could lead to a significant reduction in number of members on guidelines committees. This would lead to less consistency among physicians and practicing clinicians, which could ultimately harm patients.[34]

FCOI management in the antithrombotic guideline of the American College of Chest Physicians could serve as a model for KDIGO to involve experts with FCOIs without developing recommendations affected by those conflicts. Furthermore, along the lines of USPSTF, attaching a dollar amount to the disclosure with preset limits, disclosures of immediate family members, and a longer lookback period would be some avenues for KDIGO to explore to enhance their FCOI management process. Accordingly, CPG users should use their best judgment by employing both the level and strength of evidence behind recommendations and associated FCOIs before prescribing treatment. Finally, given the relative absence of FCOIs in the ERT, if for any CPG there is a discrepancy between findings by the ERT and the recommendations of the workgroup, then this should perhaps be highlighted in the final CPG.

Study Limitations

There are a few limitations to our study. First, we investigated only 1 nephrology professional society's guideline. There are other organizations, like the Kidney Disease Outcome Quality Initiative, the European Renal Society, and the American Society of Hypertension, whose guidelines were not evaluated for prevalence of FCOIs. Second, all FCOI data were self-reported and were not (to our knowledge) verified. Third, it does appear that different individuals interpreted disclosure requirements differently. For example, some individuals disclosed relationships with other academic and research organizations that counted toward FCOIs. A small number of guideline writers indicated that monies from companies they were associated with were directly paid to their institution. Fourth, it is unclear whether FCOIs of guideline writers are updated on the KDIGO website on a regular basis to include new additions or deletions of companies, as we have some guideline panels from 2009.

In conclusion, we found that that the majority of KDIGO guideline panelists have FCOIs, which represents a major departure from the standards outlined by the IOM. An earlier study concluded that the KDIGO guidelines were based largely on weak evidence, reflecting expert opinion. The combination of these 2 factors will invariably invite scrutiny into the nature of FCOIs associated with guideline panelists. Thus, industry support and sponsorship is a significant part of ongoing biomedical research. Input and guidance from subject experts is inevitable for progress in research, including rare diseases, where the evidence base may not be of high level. Although FCOIs are unavoidable, KDIGO should work on enhanced FCOI management and disclosure in areas where level and strength of recommendations are weak. The influence of FCOIs on CPG recommendations warrants further study.

DISCLOSURE

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AUTHOR CONTRIBUTIONS

MC contributed to data collection, analysis, and writing of the manuscript. SH contributed to corroboration of data analysis, oversight of the project, and editing of the manuscript. TP contributed to the conception of the project, data collection, writing, and editing, and submitted the final manuscript for publication.

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